Performance and Functionality in a Convenient Compact Modular Design

R-EVO Smart
Ophthalmic Equipment

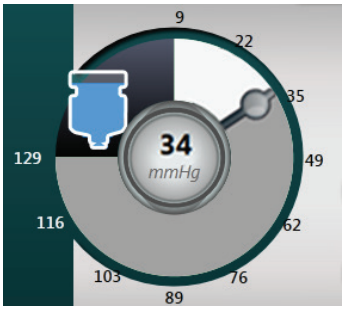
bvimedical.com

Agile Fluidics™

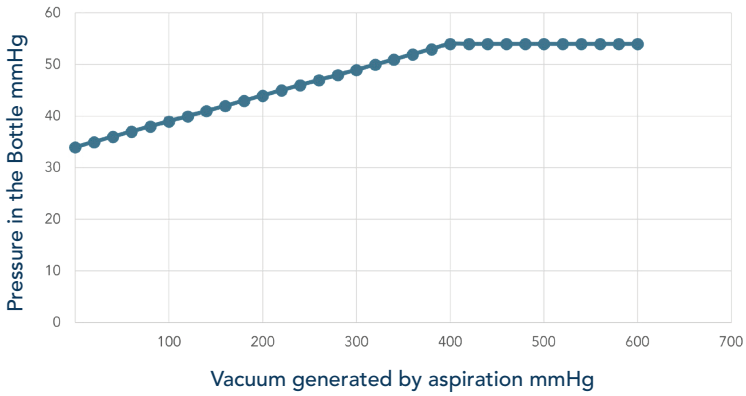
Active Irrigation System and Dynamic IOP Control

The advanced microprocessor-controlled active irrigation system linearly increases/decreases pressure in the irrigating solution container (up to a maximum of 20mmHg) to compensate for intraocular fluctuations caused by vacuum (up to a limit of 400mmHg). Active Irrigation System and Dynamic IOP Control act synergistically to mitigate surge.

PROGRAMMED IOP

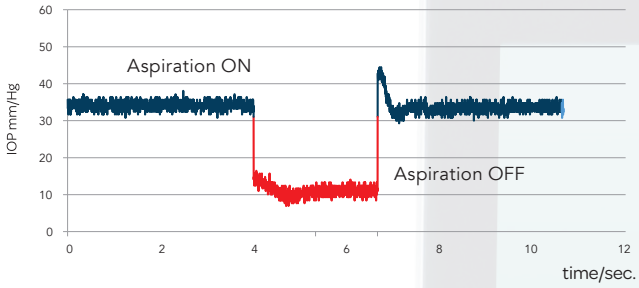


DYNAMIC IOP COMPENSATION



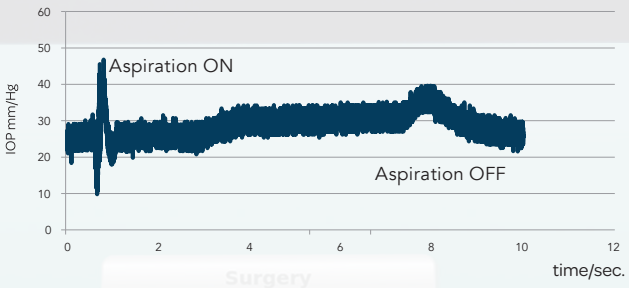
IOP MANAGEMENT

IOP 34 mmHg – VACUUM 600 mmHg
CONTROL OFF



The chart shows IOP fluctuations under active aspiration without an IOP control system*

IOP 34 mmHg – VACUUM 600 mmHg
CONTROL ON



The chart shows a constant IOP value, even under active aspiration, with the Dynamic IOP Control System*

With R-Evo Smart® a programmable IV pole is provided with the optional cart.

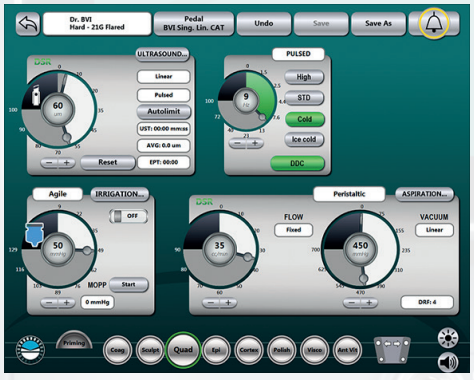
INTERCHANGEABLE FLOW AND VACUUM PUMPS

Selectable aspiration system between flow (Peristaltic) or vacuum based (Venturi) pump.

Interchangeable flow and vacuum pumps only for R-Evo Smart® S and R-Evo Smart® CR.

FLOW RANGE
1 - 65 cc/min

VACUUM RANGE
5 - 650 mmHg



VACUUM RANGE
5 - 650 mmHg

SELECTABLE
VACUUM RISE TIME
slow or fast

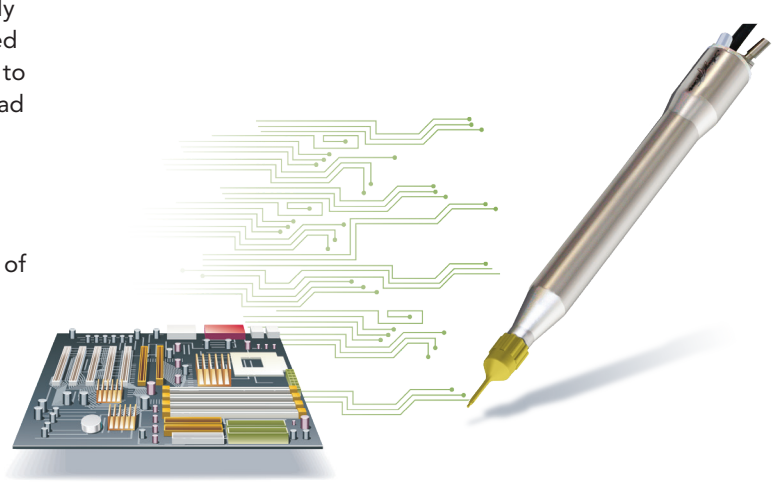
Reference:
* Data on file, BVI

Optimised Energy Management

Minimal Stress™ Technology

The patented Minimal Stress™ technology is the only system on the market that uses a feedback-controlled energy delivery to the piezoelectric crystals in order to mantain the exact tip stroke set point even under load conditions.

Minimal Stress™ technology optimises U/S energy delivery, always ensuring consistency between programmed and actual phaco tip stroke regardless of nucleus hardness.

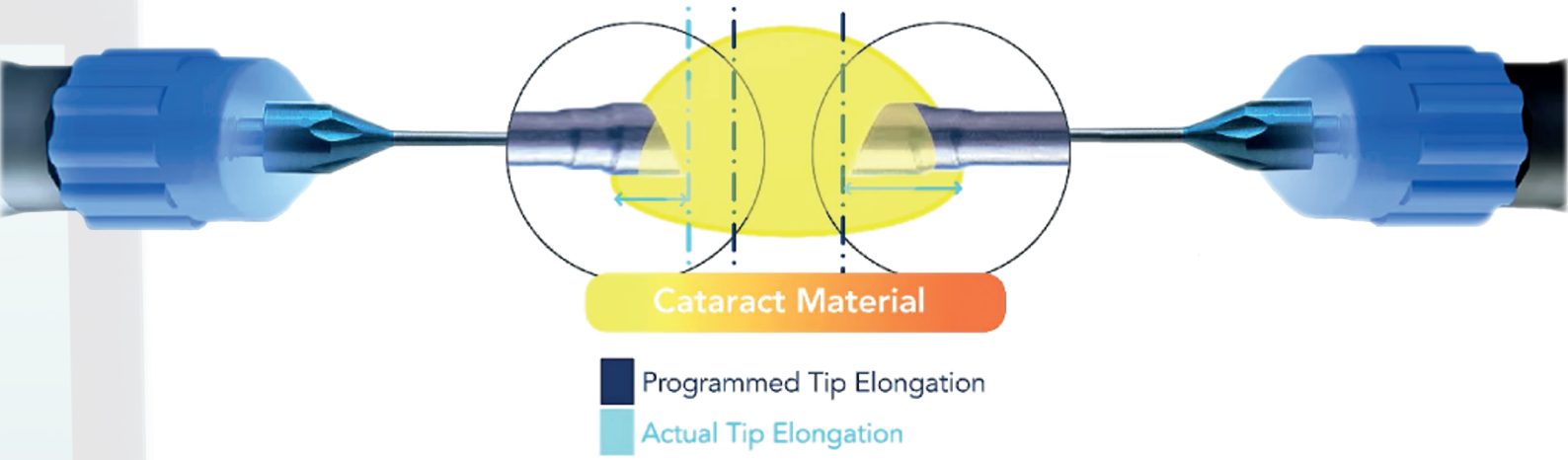


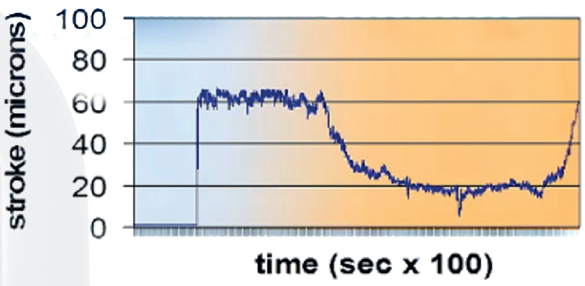
TRADITIONAL U/S DELIVERY TECHNOLOGY

TIP ELONGATION
PROGRAMMED ≠ ACTUAL

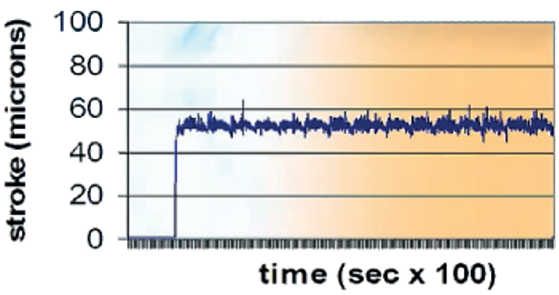
BVI® MINIMAL STRESS™ U/S DELIVERY TECHNOLOGY

TIP ELONGATION
PROGRAMMED = ACTUAL





NO consistency between the programmed phaco tip stroke and the actual tip elongation, when the phaco tip faces the resistance presented by hard lens material.*



Maintained consistency between the programmed phaco tip stroke and the actual tip elongation, when the phaco tip faces the resistance presented by hard lens material.*

Reference:
* Data on file, BVI.
Rossi T, et al. Testing a Novel Device for Accurate Ultrasound Delivery During Crystalline Lens Phacoemulsification Surgery. TVST Journal, February 2020.

LED Lighting System

The complete R-Evo Smart® CR unit is equipped with two independent, high-efficiency LED light sources, free of harmful UV and IR emissions.

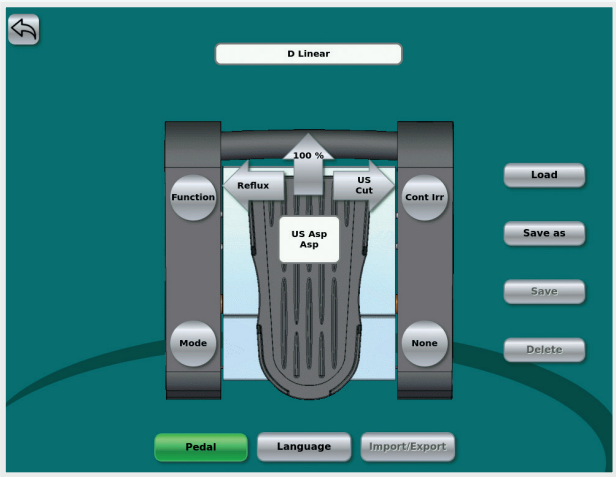
The LED lighting system allows surgeons an enhanced tissue visualisation and guarantees the maximum protection against phototoxicity.

In order to improve contrast and ocular tissue visualisation during VR surgery, both LED sources have 4 different selectable filters: three yellow (435nm, 475nm, 515nm), and one green.

Full Control Footpedal

The compact and lean R-Evo Smart® footpedal offers a streamlined programmability and accurate response.

The footplate features an integrated heel support that facilitates dual linear control, allowing simultaneous vertical and yaw control.



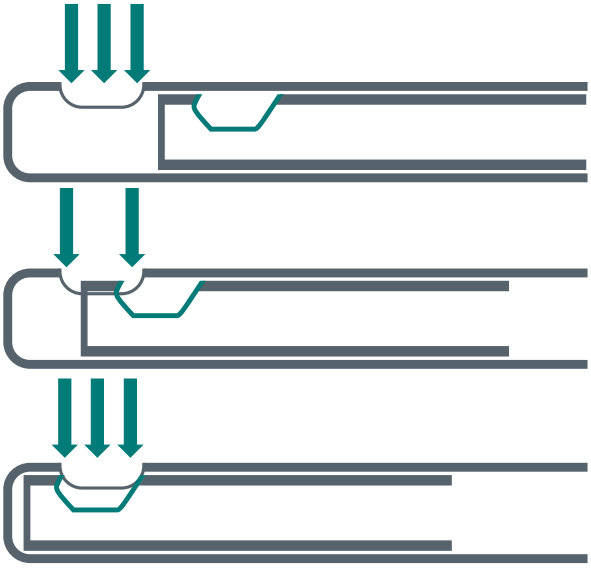
SINGLE LINEAR

DUAL LINEAR

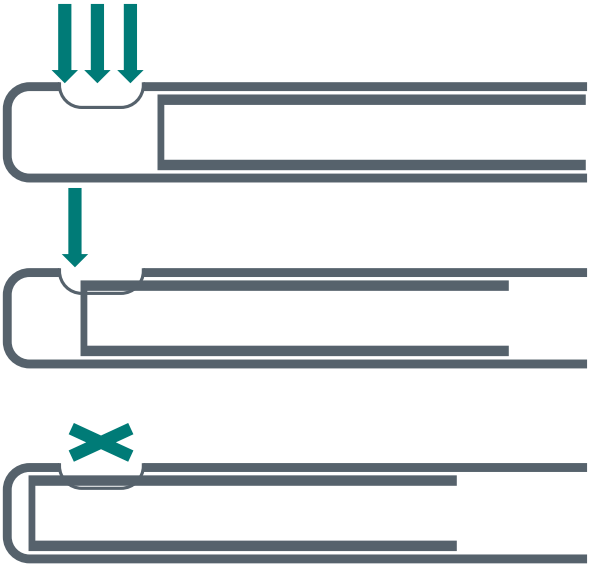
Integrated Solutions for Vitreoretinal Surgery

Twedge™ 20,000 Cuts/min Dual Blade Vitrectomy Probe

TWEDGE™ VITRECTOMY PROBE



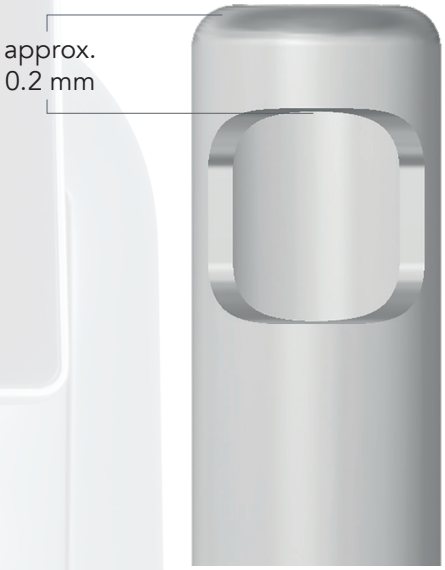
SINGLE-BLADE VITRECTOMY PROBE

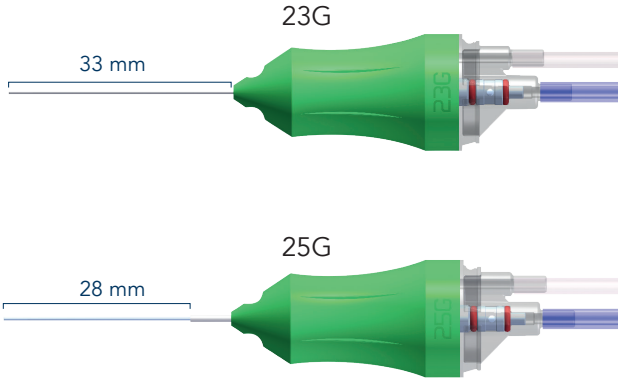


The First Dual Blade Vitrectomy Probe Ever Marketed

EVEN CLOSER TO THE RETINA

SHORT TIP TO PORT DISTANCE,
FOR ENHANCED RETINAL SHAVING ACTION





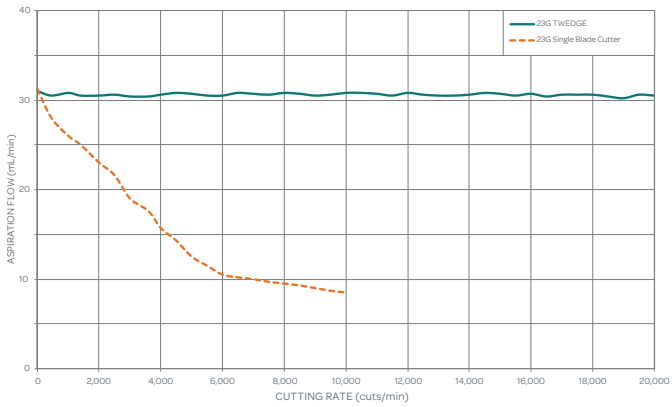
Integrated Solutions for Vitreoretinal Surgery

Optimised Vitrectomy Fluidics with the Twedge™ Vitrectomy Probe

CONSTANT FLOW AT ANY CUTTING RATE

The chart shows the different aspiration flow* achieved using the Twedge™ vitrectomy probe (solid line) compared to a single blade vitrectomy probe (dashed line), as the cutting rate changes.

In particular, the solid line shows how the flow remains constant up to 20,000 cuts/min with the Twedge™ vitrectomy probe; in comparison, the flow decreases as cutting rate increases using the single blade vitrectomy probe.

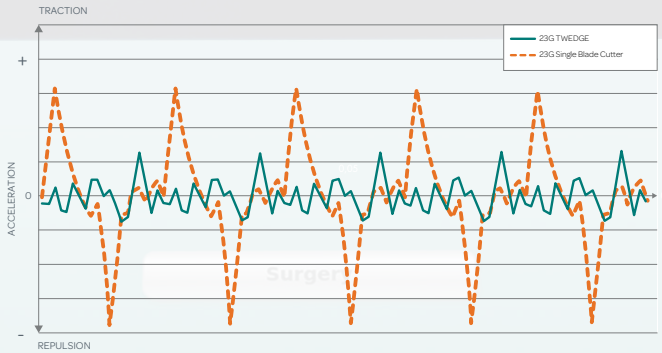


* balanced salt solution, Vacuum 650 mmHg, Venturi pump, R-Evolution® CR

ENHANCED STABILITY EVEN CLOSE TO THE RETINA

The chart shows the accelerations* induced by the Twedge™ vitrectomy probe (solid line) and a single blade vitrectomy probe (dashed line), as a function of time. At every blade work cycle the reduction of stress value using the Twedge™ generates a pulse-free action and the utmost safety close to the retina.

The Twedge™ vitrectomy probe leads to significant reduction of the stress value, generating a pulse-free action close to the retina.



* porcine vitreous, 3,000 cuts/min, 300 mmHg vacuum, Venturi pump, R-Evolution® CR

Reference:

"Fluid dynamics of vitrectomy probes" Rossi T., Querzoli G., Angelini G., Malvasi C, Iossa M., Placentino L., Ripandelli G.; Retina. 2014 Mar; 34(3): 558-67. doi: 10.1097/IAE.0b013e3182a0e628

"Introducing new Vitrectomy Probe blade shapes: a fluid dynamics study" Rossi T., Querzoli G., Angelini G., Malvasi C., Iossa M., Placentino L., Ripandelli G.; Retina. 2014 Sep; 1896-904.

"A new Vitrectomy Probe blade engineered for constant flow vitrectomy" Rossi T., Querzoli G., Malvasi C., Iossa M., Angelini G., Ripandelli G.; Retina. 2014 Jul; 34(7): 1487-91.

Technical Specifications

	R-EVO SMART®		
FLUIDICS	E	S	CR
AGILE Fluidics™	●	●	●
Gravity Fluidics	●	●	●
Integrated IV Pole (only with R-Evo Smart® cart)	●	●	●
Dynamic IOP Control	●	●	●
Reflux	●	●	●
Automatic Venting	●	●	●
One Disposable Cassette for Anterior and Posterior Procedures	-	-	●
Reusable Cassette	●	●	●
DSR (Dynamic Setting Regulation)	●	●	●
Peristaltic Pump	●	●	●
Venturi Pump	-	●	●
Linear/Fix Control	●	●	●
PHACOEMULSIFICATION			
Minimal Stress™ U/S Phaco	●	●	●
Slim 4 Handpiece	●	●	●
Six Crystal U/S Handpiece	●	●	●
U/S Emission Modes: Continuous, Burst, Pulsed with Selectable Duty Cycle Protocols	●	●	●
HD Pulse (Higher Duty) in Occlusion Status	●	●	●
Autolimit (U/S Power Limit in Occlusion Status)	●	●	●
Straight, Flared, Flared Bent Tips (20G, 21G and 22G)	●	●	●
Linear/Fix Control	●	●	●
ANTERIOR VITRECTOMY			
Twedge™ Dual Blade Cutter 23G, 25G	●	●	●
Cutting Rate up to 2,000 cuts/min	●	-	-
Cutting Rate up to 10,000 cuts/min	-	●	●
Linear/Fix Control	●	●	●

	R-EVO SMART®		
POSTERIOR VITRECTOMY	E	S	CR
Twedge™ Dual Blade Cutter 23G, 25G	-	-	●
DSR (Dynamic Setting Regulation)	-	-	●
Cutting Rate up to 10,000 cuts/min	-	-	●
Endo Phaco	-	-	●
Linear/Fix Control	-	-	●
ILLUMINATION			
2 Independent LED Sources	-	-	●
Phototoxicity Filters	-	-	●
Colour Enhancing Filters	-	-	●
Spot, Wide Angle Shielded and Wide Angle Fiber Optics 23G and 25G	-	-	●
Chandelier	-	-	●
AIR			
FAX / AFX	-	-	●
Display or Footpedal Switch	-	-	●
Dedicated Air Pump	-	-	●
Automatic Stopcock	-	-	●
SILICONE OIL			
Injection 0.4 -5 bar	-	-	●
Removal up to 650 mmHg	-	-	●
Simultaneous Active Aspiration	-	-	●
Linear/Fix Control	-	-	●
DIATHERMY			
Eso Diathermy	●	●	●
Endo Diathermy	-	-	●
Eso Diathermy Instruments	●	●	●
Endo Diathermy Disposable Probes 23G, 25G	-	-	●
Linear/Fix Control	●	●	●
FOOTPEDAL			
Programmable Dual/Single Linear Control	●	●	●
R-EVO SMART® CART			
Integrated IV Pole	●	●	●
Integrated Tray	●	●	●

R-EVO SmArt
Ophthalmic Equipment

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Customer Service: bvimedical.com/customer-service/

BVI
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Innovative Ophthalmic Equipment and Instruments

Supporting Phaco, Vitreoretinal and Cryo Procedures

BVI offers a synthesis of advanced equipment providing functionality and reliability using innovative technologies to meet surgical requirements with a continued evolution of hardware and software options.

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Surgical Equipment

R-EVOLUTION®

R-Evolution® Ophthalmic Equipment is available in two configurations for cataract and for cataract and vitreoretinal surgery. R-Evolution® offers a wide range of options to advance access to micro-incisional combined surgery, including: AGILE™ Fluidics Control with IOP management through advanced microprocessor-controlled Active Infusion and the proprietary algorithm "Dynamic IOP Control" acting synergistically to mitigate surge and IOP fluctuations by adjusting IOP in response to varying aspiration demand. Moreover the equipment offers switchable flow/vacuum based aspiration modalities. Optimized Energy Management with Minimal Stress™ technology for consistent phaco tip elongation regardless of cataract grade and multiple proven U/S power emission protocols through a wide portfolio of proprietary phaco tip and 40 KHz phaco handpiece. For vitreoretinal application, it offers a wide range of single use devices to support 23G, 25G and 27G procedures and built in LED Lighting System with three independent LED light sources with selectable colour filters for enhanced visualization, free of harmful UV and IR emissions, and integrated Green Laser Module 532 nm for endo-photocoagulation.

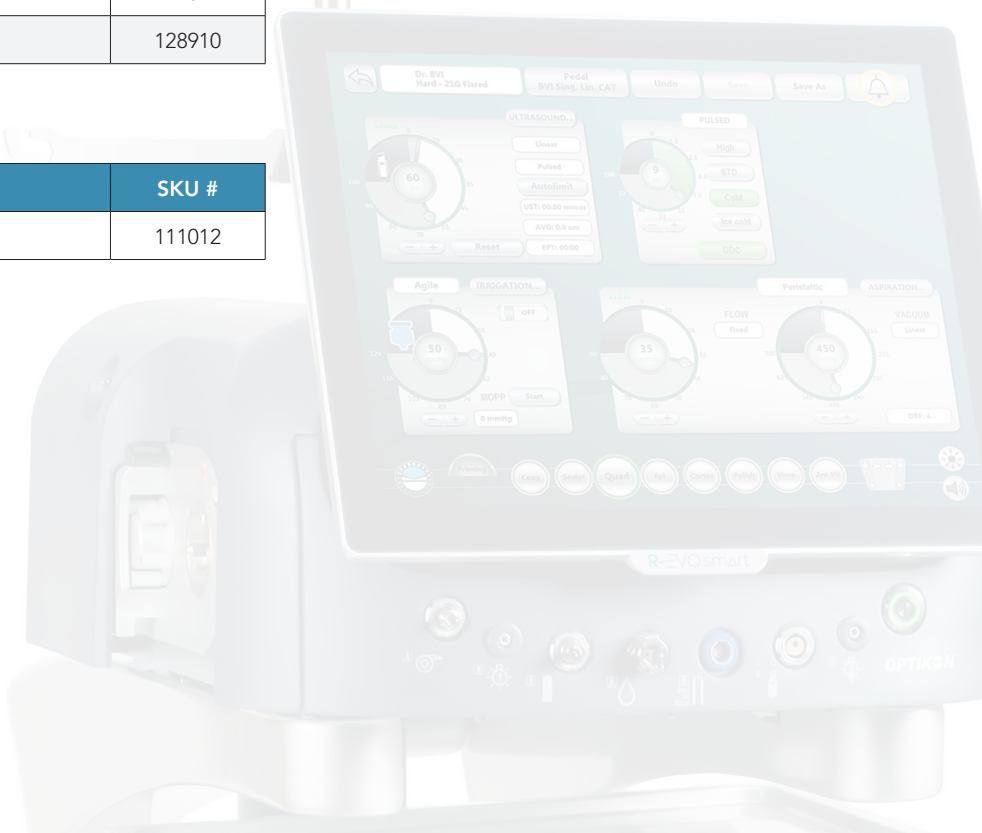
User Interface: large and high visibility 19" touch screen, wireless foot pedal programmable as single or dual linear, programmable voice and audio fee-back and remote control.

EQUIPMENT FOR CATARACT/VITREORETINAL SURGERY

Description	SKU #
R-Evolution® CR	121012
Integrated endo-laser upgrade for R-Evolution® CR	128910

EQUIPMENT FOR CATARACT SURGERY

Description	SKU #
R-Evolution® (peristaltic and rotary vane pumps)	111012



Surgical Equipment

R-EVO SMART®

R-Evo Smart® is a convenient compact modular system for cataract surgeons, fusing performances and functionality and capable of supporting also posterior segment procedures. It is designed in 3 configurations with peristaltic pump only (R-Evo Smart® E), dual pump for anterior segment surgery only (R-Evo Smart® S) and dual pump for anterior and posterior segment surgery (R-Evo Smart® CR).
R-Evo Smart® offers access to a wide portfolio of single-use and reusable devices to support anterior and posterior eye-segment procedures. R-Evo Smart® features: AGILE™ Fluidics Control with IOP management through advanced microprocessor-controlled Active Infusion and the proprietary algorithm "Dynamic IOP Control" acting synergistically to mitigate surge and IOP fluctuations by adjusting IOP in response to varying aspiration demand. Moreover the equipment offers switchable flow/vacuum based aspiration modalities. Optimized Energy Management with Minimal Stress™ technology for consistent phaco tip elongation regardless of cataract grade and multiple proven U/S power emission protocols through a wide portfolio of proprietary phaco tip and 40 KHz phaco handpiece. For vitreoretinal application, it offers a wide range of single-use devices to support 23G and 25G procedures and built in LED Lighting System with 2 independent LED light sources with selectable colour filters for enhanced visualization, free of harmful UV and IR emissions.

User Interface: high visibility 15" touch screen advanced foot pedal programmable as single or dual linear.

EQUIPMENT FOR CATARACT/VITREORETINAL SURGERY

Description	SKU #
R-Evo Smart® CR	121013

EQUIPMENT FOR CATARACT SURGERY

Description	SKU #
R-Evo Smart® E (flow-based pump only)	111009
R-Evo Smart® S (flow and vacuum based pumps and Venturi pumps)	111010

CRYO-LINE

Cryo-line is a fully pneumatic system for ophthalmic cryo-surgery employing CO2 or N2O as cryogenic gases. It is available for retina and eye-adnexa applications with a complete set of reusable cryo-probes. The system features application time, cylinder adapters, gas filter cartriges and temperature control for precise treatment.

EQUIPMENT FOR OPHTHALMIC CRYO-SURGERY

Description	SKU #
Cryo-line	131002

Accessories for Cataract and Cataract/Vitreoretinal Equipment

FOOT PEDALS

Description	SKU #
Foot pedal, wireless dual/single linear, R-Evolution® and R-Evolution® CR	112104
Foot pedal, dual/single linear, R-Evo Smart® E, S and CR	112105

REMOTE CONTROL FOR R-EVOLUTION® AND R-EVOLUTION® CR

Qty: 1/Bx

Description	SKU #
Remote control for R-Evolution® and R-Evolution® CR	122007

IRRIGATION/ASPIRATION HANDPIECE FOR CATARACT SURGERY

Qty: 1/Bx

Description	SKU #
Coaxial I/A handpiece, long barrel	114101

To be used in conjunction with any interchangeable I/A cannulas available in the multiuse section.

HANDPIECES

114301

114302

Qty: 1/Bx

Description	SKU #
Bimanual I/A, Irrigation cannula	114301
Bimanual I/A, Aspiration cannula	114302

PHACO HANDPIECE

113101

113107

Qty: 1/Bx

Description	SKU #
Phaco handpiece - Slim 4	113101
Phaco handpiece - Six	113107

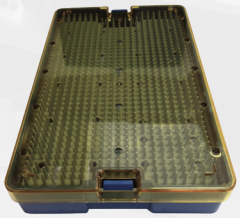
CART

Qty: 1/Bx

Description	SKU #
Cart with integrated IV pole for R-Evo Smart® E, S and CR	181006

Accessories for Cataract and Cataract/Vitreoretinal Equipment

STERILIZATION TRAY



Qty: 1/Bx

Description	SKU #
Sterilization tray 16 x 26.5 x 4 cm for phaco and I/A handpieces	116003

IRRIGATING SOLUTION CONTINUITY GUARD

Qty: 1/Bx

Description	SKU #
Irrigating Solution Continuity Guard	181007

FILTERS

Qty: 1/Bx

Description	SKU #
Filter, passive protection for Zeiss and Moller microscopes	0MR340833
Filter, passive protection for Leica microscopes	0MR340846
Filter, passive protection for Topcon microscopes	0MR340897
Filter, passive protection for 532 nm wavelength for Topcon microscopes	0MR340990
Filter, active protection for Leica microscopes	0MR340848
Filter, active protection for Zeiss and Moller microscopes	0MR340849
Filter, active protection for Topcon microscopes	0MR340898

GOGGLES

Qty: 1/Bx

Description	SKU #
Protective goggles, wavelength 532 nm	0MR640425

Accessories for Cryo-surgery Equipment

CART

Qty: 1/Bx

Description	SKU #
Equipment cart with gas cylinder holder	183001

CYLINDER ADAPTERS

132008

132009

132010

Qty: 1/Bx

Description	SKU #
Gas cylinder adapter for nitrous oxide N2O (ISO5145 standard)	132008
Gas cylinder adapter for nitrous oxide (French standard)	132010
Gas cylinder adapter for carbon dioxide (ISO5145 standard)	132009

CRYO PROBES FOR OPHTHALMIC CRYO-SURGERY

133002

133004

133005

133006

Qty: 1/Bx

Description	SKU #
Cryo probe for retina, Ball	133002
Cryo probe for retina, “T” shaped	133004
Cryo probe for retina, “Bonnet”	133005
Cryo probe for glaucoma	133006

Phaco Packs

PHACO PACKS FOR CATARACT SURGERY FOR R-EVOLUTION® AND R-EVO SMART®

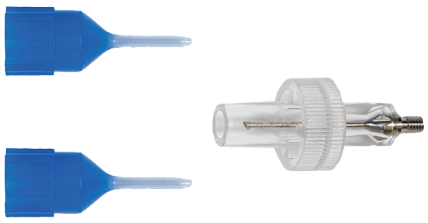
This configuration supports AGILE™ Fluidics Control (Active Fluidics) that minimizes post-occlusion break surge and stabilizes the eye across all steps of the procedure. Moreover, phaco tip pre-assembled with single-use phaco-tip wrench will drive work-flow efficiency.

FIXED COMPONENTS

Description
EasySys I/A cassette with drainage bag
Drapes (screen/Mayo arm)
Air controlled irrigation
Administration set
Test chamber

VARIABLE COMPONENTS

195220



Qty: 10/Bx

Description	Sleeve	Phaco Tip, Assembled on Tip-wrench	SKU #
AGILE™ Phaco Pack 20G F	2x Blue	20G Flared	195220
AGILE™ Phaco Pack 20G FB	2x Blue	20G Flared bent	195320
AGILE™ Phaco Pack 20G S	2x Blue	20G Straight, 30 degrees	195120
AGILE™ Phaco Pack 21G F	2x Yellow	21G Flared	195221
AGILE™ Phaco Pack 21G FB	2x Yellow	21G Flared bent	195321
AGILE™ Phaco Pack 21G S	2x Yellow	21G Straight, 30 degrees	195121

S - Straight phaco tip
F - Flared phaco tip
FB - Flared bent phaco tip

More configurations of cataract procedure packs are availble upon demand.

Vitreoretinal Packs

VITREORETINAL PACKS FOR VITREORETINAL SURGERY FOR R-EVOLUTION® CR AND R-EVO SMART® CR

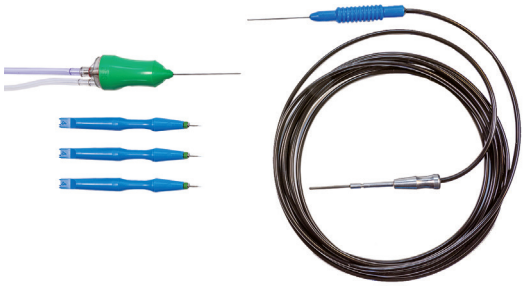
Twedge™ VitPack provides the largest portfolio of single-use devices for vitreoretinal procedure, supporting 23G, 25G and 27G pars plana vitrectomy with AGILE™ Fluidics Control and fluid/air exchange set with automatic valve and two-ways stopcock.

FIXED COMPONENTS

Description
EasySys I/A cassette with drainage bag
Drapes (screen/Mayo arm)
Air controlled irrigation
Administration set
Two-ways stopcock
Fluid/air exchange set with automatic valve

VARIABLE COMPONENTS

199323



Qty: 5/Bx

Description	Twedge™ High Speed Dual-blade Vitrectomy Probe	Valved Entry System Kit	Endo-illumination Probe	SKU #
23G Twedge™ VitPack SH	✓	23G	Shielded, wide angle	199323
23G Twedge™ VitPack SP	✓	23G	Spot	199123
25G Twedge™ VitPack SH	✓	25G	Shielded, wide angle	199325
25G Twedge™ VitPack SP	✓	25G	Spot	199125
27G Twedge™ VitPack SP	✓	27G	Spot	199127

SP - Spot endo-illumination
SH - Shielded wide angle endo-illumination

More configurations of cataract procedure packs are availble upon demand.
*For more Vitreoretinal Pack, please contact your BVI representative.

Combined Packs

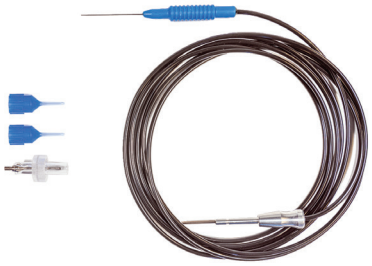
COMBINED PACKS FOR COMBINED CATARACT AND VITREORETINAL SURGERY FOR R-EVOLUTION® CR AND R-EVO SMART® CR

FIXED COMPONENTS

Description
EasySys I/A cassette with drainage bag
Drapes (screen/Mayo arm)
Air controlled irrigation
Administration set
Two-ways stopcocks
Fluid exchange set with automatic valve
Test chamber
Twedge™ high speed dual blade vitrectomy probe
One-step valved entry system kit

VARIABLE COMPONENTS

199323-20G F



Qty: 5/Bx

Description	Endo-illumination Probe	Sleeve	Phaco Tip, Assembled on Tip-wrench	SKU #
23G Twedge™ UniPack SH 20G F	Shielded, wide angle	2x Blue	Flared	199323-20G F
23G Twedge™ UniPack SP 20G F	Spot	2x Blue	Flared	199123-20G F
23G Twedge™ UniPack SH 20G FB	Shielded, wide angle	2x Blue	Flared bent	199323-20G FB
23G Twedge™ UniPack SP 20G FB	Spot	2x Blue	Flared bent	199123-20G FB
23G Twedge™ UniPack SH 21G F	Shielded, wide angle	2x Yellow	Flared	199323-21G F
23G Twedge™ UniPack SP 21G F	Spot	2x Yellow	Flared	199123-21G F
23G Twedge™ UniPack SH 21G FB	Shielded, wide angle	2x Yellow	Flared bent	199323-21G FB
23G Twedge™ UniPack SP 21G FB	Spot	2x Yellow	Flared bent	199123-21G FB

S - Straight phaco tip
F - Flared phaco tip
FB - Flared bent phaco tip
SP - Spot endo-illumination
SH - Shielded wide angle endo-illumination

More configurations of cataract procedure packs are availble upon demand.

Qty: 5/Bx

Description	Endo-illumination Probe	Sleeve	Phaco Tip, Assembled on Tip-wrench	SKU #
25G Twedge™ UniPack SP 20G F	Spot	2x Blue	Flared	199125-20G F
25G Twedge™ UniPack SP 20G FB	Spot	2x Blue	Flared bent	199125-20G FB
25G Twedge™ UniPack SP 21G F	Spot	2x Yellow	Flared	199125-21G F
25G Twedge™ UniPack SP 21G FB	Spot	2x Yellow	Flared bent	199125-21G FB
25G Twedge™ UniPack SH 20G F	Shielded, wide angle	2x Blue	Flared	199325-20G F
25G Twedge™ UniPack SH 20G FB	Shielded, wide angle	2x Blue	Flared bent	199325-20G FB
25G Twedge™ UniPack SH 21G F	Shielded, wide angle	2x Yellow	Flared	199325-21G F
25G Twedge™ UniPack SH 21G FB	Shielded, wide angle	2x Yellow	Flared bent	199325-21G FB

S - Straight phaco tip
F - Flared phaco tip
FB - Flared bent phaco tip
SP - Spot endo-illumination
SH - Shielded wide angle endo-illumination

More configurations of cataract procedure packs are availble upon demand.

Basic Packs

Qty: 10/Bx

Description	SKU #
EasySys irrigation/aspiration kit for R-Evolution® and R-Evo Smart®	192704
EasySys irrigation/aspiration kit for Assistant/ Pulsar II - ESP	192703
Irrigation/aspiration kit for Pulsar II Minimal Stress: cassette, drainage bag and tubing	191703
Irrigation/aspiration kit for Pulsar II Minimal Stress: cassette with drainage bag	191704
Irrigation/aspiration kit for Pulsar with tubings, ACS3 device and drainage bag	191702

192704

Other Devices for Irrigation/Aspiration for Cataract and Vitreoretinal Surgery

AIR CONTROLLED IRRIGATION DEVICE

Qty: 5/Bx

Description	SKU #
Air controlled irrigation device	190700

SCREEN COVER AND MAYO DRAPE FOR R-EVO SMART®

Qty: 10/Bx

Description	SKU #
Screen cover and Mayo drape for R-Evo Smart®	191616

Single Use Consumables

POSTERIOR VITRECTOMY PROBE

Twedge™ dual blade, high speed vitrectomy probe for 23G, 25G and 27G procedures, provide uninterrupted flow for vitreous removal at any cutting rate with minimal tractions to retinal tissues.

192315

Qty: 5/Bx

Description	SKU #
23G Twedge™ dual blade vitreous cutter	192313
25G Twedge™ dual blade vitreous cutter	192315
27G Twedge™ dual blade vitreous cutter	192317

VALVED TROCAR KIT

This is a kit of valved entry-system build on trocar blade, for implantation assisted by a scleral marker.

192223

Qty: 10/Bx

Description	SKU #
23G Valved trocar kit	192223
25G Valved trocar kit	192225
27G Valved trocar kit	192227

ENDO ILLUMINATION PROBES FOR VITREORETINAL SURGERY

192808

Qty: 5/Bx

Description	SKU #
23G Shielded wide angle probe	192816
25G Shielded wide angle probe	192845
23G Endoillumination probe, multiport	192807
25G Endoillumination probe, multiport	192808
27G Spot endoillumination probe, multiport	192818
25G Chandelier with adjustable ring	192817

ENDO DIATHERMY PROBES

192623

Qty: 5/Bx

Description	SKU #
23G Endo diathermy probe	192623
25G Endo diathermy probe	192625
27G Endo diathermy probe	192627

Please refer to: Reusable Devices for Surgical Equipment Diathermy - Reusable Accessories for Diathermy

Stand Alone Devices and Kits

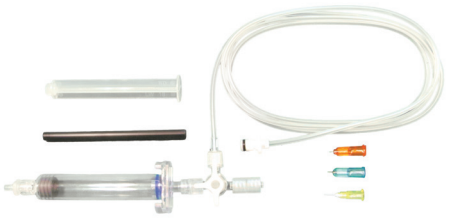
ENDO LASER PROBES FOR VITREORETINAL SURGERY

Qty: 5/Bx

Description	SKU #
23G Endo laser, straight, blue	OAK-0431/SMH
23G Endo laser, angled, blue	OAK-0435/SMH
25G Endo laser, straight, orange	OAK-0432/SMH
25G Endo laser, angled, orange	OAK-0436/SMH
27G Endo laser, straight, magenta	OAK-0433/SMH
27G Endo laser, angled, magenta	OAK-0437/SMH

More laser probe options available in the Vitreoretinal portfolio section of BVI Product Catalog

SILICONE OIL INJECTION/REMOVAL KIT



Qty: 5/Bx

Description	SKU #
Injection/removal silicone oil kit with 20G/23G/25G cannulas, single use (5 pcs)	192540

AUTOMATIC BALANCED SALINE SOLUTION/AIR INFUSION CONTROL SYSTEM

Qty: 5/Bx

Description	SKU #
Automatic balanced saline solution/air infusion control system	192550

AIR INJECTION TUBE WITH FILTER

Qty: 5/Bx

Description	SKU #
Air injection tube with filter	192513

ADAPTER SYRINGE TUBING

192516

Qty: 10/Bx

Description	SKU #
Adapter syringe tubing LLF	192519
Adapter for simultaneous connection air/minimal IOP	192516
Adapter syringe tubing LLF-Assistant/Pulsar II - ESP	192518

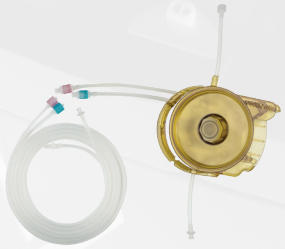
3-WAY STOPCOCK

Qty: 10/Bx

Description	SKU #
3-way stopcock	192514

Multi Use Consumables

CASSETTE, I/A TUBING, DRAINAGE BAG AND OTHER ACCESSORIES



117006

116002

116008

Qty: Varies/Bx

Description	SKU #
EasySys reusable I/A cassette for R-Evo Smart®, Qty: 2	117006
EasySys reusable cassette, drainage bag for R-Evo Smart®, Qty: 10	116002
EasySys reusable cassette, cassette-wrench for R-Evo Smart®, Qty: 1	116008
Irrigation/aspiration tubing set with ACS3 device for Pulsar, Qty: 1	117001
Irrigation/aspiration tubing set for Pulsar II Minimal Stress, Qty: 1	117004

PHACO TIPS

113240

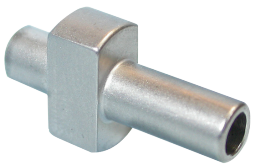
113250

113217

Qty: 1/Bx

Description	SKU #
20G Flared phaco tip, 30 degrees, blue	113240
20G Flared bent phaco tip, 30 degrees, blue	113250
20G Standard phaco tip, 30 degrees, blue	113206
21G Flared phaco tip, 30 degrees, yellow	113241
21G Flared bent phaco tip, 30 degrees, yellow	113251
21G Standard phaco tip, 30 degrees, yellow	113237
22G Flared phaco tip, 30 degrees, green	113242
22G Standard phaco tip, 30 degrees, green	113209
Pars plana phaco tip	113217

PHACO TIP WRENCH



Qty: 1/Bx

Description	SKU #
Phaco tip wrench	113402

SILICONE SLEEVES

113308

113307

113309

Qty: 3/Bx

Description	SKU #
Silicone sleeve for 20G tips - (2.8 mm incision), blue	113308
Silicone sleeve for 21G tips - (2.3 mm incision), yellow	113307
Silicone sleeve for 22G tips - (1.8 mm incision), green	113309

Multi Use Consumables

IRRIGATION/ASPIRATION CANNULAS FOR CATARACT SURGERY

114216

Qty: 1/Bx

Description	SKU #
20G Straight I/A cannula with silicone sleeve, blue	114216
20G Angled I/A cannula with silicone sleeve, blue	114217
21G Straight I/A cannula with silicone sleeve, yellow	114218
21G Angled I/A cannula with silicone sleeve, yellow	114219
22G Straight I/A cannula with silicone sleeve, green	114222
22G Angled I/A cannula with silicone sleeve, green	114223

To be used in conjunction with SKU: 114101, Coaxial I/A handpiece, long barrel

Diathermy

ESO-DIATHERMY

115301

115302

Qty: 1/Bx

Description	SKU #
Diathermy forceps	115301
Diathermy pencil eraser	115302

REUSABLE ACCESSORIES FOR DIATHERMY

115101

Qty: 1/Bx

Description	SKU #
Diathermy bipolar cable	115101

Tel: +39 06 8888355
Email: customersupport@bvimedical.com

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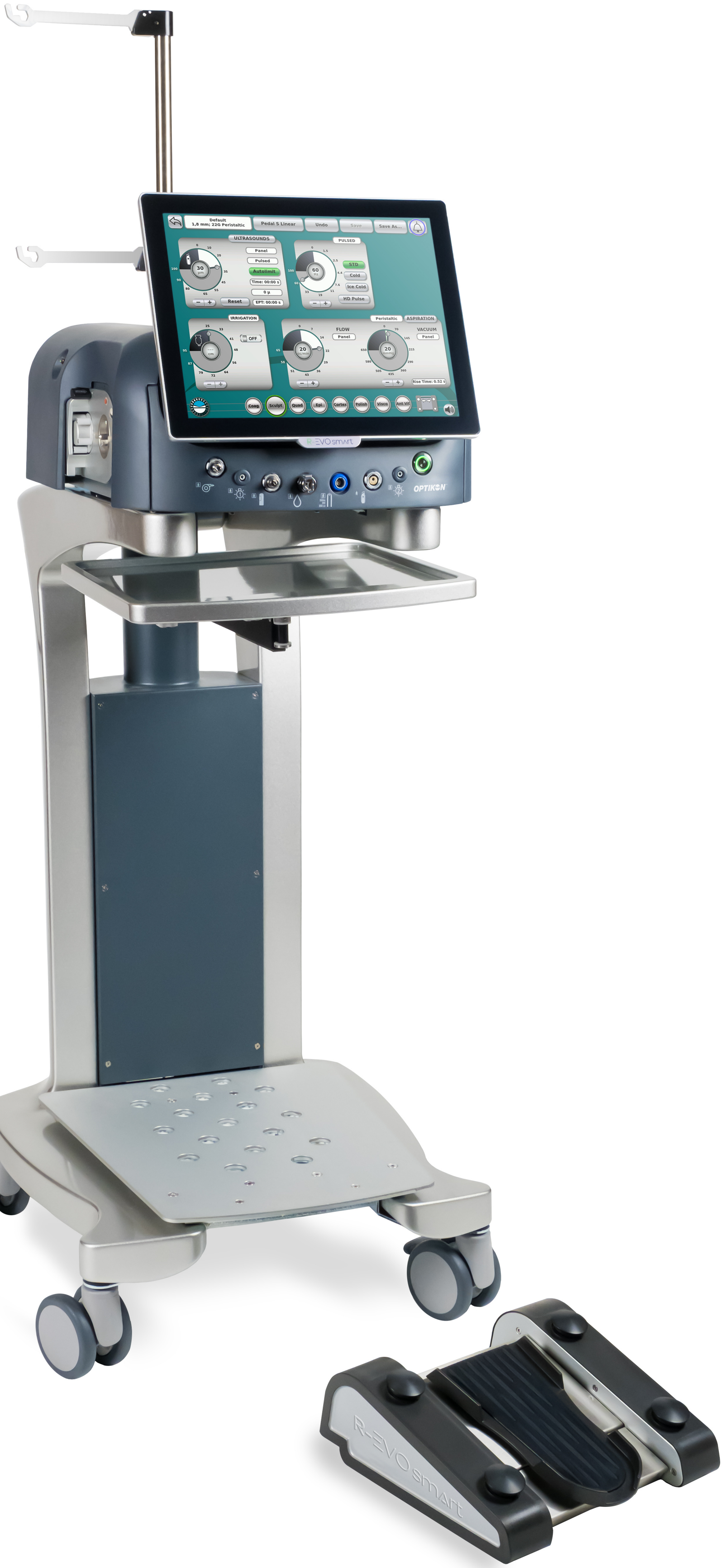

Default
1,8 mm; 22G Peristaltic
Pedal S Linear
Undo
Save
Save As...
ULTRASOUNDS
Panel
Pulsed
Autolimit
Time: 00:00 s
0 µ
Reset
EPT: 00:00 s
PULSED
STD
Cold
Ice Cold
HD Pulse
IRRIGATION
OFF
FLOW
Panel
Peristaltic
ASPIRATION
VACUUM
Panel
Rise Time: 0.52 s
Coag
Sculpt
Quad
Epi
Cortex
Polish
Visco
Ant Vit
R-EVO smart
OPTIKON
R-EVO smart

BVI

THE FUTURE IN FOCUS

Rendimiento y Funcionalidad en un Práctico Diseño Modular Compacto

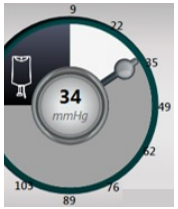
R-EVO Smart
Ophthalmic Equipment

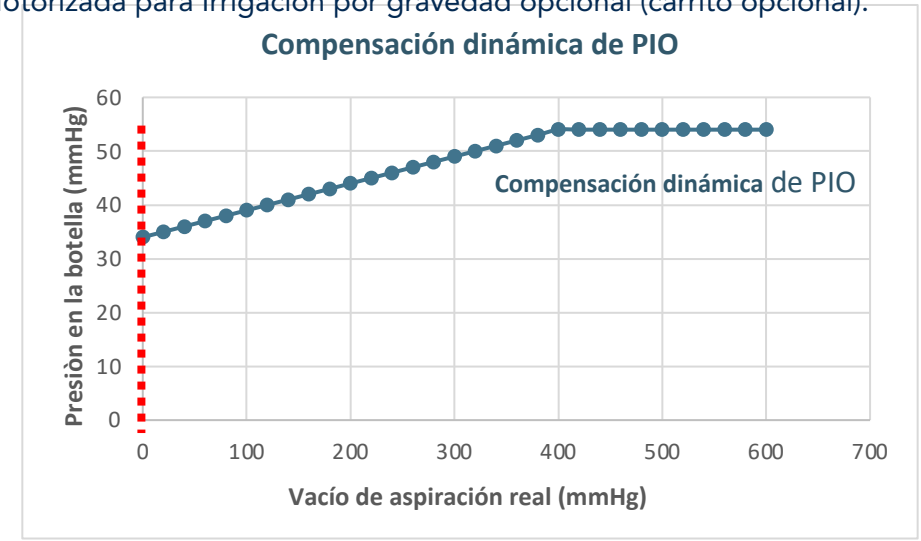
Agile Fluidics™: compensación dinámica de la PIO

Agile Fluidics™ apoya la estabilidad de la Cámara Anterior mediante:

- *Sistema de irrigación activo controlado por microprocesador Avanzado* y el algoritmo patentado Control Dinámico de la PIO que actúan de forma sinergia para mitigar la sobrecarga mediante el ajuste de la presión intraocular y respondiendo a las diferentes demandas de aspiración.
- Columna IV Motorizada para Irrigación por gravedad opcional (carrito opcional).

