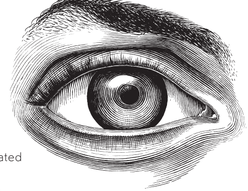
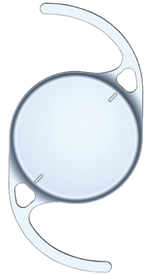
BAUSCH+LOMB SURGICAL SOLUTIONS

PARTNERING IS OUR PRACTICE.

Bausch & Lomb Optical Co.

From the very beginning to today and beyond, we are dedicated to making highly innovative, reliable products of exceptional quality with premium fit and finish and precision engineering. From introducing the world's first soft contact lenses in 1971 to today's dual-platform Stellaris Elite with eyeTELLIGENCE, Bausch + Lomb continues to offer innovative ophthalmic solutions for your practice with the quality and craftsmanship established by John Jacob Bausch and Henry Lomb.





150 MILLION
CUSTOMERS SERVED A DAY

Our close relationships with surgeons and thriving practices not only help us create solutions that respond to the needs of the modern practice, but also inspire positive outcomes with millions of patients.

7
GLOBAL MANUFACTURING FACILITIES

Our research and development team listens to the needs of our surgeon partners and develops technologies that solve the problems of tomorrow while catering to the surgery of today. Our global manufacturing presence has sites situated worldwide throughout the United States and Europe.

77
COUNTRIES SERVED

We take pride in our diverse sales force and customer service team. They demonstrate a deep understanding of the needs and preference of surgeons worldwide who trust our products and our people for innovation and support.

5
R&D LOCATIONS

Our robust investment in our research and development capabilities means that we are dedicated to not only hiring the most talented people in the industry, but also to building state-of-the-art facilities where they can use their full potential.

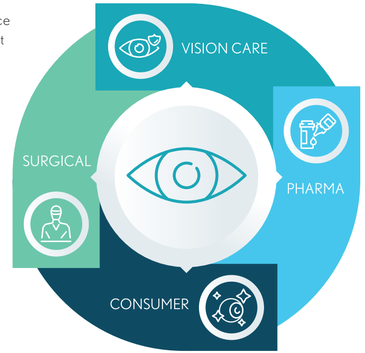
165+ YEARS DEDICATED TO INNOVATION & QUALITY

In 1853, John Jacob Bausch, a German immigrant set up a tiny optical goods shop in Rochester, New York. Soon after, Bausch's good friend, Henry Lomb, decided to make an investment in the business, and the two became full partners. By the early 1900s, Bausch + Lomb had become leaders in the technological innovation for optical products, partnering with the government to make ground-breaking sunglasses for World War II and the lenses that took the first satellite pictures of the moon.

REFRACTIVE CATARACT RETINA

A COMPREHENSIVE PORTFOLIO

As one of the best-known healthcare brands in the world, Bausch + Lomb is a hallmark of quality and innovation. Over 165 years, the company has built a comprehensive portfolio of products from contact lenses and lens care products, to pharmaceuticals, to intraocular lenses and other ophthalmic surgery products. Bausch + Lomb surgical proudly carries on this tradition of excellence in our portfolio of tools and technologies to support ophthalmic surgery for cataract, corneal, refractive, and vitreo-retinal procedures, as we strive to help each surgeon unlock their full potential and deliver exceptional patient outcomes.



RESEARCH AND DEVELOPMENT

We invest heavily in ongoing R&D efforts focused on the development of technologically innovative products to support the latest advances in cutting-edge surgical techniques and approaches.

TECHNICAL SERVICES

Our engineers receive rigorous certification to prevent problems with capital equipment before they arise. Monitoring systems enable software updates and data back-ups, with field engineers dispatched as needed.

CUSTOMER SERVICES

An effective team is available to meet customers' needs relating to orders, pricing, product availability, returns, deliveries and credit notes. These services have strengthened our relationships with healthcare professionals.

GLOBAL LOGISTIC CAPABILITIES

Orders and deliveries around the world are ensured by our global network of service representatives and distributors. Delivery time is approximately 24–48 hours.