PIO Programada



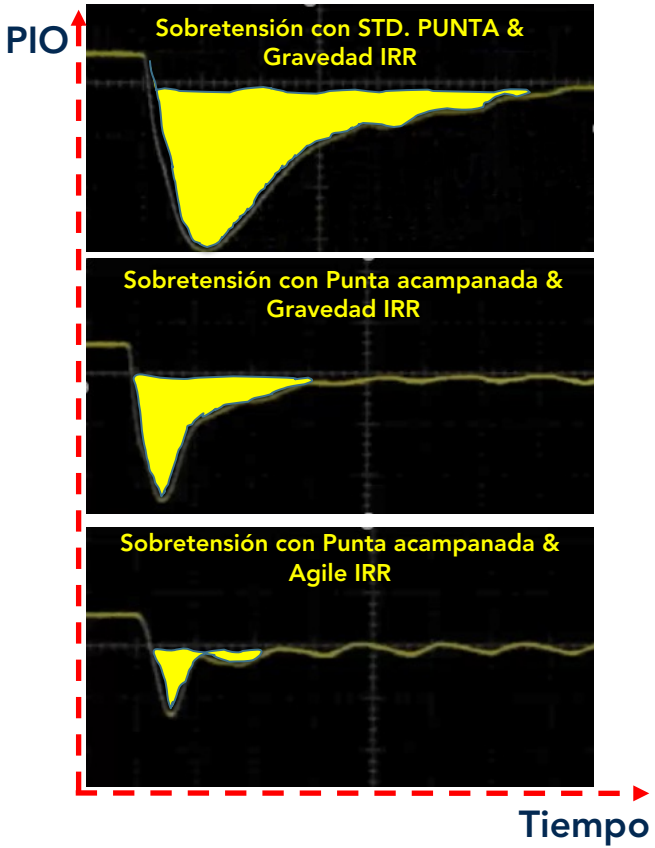


- El algoritmo SW patentado reacciona al vacío medido por el sensor del sistema alimentando con más presión a la botella de irrigación, la compensación es lineal e instantánea, tanto con niveles de vacío crecientes como decrecientes.
- El Sistema aumenta hasta un máximo de 20mmHg para vacíos de hasta 400mmHg

R-EVO Smart
Ophthalmic Equipment

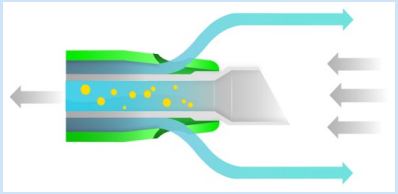
Agile Fluidics™ combinado con punta acampanada para una mayor reducción de las sobretensiones

BVI
THE FUTURE IN FOCUS



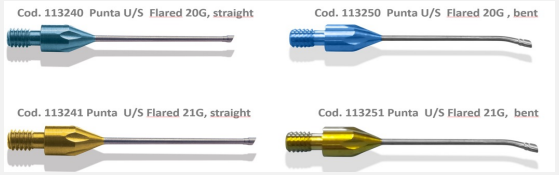
Sección transversal del tubo ASP

Lumen del eje de la punta más estrecho aumenta la Resistencia = disminuye la sobretensión



Trabajo sinérgico del tubo de aspiración rígido de pequeño calibre combinado con **el diseño más estrecho de punta acampanada**.

Recta o curva dependiendo de la preferencia personal



Codificación por colores del manguito y la punta

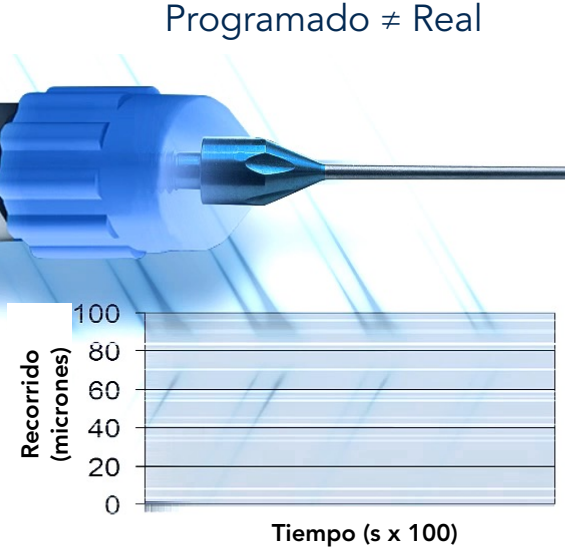
R-EVO Smart
Ophthalmic Equipment

Tecnología Minimal Stress™: Gestión Optimizada de la Energía

BVI
THE FUTURE IN FOCUS

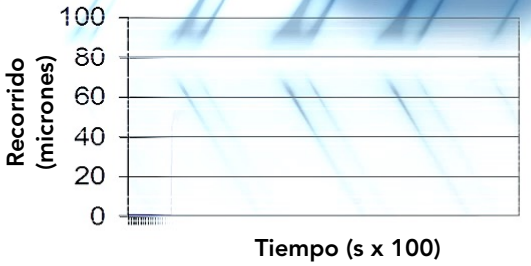
SIN Tecnología Minimal Stress™

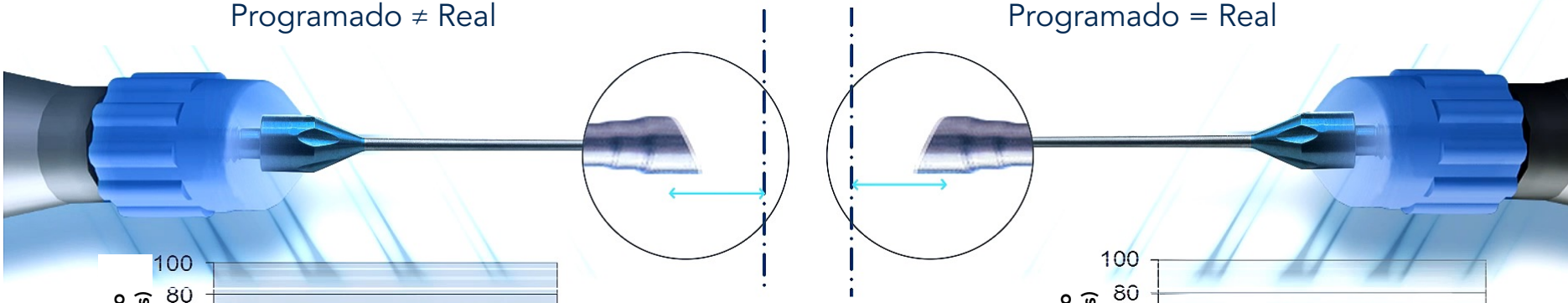
Alargamiento de la punta
Programado ≠ Real



CON Tecnología Minimal Stress™

Alargamiento de la punta
Programado = Real





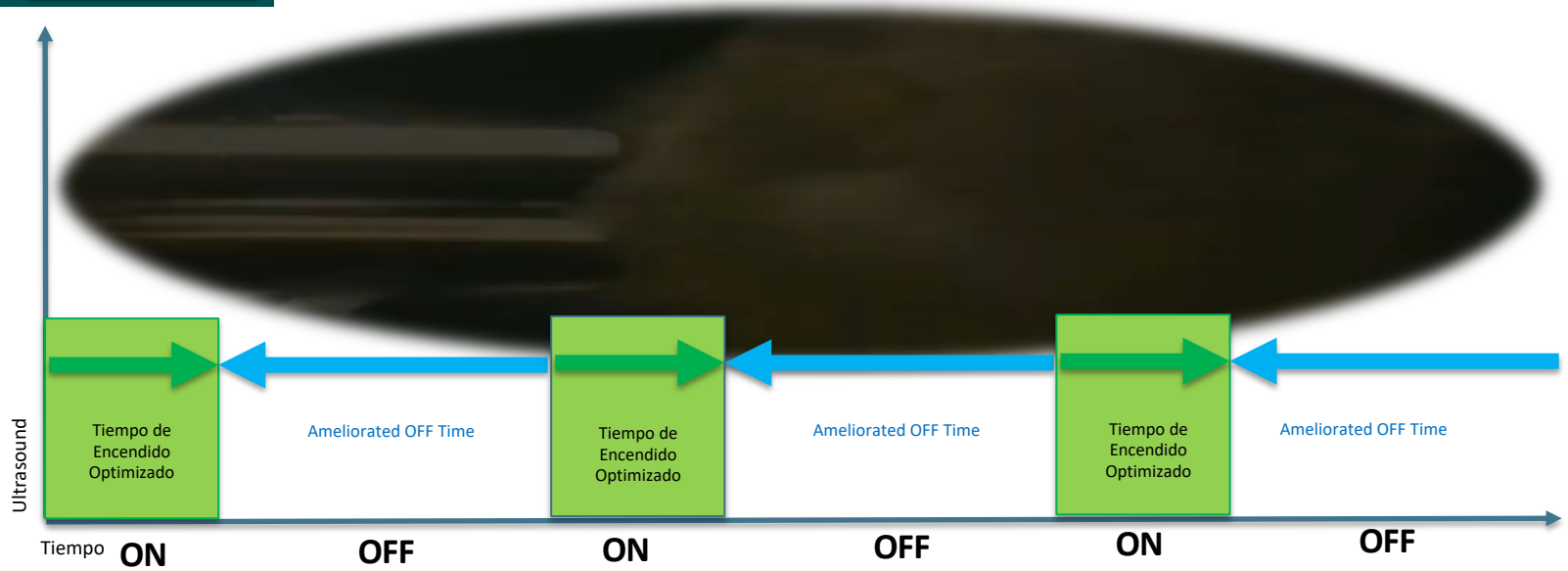
Mínima Stress™ Tecnología es una tecnología patentada que optimiza la liberación de energía U/S, garantizando siempre la **coherencia entre el recorrido de la punta de faco programado y el real** independientemente de la dureza del núcleo

R-EVO Smart
Ophthalmic Equipment

Protocolos de corte U/S PULSED equilibrados: facilitan la optimización de la eficiencia

BVI
THE FUTURE IN FOCUS

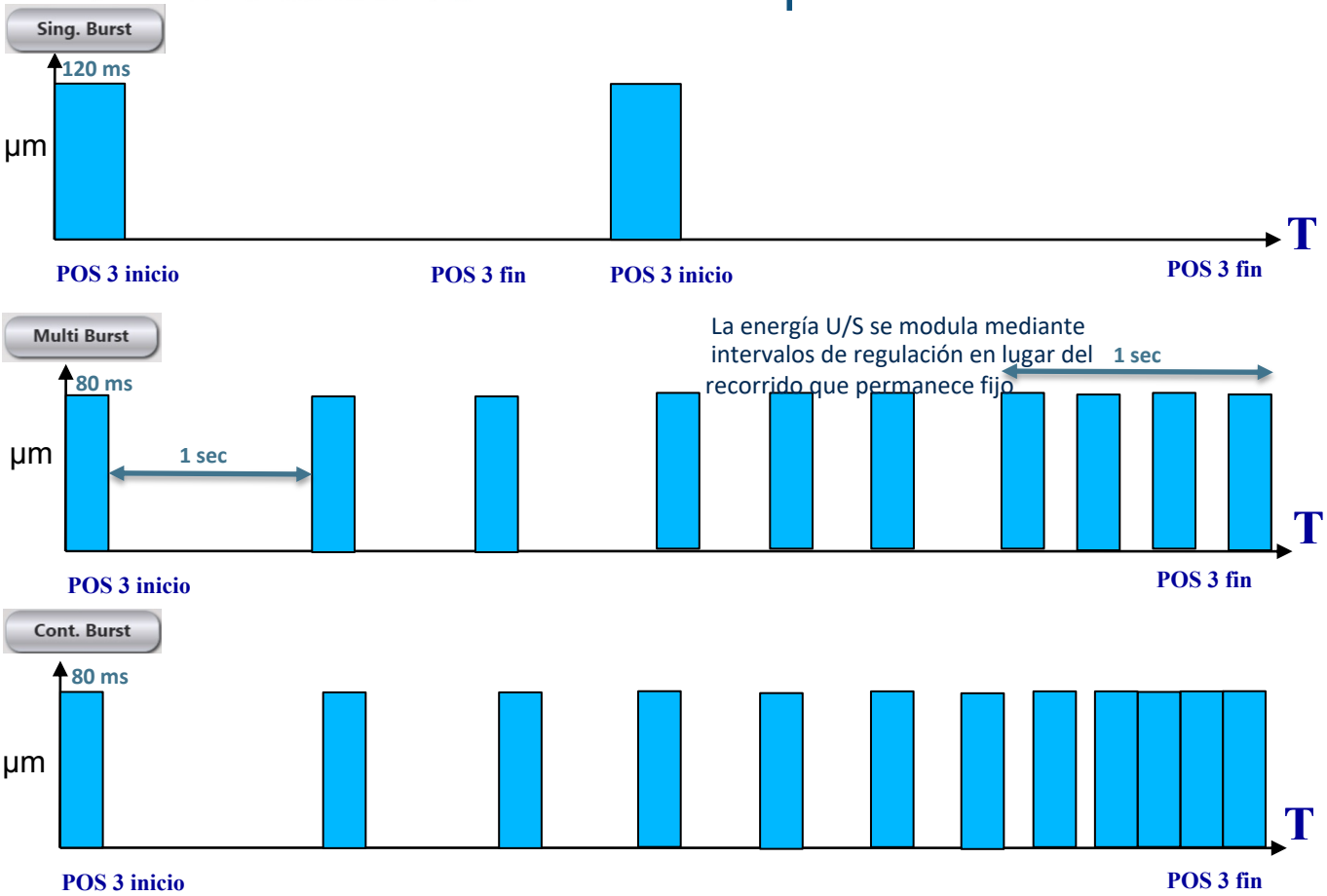
- **El tiempo de encendido Optimizado** favorece una emulsificación eficaz con calor reducido al tiempo que minimiza la repulsion.
- **El tiempo de apagado mejorado** permite que la fluídica facilite la atracción, retención y arrastre del material del cristalino emulsionado al tiempo que proporciona una refrigeración eficaz.
- **El Ciclo de Trabajo Dinámico (DDC, en inglés)** cambia automáticamente el Ciclo de Trabajo de los Pulsos al protocolo superior solo en caso de oclusión.



R-EVO Smart
Ophthalmic Equipment

Protocolos de corte U/S PULSED equilibrados: facilitan la optimización de la eficiencia

BVI
THE FUTURE IN FOCUS



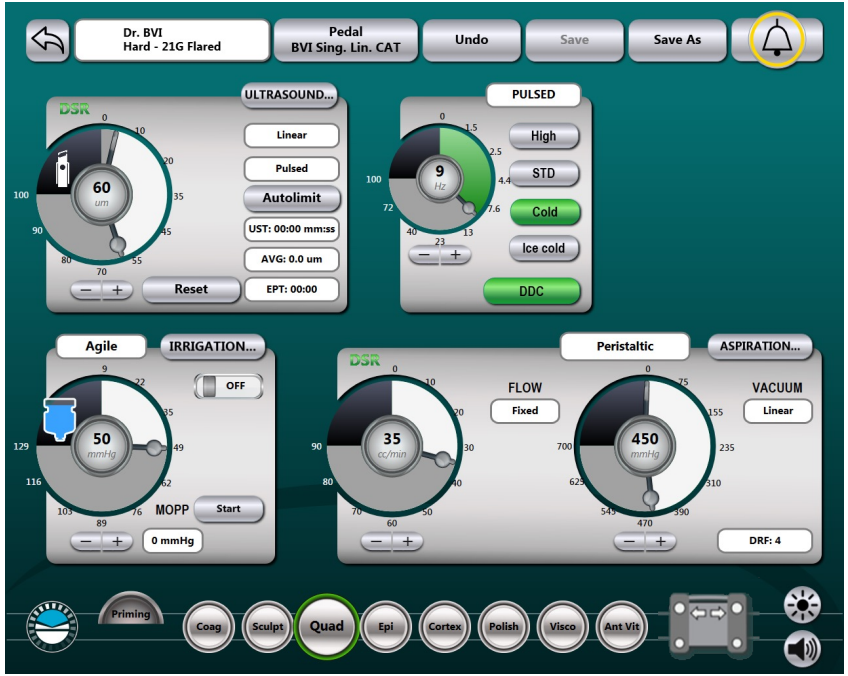
3 protocolos de energía BURST de eficacia probada

La energía U/S se modula mediante intervalos de regulación en lugar del **recorrido que permanece fijo**

R-EVO Smart
Ophthalmic Equipment

Interfaz del usuario para una interaccion humano-máquina simplificada

BVI
THE FUTURE IN FOCUS



Pantalla táctil de alta visibilidad de 19, GUI fácil de usar para **Programación directa y precisa**

Pedal avanzado programable como **Lineal Simple o Lineal Doble** con botones adicionales laterales personalizables

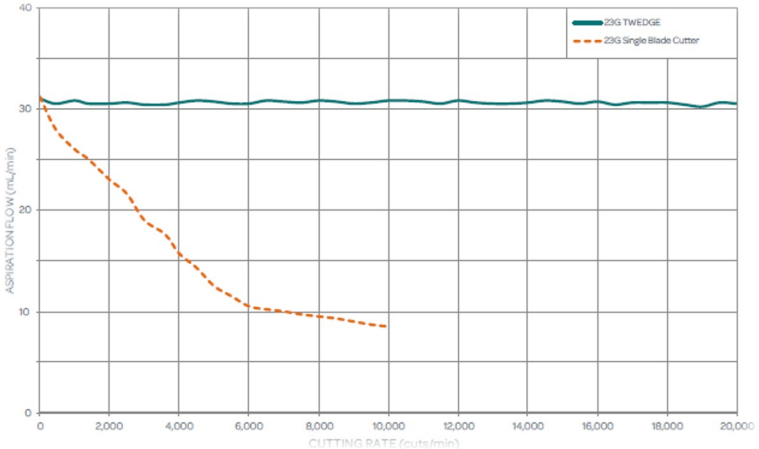
El mismo casete EasySys Faco/Retina/Combinados, compatible también con el Sistema R-Evolución®

R-EVO Smart
Ophthalmic Equipment

Vitrectomía anterior con Twedge™ 23G
Sonda de vitrectomía de doble hoja

BVI
THE FUTURE IN FOCUS

Vitrectomía anterior de doble hoja **23G Twedge™**

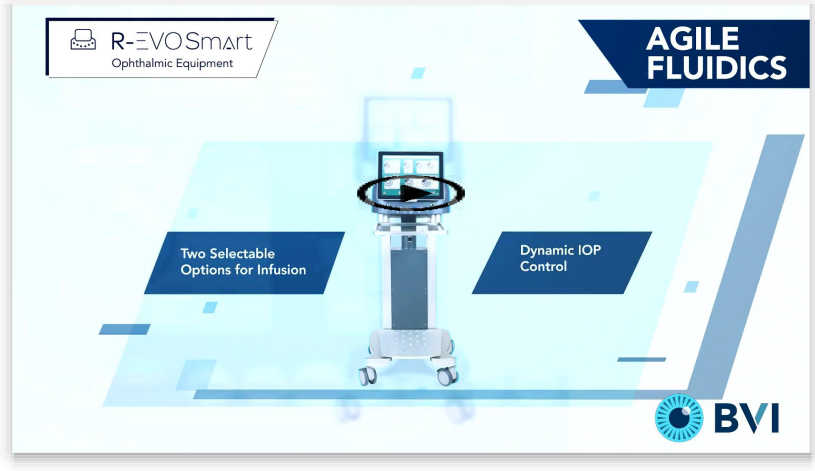


Opciones de irrigaciòn para Vitrectomìa Anterior **23G Twedge**

Sonda de irrigación para técnica bimanual (#114301)

Visitec® cánula para irrigación bimanual (#585223

Cánula de pared Delgada, curva a 45 grados,
puerto de irrigación de extremo abierto a 0.51mm


R-EVO Smart
Ophthalmic Equipment
AGILE FLUIDICS
Two Selectable Options for Infusion
Dynamic IOP Control
BVI

Clinical Ophthalmology

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ORIGINAL RESEARCH

Surgical Efficiency Comparison Between Two Phacoemulsification Systems

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Purpose: To assess the surgical efficiency in cataract surgery comparing two phacoemulsification systems.

Methods: Prospective, consecutive-comparative study in a two-site private practice. Three hundred and one eyes undergoing standard or femtosecond laser-assisted (FLACS) cataract surgery with either the R-Evo Smart (BVI, Waltham, USA) and/or the Centurion Vision System (Alcon, Fort Worth, USA). Preoperative eye characteristics (degree of cataract using the lens opacities classification system LOCS III grading) and intraoperative outcomes (total ultrasound time and total estimated fluid aspirated/drainage bag weighting) were registered in all cases.

Results: One hundred and fifty-five eyes undergone cataract surgery with the R-Evo Smart and 146 eyes with the Centurion Vision System phacoemulsification systems. Mean cataract grade was 3.07 ± 0.78 and 2.96 ± 0.85 for the R-Evo Smart and Centurion Vision System groups, respectively ($p = 0.12$). Mean total ultrasound time was 18.99 ± 12.85 and 40.24 ± 21.91 seconds for the R-Evo Smart and Centurion Vision System groups, respectively ($p < 0.01$). Mean total estimated fluid aspirated/drainage bag weighting was 53.00 ± 14.56 g and 54.33 ± 14.88 cc for the R-Evo Smart and Centurion Vision System groups, respectively ($p = 0.21$). Considering non-FLACS surgery (98 eyes with the R-Evo Smart and 63 eyes with the Centurion Vision System), mean cataract grade was 2.95 ± 0.74 and 2.97 ± 0.91 for the R-Evo Smart and Centurion Vision System groups, respectively ($p = 0.44$). Mean total ultrasound time was 19.96 ± 11.20 and 42.84 ± 28.35 seconds for the R-Evo Smart and Centurion Vision System groups, respectively ($p < 0.01$). Mean total estimated fluid aspirated/drainage bag weighting was 55.95 ± 14.76 g and 55.97 ± 13.62 cc for the R-Evo Smart and Centurion Vision System groups, respectively ($p = 0.49$). No adverse events were found in the two groups of eyes.

Conclusion: The objective measurement of surgical efficiency through total ultrasound time during lens removal and fluid consumption during both lens removal and irrigation/aspiration proved R-Evo Smart to be an efficient phacoemulsification platform, in comparison with the current standard of care Centurion Vision System.

Keywords: cataract, estimated fluid aspirated, phacoemulsification, surgical efficiency, ultrasound time

Introduction

It is well known that cataract is the main cause of reversible blindness in the world, and specifically, it has been reported that about 20 million Americans older than 40 years have cataract in either eye.[1] The number of patients affected by this pathology and consequently to be submitted to cataract surgery has been drastically increasing over time. The current gold standard procedure for cataract surgery is phacoemulsification technique due to the small number complications and excellent visual acuity outcomes.[2,3] There is a tendency to fewer surgical complication and better predicted refractions and visual outcomes.[4] This technique uses a phacoemulsifier irrigator and aspirator, and most of them use peristaltic pump technology.

Phacoemulsification has improved during the last years in order to increase surgical efficacy and reduce complications. One of these relatively new phacoemulsifier irrigator and aspirators is the Centurion Vision System (Alcon, Fort Worth, USA), which uses a small aspiration tubing and a cassette design with low compliance to minimize surge, and Active Fluidics to provide greater intraocular pressure (IOP) stability that minimizes IOP fluctuations happening during

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occlusion and post-occlusion break events. This device has been proved to be an excellent phacoemulsification system in different clinical studies published in the literature showing improved surgical efficiency.[5–9] Recently, the R-Evo Smart (BVI, Waltham, USA), a new phacoemulsification system for cataract surgery, has been developed, it incorporates two regulation systems with the aim of ensuring effectiveness and safety during surgery. The Agile Fluidics system mitigates the surge effect by adjusting the IOP based on the aspiration demand, and the Minimal Stress system makes sure that the elongation length of the phacoemulsification tip in each pulse is consistent with the programmed length, regardless of the hardness of the crystalline nucleus. It uses peristaltic and Venturi pumps, dual-infusion modality and dynamic IOP control.[10]

The main objective of the study is to compare the surgical efficiency in cataract surgery between two phacoemulsification machines, the R-Evo Smart and the Centurion Vision System, analyzing the total ultrasound time used as well as the total fluid aspirated/drainage bag weighting in each procedure.

Methods

Patients and Surgical Procedure

In this study, we have prospectively examined 301 eyes at two centers, Oftalvist Clinic in Madrid and Alicante, Spain, between May 2023 and October 2023. This study was approved by the Oftalvist Review Board. All patients signed an informed consent before surgery according to the tenets of the Declaration of Helsinki. Patients with cataracts were included in the study. Exclusion criteria considered traumatic, white or Morgagnian cataracts, subluxated crystalline lens, nystagmus, previous vitrectomy, weak zonules or narrow pupils. A full pre-operative assessment was performed in all patients, and specifically cataract degree was classified according to lens opacities classification system (LOCS) III.[11] Standard or femtosecond laser-assisted cataract surgery (FLACS) using the Catalys Precision Laser platform (Johnson & Johnson Vision, Santa Ana, USA) with 5-mm capsulotomy was performed through a 2.2-mm, temporally located, clear corneal incision. Two surgeons (MIB and POV) performed the surgeries.

Phacoemulsification Systems and Surgical Parameters

The specifications of the R-Evo Smart and the Centurion Vision Systems are indicated in Table 1. Both machines have been used under the manufacturer´s recommendations in terms of settings for fluidics and energy delivery, particularly for the latter Continuous U/S for Centurion Vision System and Pulsed-Burst U/S for R-Evo Smart. The program used with the R-Evo Smart system was sculpting with continuous ultrasound, chop and segment removal

Table 1 Specification for the Two Phacoemulsification Systems

	R-Evo Smart® (BVI)	Centurion Vision® System (Alcon)
Phaco Handpiece	Slim Four phaco handpiece with 21G Flared Bent Tip • Incision size 2.2mm • Longitudinal Tip Stroke from 5 to 100 μm: Resonant Frequency: approx. 40 KHz Minimal Stress Technology for load compensation	Centurion OZil handpiece with Balanced Tip • Incision size 2.2mm • Longitudinal Tip Stroke @ 100%: 84 ± 18 μm Resonant Frequency: 43.5±3.0 kHz • Torsional Tip Stroke @ 100%: 69 ± 23μm Resonant Frequency: 32.0±2.0 kHz
Peristaltic Aspiration System with IOP controlled infusion	• Easysys Fluidic cassette with Agile controlled infusion • Vacuum @ Sea Level: 5–650 mmHg • Aspiration Flow Rate: 2–65 cc/min • IOP Controlled Infusion: Range: 20–135 mmHg • Usable Fluid Volume: ≥400 cc (estimated)	• Active Fluidics • Vacuum @ Sea Level: 0–650 mmHg • Aspiration Flow Rate: 0–60 cc min • IOP Controlled Infusion: Range 20–110 mmHg (27–150 cm H2O) Accuracy: ± 15 mmHg • Usable Fluid Volume: ≥350 cc
I/A Handpiece	Coaxial I/A handpiece, long barrel, 21G angled I/A tip	Ultraflow II Coaxial I/A handpiece with angled Tip

Abbreviation: IOP, intraocular pressure.

with Multi Burst, epinucleus with pulse mode HD Pulse ON, cortical removal, polish and viscoelastic removal. The program used with the Centurion Vision System was sculpting with torsional/longitudinal continuous, chop and segment removal with torsional continuous, epinucleus with torsional continuous, cortical removal, polish and viscoelastic removal. Details of the surgical settings of both surgical platforms in both centers are shown in Figure 1.

Measurements and Analysis

Measurement of ultrasound time was recorded from both systems. In relation to the total estimated fluid aspiration, it was recorded directly for the Centurion Vision System. For the R-Evo Smart system the drainage bag weighting was used. The weight (measured with a precision balance) of the bag plus the weight of the liquid used for priming was subtracted from the total weight. Figure 2 visualizes where the drainage bag has been cut after each case (A) and the act of weighing the drainage bag on the high precision digital scale (B). The R-Evo Smart drainage bag has a one-way valve that prevents aspirated fluid to drop off, therefore ensuring the consistency of the measurement.

Oftalvist Madrid

BVI R-Evo smart One program "Cataract Media" for all lenses hardness grade			
Surgical Step	Settings		Modality
Sculpt	Phaco Energy: µm	40	Linear Continuous
	Vacuum: mmHg	200	Linear
	Flow: cc/min	25	Fixed
	IRR: mmHg	50	Agile
Chop & Segment Removal	Phaco Energy: µm	60	Multi Burst
	Vacuum: mmHg	450	Fixed
	Flow: cc/min	30	Fixed
	IRR: mmHg	50	Agile
Epi-Nucleous	Phaco Energy: µm	20	Fixed Pulse
	Pulse Frequency: pps	16	Ice Cold + HD Pulse
	Vacuum: mmHg	350	Linear
	Flow: cc/min	28	Linear
	IRR: mmHg	50	Agile
Cortical Removal	Vacuum: mmHg	450	Linear
	Flow: cc/min	30	Linear
	IRR: mmHg	50	Agile
Polish	Vacuum: mmHg	15	Linear
	Flow: cc/min	5	Linear
	IRR: mmHg	50	Agile
Visco Removal	Vacuum: mmHg	450	Fixed
	Flow: cc/min	40	Linear
	IRR: mmHg	50	Agile

Alcon Centurion One program "Cataract Media" for all lenses hardness grade			
Surgical Step	Settings		Modality
Sculpt	Phaco Energy: %	60	Linear Torsional
	Vacuum: mmHg	180	Linear
	Flow: cc/min	25	Fixed
	IRR: mmHg	40	Active
Chop & Segment Removal	Phaco Energy: %	55	Linear Torsional
	Vacuum: mmHg	500	Fixed
	Flow: cc/min	30	Fixed
	IRR: mmHg	40	Active
Epi-Nucleous	Phaco Energy: %	20	Linear Torsional
	Vacuum: mmHg	380	Linear
	Flow: cc/min	30	Linear
	IRR: mmHg	40	Active
Cortical Removal	Vacuum: mmHg	500	Linear
	Flow: cc/min	35	Linear
	IRR: mmHg	40	Active
Polish	Vacuum: mmHg	20	Linear
	Flow: cc/min	10	Linear
	IRR: mmHg	40	Active
Visco Removal	Vacuum: mmHg	550	Fixed
	Flow: cc/min	50	Linear
	IRR: mmHg	40	Active

Oftalvist Alicante

BVI R-Evo smart One program "Cata 2.2" for all lenses hardness grade			
Surgical Step	Settings		Modality
Sculpt	Phaco Energy: µm	30	Multi Burst
	Vacuum: mmHg	300	Linear
	Flow: cc/min	25	Fixed
	IRR: mmHg	104	Agile
Chop & Segment Removal	Phaco Energy: µm	50	Multi Burst
	Vacuum: mmHg	380	Fixed
	Flow: cc/min	28	Fixed
	IRR: mmHg	70	Agile
Epi-Nucleous	Phaco Energy: µm	30	Linear Pulse
	Pulse Frequency: pps	11	Cold
	Vacuum: mmHg	300	Fixed
	Flow: cc/min	25	Fixed
	IRR: mmHg	70	Agile
Cortical Removal	Vacuum: mmHg	500	Linear
	Flow: cc/min	25	Fixed
	IRR: mmHg	60	Agile
Polish	Vacuum: mmHg	30	Linear
	Flow: cc/min	15	Linear
	IRR: mmHg	60	Agile
Visco Removal	Vacuum: mmHg	550	Linear
	Flow: cc/min	35	Fixed
	IRR: mmHg	60	Agile

Alcon Centurion One program "Cata 2.2" for all lenses hardness grade			
Surgical Step	Settings		Modality
Sculpt	Phaco Energy: %	40	Linear Longitudinal
	Vacuum: mmHg	350	Fixed
	Flow: cc/min	28	Fixed
	IRR: mmHg	42	Active
Chop & Segment Removal	Phaco Energy: %	75	Linear Torsional
	Vacuum: mmHg	390	Fixed
	Flow: cc/min	35	Fixed
	IRR: mmHg	42	Active
Epi-Nucleous	Phaco Energy: %	60	Linear Torsional
	Vacuum: mmHg	300	Fixed
	Flow: cc/min	30	Fixed
	IRR: mmHg	50	Active
Cortical Removal	Vacuum: mmHg	500	Linear
	Flow: cc/min	25	Fixed
	IRR: mmHg	44	Active
Polish	Vacuum: mmHg	28	Linear
	Flow: cc/min	15	Linear
	IRR: mmHg	50	Active
Visco Removal	Vacuum: mmHg	575	Linear
	Flow: cc/min	40	Fixed
	IRR: mmHg	50	Active

Figure 1 Details of the surgical settings of both surgical platforms in the two clinical centers.

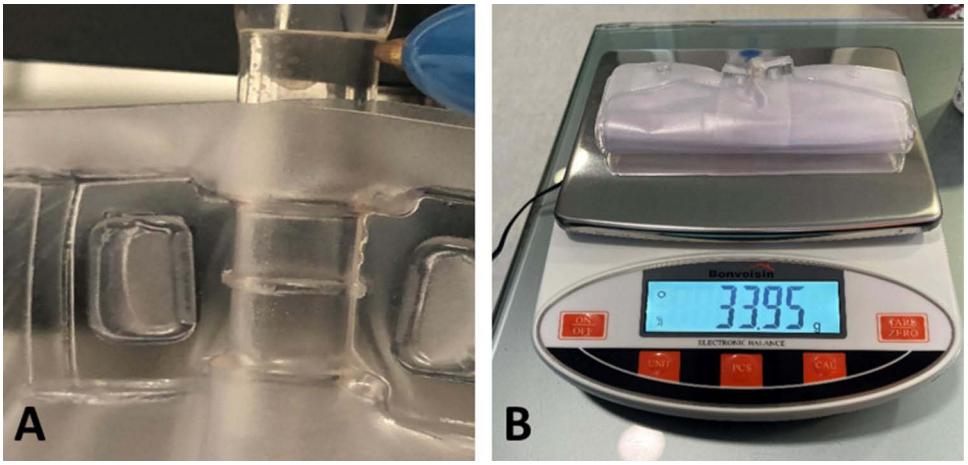

Figure 2 Picture where the drainage bag has been cut after each case (**A**) and the act of weighing the drainage bag on the high precision digital scale (**B**).

Analysis of the outcomes was carried out using Excel (2019, version 16.43, Microsoft Corporation, Redmond, USA) with all measurements given as the mean ± standard deviation (SD) and ranges. A sub-analysis of the non-FLACS eyes was done.

Results

The study comprised 155 eyes that underwent cataract surgery using the R-Evo Smart and 146 eyes that underwent cataract surgery with the Centurion Vision System. Within each study group, a sub-group of patients underwent standard phacoemulsification procedure only and the second sub-group underwent to FLACS procedure followed by phacoemulsification. No adverse events were found in the two groups of eyes during the procedures. Table 2 shows the surgical outcomes obtained. For the whole sample, our results revealed that there was no statistically significant difference between cataract degree between both groups of eyes ($p > 0.12$): mean cataract grade according to LOCS III classification was 3.07 ± 0.78 and 2.96 ± 0.85 for the R-Evo Smart and Centurion Vision System eye groups, respectively. In terms of surgical outcomes, our values revealed that the mean total ultrasound time was 18.99 ± 12.85 and 40.24 ± 21.91 seconds for the R-Evo Smart and Centurion Vision System eye groups, respectively. The differences between both groups

Table 2 Surgical Outcomes Obtained Using the Two Phacoemulsification Systems

	R-Evo Smart	Centurion®Vision System	P value
WHOLE SAMPLE			
N (eyes)	155	146	
Estimated Cataract Grade (LOCS III Grading Standard)	3.07±0.78	2.96±0.85	0.12
Total U/S Time (sec.)	18.99±12.85	40.24±21.91	<0.01
Total estimated fluid aspirated (cc) / Drainage bag weighing (g)	53.00±14.56	54.34±14.88	0.21
NON FLACS			
N (eyes)	98	63	
Estimated Cataract Grade (LOCS III Grading Standard)	2.95±0.74	2.97±0.91	0.44
Total U/S Time (sec.)	19.96±11.20	42.84±28.35	<0.01
Total estimated fluid aspirated (cc) / Drainage bag weighing (g)	55.95±14.76	55.97±13.63	0.49

Abbreviations: LOCS, lens opacities classification system; U/S, ultrasound; FLACS, femtosecond laser-assisted cataract surgery.

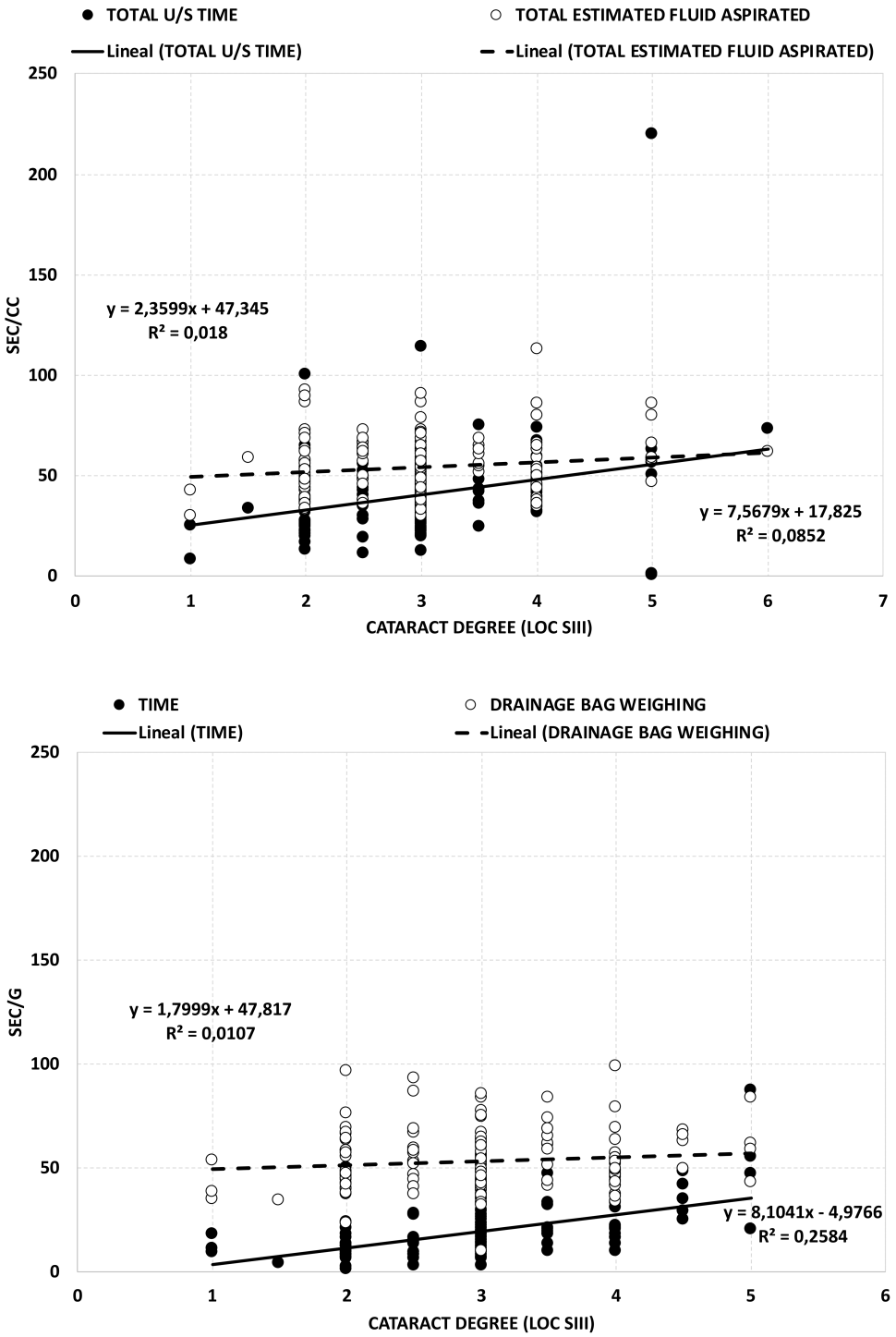

Figure 3 Total US/time and Total estimated fluid aspirated versus cataract degree (LOCS III scale) for the Centurion Vision System (top) and Time and Drainage bag weighing versus cataract degree (LOCS III scale) for the R-Evo Smart (bottom). Both graphs show the linear regression adjustments for the different parameters measured (equation and R^2 values are also shown).

of eyes were statistically significant: $p < 0.01$. The mean total estimated fluid aspirated/drainage bag weighting was 53.00 ± 14.56 g and 54.33 ± 14.88 cc for the R-Evo Smart and Centurion Vision System eye groups, respectively. In this parameter, we did not find statistically significant differences: $p = 0.21$. Regarding the possible correlation between cataract grade, ultrasound time and amount of aspirated fluid, Figure 3 shows that the higher the cataract grade, the

higher the US time for both phacoemulsification systems (Centurion R^2=0.08, R-EVO R^2=0.2). Fluid consumption tends to increase slightly with both devices with harder cataracts (Centurion R^2=0.01, R-EVO R^2=0.01).

For the non-FLACS eyes (98 versus 63 eyes for the R-Evo Smart and Centurion Vision System eye groups, respectively), our results showed no statistically significant differences between the degree of cataract: 2.95 ± 0.74 for the R-Evo Smart and 2.97 ± 0.91 for the Centurion Vision System (p = 0.44). The total ultrasound time was statistically significant between systems: 19.96 ± 11.20 and 42.84 ± 28.35 seconds for the R-Evo Smart and Centurion Vision System eye groups, respectively (p < 0.01). The mean total estimated fluid aspirated/drainage bag weighting was 55.95 ± 14.56 g and 55.97 ± 13.63 cc for the R-Evo Smart and Centurion Vision System eye groups, respectively (p = 0.49).

Discussion

The basic principle of any cataract removal procedure is to achieve maximum efficacy without compromising safety. High vacuum, a longer effective phacoemulsification time, and higher cataract density have been shown to be independent predictors of endothelial cell loss.[12–14] Developments in this area aim to reduce ultrasound energy, reducing the quantity of fluid aspirated and lowering effective phacoemulsification time while aiming at increasing the stability of the anterior chamber. In this study, we focused on the ultrasound time and effective fluid use to compare the efficacy of two different phacoemulsification systems.

The study comprised 155 eyes that underwent cataract surgery using the R-Evo Smart and 146 eyes that underwent cataract surgery with the Centurion Vision System with comparable nucleus hardness in both groups. The whole sample was divided into two subgroups for analysis depending on the use of FLACS (FLACS vs non-FLACS). The mean total ultrasound time (18.99 ± 12.85 seconds versus 40.24 ± 21.91 seconds) was lower for R-Evo Smart, while no differences in the mean total estimated fluid aspirated (53.00 ± 14.56 g versus 54.33 ± 14.88 cc, R-Evo Smart vs Centurion Vision System), were found. Subgroup analysis (FLACS vs non-FLACS) showed similar results between both groups, a statistically significant lower effective phacoemulsification time and similar fluid consumption with R-Evo Smart.

The latest phacoemulsification systems incorporate several improvements in their designs that aim to reduce effective phacoemulsification time, chatter (the phenomenon of lens material bouncing of the phaco tip),[6] and subsequent cumulative dissipated energy (torsional amplitude × torsional time × a coefficient of 0.4[6]) delivered into the eye. Centurion Vision System was released in 2013 including a newly designed phacoemulsification tip designed for torsional ultrasound (Ozil) with a 50% enhancement in sideways tip displacement (data on file, Alcon Laboratories, 2015) that minimizes stromal changes by reducing the amount of energy delivered to the incision site while reducing chatter.[15,16] R-Evo Smart incorporates a new design called "Minimal Stress™ ultrasound delivery Technology" that maintains the consistency between the programmed length of the phaco tip stroke and the actual tip elongation independently from the nucleus hardness, reducing the amount of wasted energy compared to traditional ultrasound systems.[10] According to the study published by Cimino et al,[17] the most important factors that result in tissue fragmentation are stroke amplitude, suction and acceleration of the tip, while Chen et al[6] showed that higher frequency produces better tissue fragmentation with a lower effective phacoemulsification time and lower delivery of cavitation bubbles. R-Evo Smart maintains the consistency of the stroke length and reduces surge through synergic work of a small-bore rigid aspiration tubing (1.3 mm) combined with a narrower design of a flared tip. According to the results of the current study, the innovative ultrasound delivery technology (Minimal Stress) in association with advanced design of energy emission forms (Multi Burst, HD Pulse) and in conjunction with the safety supported by Agile fluidics may help reduce the total ultrasound time compared to the current standard of practice.

The mean total fluid aspirated or effective fluid use (as described by other authors[18]), plays an important role in endothelial safety during cataract surgery, since a higher fluid consumption increases the loss of endothelial cells.[19] According to our results, both phacoemulsification systems have comparable fluid consumption. Centurion uses an active fluid dynamic management system that applies pressure directly to the irrigation bag, constantly adjusting fluctuations that result in a more stable anterior chamber, minimizing abrupt swings in aspiration flow rate, pressure, and rate of vacuum (data on file, Alcon Laboratories, 2015).[6] R-Evo Smart incorporates a system that regulates intraocular pressure to avoid fluctuations called "Agile Fluidics™ that consists of a set of controlled irrigation that enables a dynamic

intraocular pressure management, as well as a compatible rigid irrigation solution container, plus the "Easysys Fluidic System". It works through a proprietary algorithm that reacts to the vacuum measured by the system sensor with more pressure feeding into the irrigation bottle. The compensation is linear and instantaneous both with increasing and decreasing vacuum levels. The system increases up to only 20 mmHg, for vacuums up to 400 mmHg.

We need to consider some limitations of our study. The main variable used for comparison between R-Evo Smart and Centurion was the total ultrasound time (or effective phacoemulsification time), widely used in numerous studies for comparison of outcomes between phacoemulsification devices.[20–22] The cumulative dissipated energy is another parameter used for comparative studies, but exclusively among different Alcon´s devices, since it is a proprietary measurement of that company. Second, the measurement of the total fluid aspirated is given automatically by Centurion, but not by R-Evo Smart that required a precision balance and a mathematical calculation to subtract the bag's weight from the total weight after each surgery. And finally, it would also be of interest to consider the frequency of the ultrasound that each system uses for comparison, since a higher frequency phacoemulsification was associated with a lower effective phacoemulsification time and effective fluid use as well as better endothelial preservation according to Dewan et al.[18] Future studies considering these points and quantitative assessment of corneal endothelium would be desirable to confirm the outcomes reported.

Conclusions

In summary, the current clinical study demonstrates that both phacoemulsification systems are safe and efficient for different degrees of cataracts with no surgical complications. Patients with cataracts may benefit from the use of these two systems when submitted to cataract surgery. Specifically, our study indicates that the R-Evo Smart is an efficient phacoemulsification platform when measuring surgical efficiency through total ultrasound time and fluid consumption, in comparison with the current standard of care Centurion Vision System.