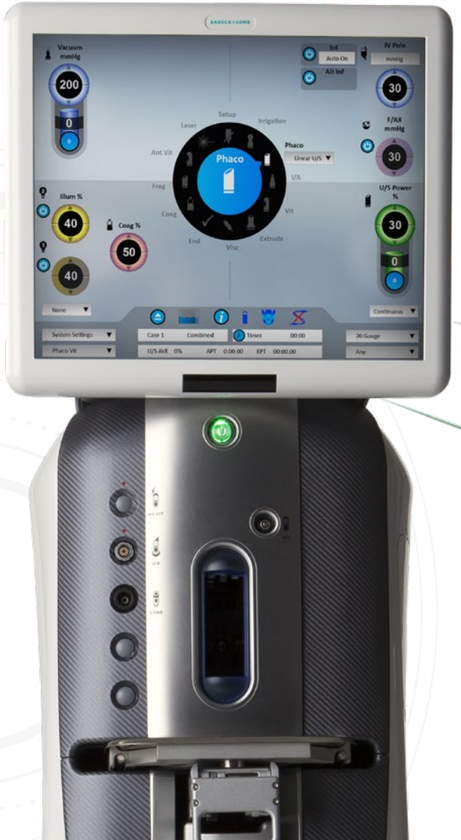
INNOVATION IN
CATARACT & REFRACTIVE SURGERY

We have a full range of products for cataract and refractive ophthalmic surgery designed with both doctors and their patients in mind. From high-performing platforms with responsive performance and refreshing stability, to our IOLs that we designed for high quality vision and long lasting performance, we are proud to offer solutions that work in any practice.

VICTUS®
Femtosecond Laser Platform

eyeTELLIGENCE® TM
Software

Stellaris Elite®
Vision Enhancement System



Amvisc® Plus
Viscoelastic

Storz®
Ophthalmic Instruments

CATARACT

VICTUS FEMTOSECOND LASER

- Dual functionality for cataract surgery and corneal incisions
- Live, continuous visualization with REALEYEZ™ swept-source OCT

STELLARIS ELITE

- Proactive infusion management to achieve exceptional chamber stability[1,2]
- Adaptive Fluidics™ System integrates precision aspiration control with dynamic infusion compensation[1,2]
- Attune® energy management[1,2]
- Dual linear foot pedal allows for independent control of vacuum and ultrasound power

VISCOELASTICS

Amvisc, Amvisc Plus, OcuCoat

- Powerful choices to fit a wide range of surgical needs[3]

STORZ INSTRUMENTS

- A pipeline of innovation developed through key thought leader collaboration
- Comprehensive portfolio of products for the ophthalmic procedure
- Premium quality products backed with a lifetime warranty and sales support

CUSTOM PROCEDURE PACKS

- Wide choice of surgical components including CapsuleGuard and Storz cannulas
- Built to individual specifications

Reference:
1. Data on file. Bausch & Lomb Inc.
2. Mark E. Schafer, PhD. Analysis of the Cutting Forces using Different Phacoemulsification Modalities. ASCRS 2009.
3. Amvisc and Amvisc Plus Directions for Use.

enVista®
Hydrophobic Acrylic IOL

enVista® Toric
Hydrophobic Acrylic Toric IOL

Crystalens®
AO IOL

Trulign®
Toric IOL

CATARACT

Akreos®
MICS IOL

Akreos®
AO IOL

SofPort®
Silicone IOL

ENVISTA IOL

- TruSight optic – Glistening free[2]
- AccuSet haptics – Adaptive, predictability[3]
- Aspheric Neutral – High Quality Vision
- StableFlex technology – controlled unfolding
- SureEdge design – Continuous 360° posterior square edge[4]

ENVISTA TORIC IOL

- Excellent visual acuity[1]
- Treats a broad population of adult astigmatic patients[1]
- Exceptional rotational stability[1]

CRYSTALENS AO IOL

- Provides exceptional contrast sensitivity by focusing 100% of light, 100% of the time[5]

TRULIGN TORIC IOL

- Delivers true performance at all distances for cataract patients with astigmatism[6]

AKREOS MICS IOL

- Allow for an incision size as small as 1.8mm[7]
- Four-points of capsular bag contact for the potential of increased stability[8]
- An equi-biconvex design which has been shown in other IOLs to minimize reflected light compared to an unequal biconvex design

AKREOS AO IOL

- Four-points of capsular bag contact for the potential of increased stability[9]
- An equi-biconvex design which has been shown in other IOLs to minimize reflected light compared to an unequal biconvex design[9]

SOFPORT SILICONE IOL

- SofPort AO aberration-free optic design[10]
- SofPort AO less sensitive to the effects of misalignment or decentration[11]
- Designed with a sharp 360° square posterior edge

References:
1. enVista Toric Direction for Use.
2. enVista Directions for Use.
3. Data on file.
4. Data on file.
5. Ang et al. Prospective evaluation of visual outcomes with three presbyopia-correcting intraocular lenses following cataract surgery. Clinical Ophthalmology. 2013:7 1811-1823.
6. Data on file.
7. Data on file.
8. Lombardo et al. Analysis of intraocular lens surface adhesiveness by atomic force microscopy. J Cataract Refract Surgery. 2009; 35:1266-1272.
9. Packer et al. Clinical properties of a novel glistening-free single-piece, hydrophobic acrylic IOL. Clinical Ophthalmology. 2014:8 421-427.
10. Altmann et al. Optical performance of 3 intraocular lens design in the presence of decentration. J Cataract Refract Surgery. 2005; 31:574-585.
11. Buehl et al. Effect of intraocular lens design on posterior capsule opacification. J Cataract Refract Surgery. 2008; 34:1976-1985.

INNOVATION IN RETINA SURGERY

In the rapidly growing field of vitreoretinal surgery, our enhanced research and development facilities and staff are highly responsive to the evolving needs of our surgeon partners. We are developing technology designed to unlock each surgeon's highest potential. Our complete portfolio of retinal surgery products is meant to not only meet your everyday needs but also the needs of your most complicated cases.

RETINA

Stellaris Elite®
Vision Enhancement System

Pinnacle 360™
with Reddy End Grasping Forceps

FreeFlow™
Infusion

Bi-Blade®
Vitrectomy Cutter

Illuminated Directional
Laser Probes

FREEFLOW INFUSION

- Facilitates up to 96% higher flow rate than traditional infusion lines*
  *27ga results acquired using water and an infusion pressure of 30mmHg

BI-BLADE VITRECTOMY CUTTER

- Always-open duty cycle enables effective cut rates up to 15,000 CPM
- The dual-port design allows for up to a 230% faster flow rate*
  *Compared to traditional single-port cutters in BSS on systems in 7500 CPM mode

PINNACLE 360 INSTRUMENTATION

- 360° actuation with a wide range of specialty tips

ILLUMINATED DIRECTIONAL LASER PROBES

- Straight access through valved cannulas, with 90° actuation in the eye to reach the far prehiphery

STELLARIS ELITE WITH EYETELLIGENCE

- Optimized to deliver precise control and extraordinary efficiency for retina procedures
- Offering an exclusive combination of leading-edge cutting technologies with a full range of gauge sizes

CONTINUOUS RESEARCH AND DEVELOPMENT

Our full portfolio of ophthalmic solutions are inspired by you, which is why our robust research and development resources are tasked with finding the most innovative solutions for modern surgery. We proactively seek to create the products of tomorrow so we are never stuck reacting to yesterday's industry trends.

COMMITTED TO

INNOVATION AND QUALITY

2003

2007

2009

2010

2012

2013

2017

2018

2019

2003 CRYSTALENS® AO **2007** STELLARIS® **2009** AKREOS® MICS IOL **2010** STELLARIS® PC **2012** ENVISTA® IOL | VICTUS **2013** TRULIGN® TORIC IOL

2017 STELLARIS ELITE® **2018** EYETELLIGENCE™ SOFTWARE | ENVISTA® TORIC IOL | BI-BLADE® **2019** REDDY END GRASPING FORCEPS | FREEFLOW™

PARTNERING THAT EXCEEDS YOUR EXPECTATIONS

Partnering is our practice because our success depends on the success of those who trust us the most. Our trusted advisor network will help you find the perfect solutions for your practice's unique needs, and our on-demand customer service is always available to answer questions about our entire comprehensive portfolio of products.