Data Sharing Statement

The data are not available for sharing.

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DISPOSITIVO MÉDICO PARA CIRUGÍA OCULAR

MANUAL DE INSTALACIÓN Y USO

Optikon 2000 S.p.A. es el fabricante de R-Evo Smart, dispositivo médico para facoemulsificación y vitrectomía.

El producto es conforme a los requisitos de la Directiva 93/42/CEE, relativa a los dispositivos médicos.

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1. EXENCIÓN DE RESPONSABILIDAD

El usuario del presente dispositivo médico debe leer atentamente las advertencias específicas que se contienen en el manual. El operador será responsable de que su personal conozca en profundidad el funcionamiento del dispositivo antes de usarlo. En ningún caso el fabricante será responsable de posibles daños accidentales o indirectos causados al comprador, a los operarios o a los pacientes por el uso del producto.

El uso del dispositivo médico está sujeto a evaluación médica profesional. El fabricante no será responsable de ningún problema clínico derivado del uso incorrecto del dispositivo y no proporcionará ninguna recomendación médica.

El fabricante se declara responsable de la seguridad, la fiabilidad y las prestaciones solamente en los siguientes casos:

- si las actualizaciones, las calibraciones y las reparaciones son realizadas por personal autorizado por el fabricante;
- si el instrumento se usa de conformidad con las instrucciones de uso;
- si el sistema eléctrico al que se conecta el dispositivo es conforme con las normas de seguridad IEC.

NOTA IMPORTANTE:

Se ha hecho todo lo posible para que, en el momento de la impresión del presente manual, todas las ilustraciones y el contenido reflejen de modo preciso el producto y su funcionamiento. No obstante, es posible que, en el transcurso de la existencia del presente manual, se introduzcan modificaciones en el producto destinadas a seguir satisfaciendo las necesidades de los usuarios. Dichas modificaciones pueden producirse sin previo aviso.

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NOTA
La información que contiene el presente manual es propiedad exclusiva de OPTIKON 2000 S.p.A. La reproducción total del manual solamente estará permitida previa autorización escrita de OPTIKON 2000 S.p.A.

2. CONDICIONES DE LA GARANTÍA LIMITADA

Todos los instrumentos y los accesorios vendidos e instalados en la Unión Europea están garantizados por el fabricante contra defectos de fabricación y de materiales durante UN AÑO desde la fecha de factura. La garantía sobre el material consumible se limita al primer uso del dispositivo.

En cuanto a las condiciones de garantía aplicables en el exterior de la Unión Europea, consulte a su distribuidor autorizado.

Todos los elementos cubiertos por la garantía serán reparados o sustituidos de forma gratuita.

La garantía cubre la investigación de la causa del defecto, la reparación de la avería y la inspección final del equipo o los componentes.

La garantía no cubre problemas resultantes del uso inapropiado, accidentes, el uso incorrecto y las manipulaciones o alteraciones realizadas por personas ajenas al servicio técnico autorizado del fabricante.

El fabricante se reserva el derecho de indagar, en caso de avería, si el instrumento o sus accesorios han sido alterados o manipulados de algún modo, o si han resultado dañados por un uso inapropiado.

Asimismo, el fabricante se reserva el derecho de modificar el instrumento o sus accesorios en aquellos casos en que los técnicos lo consideren necesario.

La garantía no será válida si el número de serie del instrumento o de los accesorios incluidos se ha perdido o ha sido alterado hasta resultar ilegible.

La garantía no cubre los gastos del envío del instrumento y sus accesorios: todos los gastos de transporte, embalaje, etc. correrán a cargo del cliente.

En caso de solicitud explícita de intervención por parte de los técnicos del fabricante, todos los gastos de viaje y alojamiento correrán a cargo del cliente.

OPTIKON 2000 S.p.A. no se responsabiliza de los posibles daños provocados por el transporte de los productos. se produjeren, el cliente deberá notificarlo inmediatamente al transportista encargado de la entrega.

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3. INFORMACIÓN GENERAL

3.1 LEYENDA DE LOS SÍMBOLOS

Se proporciona toda la información sobre los aspectos relativos a la seguridad presentes en el funcionamiento de este dispositivo médico. En este apartado se resume la información más importante relativa a la seguridad.

Símbolos de peligro

En el manual de uso se han introducido las siguientes indicaciones de seguridad. Tome buena nota de ellas y actúe con particular atención en los casos señalados con ellas.

⚠	**ATENCIÓN**	indica un peligro que puede causar **daños que produzcan lesiones mortales o graves.**
⚠	ADVERTENCIA	Indica un peligro que puede causar **accidentes que requieran atención médica.**
	INFORMACIÓN	Indica un peligro que puede causar **accidentes que no requieran atención médica.**

3.2 TABLA DE SÍMBOLOS

La tabla que figura a continuación muestra algunos símbolos aprobados por la I.E.C. (Comisión Electrotécnica Internacional) y sus correspondientes significados. Se trata de símbolos que se incluyen a menudo en instrumentos médicos para comunicar de forma rápida y sencilla información y advertencias. A veces, se combinan dos o más símbolos para indicar significados particulares.

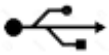
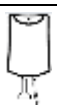
Estos símbolos figuran en la etiqueta de. R-Evo Smart. Antes de usar el equipo, familiarícese con los símbolos y las definiciones de la tabla.

SÍMBOLOS PUBLICADOS POR I.E.C.

SÍMBOLO	DESCRIPCIÓN
	FABRICANTE
	FECHA DE FABRICACIÓN
	CORRIENTE ALTERNA
	EMISIONES RF
	APAGADO (DESCONECTADO DE LA RED ELÉCTRICA)
	ENCENDIDO (CONECTADO A LA RED ELÉCTRICA)
	PARTE APLICADA DE TIPO B
	PARTE APLICADA DE TIPO BF
	DESECHO SEPARADO DE DISPOSITIVOS ELÉCTRICOS Y ELECTRÓNICOS
	EQUIPOTENCIALIDAD
	CONSULTAR LAS INTRUCCIONES DE FUNCIONAMIENTO

	VALOR NOMINAL DEL FUSIBLE
	AIRE COMPRIMIDO EN ENTRADA
	TOMA DE INYECCIÓN DE AIRE
	TOMA DE FUENTE DE ALUMBRADO
	TOMA PARA DIATERMIA
	TOMA DEL INTERRUPTOR DE PEDAL

OTROS SÍMBOLOS PRESENTES EN EL DISPOSITIVO

	TOMA DE INYECCIÓN DE ACEITE DE SILICONA
	TOMA FACO
	TOMA PARA VITRECTOMÍA
	POMO DE DESBLOQUEO DE LA CAJA
	TOMA USB
	Solución de irrigación
	IRRIGACIÓN CONTROLADA

3.3 GRUPO DE DESTINO

El presente manual de uso está destinado a médicos, enfermeros y demás personal sanitario y técnico que participe en la preparación, el funcionamiento o el mantenimiento del dispositivo tras una formación apropiada. El cliente o la institución serán responsables de instruir y formar a todo el personal que vaya a utilizar el dispositivo médico.

Las actividades de servicio técnico adicionales no forman parte del presente manual de uso. Dichas actividades serán realizadas por personal formado específicamente a tal fin por OPTIKON 2000 S.p.A.

Ámbito de aplicación

Objetivo

El dispositivo médico quirúrgico R-Evo Smart ha sido creado para su uso en quirófanos por parte de personal médico cualificado (cirujanos oculistas) en procedimientos quirúrgicos para el tratamiento del segmento ocular anterior. El dispositivo ha sido diseñado para la realización de irrigación, irrigación/aspiración, facoemulsificación del cristalino, vitrectomía anterior, técnicas de coagulación por diatermia bipolar. El R-Evo Smart CR dispone, además, de las funciones de vitrectomía posterior, tamponamiento con aire y aceite de silicona, iluminación endoocular. El dispositivo médico está destinado al uso en clínicas, hospitales y otras instituciones dedicadas a la medicina humana.

3.4 USO PREVISTO

El dispositivo R-Evo Smart está destinado a su uso en tratamientos quirúrgicos como extracciones extracapsulares, facoemulsificación o glaucoma del segmento anterior del ojo humano; el modelo R-Evo Smart CR también es apropiado para tratamientos quirúrgicos del desprendimiento de retina y otras patologías del cuerpo vítreo y del segmento posterior del ojo humano. Los posibles funcionamientos anómalos que se produzcan durante el uso del sistema se indican mediante mensajes que aparecen en la pantalla y mediante señales de alarma.

No están previstos usos distintos de los especificados anteriormente, y podrían causar peligros imprevistos. En particular, queda descartado el uso del dispositivo médico en intervenciones de neurocirugía y cardiocirugía.

⚠ **ATENCIÓN**

¡Peligro de lesiones para el paciente!

- La sección para la diatermia de los sistemas quirúrgicos R-Evo Smart no debe usarse en pacientes portadores de marcapasos u otros estimuladores cardiacos sin consultar con un cardiólogo.

3.5 ADVERTENCIAS PARA EL OPERARIO

- Use el dispositivo médico exclusivamente para los objetivos previstos, como está descrito.
- Respete la legalidad en materia de supervisión del mercado y las señalizaciones obligatorias aplicables en el país, así como cualesquiera normas o estándares adicionalmente aplicables.

Cualificación del usuario

- Se ruega familiarizarse a fondo con el contenido del manual de uso antes de poner en marcha el dispositivo. Tenga en cuenta las instrucciones de uso de otros dispositivos.
- Antes de usar el dispositivo médico, todo el personal médico deberá haber leído y comprendido la totalidad de las instrucciones contenidas en el manual de uso.
- Conserve el manual de uso en un lugar al que el personal pueda acceder fácilmente en cualquier momento durante el uso del dispositivo médico.
- Solamente podrá usar el dispositivo médico personal médico con la debida cualificación, con conocimiento de los posibles riesgos derivados del su uso y con una formación completa y adecuada para la prevención y la gestión de posibles complicaciones clínicas.
- El dispositivo médico deberá ser usado exclusivamente por personal con la debida formación e instrucción. El cliente o la institución serán responsables de instruir y formar a todo el personal que vaya a utilizarlo.

- Es fundamental tener la formación adecuada para instalar y utilizar correctamente los dispositivos R-Evo Smart; OPTIKON 2000 S.p.A. ofrece dicha formación. Pida más información al centro de servicio técnico local de OPTIKON 2000 S.p.A.

Transporte

⚠ **ADVERTENCIA**

Peligro de lesiones oculares en el paciente

El dispositivo médico está embalado de modo que se reduzca al mínimo el riesgo de daños durante el transporte.

- En caso de observarse cualquier daño debido al transporte, notifíquelo al transportista y no use el dispositivo.
- En el caso de transporte de larga distancia (por ejemplo, desmontaje, devolución para reparación, etc.), será necesario colocar el dispositivo en su embalaje original o en embalajes especiales. Pida más información al propio revendedor o al servicio técnico de OPTIKON 2000 S.p.A.

Montaje e instalación

INFORMACIÓN

¡Peligro de daños en el dispositivo médico!

- Asegúrese de que la instalación y el uso del dispositivo sean conformes a los requisitos quirúrgicos:
  - bajas vibraciones
  - ambiente limpio
  - ausencia de cargas mecánicas excesivas

INFORMACIÓN

¡Riesgo de interferencias y mal funcionamiento!

Este dispositivo médico requiere precauciones especiales con respecto a la compatibilidad electromagnética (EMC, por sus siglas en inglés), debe instalarse y ponerse en servicio de acuerdo con la información y las indicaciones de EMC que figuran en los documentos que se acompañan.

INFORMACIÓN

¡Riesgo de interferencias y mal funcionamiento!

Este Dispositivo Médico no debe usarse cerca de otros dispositivos. Si debe usarse cerca de otro equipo, debe observarse cuidadosamente para verificar el funcionamiento normal en la configuración real en la que se usa.

INFORMACIÓN

¡Peligro de daños en el dispositivo médico!

La altura máxima del portasueros es de 225 cm desde el suelo.

- No instale los sistemas R-EVO SMART en ambientes con techo bajo.

INFORMACIÓN

¡Peligro de daños en el dispositivo médico!

Si las aberturas de ventilación quedan cerradas u obstruidas, el dispositivo puede recalentarse.

- Instale el sistema R-EVO SMART de forma que las aberturas de ventilación no queden cerradas ni obstruidas.

⚠ **ATENCIÓN**

Peligro de incendio o explosiones

El dispositivo médico no es apropiado para su uso en zonas peligrosas.

- Los sistemas R-Evo Smart no deben usarse:
  - en zonas potencialmente explosivas;
  - en presencia de anestésicos o disolventes volátiles, como el alcohol, el benceno o productos químicos similares; estos deberán mantenerse a una distancia mínima de 25 cm.

- No use ni almacene el dispositivo médico en ambientes húmedos. No exponga el sistema a deslizamientos, caídas o salpicaduras de agua.

- Para garantizar un funcionamiento seguro, no instale el dispositivo médico en lugares que puedan estar expuestos a dispositivos de calefacción o radiadores, a la luz solar directa o a cualquier otra fuente de calor con temperaturas demasiado elevadas.

Funcionamiento

⚠ **ADVERTENCIA**

Peligro de lesiones para el paciente o el usuario

- Observe las cargas máximas indicadas para los siguientes componentes:
  - Carga máxima en la bandeja del instrumento, 1 kg
  - Carga máxima de la botella y de la solución para la irrigación, 0,5 kg.

⚠ **ADVERTENCIA**

Peligro de lesiones para el paciente o el usuario

Peligro de basculación cuando se pasan umbrales.

- Empuje el dispositivo médico lentamente y con precaución mediante sus asas cuando se pasen umbrales hasta 3 cm. Si el umbral el más alto de 3 cm, deberá ser desplazado por dos personas.

INFORMACIÓN

Peligro de lesiones leves para el paciente

Un logotipo con puntitos blancos en movimiento situado en el borde inferior derecho de la pantalla indica que el dispositivo está funcionando correctamente.

- Si los puntos que rodean el logotipo dejan de moverse, el dispositivo está detenido y se debe dejar de usarlo.
- Antes de cualquier uso, realice la instalación, la configuración quirúrgica y los procedimientos operativos aquí descritos. Si se constata un funcionamiento incorrecto que se pueda corregir con la ayuda del capítulo "Corrección de las averías", se ruega colocar en el dispositivo la etiqueta "no funciona" y consultar con el servicio técnico de OPTIKON 2000 S.p.A.

- Siga escrupulosamente las instrucciones de instalación y uso del equipo para evitar interferencias peligrosas con otros dispositivos. Este dispositivo médico ha sido probado y cumple con los límites de emisión e inmunidad establecidos por la norma IEC60601-1-2: 2014 para dispositivos electromédicos. Estos límites están concebidos para garantizar la protección adecuada contra interferencias en un entorno médico típico. Sin embargo, aún pueden existir interferencias en una instalación específica. Si el dispositivo médico provoca interferencias peligrosas con otros dispositivos (se pueden detectar apagando y encendiendo el equipo), el usuario debe tratar de resolver la interferencia mediante una de las siguientes medidas:
    - reorientar o recolocar los otros dispositivos;
    - aumentar la distancia entre los dispositivos;
    - conectar el equipo a una toma de alimentación distinta de aquella a la que estén conectados los demás dispositivos;
    - consultar al revendedor o al servicio técnico de OPTIKON 2000 S.p.A.
- La capacidad de emisión sonora del dispositivo se debe probar en el arranque.
  Compruebe que se emita una señal sonora durante el inicio del sistema.
- Los posibles funcionamientos anómalos que se produzcan durante el uso del dispositivo médico se indican mediante mensajes que aparecen en la pantalla y señales de alarma. Resuelva el funcionamiento anómalo y confirme la lectura del mensaje pulsando en la pantalla el botón correspondiente. Si no se puede eliminar el funcionamiento anómalo, o bien si el error se produce de nuevo, no siga usando el dispositivo, sino coloque una señal que indique que "no funciona" y diríjase a su revendedor o al servicio técnico de OPTIKON 2000 S.p.A.
- No tire de los cables de alimentación ni de otros cables de conexión.
- Desplace el dispositivo médico comprobando que ningún tubo resulte aplastado ni extraído.
- Las emisiones procedentes de aparatos portátiles de telecomunicaciones pueden influir en las prestaciones

del equipo.

- No deje nunca el dispositivo médico sin vigilancia cuando la fuente de alimentación esté encendida, para evitar causar daños en la retina del paciente a causa de un tiempo de irradiación excesivo.

Mantenimiento

- El dispositivo médico es un producto sofisticado de alta tecnología. Para garantizar las mejores prestaciones y unas condiciones de uso seguras, es indispensable, como parte de un programa de mantenimiento normal, encargar una inspección anual a personal técnico autorizado por OPTIKON 2000 S.p.A.
- Para evitar una disminución de la seguridad del dispositivo médico debida al envejecimiento, el desgaste, etc., la institución que use el instrumento debe asegurarse, de conformidad con la normativa nacional aplicable, de que se hayan realizado los controles técnicos de seguridad normales indicados para este dispositivo en los plazos previstos y con el alcance estipulado. Los controles técnicos de seguridad deben ser realizados exclusivamente por el fabricante o por personal cualificado. Los controles técnicos de seguridad deben extenderse al menos a los siguientes aspectos:
  - Disponibilidad del manual de uso
  - Inspección visual del dispositivo y de sus accesorios para comprobar que no existan daños y que los símbolos y las etiquetas sean legibles
  - Prueba de impedancia de la puesta a tierra
  - Prueba de dispersión de corriente
  - Prueba de funcionamiento de todos los interruptores, botones, conectores y testigos del dispositivo médico

Modificaciones

⚠ **ATENCIÓN**

Peligro de lesiones oculares en el paciente
Los productos modificados pueden romperse durante su aplicación y causar funcionamientos anómalos en el dispositivo.

- No modifique la forma de la pieza de mano para la vitrectomía ni la punta faco usada con los sistemas R-EVO SMART (por ejemplo, no lo pliegue, no lo corte ni lo raye).

ATENCIÓN

Peligro de lesiones oculares en el paciente
Las modificaciones debidas a la aplicación de fuerza manual en el portasueros pueden provocar un nivel incorrecto de la botella y lesiones en el paciente.

- El nivel del portasueros no debe modificarse mediante fuerza manual.
- Las modificaciones y las reparaciones del dispositivo médico o de cualquier otro sistema usado junto con él deberán ser realizadas exclusivamente por el servicio técnico de OPTIKON 2000 S.p.A. o por otro personal autorizado oportunamente.

Desecho

ADVERTENCIA

Contaminación medioambiental
Si el desecho se produce de forma incorrecta, puede producirse una contaminación medioambiental.

- No deseche el dispositivo médico a través de los mecanismos de recogida de los desechos domésticos normales.
  Deséchelo por separado, siguiendo las normas y las leyes locales y gubernamentales sobre el desecho de dispositivos eléctricos y electrónicos.
- Las partes infectadas pueden contaminar al usuario o el medio ambiente. Deseche los líquidos usados conforme a las normas y las leyes locales o gubernamentales en materia de desecho de materias orgánicas.

Accesorios aprobados

ATENCIÓN

Peligro de lesiones oculares en el paciente

- Use exclusivamente los artículos aprobados y recomendados por OPTIKON 2000 S.p.A.

ADVERTENCIA

Peligro de lesiones oculares en el paciente

- Use exclusivamente accesorios y materiales consumibles originales elaborados por OPTIKON 2000 S.p.A. y destinados al uso con los sistemas R-EVO SMART. Consulte las instrucciones de uso de los accesorios para comprobar su compatibilidad con los sistemas R-EVO SMART.

- El uso de accesorios y cables no incluidos en el embalaje del dispositivo médico puede causar un aumento de las interferencias electromagnéticas o reducir la inmunidad del sistema a dichas interferencias. Use exclusivamente los repuestos aprobados por OPTIKON 2000 S.p.A. para estos sistemas.
- El equipo adicional conectado a los dispositivos médicos eléctricos debe ser conforme a las normas IEC o ISO (por ejemplo, la IEC 60950 relativa al equipamiento para tratamiento de datos). Asimismo, todas las configuraciones deben cumplir los requisitos para sistemas eléctricos médicos (consulte la IEC 60601-1-1 o la cláusula 16 de la 3.ª edición de la IEC 60601-1). Toda persona que conecte equipo adicional a un aparato eléctrico médico está configurando un sistema médico y, por lo tanto, es responsable del cumplimiento de las normas relativas a los sistemas eléctricos médicos. Tenga en cuenta que las leyes locales tienen prioridad sobre las normas arriba indicadas. En caso de duda, consulte a su revendedor o al servicio técnico de OPTIKON 2000 S.p.A.

Sistema eléctrico

INFORMACIÓN

Riesgo de funcionamiento anómalo de los dispositivos

- Nunca conecte un dispositivo USB al dispositivo médico mientras esté en uso.
- Deben usarse exclusivamente memorias USB sin virus.

- El dispositivo médico está configurado para su uso con una tensión de línea de 100–240 V (±10 %), 50-60 Hz. Compruebe que la tensión de la línea local se corresponda con esos valores.
- Cambie siempre el fusible por uno del mismo tipo.
- Para reducir el peligro de electrocución, no retire la cubierta protectora. Para cambiar el fusible, diríjase a un servicio técnico autorizado.
- Conecte el dispositivo R-EVO SMART a una fuente de alimentación principal con las características indicadas en el panel trasero de la consola. Para garantizar un funcionamiento seguro, el dispositivo médico debe disponer de una puesta a tierra adecuada.
- Para evitar el peligro de electrocución, el dispositivo debe conectarse exclusivamente a una fuente de alimentación provista de una puesta a tierra apropiada.
- Antes de conectar o desconectar la unidad a la fuente de alimentación, compruebe que el interruptor principal esté desconectado.
- El interruptor principal debe mantenerse apagado cuando el sistema no esté en uso.
- Antes de cambiar los fusibles, apague el dispositivo y déjelo enfriar unos minutos.
- Si la normativa y las directrices del país en que se use así lo exigen, el dispositivo médico deberá estar conectado a un grupo de continuidad.
- No coloque recipientes que contengan líquidos sobre el dispositivo médico. Asegúrese de que no penetren en el dispositivo productos de limpieza.
- No trate nunca de conectar conectores eléctricos (enchufes, tomas) a la fuerza. Si un enchufe no entra fácilmente en la toma, compruebe que no esté destinado a una distinta. Si algún enchufe está dañado,

diríjase al servicio técnico local de OPTIKON 2000 S.p.A.

- No use prolongadores eléctricos ni conectores múltiples.
- Los sistemas deben tener una puesta a tierra correcta para garantizar su funcionamiento seguro.
- Ecualización de potencial adicional: el dispositivo médico debe estar provisto de conectores con protección de tierra.

Aplicación de diatermia

ATENCIÓN

Peligro de lesiones en pacientes con marcapasos

Existe peligro potencial para pacientes con marcapasos o estimuladores cardiacos, ya que el generador para la diatermia puede causar interferencias RF. El marcapasos puede averiarse.

- En caso de duda al respecto, consulte a un médico especializado.

ATENCIÓN

Peligro de lesiones oculares en el paciente

- Cuando la pieza de mano para la diatermia bipolar y el sistema de control se usen simultáneamente, todos los electrodos del sistema de control que no estén protegidos por resistores o por inductores de alta frecuencia deben estar situados lo más lejos posible de los electrodos de la diatermia.
- Peligro de quemaduras o incendio; no use la diatermia cerca de materiales conductores, como partes metálicas de la cama, colchones de muelles y similares. Cambie los cables de los electrodos apenas empiecen a parecer desgastados.
- Use exclusivamente cables para diatermia originales de OPTIKON 2000 S.p.A.
- Pueden producirse graves quemaduras de RF (radiofrecuencia) si la corriente de salida del sistema para diatermia se desvía hacia el operario a causa de un uso imprudente.
- El cable para diatermia bipolar no debe tocar al paciente ni otros cables.
- Use siempre la intensidad de potencia de salida más baja de la diatermia, compatible con aplicaciones quirúrgicas.
- Los signos evidentes de una intensidad de potencia de salida baja o los errores de funcionamiento de la pieza de mano para diatermia bipolar, incluso aunque el dispositivo pueda estar configurado para un uso normal, pueden indicar un contacto no apropiado entre las conexiones de los electrodos.

Cuando use la pieza de mano para diatermia bipolar, no use anestésicos inflamables, monóxido de azufre u oxígeno si no está garantizada una buena ventilación

mediante un sistema de aspiración adecuado.

- Los materiales inflamables, como los agentes desinfectantes y los productos de limpieza, deben dejarse evaporar antes de usar la pieza de mano para diatermia bipolar. Algunos materiales, como la lana, el algodón o la gasa, si están impregnados con oxígeno, pueden prender a causa de chispas que salgan del dispositivo durante su uso normal.

- Es posible que se produzcan interferencias con otros aparatos médicos debido al uso de la pieza de mano para diatermia bipolar.

Aplicaciones de irrigación/aspiración

ATENCIÓN

Peligro de lesiones oculares en el paciente
Colocar la solución de irrigación demasiado baja puede causar que la presión en el ojo del paciente sea demasiado baja.

- Compruebe que la solución de irrigación siempre esté colocada a un nivel superior respecto del ojo del paciente.
- Observe las indicaciones del capítulo "Colocación de los tubos de irrigación/aspiración" en el presente manual. Si no se siguen las indicaciones que se recogen en él, pueden producirse graves consecuencias.
- Es fundamental colocar correctamente los tubos de irrigación y aspiración para asegurar que los sistemas R-EVO SMART funcionen correctamente.
- El paso de la modalidad peristáltica a la modalidad Venturi puede causar un colapso de la cámara anterior si se usa una punta faco de baja impedancia (por ejemplo, una punta faco de gran diámetro) y si el vacío está ajustado a nivel alto. Para garantizar la seguridad del paciente, antes de volver a iniciar la aspiración después de haber pasado de un tipo de bomba a otro, compruebe siempre que el ajuste del vacío sea correcto para el tipo de bomba que se utilice.
- Use exclusivamente tubos originales de OPTIKON 2000 S.p.A.
- Nunca inicie la pieza de mano faco (priming) cuando esté situado en el ojo del paciente; de lo contrario, puede causarle lesiones.
- Antes de cualquier intervención, compruebe que exista una cantidad suficiente de solución salina equilibrada. Compruebe la cantidad de solución salina equilibrada durante todo el tiempo que dure la intervención.
- Durante el funcionamiento, no deje de comprobar el nivel de la solución salina equilibrada en la botella de infusión. Si la cantidad de solución salina equilibrada se considera insuficiente para completar la operación, avise inmediatamente al cirujano y cambie la botella o la bolsa de infusión con los procedimientos que se indican a continuación:

IRRIGACIÓN POR GRAVEDAD

- Interrumpa el procedimiento quirúrgico y retire la pieza de mano de la incisión.
- Cierre la morsa del tubo de infusión.
- Desenganche la botella del portasueros cuando esté casi vacía.
- Retire el perforador del deflusor de la botella, prestando atención a no tocarlo con las manos ni con ningún otro material no estéril.
- Introduzca el perforador del deflusor en el tapón de la botella nueva y engánchela en el portasueros.
- Si la cámara de goteo se vacía completamente, apriétela para llenarla otra vez de solución salina equilibrada más o menos hasta el 50 %.
- Vuelva a abrir la morsa de infusión.

- Si se observan burbujas de aire en el tubo de infusión o en los tubos de irrigación, pida al cirujano que active la irrigación hasta que las burbujas resulten expulsadas antes de volver a insertar la punta de la pieza de mano en el ojo del paciente.

INFUSIÓN CONTROLADA

- Interrumpa el procedimiento quirúrgico y retire la pieza de mano de la incisión.
- Cierre la morsa del tubo de infusión.
- Desconecte el tubo del aire de la salida "CONTROLADA" situada en la placa de burbujas del R-Evo Smart.
- Desenganche el contenedor del líquido de infusión semivacío de su soporte.
- Retire el perforador del deflusor, prestando atención a no tocarlo con las manos ni con ningún otro material no estéril.
- Inserte el perforador del deflusor en el tapón de un contenedor nuevo y cuélguelo en el soporte al efecto.
- Conecte el tubo del aire de la salida "CONTROLADA" del dispositivo R-Evo Smart.
- Vuelva a abrir la morsa de irrigación.

- Si se observan burbujas de aire en el tubo de infusión o en los tubos de irrigación, pida al cirujano que active la irrigación hasta que las burbujas resulten expulsadas antes de volver a insertar la punta de la pieza de mano en el ojo del paciente.

Aplicación de ultrasonidos

ATENCIÓN

Peligro de lesiones para el paciente o el usuario
No compruebe el funcionamiento ni la vibración de la punta faco tocándola con los dedos: la exposición prolongada o el contacto directo con la punta faco mientras vibra puede causar daños en los tejidos.

- No coloque nunca las manos ni los dedos en la punta faco ni en el manguito de silicona la pieza de mano faco mientras prueba este último (priming).

ADVERTENCIA

Peligro de lesiones oculares en el paciente
Quemaduras causadas por exceso de energía de los ultrasonidos.

- El ruido de las vibraciones debe aumentar ajustando la potencia de los ultrasonidos a valores más altos; un ruido elevado constante a todos los niveles de potencia indica que el aparato funciona mal.

ADVERTENCIA

Peligro de lesiones oculares en el paciente
El movimiento incorrecto de la punta faco o del manguito de silicona en la incisión puede causar daños en la córnea del paciente.

- No tuerza ni aplique presión en la incisión.

ADVERTENCIA

Peligro de lesiones oculares en el paciente
Quemaduras en la córnea causadas por exceso de energía de los ultrasonidos.

- Use siempre la intensidad de potencia de salida más baja de los ultrasonidos, compatible con la aplicación quirúrgica.
- Para comprobar el funcionamiento la pieza de mano, no active los ultrasonidos con la punta faco en el aire. La potencia de los ultrasonidos debe aplicarse en la pieza de mano faco con la punta insertada en una cámara estéril para pruebas rellena con solución salina equilibrada o en un contenedor con líquido estéril a temperatura ambiente. Si no se siguen estas instrucciones, es posible que resulte dañada la punta faco o la pieza de mano faco.
- Compruebe que la pieza de mano faco esté conectado correctamente al sistema de irrigación o aspiración del

dispositivo R-Evo Smart y que se use exclusivamente junto con este último.

- Un ruido fuerte prolongado procedente de la pieza de mano faco con regulación mínima de la potencia puede indicar un funcionamiento incorrecto de la regulación de la potencia y provocar quemaduras en la córnea o daños endoteliales. consultar al revendedor o al servicio técnico de OPTIKON 2000 S.p.A.
- No apriete nunca la punta faco ni el manguito de silicona contra la herida para evitar que la punta faco se recaliente.
- Los aumentos no deseados de la potencia en salida pueden indicar un funcionamiento incorrecto del dispositivo médico quirúrgico R-Evo Smart. consultar al revendedor o al servicio técnico de OPTIKON 2000 S.p.A.

Aplicaciones de vitrectomía

- No active nunca la pieza de mano para la vitrectomía con la hoja en el aire. El vitréctomo siempre debe probarse con la hoja en un contenedor con solución estéril. Si la prueba se realiza en el aire, se producirán daños irreparables en el sistema de corte.

Iluminación (solo R-Evo Smart CR)

⚠ **ATENCIÓN** **Peligro de lesiones oculares en el paciente**

- Adapte la intensidad de la emisión luminosa y la duración de la exposición mediante el ajuste de emisión adecuado.

⚠ **ATENCIÓN** **Peligro de lesiones oculares en el paciente**

Daños en la retina debidos a exceso de potencia.

- Aunque el sistema de iluminación endoocular de fibra óptica esté diseñado para no emitir radiaciones infrarrojas y ultravioletas, salvo en cantidades mínimas, para evitar posibles daños en la retina use siempre la intensidad mínima de la potencia compatible con las aplicaciones quirúrgicas.

INFORMACIÓN **Peligro de lesiones leves para el usuario**

Los conectores de salida de la luz están calientes cuando la luz está encendida.

- Apague la luz y espera unos minutos antes de tocar los conectores de salida de la luz.
- Para reducir el peligro de daños en la retina, la punta de la sonda de iluminación de fibra óptica no debe estar situada inmediatamente junto a la retina.

Tamponamiento con aire y aceite de silicona (solo R-Evo Smart CR)

ATENCIÓN **Peligro de lesiones debido a exceso de presión del aire**

- Una pérdida de aire audible al encender puede indicar un funcionamiento incorrecto de la sección de silicona. Consulte al servicio técnico de OPTIKON 2000 S.p.A.

- Para evitar posibles infecciones en el ojo, use exclusivamente tubos de tamponamiento con aire originales de OPTIKON 2000 S.p.A. dotados de filtro de esterilización del aire.
- Usar un juego de tubos de tamponamiento con aire no estándar puede afectar a la precisión de la presión intraocular y alterar la esterilidad del aire introducido.
- Durante la inyección de aceite de silicona, la presión intraocular no es controlada por el R-Evo Smart CR, por lo que el cirujano debe ocuparse de controlar la presión intraocular (PIO). Es importante comprobar el flujo de silicona a la presión de inyección ajustada antes de introducir la cánula en el ojo.
- Suelte el pedal para interrumpir la inyección de aceite de silicona. En caso de emergencia, se pueden quitar los tubos de infusión del aceite de silicona de la unidad de alimentación de silicona.

3.6 ESPECIFICACIONES GENERALES

PARÁMETRO	ESPECIFICACIÓN
Fabricante:	OPTIKON 2000 S.p.A. Via del Casale di Settebagni, 13 00138 Roma - Italia
Modelo:.....	R-Evo Smart E/R-Evo Smart S/R-Evo Smart CR
Conformidad con la normativa: .	Directiva 93/42/CEE relativa a los productos sanitarios
Normas técnicas:	EN60601-1; EN60601-1-2; EN60601-2-2 EN80601-2-58
ESPECIFICACIONES MEDIOAMBIENTALES	
Embalaje y transporte:	temperatura de –10 °C a +70 °C, humedad del 10% al 100 % (sin condensación), presión atmosférica de 500 a 1 060 hPa
Funcionamiento:.....	intervalo de temperatura de +10 °C a +35 °C, humedad del 30 % al 75 %, presión atmosférica de 900 a 1 060 hPa (para vacío máximo); 810 a 1060 hPa (para vacío hasta 500 mmHg)
ESPECIFICACIONES ELÉCTRICAS	
Tensión de entrada:.....	100-240 V CA.
Frecuencia:.....	50/60 Hz
Potencia necesaria:	200 VA
Fusibles:.....	100-240 voltios: T3, 15 AH 250 V
ESPECIFICACIONES DEL AIRE COMPRIMIDO (solo R-Evo Smart S y CR)	
Presión del aire de entrada:	de 500 a 800 KPa (de 72 a 116 PSI)
Consumo de aire:	32 normal litros/minuto
IRRIGACIÓN	
Aportación del líquido:	por gravedad: presión ocular determinada por la altura de la fuente de irrigación, o irrigación controlada
Válvulas:	válvula solenoide
Control:	Pedal del sistema
ASPIRACIÓN	
Tipos de bomba de aspiración: ..	R-Evo Smart E: peristáltica R-Evo Smart S y CR: peristáltica y Venturi
Modos de accionamiento:	(bomba Venturi) aire comprimido procedente de fuente externa a 500÷800 KPa (72÷116 PSI)
Nivel del vacío predefinido:.....	programable por parte del usuario
Intervalo de vacío disponible: ...	de 5 a 650 mmHg
Flujo predeterminado:.....	programable por parte del usuario

PARÁMETRO	ESPECIFICACIÓN
Intervalo de flujo disponible:	de 1 a 65 cc/min (solo peristáltica)
Tiempo de subida del vacío:	regulable a 25 niveles (0,5 s - 12 s)
Modo de aspiración lineal:	control lineal de la aspiración, mediante pedal de sistema (por vacío y/o flujo), del valor mínimo a máximo, programable
Dispositivo de seguridad:	sensor de vacío, medición del vacío en la línea de aspiración
Control:	pedal de sistema

VITRECTOMÍA POSTERIOR (solo R-Evo Smart CR)

Tipo de pieza de mano:.....	cortante neumático con hoja de guillotina (VIT)
Modos de corte:.....	movimiento alternativo
Frecuencia de corte predefinida:	programable por parte del usuario
Frecuencia de corte disponible:.	de 60 a 5 000 cortes por minuto (OptiVit) de 120 a 10 000 cortes por minuto (Twedge)
Dimensiones de la puerta:.....	0,5 mm
Modos de accionamiento:	aire comprimido procedente de fuente externa
Presión de funcionamiento:	2,6 bar
Modo de corte lineal:	control lineal de la frecuencia de corte mediante pedal
Control:	pedal de sistema

VITRECTOMÍA ANTERIOR

Tipo de pieza de mano:.....	cortante neumático con hoja de guillotina
Modos de corte:.....	movimiento alternativo
Frecuencia de corte predefinida:	programable por parte del usuario
Frecuencia de corte disponible:.	de 60 a 1 000 cortes por minuto (R-Evo E) de 60 a 5 000 cortes por minuto (R-Evo S, CR)
Dimensiones de la puerta:.....	0,5 mm
Modos de accionamiento:	aire comprimido procedente de fuente externa (R-Evo Smart S y CR) o de compresor de seco integrado (R-Evo Smart E)
Presión de funcionamiento:	2,6 bar
Modo de corte lineal:	control lineal de la frecuencia de corte mediante pedal, desde 0 hasta valor predefinido
Control:	pedal de sistema

DIATH (DIATERMIA)

Tipo:.....	generador bipolar, el generador se detiene cuando la alimentación de RF no es necesaria.

PARÁMETRO	ESPECIFICACIÓN
Frecuencia de funcionamiento: .	2 MHz
Potencia nominal:	9W (200 Ohm CARGA)
Tensión máxima sin carga:	100 V
Potencia predefinida:	programable por parte del usuario
Potencia disponible:.....	del 5 % al 100 % (porcentaje)
Modo lineal:	permite el control lineal de la potencia de la DIATERMIA mediante pedal.
Tipo de pieza de mano:.....	micropinzas bipolares, lápiz diatérmico superficial, pieza de mano para diatermia intraocular
Cable para diatermia:.....	dos conductores, 26 Gauge, 75 Ohm, 200 V máx., se puede introducir en autoclave de vapor; use solo el cable para diatermia original.
Control:	pedal de sistema
ILUMINACIÓN (solo R-Evo Smart CR)	
Tipo de fuente:	dos lámparas LED independientes
Flujo luminoso:	400+400 lm
Regulación de la intensidad:	20 niveles + 4 filtros de protección y mejora de visualización de membranas epirretínicas
SECCIÓN PARA LA INYECCIÓN DE AIRE (solo R-Evo Smart CR)	
Presión nominal:	de 5 a 120 mmHg
PIO efectiva:	presión nominal + 3 mmHg
Dispositivos de seguridad:	alarma acústica por activación de aire
SECCIÓN PARA LA INYECCIÓN DE SILICONA (solo R-Evo Smart CR)	
Presión nominal:	de 0,4 a 5 bar
Señales:	alarma acústica por activación de inyección de silicona, alarma de presión baja en entrada de aire
FACOEMULSIFICADOR	
Tipo de pieza de mano:.....	piezoeléctrico disponible de cuatro o de seis cristales
Frecuencia:	aprox. 40 KHz
Elongación de la punta:.....	de 0 a 100 µm
Control de potencia:	mando de panel o lineal, mediante pedal, de la energía U/S emitida
Modos U/S:	lineal o de panel, continua, autolimit, impulso breve, pulso HD, ráfaga única, ráfaga múltiple, ráfaga continua
Temporizador U/S:	de 0,00 a 9,59 minutos; pantalla del tiempo faco equivalente

PARÁMETRO	ESPECIFICACIÓN	

CLASIFICACIÓN DEL DISPOSITIVO CONFORME A LA NORMA IEC 60601-1

Tipo de protección contra descarga eléctrica:	Clase I
Grado de protección contra descarga eléctrica:	
Diatermia:	Tipo BF, fluctuante a alta y baja frecuencia
U/S:	Tipo B
Vitrectomía	Tipo BF
Iluminación:	Tipo BF
Aire:	Tipo BF
Silicona:	Tipo BF
Nivel de protección contra Entrada de agua (unidad):	IPX0
Nivel de protección contra Entrada de agua (pedal):	IPX8
Grado de seguridad de la aplicación en presencia de mezclas anestésicas inflamables:	No apto

DIMENSIONES

Alto:	35 cm	(152 cm con carro)
Ancho:	43 cm	(57 cm con carro)
Profundidad:	50 cm	(74 cm con carro)
Peso:	17 Kg	(60 kg con carro y pedal)

NOTA:
1) El peso y las dimensiones indicadas son aproximados.
2) Las especificaciones están sujetas a modificaciones sin previo aviso.

3.7 TABLAS CEM

EMISIONES ELECTROMAGNÉTICAS

	Las emisiones de este dispositivo lo hacen adecuado para su uso en áreas industriales y hospitales (CISPR 11 Clase A). Si se usa en un entorno residencial (para el cual normalmente se requiere CISPR 11 Clase B), este dispositivo puede no proporcionar una protección adecuada para los servicios de comunicación por radiofrecuencia. El usuario puede necesitar tener medios de mitigación, como reposicionar o redirigir el dispositivo.

GUIA Y DECLARACIÓN DEL FABRICANTE – EMISIONES ELECTROMAGNÉTICAS Los sistemas **R-evo Smart** se ha diseñado para usarse en el entorno electromagnético que se describe más abajo. El cliente o usuario del **R-evo Smart** deberá asegurase de que se usa en dicho entorno.		
Prueba de emisiones	**Conformidad**	**Entorno electromagnético**
Emisiones de RF CISPR 11	Grupo 1	El dispositivo médico **R-evo Smart** utiliza energía de RF sólo para su funcionamiento interno. Por lo tanto, las emisiones de RF son muy bajas y es probable que no causen ninguna interferencia en los equipos electrónicos cercanos.
Emisiones de RF CISPR 11	Clase A	El dispositivo médico **R-evo Smart** es apropiado para el uso en todos los establecimientos que no sean establecimientos domésticos y aquellos que están directamente conectados con una red de distribución de baja tensión que alimenta a los edificios para fines domésticos.
Emisiones armónicas IEC 61000-3-2	No se aplica	
Fluctuaciones de tensión/ Emisiones de parpadeo IEC 61000-3-3	No se aplica	

INMUNIDAD ELECTROMAGNÉTICA

GUIA Y DECLARACIÓN DEL FABRICANTE – INMUNIDAD ELECTROMAGNÉTICA Los sistemas **R-evo Smart** se ha diseñado para su uso en el entorno electromagnético que se describe más abajo. El cliente o usuario del **R-evo Smart** deberá asegurase de que se usa en dicho entorno.			
Prueba de inmunidad	**Nivel de la prueba IEC 60601-1-2**	**Nivel de conformidad**	**Entorno electromagnético**
Descarga electrostática (ESD) IEC 61000-4-2	±8 kV contacto ± 2; 4; 8; 15 kV aire	±8 kV contacto ± 2; 4; 8; 15 kV aire	Los suelos deberán ser de madera, de hormigón o de baldosas de cerámica. Si los suelos están recubiertos con un material sintético, la humedad relativa deberá ser de al menos un 30%.
Ráfaga / rápidos transitorios eléctricos IEC 61000-4-4	±2 kV para las líneas del suministro de energía ±1 kV para las líneas de entrada/salida 100kHz	±2 kV para las líneas del suministro de energía ±1 kV para las líneas de entrada/salida 100kHz	La calidad de la alimentación principal deberá ser la típica de un entorno comercial u hospitalario.
Sobretensión IEC 61000-4-5	±1 kV modo diferencial ±2 kV modo común	±1 kV modo diferencial ±2 kV modo común	La calidad de la alimentación principal deberá ser la típica de un entorno comercial u hospitalario.
Las caídas de tensión, las interrupciones cortas y las variaciones de voltaje en las líneas de entrada de suministro de energía IEC 61000-4-11	0% U_T para 0.5 ciclos 0 % U_T para 1 ciclo 70 % U_T para 25 ciclos 0 % U_T para 250 ciclos	0% U_T para 0.5 ciclos 0 % U_T para 1 ciclo 70 % U_T para 25 ciclos 0 % U_T para 250 ciclos	La calidad de la alimentación principal deberá ser la típica de un entorno comercial u hospitalario. Si el usuario del **R-evo Smart** requiere un funcionamiento continuo durante las interrupciones de la alimentación eléctrica, se recomienda que el **R-evo Smart** se alimente de un suministro de energía ininterrumpida o de una batería.
Frecuencia industrial (50/60 Hz) Campo magnético IEC 61000-4-8	30 A/m	30 A/m	El campo magnético de la frecuencia industrial debería estar al nivel característico de un emplazamiento típico en un entorno comercial u hospitalario.

Nota: U_T es la tensión de red de corriente alterna antes de la aplicación del nivel de la prueba

GUIA Y DECLARACIÓN DEL FABRICANTE – INMUNIDAD ELECTROMAGNÉTICA

Los sistemas **R-evo Smart** se ha diseñado para su uso en el entorno electromagnético que se describe más abajo. El cliente o usuario del **R-evo Smart** deberá asegurase de que se usa en dicho entorno.

El equipo de comunicaciones de RF móvil y portátil no debería usarse más cerca de ninguna parte del **R-evo Smart**, incluyendo los cables, que la distancia de separación recomendada calculada de la ecuación aplicable a la frecuencia del transmisor.

Prueba de inmunidad	**Nivel de la prueba IEC 60601-1-2**		**Nivel de conformidad**	**Distancia de separación recomendada**
RF conducida EN 61000-4-6	3 Veff 150kHz to 80MHz		3 Veff	**d**= 30cm
RF irradiada EN 61000-4-3	3 V/m and 10V/m 80MHz to 2.7GHz		3 V/m	**d**= 30cm
Inmunidad a los campos de proximidad de dispositivos inalámbricos de comunicación RF IEC 61000-4-3	TETRA 400 380 – 390 MHz	27 V/m	27 V/m	**d**= 30cm
	GMRS 460 FRS 460 430 – 170 MHz	28 V/m	28 V/m	
	LTE Band 13, 17 704 – 787 MHz	9 V/m	9 V/m	
	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 800 960 MHz	28 V/m	28 V/m	
	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 5 1700 – 1990 MHz	28 V/m	28 V/m	
	Bluetooth, WLAN, 802.11 b/g/n, RIFD 2450, LTE Band 70 2400 – 2570 MHz	28 V/m	28 V/m	
	WLAN 802.11 a/n 5100 – 5800 MHz	9 V/m	9 V/m	
				Pueden producirse interferencias en las proximidades del equipo marcadas con el siguiente símbolo:

El R-evo Smart ha sido diseñado para usarse en un entorno electromagnético en el cual las perturbaciones de RF emitidas estén controladas. El cliente o usuario **del R-evo Smart** puede ayudar a prevenir las interferencias electromagnéticas manteniendo una distancia mínima entre el equipo de comunicación de RF móvil y portátil (transmisor) y el **R-evo Smart**, tal y como se recomienda más abajo, de acuerdo con la potencia de salida máxima del equipo de comunicación.

Potencia de salida nominal máxima del transmisor (W)	**Distancia de separación de acuerdo con la frecuencia del transmisor (m)**		
	150KHz to 80MHz $d = 1.2 \times \sqrt{P}$	**80MHz to 800MHz** $d = 1.2 \times \sqrt{P}$	**800MHz to 2.5GHz** $d = 2.3 \times \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Para transmisores con tasa de potencia de salida máxima que no aparezcan en la tabla anterior, la distancia de separación recomendada en metros (m) se puede calcular usando la ecuación que se aplica a la frecuencia del transmisor, donde *P* es la potencia de salida máxima del transmisor en vatios (W) de acuerdo con el fabricante del transmisor.

Notas:

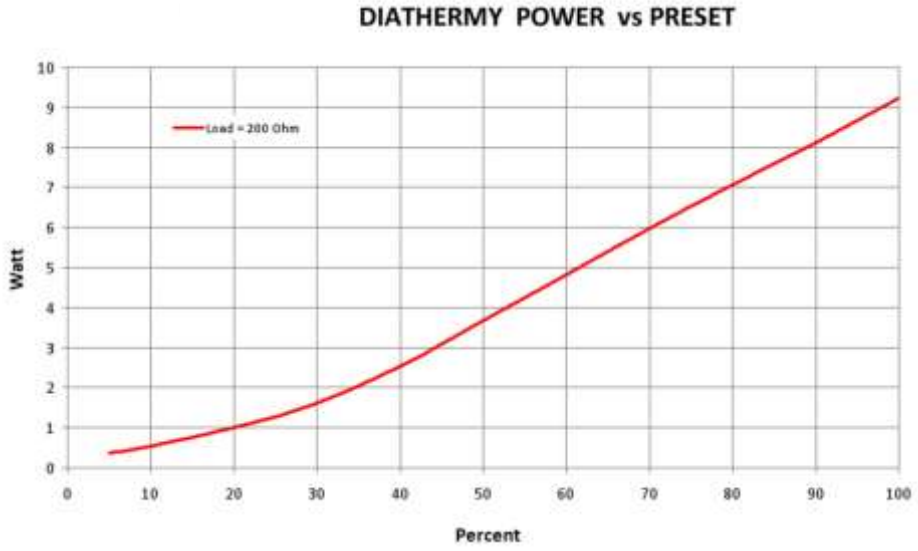
(1) at 80MHz and 800MHz, se aplica la distancia de separación para la gama de frecuencia más alta.

(2) Estas pautas no se aplican en todas las situaciones. La propagación electromagnética se ve afectada por la absorción y reflexión de las estructuras, objetos y personas.

Las intensidades de campo para transmisores fijos tales como estaciones base para teléfonos de radio (celulares y inalámbricos) y radios móviles terrestres, radioaficionados, transmisores de radio AM y FM y transmisores de TV no pueden predecirse teórica y precisamente. Para evaluar un entorno electromagnético causado por transmisores de RF fijos, se debe considerar un estudio del sitio electromagnético. Si la intensidad de campo medida en el lugar donde se usa el **R-Evo Smart** excede el nivel de cumplimiento aplicable anterior, se debe monitorear el comportamiento del **R-Evo Smart**. Si se observa un rendimiento anormal, pueden ser necesarias medidas adicionales, como una orientación o posición diferente del **R-Evo Smart**.

La intensidad de campo en el rango de frecuencia de 150 kHz a 80 MHz debe ser inferior a 3 V / m.

3.8 CARACTERÍSTICAS DE LA POTENCIA EN APLICACIONES DE DIATERMIA



3.9 ESQUEMAS ELÉCTRICOS

Previa solicitud, OPTIKON 2000 S.p.A. proporcionará esquemas eléctricos, listas de componentes, descripciones, instrucciones de calibración u otra información que ayude al personal técnico cualificado del operador a reparar los elementos reparables del dispositivo.

4. INSTALACIÓN Y USO

Antes de la primera puesta en marcha

ADVERTENCIA

Peligro de lesiones oculares en el paciente

El dispositivo médico deberá ser instalado por el servicio técnico de OPTIKON 2000 S.p.A. o por un experto autorizado por esta. Asegúrese de que se satisfagan los siguientes requisitos a lo largo de todo el tiempo de funcionamiento:

- Los elementos de conexión están insertados correctamente. Los tornillos de conexión están apretados.
- Todos los cables y los enchufes están en perfecto estado, por ejemplo, no muestran ningún signo de desgaste, nudos ni otros daños.
- La tensión indicada en la placa de datos del equipo se corresponde con la tensión de la línea de red del lugar de instalación.
- El enchufe solo se podrá conectar a una toma dotada de un conductor de puesta a tierra en perfecto estado.
- El dispositivo está conectado al cable de alimentación suministrado por OPTIKON 2000 S.p.A.

Antes de cada uso

ADVERTENCIA

Peligro de lesiones oculares en el paciente

- Asegúrese de que se cumplen todos los "Requisitos para el funcionamiento" especificados.
- Coloque de nuevo las cubiertas o las tapas retiradas anteriormente. Cierre todas las aberturas existentes con sus correspondientes tapas.
- Anote todos los símbolos y señales colocadas en el dispositivo médico.
- Las aberturas de ventilación no deben estar cerradas ni obstruidas.
- Compruebe que el sistema R-EVO SMART esté situado en un lugar con espacio suficiente para manejarlo, de modo que se evite dañar los cables, que exista total

libertad de movimiento del dispositivo médico y que además exista fácil acceso al interruptor de alimentación para desconectarlo de la red eléctrica.

- Conecte el conector equipotencial de la parte trasera del dispositivo al conector equipotencial del quirófano mediante un cable equipotencial. Si es necesario, puede ser conveniente disponer de una segunda puesta a tierra en caso de mal funcionamiento de la puesta a tierra principal.
- El conector de alimentación se usa como medio para aislar eléctricamente de forma simultánea todos los polos de la ALIMENTACIÓN DE RED. No coloque el dispositivo de forma que resulte difícil desconectar el conector de alimentación de la toma de red.
- Compruebe la configuración de los parámetros del perfil de usuario seleccionado para evitar comportamientos no deseados del dispositivo médico.

Después de cada uso

- Al concluir la sesión operatoria, desconecte todos los accesorios quirúrgicos. Coloque el recipiente portainstrumentos en su lugar debajo de la consola.
- Use el interruptor de alimentación principal para apagar el dispositivo médico.
- El interruptor principal debe mantenerse apagado cuando el sistema no esté en uso. El enchufe del cable de alimentación deberá extraerse de la toma de la red principal.
- (Solo CR) Desconecte el tubo de alimentación del aire comprimido del equipo del quirófano.

Responsabilidad y garantía

La garantía y la responsabilidad dependen de las estipulaciones contractuales aplicables.

INFORMACIÓN

Pérdida del derecho de garantía

No debe realizarse ninguna modificación en el dispositivo médico. El fabricante no será responsable de daños causados por manipulaciones realizadas en el dispositivo por personas no autorizadas. Asimismo, estas harán perder todo derecho de solicitar intervenciones cubiertas por la garantía.

4.1 DESCRIPCIÓN DEL EQUIPO

Los sistemas **R-Evo Smart** ofrecen los módulos y las funciones quirúrgicas que se describen a continuación:

Sistema de irrigación

Los sistemas quirúrgicos R-EVO SMART disponen tanto de irrigación por gravedad como de irrigación controlada.

Irrigación por gravedad

Cuando la irrigación se alimenta por gravedad, el flujo del líquido y la presión de irrigación son determinados por la altura a la que se sitúa la fuente de infusión. El R-EVO SMART controla un portasueros motorizado automático que puede situarse de forma que se pueda adaptar la altura del recipiente de irrigación.

⚠ **ADVERTENCIA** **Peligro de lesiones oculares en el paciente**

En la cirugía del segmento anterior, cuelgue la botella de solución salina equilibrada en el gancho más alto del portasueros.
En la cirugía del segmento posterior, utilice el gancho bajo.

Irrigación controlada

Si se usa la función de "Irrigación controlada", la presión de la irrigación es configurada automáticamente por el R-EVO SMART. Este sistema ofrece diversas ventajas para controlar la presión de irrigación, en contraste con el sistema de irrigación por gravedad, como el control dinámico de la presión intraocular con compensación de las fluctuaciones debidas al flujo de aspiración, tanto en la cirugía de las cataratas como en la de retina. Para utilizar la irrigación controlada se necesita disponer de la bolsa de irrigación controlada o de la cámara de goteo para irrigación controlada. Estos accesorios opcionales son suministrados por OPTIKON 2000 S.p.A. Una válvula controlable bien mediante pedal o bien mediante pantalla táctil en la interfaz gráfica de software permite el control encendido/apagado de la irrigación.
En caso de irrigación controlada, use el gancho más bajo del portasueros.

Sistema de aspiración

Los sistemas quirúrgicos R-EVO SMART S y R-Evo Smart CR disponen de una función de aspiración realizada mediante un sistema de dos bombas. Según las necesidades quirúrgicas o las preferencias, el cirujano puede seleccionar una bomba de flujo (peristáltica) o una bomba de vacío (Venturi).

El R-Evo Smart E dispone solo de la bomba peristáltica.

La caja I/A está alojada en la placa de la bomba, en el lado de la máquina.

Los líquidos y los materiales de partículas se aspiran con los extremos distales de la punta y se depositan en el recipiente colector de la caja I/A.

Un sensor de seguridad del vacío controla el nivel del vacío en el tubo de aspiración y adapta la acción de la bomba según las necesidades. Dicha lectura del vacío se realiza con un "sistema cerrado": una membrana estéril situada en la caja I/A separa completamente el sensor del vacío de los líquidos estériles.

⚠ **ADVERTENCIA** **Peligro de infección ocular en el paciente**

No reutilice el material de un solo uso.

Las bombas del R-EVO SMART son controladas por un microprocesador. El nivel del vacío puede preajustarse desde la pantalla táctil o puede ser controlado por el cirujano con el interruptor de pedal (modo lineal).

Vitrectomía

La pieza de mano para la vitrectomía se conecta a la toma para vitrectomía. Esencialmente, está formado por dos partes:

- PUNTA DEL FILO (hoja) y
- CUERPO (que contiene el mecanismo de mando de aire comprimido).

La pieza de mano para la vitrectomía usa el principio del accionador de efecto sencillo: la presión causa el movimiento hacia delante de la hoja (cierre de la boca de corte). Cuando se deja de aplicar la presión, el movimiento de retorno se realiza mediante un muelle incorporado.

La punta contiene el elemento cortante, formado por una

parte externa (fija) y un tubo interno, que se mueve hacia delante y hacia atrás en sentido longitudinal, acoplados el uno al otro.

El tubo interno se usa para la aspiración y dispone de una hoja situada en el extremo anterior con un borde externo cortante. En el extremo anterior, el tubo externo tiene una abertura lateral para el corte y la aspiración. Los tejidos se cortan y se aspiran de forma simultánea gracias a la acción recíproca longitudinal del tubo interno, generada por impulsos neumáticos procedentes del sistema quirúrgico.

La distancia extremadamente cercana entre los tubos externo e interno crea una ligera tensión constante que proporciona un efecto autoafilante. Es evidente que dicha precisión combina con el diseño de guillotina para ofrecer características de corte ideales. La velocidad de corte (de 60 a 5 000 cortes/min Vit, y de 120 a 10 000 cortes/min Twedge con el R-Evo Smart CR) y el nivel del vacío (de 5 a 650 mmHg) puede regularse mediante los elementos de control gráfico de la pantalla táctil.

Diatermia bipolar

La diatermia bipolar usa corrientes de radiofrecuencia (RF) para producir calor en los tejidos del cuerpo y causar la coagulación. La energía de un oscilador de RF (en el interior del dispositivo) se conduce a una pareja de electrodos (pinzas para diatermia o lápiz diatérmico) que toca los tejidos biológicos que se van a tratar. La aplicación de alta frecuencia bipolar (RF) contribuye a reducir la estimulación neuromuscular no deseada.

Ambos sistemas quirúrgicos generan una potencia de salida regulable de 0,1 a aprox. 9 watt @ 200 Ω.

Iluminación (solo R-Evo Smart CR)

El R-Evo Smart CR dispone de dos lámparas LED de alta intensidad (fuente para iluminación de fibra óptica) y, en dos de ellas, de filtros de protección para la retina del componente azul de la luz y para obtener condiciones de visualización óptimas durante los procedimientos quirúrgicos de la retina.

Cada uno de los sistemas de iluminación independientes es alimentado por una lámpara LED enfocada sobre el cabezal de la fibra óptica. Las lámparas LED no emiten radiación fuera del espectro visible; por esa razón no son necesarios filtros de protección UV ni IR y está garantizada la máxima

seguridad para el paciente.Un sistema electrónico permite regular la intensidad de la iluminación en 20 niveles, sin influir en el color de la luz. Hay disponibles 3 filtros amarillos (435 nm, 475 nm y 515 nm) para enfatizar la presencia de membranas cuando se usan colorantes y proteger el ojo del paciente de una exposición no necesaria a las radiaciones luminosas azules, lo que permite tratamientos de larga duración. Un filtro verde permite mejorar el contraste, incluso en ausencia de colorantes, oscureciendo las estructuras de color rojo respecto de las membranas (blancas) y los demás tejidos oculares.

Tamponamiento de aire (solo R-Evo Smart CR)

El sistema de tamponamiento de aire utiliza una sofisticada tecnología para controlar automáticamente la presión ocular. Eso permite al cirujano introducir aire estéril a una presión predefinida (en mmHg), mientras el sistema equilibra automáticamente las variaciones debidas a posibles pérdidas procedentes de incisiones quirúrgicas.

El módulo de obtención de aire del dispositivo médico R-Evo Smart CR está diseñado para suministrar aire estéril a baja presión regulable durante todo el intervalo de 5 a 120 mmHg.
Un filtro de membrana de un solo uso encapsulado está montado en el tubo de alimentación del aire externo, conectado a la toma de aire del panel delantero, de forma que en la práctica todos los tipos de partículas se eliminan cuando el aire pasa por dicho filtro. Un sistema automático controlado mediante pantalla táctil o pedal permite pasar de la irrigación con BSS al tamponamiento con aire y viceversa sin necesidad de accionar ninguna llave manual.

Tamponamiento con aceite de silicona (solo R-Evo Smart CR)

El dispositivo de inyección del aceite de silicona es una unidad formada por una jeringa, rellena previamente de aceite de silicona, conectada mediante tubos de alta presión al panel delantero del dispositivo médico.

La jeringa se activa mediante aire comprimido controlado de forma lineal por el interruptor de pedal.

Facoemulsificación

La pieza de mano faco piezoeléctrico fabricado por

OPTIKON 2000 S.p.A. puede conectarse a la toma faco. La pieza de mano faco contiene un piezotransductor que oscila a una frecuencia de 40 KHz (+4,5 kHz/-1 kHz) con amplitud de aprox. 100 µm. El piezotransductor de la pieza de mano faco incluye tres componentes distintos:

- El **ELEMENTO PIEZOELÉCTRICO CERÁMICO** que convierte la energía eléctrica suministrada por la consola de control directamente en movimientos oscilatorios mecánicos a aprox. 40 000 ciclos por segundo (40 kHz).
- El **CUERPO** que amplifica y transmite mecánicamente el movimiento del elemento piezoeléctrico cerámico a la punta faco.
- La **PUNTA FACO** que vibra longitudinalmente y facilita así la fragmentación del tejido en un área circunscrita de la superficie de contacto entre la punta y la catarata. La cantidad máxima de reutilizaciones de las puntas faco se describe en las instrucciones de uso suministradas junto con las propias puntas.

Los procesos de pérdida de energía interna del elemento piezoeléctrico cerámico causan un recalentamiento del piezotransductor cuando vibra a altas frecuencias, el líquido aspirado del ojo se usa también para disipar el calor producido.

Los sistemas R-EVO SMART disponen del sistema patentado Minimal Stress, que facilita la medición del movimiento (carrera) de la punta faco en tiempo real. Esta información es usada por el microprocesador para estabilizar la carrera de la punta faco.

Las principales ventajas de este sistema son las siguientes:

- La potencia predefinida U/S indica la carrera efectiva de la punta faco y corresponde a los micrones de amplitud del movimiento oscilatorio de la propia punta faco.
- Las distintas piezas de mano faco son ecualizadas y compensadas respecto de la típica pérdida de eficiencia debida a los efectos del tiempo.
- La vibración de la punta ya no se ve influida por las diferencias de dureza de la catarata ni por las fluctuaciones de la temperatura de la pieza de mano.
- La energía media necesaria y la energía de pico son inferiores respecto de la facoemulsificación estándar.
- Reducción del retorno de fragmentos de catarata.

- El dispositivo puede probar las piezas de mano faco para comprobar su funcionamiento y evitar que el dispositivo funcione por debajo de los límites aceptables.

La potencia de los ultrasonidos puede generarse en modo continuo o a impulsos.

- En **modo continuo**, la energía faco es suministrada a la pieza de mano de forma continua y sin interrupciones si se pulsa el interruptor de pedal más allá del punto de retroacción mecánica 2 (zona C, ver descripción “Pedal de sistema”).

- En **modo a impulsos**, la potencia es emitida en forma de impulsos a intervalos preestablecidos, si el interruptor de pedal se encuentra en la zona C, tras haber superado la posición 2. El cirujano puede seleccionar los siguientes ajustes en el modo a impulsos:

- Modo "pulsado": los ultrasonidos están disponibles tanto en el modo de panel como con control lineal. Se generan impulsos de ultrasonidos, la frecuencia de repetición de los impulsos puede regularse entre 1 y 100 Hz. Para cualquier frecuencia, es posible regular la duración del ciclo activo (duty cycle) en uno de los tres niveles (denominados "standard", "cold" y "ice cold" y correspondientes aproximadamente a un ciclo activo del 50 %, del 25 % y del 10 % respectivamente), de forma que se limita la energía ultrasonora utilizada al mínimo necesario.
- El modo "HD pulse" adapta automáticamente el duty cicle del pulsado al estado de oclusión de la punta, de forma que se emulsifican más rápido los fragmentos de catarata "capturados" por la punta sin ejercer energía no necesaria cuando la punta está libre de oclusiones.

- El modo **single burst** (ráfaga sencilla) proporciona ráfagas sencillas de ultrasonidos de 120 ms de duración. El cirujano debe devolver el interruptor de pedal a la zona C, ponerlo en pausa durante aprox. medio segundo y pulsarlo de nuevo en la zona C para obtener una nueva ráfaga sencilla.

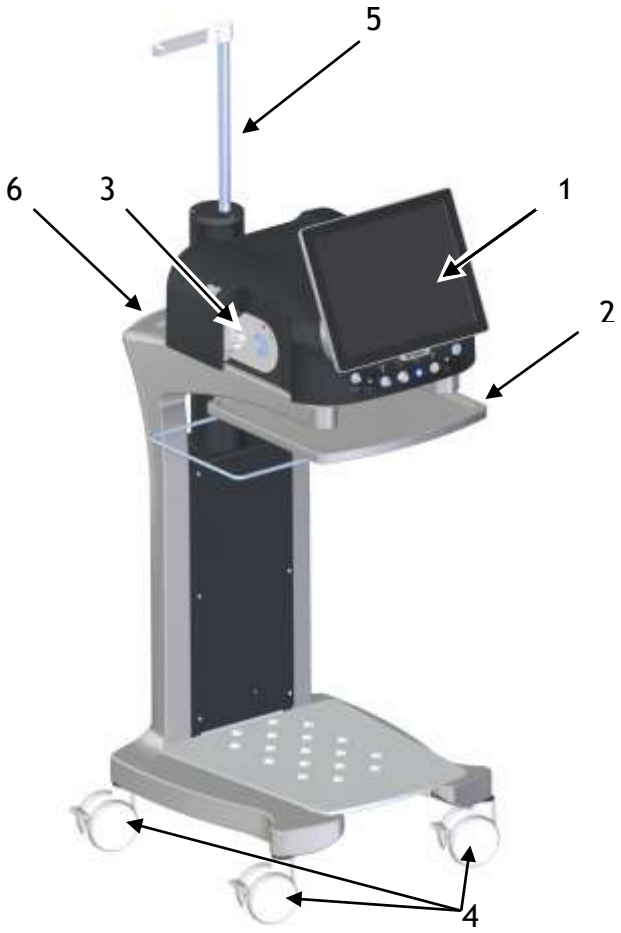
- El modo **multi burst** (ráfaga múltiple) genera ultrasonidos de 80 ms de duración, con ráfagas adicionales generadas (aprox. 1 ráfaga por segundo) cuando el interruptor de pedal pasa de la posición táctil

2 y alcanza la zona C. Cuando el interruptor de pedal se presiona más allá del límite de parada, la frecuencia de los impulsos aumenta hasta la velocidad máxima de 4 ráfagas por segundo.

- El modo **cont burst** (ráfaga continua) produce un impulso de 80 ms de duración. Cuando el interruptor de pedal supera la posición táctil 2 y alcanza la zona C, el impulso se genera de modo consecutivo a una velocidad creciente. Con la presión máxima del interruptor de pedal, las ráfagas se funden y las unidades obtienen los ultrasonidos a potencia continua.

4.2 COMPONENTES DEL DISPOSITIVO MÉDICO

4.2.1 Visión de conjunto (carro con recipiente y alzabotellas opcional)



1 Pantalla táctil de 15"
La pantalla táctil permite al operario ajustar los parámetros y leer su valor actual. La pantalla táctil puede cubrirse con un tejido adecuado para ser utilizado de forma estéril.

2 Recipiente portainstrumentos
El recipiente portainstrumentos extraíble permite al cirujano o al enfermero preparar el juego quirúrgico y los accesorios necesarios. El recipiente está conectado a un brazo articulado. Para un uso estéril, OPTIKON 2000 S.p.A. suministra una lona de cobertura de un solo uso. Si no se usa el recipiente portainstrumentos, puede conservarse en su alojamiento.

3 Caja I/A y placa de burbujas
La caja I/A debe estar instalada en esta posición.

4 Ruedas con sistema de bloqueo
Los sistemas R-Evo Smart disponen de cuatro ruedas que giran sobre sí mismas y permiten colocar fácilmente el dispositivo en el quirófano. Las lengüetas de bloqueo sirven para evitar que el dispositivo médico se descoloque.

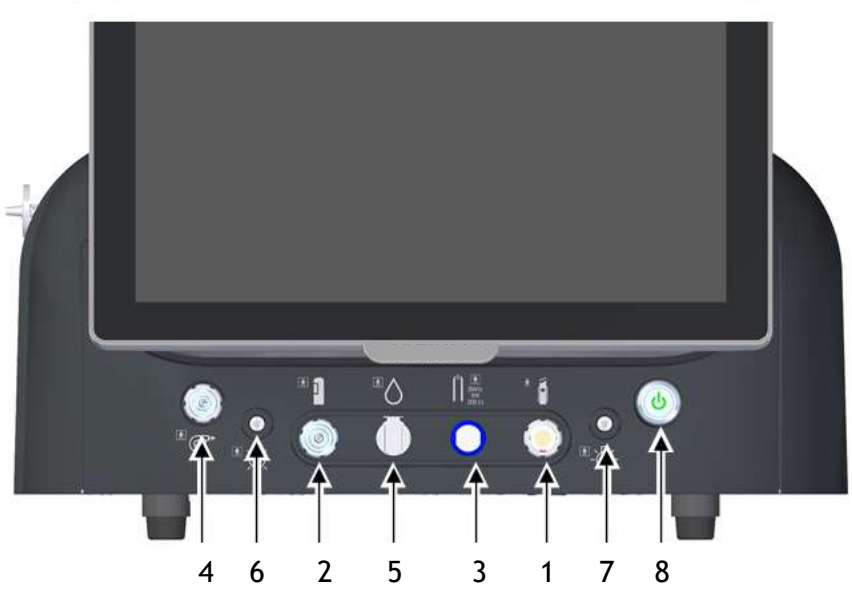
Para situar el dispositivo, deben estar presionadas hacia abajo al menos dos de las lengüetas de bloqueo.

- Presione la lengüeta de bloqueo hacia abajo para bloquear la rueda.
- Tire de la lengüeta de bloqueo hacia arriba para desbloquear la rueda.

5 Portasueros para infusión con soporte portabotellas
El portasueros eléctrico controlado por computadora permite desplazar a la altura memorizada el contenedor de la solución salina equilibrada durante los procedimientos relacionados con la irrigación por gravedad.
El gancho alto se usa exclusivamente en la cirugía del segmento anterior con irrigación por gravedad. El gancho bajo se usa en la cirugía del segmento posterior y, en cualquier caso, también para suspender la bolsa de irrigación presurizada durante los procedimientos quirúrgicos que usan la "irrigación controlada".

6 Empuñadura
Se usa para desplazar y situar el dispositivo médico en el quirófano.

4.2.2 **Conectores del panel delantero y elementos de mando (CR)**



1 Toma US (Faco)
El conector de la pieza de mano faco se conecta a esta toma

2 Toma de vitrectomía
El conector de la pieza de mano para vitrectomía se conecta a esta toma.

3 Toma de diatermia
El conector de la pieza de mano para diatermia bipolar se conecta a esta toma.

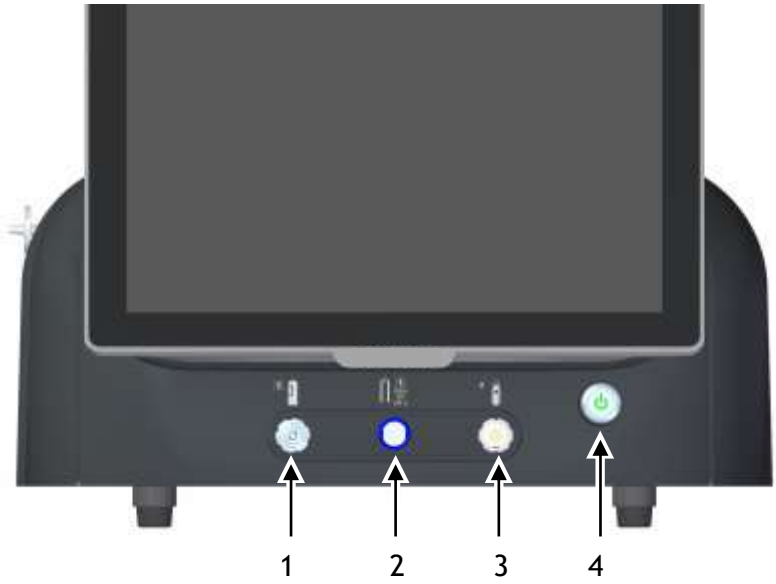
4 Toma de aire
El conector del tubo del aire con el filtro se conecta a esta toma.

5 Toma de inyección de aceite de silicona
El conector del sistema de tamponamiento con aceite de silicona se conecta a esta toma.

6-7 Tomas de fuentes de iluminación LED con filtros
El conector de la fibra óptica se conecta a esta toma.

8 Botón de encendido
Este botón con indicador luminoso permite encender el dispositivo, sacándolo del estado de espera. El interruptor de red del panel posterior debe estar en la posición (I), encendido. El apagado debe realizarse con el botón de software de la pantalla táctil.

4.2.3 **Conectores del panel delantero y elementos de mando (E y S)**



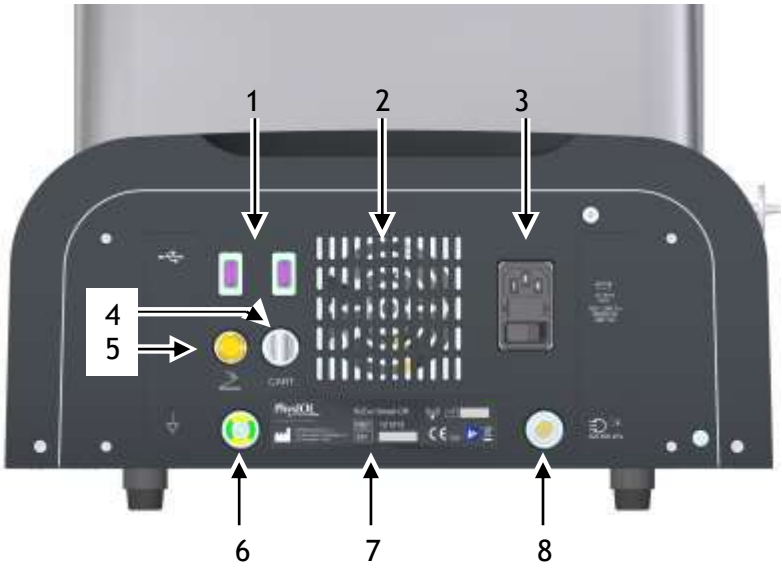
1 Toma US (Faco)
El conector de la pieza de mano faco se conecta a esta toma

2 Toma de vitrectomía
El conector de la pieza de mano para vitrectomía se conecta a esta toma.

3 Toma de diatermia
El conector de la pieza de mano para diatermia bipolar se conecta a esta toma.

4 Botón de encendido
Este botón con indicador luminoso permite encender el dispositivo, sacándolo del estado de espera. El interruptor de red del panel posterior debe estar en la posición (I), encendido. El apagado debe realizarse con el botón de software de la pantalla táctil.

4.2.4 **Conectores del panel trasero y elementos de mando**



1 Conectores USB
A estas tomas se puede conectar un dispositivo de memoria USB para actualizar el software o para importar o exportar programas de usuario.

2 Rejilla de ventilación
Toma de aire del sistema de ventilación interna del dispositivo. Al situar el dispositivo en el quirófano, preste atención a no obstruir la rejilla de ventilación.

3 Interruptor de alimentación, portafusibles y enchufe de alimentación
El interruptor de alimentación sirve para encender y apagar el dispositivo médico.
Una vez encendido mediante este interruptor, el dispositivo se pone en estado de espera (standby); para ponerlo en estado de funcionamiento, pulse el botón "Encendido" del panel delantero. No conecte el dispositivo médico más que a tomas dotadas de un conductor de puesta a tierra.

4 Conector Cart
Conecte a esta toma el carro portainstrumentos opcional. La conexión permite accionar el alzabotellas eléctrico integrado en el carro.

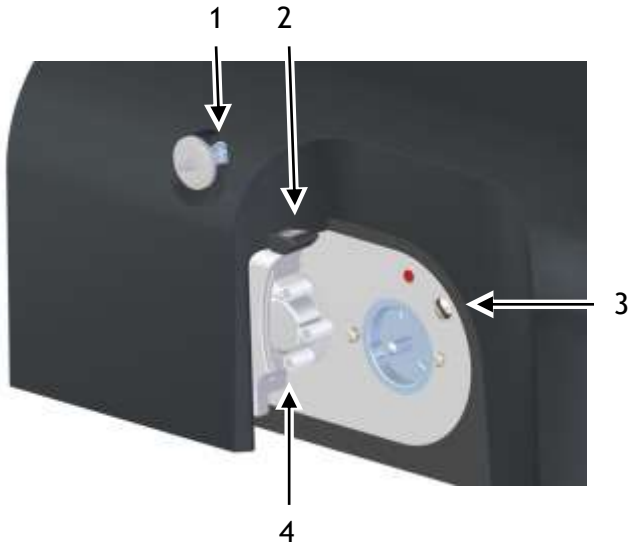
5 Conector de pedal
El conector del pedal se conecta a esta toma.

6 Conector de puesta a tierra
Este conector puede usarse para conectar el R-EVO SMART CR a la toma de puesta a tierra del sistema.

7 Etiqueta de placa de datos
Contiene datos como el fabricante, el número de serie y el año de fabricación del dispositivo médico, etc.

8 Toma de entrada de aire
Entrada para el aire comprimido externo para la bomba Venturi, la pieza de mano para vitrectomía y la inyección de aceite de silicona.
La presión del aire debe ser de 500 a 800 kPa. El flujo disponible debe ser de al menos 32 Nl/min.

4.2.5 **Vista lateral**



1 Toma de irrigación controlada
El conector para la presurización de la botella de solución salina equilibrada o el de la presurización de la bolsa de infusión controlada deben conectarse a esta toma.

2 Botón de desbloqueo de caja I/A
Al pulsar brevemente este botón, el rotor de la bomba peristáltica retrocede y permite girar a la caja I/A en sentido contrario al de las agujas del reloj y extraerla de la placa de la bomba.

3 Sensor de niveles del líquido
Este sensor detecta la presencia de la caja I/A y el nivel que alcanzan los líquidos aspirados en el depósito colector. Detiene la aspiración cuando el depósito está lleno.

4 Rotor de la bomba peristáltica
Permite aspirar con bomba peristáltica, tiene también la función de válvula en caso de aspiración con bomba Venturi (R-Evo Smart S y CR).

4.2.6 Pedal de sistema

El pedal para instrumentos quirúrgicos permite al cirujano activar la función seleccionada en el dispositivo que esté usando. Las funciones "encendido/apagado" se activan con los botones laterales, mientras que las funciones lineales se activan con el pedal central.

El pedal dispone de las siguientes funciones:

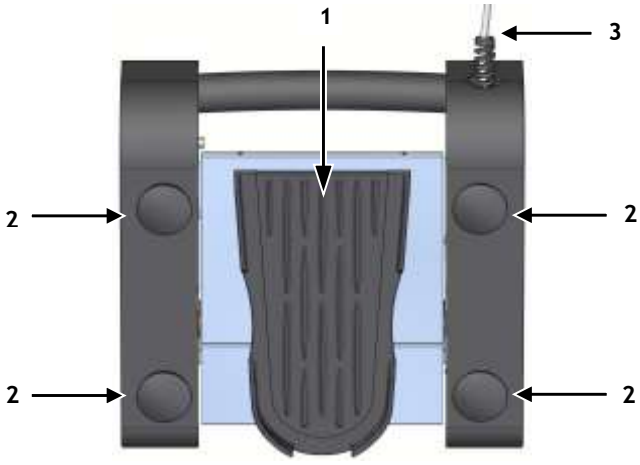
- Nueve mandos de tipo "encendido/apagado" según los ajustes del dispositivo al que está conectado.
- Control lineal simultáneo de dos funciones, pulsando o girando lateralmente el pedal. Por ejemplo: la potencia U/S y el grado de aspiración o la frecuencia de corte de la vitrectomía y el grado de aspiración.

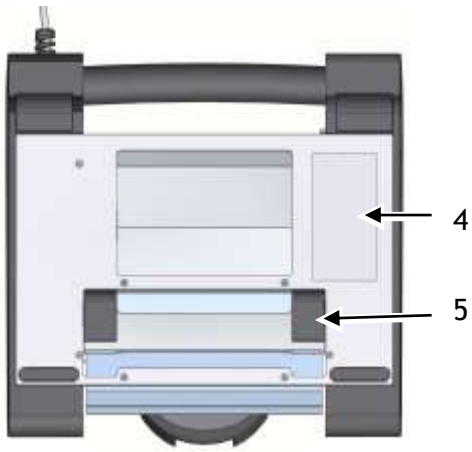
⚠ **ADVERTENCIA** **Peligro de infección**

El pedal no puede introducirse en autoclave.

- Puede consultar información sobre la limpieza o la desinfección del pedal en el capítulo "Cuidado y mantenimiento" del presente manual.

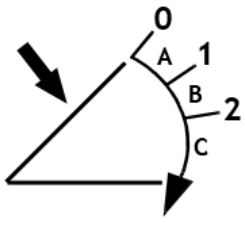
El pedal de sistema está formado por los siguientes elementos:





1 Plataforma central

Se puede desplazar horizontal y verticalmente para activar determinadas funciones. La dirección vertical se divide en tres zonas con dos posiciones táctiles. Algunas funciones se asignan a cada zona y pueden accionarse pulsando el pedal (ver imagen al lado).



Posición de reposo

La zona A se encuentra entre la posición de reposo 0 y la primera posición

táctil 1.

Posición táctil 1
La zona B se encuentra entre la primera posición táctil y la segunda posición táctil.
Posición táctil 2
La zona C se encuentra entre la segunda posición táctil y el límite de detención.

2 Botones laterales

3 Cable de conexión
Para conectar el pedal a la toma en el panel posterior del R-EVO SMART.

4 Etiqueta de placa de datos
Contiene datos como el fabricante, el número de serie y el año de fabricación del dispositivo médico, etc.

5 Pies regulables
Estos pies pueden elevarse para regular la altura de la parte posterior del pedal en dos posiciones.

El pedal multifunción puede programarse mediante el monitor de pantalla táctil del R-EVO SMART. Consulte más detalles en el capítulo "5.6.8 Programación del pedal".

4.2.7 PANTALLA TÁCTIL E INTERFAZ DE USUARIO

Los sistemas R-Evo Smart están dotados de una pantalla táctil interactiva LCD (pantalla de cristal líquido). La interfaz de usuario consta de un software gráfico que funciona sobre una plataforma Linux y simula los diversos botones y pantallas.

El usuario puede seleccionar las funciones del equipo y regular los parámetros correspondientes tocando la pantalla en las zonas apropiadas. Se muestran los valores actuales y los predefinidos para cada parámetro. Si se coloca sobre el monitor un paño transparente estéril, es posible manejar el equipo con guantes estériles.

Para que la pantalla de la interfaz sea lo más legible posible, la interfaz de usuario del sistema R-Evo Smart ha sido diseñada de modo que los botones de funciones y los valores de los parámetros predefinidos y actuales siempre estén presentes en la pantalla, mientras que los botones de ajuste usados con menor frecuencia queden ocultos durante el uso del equipo. Los parámetros están agrupados de forma lógica en las ventanas de parámetros.

En el ejemplo de la izquierda, el límite máximo predefinido de la potencia U/S (35 µm) se muestra tanto en el centro del recuadro como en el indicador radial.

Los ultrasonidos se emiten en modo pulsado (33 Hz) con bajo duty cicle (Cold).

La potencia U/S actual (20 µm) se indica mediante la zona de color verde de 0 a 20.

Para regular el valor del parámetro, el usuario puede tocar la zona del recuadro junto al nuevo límite que se desee establecer como predefinido.

Es posible realizar una regulación precisa mediante los botones - y + situados bajo el recuadro.

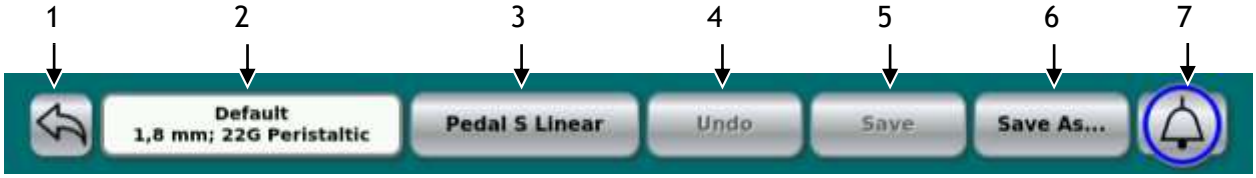
Para ajustar el estado o el valor de los parámetros que se cambian con menor frecuencia, como el control lineal o de panel (fijo) o el modo de emisión, se puede tocar el botón "Ultrasound" (ultrasonido), situado en la parte superior de la ventana.

Al hacerlo, se abre una nueva ventana que permite controlar todos los parámetros adicionales.

Pulse un botón para modificar el parámetro que desee, y después "OK" para cerrar la ventana abierta.

Algunos ajustes, como, por ejemplo, Pulsado, pueden hacer necesario que el sistema presente al usuario un recuadro, botones u otros controles adicionales.

En una barra situada en la parte superior de la pantalla táctil existe una serie de botones e indicadores:



1. Botón "Atrás"
   Pulsando este botón se vuelve a la pantalla anterior, en la que se puede seleccionar un nuevo programa de usuario.
2. Indicador del programa del usuario
   Muestra el nombre del programa de usuario en uso en este momento.
3. Botón/indicador del programa del interruptor de pedal.
   El interruptor de pedal se puede configurar para que funcione según las preferencias del cirujano. Para ver la lista de los programas disponibles para el interruptor de pedal, pulse este botón.
4. Botón Anular
   Permite anular cualquier cambio realizado por el usuario en el programa activo. El botón no está activo (texto gris) mientras siga sin haberse realizado ninguna modificación.
5. Botón Grabar
   Permite actualizar el programa de usuario actual con todos los cambios

realizados por él (configuración actual). Los programas predefinidos no se pueden modificar y grabar con el mismo nombre.

6. Botón Grabar como...
   Permite grabar la configuración actual como un nuevo programa de usuario.
7. Botón/indicador de alarmas.
   Al pulsarlo, aparece en la pantalla una lista de las alarmas activas en este momento. El marco que rodea el botón cambia de color según el error más grave que pueda estar activo:

   gris: ningún error; azul: aviso; amarillo: avería parcial; rojo: avería y situación de peligro.

En una barra de estado situada en la parte inferior de la pantalla se muestra el estado actual del equipo mostrando expandido el indicador relativo a la función quirúrgica activa (en el ejemplo que se ofrece arriba, "Sculpt", es decir, tallado).

Al pulsar el indicador de cualquier otra función quirúrgica, el equipo pasa al modo de funcionamiento deseado.

Un logotipo rodeado de puntitos blancos parpadeantes indica que el software del dispositivo médico funciona con normalidad.

INFORMACIÓN

Peligro de lesiones leves para el paciente

- Si los puntos que rodean el logotipo dejan de parpadear, el dispositivo médico está detenido y se debe dejar de usarlo.
  El usuario debe observar periódicamente el logotipo para comprobar el estado del dispositivo.

Los mensajes de error del equipo se dividen en tres grados de gravedad:

- Las señales de atención tienen la prioridad más alta. Los errores que recaen en este grado se numeran con 1xx y se indican con un símbolo rojo. Un error de esta prioridad exige la interrupción del uso del equipo.

- Las señales de advertencia tienen una prioridad menor que las del grupo anterior. Los errores que recaen en este grado se numeran con 2xx y se indican con un símbolo amarillo. Un error de esta prioridad impide solamente el uso de una función específica.

- Los mensajes de información tienen la prioridad más baja. Los errores que recaen en este grado se numeran con 3xx y se indican con un símbolo azul. Un error de esta prioridad llama la atención al usuario para que realice alguna acción específica.

Consulte el apartado "Mensajes de alarma del sistema" del presente manual la descripción detallada de todos los mensajes de error, su causa y las posibles medidas correctivas.

Los avisos del equipo y los mensajes de error aparecen en ventanas emergentes en la pantalla. Cuando el usuario confirma la lectura del aviso o el mensaje de error, la ventana emergente desaparece y el error se memoriza en la tabla de avisos/mensajes de error.

Como recordatorio del tipo de alarma aún activo, el símbolo de las alarmas (la campana situada arriba a la derecha de la pantalla) aparecerá rodeada del color de la prioridad de la alarma activa de mayor prioridad.

Al pulsar el símbolo de las alarmas, el dispositivo mostrará la lista de todas las alarmas activas.

Pulse el botón OK para cerrar la lista de las alarmas y volver al funcionamiento normal.

Todos los errores se introducen automáticamente en la memoria del sistema y son accesibles mediante el modo de servicio técnico por parte del personal de servicio técnico de OPTIKON 2000 S.p.A.

Si desea más información sobre la interfaz gráfica de usuario, puede consultar la descripción del uso de cada función del equipo.

4.3 PROCEDIMIENTO DE INSTALACIÓN

4.3.1 Instalación de los dispositivos

El equipo está embalado de modo que se reduzca al mínimo el riesgo de daños durante el transporte.

- Abra el embalaje y examine los componentes para comprobar si hay daños. Cuando corte el material de embalaje, preste atención a no dañar el contenido.

El R-Evo Smart E REF 111009 (S 111010) (CR 121012) consta de las siguientes partes:

Código	DESCRIPCIÓN
111009 111010 121012	Consola R-Evo Smart E, o Consola R-Evo Smart S, o Consola R-Evo Smart CR
	Cubierta protectora
1X10XXU0	Instrucciones de uso multilingües
	Informe de pruebas de seguridad IEC 60601 (anexo al manual)
	2 fusibles 3,1 AHT
554138	Cable de red
374578	Tubo de alimentación de aire comprimido (solo CR y S)
112105	Pedal multifunción

Carro opcional:

REF.	DESCRIPCIÓN
181006	CART
181006U	Manual de uso Carrito alzabotellas

⚠ **ADVERTENCIA**

Peligro de lesiones causadas por daños producidos durante el transporte

- Si el embalaje o el contenido están dañados, avise inmediatamente al transportista (servicio postal, ferroviario o marítimo) y al servicio técnico de OPTIKON 2000 S.p.A.
- Compruebe que el contenido corresponda a lo indicado en la documentación de envío adjunta. Avise inmediatamente al servicio técnico de OPTIKON 2000 S.p.A. si existe cualquier discrepancia.

Para instalar el dispositivo médico proceda como se indica a

continuación:

Es de fundamental importancia recibir una formación adecuada para que la instalación y el funcionamiento de los sistemas R-EVO SMART sean correctos. La formación es proporcionada por OPTIKON 2000 S.p.A. Consulte al servicio técnico de OPTIKON 2000 S.p.A. para recibir información más detallada.

Es responsabilidad del usuario limpiar y esterilizar las piezas de mano, las puntas y cualquier otro accesorio microquirúrgico reutilizable.

- Abra el embalaje del dispositivo médico y sus accesorios.
- Extraiga el R-EVO SMART de su embalaje de transporte.
- Observe las instrucciones de uso al extraer del embalaje los accesorios microquirúrgicos estériles y reesterilizables.
- En los R-Evo Smart S y CR, compruebe que la alimentación de la presión sea conforme con el valor indicado en el panel trasero (de 500 a 800 kPa, de 72,5 a 116 PSI).
- En los R-Evo Smart S y CR, conecte conecte la manguera de suministro de aire comprimido a la entrada de gas en el panel posterior y a la línea de suministro de aire de la sala.
- Conecte el cable del pedal a la toma en el panel trasero del R-Evo Smart.
- Si se usa el carro portainstrumentos opcional, conecte el cable de control del alzabotellas eléctrico al panel trasero del R-Evo Smart.
- Conecte el cable de alimentación de la corriente alterna a la toma de corriente del R-Evo Smart.
- Conecte el otro cabo del cable de alimentación CA a la toma de red de la pared.

Desplazamiento del dispositivo

Si se utiliza el carro portainstrumentos opcional, este lleva una asidera que puede usarse para transportar el dispositivo médico de forma fácil y segura a un lugar de instalación distinta. Use la asidera para el fin indicado.

ADVERTENCIA

Peligro de lesiones causadas por daños producidos durante el desplazamiento

- Si el instrumento se desplaza con el carro opcional, si se debe superar algún escalón pequeño (máx. 3 cm),

empuje muy despacio mediante la asidera.

Las cuatro ruedas llevan sendas lengüetas de bloqueo que permiten encontrar de forma ágil la posición de instalación.

- Si ninguna de las lengüetas de bloqueo está presionada: El carro se puede situar fácilmente y sin esfuerzo, en cualquier orientación, en el quirófano junto a la mesa de operaciones.
- Todas las lengüetas de bloqueo están presionadas: El carro portainstrumentos queda fijo en el sitio y se evita cualquier desplazamiento. Una vez situado el dispositivo médico en el lugar deseado de la zona de operaciones, presione hacia abajo las lengüetas de bloqueo.

Instalación del dispositivo médico en el quirófano

Para instalar el dispositivo en el quirófano mediante el carro opcional, proceda como se describe a continuación:

- Suelte todas las lengüetas de bloqueo de las ruedas.
- Agarre el carro portainstrumentos por la asidera y empújelo suavemente hacia la posición que desee.
- El carro debe estar situado sobre un suelo nivelado.
- Presione al menos dos de las lengüetas de bloqueo de las ruedas y compruebe que el carro no se pueda desplazar solo.
- El conector de alimentación se usa como medio para aislar eléctricamente de forma simultánea todos los polos de la ALIMENTACIÓN DE RED. No coloque el dispositivo de forma que resulte difícil desconectar el conector de alimentación de la toma de red.

Preparativos para operaciones estériles

ADVERTENCIA

Peligro de infección

El paciente o el usuario pueden infectarse si los accesorios pierden la esterilidad.

- Ordene los accesorios estériles en el recipiente portainstrumentos o, en todo caso, sobre una superficie segura, para evitar caídas accidentales.
- Para el uso estéril de la pantalla táctil, use el paño estéril transparente suministrado.
- Si se usa el recipiente portainstrumentos, use el correspondiente paño estérile.
- Solo puede usar el dispositivo médico personal con la instrucción apropiada.

Para usar el recipiente y la pantalla táctil en condiciones de esterilidad, se pueden usar paños estériles monouso. En el R-EVO SMART hay disponibles los siguientes accesorios:

- PAÑO CUBREPANTALLA PARA R-EVO SMART
- CUBIERTA PARA RECIPIENTE R-EVO SMART

Observe las instrucciones de uso de cada uno de estos artículos antes de usarlos.

Encendido del dispositivo

Antes de encender el dispositivo, compruebe lo que se indica a continuación:

- La línea del aire comprimido está conectada (solo R-Evo Smart S y CR).
- El cable de alimentación está conectado.
- El pedal está conectado.

⚠ **ATENCIÓN**

Peligro de lesiones oculares en el paciente

- Una pérdida de aire audible como un silbido al encender puede indicar un funcionamiento incorrecto de la sección de silicona.

  consultar al revendedor o al servicio técnico de OPTIKON 2000 S.p.A.

⚠ **ADVERTENCIA**

Prueba de funcionamiento

- El software comprueba la validez de la calibración durante el encendido. Si existe cualquier discrepancia, el calibrado seguro predefinido se memoriza y se solicita calibrar el dispositivo (5 señales sonoras).

  Consulte con el revendedor o el servicio técnico de OPTIKON 2000 S.p.A.

Para instalar el dispositivo médico, proceda como se indica a continuación:

- Ponga el interruptor de alimentación del panel trasero en encendido (I).
- Pulse el botón de encendido en el panel delantero hasta que se encienda el indicador luminoso.
  - El portasueros asciende y desciende pocos centímetros.
- El dispositivo realiza una autoprueba durante la cual una pantalla de inicio muestra el logotipo de R-Evo Smart.
- Una vez el dispositivo está encendido, aparece el primer menú en la pantalla. El usuario puede elegir entre "Cirugía", "Configuraciones del Sistema" y "Servicio".
- En la primera puesta en marcha, la interfaz operativa

de R-evo está configurada en inglés, la página "Cirugía" muestra los perfiles de usuario estándar (Default), el usuario puede elegir un idioma diferente en la página " Configuraciones del Sistema". Durante los accesos posteriores, el sistema también muestra cualquier nuevo usuario y programa agregado, la interfaz estará en el idioma elegido.

4.3.2 Instalación de la caja I/A

Para instalar correctamente la caja, proceda como se describe a continuación:

- Conecte el conector Luer lock macho del grupo deflusor al conector correspondiente del tubo corto en la parte superior de la caja I/A.
- Inserte la caja I/A en el panel lateral alineando la línea de referencia en la caja I/A con el punto correspondiente del panel lateral.
- Gire en sentido de las agujas del reloj la caja I/A hasta que quede fija.

⚠ **ADVERTENCIA**

Peligro de infección

Durante el cambio de la botella de infusión, pueden penetrar agentes patógenos y contaminar la solución salina equilibrada.

- Nunca toque el perforador de la cámara de goteo cuando se conecta, se cambia o se quita la botella de infusión.
- Introduzca el perforador de la cámara de goteo en el tapón de goma de la botella de infusión de la bolsa de infusión para irrigación controlada.
- Conecte el extremo de los tubos de irrigación y aspiración a los conectores correspondientes de cada pieza de mano.

⚠ **ADVERTENCIA**

Peligro de lesiones para el paciente

- Antes de usar la pieza de mano faco, realice siempre el procedimiento de "priming" para el cebado y la prueba de los tubos de irrigación/aspiración. Durante dicho procedimiento, se comprueban el funcionamiento y la correcta instalación de la caja I/A y de los tubos de irrigación/aspiración; el sistema I/A, asimismo, se rellena con solución salina estéril. De esta forma se evitan posibles averías y lesiones al paciente.

Para quitar la caja I/A, proceda como se describe a continuación:

Para quitar la caja I/A al final de la intervención quirúrgica, pulse el botón "PUSH" (pulsar).

Espere a que la bomba peristáltica esté completamente retraída.

- Gire en sentido contrario al de las agujas del reloj la caja I/A hasta que su línea de referencia y el punto correspondiente del panel trasero queden alineados.

- Quite la caja I/A.

4.3.3 Instalación de los accesorios faco

ATENCIÓN

Peligro de lesiones oculares en el paciente
Si el "priming" se realiza con la punta faco en uso sobre el paciente, se pueden producir graves daños en la estructura ocular.
- Nunca realice el procedimiento de cebado y prueba "priming" si está usando el dispositivo sobre un paciente.

Conexión de la punta faco a la pieza de mano faco

- Atornille la punta faco que desee (2) en el extremo de una pieza de mano faco (1), comprobando que los fileteados estén correctamente unidos. Apriete la punta solamente con los dedos.