Here are just a few more ways we put partnering into practice:

- Development and training initiatives
- Field service & product maintenance
- Easy online ordering
- Fast Fulfillment

BAUSCH+LOMB SURGICAL SOLUTIONS

PARTNERING IS OUR PRACTICE.

INDICATIONS AND IMPORTANT SAFETY INFORMATION
Akreos® IOL AO60 and MI60L

INDICATIONS: Akreos® posterior chamber intraocular lenses are indicated for primary implantation for correction of aphakia in adult patients in whom a cataractous lens has been removed by phacoemulsification. The lens is intended for placement in the capsular bag.

CONTRAINDICATIONS: Implantation is not advisable when the IOL may aggravate an existing condition, interfere with the diagnosis or treatment of a pathology, or present a risk to the sight of the patient. These conditions are uncontrolled glaucoma, rubeotic cataract, retinal detachment, atrophy of the iris, microphthalmia, developing chronic eye infections, endothelial corneal dystrophy, perioperative complications (such as vitreous loss, hemorrhage, etc), foreseeable post-operative complications.

WARNINGS: Before implanting Akreos® lenses in patients, preoperative evaluation should be performed by a surgeon to consider the potential benefit/risk ratio. There are insufficient clinical data to demonstrate safety and efficacy for placement in the ciliary sulcus. Improper handling or folding techniques may cause damage to the haptic or optic portions of the lenses. Use only validated folding instruments. Exercise care during handling and insertion to avoid permanent forceps marks in the central optic zone.

PRECAUTIONS: Do not attempt to resterilize these lenses. Do not store the IOL package in direct sunlight or at a temperature below freezing (<0°C). Avoid high temperatures (>45°C). Do not reuse the IOL. Do not soak or rinse lenses in solutions other than balanced salt solution or equivalent. Akreos® lenses can absorb substances that they contact (disinfectant, drug). Do not place the lens in contact with surfaces where such contamination can occur.

ADVERSE EVENTS: The incidence of adverse events experienced during the clinical trial, including hyphema, macular edema, retinal detachment, etc., was comparable to or lower than the incidence reported in the historic control (“FDA grid”) population.

ATTENTION: Refer to the Directions for Use labeling for a complete listing of indications, warnings and precautions, clinical trial information, etc.

CAUTION: Federal (USA) law restricts this device to the sale by or on the order of a physician.

INDICATIONS AND IMPORTANT SAFETY INFORMATION
Amvisc® and Amvisc® Plus Viscoelastics

INDICATIONS: Amvisc® and Amvisc® Plus are indicated for use as a surgical aid in ophthalmic anterior and posterior segment procedures including: Extraction of a cataract, implantation of an intraocular lens (IOL), corneal transplantation surgery, glaucoma filtering surgery, and surgical procedures to reattach the retina.

Because of its lubricating and viscoelastic properties, transparency, and ability to protect corneal endothelial cells, Amvisc® and Amvisc® Plus helps maintain anterior chamber depth and visibility, minimizes interaction between tissues, and acts as a tamponade and vitreous substitute during retinal reattachment surgery. Amvisc® and Amvisc® Plus also preserves tissue integrity and good visibility when used to fill the anterior and posterior segments of the eye following open sky procedures.

PRECAUTIONS: There may be increased intraocular pressure following surgery caused by pre- existing glaucoma or by the surgery itself. An excess quantity of Amvisc® and Amvisc® Plus should not be used. Amvisc® and Amvisc® Plus should be removed from the anterior chamber at the end of surgery to prevent or minimize post-operative intraocular pressure increases (spikes). If the postoperative pressure increases above expected values, correcting therapy should be administered. Reuse of cannula should be avoided. Store at 2-8° C. Protect fromfreezing.