- Sitúe atentamente la apertura de la llave (en el lado de la brida) en la punta faco (2) sin dañar la punta, de forma que la llave se introduzca en las hendiduras de la base de la punta.
- Apriete con cuidado la punta faco con la llave en sentido contrario al de las agujas del reloj.
- Retire la llave de la punta faco.

Conexión de manguito (sleeve) de silicona a la punta faco

Haga discurrir con atención el manguito fileteado de silicona (3) en la punta faco hasta que los fileteados queden fijos.

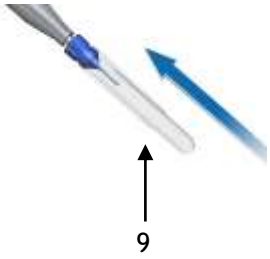
- Apriete lentamente el manguito de silicona en la pieza de mano faco hasta que el terminal del manguito de silicona deje expuesta la cantidad de punta faco que el cirujano desee.
- La pieza de mano faco (1) ahora está listo para recibir los tubos de irrigación/aspiración de los sistemas quirúrgicos.

Conexión de los tubos de irrigación/aspiración

- Para conectar el tubo de aspiración del grupo de tubos de irrigación/aspiración, introduzca el extremo del conector hembra en el conector macho correspondiente de la pieza de mano faco y apriete presionando mientras gira ligeramente.

- Para conectar el tubo de irrigación del grupo de tubos de irrigación/aspiración, introduzca el extremo del Luer macho en el conector hembra correspondiente de la pieza de mano faco y apriete presionando mientras gira ligeramente.

Procedimiento de cebado y de prueba "priming"



- Rellene la cámara de prueba (9) de solución salina equilibrada y hágala discurrir por el manguito de silicona.

- Coloque la cámara de prueba al nivel del ojo del paciente.

- Conecte la caja I/A a la consola, si aún no lo ha hecho, y conéctela a la botella de infusión.

- Fije el conector de alimentación eléctrica de la pieza de mano faco a la toma U/S (1) en la parte delantera de la unidad.

- Pulse el botón "Prime" (cebado) en la esquina inferior izquierda de la pantalla.

- Tras haber completado el procedimiento de cebado, en la pantalla aparece el mensaje "ultrasonidos preparados".

4.4 PROGRAMAS DEL USUARIO

Configuración de los programas del usuario

Todos los parámetros predefinidos del R-EVO SMART pueden adaptarse a las necesidades específicas del usuario. Los parámetros ajustados de esta forma se graban para reutilizarse más adelante en programas asignados a los usuarios.

El R-EVO SMART puede memorizar hasta 30 usuarios distintos y hasta 40 programas por usuario.

⚠ **ADVERTENCIA**

Peligro de lesiones para el paciente

- La modificación de los ajustes del software durante la aplicación puede causar lesiones al paciente.

Creación de usuarios y programas

Creación de un nuevo usuario o de un nuevo programa

- Antes de crear un usuario nuevo o un programa nuevo, ajuste los parámetros que desee en el modo de catarata (segmento anterior) o retina (segmento posterior).
- El botón "Anular" se activa cuando se modifica un parámetro. Si se pulsa el botón "Anular", se recuperan los ajustes anteriores a las modificaciones.
- Pulse el botón "Guardar como".
- Aparece un teclado virtual con el nombre de usuario actual.
- Si el nuevo programa pertenece al usuario actual, introduzca el nombre del nuevo programa y pulse el botón "Guardar". Si se desea grabar un programa nuevo, su nombre debe incluir al menos tres caracteres y una letra.
- Para crear un usuario nuevo, pulse "Usuario nuevo". El cursor se desplaza al campo "Usuario", donde se puede introducir un nombre para el nuevo usuario.
- Confirme el nombre del nuevo usuario pulsando el botón "Guardar"; ponga después el cursor en el campo "Programa".

Grabar el programa para un usuario existente

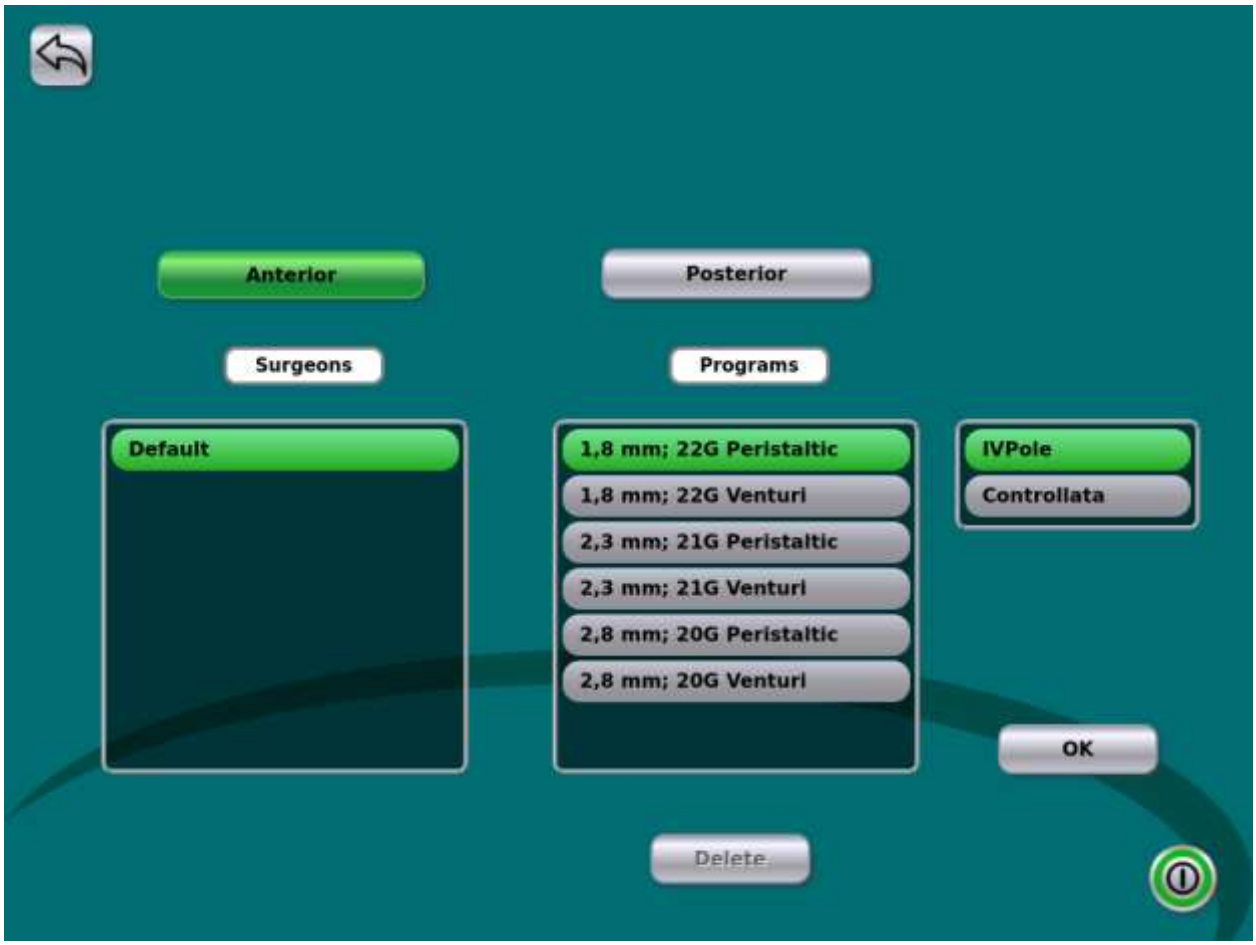
- Pulse el botón "Seleccionar usuario". Los usuarios existentes aparecen en una ventana emergente.
- Seleccione uno de los usuarios y pulse el botón "OK".
- La ventana emergente se cierra y el cursor se desplaza al campo "Programa", en el que se puede introducir el nombre del nuevo programa.

Modificar programas

- Adapte los distintos parámetros del dispositivo médico a los modos catarata o retina.
- Se activa el botón "Anular" (anular las modificaciones) para indicar que se ha modificado un programa. Si se pulsa el botón "Anular", se recuperan los ajustes anteriores a las modificaciones.
- Para grabar de forma permanente las modificaciones realizadas en el programa, pulse el botón "Guardar".

  Las modificaciones de programas predefinidos (default) no se pueden grabar. Para grabar las modificaciones en programa nuevo, se debe crear un programa nuevo (Guardar como...).

Borrar un programa



- Seleccione el programa que desee borrar.
- El botón con el nombre del programa activo está en verde. Pulse el botón "Borrar" para borrar el programa activo (después de confirmar).
- Se carga el programa anterior del mismo usuario, si existe.

Si todos los programas del usuario activo han sido borrados, el usuario se elimina y el dispositivo carga el programa PREDEFINIDO (DEFAULT). Los programas predefinidos no se pueden borrar.

4.5 FUNCIONAMIENTO

4.5.1 Irrigación/aspiración

Instalación de los tubos de irrigación y aspiración y de la caja I/A

- Consulte en el capítulo correspondiente la información sobre la instalación de los tubos de irrigación y aspiración y de la caja I/A.

Conexión de tubos y pieza de mano

- Seleccione la cánula I/A necesaria e introdúzcala con precaución en la pieza de mano coaxial I/A.
- Gire el manguito de silicona sobre la caperuza de la cánula I/A.

El capuchón de silicona debe presionarse delicadamente hasta que el manguito de silicona supere el conector de aspiración situado en la cánula I/A.

- Conecte los tubos de irrigación/aspiración de las líneas de irrigación/aspiración instaladas haciendo discurrir los conectores de los extremos en los correspondientes conectores de irrigación y aspiración del tubo de la pieza de mano.

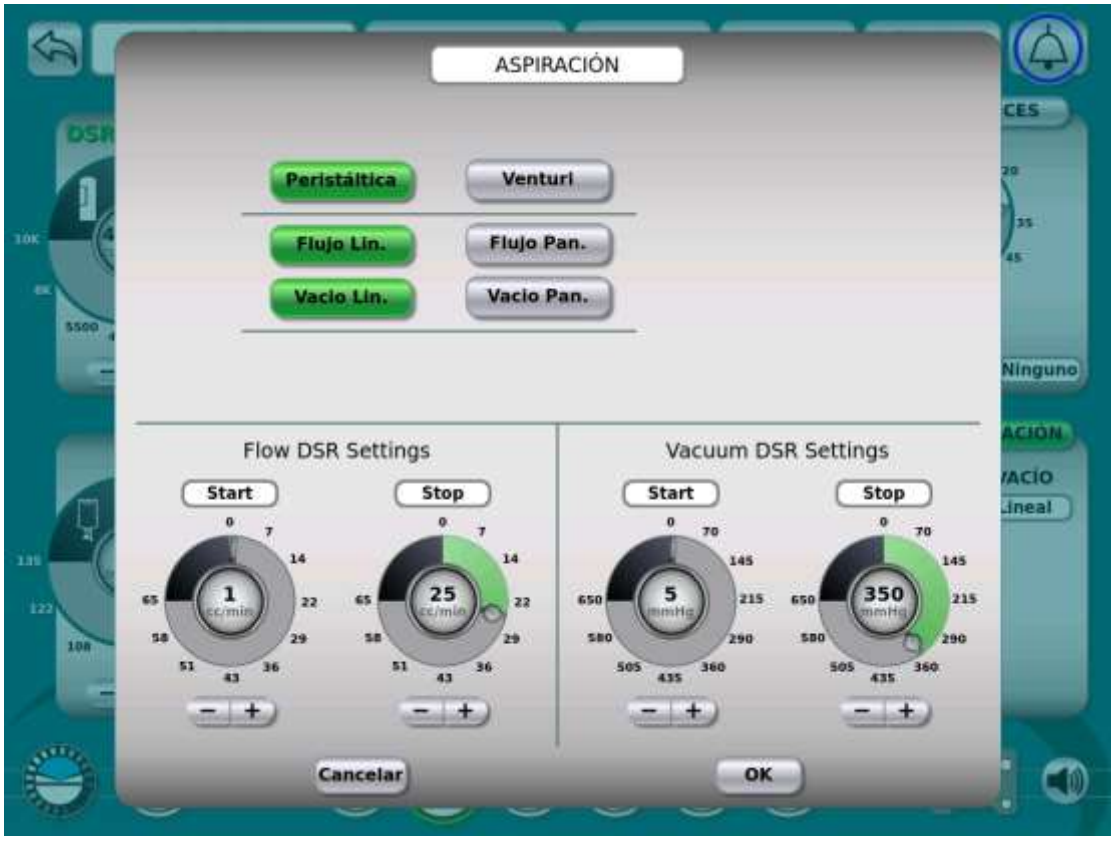
Consulte en las instrucciones de uso de la pieza de mano correspondiente la información sobre la instalación y la aplicación de la pieza de mano bimanuales.

Selección de la función

- Pulse el botón "Córtex" (cortical).

Ajustes para la aspiración

- Los sistemas R-EVO SMART están equipados con una caja I/A, de modo que tanto la bomba peristáltica como la bomba Venturi (solo R-Evo Smart S y CR) estén disponibles contemporáneamente. Para conmutar entre los dos modos de aspiración, pulse el botón "Peristáltica" o "Venturi" en el recuadro "Aspiración".



⚠ **ADVERTENCIA** **Peligro de lesiones oculares en el paciente**

- Cuando se pasa de la bomba peristáltica a la bomba Venturi o rotativa durante la intervención quirúrgica sin cambiar los ajustes, existe peligro de lesiones para el paciente.

INFORMACIÓN: El flujo y el límite del vacío se pueden ajustar de forma independiente para la bomba peristáltica; para la bomba Venturi o rotativa, puede ajustarse solo el vacío. Con la bomba Venturi o la rotativa, el flujo actual aumenta con los ajustes del vacío y la medida de la cánula de aspiración.

⚠ **ATENCIÓN** **Peligro de lesiones oculares en el paciente**

Modificando el nivel de la altura del portasueros para infusión forzándo manualmente, se puede obtener una indicación errónea de la altura de la botella y lesionar al paciente.

- No fuerce el portasueros para modificar su altura.

⚠ **ADVERTENCIA** **Peligro de lesiones oculares en el paciente**

Se puede causar una inestabilidad en la cámara anterior si el nivel de la altura del portasueros o los ajustes del vacío no son correctos.

- Inicie con ajustes de seguridad básicos para el vacío y aumente gradualmente para determinar los ajustes correctos del vacío y de la altura del portasueros, comprobando que la cámara anterior esté estable.

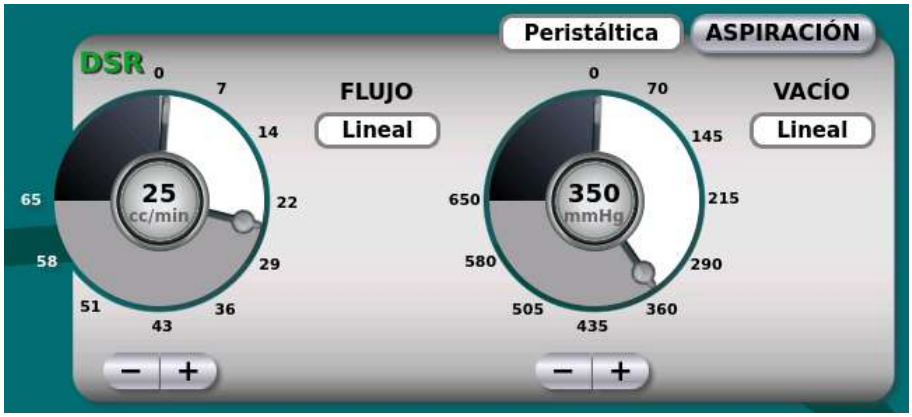
Los valores de flujo especificados (solo para la bomba peristáltica) y el nivel del vacío se pueden regular con los botones + y - o el cursor.

El vacío y el flujo se pueden controlar tanto en el modo de control "panel" (o fijo) como en el modo "lineal".

Para pasar al modo "lineal", pulse el botón "Flujo lin." o "Vacío lín.", y, para pasar al modo "panel" (fijo), pulse el botón "Flujo pan." o "Vacío pan.".

En modo "panel", una función, si se activa mediante pedal, alcanza automáticamente el valor definido en el programa de usuario.
En modo “lineal”, el cirujano puede, pulsando o rotando el interruptor de pie, controlar linealmente el valor de la función desde un valor de inicio hasta un valor final de parada previamente configurado en “DSR Settings” (Ajustes DSR, Regulación dinámica de parámetro).

Los valores configurados en “DRS Settings” se muestran en la pantalla de trabajo con dos índices que delimitan el intervalo de regulación lineal.



Ajustes de irrigación

- Ajuste la altura de del portasueros en función de los ajustes del vacío y de la punta conectada, de forma que se mantenga un equilibrio adecuado de los líquidos.
- Active la irrigación pulsando el interruptor de pedal más allá de su posición de espera.

La irrigación continua (la irrigación fluye también tras haber soltado el interruptor de pedal) se puede activar pulsando el botón "ON" de la pantalla táctil, o bien pulsando el correspondiente pulsador lateral del interruptor de pedal, según la programación de este último.

- Para interrumpir la irrigación continua, pulse el botón "OFF" de la pantalla táctil, o bien pulse de nuevo el interruptor de pedal.

⚠ **ATENCIÓN**

Peligro de lesiones oculares en el paciente
La presión intraocular se reduce si la cantidad de solución salina equilibrada no es suficiente.

- Compruebe el nivel de la solución salina equilibrada en la botella de infusión durante la intervención quirúrgica. Si el nivel es demasiado bajo, el cirujano puede cambiar la botella o la bolsa de infusión.

4.5.2 **Facoemulsificación**

Si en la pantalla aparece el mensaje "Connect handpiece" (conectar la pieza de mano), la pieza de mano faco no está conectado o la máquina no la reconoce.

Cebado y prueba ("Priming")

El mensaje "Realice el priming, por favor" indica que es necesario realizar el procedimiento de cebado y prueba "Priming". Pulse el botón "Prime" (Cebado) para iniciar el procedimiento; se controlan las conexiones y el funcionamiento correcto de los tubos de irrigación/aspiración, y estos se rellenan completamente de solución salina equilibrada. El cebado y la prueba de la irrigación/aspiración se puede omitir en determinadas condiciones, por ejemplo, cuando la pieza de mano faco o la punta faco deben cambiarse tras haber superado el priming anterior correctamente. Para omitir el procedimiento de cebado y prueba de la irrigación/aspiración, pulse el interruptor de pedal más allá de la zona C: se abre una ventana emergente que pregunta

si se desea realmente omitir el procedimiento de cebado.

Prueba de ultrasonidos (regulación y comprobación de ultrasonidos)

Cada vez que se conecta o se cambia una pieza de mano faco, es necesario realizar una sencilla prueba previa de los ultrasonidos. El objetivo de dicho procedimiento es sintonizar la unidad de facoemulsificación con la pieza de mano faco conectado, comprobando al mismo tiempo el correcto funcionamiento del sistema. Al concluir el procedimiento de "priming" o si se ha omitido, la unidad inicia automáticamente el procedimiento de prueba de ultrasonidos. Si la regulación y la comprobación no tienen resultado positivo, aparece el mensaje "Please check tip" (compruebe la punta) durante cuatro segundos, y el usuario debe repetir el procedimiento de cebado.

INFORMACIÓN

Daños en la punta faco

- No active la pieza de mano faco con la punta faco en el aire. Los ultrasonidos deben activarse con la punta faco introducida en una cámara de prueba rellena con solución de infusión o en un contenedor con líquido estéril a temperatura ambiente. Si no se siguen estas instrucciones, es posible que resulte dañada la punta faco o la pieza de mano faco.

⚠ **ATENCIÓN**

Peligro de lesiones oculares en el paciente

Aunque los sistemas R-EVO SMART están equipados con un sofisticado circuito de control de la potencia para limitar la potencia de los ultrasonidos que se aplica sobre el ojo, es necesario prestar atención para no dañar el endotelio del ojo (daños en la córnea).

- Use siempre la potencia más baja de ultrasonidos suficiente para eliminar la catarata.
- La incisión no debe realizarse demasiado estrecha respecto del manguito de silicona y debe permitir una cierta pérdida de solución salina equilibrada.
- No someta la incisión a estrés con torsiones mientras se intenta alcanzar fragmentos del núcleo en el ojo.
- Si la punta faco está completamente ocluida en el núcleo, el flujo de aspiración de detiene y la punta no se refrigera correctamente. No active ultrasonidos durante periodos de tiempo demasiado largos o a niveles elevados si la punta faco está ocluida.

En modo de ultrasonidos, más allá de los parámetros de irrigación y aspiración descritos en la sección anterior se pueden regular el modo y el nivel de emisión de los ultrasonidos.

Los ultrasonidos pueden emitirse en modo continuo, pulsado (con tres niveles de duty cicle, denominados "STD", "Cold" y "Ice cold"), ráfaga sencilla, ráfaga múltiple, ráfaga continua.

Si para la aspiración se usa la bomba peristáltica, se puede seleccionar el modo "Autolimit", que limita la potencia emitida a un máximo de 50 micrones en caso de oclusión, reduciendo así la posibilidad de daños en la córnea.

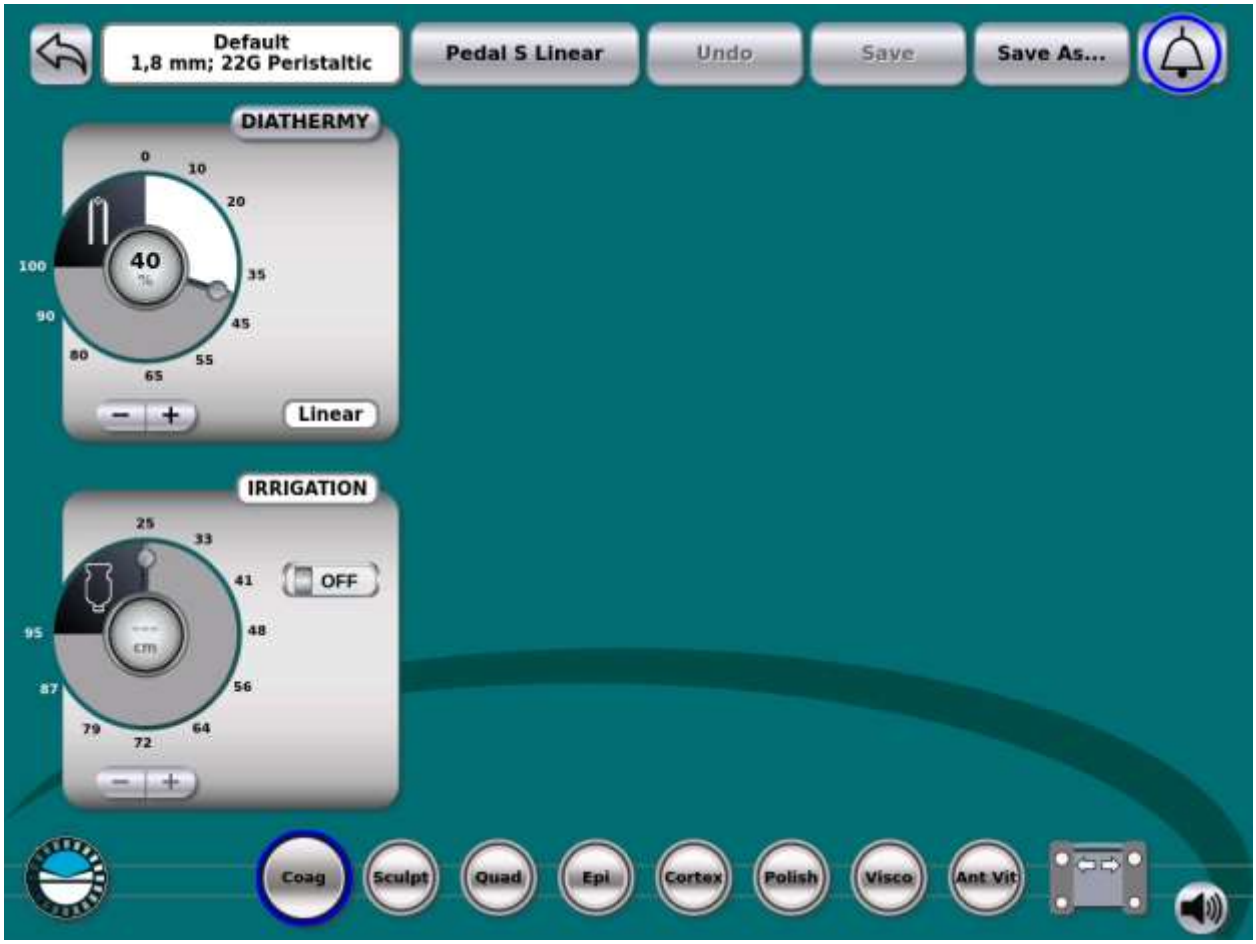
El modo "HD Pulse", disponible también con la bomba peristáltica, cambia automáticamente el duty cycle al modo pulsado en función del estado de oclusión de la punta faco, de forma que se reduce al mínimo el tiempo de emulsificación de la catarata, incluso manteniendo baja la energía ultrasonora emitida.

Ajustes básicos para las modalidades de la retina

4.5.3 Endodiatermia bipolar para cirugía de la retina

Conexiones de accesorios

- Introduzca la pieza de mano para endodiatermia que desee, como, por ejemplo, la punta para diatermia, en el cable de diatermia bipolar.
- Introduzca el conector del cable de diatermia bipolar en la toma para diatermia en la consola.



Ajustes para la diatermia

- Regule el nivel de potencia predefinido en el cuadro "Diathermy" (diatermia) con los botones + y - o con el cursor. Si no está seguro del nivel de potencia que debe usar, es preferible comenzar con ajustes bajos y, si procede, aumentarlos gradualmente hasta obtener el efecto quirúrgico deseado.

La diatermia bipolar puede activarse tanto en modo de control "fijo" como "lineal". En el segundo caso, la potencia emitida es controlada linealmente desde el 5 % hasta el límite predefinido, pulsando el pedal.

- Para conmutar entre los modos "lineal" y "fijo", pulse los botones "lineal" y "panel" (fijo).

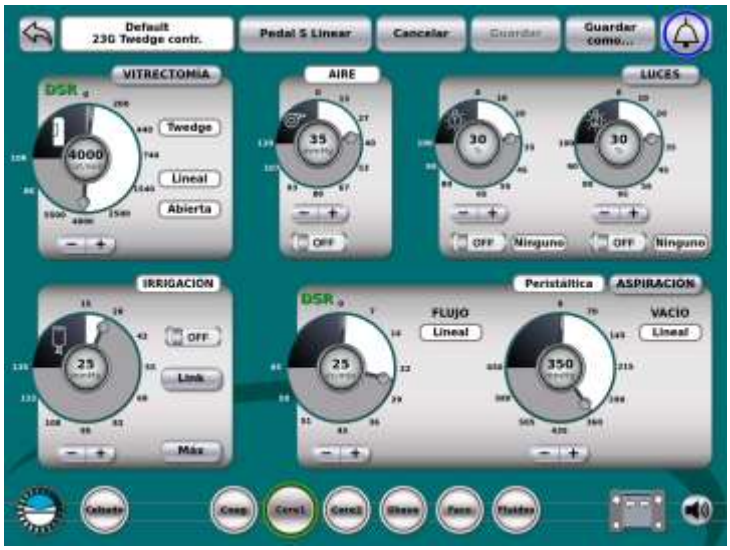
Al regular un parámetro no se modifican los parámetros predefinidos. Para volver a los parámetros anteriores, pulse "Anular"; para grabar de forma permanente los nuevos ajustes en la memoria del dispositivo, consulte el capítulo "Crear un programa de usuario".

4.5.4 **Vitrectomía**

ATENCIÓN

Peligro de lesiones oculares en el paciente
Si la pieza de mano para la vitrectomía no se conecta correctamente, puede penetrar aire no estéril en el ojo del paciente.

- Debe comprobarse siempre que la pieza de mano para la vitrectomía funcione correctamente sirviéndose de un contenedor con solución estéril antes de situarlo en el ojo del paciente.

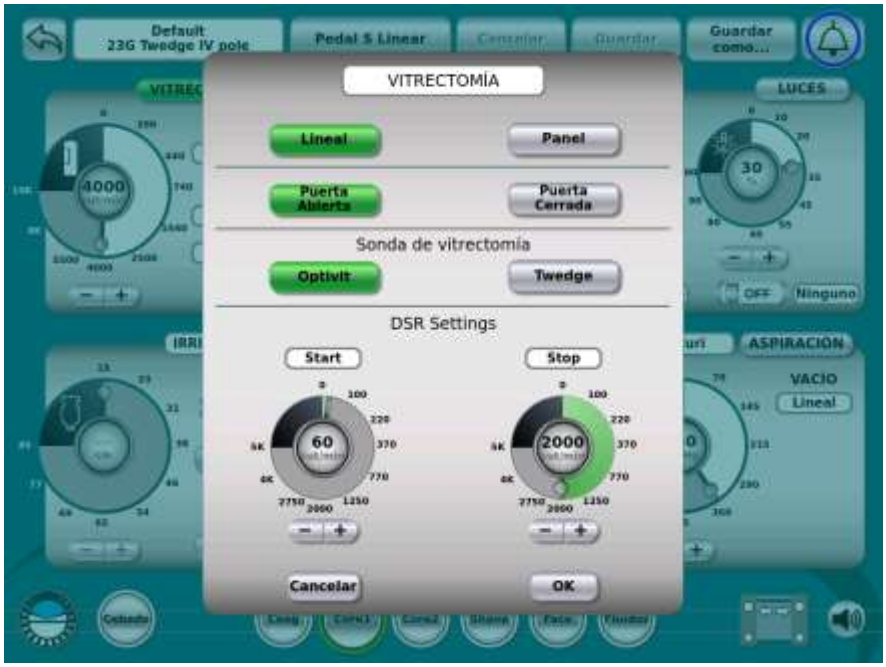


En modo "vitrectomía" hay tres submodos disponibles: “core1”, “core2” y “shaving”.
Se trata de tres áreas de memoria en que se puede grabar parámetros ideales de irrigación, aspiración y corte para las distintas fases de la vitrectomía.
Se puede conmutar entre las tres fases bien mediante la pantalla táctil o bien mediante el pedal multifunción.
En el cuadro de diálogo de irrigación hay un botón “Link” (Vincular) que permite vincular la presión de irrigación en todas las fases de la vitrectomía.
Si el botón “Link” (Vincular) no está activo, se puede configurar independientemente la presión de irrigación de las diferentes.El botón "Máx", en el cuadro de irrigación, eleva la presión de irrigación por encima de la presión arterial para detener provisionalmente hemorragias de la retina.

ATENCIÓN

Peligro de lesiones oculares en el paciente
Mantener la presión de irrigación en valores superiores a la presión arterial puede causar daños permanentes en la función de la retina.

- El botón "Máx" debe estar activado el tiempo más breve posible. Si la presión de irrigación se lleva a más de 70 mmHg, al cabo de alrededor de un minuto se activa una alarma.



Al pulsar el botón "Vitrectomía" se accede a las regulaciones del vitréctomo.
Se puede elegir la posición de reposo (pedal no presionado) de la puerta de corte entre "puerta abierta" y "puerta cerrada".
El duty cycle del vitréctomo se puede ajustar en uno de tres niveles ("bajo", "medio" y "alto"). Esto influye, a igualdad de nivel de aspiración y frecuencia de corte, la velocidad con que se extrae el vítreo (a un duty cycle más elevado corresponde una mayor capacidad de extracción).
La frecuencia de corte puede controlarse tanto en modo "panel" como en modo "lineal". Si se elige el modo de control lineal, la frecuencia de corte se puede controlar linealmente pulsado o girando el interruptor de pie desde una potencia inicial hasta una potencia de parada (modalidad DSR). Tenga en cuenta que la frecuencia de inicio puede ser menor o mayor que la frecuencia de parada.

4.5.5 **Iluminación**

El R-EVO SMART está equipado con un sistema de iluminación con luces LED dotado de dos fuentes luminosas independientes. Las lámparas están dotadas de filtros para la reducción del componente azul y de un filtro verde.

- Conecte la fibra óptica para endoiluminación en la toma para la guía de la luz en fibra que desee del

panel delantero.

⚠ **ATENCIÓN**

Peligro de lesiones oculares en el paciente

- Aunque el sistema de iluminación endoocular de fibra óptica no emita rayos infrarrojos ni ultravioletas, para evitar posibles daños en la retina use siempre la intensidad mínima suficiente para la aplicación quirúrgica.

⚠ **ATENCIÓN**

Peligro de lesiones oculares en el paciente

- Para reducir el peligro de daños en la retina, el extremo de la sonda de iluminación de fibra óptica no debe estar situado demasiado cerca de la retina.

INFORMACIÓN

Duración de la intervención quirúrgica

Si la luz está encendida y el conector correspondiente está libre (fibra óptica no conectada), el R-EVO SMART reduce automáticamente la emisión luminosa para no molestar al cirujano.

- Seleccione la fuente que desee regular y enciéndala/apáguela con los botones "ON/OFF".
- Regule la intensidad de la iluminación de la lámpara seleccionada con los botones + y - o con el cursor.

El cirujano puede elegir uno de entre cuatro filtros estudiados para destacar la presencia de membranas.

Los filtros amarillos, además, protegen el ojo del paciente de una exposición no necesaria a las radiaciones azules y, de ese modo, permiten tratamientos de larga duración.

4.5.6 Tamponamiento

⚠ **ATENCIÓN**

Peligro de lesiones oculares en el paciente

- Para evitar posibles infecciones en el ojo del paciente, use exclusivamente el tubo de inyección original de OPTIKON 2000 S.p.A., que está equipado con un filtro de esterilización de aire para el tamponamiento con aire.

⚠ **ADVERTENCIA**

Peligro de lesiones para el paciente

- El control automático de la presión intraocular se

calibra para el uso exclusivo de accesorios fabricados y distribuidos por OPTIKON 2000 S.p.A. (filtros de membrana, tubos, guías esclerales).

⚠ **ATENCIÓN**

Peligro de lesiones oculares en el paciente

- La válvula de detención de silicona se controla durante el encendido. Compruebe que no exista silbido durante el encendido del dispositivo.

⚠ **ADVERTENCIA**

Peligro de lesiones oculares en el paciente

- Durante la inyección de aceite de silicona, la presión intraocular (PIO) no es controlada por el R-Evo Smart CR, por lo que el cirujano debe ocuparse de controlarla. Es importante comprobar que el flujo del aceite de silicona corresponda a la presión de inyección ajustada antes de introducir la cánula en el ojo.

⚠ **ADVERTENCIA**

Peligro de lesiones oculares en el paciente

- Suelte el pedal para interrumpir la inyección de aceite de silicona. En caso de emergencia, cierre la llave de detención de la inyección o quite los tubos de inyección del aceite de silicona de la unidad de alimentación de silicona.

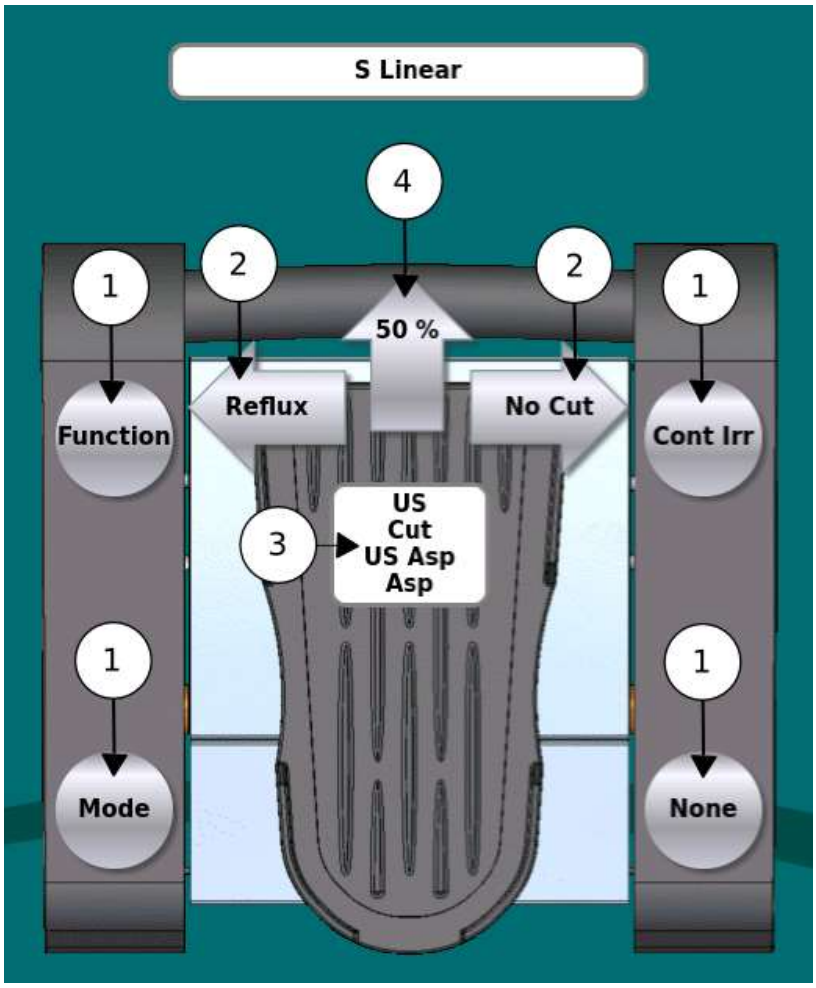
INFORMACIÓN

Pérdida de aceite de silicona

- Para evitar pérdidas de aceite de silicona en la línea de aspiración de la caja I/A, el depósito de recogida del aceite de silicona debe mantenerse en posición vertical y debe cambiarse apenas se observe que está lleno de aceite de silicona.

- Para acelerar la retirada del aceite de alta densidad, se puede usar el conector en Y incluso para conectar dos grupos de extracción y usarlos a la vez.
- Si necesita más información, consulte la documentación suministrada con el grupo de extracción del aceite de silicona.

4.5.7 **Programación del pedal**



Pulse "Ajustes del sistema" para acceder a la interfaz gráfica de programación del pedal. Mediante esta interfaz el usuario puede personalizar las distintas funciones del pedal.

a. Si el usuario pulsa uno de los cuatro botones laterales (1) o uno de los botones de flecha lateral (2), aparece una ventana donde se puede escoger qué función asociar a cada botón o movimiento lateral de la plataforma principal.

Debe tenerse en cuenta que no todas las funciones pueden estar asociadas a cualquier botón o movimiento de la plataforma. Las funciones no habilitadas están en gris.

b. En la etiqueta (3) se indican las funciones asociadas al movimiento vertical de la plataforma principal (en el ejemplo, U/S, el corte y la aspiración).

c. Pulsando la flecha hacia arriba (4) se puede regular el punto de partida de los U/S, lo que permite dividir, según prefiera el cirujano, la carrera vertical de la plataforma entre aspiración lineal y regulación lineal de los ultrasonidos.

Una vez que el pedal ha sido programado y grabado con nombre, se puede recuperar y utilizar en el interior de los programas de usuario.

5. Mensajes de alarma del sistema

ATENCIÓN

Mensajes de error en la pantalla táctil
Los mensajes de error con una señal de atención roja indican un error grave del dispositivo que no puede solucionar el usuario.

- En caso de mensajes de error con esta señal de atención, diríjase al servicio técnico de OPTIKON 2000 S.p.A.
- Tome nota de las explicaciones de cada uno de los mensajes de error de las siguientes páginas.

ADVERTENCIA

Mensajes de error en la pantalla táctil
Los mensajes de error con una señal de advertencia amarilla indican un error moderado que pueden solucionar el usuario o nuestro servicio técnico.

- Tome nota de las explicaciones de cada uno de los mensajes de error de las siguientes páginas.

INFORMACIÓN

Mensajes de error en la pantalla táctil
Los mensajes de error indicados con una señal azul indican un error leve, un aviso o una indicación para el usuario.

- Tome nota de las explicaciones de cada uno de los mensajes de error de las siguientes páginas.

100 Mensajes de error

Id.	Mensaje	Posible causa	Medida correctiva
100	"Error presión aire"	Mensaje visual + sonoro Error en el sistema de tamponamiento con aire o de infusión controlada (la presión de salida es mucho mayor o menor que la predefinida).	Consulte al servicio técnico de OPTIKON 2000 S.p.A.
101	"Error nivel de presión"	Mensaje visual + sonoro Presión incorrecta en la salida de la válvula proporcional.	Consulte al servicio técnico de OPTIKON 2000 S.p.A.

102	"Error nivel de vacío"	El vacío supera el valor predefinido en el modo Venturi.	Consulte al servicio técnico de OPTIKON 2000 S.p.A.
103	"Potencia de la diatermia no válida"	Error en el sistema de la diatermia (la potencia en salida es mucho mayor o menor que la predefinida).	Consulte al servicio técnico de OPTIKON 2000 S.p.A.
104	"Error de habilitación de los ultrasonidos"	Error en el sistema de los ultrasonidos (la potencia en salida no se activa aunque se muestre lo contrario por un error de la puerta de activación o por un contacto incorrecto de los cables).	Consulte al servicio técnico de OPTIKON 2000 S.p.A.

200 Mensajes de error

Id.	**Mensaje**	**Posible causa**	**Medida correctiva**
200	"Error de habilitación del aire"	Error en el sistema de tamponamiento con aire y de infusión controlada (el transporte secundario del interruptor de seguridad se comprueba en el inicio).	Consulte al servicio técnico de OPTIKON 2000 S.p.A.
201	"Error watchdog"	Error en el circuito de control (comprobado en el inicio).	Consulte al servicio técnico de OPTIKON 2000 S.p.A.
202	"Error de comunicación de serie"	Error de comunicación entre la interfaz gráfica de usuario y el panel de control.	Consulte al servicio técnico de OPTIKON 2000 S.p.A.
203	"Atención: diatermia activa"	Error en el sistema de la diatermia (la potencia en salida es activada por un error de la puerta de activación).	Consulte al servicio técnico de OPTIKON 2000 S.p.A.

Id.	Mensaje	Posible causa	Medida correctiva
205	"Error de habilitación de la diatermia"	Error en el sistema de la diatermia (la potencia en salida no se activa aunque se muestre lo contrario por un error de la puerta de activación o por un contacto incorrecto de los cables).	Consulte al servicio técnico de OPTIKON 2000 S.p.A.
206	"Error tensión de referencia o alimentación"	Tensión de referencia incorrecta en el transductor A/D o valor de la potencia +5 V incorrecto (comprobado en el inicio).	Consulte al servicio técnico de OPTIKON 2000 S.p.A.
208	"Atención: ultrasonidos activos"	Error en el sistema de los ultrasonidos (la potencia en salida es activada por un error de la puerta de activación).	Consulte al servicio técnico de OPTIKON 2000 S.p.A.
209	"Error de compensación del vacío"	Error durante el cebado: lectura excesiva del sensor en ausencia de vacío.	a) El procedimiento de cebado ha sido reiniciado tras el error 210. Abra la morsa de la infusión del grupo de infusión, abra brevemente la irrigación continua y reinicie el procedimiento de cebado. b) El sensor del vacío debe ser calibrado. Consulte al servicio técnico de OPTIKON 2000 S.p.A. para calibrar la unidad.
210	"Ausencia de irrigación"	Error durante el cebado: El vacío no disminuye después de haber abierto la válvula de ventilación.	Abra la morsa de la infusión del grupo de infusión, abra brevemente la

Id.	Mensaje	Posible causa	Medida correctiva
			irrigación continua y reinicie el procedimiento de cebado.
211	"Presión de infusión demasiado elevada"	El portasueros para infusión está situada a un nivel demasiado elevado.	Baje lo más posible el portasueros.
212	"Error del portasueros"	Error del portasueros para infusión.	Consulte al servicio técnico de OPTIKON 2000 S.p.A.
213 216	“Recalentamiento LED 1” "Recalentamiento LED 2”	Los sistemas de endoiluminación 1 o 2 han alcanzado una temperatura excesiva.	Compruebe que las rejillas de ventilación del panel trasero estén libres de obstrucciones. Apague el LED recalentado y utilice una de las otras dos fuentes. Si el problema persiste, consulte con el servicio técnico de OPTIKON 2000 S.p.A.

300 Mensajes de error

Id.	Mensaje	Posible causa	Medida correctiva
300	"Instale la caja I/A"	La caja I/A no está conectada.	Conecte la caja I/A
301	"Caja I/A llena, aspiración detenida"	El depósito colector de la caja I/A está lleno.	Cambie la caja I/A.
302	"Baja presión en entrada"	La presión de alimentación del aire exterior es demasiado baja o igual a cero.	a) El dispositivo no está conectado a la alimentación del aire comprimido o la llave de detención está cerrada. Conecte el dispositivo de la fuente del aire comprimido o abra la llave de detención. b) La presión de alimentación del aire comprimido del dispositivo es inferior a 450 kPa (65 PSI). Compruebe la presión del circuito del aire comprimido.
303	"Pérdida importante"	Error durante el cebado (priming): la bomba peristáltica no llega a crear un vacío de 100 mmHg en un plazo de 30 segundos.	a) La cámara de prueba no está instalada en el manguito. Compruebe que la cámara de prueba esté instalada correctamente en el manguito. b) Los tubos de irrigación/aspiración no están conectados al manguito. Conecte los tubos de irrigación/aspiración de la caja la pieza de mano faco. c) La caja I/A está defectuosa.

Id.	Mensaje	Posible causa	Medida correctiva
			Cambie la caja I/A. d) El sistema de la bomba debe calibrarse nuevamente, diríjase al servicio técnico de OPTIKON 2000 S.p.A.
304	"Línea de aspiración ocluida"	Error durante el cebado (priming): el nivel del vacío durante el cebado supera 300 mmHg.	a) la pieza de mano y la punta no han sido limpiados correctamente antes de la esterilización. Cambie la punta o la pieza de mano. b) La caja I/A está defectuosa. Cambie la caja I/A.
305	"Pérdida pequeña"	Error durante el cebado (priming): la bomba peristáltica no puede crear un vacío de 300 mmHg.	a) Los conectores de irrigación/aspiración no están completamente insertados en los contenedores de la pieza de mano. Conecte correctamente los conectores. b) El manguito o la cámara de prueba no están instalados correctamente. Compruebe que la cámara de prueba esté completamente fijada al manguito y que este esté colocado correctamente en la pieza de mano.

Id.	Mensaje	Posible causa	Medida correctiva
306	"Compruebe la punta U/S"	Error durante el cebado: la pieza de mano faco no puede sintonizarse.	a) La punta faco se ha aflojado. Atornille correctamente la punta faco en la pieza de mano con una llave para punta faco. b) La punta faco está dañada. Compruebe la punta faco y cámbiela si es necesario. c) La pieza de mano faco está dañado. Cambie la pieza de mano faco.
307	" Pieza de mano débil"	La pieza de mano faco no logra oscilar a más de 50 micrómetros.	a) Compruebe si la punta faco se ha aflojado y, en tal caso, apriétela adecuadamente con una llave para puntas faco. b) Es normal que el elemento de piezocerámica se deteriore con el uso y al cabo de cierto número de ciclos de esterilización. Envíe la pieza de mano al servicio técnico de OPTIKON 2000 S.p.A.
308	Instale la irrigación controlada.	La línea del aire de la irrigación controlada no está instalada.	Instale el sistema de infusión controlada antes de continuar, o use el sistema de gravedad.
310	"Baja potencia US"	La pieza de mano de los ultrasonidos no logra oscilar con la amplitud definida.	a) Compruebe si la punta faco se ha aflojado y, en tal caso, apriétela

Id.	Mensaje	Posible causa	Medida correctiva
			adecuadamente con una llave para puntas faco. b) Es normal que el elemento de piezocerámica se deteriore con el uso y al cabo de cierto número de ciclos de esterilización. Devuelva la pieza de mano al servicio técnico de OPTIKON 2000 S.p.A.
311	Connecte la pieza de mano U/S.	La pieza de mano U/S no está conectado a la unidad.	Conecte la pieza de mano U/S a la unidad. Si el problema persiste también después, cambie la pieza de mano.
312	Realice el Cebado, por favor.	La pieza de mano faco está conectado, pero no iniciado.	Consulte "5.4.3 Instalación de los accesorios faco".
313	Realice el cebado (del vitréctomo), por favor.	La pieza de mano de vitrectomía está conectado, pero no iniciado.	Siga las instrucciones de la pantalla para iniciar y comprobar el funcionamiento de la pieza de mano.
314	Realice el priming (de la caja I/A), por favor.	La caja I/A está conectada, pero no iniciada.	Siga las instrucciones de la pantalla para iniciar y comprobar el funcionamiento de la caja I/A.
318	Seleccione peristáltica para aspirar.	En modo "Líquidos", mientras se inyecta silicona, la bomba Venturi no puede usarse.	Seleccione la bomba peristáltica para aspirar mientras se inyecta aceite de silicona.

400 Otros mensajes

Id.	Mensaje	Posible causa	Medida correctiva
400	"¿Desea omitir el cebado?"	Uno de los interruptores del pedal ha sido presionado. La pieza de mano faco está conectado, pero no iniciado.	a) El usuario activa por error el interruptor de pedal. Retire el pie y pulse "NO" en la pantalla. b) Interruptor de pedal defectuoso. Cambie el pedal.
401	Detenga el priming	Durante el procedimiento de priming, el usuario presiona el pedal.	Consulte "5.4.3 Instalación de los accesorios faco".

6. Cuidados y mantenimiento

6.1 MANTENIMIENTO DEL DISPOSITIVO

Sustitución de los fusibles

Los fusibles de la unidad de control se encuentran en la toma de entrada de la parte trasera del equipo. Para cambiar los fusibles, proceda como se indica a continuación.

⚠ **ADVERTENCIA**

Peligro de lesiones para el usuario

Los fusibles calientes pueden causar quemaduras.

- Antes de cambiar los fusibles, apague el dispositivo y déjelo enfriar unos minutos.

- Apague el dispositivo médico con el interruptor de alimentación.

- Extraiga el cable eléctrico.
- Apriete la leva de bloqueo (1) y extraiga el portafusibles.
- Saque los fusibles defectuosos e instale nuevos.

INFORMACIÓN

¡Peligro de daños en el dispositivo médico!

El uso de fusibles incorrectos puede causar daños en el dispositivo.

- Use exclusivamente fusibles de amperaje correcto. Consulte lo indicado en la etiqueta del panel trasero si necesita información detallada.

- Coloque de nuevo en su sitio el portafusibles. Bloquee la leva (1) haciéndola encajar en su sitio.
- Inserte el cable de alimentación.
- Encienda la unidad con el interruptor de alimentación.

Mantenimiento del dispositivo médico quirúrgico

ADVERTENCIA

Peligro de lesiones oculares en el paciente
Un mal funcionamiento del sistema puede causar peligro de lesiones para el paciente.

- Encargue al servicio técnico autorizado que inspeccione el dispositivo de conformidad con la norma IEC 62353 en los siguientes casos:

- Durante la instalación del dispositivo médico
- A intervalos periódicos (cada 12 meses)
- Durante las intervenciones de mantenimiento
- Tras reparaciones, modernizaciones, calibraciones y actualizaciones del software y el firmware

INFORMACIÓN

¡Peligro de daños en el dispositivo médico!

- Para mantener la seguridad del dispositivo, inspeccione su conformidad con los límites de dispersión de corriente eléctrica, como establecido en la norma EN 60601-1, al menos una vez al año. Diríjase al departamento de tecnología médica de su propio centro, con su distribuidor autorizado o con el servicio técnico de OPTIKON 2000 S.p.A.
- Mantenga el R-EVO SMART en un lugar limpio y seco.
- Quite la caja I/A tras cada uso.
- Para evitar una disminución de la seguridad del sistema debida al envejecimiento, el desgaste, etc., el usuario debe asegurarse, de conformidad con la normativa nacional aplicable, de que se hayan realizado los controles técnicos de seguridad normales indicados para este dispositivo médico en los plazos previstos y con el alcance estipulado. Los controles técnicos de seguridad deben ser realizados exclusivamente por el fabricante o por personal cualificado. Los controles técnicos de seguridad deben extenderse al menos a los siguientes aspectos:

- Disponibilidad del manual de uso
- Inspección visual del dispositivo médico y de sus accesorios para comprobar que no existan daños y que las etiquetas sean legibles
- Prueba de la puesta a tierra
- Prueba de dispersión de corriente
- Prueba de funcionamiento de todos los interruptores, botones, conectores y testigos del dispositivo

6.2 MANTENIMIENTO DE LOS ACCESORIOS

ADVERTENCIA **Peligro de lesiones para el paciente o el usuario**

Las superficies húmedas pueden causar descargas eléctricas, ya que son conductoras de corriente RF.

- Asegúrese de que la pieza de mano de diatermia esté completamente seco antes de usarlo.
- Evite la caída o el uso incorrecto de las piezas de mano y accesorios.
- Es fundamental manejar dichos componentes con la máxima cautela e inspeccionarlos escrupulosamente para detectar posibles daños o desgastes tras cada uso.
- Inspeccione periódicamente los conductos de líquidos, las uniones, las juntas tóricas externas y las piezas de mano para comprobar si existen daños o desgastes.
- Vuelva a montar todos los componentes antes del almacenamiento.
- Coloque las caperuzas de protección de las puntas de los las piezas de mano (cuando se hayan suministrado) antes del embalaje y el almacenamiento.

6.3 CUIDADOS DEL DISPOSITIVO

Limpieza

El personal médico será responsable del mantenimiento del dispositivo médico y de todo el equipamiento en condiciones de funcionamiento óptimas. Los sencillos pasos que se presentan a continuación constituyen las directrices para elaborar un programa de cuidado y mantenimiento apropiado.

⚠ **ADVERTENCIA**

Peligro de infección

- Limpie el panel delantero con un paño suave humedecido con agua destilada.

Si es necesario, use solamente detergente neutro.

- No está permitido usar sustancias que puedan dañar el dispositivo.
- Para la limpieza, consulte las indicaciones de las instrucciones de uso correspondientes.

Esterilización

⚠ **ATENCIÓN**

Peligro de lesiones para el paciente o el usuario

La consola, el pedal y el portasueros no se pueden esterilizar.

- En relación con la esterilización de los accesorios quirúrgicos, como las puntas faco, consulte las indicaciones de las correspondientes instrucciones de uso.

Desinfección

INFORMACIÓN

Daños en la superficie del dispositivo

- Use un desinfectante a base de aldehído o alcohol. Se permite la adición de compuestos cuaternarios. Para evitar dañar las superficies, no se deben usar desinfectantes distintos de los que se enumeran a continuación.

Las concentraciones máximas son:

- Para el alcohol (probado con 2-propanol): 60%
- Para el aldehído (probado con glutaraldehído): 2%
- Para los compuestos cuaternarios (probado con DDAC): 0,2%

7. ACCESORIOS

Esta sección enumera accesorios, recambios y materiales consumibles para el R-Evo Smart suministrados por OPTIKON 2000 S.p.A.
Consulte al distribuidor local y la web www.optikon.com si necesita detalles sobre productos específicos.

ADVERTENCIA

Peligro de lesiones oculares en el paciente

- Use exclusivamente accesorios y materiales consumibles originales elaborados por OPTIKON 2000 S.p.A. y destinados al uso con los sistemas R-EVO SMART. Consulte las instrucciones de uso de los accesorios para comprobar su compatibilidad con los sistemas R-EVO SMART.

Accesorios de uso general

REF.	Descripción
112105	Pedal multifunción

Accesorios para el segmento posterior (solo CR)

Vitrectomía posterior
Vitréctomos “Optivit” 20, 23, 25G
Vitréctomos “Twedge” (doble corte) 23, 25G
Endoiluminación
Sondas para endoiluminación “Standard” 20, 23, 25G
Sondas para endoiluminación “Wide angle” 20, 23, 25G
Endoiluminadores “Candeliere” 20, 23, 25G
Irrigación y aspiración
Deflusor para irrigación controlada
Caja I/A "Easysys"
Cánulas de infusión 20G
Cánulas de extracción de líquidos 20, 23, 25G
Trócar con válvula 23, 25G
Trócar sin válvula 23, 25G
Piezas de mano de aspiración "Charles" activos y pasivos
Cambio de líquidos
Tubo de aire con filtro con llave automática
Juego de inyección/extracción de aceite de silicona

Diatermia
Pieza de mano para endotermia 20, 23, 25G
Pinzas diatérmicas
Esodiatermias de lápiz
Cable para diatermia
Facoemulsificación
Pieza de mano para facoemulsificación (anterior y posterior) "Slim 4"
Pieza de mano para facoemulsificación (anterior y posterior) "Six"
Puntas para facoemulsificación por Pars Plana "low friction"

Accesorios para el segmento anterior

Facoemulsificación
Pieza de mano para facoemulsificación (anterior y posterior) "Slim 4"
Pieza de mano para facoemulsificación (anterior y posterior) "Six"
Puntas para facoemulsificación para incisiones de 1,5 a 3,2 mm
Puntas para facoemulsificación "flared" para incisiones de 1,8 a 2,9 mm
Manguitos de silicona (sleeves) para incisiones de 1,8 a 3,2 mm
Irrigación y aspiración
Deflusor para irrigación controlada
Caja I/A "Easysys"
Pieza de mano I/A para puntas de fijación rápida
Puntas I/A rectas, con sleeve de silicona para incisiones de 1,8 a 3,2 mm
Puntas I/A anguladas, con sleeve de silicona para incisiones de 1,8 a 3,2 mm
Puntas I/A con sleeve metálico
Diatermia
Esodiatermias de lápiz
Pinzas diatérmicas
Cable para diatermia
Vitrectomía anterior
Vitréctomo 20G con sleeve de irrigación
Vitréctomos sin irrigación 20, 23, 25G

Paquetes de procedimiento para R-Evo Smart
OPTIKON 2000 S.p.A. suministra paquetes de procedimiento personalizables para vitrectomía y para facoemulsificación.
Los paquetes de procedimiento constan de conjuntos de accesorios que aparecen en las tablas anteriores.
Consulte al distribuidor local si necesita más detalles.

Especificaciones técnicas: R-Evo Smart® E

INFORMACIÓN GENERAL

Fabricante	OPTIKON 2000 S.p.A. Via del Casale di Settebagni, 13 - 00138 Roma - Italia
Modelo	R-Evo Smart® E
Ref	111009
Cumplimiento normativo	Directiva para dispositivos médicos (MDD) 93/42/EEC
Normativa técnica	EN60601-1 EN60601-1-2 EN60601-2-2 EN80601-2-58

ESPECIFICACIONES MEDIOAMBIENTALES

Almacenamiento y transporte	Temperatura -10 °C - +70 °C, humedad 10% - 100% (sin condensación), presión atmosférica 500 - 1060 hPa
Funcionamiento	Rango de temperatura +10 °C - +35 °C, humedad 30% - 75%, presión atmosférica 900 - 1060 hPa (para vacío de aspiración máximo); 810 - 1060 hPa (vacío de aspiración de hasta 500 mmHg)

ESPECIFICACIONES ELÉCTRICAS

Tensión de entrada	100-240 VCA
Frecuencia	50/60 Hz
Suministro eléctrico	200 VA
Fusibles	100-240 voltios: T3.15AH 250V

IRRIGACIÓN

Suministro de fluidos	Infusión activa controlada por microprocesador o por la fuerza de la gravedad (presión ocular determinada por la altura de la fuente de irrigación)
Válvulas	Válvula de pinza
Control	Pedal

ASPIRACIÓN

Tipos de bomba de aspiración	Peristáltica
Nivel de vacío predeterminado	Programable por el usuario
Rango de vacío disponible	5 - 650 mmHg
Caudal predeterminado	Programable por el usuario
Rango de caudal disponible	1-65 cm^3/min
Tiempo de aumento de vacío	Ajustable en 25 niveles (0,5 s-12 s)
Modo de aspiración	Caudal fijo o lineal combinado con vacío fijo o lineal
Información del sistema	Sensor de vacío, que mide el vacío en la línea de aspiración
Control	Pedal

VITRECTOMÍA ANTERIOR

Tipo de pieza de mano	Cortadora de guillotina de accionamiento neumático
Índice de corte predeterminado	Programable por el usuario
Índice de corte disponible	60 - 1,000 cortes/min 120 - 2,000 cortes/min con tecnología Twedge™
Accionamiento neumático	Aire presurizado del compresor de aire seco integrado
Modo de corte	Fijo o lineal
Control	Pedal

DIATERMIA

Tipo	Generador bipolar: el generador se detiene cuando no se necesita la alimentación de RF
Frecuencia de funcionamiento	2 MHz
Potencia nominal	9 W (carga de 200 ohmios)
Tensión máxima sin carga	100 V
Potencia predeterminada	Programable por el usuario
Rango disponible	5% - 100%
Tipo de pieza de mano	Pinzas bipolares, cepillo de diatermia, sondas de endodiatermia
Cable de diatermia	Bipolar, 75 ohmios, 200 V máx., autoclave de vapor
Control	Control lineal de la potencia de DIATERMIA a través del pedal

FACOEMULSIÓN

Tipo de pieza de mano	Piezoeléctrico disponible con cuatro o seis cristales
Frecuencia	Aprox. 40 kHz
Pulsación de punta	Pasos de 5 µm hasta 100 µm
Control de potencia	Control fijo o lineal de la potencia U/S mediante el pedal
Modo U/S	Continuo, pulsado (con ciclo de trabajo preajustado), ráfaga simple-múltiple-continua
Modo de oclusión	Autolímite, pulso HD
Timer U/S	0:00-9:59 min - Tiempo de faco equivalente (EPT)

CLASIFICACIÓN DE EQUIPOS SEGÚN LA NORMA EN 60601-1

Tipo de protección contra descargas eléctricas	Clase I
Grado de protección contra descargas eléctricas:	
Diatermia	Tipo BF, flotante en altas y en bajas frecuencias
U/S	Tipo B
Vitrectomía	Tipo BF
Grado de protección frente al agua (unidad del sistema)	IPX0
Grado de protección frente al agua (pedal)	IPX8
Grado de seguridad en presencia de un anestésico inflamable	No adecuado

Ancho x prof. x alt:
43 x 50 x 35 cm

Ancho x prof. x alt. (con carro):
57 x 74 x 152 cm

Peso:
17 Kg (60 kg con carro y pedal)

NOTA:
1) El peso y las dimensiones indicadas son aproximados.
2) Las especificaciones están sujetas a cambios sin previo aviso.

R-EVO Smart
Ophthalmic Equipment

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Especificaciones técnicas: R-Evo Smart® S

INFORMACIÓN GENERAL

Fabricante	OPTIKON 2000 S.p.A. Via del Casale di Settebagni, 13 - 00138 Roma - Italia
Modelo	R-Evo Smart® S
Ref	111010
Cumplimiento normativo	Directiva para dispositivos médicos (MDD) 93/42/EEC
Normativa técnica	EN60601-1 EN60601-1-2 EN60601-2-2 EN80601-2-58

ESPECIFICACIONES MEDIOAMBIENTALES

Almacenamiento y transporte	Temperatura -10 °C - +70 °C, humedad 10% - 100% (sin condensación), presión atmosférica 500 - 1060 hPa
Funcionamiento	Rango de temperatura +10 °C - +35 °C, humedad 30% - 75%, presión atmosférica 900 - 1060 hPa (para vacío de aspiración máximo); 810 - 1060 hPa (vacío de aspiración de hasta 500 mmHg)

ESPECIFICACIONES ELÉCTRICAS

Tensión de entrada	100-240 VCA
Frecuencia	50/60 Hz
Suministro eléctrico	200 VA
Fusibles	100-240 voltios: T3.15AH 250V

ESPECIFICACIONES DE AIRE COMPRIMIDO

Presión de entrada de aire	500-800 kPa (72-116 PSI; 5-8 bares)
Consumo de aire	32 litros normales/min

IRRIGACIÓN

Suministro de fluidos	Infusión activa controlada por microprocesador o por la fuerza de la gravedad (presión ocular determinada por la altura de la fuente de irrigación)
Válvulas	Válvula de pinza
Control	Pedal

ASPIRACIÓN

Tipos de bomba de aspiración	Peristáltico y Venturi
Medio de accionamiento	Bomba peristáltica: rodillos Bomba Venturi: aire de una fuente externa a 500-800 kPa (72-116 PSI: 5-8 bares)
Nivel de vacío predeterminado	Programable por el usuario
Rango de vacío disponible	5 - 650 mmHg
Caudal predeterminado	Programable por el usuario
Rango de caudal disponible	1-65 cm^3/min (solo peristáltico)
Tiempo de aumento de vacío	Peristáltico: ajustable en 25 niveles (0,5 s-12 s) Venturi: ajustable en 2 niveles (rápido/lento)
Modo de aspiración	Peristáltico: caudal fijo o lineal combinado con vacío fijo o lineal Venturi: vacío fijo o lineal
Información del sistema	Sensor de vacío, que mide el vacío en la línea de aspiración

Control	Pedal

VITRECTOMÍA ANTERIOR

Tipo de pieza de mano	Cortadora de guillotina de accionamiento neumático
Índice de corte predeterminado	Programable por el usuario
Índice de corte disponible	60 - 5,000 cortes/min 120 - 10,000 cortes/min con tecnología Twedge™
Accionamiento neumático	Aire presurizado de una fuente externa
Modo de corte	Fijo o lineal
Control	Pedal

DIATERMIA

Tipo	Generador bipolar: el generador se detiene cuando no se necesita la alimentación de RF
Frecuencia de funcionamiento	2 MHz
Potencia nominal	9 W (carga de 200 ohmios)
Tensión máxima sin carga	100 V
Potencia predeterminada	Programable por el usuario
Rango disponible	5% - 100%
Tipo de pieza de mano	Pinzas bipolares, cepillo de diatermia, sondas de endodiatermia
Cable de diatermia	Bipolar, 75 ohmios, 200 V máx., autoclave de vapor
Control	Control lineal de la potencia de DIATERMIA a través del pedal

FACOEMULSIÓN

Tipo de pieza de mano	Piezoeléctrico disponible con cuatro o seis cristales
Frecuencia	Aprox. 40 kHz
Pulsación de punta	Pasos de 5 µm hasta 100 µm
Control de potencia	Control fijo o lineal de la potencia U/S mediante el pedal
Modo U/S	Continuo, pulsado (con ciclo de trabajo preajustado), ráfaga simple-múltiple-continua
Modo de oclusión	Autolímite, pulso HD

Temporizador U/S	0:00-9:59 min - Tiempo de faco equivalente (EPT)

CLASIFICACIÓN DE EQUIPOS SEGÚN LA NORMA EN 60601-1

Tipo de protección contra descargas eléctricas	Clase I
Grado de protección contra descargas eléctricas:	
Diatermia	Tipo BF, flotante en altas y en bajas frecuencias
U/S	Tipo B
Vitrectomía	Tipo BF
Grado de protección frente al agua (unidad del sistema)	IPX0
Grado de protección frente al agua (pedal)	IPX8
Grado de seguridad en presencia de un anestésico inflamable	No adecuado

Ancho x prof. x alt:
43 x 50 x 35 cm

Ancho x prof. x alt. (con carro):
57 x 74 x 152 cm

Peso:
17 Kg (60 kg con carro y pedal)

NOTA:
1) El peso y las dimensiones indicadas son aproximados.
2) Las especificaciones están sujetas a cambios sin previo aviso.

R-EVO Smart
Ophthalmic Equipment

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Especificaciones técnicas: R-Evo Smart® CR

INFORMACIÓN GENERAL

Fabricante	OPTIKON 2000 S.p.A. Via del Casale di Settebagni, 13 - 00138 Roma - Italia
Modelo	R-Evo Smart® CR
Ref	121013
Cumplimiento normativo	Directiva para dispositivos médicos (MDD) 93/42/EEC
Normativa técnica	EN60601-1 EN60601-1-2 EN60601-2-2 EN80601-2-58 ISO15752

ESPECIFICACIONES MEDIOAMBIENTALES

Almacenamiento y transporte	Temperatura -10 °C - +70 °C, humedad 10 % - 100 % (sin condensación), presión atmosférica 500 - 1060 hPa
Funcionamiento	Rango de temperatura +10 °C - +35 °C, humedad 30 % - 75 %, presión atmosférica 900 - 1060 hPa (para vacío de aspiración máximo); 810 - 1060 hPa (vacío de aspiración de hasta 500 mmHg)

ESPECIFICACIONES ELÉCTRICAS

Voltaje de entrada	100-240 VCA
Frecuencia	50/60 Hz
Suministro eléctrico	200 VA
Fusibles	100-240 voltios: T3.15AH 250V

ESPECIFICACIONES DE AIRE COMPRIMIDO

Presión de entrada de aire	500-800 kPa (72-116 PSI; 5-8 bares)
Consumo de aire	32 litros normales/min

IRRIGACIÓN

Suministro de fluidos	Infusión activa controlada por microprocesador o por la fuerza de la gravedad (presión ocular determinada por la altura de la fuente de irrigación)
Válvulas	Válvula de pinza
Control	Pedal

ASPIRACIÓN

Tipos de bomba de aspiración	Peristáltico y Venturi
Medio de accionamiento	Bomba peristáltica: rodillos Bomba Venturi: aire de una fuente externa a 500-800 kPa (72-116 PSI: 5-8 bares)
Nivel de vacío predeterminado	Programable por el usuario
Rango de vacío disponible	5 - 650 mmHg
Caudal predeterminado	Programable por el usuario
Rango de caudal disponible	1-65 cm^3/min (solo peristáltico)
Tiempo de aumento de vacío	Peristáltico: ajustable en 25 niveles (0,5 s-12 s) Venturi: ajustable en 2 niveles (rápido/lento)
Modo de aspiración	Peristáltico: caudal fijo o lineal combinado con vacío fijo o lineal Venturi: vacío fijo o lineal
Información del sistema	Sensor de vacío, que mide el vacío en la línea de aspiración

Control	Pedal

VITRECTOMÍA ANTERIOR

Tipo de pieza de mano	Cortadora de guillotina de accionamiento neumático
Índice de corte predeterminado	Programable por el usuario
Índice de corte disponible	60 - 5,000 cortes/min 120 - 10,000 cortes/min con tecnología Twedge™
Accionamiento neumático	Aire presurizado de una fuente externa
Modo de corte	Fijo o lineal
Control	Pedal

VITRECTOMÍA POSTERIOR

Tipo de pieza de mano	Cortadora de guillotina de accionamiento neumático
Índice de corte predeterminado	Programable por el usuario
Índice de corte disponible	60 - 5,000 cortes/min 120 - 10,000 cortes/min con tecnología Twedge™
Accionamiento neumático	Aire presurizado de una fuente externa
Modo de corte	Fijo o lineal
Control	Pedal

DIATERMIA

Tipo	Generador bipolar: el generador se detiene cuando no se necesita la alimentación de RF
Frecuencia de funcionamiento	2 MHz
Potencia nominal	9 W (carga de 200 ohmios)
Tensión máxima sin carga	100 V
Potencia predeterminada	Programable por el usuario
Rango disponible	5% - 100%
Tipo de pieza de mano	Pinzas bipolares, cepillo de diatermia, sondas de endodiatermia
Cable de diatermia	Bipolar, 75 ohmios, 200 V máx., autoclave de vapor
Control	Control lineal de la potencia de DIATERMIA a través del pedal

ILUMINACIÓN

Fuente de iluminación	Dos lámparas LED independientes
Flujo luminoso	400+400 lm
Ajuste de intensidad	20 niveles
Filtros de luz	4 filtros de color seleccionables libres de emisiones nocivas UV e IR

INTERCAMBIO DE FLUIDO/AIRE

Presión disponible	5 - 120 mmHg
Tolerancia	Presión establecida ± 3 mmHg
Información del sistema	Sonido digital que indica que el aire está conectado

INYECCIÓN DE ACEITE DE SILICONA

Presión disponible	0.4 - 5 bares
Información del sistema	Sonido digital que indica la inyección de aceite de silicona

FACOEMULSIÓN

Tipo de pieza de mano	Piezoeléctrico disponible con cuatro o seis cristales
Frecuencia	Aprox. 40 kHz
Pulsación de punta	Pasos de 5µm hasta 100µm
Control de potencia	Control fijo o lineal de la potencia U/S mediante el pedal
Modo U/S	Continuo, pulsado (con ciclo de trabajo preajustado), ráfaga simple-múltiple-continua
Modo de oclusión	Autolímite, pulso HD
Temporizador U/S	0:00-9:59 min - Tiempo de faco equivalente (EPT)

CLASIFICACIÓN DE EQUIPOS SEGÚN LA NORMA EN 60601-1

Tipo de protección contra descargas eléctricas	Clase I
Grado de protección contra descargas eléctricas:	
Diatermia	Tipo BF, flotante en altas y en bajas frecuencias
U/S	Tipo B
Vitrectomía	Tipo BF
Iluminación	Tipo BF
Aire	Tipo BF
Silicona	Tipo BF
Grado de protección frente al agua (unidad del sistema)	IPX0
Grado de protección frente al agua (pedal)	IPX8
Grado de seguridad en presencia de un anestésico inflamable	No adecuado

Ancho x prof. x alt:
43 x 50 x 35 cm

Ancho x prof. x alt. (con carro):
57 x 74 x 152 cm

Peso:
17 Kg (60 kg con carro y pedal)

NOTA:
1) El peso y las dimensiones indicadas son aproximados.
2) Las especificaciones están sujetas a cambios sin previo aviso.

R-EVO Smart
Ophthalmic Equipment

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23G Twedge VitPack SP

Pack for Vitrectomy - Sterile - Single use

Product Information

23G TWEDGE VITPACK SP	Name	Description	Qty/Bx	SKU #
	23G TWEDGE VITPACK SP	Pack for Vitrectomy - Sterile - Single use	5	199123

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 5x	**Biocompatibility**
The devices that make up the kit are packaged as follows. Two individual stiff blisters consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: 1st - tubing, cassette and infusion set 2nd - accessories for vitrectomy A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. 5 (five) blisters containing the cassette, plus 5 (five) blisters containing accessories, plus 5 (five) pouchs containing drapes, plus 5 (five) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	The standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 128510 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-Evolution CR and R-EVO SMART CR for vitreo-retinal surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 193313

Components

Q.ty	SKU #		Image
1	**192223** 23G TROCAR SYSTEM, ONE-STEP WITH VALVE Risk class according to MDD 93/42 **IIa** CND category **Q020199** CE 0051	23G valved entry system kit "One Step" 23G trocar kit. The kit contains **3 valved trocars** mounted on a scleral knife and one infusion cannula.	
1	**192313** 23G OPTI-VIT TWEDGE VITREOUS CUTTER Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	23G Twedge™ high speed dual blade vitrectomy probe 23G (approx. 0.6 mm) "**Twedge™**" probe for posterior vitrectomy with high speed, guillotine-type pneumatically actuated **dual blade** and tubing. Cut rate of up to 10,000 cuts per minute (20,000 with dual blade) for R-Evolution® CR (recommended range of 7,000 to 8,000 cuts per minute, 14,000/16,000 with dual blade) and 5,000 cuts per minute (10,000 with dual blade) for R-Evo Smart® CR. Selecting a high cut rate reduces fluctuation of the retina and membranes. The specific geometry and sharpening of the cutting mouth improve cutting performance and prevent hazardous vitreous incarceration. Low weight and lack of vibration make it comfortable to use, even during lengthy procedures.	
1	**192807** 23G ENDOILLUMINATION PROBE, MULTIPORT Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	23G spot endoillumination probe 23G (approx. 0.6 mm) "standard - spot" fiber optic, multiport endoillumination probe. The tip provides a conical light beam (approx. 35°) of intense, uniform illumination over a large surface of the retina.	

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Components

Q.ty	SKU #		Image
1	**192514** 2-WAY STOPCOCK Risk class according to MDD 93/42 **IIa** CND category **A0701** CE 0051	3-WAY STOPCOCK 3-way stopcock with adapters, which switches 2 input lines to one output line. Fitted with a mechanical stop on two positions, thus preventing any switching errors.	
1	**192550** FLUIDS EXCHANGE SET WITH AUTOMATIC VALVE Risk class according to MDD 93/42 **IIa** CND category **Q02030199** CE 0051	Automatic fluid/air exchange set Automatic fluid/air exchange system. The device is indicated in vitreoretinal ophthalmic surgery, particularly tamponade with fluids. It enables automatic switching between irrigation of sterile balanced saline solution and infusion of sterile air into the eyeball. The irrigation of balanced saline solution and infusion of sterile air are channeled along the same infusion line. The anti-reflux valve on the air infusion tube prevents solution from entering the latter while irrigating with balanced saline solution. Conversely, it blocks the flow of saline solution during sterile air infusion. Consisting of the following parts: 1) Tubing for channeling filtered air 2) Filter connecting the device to the vitreoretinal surgery machine and filtering the air introduced into the eye 3) "Y" air connector 4) One-way valve to control air flow direction	

Contact Information:
www.bvimedical.com/customer-support

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23G Twedge UniPack SP 20G F

Pack for combined surgery involving 23G vitrectomy and phacoemulsification - Sterile - Single use

Product Information

23G TWEDGE UNIPACK SP 20G F	Name	Description	Qty/Bx	SKU #
	23G TWEDGE UNIPACK SP 20G F	Pack for combined surgery involving 23G vitrectomy and phacoemulsification - Sterile - Single use	5	199123 20G – F

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 5x	**Biocompatibility**
The devices that make up the kit are packaged as follows. Two individual stiff blisters consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: 1st - tubing, cassette and infusion set 2nd - accessories for vitrectomy A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 5 (five) blisters containing the cassette, plus 5 (five) blisters containing accessories for vitrectomy, plus 5 (five) pouchs containing accessories for phacoemulsification, plus 5 (five) pouchs containing drapes, plus 5 (five) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	The standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 129561 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-Evolution CR and R-EVO SMART CR for combined vitrectomy and phacoemulsification surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 193313 and 19501Y

Components

Q.ty	SKU #		Image
1	**192223** 23G TROCAR SYSTEM, ONE-STEP WITH VALVE Risk class according to MDD 93/42 **IIa** CND category **Q020199** CE 0051	23G valved entry system kit "One Step" 23G trocar kit. The kit contains **3 valved trocars** mounted on a scleral knife and one infusion cannula.	
1	**192313** 23G OPTI-VIT TWEDGE VITREOUS CUTTER Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	23G Twedge™ high speed dual blade vitrectomy probe 23G (approx. 0.6 mm) "**Twedge™**" probe for posterior vitrectomy with high speed, guillotine-type pneumatically actuated **dual blade** and tubing. Cut rate of up to 10,000 cuts per minute (20,000 with dual blade) for R-Evolution® CR (recommended range of 7,000 to 8,000 cuts per minute, 14,000/16,000 with dual blade) and 5,000 cuts per minute (10,000 with dual blade) for R-Evo Smart® CR. Selecting a high cut rate reduces fluctuation of the retina and membranes. The specific geometry and sharpening of the cutting mouth improve cutting performance and prevent hazardous vitreous incarceration. Low weight and lack of vibration make it comfortable to use, even during lengthy procedures.	
1	**192807** 23G ENDOILLUMINATION PROBE, MULTIPORT Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	23G spot endoillumination probe 23G (approx. 0.6 mm) "standard - spot" fiber optic, multiport endoillumination probe. The tip provides a conical light beam (approx. 35°) of intense, uniform illumination over a large surface of the retina.	

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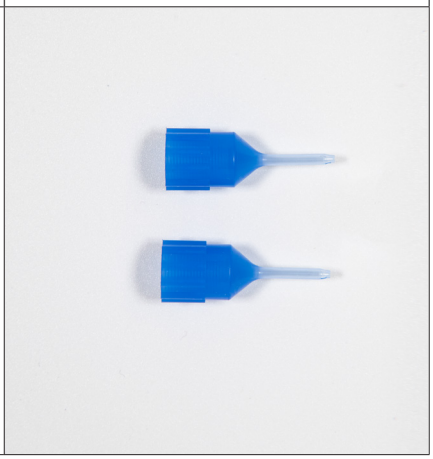
Components

Q.ty	SKU #		Image
1	**192514** 2-WAY STOPCOCK Risk class according to MDD 93/42 **IIa** CND category **A0701** CE 0051	3-WAY STOPCOCK 3-way stopcock with adapters, which switches 2 input lines to one output line. Fitted with a mechanical stop on two positions, thus preventing any switching errors.	
1	**192550** FLUIDS EXCHANGE SET WITH AUTOMATIC VALVE Risk class according to MDD 93/42 **IIa** CND category **Q02030199** CE 0051	Automatic fluid/air exchange set Automatic fluid/air exchange system. The device is indicated in vitreoretinal ophthalmic surgery, particularly tamponade with fluids. It enables automatic switching between irrigation of sterile balanced saline solution and infusion of sterile air into the eyeball. The irrigation of balanced saline solution and infusion of sterile air are channeled along the same infusion line. The anti-reflux valve on the air infusion tube prevents solution from entering the latter while irrigating with balanced saline solution. Conversely, it blocks the flow of saline solution during sterile air infusion. Consisting of the following parts: 1) Tubing for channeling filtered air 2) Filter connecting the device to the vitreoretinal surgery machine and filtering the air introduced into the eye 3) "Y" air connector 4) One-way valve to control air flow direction	
2	**191338** 20G BLUE SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 20G tips 2x blue sleeves for 2.6-2.8 mm incision (for 20G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	

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Components

Q.ty	SKU #		Image
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	
1	**191206** 20G FLARED PHACO TIP Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	20G flared phaco tip, 30° 20G "FLARED" Titanium tip for ultrasonic phacoemulsification, for 2.6 - 2.8 mm incision, pre-assembled on a single-use tightening wrench.	

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23G Twedge UniPack SP 21G F

Pack for combined surgery involving 23G vitrectomy and phacoemulsification - Sterile - Single use

Product Information

23G TWEDGE UNIPACK SP 21G F	Name	Description	Qty/Bx	SKU #
	23G TWEDGE UNIPACK SP 21G F	Pack for combined surgery involving 23G vitrectomy and phacoemulsification - Sterile - Single use	5	199123 21G - F

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 5x	**Biocompatibility**
The devices that make up the kit are packaged as follows. Two individual stiff blisters consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: 1st - tubing, cassette and infusion set 2nd - accessories for vitrectomy A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 5 (five) blisters containing the cassette, plus 5 (five) blisters containing accessories for vitrectomy, plus 5 (five) pouchs containing accessories for phacoemulsification, plus 5 (five) pouchs containing drapes, plus 5 (five) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	The standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 129563 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-Evolution CR and R-EVO SMART CR for combined vitrectomy and phacoemulsification surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 193313 and 19511Y

Components

Q.ty	SKU #		Image
1	**192223** 23G TROCAR SYSTEM, ONE-STEP WITH VALVE Risk class according to MDD 93/42 **IIa** CND category **Q020199** CE 0051	23G valved entry system kit "One Step" 23G trocar kit. The kit contains **3 valved trocars** mounted on a scleral knife and one infusion cannula.	
1	**192313** 23G OPTI-VIT TWEDGE VITREOUS CUTTER Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	23G Twedge™ high speed dual blade vitrectomy probe 23G (approx. 0.6 mm) "**Twedge™**" probe for posterior vitrectomy with high speed, guillotine-type pneumatically actuated **dual blade** and tubing. Cut rate of up to 10,000 cuts per minute (20,000 with dual blade) for R-Evolution® CR (recommended range of 7,000 to 8,000 cuts per minute, 14,000/16,000 with dual blade) and 5,000 cuts per minute (10,000 with dual blade) for R-Evo Smart® CR. Selecting a high cut rate reduces fluctuation of the retina and membranes. The specific geometry and sharpening of the cutting mouth improve cutting performance and prevent hazardous vitreous incarceration. Low weight and lack of vibration make it comfortable to use, even during lengthy procedures.	
1	**192807** 23G ENDOILLUMINATION PROBE, MULTIPORT Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	23G spot endoillumination probe 23G (approx. 0.6 mm) "standard - spot" fiber optic, multiport endoillumination probe. The tip provides a conical light beam (approx. 35°) of intense, uniform illumination over a large surface of the retina.	

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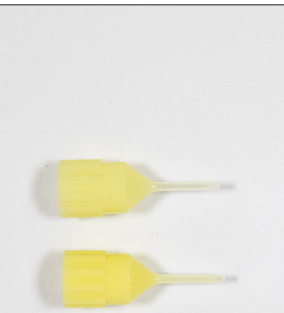
Components

Q.ty	SKU #		Image
1	**192514** 2-WAY STOPCOCK Risk class according to MDD 93/42 **IIa** CND category **A0701** CE 0051	3-WAY STOPCOCK 3-way stopcock with adapters, which switches 2 input lines to one output line. Fitted with a mechanical stop on two positions, thus preventing any switching errors.	
1	**192550** FLUIDS EXCHANGE SET WITH AUTOMATIC VALVE Risk class according to MDD 93/42 **IIa** CND category **Q02030199** CE 0051	Automatic fluid/air exchange set Automatic fluid/air exchange system. The device is indicated in vitreoretinal ophthalmic surgery, particularly tamponade with fluids. It enables automatic switching between irrigation of sterile balanced saline solution and infusion of sterile air into the eyeball. The irrigation of balanced saline solution and infusion of sterile air are channeled along the same infusion line. The anti-reflux valve on the air infusion tube prevents solution from entering the latter while irrigating with balanced saline solution. Conversely, it blocks the flow of saline solution during sterile air infusion. Consisting of the following parts: 1) Tubing for channeling filtered air 2) Filter connecting the device to the vitreoretinal surgery machine and filtering the air introduced into the eye 3) "Y" air connector 4) One-way valve to control air flow direction	
2	**191339** 21G YELLOW SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 21G tips 2x yellow sleeves for 2.2 - 2.4 mm incision (for 21G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	

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Components

Q.ty	SKU #		Image
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	
1	**191216** 21G FLARED PHACO TIP Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	21G flared phaco tip, 30° 21G "FLARED" Titanium tip for ultrasonic phacoemulsification, for 2.2 - 2.4 mm incision, pre-assembled on a single-use tightening wrench.	

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23G Twedge UniPack SP 21G FB

Pack for combined surgery involving 23G vitrectomy and phacoemulsification - Sterile - Single use

Product Information

23G TWEDGE UNIPACK SP 21G FB	Name	Description	Qty/Bx	SKU #
	23G TWEDGE UNIPACK SP 21G FB	Pack for combined surgery involving 23G vitrectomy and phacoemulsification - Sterile - Single use	5	199123 21G – FB

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 5x	**Biocompatibility**
The devices that make up the kit are packaged as follows. Two individual stiff blisters consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: 1st - tubing, cassette and infusion set 2nd - accessories for vitrectomy A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 5 (five) blisters containing the cassette, plus 5 (five) blisters containing accessories for vitrectomy, plus 5 (five) pouchs containing accessories for phacoemulsification, plus 5 (five) pouchs containing drapes, plus 5 (five) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	The standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 129564 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-Evolution CR and R-EVO SMART CR for combined vitrectomy and phacoemulsification surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 193313 and 19511Z

Components

Q.ty	SKU #		Image
1	**192223** 23G TROCAR SYSTEM, ONE-STEP WITH VALVE Risk class according to MDD 93/42 **IIa** CND category **Q020199** CE 0051	23G valved entry system kit "One Step" 23G trocar kit. The kit contains **3 valved trocars** mounted on a scleral knife and one infusion cannula.	
1	**192313** 23G OPTI-VIT TWEDGE VITREOUS CUTTER Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	23G Twedge™ high speed dual blade vitrectomy probe 23G (approx. 0.6 mm) "**Twedge™**" probe for posterior vitrectomy with high speed, guillotine-type pneumatically actuated **dual blade** and tubing. Cut rate of up to 10,000 cuts per minute (20,000 with dual blade) for R-Evolution® CR (recommended range of 7,000 to 8,000 cuts per minute, 14,000/16,000 with dual blade) and 5,000 cuts per minute (10,000 with dual blade) for R-Evo Smart® CR. Selecting a high cut rate reduces fluctuation of the retina and membranes. The specific geometry and sharpening of the cutting mouth improve cutting performance and prevent hazardous vitreous incarceration. Low weight and lack of vibration make it comfortable to use, even during lengthy procedures.	
1	**192807** 23G ENDOILLUMINATION PROBE, MULTIPORT Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	23G spot endoillumination probe 23G (approx. 0.6 mm) "standard - spot" fiber optic, multiport endoillumination probe. The tip provides a conical light beam (approx. 35°) of intense, uniform illumination over a large surface of the retina.	

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Components

Q.ty	SKU #		Image
1	**192514** 2-WAY STOPCOCK Risk class according to MDD 93/42 **IIa** CND category **A0701** CE 0051	3-WAY STOPCOCK 3-way stopcock with adapters, which switches 2 input lines to one output line. Fitted with a mechanical stop on two positions, thus preventing any switching errors.	
1	**192550** FLUIDS EXCHANGE SET WITH AUTOMATIC VALVE Risk class according to MDD 93/42 **IIa** CND category **Q02030199** CE 0051	Automatic fluid/air exchange set Automatic fluid/air exchange system. The device is indicated in vitreoretinal ophthalmic surgery, particularly tamponade with fluids. It enables automatic switching between irrigation of sterile balanced saline solution and infusion of sterile air into the eyeball. The irrigation of balanced saline solution and infusion of sterile air are channeled along the same infusion line. The anti-reflux valve on the air infusion tube prevents solution from entering the latter while irrigating with balanced saline solution. Conversely, it blocks the flow of saline solution during sterile air infusion. Consisting of the following parts: 1) Tubing for channeling filtered air 2) Filter connecting the device to the vitreoretinal surgery machine and filtering the air introduced into the eye 3) "Y" air connector 4) One-way valve to control air flow direction	
2	**191339** 21G YELLOW SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 21G tips 2x yellow sleeves for 2.2 - 2.4 mm incision (for 21G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	

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Components

Q.ty	SKU #		Image
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	
1	**191217** 21/22G FLARED BENT PHACO TIP Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	21/22G flared bent phaco tip, 30° 21G "Flared-bent" Titanium tip for ultrasonic phacoemulsification, for 2.2 - 2.4 mm incision, pre-assembled on a single-use tightening wrench.	

Contact Information:
www.bvimedical.com/customer-support

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25G Twedge VitPack SP

Pack for Vitrectomy - Sterile - Single use

Product Information

25G TWEDGE VITPACK SP	Name	Description	Qty/Bx	SKU #
	25G TWEDGE VITPACK SP	Pack for Vitrectomy - Sterile - Single use	5	199125

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 5x	**Biocompatibility**
The devices that make up the kit are packaged as follows. Two individual stiff blisters consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: 1st - tubing, cassette and infusion set 2nd - accessories for vitrectomy A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. 5 (five) blisters containing the cassette, plus 5 (five) blisters containing accessories, plus 5 (five) pouchs containing drapes, plus 5 (five) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	The standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 128513 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-Evolution CR and R-EVO SMART CR for vitreo-retinal surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 193513

Components

Q.ty	SKU #		Image
1	**192225** 25G TROCAR SYSTEM, ONE-STEP WITH VALVE Risk class according to MDD 93/42 **IIa** CND category **Q020199** CE 0051	25G valved entry system kit "One Step" 25G trocar kit. The kit contains 3 valved trocars mounted on a scleral knife and one infusion cannula.	
1	**192315** 25G OPTI-VIT TWEDGE VITREOUS CUTTER Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	25G Twedge™ high speed dual blade vitrectomy probe 25G (approx. 0.5 mm) "**Twedge™**" probe for posterior vitrectomy with high speed, guillotine-type pneumatically actuated **dual blade** and tubing. Cut rate of up to 10,000 cuts per minute (20,000 with dual blade) for R-Evolution® CR (recommended range of 7,000 to 8,000 cuts per minute, 14,000/16,000 with dual blade) and 5,000 cuts per minute (10,000 with dual blade) for R-Evo Smart® CR. Selecting a high cut rate reduces fluctuation of the retina and membranes. The specific geometry and sharpening of the cutting mouth improve cutting performance and prevent hazardous vitreous incarceration. Low weight and lack of vibration make it comfortable to use, even during lengthy procedures.	
1	**192808** 25G ENDOILLUMINATION PROBE, MULTIPORT Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	25G spot endoillumination probe 25G (approx. 0.5 mm) "standard - spot" fiber optic, multiport endoillumination probe. The tip provides a conical light beam (approx. 35°) of intense, uniform illumination over a large surface of the retina	

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Components

Q.ty	SKU #		Image
1	**192514** 2-WAY STOPCOCK Risk class according to MDD 93/42 **IIa** CND category **A0701** CE 0051	3-WAY STOPCOCK 3-way stopcock with adapters, which switches 2 input lines to one output line. Fitted with a mechanical stop on two positions, thus preventing any switching errors.	
1	**192550** FLUIDS EXCHANGE SET WITH AUTOMATIC VALVE Risk class according to MDD 93/42 **IIa** CND category **Q02030199** CE 0051	Automatic fluid/air exchange set Automatic fluid/air exchange system. The device is indicated in vitreoretinal ophthalmic surgery, particularly tamponade with fluids. It enables automatic switching between irrigation of sterile balanced saline solution and infusion of sterile air into the eyeball. The irrigation of balanced saline solution and infusion of sterile air are channeled along the same infusion line. The anti-reflux valve on the air infusion tube prevents solution from entering the latter while irrigating with balanced saline solution. Conversely, it blocks the flow of saline solution during sterile air infusion. Consisting of the following parts: 1) Tubing for channeling filtered air 2) Filter connecting the device to the vitreoretinal surgery machine and filtering the air introduced into the eye 3) "Y" air connector 4) One-way valve to control air flow direction	

Contact Information:
www.bvimedical.com/customer-support

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25G Twedge UniPack SP 20G

Pack for combined surgery involving 25G vitrectomy and phacoemulsification - Sterile - Single use

Product Information

25G TWEDGE UNIPACK SP 20G	Name	Description	Qty/Bx	SKU #
	25G TWEDGE UNIPACK SP 20G	Pack for combined surgery involving 25G vitrectomy and phacoemulsification - Sterile - Single use	5	199125 20G - F

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 5x	**Biocompatibility**
The devices that make up the kit are packaged as follows. Two individual stiff blisters consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: 1st - tubing, cassette and infusion set 2nd - accessories for vitrectomy A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 5 (five) blisters containing the cassette, plus 5 (five) blisters containing accessories for vitrectomy, plus 5 (five) pouchs containing accessories for phacoemulsification, plus 5 (five) pouchs containing drapes, plus 5 (five) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	TThe standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 129565 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-Evolution CR and R-EVO SMART CR for combined vitrectomy and phacoemulsification surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 193513 and 19501Y

Components

Q.ty	SKU #		Image
1	**192225** 25G TROCAR SYSTEM, ONE-STEP WITH VALVE Risk class according to MDD 93/42 **IIa** CND category **Q020199** CE 0051	25G valved entry system kit "One Step" 25G trocar kit. The kit contains 3 valved trocars mounted on a scleral knife and one infusion cannula.	
1	**192315** 25G OPTI-VIT TWEDGE VITREOUS CUTTER Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	25G Twedge™ high speed dual blade vitrectomy probe 25G (approx. 0.5 mm) "**Twedge™**" probe for posterior vitrectomy with high speed, guillotine-type pneumatically actuated **dual blade** and tubing. Cut rate of up to 10,000 cuts per minute (20,000 with dual blade) for R-Evolution® CR (recommended range of 7,000 to 8,000 cuts per minute, 14,000/16,000 with dual blade) and 5,000 cuts per minute (10,000 with dual blade) for R-Evo Smart® CR. Selecting a high cut rate reduces fluctuation of the retina and membranes. The specific geometry and sharpening of the cutting mouth improve cutting performance and prevent hazardous vitreous incarceration. Low weight and lack of vibration make it comfortable to use, even during lengthy procedures.	
1	**192808** 25G ENDOILLUMINATION PROBE, MULTIPORT Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	25G spot endoillumination probe 25G (approx. 0.5 mm) "standard - spot" fiber optic, multiport endoillumination probe. The tip provides a conical light beam (approx. 35°) of intense, uniform illumination over a large surface of the retina	

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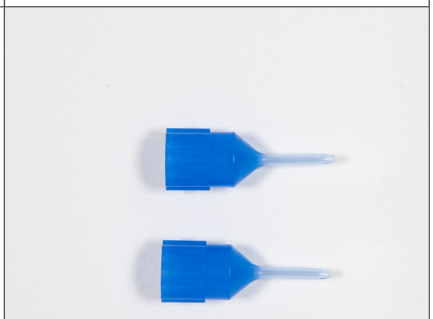
Components

Q.ty	SKU #		Image
1	**192514** 2-WAY STOPCOCK Risk class according to MDD 93/42 **IIa** CND category **A0701** CE 0051	3-WAY STOPCOCK 3-way stopcock with adapters, which switches 2 input lines to one output line. Fitted with a mechanical stop on two positions, thus preventing any switching errors.	
1	**192550** FLUIDS EXCHANGE SET WITH AUTOMATIC VALVE Risk class according to MDD 93/42 **IIa** CND category **Q02030199** CE 0051	Automatic fluid/air exchange set Automatic fluid/air exchange system. The device is indicated in vitreoretinal ophthalmic surgery, particularly tamponade with fluids. It enables automatic switching between irrigation of sterile balanced saline solution and infusion of sterile air into the eyeball. The irrigation of balanced saline solution and infusion of sterile air are channeled along the same infusion line. The anti-reflux valve on the air infusion tube prevents solution from entering the latter while irrigating with balanced saline solution. Conversely, it blocks the flow of saline solution during sterile air infusion. Consisting of the following parts: 1) Tubing for channeling filtered air 2) Filter connecting the device to the vitreoretinal surgery machine and filtering the air introduced into the eye 3) "Y" air connector 4) One-way valve to control air flow direction	
2	**191338** 20G BLUE SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 20G tips 2x blue sleeves for 2.6-2.8 mm incision (for 20G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	

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Components

Q.ty	SKU #		Image
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	
1	**191206** 20G FLARED PHACO TIP Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	20G flared phaco tip, 30° 20G "FLARED" Titanium tip for ultrasonic phacoemulsification, for 2.6 - 2.8 mm incision, pre-assembled on a single-use tightening wrench.	

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23G Twedge UniPack SH 20G F

Pack for combined surgery involving 23G vitrectomy and phacoemulsification - Sterile - Single use

Product Information

23G TWEDGE UNIPACK SH 20G F	Name	Description	Qty/Bx	SKU #
	23G TWEDGE UNIPACK SH 20G F	Pack for combined surgery involving 23G vitrectomy and phacoemulsification - Sterile - Single use	5	199323 20G – F

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 5x	**Biocompatibility**
The devices that make up the kit are packaged as follows. Two individual stiff blisters consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: 1st - tubing, cassette and infusion set 2nd - accessories for vitrectomy A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 5 (five) blisters containing the cassette, plus 5 (five) blisters containing accessories for vitrectomy, plus 5 (five) pouchs containing accessories for phacoemulsification, plus 5 (five) pouchs containing drapes, plus 5 (five) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	The standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 128521 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-Evolution CR and R-EVO SMART CR for combined vitrectomy and phacoemulsification surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 193333 and 19501Y

Components

Q.ty	SKU #		Image
1	**192223** 23G TROCAR SYSTEM, ONE-STEP WITH VALVE Risk class according to MDD 93/42 **IIa** CND category **Q020199** CE 0051	23G valved entry system kit "One Step" 23G trocar kit. The kit contains **3 valved trocars** mounted on a scleral knife and one infusion cannula.	
1	**192313** 23G OPTI-VIT TWEDGE VITREOUS CUTTER Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	23G Twedge™ high speed dual blade vitrectomy probe 23G (approx. 0.6 mm) "**Twedge™**" probe for posterior vitrectomy with high speed, guillotine-type pneumatically actuated **dual blade** and tubing. Cut rate of up to 10,000 cuts per minute (20,000 with dual blade) for R-Evolution® CR (recommended range of 7,000 to 8,000 cuts per minute, 14,000/16,000 with dual blade) and 5,000 cuts per minute (10,000 with dual blade) for R-Evo Smart® CR. Selecting a high cut rate reduces fluctuation of the retina and membranes. The specific geometry and sharpening of the cutting mouth improve cutting performance and prevent hazardous vitreous incarceration. Low weight and lack of vibration make it comfortable to use, even during lengthy procedures.	
1	**192816** 23G SHIELDED W/A ENDOILLUMINATION PROBE, MULTIPORT Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	23G shielded wide angle endoillumination probe 23G (approx. 0.6 mm) "shielded wide-angle" fiber optic, multiport endoillumination probe. The tip provides an asymmetrical conical light beam, due to shielding (approx. 60°), of intense, uniform illumination over a large surface of the retina. The shield protects the surgeon from any reflected light generated by the light source.	

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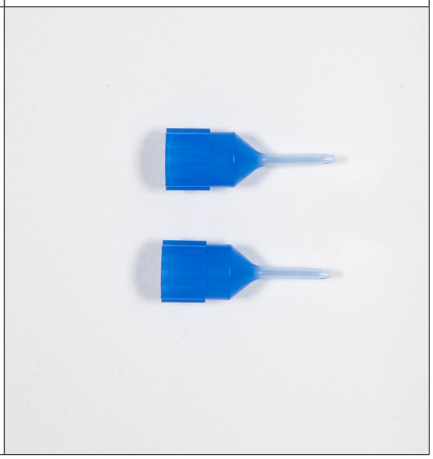
Components

Q.ty	SKU #		Image
1	**192514** 2-WAY STOPCOCK Risk class according to MDD 93/42 **IIa** CND category **A0701** CE 0051	3-WAY STOPCOCK 3-way stopcock with adapters, which switches 2 input lines to one output line. Fitted with a mechanical stop on two positions, thus preventing any switching errors.	
1	**192550** FLUIDS EXCHANGE SET WITH AUTOMATIC VALVE Risk class according to MDD 93/42 **IIa** CND category **Q02030199** CE 0051	Automatic fluid/air exchange set Automatic fluid/air exchange system. The device is indicated in vitreoretinal ophthalmic surgery, particularly tamponade with fluids. It enables automatic switching between irrigation of sterile balanced saline solution and infusion of sterile air into the eyeball. The irrigation of balanced saline solution and infusion of sterile air are channeled along the same infusion line. The anti-reflux valve on the air infusion tube prevents solution from entering the latter while irrigating with balanced saline solution. Conversely, it blocks the flow of saline solution during sterile air infusion. Consisting of the following parts: 1) Tubing for channeling filtered air 2) Filter connecting the device to the vitreoretinal surgery machine and filtering the air introduced into the eye 3) "Y" air connector 4) One-way valve to control air flow direction	
2	**191338** 20G BLUE SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 20G tips 2x blue sleeves for 2.6-2.8 mm incision (for 20G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	

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Components

Q.ty	SKU #		Image
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	
1	**191206** 20G FLARED PHACO TIP Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	20G flared phaco tip, 30° 20G "FLARED" Titanium tip for ultrasonic phacoemulsification, for 2.6 - 2.8 mm incision, pre-assembled on a single-use tightening wrench.	

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23G Twedge UniPack SH 20G

Pack for combined surgery involving 23G vitrectomy and phacoemulsification - Sterile - Single use

Product Information

23G TWEDGE UNIPACK SH 20G	Name	Description	Qty/Bx	SKU #
	23G TWEDGE UNIPACK SH 20G	Pack for combined surgery involving 23G vitrectomy and phacoemulsification - Sterile - Single use	5	199323 20G – FB

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 5x	**Biocompatibility**
The devices that make up the kit are packaged as follows. Two individual stiff blisters consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: 1st - tubing, cassette and infusion set 2nd - accessories for vitrectomy A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 5 (five) blisters containing the cassette, plus 5 (five) blisters containing accessories for vitrectomy, plus 5 (five) pouchs containing accessories for phacoemulsification, plus 5 (five) pouchs containing drapes, plus 5 (five) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	The standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 128522 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-Evolution CR and R-EVO SMART CR for combined vitrectomy and phacoemulsification surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 1193333 and 19501Z

Components

Q.ty	SKU #		Image
1	**192223** 23G TROCAR SYSTEM, ONE-STEP WITH VALVE Risk class according to MDD 93/42 **IIa** CND category **Q020199** CE 0051	23G valved entry system kit "One Step" 23G trocar kit. The kit contains **3 valved trocars** mounted on a scleral knife and one infusion cannula.	
1	**192313** 23G OPTI-VIT TWEDGE VITREOUS CUTTER Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	23G Twedge™ high speed dual blade vitrectomy probe 23G (approx. 0.6 mm) "**Twedge™**" probe for posterior vitrectomy with high speed, guillotine-type pneumatically actuated **dual blade** and tubing. Cut rate of up to 10,000 cuts per minute (20,000 with dual blade) for R-Evolution® CR (recommended range of 7,000 to 8,000 cuts per minute, 14,000/16,000 with dual blade) and 5,000 cuts per minute (10,000 with dual blade) for R-Evo Smart® CR. Selecting a high cut rate reduces fluctuation of the retina and membranes. The specific geometry and sharpening of the cutting mouth improve cutting performance and prevent hazardous vitreous incarceration. Low weight and lack of vibration make it comfortable to use, even during lengthy procedures.	
1	**192816** 23G SHIELDED W/A ENDOILLUMINATION PROBE, MULTIPORT Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	23G shielded wide angle endoillumination probe 23G (approx. 0.6 mm) "shielded wide-angle" fiber optic, multiport endoillumination probe. The tip provides an asymmetrical conical light beam, due to shielding (approx. 60°), of intense, uniform illumination over a large surface of the retina. The shield protects the surgeon from any reflected light generated by the light source.	

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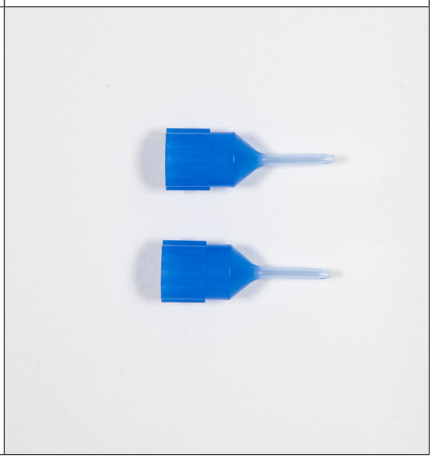
Components

Q.ty	SKU #		Image
1	**192514** 2-WAY STOPCOCK Risk class according to MDD 93/42 **IIa** CND category **A0701** CE 0051	3-WAY STOPCOCK 3-way stopcock with adapters, which switches 2 input lines to one output line. Fitted with a mechanical stop on two positions, thus preventing any switching errors.	
1	**192550** FLUIDS EXCHANGE SET WITH AUTOMATIC VALVE Risk class according to MDD 93/42 **IIa** CND category **Q02030199** CE 0051	Automatic fluid/air exchange set Automatic fluid/air exchange system. The device is indicated in vitreoretinal ophthalmic surgery, particularly tamponade with fluids. It enables automatic switching between irrigation of sterile balanced saline solution and infusion of sterile air into the eyeball. The irrigation of balanced saline solution and infusion of sterile air are channeled along the same infusion line. The anti-reflux valve on the air infusion tube prevents solution from entering the latter while irrigating with balanced saline solution. Conversely, it blocks the flow of saline solution during sterile air infusion. Consisting of the following parts: 1) Tubing for channeling filtered air 2) Filter connecting the device to the vitreoretinal surgery machine and filtering the air introduced into the eye 3) "Y" air connector 4) One-way valve to control air flow direction	
2	**191338** 20G BLUE SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 20G tips 2x blue sleeves for 2.6-2.8 mm incision (for 20G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	

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Components

Q.ty	SKU #		Image
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	
1	**191207** 20G FLARED BENT PHACO TIP Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	20G flared bent phaco tip, 30° 20G "FLARED BENT" Titanium tip for ultrasonic phacoemulsification, for 2.6 - 2.8 mm incision, pre-assembled on a single-use tightening wrench	

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23G Twedge UniPack SH 21G F

Pack for combined surgery involving 23G vitrectomy and phacoemulsification - Sterile - Single use

Product Information

23G TWEDGE UNIPACK SH 21G F	Name	Description	Qty/Bx	SKU #
	23G TWEDGE UNIPACK SH 21G F	Pack for combined surgery involving 23G vitrectomy and phacoemulsification - Sterile - Single use	5	199323 21G - F

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 5x	**Biocompatibility**
The devices that make up the kit are packaged as follows. Two individual stiff blisters consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: 1st - tubing, cassette and infusion set 2nd - accessories for vitrectomy A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 5 (five) blisters containing the cassette, plus 5 (five) blisters containing accessories for vitrectomy, plus 5 (five) pouchs containing accessories for phacoemulsification, plus 5 (five) pouchs containing drapes, plus 5 (five) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	The standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 128523 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-Evolution CR and R-EVO SMART CR for combined vitrectomy and phacoemulsification surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 193333 and 19511Y

Components

Q.ty	SKU #		Image
1	**192223** 23G TROCAR SYSTEM, ONE-STEP WITH VALVE Risk class according to MDD 93/42 **IIa** CND category **Q020199** CE 0051	23G valved entry system kit "One Step" 23G trocar kit. The kit contains **3 valved trocars** mounted on a scleral knife and one infusion cannula.	
1	**192313** 23G OPTI-VIT TWEDGE VITREOUS CUTTER Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	23G Twedge™ high speed dual blade vitrectomy probe 23G (approx. 0.6 mm) "**Twedge™**" probe for posterior vitrectomy with high speed, guillotine-type pneumatically actuated **dual blade** and tubing. Cut rate of up to 10,000 cuts per minute (20,000 with dual blade) for R-Evolution® CR (recommended range of 7,000 to 8,000 cuts per minute, 14,000/16,000 with dual blade) and 5,000 cuts per minute (10,000 with dual blade) for R-Evo Smart® CR. Selecting a high cut rate reduces fluctuation of the retina and membranes. The specific geometry and sharpening of the cutting mouth improve cutting performance and prevent hazardous vitreous incarceration. Low weight and lack of vibration make it comfortable to use, even during lengthy procedures.	
1	**192816** 23G SHIELDED W/A ENDOILLUMINATION PROBE, MULTIPORT Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	23G shielded wide angle endoillumination probe 23G (approx. 0.6 mm) "shielded wide-angle" fiber optic, multiport endoillumination probe. The tip provides an asymmetrical conical light beam, due to shielding (approx. 60°), of intense, uniform illumination over a large surface of the retina. The shield protects the surgeon from any reflected light generated by the light source.	

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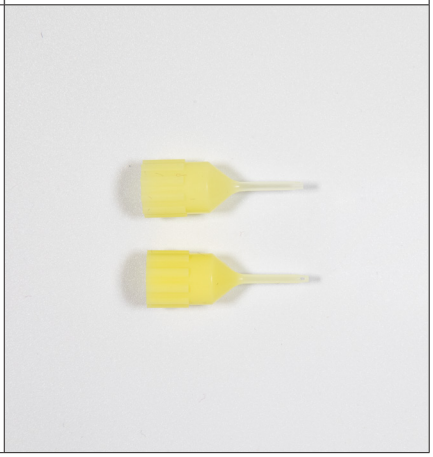
Components

Q.ty	SKU #		Image
1	**192514** 2-WAY STOPCOCK Risk class according to MDD 93/42 **IIa** CND category **A0701** CE 0051	3-WAY STOPCOCK 3-way stopcock with adapters, which switches 2 input lines to one output line. Fitted with a mechanical stop on two positions, thus preventing any switching errors.	
1	**192550** FLUIDS EXCHANGE SET WITH AUTOMATIC VALVE Risk class according to MDD 93/42 **IIa** CND category **Q02030199** CE 0051	Automatic fluid/air exchange set Automatic fluid/air exchange system. The device is indicated in vitreoretinal ophthalmic surgery, particularly tamponade with fluids. It enables automatic switching between irrigation of sterile balanced saline solution and infusion of sterile air into the eyeball. The irrigation of balanced saline solution and infusion of sterile air are channeled along the same infusion line. The anti-reflux valve on the air infusion tube prevents solution from entering the latter while irrigating with balanced saline solution. Conversely, it blocks the flow of saline solution during sterile air infusion. Consisting of the following parts: 1) Tubing for channeling filtered air 2) Filter connecting the device to the vitreoretinal surgery machine and filtering the air introduced into the eye 3) "Y" air connector 4) One-way valve to control air flow direction	
2	**191339** 21G YELLOW SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 21G tips 2x yellow sleeves for 2.2 - 2.4 mm incision (for 21G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	

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Components

Q.ty	SKU #		Image
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	
1	**191216** 21G FLARED PHACO TIP Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	21G flared phaco tip, 30° 21G "FLARED" Titanium tip for ultrasonic phacoemulsification, for 2.2 - 2.4 mm incision, pre-assembled on a single-use tightening wrench.	

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23G Twedge UniPack SH 21G FB

Pack for combined surgery involving 23G vitrectomy and phacoemulsification - Sterile - Single use

Product Information

23G TWEDGE UNIPACK SH 21G FB	Name	Description	Qty/Bx	SKU #
	23G TWEDGE UNIPACK SH 21G FB	Pack for combined surgery involving 23G vitrectomy and phacoemulsification - Sterile - Single use	5	199323 21G – FB

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 5x	**Biocompatibility**
The devices that make up the kit are packaged as follows. Two individual stiff blisters consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: 1st - tubing, cassette and infusion set 2nd - accessories for vitrectomy A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 5 (five) blisters containing the cassette, plus 5 (five) blisters containing accessories for vitrectomy, plus 5 (five) pouchs containing accessories for phacoemulsification, plus 5 (five) pouchs containing drapes, plus 5 (five) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	The standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 128524 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-Evolution CR and R-EVO SMART CR for combined vitrectomy and phacoemulsification surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 193333 and 19511Z

Components

Q.ty	SKU #		Image
1	**192223** 23G TROCAR SYSTEM, ONE-STEP WITH VALVE Risk class according to MDD 93/42 **IIa** CND category **Q020199** CE 0051	23G valved entry system kit "One Step" 23G trocar kit. The kit contains **3 valved trocars** mounted on a scleral knife and one infusion cannula.	
1	**192313** 23G OPTI-VIT TWEDGE VITREOUS CUTTER Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	23G Twedge™ high speed dual blade vitrectomy probe 23G (approx. 0.6 mm) "**Twedge™**" probe for posterior vitrectomy with high speed, guillotine-type pneumatically actuated **dual blade** and tubing. Cut rate of up to 10,000 cuts per minute (20,000 with dual blade) for R-Evolution® CR (recommended range of 7,000 to 8,000 cuts per minute, 14,000/16,000 with dual blade) and 5,000 cuts per minute (10,000 with dual blade) for R-Evo Smart® CR. Selecting a high cut rate reduces fluctuation of the retina and membranes. The specific geometry and sharpening of the cutting mouth improve cutting performance and prevent hazardous vitreous incarceration. Low weight and lack of vibration make it comfortable to use, even during lengthy procedures.	
1	**192816** 23G SHIELDED W/A ENDOILLUMINATION PROBE, MULTIPORT Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	23G shielded wide angle endoillumination probe 23G (approx. 0.6 mm) "shielded wide-angle" fiber optic, multiport endoillumination probe. The tip provides an asymmetrical conical light beam, due to shielding (approx. 60°), of intense, uniform illumination over a large surface of the retina. The shield protects the surgeon from any reflected light generated by the light source.	

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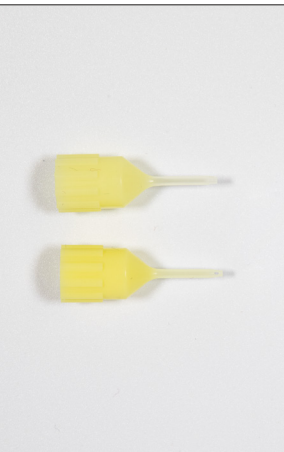
Components

Q.ty	SKU #		Image
1	**192514** 2-WAY STOPCOCK Risk class according to MDD 93/42 **IIa** CND category **A0701** CE 0051	3-WAY STOPCOCK 3-way stopcock with adapters, which switches 2 input lines to one output line. Fitted with a mechanical stop on two positions, thus preventing any switching errors.	
1	**192550** FLUIDS EXCHANGE SET WITH AUTOMATIC VALVE Risk class according to MDD 93/42 **IIa** CND category **Q02030199** CE 0051	Automatic fluid/air exchange set Automatic fluid/air exchange system. The device is indicated in vitreoretinal ophthalmic surgery, particularly tamponade with fluids. It enables automatic switching between irrigation of sterile balanced saline solution and infusion of sterile air into the eyeball. The irrigation of balanced saline solution and infusion of sterile air are channeled along the same infusion line. The anti-reflux valve on the air infusion tube prevents solution from entering the latter while irrigating with balanced saline solution. Conversely, it blocks the flow of saline solution during sterile air infusion. Consisting of the following parts: 1) Tubing for channeling filtered air 2) Filter connecting the device to the vitreoretinal surgery machine and filtering the air introduced into the eye 3) "Y" air connector 4) One-way valve to control air flow direction	
2	**191339** 21G YELLOW SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 21G tips 2x yellow sleeves for 2.2 - 2.4 mm incision (for 21G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	

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Components

Q.ty	SKU #		Image
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	
1	**191217** 21/22G FLARED BENT PHACO TIP Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	21/22G flared bent phaco tip, 30° 21G "Flared-bent" Titanium tip for ultrasonic phacoemulsification, for 2.2 - 2.4 mm incision, pre-assembled on a single-use tightening wrench.	

Contact Information:
www.bvimedical.com/customer-support

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23G Twedge VitPack SH

Pack for Vitrectomy - Sterile - Single use

Product Information

23G TWEDGE VITPACK SH	Name	Description	Qty/Bx	SKU #
	23G TWEDGE VITPACK SH	Pack for Vitrectomy - Sterile - Single use	5	199323

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 5x	**Biocompatibility**
The devices that make up the kit are packaged as follows. Two individual stiff blisters consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: 1st - tubing, cassette and infusion set 2nd - accessories for vitrectomy A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. 5 (five) blisters containing the cassette, plus 5 (five) blisters containing accessories, plus 5 (five) pouchs containing drapes, plus 5 (five) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	The standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 128510 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-Evolution CR and R-EVO SMART CR for vitreo-retinal surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 193333

Components

Q.ty	SKU #		Image
1	**192223** 23G TROCAR SYSTEM, ONE-STEP WITH VALVE Risk class according to MDD 93/42 **IIa** CND category **Q020199** CE 0051	23G valved entry system kit "One Step" 23G trocar kit. The kit contains **3 valved trocars** mounted on a scleral knife and one infusion cannula.	
1	**192313** 23G OPTI-VIT TWEDGE VITREOUS CUTTER Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	23G Twedge™ high speed dual blade vitrectomy probe 23G (approx. 0.6 mm) "**Twedge™**" probe for posterior vitrectomy with high speed, guillotine-type pneumatically actuated **dual blade** and tubing. Cut rate of up to 10,000 cuts per minute (20,000 with dual blade) for R-Evolution® CR (recommended range of 7,000 to 8,000 cuts per minute, 14,000/16,000 with dual blade) and 5,000 cuts per minute (10,000 with dual blade) for R-Evo Smart® CR. Selecting a high cut rate reduces fluctuation of the retina and membranes. The specific geometry and sharpening of the cutting mouth improve cutting performance and prevent hazardous vitreous incarceration. Low weight and lack of vibration make it comfortable to use, even during lengthy procedures.	
1	**192816** 23G SHIELDED W/A ENDOILLUMINATION PROBE, MULTIPORT Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	23G shielded wide angle endoillumination probe 23G (approx. 0.6 mm) "shielded wide-angle" fiber optic, multiport endoillumination probe. The tip provides an asymmetrical conical light beam, due to shielding (approx. 60°), of intense, uniform illumination over a large surface of the retina. The shield protects the surgeon from any reflected light generated by the light source.	

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Components

Q.ty	SKU #		Image
1	**192514** 2-WAY STOPCOCK Risk class according to MDD 93/42 **IIa** CND category **A0701** CE 0051	3-WAY STOPCOCK 3-way stopcock with adapters, which switches 2 input lines to one output line. Fitted with a mechanical stop on two positions, thus preventing any switching errors.	
1	**192550** FLUIDS EXCHANGE SET WITH AUTOMATIC VALVE Risk class according to MDD 93/42 **IIa** CND category **Q02030199** CE 0051	Automatic fluid/air exchange set Automatic fluid/air exchange system. The device is indicated in vitreoretinal ophthalmic surgery, particularly tamponade with fluids. It enables automatic switching between irrigation of sterile balanced saline solution and infusion of sterile air into the eyeball. The irrigation of balanced saline solution and infusion of sterile air are channeled along the same infusion line. The anti-reflux valve on the air infusion tube prevents solution from entering the latter while irrigating with balanced saline solution. Conversely, it blocks the flow of saline solution during sterile air infusion. Consisting of the following parts: 1) Tubing for channeling filtered air 2) Filter connecting the device to the vitreoretinal surgery machine and filtering the air introduced into the eye 3) "Y" air connector 4) One-way valve to control air flow direction	

Contact Information:
www.bvimedical.com/customer-support

bvimedical.com

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25G Twedge UniPack SH 20G

Pack for combined surgery involving 25G vitrectomy and phacoemulsification - Sterile - Single use

Product Information

25G TWEDGE UNIPACK SH 20G	Name	Description	Qty/Bx	SKU #
	25G TWEDGE UNIPACK SH 20G	Pack for combined surgery involving 25G vitrectomy and phacoemulsification - Sterile - Single use	5	199325 20G - F

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 5x	**Biocompatibility**
The devices that make up the kit are packaged as follows. Two individual stiff blisters consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: 1st - tubing, cassette and infusion set 2nd - accessories for vitrectomy A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 5 (five) blisters containing the cassette, plus 5 (five) blisters containing accessories for vitrectomy, plus 5 (five) pouchs containing accessories for phacoemulsification, plus 5 (five) pouchs containing drapes, plus 5 (five) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	TThe standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 128526 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-Evolution CR and R-EVO SMART CR for combined vitrectomy and phacoemulsification surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 193533 and 19501Y

Components

Q.ty	SKU #		Image
1	**192225** 25G TROCAR SYSTEM, ONE-STEP WITH VALVE Risk class according to MDD 93/42 **IIa** CND category **Q020199** CE 0051	25G valved entry system kit "One Step" 25G trocar kit. The kit contains 3 valved trocars mounted on a scleral knife and one infusion cannula.	
1	**192315** 25G OPTI-VIT TWEDGE VITREOUS CUTTER Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	25G Twedge™ high speed dual blade vitrectomy probe 25G (approx. 0.5 mm) "**Twedge™**" probe for posterior vitrectomy with high speed, guillotine-type pneumatically actuated **dual blade** and tubing. Cut rate of up to 10,000 cuts per minute (20,000 with dual blade) for R-Evolution® CR (recommended range of 7,000 to 8,000 cuts per minute, 14,000/16,000 with dual blade) and 5,000 cuts per minute (10,000 with dual blade) for R-Evo Smart® CR. Selecting a high cut rate reduces fluctuation of the retina and membranes. The specific geometry and sharpening of the cutting mouth improve cutting performance and prevent hazardous vitreous incarceration. Low weight and lack of vibration make it comfortable to use, even during lengthy procedures.	
1	**192845** 25G W/A SHIELDED ENDOILLUMINATION PROBE, MULTIPORT Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	25G shielded wide angle endoillumination probe 25G (approx. 0.5 mm) "shielded wide-angle" fiber optic, multiport endoillumination probe. The tip provides an asymmetrical conical light beam, due to shielding (approx. 60°), of intense, uniform illumination over a large surface of the retina. The shield protects the surgeon from any reflected light generated by the light source.	

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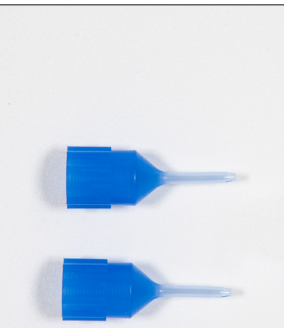
Components

Q.ty	SKU #		Image
1	**192514** 2-WAY STOPCOCK Risk class according to MDD 93/42 **IIa** CND category **A0701** CE 0051	3-WAY STOPCOCK 3-way stopcock with adapters, which switches 2 input lines to one output line. Fitted with a mechanical stop on two positions, thus preventing any switching errors.	
1	**192550** FLUIDS EXCHANGE SET WITH AUTOMATIC VALVE Risk class according to MDD 93/42 **IIa** CND category **Q02030199** CE 0051	Automatic fluid/air exchange set Automatic fluid/air exchange system. The device is indicated in vitreoretinal ophthalmic surgery, particularly tamponade with fluids. It enables automatic switching between irrigation of sterile balanced saline solution and infusion of sterile air into the eyeball. The irrigation of balanced saline solution and infusion of sterile air are channeled along the same infusion line. The anti-reflux valve on the air infusion tube prevents solution from entering the latter while irrigating with balanced saline solution. Conversely, it blocks the flow of saline solution during sterile air infusion. Consisting of the following parts: 1) Tubing for channeling filtered air 2) Filter connecting the device to the vitreoretinal surgery machine and filtering the air introduced into the eye 3) "Y" air connector 4) One-way valve to control air flow direction	
2	**191338** 20G BLUE SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 20G tips 2x blue sleeves for 2.6-2.8 mm incision (for 20G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	

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Components

Q.ty	SKU #		Image
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	
1	**191206** 20G FLARED PHACO TIP Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	20G flared phaco tip, 30° 20G "FLARED" Titanium tip for ultrasonic phacoemulsification, for 2.6 - 2.8 mm incision, pre-assembled on a single-use tightening wrench.	

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25G Twedge UniPack SH 20G

Pack for combined surgery involving 25G vitrectomy and phacoemulsification - Sterile - Single use

Product Information

25G TWEDGE UNIPACK SH 20G	Name	Description	Qty/Bx	SKU #
	25G TWEDGE UNIPACK SH 20G	Pack for combined surgery involving 25G vitrectomy and phacoemulsification - Sterile - Single use	5	199325 20G – FB

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 5x	**Biocompatibility**
The devices that make up the kit are packaged as follows. Two individual stiff blisters consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: 1st - tubing, cassette and infusion set 2nd - accessories for vitrectomy A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 5 (five) blisters containing the cassette, plus 5 (five) blisters containing accessories for vitrectomy, plus 5 (five) pouchs containing accessories for phacoemulsification, plus 5 (five) pouchs containing drapes, plus 5 (five) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	TThe standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 128533 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-Evolution CR and R-EVO SMART CR for combined vitrectomy and phacoemulsification surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 193533 and 19501Z

Components

Q.ty	SKU #		Image
1	**192225** 25G TROCAR SYSTEM, ONE-STEP WITH VALVE Risk class according to MDD 93/42 **IIa** CND category **Q020199** CE 0051	25G valved entry system kit "One Step" 25G trocar kit. The kit contains 3 valved trocars mounted on a scleral knife and one infusion cannula.	
1	**192315** 25G OPTI-VIT TWEDGE VITREOUS CUTTER Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	25G Twedge™ high speed dual blade vitrectomy probe 25G (approx. 0.5 mm) "**Twedge™**" probe for posterior vitrectomy with high speed, guillotine-type pneumatically actuated **dual blade** and tubing. Cut rate of up to 10,000 cuts per minute (20,000 with dual blade) for R-Evolution® CR (recommended range of 7,000 to 8,000 cuts per minute, 14,000/16,000 with dual blade) and 5,000 cuts per minute (10,000 with dual blade) for R-Evo Smart® CR. Selecting a high cut rate reduces fluctuation of the retina and membranes. The specific geometry and sharpening of the cutting mouth improve cutting performance and prevent hazardous vitreous incarceration. Low weight and lack of vibration make it comfortable to use, even during lengthy procedures.	
1	**192845** 25G W/A SHIELDED ENDOILLUMINATION PROBE, MULTIPORT Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	25G shielded wide angle endoillumination probe 25G (approx. 0.5 mm) "shielded wide-angle" fiber optic, multiport endoillumination probe. The tip provides an asymmetrical conical light beam, due to shielding (approx. 60°), of intense, uniform illumination over a large surface of the retina. The shield protects the surgeon from any reflected light generated by the light source.	

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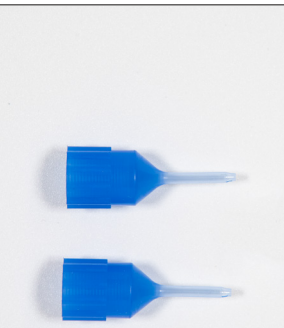
Components

Q.ty	SKU #		Image
1	**192514** 2-WAY STOPCOCK Risk class according to MDD 93/42 **IIa** CND category **A0701** CE 0051	3-WAY STOPCOCK 3-way stopcock with adapters, which switches 2 input lines to one output line. Fitted with a mechanical stop on two positions, thus preventing any switching errors.	
1	**192550** FLUIDS EXCHANGE SET WITH AUTOMATIC VALVE Risk class according to MDD 93/42 **IIa** CND category **Q02030199** CE 0051	Automatic fluid/air exchange set Automatic fluid/air exchange system. The device is indicated in vitreoretinal ophthalmic surgery, particularly tamponade with fluids. It enables automatic switching between irrigation of sterile balanced saline solution and infusion of sterile air into the eyeball. The irrigation of balanced saline solution and infusion of sterile air are channeled along the same infusion line. The anti-reflux valve on the air infusion tube prevents solution from entering the latter while irrigating with balanced saline solution. Conversely, it blocks the flow of saline solution during sterile air infusion. Consisting of the following parts: 1) Tubing for channeling filtered air 2) Filter connecting the device to the vitreoretinal surgery machine and filtering the air introduced into the eye 3) "Y" air connector 4) One-way valve to control air flow direction	
2	**191338** 20G BLUE SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 20G tips 2x blue sleeves for 2.6-2.8 mm incision (for 20G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	

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Components

Q.ty	SKU #		Image
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	
1	**191207** 20G FLARED BENT PHACO TIP Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	20G flared bent phaco tip, 30° 20G "FLARED BENT" Titanium tip for ultrasonic phacoemulsification, for 2.6 - 2.8 mm incision, pre-assembled on a single-use tightening wrench.	

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25G Twedge UniPack SH 21G

Pack for combined surgery involving 25G vitrectomy and phacoemulsification - Sterile - Single use

Product Information

25G TWEDGE UNIPACK SH 21G	Name	Description	Qty/Bx	SKU #
	25G TWEDGE UNIPACK SH 21G	Pack for combined surgery involving 25G vitrectomy and phacoemulsification - Sterile - Single use	5	199325 21G - F

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 5x	**Biocompatibility**
The devices that make up the kit are packaged as follows. Two individual stiff blisters consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: 1st - tubing, cassette and infusion set 2nd - accessories for vitrectomy A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 5 (five) blisters containing the cassette, plus 5 (five) blisters containing accessories for vitrectomy, plus 5 (five) pouchs containing accessories for phacoemulsification, plus 5 (five) pouchs containing drapes, plus 5 (five) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	TThe standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 128534 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-Evolution CR and R-EVO SMART CR for combined vitrectomy and phacoemulsification surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 193533 and 19511Y

Components

Q.ty	SKU #		Image
1	**192225** 25G TROCAR SYSTEM, ONE-STEP WITH VALVE Risk class according to MDD 93/42 **IIa** CND category **Q020199** CE 0051	25G valved entry system kit "One Step" 25G trocar kit. The kit contains 3 valved trocars mounted on a scleral knife and one infusion cannula.	
1	**192315** 25G OPTI-VIT TWEDGE VITREOUS CUTTER Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	25G Twedge™ high speed dual blade vitrectomy probe 25G (approx. 0.5 mm) "**Twedge™**" probe for posterior vitrectomy with high speed, guillotine-type pneumatically actuated **dual blade** and tubing. Cut rate of up to 10,000 cuts per minute (20,000 with dual blade) for R-Evolution® CR (recommended range of 7,000 to 8,000 cuts per minute, 14,000/16,000 with dual blade) and 5,000 cuts per minute (10,000 with dual blade) for R-Evo Smart® CR. Selecting a high cut rate reduces fluctuation of the retina and membranes. The specific geometry and sharpening of the cutting mouth improve cutting performance and prevent hazardous vitreous incarceration. Low weight and lack of vibration make it comfortable to use, even during lengthy procedures.	
1	**192845** 25G W/A SHIELDED ENDOILLUMINATION PROBE, MULTIPORT Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	25G shielded wide angle endoillumination probe 25G (approx. 0.5 mm) "shielded wide-angle" fiber optic, multiport endoillumination probe. The tip provides an asymmetrical conical light beam, due to shielding (approx. 60°), of intense, uniform illumination over a large surface of the retina. The shield protects the surgeon from any reflected light generated by the light source.	

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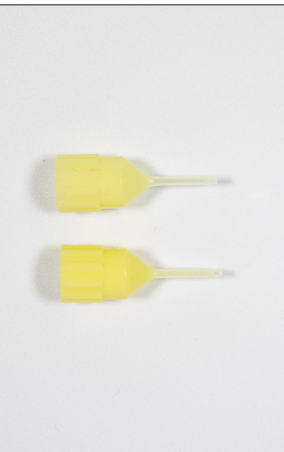
Components

Q.ty	SKU #		Image
1	**192514** 2-WAY STOPCOCK Risk class according to MDD 93/42 **IIa** CND category **A0701** CE 0051	3-WAY STOPCOCK 3-way stopcock with adapters, which switches 2 input lines to one output line. Fitted with a mechanical stop on two positions, thus preventing any switching errors.	
1	**192550** FLUIDS EXCHANGE SET WITH AUTOMATIC VALVE Risk class according to MDD 93/42 **IIa** CND category **Q02030199** CE 0051	Automatic fluid/air exchange set Automatic fluid/air exchange system. The device is indicated in vitreoretinal ophthalmic surgery, particularly tamponade with fluids. It enables automatic switching between irrigation of sterile balanced saline solution and infusion of sterile air into the eyeball. The irrigation of balanced saline solution and infusion of sterile air are channeled along the same infusion line. The anti-reflux valve on the air infusion tube prevents solution from entering the latter while irrigating with balanced saline solution. Conversely, it blocks the flow of saline solution during sterile air infusion. Consisting of the following parts: 1) Tubing for channeling filtered air 2) Filter connecting the device to the vitreoretinal surgery machine and filtering the air introduced into the eye 3) "Y" air connector 4) One-way valve to control air flow direction	
2	**191339** 21G YELLOW SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 21G tips 2x yellow sleeves for 2.2 - 2.4 mm incision (for 21G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	

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Components

Q.ty	SKU #		Image
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	
1	**191216** 21G FLARED PHACO TIP Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	21G flared phaco tip, 30° 21G "FLARED" Titanium tip for ultrasonic phacoemulsification, for 2.2 - 2.4 mm incision, pre-assembled on a single-use tightening wrench.	

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25G Twedge UniPack SH 21G

Pack for combined surgery involving 25G vitrectomy and phacoemulsification - Sterile - Single use

Product Information

25G TWEDGE UNIPACK SH 21G	Name	Description	Qty/Bx	SKU #
	25G TWEDGE UNIPACK SH 21G	Pack for combined surgery involving 25G vitrectomy and phacoemulsification - Sterile - Single use	5	199325 21G – FB

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 5x	**Biocompatibility**
The devices that make up the kit are packaged as follows. Two individual stiff blisters consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: 1st - tubing, cassette and infusion set 2nd - accessories for vitrectomy A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 5 (five) blisters containing the cassette, plus 5 (five) blisters containing accessories for vitrectomy, plus 5 (five) pouchs containing accessories for phacoemulsification, plus 5 (five) pouchs containing drapes, plus 5 (five) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	TThe standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 128535 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-Evolution CR and R-EVO SMART CR for combined vitrectomy and phacoemulsification surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 193533 and 19511Z

Components

Q.ty	SKU #		Image
1	**192225** 25G TROCAR SYSTEM, ONE-STEP WITH VALVE Risk class according to MDD 93/42 **IIa** CND category **Q020199** CE 0051	25G valved entry system kit "One Step" 25G trocar kit. The kit contains 3 valved trocars mounted on a scleral knife and one infusion cannula.	
1	**192315** 25G OPTI-VIT TWEDGE VITREOUS CUTTER Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	25G Twedge™ high speed dual blade vitrectomy probe 25G (approx. 0.5 mm) "**Twedge™**" probe for posterior vitrectomy with high speed, guillotine-type pneumatically actuated **dual blade** and tubing. Cut rate of up to 10,000 cuts per minute (20,000 with dual blade) for R-Evolution® CR (recommended range of 7,000 to 8,000 cuts per minute, 14,000/16,000 with dual blade) and 5,000 cuts per minute (10,000 with dual blade) for R-Evo Smart® CR. Selecting a high cut rate reduces fluctuation of the retina and membranes. The specific geometry and sharpening of the cutting mouth improve cutting performance and prevent hazardous vitreous incarceration. Low weight and lack of vibration make it comfortable to use, even during lengthy procedures.	
1	**192845** 25G W/A SHIELDED ENDOILLUMINATION PROBE, MULTIPORT Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	25G shielded wide angle endoillumination probe 25G (approx. 0.5 mm) "shielded wide-angle" fiber optic, multiport endoillumination probe. The tip provides an asymmetrical conical light beam, due to shielding (approx. 60°), of intense, uniform illumination over a large surface of the retina. The shield protects the surgeon from any reflected light generated by the light source.	

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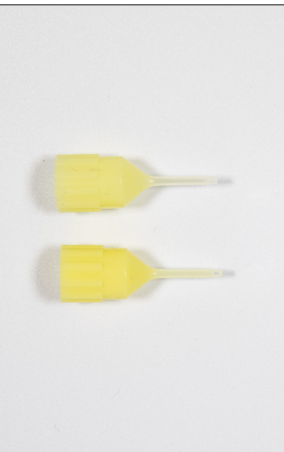
Components

Q.ty	SKU #		Image
1	**192514** 2-WAY STOPCOCK Risk class according to MDD 93/42 **IIa** CND category **A0701** CE 0051	3-WAY STOPCOCK 3-way stopcock with adapters, which switches 2 input lines to one output line. Fitted with a mechanical stop on two positions, thus preventing any switching errors.	
1	**192550** FLUIDS EXCHANGE SET WITH AUTOMATIC VALVE Risk class according to MDD 93/42 **IIa** CND category **Q02030199** CE 0051	Automatic fluid/air exchange set Automatic fluid/air exchange system. The device is indicated in vitreoretinal ophthalmic surgery, particularly tamponade with fluids. It enables automatic switching between irrigation of sterile balanced saline solution and infusion of sterile air into the eyeball. The irrigation of balanced saline solution and infusion of sterile air are channeled along the same infusion line. The anti-reflux valve on the air infusion tube prevents solution from entering the latter while irrigating with balanced saline solution. Conversely, it blocks the flow of saline solution during sterile air infusion. Consisting of the following parts: 1) Tubing for channeling filtered air 2) Filter connecting the device to the vitreoretinal surgery machine and filtering the air introduced into the eye 3) "Y" air connector 4) One-way valve to control air flow direction	
2	**191339** 21G YELLOW SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 21G tips 2x yellow sleeves for 2.2 - 2.4 mm incision (for 21G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	

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Components

Q.ty	SKU #		Image
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	
1	**191217** 21/22G FLARED BENT PHACO TIP Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	21/22G flared bent phaco tip, 30° 21G "Flared-bent" Titanium tip for ultrasonic phacoemulsification, for 2.2 - 2.4 mm incision, pre-assembled on a single-use tightening wrench.	

Contact Information:
www.bvimedical.com/customer-support

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25G Twedge VitPack SH

Pack for Vitrectomy - Sterile - Single use

Product Information

25G TWEDGE VITPACK SH	Name	Description	Qty/Bx	SKU #
	25G TWEDGE VITPACK SH	Pack for Vitrectomy - Sterile - Single use	5	199325

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 5x	**Biocompatibility**
The devices that make up the kit are packaged as follows. Two individual stiff blisters consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: 1st - tubing, cassette and infusion set 2nd - accessories for vitrectomy A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. 5 (five) blisters containing the cassette, plus 5 (five) blisters containing accessories, plus 5 (five) pouchs containing drapes, plus 5 (five) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	The standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 128518 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-Evolution CR and R-EVO SMART CR for vitreo-retinal surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 193533

Components

Q.ty	SKU #		Image
1	**192225** 25G TROCAR SYSTEM, ONE-STEP WITH VALVE Risk class according to MDD 93/42 **IIa** CND category **Q020199** CE 0051	25G valved entry system kit "One Step" 25G trocar kit. The kit contains 3 valved trocars mounted on a scleral knife and one infusion cannula.	
1	**192315** 25G OPTI-VIT TWEDGE VITREOUS CUTTER Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	25G Twedge™ high speed dual blade vitrectomy probe 25G (approx. 0.5 mm) "**Twedge™**" probe for posterior vitrectomy with high speed, guillotine-type pneumatically actuated **dual blade** and tubing. Cut rate of up to 10,000 cuts per minute (20,000 with dual blade) for R-Evolution® CR (recommended range of 7,000 to 8,000 cuts per minute, 14,000/16,000 with dual blade) and 5,000 cuts per minute (10,000 with dual blade) for R-Evo Smart® CR. Selecting a high cut rate reduces fluctuation of the retina and membranes. The specific geometry and sharpening of the cutting mouth improve cutting performance and prevent hazardous vitreous incarceration. Low weight and lack of vibration make it comfortable to use, even during lengthy procedures.	
1	**192845** 25G W/A SHIELDED ENDOILLUMINATION PROBE, MULTIPORT Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	25G shielded wide angle endoillumination probe 25G (approx. 0.5 mm) "shielded wide-angle" fiber optic, multiport endoillumination probe. The tip provides an asymmetrical conical light beam, due to shielding (approx. 60°), of intense, uniform illumination over a large surface of the retina. The shield protects the surgeon from any reflected light generated by the light source.	

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Components

Q.ty	SKU #		Image
1	**192514** 2-WAY STOPCOCK Risk class according to MDD 93/42 **IIa** CND category **A0701** CE 0051	3-WAY STOPCOCK 3-way stopcock with adapters, which switches 2 input lines to one output line. Fitted with a mechanical stop on two positions, thus preventing any switching errors.	
1	**192550** FLUIDS EXCHANGE SET WITH AUTOMATIC VALVE Risk class according to MDD 93/42 **IIa** CND category **Q02030199** CE 0051	Automatic fluid/air exchange set Automatic fluid/air exchange system. The device is indicated in vitreoretinal ophthalmic surgery, particularly tamponade with fluids. It enables automatic switching between irrigation of sterile balanced saline solution and infusion of sterile air into the eyeball. The irrigation of balanced saline solution and infusion of sterile air are channeled along the same infusion line. The anti-reflux valve on the air infusion tube prevents solution from entering the latter while irrigating with balanced saline solution. Conversely, it blocks the flow of saline solution during sterile air infusion. Consisting of the following parts: 1) Tubing for channeling filtered air 2) Filter connecting the device to the vitreoretinal surgery machine and filtering the air introduced into the eye 3) "Y" air connector 4) One-way valve to control air flow direction	

Contact Information:
www.bvimedical.com/customer-support

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23G Twedge UniPack w/o Light probe 20G FB

Pack for combined surgery involving 23G vitrectomy and phacoemulsification - Sterile - Single use

Product Information

23G TWEDGE UNIPACK W/O LIGHT PROBE 20G FB	Name	Description	Qty/Bx	SKU #
	23G TWEDGE UNIPACK W/O LIGHT PROBE 20G FB	Pack for combined surgery involving 23G vitrectomy and phacoemulsification - Sterile - Single use	5	199023 -20G FB

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 5x	**Biocompatibility**
The devices that make up the kit are packaged as follows. Two individual stiff blisters consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: 1st - tubing, cassette and infusion set 2nd - accessories for vitrectomy A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 5 (five) blisters containing the cassette, plus 5 (five) blisters containing accessories for vitrectomy, plus 5 (five) pouchs containing accessories for phacoemulsification, plus 5 (five) pouchs containing drapes, plus 5 (five) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	The standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 137151 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-Evolution CR and R-EVO SMART CR for combined vitrectomy and phacoemulsification surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 193303 and 19501Z

Components

Q.ty	SKU #		Image
1	**192223** 23G TROCAR SYSTEM, ONE-STEP WITH VALVE Risk class according to MDD 93/42 **IIa** CND category **Q020199** CE 0051	23G valved entry system kit "One Step" 23G trocar kit. The kit contains **3 valved trocars** mounted on a scleral knife and one infusion cannula.	
1	**192313** 23G OPTI-VIT TWEDGE VITREOUS CUTTER Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	23G Twedge™ high speed dual blade vitrectomy probe 23G (approx. 0.6 mm) "**Twedge™**" probe for posterior vitrectomy with high speed, guillotine-type pneumatically actuated **dual blade** and tubing. Cut rate of up to 10,000 cuts per minute (20,000 with dual blade) for R-Evolution® CR (recommended range of 7,000 to 8,000 cuts per minute, 14,000/16,000 with dual blade) and 5,000 cuts per minute (10,000 with dual blade) for R-Evo Smart® CR. Selecting a high cut rate reduces fluctuation of the retina and membranes. The specific geometry and sharpening of the cutting mouth improve cutting performance and prevent hazardous vitreous incarceration. Low weight and lack of vibration make it comfortable to use, even during lengthy procedures.	
1	**192514** 2-WAY STOPCOCK Risk class according to MDD 93/42 **IIa** CND category **A0701** CE 0051	3-WAY STOPCOCK 3-way stopcock with adapters, which switches 2 input lines to one output line. Fitted with a mechanical stop on two positions, thus preventing any switching errors.	

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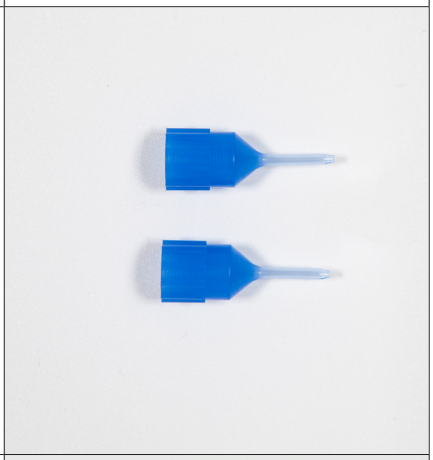
Components

Q.ty	SKU #		Image
1	**192550** FLUIDS EXCHANGE SET WITH AUTOMATIC VALVE Risk class according to MDD 93/42 **IIa** CND category **Q02030199** CE 0051	Automatic fluid/air exchange set Automatic fluid/air exchange system. The device is indicated in vitreoretinal ophthalmic surgery, particularly tamponade with fluids. It enables automatic switching between irrigation of sterile balanced saline solution and infusion of sterile air into the eyeball. The irrigation of balanced saline solution and infusion of sterile air are channeled along the same infusion line. The anti-reflux valve on the air infusion tube prevents solution from entering the latter while irrigating with balanced saline solution. Conversely, it blocks the flow of saline solution during sterile air infusion. Consisting of the following parts: 1) Tubing for channeling filtered air 2) Filter connecting the device to the vitreoretinal surgery machine and filtering the air introduced into the eye 3) "Y" air connector 4) One-way valve to control air flow direction	
2	**191338** 20G BLUE SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 20G tips 2x blue sleeves for 2.6-2.8 mm incision (for 20G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	

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Components

Q.ty	SKU #		Image
1	**191207** 20G FLARED BENT PHACO TIP Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	20G flared bent phaco tip, 30° 20G "FLARED BENT" Titanium tip for ultrasonic phacoemulsification, for 2.6 - 2.8 mm incision, pre-assembled on a single-use tightening wrench	

Contact Information:
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23G Twedge UniPack w/o Light probe 21G FB

Pack for combined surgery involving 23G vitrectomy and phacoemulsification - Sterile - Single use

Product Information

23G TWEDGE UNIPACK W/O LIGHT PROBE 21G FB	Name	Description	Qty/Bx	SKU #
	23G TWEDGE UNIPACK W/O LIGHT PROBE 21G FB	Pack for combined surgery involving 23G vitrectomy and phacoemulsification - Sterile - Single use	5	199023 -21G FB

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 5x	**Biocompatibility**
The devices that make up the kit are packaged as follows. Two individual stiff blisters consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: 1st - tubing, cassette and infusion set 2nd - accessories for vitrectomy A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 5 (five) blisters containing the cassette, plus 5 (five) blisters containing accessories for vitrectomy, plus 5 (five) pouchs containing accessories for phacoemulsification, plus 5 (five) pouchs containing drapes, plus 5 (five) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	The standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 137153 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-Evolution CR and R-EVO SMART CR for combined vitrectomy and phacoemulsification surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 193303 and 19511Z

Components

Q.ty	SKU #		Image
1	**192223** 23G TROCAR SYSTEM, ONE-STEP WITH VALVE Risk class according to MDD 93/42 **IIa** CND category **Q020199** CE 0051	23G valved entry system kit "One Step" 23G trocar kit. The kit contains **3 valved trocars** mounted on a scleral knife and one infusion cannula.	
1	**192313** 23G OPTI-VIT TWEDGE VITREOUS CUTTER Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	23G Twedge™ high speed dual blade vitrectomy probe 23G (approx. 0.6 mm) "**Twedge™**" probe for posterior vitrectomy with high speed, guillotine-type pneumatically actuated **dual blade** and tubing. Cut rate of up to 10,000 cuts per minute (20,000 with dual blade) for R-Evolution® CR (recommended range of 7,000 to 8,000 cuts per minute, 14,000/16,000 with dual blade) and 5,000 cuts per minute (10,000 with dual blade) for R-Evo Smart® CR. Selecting a high cut rate reduces fluctuation of the retina and membranes. The specific geometry and sharpening of the cutting mouth improve cutting performance and prevent hazardous vitreous incarceration. Low weight and lack of vibration make it comfortable to use, even during lengthy procedures.	
1	**192514** 2-WAY STOPCOCK Risk class according to MDD 93/42 **IIa** CND category **A0701** CE 0051	3-WAY STOPCOCK 3-way stopcock with adapters, which switches 2 input lines to one output line. Fitted with a mechanical stop on two positions, thus preventing any switching errors.	

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Components

Q.ty	SKU #		Image
1	**192550** FLUIDS EXCHANGE SET WITH AUTOMATIC VALVE Risk class according to MDD 93/42 **IIa** CND category **Q02030199** CE 0051	Automatic fluid/air exchange set Automatic fluid/air exchange system. The device is indicated in vitreoretinal ophthalmic surgery, particularly tamponade with fluids. It enables automatic switching between irrigation of sterile balanced saline solution and infusion of sterile air into the eyeball. The irrigation of balanced saline solution and infusion of sterile air are channeled along the same infusion line. The anti-reflux valve on the air infusion tube prevents solution from entering the latter while irrigating with balanced saline solution. Conversely, it blocks the flow of saline solution during sterile air infusion. Consisting of the following parts: 1) Tubing for channeling filtered air 2) Filter connecting the device to the vitreoretinal surgery machine and filtering the air introduced into the eye 3) "Y" air connector 4) One-way valve to control air flow direction	
2	**191339** 21G YELLOW SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 21G tips 2x yellow sleeves for 2.2 - 2.4 mm incision (for 21G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	

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Components

Q.ty	SKU #		Image
1	**191217** 21/22G FLARED BENT PHACO TIP Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	21/22G flared bent phaco tip, 30° 21G "Flared-bent" Titanium tip for ultrasonic phacoemulsification, for 2.2 - 2.4 mm incision, pre-assembled on a single-use tightening wrench.	

Contact Information:
www.bvimedical.com/customer-support

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23G Twedge UniPack w/o Light probe 20G F

Pack for combined surgery involving 23G vitrectomy and phacoemulsification - Sterile - Single use

Product Information

23G TWEDGE UNIPACK W/O LIGHT PROBE 20G F	Name	Description	Qty/Bx	SKU #
	23G TWEDGE UNIPACK W/O LIGHT PROBE 20G F	Pack for combined surgery involving 23G vitrectomy and phacoemulsification - Sterile - Single use	5	199023 -20G F

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 5x	**Biocompatibility**
The devices that make up the kit are packaged as follows. Two individual stiff blisters consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: 1st - tubing, cassette and infusion set 2nd - accessories for vitrectomy A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 5 (five) blisters containing the cassette, plus 5 (five) blisters containing accessories for vitrectomy, plus 5 (five) pouchs containing accessories for phacoemulsification, plus 5 (five) pouchs containing drapes, plus 5 (five) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	The standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 137150 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-Evolution CR and R-EVO SMART CR for combined vitrectomy and phacoemulsification surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 193303 and 19501Y

Components

Q.ty	SKU #		Image
1	**192223** 23G TROCAR SYSTEM, ONE-STEP WITH VALVE Risk class according to MDD 93/42 **IIa** CND category **Q020199** CE 0051	23G valved entry system kit "One Step" 23G trocar kit. The kit contains **3 valved trocars** mounted on a scleral knife and one infusion cannula.	
1	**192313** 23G OPTI-VIT TWEDGE VITREOUS CUTTER Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	23G Twedge™ high speed dual blade vitrectomy probe 23G (approx. 0.6 mm) "**Twedge™**" probe for posterior vitrectomy with high speed, guillotine-type pneumatically actuated **dual blade** and tubing. Cut rate of up to 10,000 cuts per minute (20,000 with dual blade) for R-Evolution® CR (recommended range of 7,000 to 8,000 cuts per minute, 14,000/16,000 with dual blade) and 5,000 cuts per minute (10,000 with dual blade) for R-Evo Smart® CR. Selecting a high cut rate reduces fluctuation of the retina and membranes. The specific geometry and sharpening of the cutting mouth improve cutting performance and prevent hazardous vitreous incarceration. Low weight and lack of vibration make it comfortable to use, even during lengthy procedures.	
1	**192514** 2-WAY STOPCOCK Risk class according to MDD 93/42 **IIa** CND category **A0701** CE 0051	3-WAY STOPCOCK 3-way stopcock with adapters, which switches 2 input lines to one output line. Fitted with a mechanical stop on two positions, thus preventing any switching errors.	

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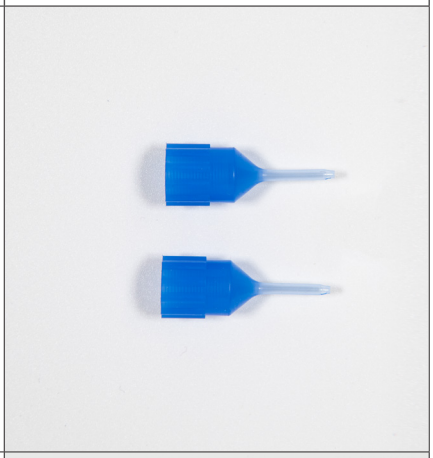
Components

Q.ty	SKU #		Image
1	**192550** FLUIDS EXCHANGE SET WITH AUTOMATIC VALVE Risk class according to MDD 93/42 **IIa** CND category **Q02030199** CE 0051	Automatic fluid/air exchange set Automatic fluid/air exchange system. The device is indicated in vitreoretinal ophthalmic surgery, particularly tamponade with fluids. It enables automatic switching between irrigation of sterile balanced saline solution and infusion of sterile air into the eyeball. The irrigation of balanced saline solution and infusion of sterile air are channeled along the same infusion line. The anti-reflux valve on the air infusion tube prevents solution from entering the latter while irrigating with balanced saline solution. Conversely, it blocks the flow of saline solution during sterile air infusion. Consisting of the following parts: 1) Tubing for channeling filtered air 2) Filter connecting the device to the vitreoretinal surgery machine and filtering the air introduced into the eye 3) "Y" air connector 4) One-way valve to control air flow direction	
2	**191338** 20G BLUE SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 20G tips 2x blue sleeves for 2.6-2.8 mm incision (for 20G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	

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Components

Q.ty	SKU #		Image
1	**191206** 20G FLARED PHACO TIP Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	20G flared phaco tip, 30° 20G "FLARED" Titanium tip for ultrasonic phacoemulsification, for 2.6 - 2.8 mm incision, pre-assembled on a single-use tightening wrench.	

Contact Information:
www.bvimedical.com/customer-support

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25G Twedge UniPack w/o Light probe 20G F

Pack for combined surgery involving 25G vitrectomy and phacoemulsification - Sterile - Single use

Product Information

25G TWEDGE UNIPACK W/O LIGHT PROBE 20G F	Name	Description	Qty/Bx	SKU #
	25G TWEDGE UNIPACK W/O LIGHT PROBE 20G F	Pack for combined surgery involving 25G vitrectomy and phacoemulsification - Sterile - Single use	5	199025 -20G F

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 5x	**Biocompatibility**
The devices that make up the kit are packaged as follows. Two individual stiff blisters consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: 1st - tubing, cassette and infusion set 2nd - accessories for vitrectomy A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 5 (five) blisters containing the cassette, plus 5 (five) blisters containing accessories for vitrectomy, plus 5 (five) pouchs containing accessories for phacoemulsification, plus 5 (five) pouchs containing drapes, plus 5 (five) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	TThe standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 137154 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-Evolution CR and R-EVO SMART CR for combined vitrectomy and phacoemulsification surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 193503 and 19501Y

Components

Q.ty	SKU #		Image
1	**192225** 25G TROCAR SYSTEM, ONE-STEP WITH VALVE Risk class according to MDD 93/42 **IIa** CND category **Q020199** CE 0051	25G valved entry system kit "One Step" 25G trocar kit. The kit contains 3 valved trocars mounted on a scleral knife and one infusion cannula.	
1	**192315** 25G OPTI-VIT TWEDGE VITREOUS CUTTER Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	25G Twedge™ high speed dual blade vitrectomy probe 25G (approx. 0.5 mm) "**Twedge™**" probe for posterior vitrectomy with high speed, guillotine-type pneumatically actuated **dual blade** and tubing. Cut rate of up to 10,000 cuts per minute (20,000 with dual blade) for R-Evolution® CR (recommended range of 7,000 to 8,000 cuts per minute, 14,000/16,000 with dual blade) and 5,000 cuts per minute (10,000 with dual blade) for R-Evo Smart® CR. Selecting a high cut rate reduces fluctuation of the retina and membranes. The specific geometry and sharpening of the cutting mouth improve cutting performance and prevent hazardous vitreous incarceration. Low weight and lack of vibration make it comfortable to use, even during lengthy procedures.	
1	**192514** 2-WAY STOPCOCK Risk class according to MDD 93/42 **IIa** CND category **A0701** CE 0051	3-WAY STOPCOCK 3-way stopcock with adapters, which switches 2 input lines to one output line. Fitted with a mechanical stop on two positions, thus preventing any switching errors.	

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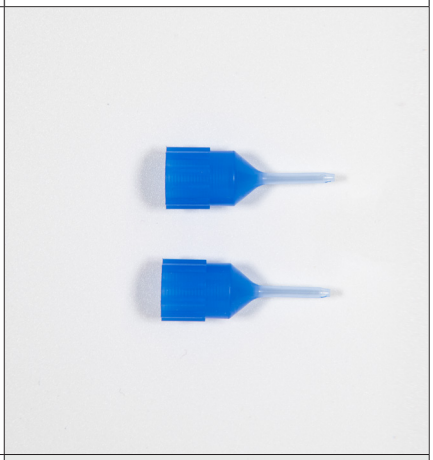
Components

Q.ty	SKU #		Image
1	**192550** FLUIDS EXCHANGE SET WITH AUTOMATIC VALVE Risk class according to MDD 93/42 **IIa** CND category **Q02030199** CE 0051	Automatic fluid/air exchange set Automatic fluid/air exchange system. The device is indicated in vitreoretinal ophthalmic surgery, particularly tamponade with fluids. It enables automatic switching between irrigation of sterile balanced saline solution and infusion of sterile air into the eyeball. The irrigation of balanced saline solution and infusion of sterile air are channeled along the same infusion line. The anti-reflux valve on the air infusion tube prevents solution from entering the latter while irrigating with balanced saline solution. Conversely, it blocks the flow of saline solution during sterile air infusion. Consisting of the following parts: 1) Tubing for channeling filtered air 2) Filter connecting the device to the vitreoretinal surgery machine and filtering the air introduced into the eye 3) "Y" air connector 4) One-way valve to control air flow direction	
2	**191338** 20G BLUE SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 20G tips 2x blue sleeves for 2.6-2.8 mm incision (for 20G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	

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Components

Q.ty	SKU #		Image
1	**191206** 20G FLARED PHACO TIP Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	20G flared phaco tip, 30° 20G "FLARED" Titanium tip for ultrasonic phacoemulsification, for 2.6 - 2.8 mm incision, pre-assembled on a single-use tightening wrench.	

Contact Information:
www.bvimedical.com/customer-support

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25G Twedge UniPack w/o Light probe 20G FB

Pack for combined surgery involving 25G vitrectomy and phacoemulsification - Sterile - Single use

Product Information

25G TWEDGE UNIPACK W/O LIGHT PROBE 20G FB	Name	Description	Qty/Bx	SKU #
	25G TWEDGE UNIPACK W/O LIGHT PROBE 20G FB	Pack for combined surgery involving 25G vitrectomy and phacoemulsification - Sterile - Single use	5	199025 -20G FB

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 5x	**Biocompatibility**
The devices that make up the kit are packaged as follows. Two individual stiff blisters consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: 1st - tubing, cassette and infusion set 2nd - accessories for vitrectomy A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 5 (five) blisters containing the cassette, plus 5 (five) blisters containing accessories for vitrectomy, plus 5 (five) pouchs containing accessories for phacoemulsification, plus 5 (five) pouchs containing drapes, plus 5 (five) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	TThe standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 137155 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-Evolution CR and R-EVO SMART CR for combined vitrectomy and phacoemulsification surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 193503 and 19510Z

Components

Q.ty	SKU #		Image
1	**192225** 25G TROCAR SYSTEM, ONE-STEP WITH VALVE Risk class according to MDD 93/42 **IIa** CND category **Q020199** CE 0051	25G valved entry system kit "One Step" 25G trocar kit. The kit contains 3 valved trocars mounted on a scleral knife and one infusion cannula.	
1	**192315** 25G OPTI-VIT TWEDGE VITREOUS CUTTER Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	25G Twedge™ high speed dual blade vitrectomy probe 25G (approx. 0.5 mm) "**Twedge™**" probe for posterior vitrectomy with high speed, guillotine-type pneumatically actuated **dual blade** and tubing. Cut rate of up to 10,000 cuts per minute (20,000 with dual blade) for R-Evolution® CR (recommended range of 7,000 to 8,000 cuts per minute, 14,000/16,000 with dual blade) and 5,000 cuts per minute (10,000 with dual blade) for R-Evo Smart® CR. Selecting a high cut rate reduces fluctuation of the retina and membranes. The specific geometry and sharpening of the cutting mouth improve cutting performance and prevent hazardous vitreous incarceration. Low weight and lack of vibration make it comfortable to use, even during lengthy procedures.	
1	**192514** 2-WAY STOPCOCK Risk class according to MDD 93/42 **IIa** CND category **A0701** CE 0051	3-WAY STOPCOCK 3-way stopcock with adapters, which switches 2 input lines to one output line. Fitted with a mechanical stop on two positions, thus preventing any switching errors.	

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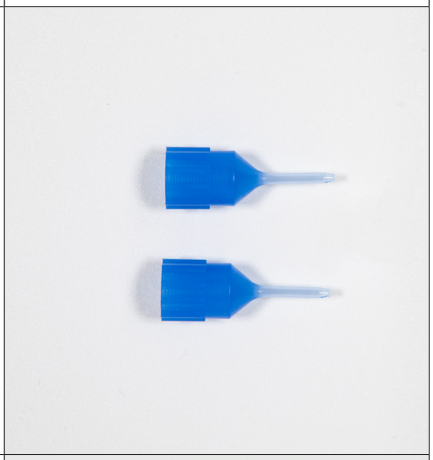
Components

Q.ty	SKU #		Image
1	**192550** FLUIDS EXCHANGE SET WITH AUTOMATIC VALVE Risk class according to MDD 93/42 **IIa** CND category **Q02030199** CE 0051	Automatic fluid/air exchange set Automatic fluid/air exchange system. The device is indicated in vitreoretinal ophthalmic surgery, particularly tamponade with fluids. It enables automatic switching between irrigation of sterile balanced saline solution and infusion of sterile air into the eyeball. The irrigation of balanced saline solution and infusion of sterile air are channeled along the same infusion line. The anti-reflux valve on the air infusion tube prevents solution from entering the latter while irrigating with balanced saline solution. Conversely, it blocks the flow of saline solution during sterile air infusion. Consisting of the following parts: 1) Tubing for channeling filtered air 2) Filter connecting the device to the vitreoretinal surgery machine and filtering the air introduced into the eye 3) "Y" air connector 4) One-way valve to control air flow direction	
2	**191338** 20G BLUE SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 20G tips 2x blue sleeves for 2.6-2.8 mm incision (for 20G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	

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Components

Q.ty	SKU #		Image
1	**191207** 20G FLARED BENT PHACO TIP Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	20G flared bent phaco tip, 30° 20G "FLARED BENT" Titanium tip for ultrasonic phacoemulsification, for 2.6 - 2.8 mm incision, pre-assembled on a single-use tightening wrench.	

Contact Information:
www.bvimedical.com/customer-support

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25G Twedge UniPack w/o Light probe 21G FB

Pack for combined surgery involving 25G vitrectomy and phacoemulsification - Sterile - Single use

Product Information

25G TWEDGE UNIPACK W/O LIGHT PROBE 21G FB	Name	Description	Qty/Bx	SKU #
	25G TWEDGE UNIPACK W/O LIGHT PROBE 21G FB	Pack for combined surgery involving 25G vitrectomy and phacoemulsification - Sterile - Single use	5	199025 -21G FB

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 5x	**Biocompatibility**
The devices that make up the kit are packaged as follows. Two individual stiff blisters consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: 1st - tubing, cassette and infusion set 2nd - accessories for vitrectomy A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 5 (five) blisters containing the cassette, plus 5 (five) blisters containing accessories for vitrectomy, plus 5 (five) pouchs containing accessories for phacoemulsification, plus 5 (five) pouchs containing drapes, plus 5 (five) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	TThe standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 137158 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-Evolution CR and R-EVO SMART CR for combined vitrectomy and phacoemulsification surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 193503 and 19511Z

Components

Q.ty	SKU #		Image
1	**192225** 25G TROCAR SYSTEM, ONE-STEP WITH VALVE Risk class according to MDD 93/42 **IIa** CND category **Q020199** CE 0051	25G valved entry system kit "One Step" 25G trocar kit. The kit contains 3 valved trocars mounted on a scleral knife and one infusion cannula.	
1	**192315** 25G OPTI-VIT TWEDGE VITREOUS CUTTER Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	25G Twedge™ high speed dual blade vitrectomy probe 25G (approx. 0.5 mm) "**Twedge™**" probe for posterior vitrectomy with high speed, guillotine-type pneumatically actuated **dual blade** and tubing. Cut rate of up to 10,000 cuts per minute (20,000 with dual blade) for R-Evolution® CR (recommended range of 7,000 to 8,000 cuts per minute, 14,000/16,000 with dual blade) and 5,000 cuts per minute (10,000 with dual blade) for R-Evo Smart® CR. Selecting a high cut rate reduces fluctuation of the retina and membranes. The specific geometry and sharpening of the cutting mouth improve cutting performance and prevent hazardous vitreous incarceration. Low weight and lack of vibration make it comfortable to use, even during lengthy procedures.	
1	**192514** 2-WAY STOPCOCK Risk class according to MDD 93/42 **IIa** CND category **A0701** CE 0051	3-WAY STOPCOCK 3-way stopcock with adapters, which switches 2 input lines to one output line. Fitted with a mechanical stop on two positions, thus preventing any switching errors.	

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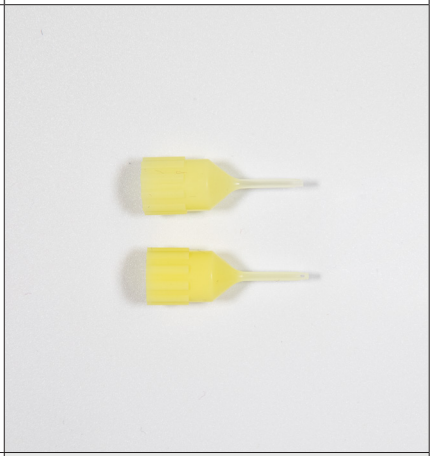
Components

Q.ty	SKU #		Image
1	**192550** FLUIDS EXCHANGE SET WITH AUTOMATIC VALVE Risk class according to MDD 93/42 **IIa** CND category **Q02030199** CE 0051	Automatic fluid/air exchange set Automatic fluid/air exchange system. The device is indicated in vitreoretinal ophthalmic surgery, particularly tamponade with fluids. It enables automatic switching between irrigation of sterile balanced saline solution and infusion of sterile air into the eyeball. The irrigation of balanced saline solution and infusion of sterile air are channeled along the same infusion line. The anti-reflux valve on the air infusion tube prevents solution from entering the latter while irrigating with balanced saline solution. Conversely, it blocks the flow of saline solution during sterile air infusion. Consisting of the following parts: 1) Tubing for channeling filtered air 2) Filter connecting the device to the vitreoretinal surgery machine and filtering the air introduced into the eye 3) "Y" air connector 4) One-way valve to control air flow direction	
2	**191339** 21G YELLOW SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 21G tips 2x yellow sleeves for 2.2 - 2.4 mm incision (for 21G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	

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Components

Q.ty	SKU #		Image
1	**191217** 21/22G FLARED BENT PHACO TIP Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	21/22G flared bent phaco tip, 30° 21G "Flared-bent" Titanium tip for ultrasonic phacoemulsification, for 2.2 - 2.4 mm incision, pre-assembled on a single-use tightening wrench.	

Contact Information:
www.bvimedical.com/customer-support

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27G Twedge VitPack w/o Light probe

Pack for Vitrectomy - Sterile - Single use

Product Information

27G TWEDGE VITPACK W/O LIGHT PROBE	Name	Description	Qty/Bx	SKU #
	27G TWEDGE VITPACK W/O LIGHT PROBE	Pack for Vitrectomy - Sterile - Single use	5	199027

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 5x	**Biocompatibility**
The devices that make up the kit are packaged as follows. Two individual stiff blisters consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: 1st - tubing, cassette and infusion set 2nd - accessories for vitrectomy A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. 5 (five) blisters containing the cassette, plus 5 (five) blisters containing accessories, plus 5 (five) pouchs containing drapes, plus 5 (five) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	The standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 137159 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-Evolution CR and R-EVO SMART CR for vitreo-retinal surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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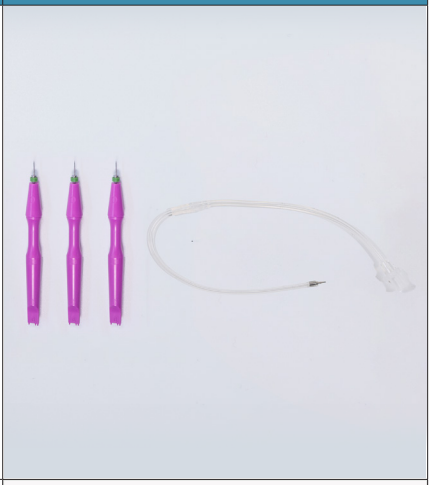
The SKU# listed in the table below are included in the CE marked kit 193703

Components

Q.ty	SKU #		Image
1	**192227** 27G TROCAR SYSTEM, ONE-STEP WITH VALVE Risk class according to MDD 93/42 **IIa** CND category **Q020199** CE 0051	27G valved entry system kit "One Step" 27G trocar kit. The kit contains 3 valved trocars mounted on a scleral knife and one infusion cannula.	
1	**192317** 27G OPTI-VIT TWEDGE VITREOUS CUTTER Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	27G Twedge™ high speed dual blade vitrectomy probe 27G (approx. 0.4 mm) "**Twedge™**" probe for posterior vitrectomy with high speed, guillotine-type pneumatically actuated **dual blade** and tubing. A frequency of up to 10,000 cuts per minute (20,000 for dual blade effect) for R-Evolution® CR (recommended range of 7,000 to 8,000 cuts per minute, 14,000/16,000 for dual blade effect). Selecting a high cut rate reduces fluctuation of the retina and membranes. The specific geometry and sharpening of the cutting mouth improve cutting performance and prevent hazardous vitreous incarceration. Low weight and lack of vibration make it comfortable to use, even during lengthy procedures.	
1	**192514** 2-WAY STOPCOCK Risk class according to MDD 93/42 **IIa** CND category **A0701** CE 0051	3-WAY STOPCOCK 3-way stopcock with adapters, which switches 2 input lines to one output line. Fitted with a mechanical stop on two positions, thus preventing any switching errors.	

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Components

Q.ty	SKU #		Image
1	**192550** FLUIDS EXCHANGE SET WITH AUTOMATIC VALVE Risk class according to MDD 93/42 **IIa** CND category **Q02030199** CE 0051	Automatic fluid/air exchange set Automatic fluid/air exchange system. The device is indicated in vitreoretinal ophthalmic surgery, particularly tamponade with fluids. It enables automatic switching between irrigation of sterile balanced saline solution and infusion of sterile air into the eyeball. The irrigation of balanced saline solution and infusion of sterile air are channeled along the same infusion line. The anti-reflux valve on the air infusion tube prevents solution from entering the latter while irrigating with balanced saline solution. Conversely, it blocks the flow of saline solution during sterile air infusion. Consisting of the following parts: 1) Tubing for channeling filtered air 2) Filter connecting the device to the vitreoretinal surgery machine and filtering the air introduced into the eye 3) "Y" air connector 4) One-way valve to control air flow direction	

Contact Information:
www.bvimedical.com/customer-support

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23G Twedge VitPack w/o Light probe

Pack for Vitrectomy - Sterile - Single use

Product Information

23G TWEDGE VITPACK W/O LIGHT PROBE	Name	Description	Qty/Bx	SKU #
	23G TWEDGE VITPACK W/O LIGHT PROBE	Pack for Vitrectomy - Sterile - Single use	5	199023

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 5x	**Biocompatibility**
The devices that make up the kit are packaged as follows. Two individual stiff blisters consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: 1st - tubing, cassette and infusion set 2nd - accessories for vitrectomy A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. 5 (five) blisters containing the cassette, plus 5 (five) blisters containing accessories, plus 5 (five) pouchs containing drapes, plus 5 (five) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	The standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 129796 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-Evolution CR and R-EVO SMART CR for vitreo-retinal surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 193303

Components

Q.ty	SKU #		Image
1	**192223** 23G TROCAR SYSTEM, ONE-STEP WITH VALVE Risk class according to MDD 93/42 **IIa** CND category **Q020199** CE 0051	23G valved entry system kit "One Step" 23G trocar kit. The kit contains **3 valved trocars** mounted on a scleral knife and one infusion cannula.	
1	**192313** 23G OPTI-VIT TWEDGE VITREOUS CUTTER Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	23G Twedge™ high speed dual blade vitrectomy probe 23G (approx. 0.6 mm) "**Twedge™**" probe for posterior vitrectomy with high speed, guillotine-type pneumatically actuated **dual blade** and tubing. Cut rate of up to 10,000 cuts per minute (20,000 with dual blade) for R-Evolution® CR (recommended range of 7,000 to 8,000 cuts per minute, 14,000/16,000 with dual blade) and 5,000 cuts per minute (10,000 with dual blade) for R-Evo Smart® CR. Selecting a high cut rate reduces fluctuation of the retina and membranes. The specific geometry and sharpening of the cutting mouth improve cutting performance and prevent hazardous vitreous incarceration. Low weight and lack of vibration make it comfortable to use, even during lengthy procedures.	
1	**192514** 2-WAY STOPCOCK Risk class according to MDD 93/42 **IIa** CND category **A0701** CE 0051	3-WAY STOPCOCK 3-way stopcock with adapters, which switches 2 input lines to one output line. Fitted with a mechanical stop on two positions, thus preventing any switching errors.	

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Components

Q.ty	SKU #		Image
1	**192550** FLUIDS EXCHANGE SET WITH AUTOMATIC VALVE Risk class according to MDD 93/42 **IIa** CND category **Q02030199** CE 0051	Automatic fluid/air exchange set Automatic fluid/air exchange system. The device is indicated in vitreoretinal ophthalmic surgery, particularly tamponade with fluids. It enables automatic switching between irrigation of sterile balanced saline solution and infusion of sterile air into the eyeball. The irrigation of balanced saline solution and infusion of sterile air are channeled along the same infusion line. The anti-reflux valve on the air infusion tube prevents solution from entering the latter while irrigating with balanced saline solution. Conversely, it blocks the flow of saline solution during sterile air infusion. Consisting of the following parts: 1) Tubing for channeling filtered air 2) Filter connecting the device to the vitreoretinal surgery machine and filtering the air introduced into the eye 3) "Y" air connector 4) One-way valve to control air flow direction	

Contact Information:
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25G Twedge VitPack w/o Light probe

Pack for Vitrectomy - Sterile - Single use

Product Information

25G TWEDGE VITPACK W/O LIGHT PROBE	Name	Description	Qty/Bx	SKU #
	25G TWEDGE VITPACK W/O LIGHT PROBE	Pack for Vitrectomy - Sterile - Single use	5	199025

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 5x	**Biocompatibility**
The devices that make up the kit are packaged as follows. Two individual stiff blisters consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: 1st - tubing, cassette and infusion set 2nd - accessories for vitrectomy A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. 5 (five) blisters containing the cassette, plus 5 (five) blisters containing accessories, plus 5 (five) pouchs containing drapes, plus 5 (five) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	The standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 129797 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-Evolution CR and R-EVO SMART CR for vitreo-retinal surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 193503

Components

Q.ty	SKU #		Image
1	**192225** 25G TROCAR SYSTEM, ONE-STEP WITH VALVE Risk class according to MDD 93/42 **IIa** CND category **Q020199** CE 0051	25G valved entry system kit "One Step" 25G trocar kit. The kit contains 3 valved trocars mounted on a scleral knife and one infusion cannula.	
1	**192315** 25G OPTI-VIT TWEDGE VITREOUS CUTTER Risk class according to MDD 93/42 **IIa** CND category **Q020499** CE 0051	25G Twedge™ high speed dual blade vitrectomy probe 25G (approx. 0.5 mm) "**Twedge™**" probe for posterior vitrectomy with high speed, guillotine-type pneumatically actuated **dual blade** and tubing. Cut rate of up to 10,000 cuts per minute (20,000 with dual blade) for R-Evolution® CR (recommended range of 7,000 to 8,000 cuts per minute, 14,000/16,000 with dual blade) and 5,000 cuts per minute (10,000 with dual blade) for R-Evo Smart® CR. Selecting a high cut rate reduces fluctuation of the retina and membranes. The specific geometry and sharpening of the cutting mouth improve cutting performance and prevent hazardous vitreous incarceration. Low weight and lack of vibration make it comfortable to use, even during lengthy procedures.	
1	**192514** 2-WAY STOPCOCK Risk class according to MDD 93/42 **IIa** CND category **A0701** CE 0051	3-WAY STOPCOCK 3-way stopcock with adapters, which switches 2 input lines to one output line. Fitted with a mechanical stop on two positions, thus preventing any switching errors.	

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Components

Q.ty	SKU #		Image
1	**192550** FLUIDS EXCHANGE SET WITH AUTOMATIC VALVE Risk class according to MDD 93/42 **IIa** CND category **Q02030199** CE 0051	Automatic fluid/air exchange set Automatic fluid/air exchange system. The device is indicated in vitreoretinal ophthalmic surgery, particularly tamponade with fluids. It enables automatic switching between irrigation of sterile balanced saline solution and infusion of sterile air into the eyeball. The irrigation of balanced saline solution and infusion of sterile air are channeled along the same infusion line. The anti-reflux valve on the air infusion tube prevents solution from entering the latter while irrigating with balanced saline solution. Conversely, it blocks the flow of saline solution during sterile air infusion. Consisting of the following parts: 1) Tubing for channeling filtered air 2) Filter connecting the device to the vitreoretinal surgery machine and filtering the air introduced into the eye 3) "Y" air connector 4) One-way valve to control air flow direction	

Contact Information:
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Agile Phaco Pack 20G S

Pack for cataract surgery through 20G incision using phacoemulsification technique - Sterile - Single use

Product Information

AGILE PHACO PACK 20G S	Name	Description	Qty/Bx	SKU #
	AGILE PHACO PACK 20G S	Pack for cataract surgery through 20G incision using phacoemulsification technique - Sterile - Single use	10	195120

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 10x	**Biocompatibility**
The devices that make up the kit are packaged as follows. One single stiff blister consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: tubing, cassette and infusion set A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 10 (ten) blisters containing the cassette, plus 10 (ten) pouchs containing accessories for phacoemulsification, plus 10 (ten) pouchs containing drapes, plus 10 (ten) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	The standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 129552 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-EVOLUTION and R-Evolution CR and R-EVO SMART E, S and R-EVO SMART CR for cataract surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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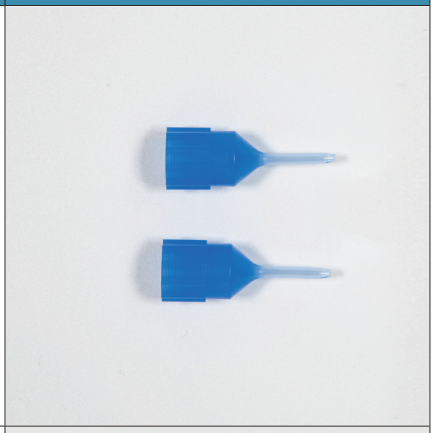
The SKU# listed in the table below are included in the CE marked kit 19576X

Components

Q.ty	SKU #		Image
2	**191338** 20G BLUE SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 20G tips 2x blue sleeves for 2.6-2.8 mm incision (for 20G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	
1	**191203** 20G 30° PHACO TIP Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	20G straight phaco tip, 30° 20G "STANDARD" Titanium tip for ultrasonic phacoemulsification for 2.6 - 2.8 mm incision, pre-assembled on a single-use tightening wrench.	

Contact Information:
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Agile Phaco Pack 21G S

Pack for cataract surgery through 21G incision using phacoemulsification technique - Sterile - Single use

Product Information

AGILE PHACO PACK 21G S	Name	Description	Qty/Bx	SKU #
	AGILE PHACO PACK 21G S	Pack for cataract surgery through 21G incision using phacoemulsification technique - Sterile - Single use	10	195121

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 10x	**Biocompatibility**
The devices that make up the kit are packaged as follows. One single stiff blister consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: tubing, cassette and infusion set. A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 10 (ten) blisters containing the cassette, plus 10 (ten) pouchs containing accessories for phacoemulsification, plus 10 (ten) pouchs containing drapes, plus 10 (ten) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	The standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 129555 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-EVOLUTION and R-Evolution CR and R-EVO SMART E, S and R-EVO SMART CR for cataract surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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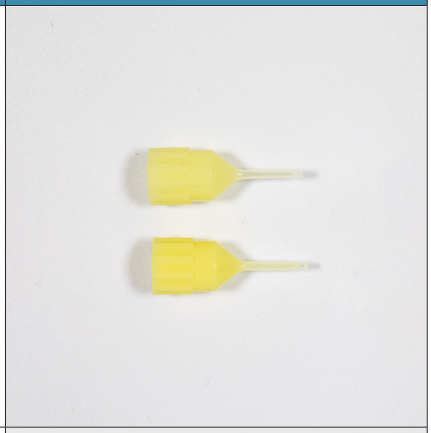
The SKU# listed in the table below are included in the CE marked kit 19577X

Components

Q.ty	SKU #		Image
2	**191339** 21G YELLOW SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 21G tips 2x yellow sleeves for 2.2 - 2.4 mm incision (for 21G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	
1	**191213** 21G PHACO TIP, 30° Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	21G straight phaco tip, 30° 21G “Standard” Titanium tip for ultrasonic phacoemulsification, 30°, for 2.2 - 2.4 mm incision, pre-assembled on a single-use tightening wrench.	

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Agile Phaco Pack 20G F

Pack for cataract surgery through 20G incision using phacoemulsification technique - Sterile - Single use

Product Information

AGILE PHACO PACK 20G F	Name	Description	Qty/Bx	SKU #
	AGILE PHACO PACK 20G F	Pack for cataract surgery through 20G incision using phacoemulsification technique - Sterile - Single use	10	195220

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 10x	**Biocompatibility**
The devices that make up the kit are packaged as follows. One single stiff blister consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: tubing, cassette and infusion set A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 10 (ten) blisters containing the cassette, plus 10 (ten) pouchs containing accessories for phacoemulsification, plus 10 (ten) pouchs containing drapes, plus 10 (ten) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	The standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 129553 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-EVOLUTION and R-Evolution CR and R-EVO SMART E, S and R-EVO SMART CR for cataract surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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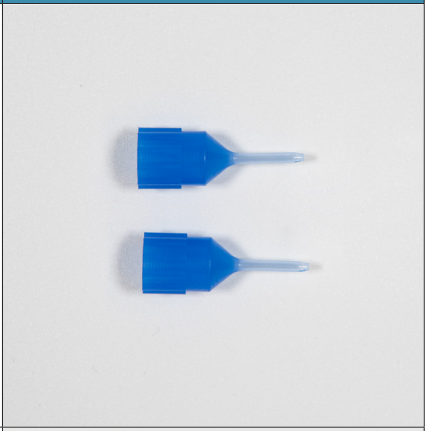
The SKU# listed in the table below are included in the CE marked kit 19501Y

Components

Q.ty	SKU #		Image
2	**191338** 20G BLUE SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 20G tips 2x blue sleeves for 2.6-2.8 mm incision (for 20G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	
1	**191206** 20G FLARED PHACO TIP Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	20G flared phaco tip, 30° 20G "FLARED" Titanium tip for ultrasonic phacoemulsification, for 2.6 - 2.8 mm incision, pre-assembled on a single-use tightening wrench.	

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Agile Phaco Pack 21G F

Pack for cataract surgery through 21G incision using phacoemulsification technique - Sterile - Single use

Product Information

AGILE PHACO PACK 21G F	Name	Description	Qty/Bx	SKU #
	AGILE PHACO PACK 21G F	Pack for cataract surgery through 21G incision using phacoemulsification technique - Sterile - Single use	10	195221

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 10x	**Biocompatibility**
The devices that make up the kit are packaged as follows. One single stiff blister consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: tubing, cassette and infusion set A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 10 (ten) blisters containing the cassette, plus 10 (ten) pouchs containing accessories for phacoemulsification, plus 10 (ten) pouchs containing drapes, plus 10 (ten) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	The standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 129556 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-EVOLUTION and R-Evolution CR and R-EVO SMART E, S and R-EVO SMART CR for cataract surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 19511Y

Components

Q.ty	SKU #		Image
2	**191339** 21G YELLOW SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 21G tips 2x yellow sleeves for 2.2 - 2.4 mm incision (for 21G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	
1	**191216** 21G FLARED PHACO TIP Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	21G flared phaco tip, 30° 21G "FLARED" Titanium tip for ultrasonic phacoemulsification, for 2.2 - 2.4 mm incision, pre-assembled on a single-use tightening wrench.	

Contact Information:
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Agile Phaco Pack 22G F

Pack for cataract surgery through 22G incision using phacoemulsification technique - Sterile - Single use

Product Information

AGILE PHACO PACK 22 G F	Name	Description	Qty/Bx	SKU #
	AGILE PHACO PACK 22G F	Pack for cataract surgery through 22G incision using phacoemulsification technique - Sterile - Single use	10	195222

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 10x	**Biocompatibility**
The devices that make up the kit are packaged as follows. One single stiff blister consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: tubing, cassette and infusion set A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 10 (ten) blisters containing the cassette, plus 10 (ten) pouchs containing accessories for phacoemulsification, plus 10 (ten) pouchs containing drapes, plus 10 (ten) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	The standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 129558 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-EVOLUTION and R-Evolution CR and R-EVO SMART E, S and R-EVO SMART CR for cataract surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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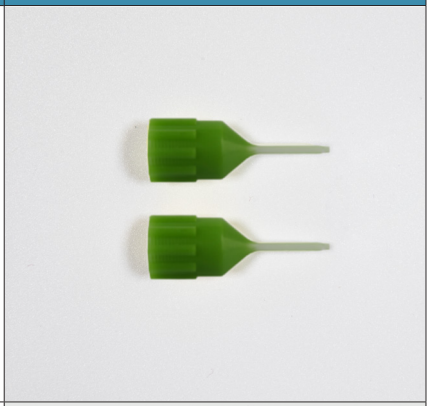
The SKU# listed in the table below are included in the CE marked kit 19521Y

Components

Q.ty	SKU #		Image
2	**191337** 22G GREEN SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 22G tips 2x green sleeves for 1.8 mm incision (for 22G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	
1	**191226** 22G FLARED PHACO TIP Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	22G flared phaco tip, 30° 22G "FLARED" Titanium tip for ultrasonic phacoemulsification, for 1.8 mm incision, pre-assembled on a single-use tightening wrench.	

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Agile Phaco Pack 20G FB

Pack for cataract surgery through 20G incision using phacoemulsification technique - Sterile - Single use

Product Information

AGILE PHACO PACK 20G FB	Name	Description	Qty/Bx	SKU #
	AGILE PHACO PACK 20G FB	Pack for cataract surgery through 20G incision using phacoemulsification technique - Sterile - Single use	10	195320

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 10x	**Biocompatibility**
The devices that make up the kit are packaged as follows. One single stiff blister consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: tubing, cassette and infusion set A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 10 (ten) blisters containing the cassette, plus 10 (ten) pouchs containing accessories for phacoemulsification, plus 10 (ten) pouchs containing drapes, plus 10 (ten) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	The standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 129554 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-EVOLUTION and R-Evolution CR and R-EVO SMART E, S and R-EVO SMART CR for cataract surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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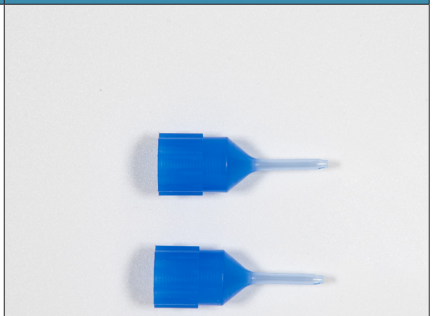
The SKU# listed in the table below are included in the CE marked kit 19501Z

Components

Q.ty	SKU #		Image
2	**191338** 20G BLUE SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 20G tips 2x blue sleeves for 2.6-2.8 mm incision (for 20G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	
1	**191207** 20G FLARED BENT PHACO TIP Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	20G flared bent phaco tip, 30° 20G "FLARED BENT" Titanium tip for ultrasonic phacoemulsification, for 2.6 - 2.8 mm incision, pre-assembled on a single-use tightening wrench.	

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Agile Phaco Pack 21G FB

Pack for cataract surgery using phacoemulsification technique through 21G incision - Sterile - Single use

Product Information

AGILE PHACO PACK 21G FB	Name	Description	Qty/Bx	SKU #
	AGILE PHACO PACK 21G FB	Pack for cataract surgery using phacoemulsification technique through 21G incision - Sterile - Single use	10	195321

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 10x	**Biocompatibility**
The devices that make up the kit are packaged as follows. A stiff blister consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: tubing, cassette and infusion set A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 10 (ten) blisters containing the cassette, plus 10 (ten) pouchs containing accessories for phacoemulsification, plus 10 (ten) pouchs containing drapes, plus 10 (ten) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	The standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 129557 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-EVOLUTION and R-Evolution CR and R-EVO SMART E, S and R-EVO SMART CR for cataract surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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The SKU# listed in the table below are included in the CE marked kit 19511Z

Components

Q.ty	SKU #		Image
2	**191339** 21G YELLOW SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 21G tips 2x yellow sleeves for 2.2 - 2.4 mm incision (for 21G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	
1	**191217** 21/22G FLARED BENT PHACO TIP Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	21/22G flared bent phaco tip, 30° 21G “Flared-bent” Titanium tip for ultrasonic phacoemulsification, for 2.2 - 2.4 mm incision, pre-assembled on a single-use tightening wrench.	

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Agile Phaco Pack 22G FB

Pack for cataract surgery through 22G incision using phacoemulsification technique - Sterile - Single use

Product Information

AGILE PHACO PACK 22G FB	Name	Description	Qty/Bx	SKU #
	AGILE PHACO PACK 22G FB	Pack for cataract surgery through 22G incision using phacoemulsification technique - Sterile - Single use	10	195322

Manufacturer	Product Compliance
Optikon 2000 S.p.A. Via del Casale di Settebagni 13 00138 Rome - Italy C.C.I.A.A. (Italian Chamber of Commerce, Industry, Agriculture and Small Business) registration: No. 792919	EN 556-1 EN 868-5 EN 1041 EN ISO 10993-1 EN ISO 10993-7 EN ISO 11135-1 EN ISO 11607-1 EN ISO 11607-2 EN ISO 14644-1 EN ISO 14971
Packaging 10x	**Biocompatibility**
The devices that make up the kit are packaged as follows. One single stiff blister consisting of a PET tray sealed with a Tyvek® cap (sterile barrier system), containing: tubing, cassette and infusion set A coupled polyester-medical paper pouch containing screen cover drape and instrument tray cover. A coupled polyester-medical paper pouch containing an infusion set for controlled irrigation. A coupled polyester-medical paper pouch containing accessories for phacoemulsification. 10 (ten) blisters containing the cassette, plus 10 (ten) pouchs containing accessories for phacoemulsification, plus 10 (ten) pouchs containing drapes, plus 10 (ten) pouchs containing sterile disposable infusion sets, are placed in an easy-opening (EasyPack) case. Each case is further packaged in a carton for transport.	All materials in the kit devices that come into direct or indirect contact with the patient have been declared: - Biocompatible (by the respective manufacturers) - Compliant with EN ISO 10993-1 standard (by accredited laboratories).

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Product Information

Latex	Phthalates
None of the kit components contain natural latex.	None of the kit components contain phthalates.
Inspections	**Identification**
All devices included in the kit undergo inspections during the manufacturing process and final inspections. Inspection reports are collected by the quality service and stored for 10 (ten) years from the kit manufacturing date.	The standard packaging includes the following: label written in Italian stating the manufacturer, code and commercial name of the kit, definition and quantity of the kit contents, sterilization method, CE marking, batch number, manufacturing date and expiration date; two detachable adhesive labels for traceability, stating the manufacturer, batch number and expiration date.
Certification Information	**Sterilization**
CE certified IMQ No.: 1991/MDD Notified Body: IMQ S.p.A. Risk class according to MDD 93/42: N/A CND (Italian National Classification for Medical Devices) category: N/A Registration in Medical Device Directory (RDM): 129559 ISO: EN ISO 13485:2016	By EO (ethylene oxide) using a validated cycle that complies with Official Pharmacopoeia and EN ISO 11135-1 standard requirements.
Batch release criteria	**Intended use**
Negative for biological indicators EO residues ≤ 2 ppm on released product	The kit is intended to be used with the Optikon 2000 models R-EVOLUTION and R-Evolution CR and R-EVO SMART E, S and R-EVO SMART CR for cataract surgery. The kit is intended for use at facilities performing ocular surgical procedures. It must therefore be used by qualified healthcare practitioners only. All other use of the kit falls outside the intended scope of application and must be considered improper.
Method of use	**Validity**
Specified in the directions for use on each kit.	Indicative: 5 (five) years from the date of sterilization and in any case by the date shown on the package.
Storage	**Disposal**
The package containing this kit should be stored in a dust-free environment at a maximum temperature of 25°C and relative humidity below 65%, away from heat sources and direct sunlight.	Once used, the product must be disposed of in accordance with internal hospital regulations on infectious waste disposal.

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Components

Q.ty	SKU #		Image
1	**192704** R-EVOLUTION HI-VAC EASYSYS KIT Risk class according to MDD 93/42 **IIa** CND category **Z1212020785** CE 0051	EasySys cassette kit The kit includes: I/A tubing set complete with EasySys High Vacuum cassette and aspirated fluid collection bag. The tubing set has a single I/A cassette for phacoemulsification and vitrectomy that operates with both peristaltic and Venturi pumps; the cassette is fitted with an anti-collapse device and small-diameter aspiration line that reduce anterior chamber fluctuations during surgery. The ergonomic cassette can be mounted directly by the user with no loss of asepsis. Irrigation line with drip chamber (infusion set). It is supplied with a dedicated drip chamber to maximize irrigation flow. Transparent, waterproof screen cover, which allows the user to adjust equipment features and parameters using the touch screen on the monitor with no loss of asepsis. Transparent, waterproof tray cover (Mayo cover 80 x 90 cm), which is used to cover the instrument tray and maintain asepsis. The kit ensures: **Ergonomics** The device can simply be connected to the equipment without the need for complex, laborious tubing. **Hermeticity** The I/A tubing set with cassette includes both a reservoir and collection bag. These prevent contact between aspirated fluids and users. **Regular fluidics** The ACS3 system introduced by Optikon ensures maximum stability of the anterior ocular chamber during surgery, eliminating the risk of rupture of the posterior capsule. **Immediate response** With its improved rigidity, the PVC tubing gives the system a more immediate response to aspiration during surgery. **Maximum irrigation flow** The drip chamber perforator features a large drainage hole to maximize irrigation flow.	
1	**190700** INFUSION SET FOR CONTROLLED IRRIGATION Risk class according to MDD 93/42 **IIa** CND category **A03010299** CE 0051	AGILE Infusion Set The device consists of a two-way infusion set with a perforator air intake extended such that, once inserted into a bottle of irrigation solution, the end is positioned in the area above the fluid, with a tube that connects the air intake to the compressed air source controlled by the equipment. An absolute filter is situated on this line to introduce sterile air into the bottle.	

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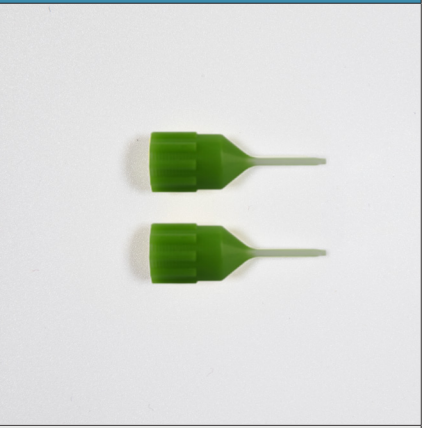
The SKU# listed in the table below are included in the CE marked kit 19521Z

Components

Q.ty	SKU #		Image
2	**191337** 22G GREEN SLEEVE Risk class according to MDD 93/42 Class **IIa** device CND category **Q020699** CE 0051	Silicone sleeves for 22G tips 2x green sleeves for 1.8 mm incision (for 22G phaco tip), which channels the sterile saline solution from the irrigation bottle to the anterior chamber while separating surrounding tissues from the surface of the Titanium tip, thus reducing any risk of burning. The material in direct contact with the patient is silicone rubber.	
1	**191601** TEST CHAMBER, DISPOSABLE Risk class according to MDD 93/42 Class **I** device CND category **Z1212020780** CE 0051	Test chamber The (transparent) test chamber is intended to simulate the anterior chamber of the human eye. It is used when priming the phacoemulsifier to ensure continuity of the irrigation/ aspiration circuit of the system. It can also be used to make sure that selection of I/A parameters is such as to prevent anterior chamber collapse. The material in indirect contact with the patient is silicone rubber.	
1	**191217** 21/22G FLARED BENT PHACO TIP Risk class according to MDD 93/42 **IIa** CND category **Q020699** CE 0051	21/22G flared bent phaco tip, 30° 21G "Flared-bent" Titanium tip for ultrasonic phacoemulsification, for 2.2 - 2.4 mm incision, pre-assembled on a single-use tightening wrench.	

Contact Information:
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