ADVERSE EVENTS: Transient postoperative inflammatory reactions were reported in clinical trials and oral and topical steroid preparations were administered. The best index of the degree of phlogistic response is the postoperative clarity of the vitreous cavity. Transient postoperative increase in intraocular pressure has been observed following the use of sodium hyaluronate in anterior segment surgery. On rare occasions postoperative reactions, including inflammation, corneal edema, and corneal decompensation have been reported.

ATTENTION: Refer to the Directions for Use labeling for a complete listing of indications, warnings and precautions, clinical trial information, etc.

CAUTION: Federal (USA) law restricts this device to the sale by or on the order of a physician.

INDICATIONS AND IMPORTANT SAFETY INFORMATION
Crystalens® posterior chamber accommodating IOL

INDICATIONS FOR USE: The Crystalens® posterior chamber accommodating intraocular lens (IOL) is intended for primary implantation in the capsular bag of the eye for the visual correction of aphakia secondary to the removal of a cataractous lens in adult patients with and without presbyopia. Crystalens® provides approximately one diopter of monocular accommodation which allows for near, intermediate, and distance vision without spectacles.

WARNINGS: The safety and effectiveness of the Crystalens® AO IOL has not been established in patients with preexisting conditions. Careful preoperative evaluation and sound clinical judgement should be used by the surgeon to decide the risk / benefit ratio before implanting a lens in a patient with conditions as outlined in the Crystalens® AO IOL Directions for Use. Unlike most other IOLs, the Crystalens® AO IOL optic has hinges connecting it to the haptic; please see adverse events section below for more information.

PRECAUTIONS: Do not resterilize this intraocular lens by any method. Do not store lenses at temperatures over 45°C (113°F). Do not implant this lens in the anterior chamber or the ciliary sulcus.

ADVERSE EVENTS: The incidence of adverse events experienced during the clinical trial was comparable to or lower than the incidence reported in the historic control ("FDA grid") population. As with any surgical procedure, risk is involved. Vaulting is a post-operative adverse event where the Crystalens® AO IOL optic hinges move into and remain in a displaced configuration. If vaulting occurs, please see Directions for Use for a detailed listing of symptoms, information regarding diagnosis, potential causes, and sequelae. Physicians should consider the characteristics of each individual vaulting case prior to determining the appropriate treatment. Data on long-term follow-up after treatment of vaulting is not available.

ATTENTION: Refer to the Directions for Use labeling for a complete listing of indications, warnings and precautions, clinical trial information, etc.

CAUTION: Federal (USA) law restricts this device to the sale by or on the order of a physician.

INDICATIONS AND IMPORTANT SAFETY INFORMATION
TRULIGN® toric posterior chamber IOL

INDICATIONS FOR USE: The TRULIGN® toric posterior chamber intraocular lens (IOL) is intended for primary implantation in the capsular bag of the eye for the visual correction of aphakia and postoperative refractive astigmatism secondary to removal of a cataractous lens in adult patients with or without presbyopia who desire reduction of residual refractive cylinder with increased spectacle independence and improved uncorrected near, intermediate and distance vision.

WARNINGS: Careful preoperative evaluation and sound clinical judgement should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient. Rotation of toric lenses away from their intended axis can reduce their effectiveness, and misalignment can increase postoperative refractive cylinder. The TRULIGN® Toric IOL should only be repositioned when the refractive needs of the patient outweigh the potential risks inherent in any surgical reintervention into the eye. Unlike most other IOLs, the TRULIGN® Toric IOL optic has hinges connecting it to the haptic; please see adverse events section below for more information.

PRECAUTIONS: The safety and effectiveness of the TRULIGN® Toric intraocular lenses have not been substantiated in patients with preexisting ocular conditions and intraoperative complications. Long-term stability in the human eye has not been established; therefore postoperative monitoring after implant should be performed on a regular basis. The potential for the lens to rotate causing misalignments that will reduce the effectiveness of the TRULIGN® Toric IOL may be greater in some eyes. Lens rotation less than 5° may not warrant reorientation. Do not resterilize this intraocular lens by any method. Do not store lenses at temperatures over 45°C (113°F). Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient with conditions as outlinedin the TRULIGN® Toric IOL directions for use.

ADVERSE EVENTS: The incidence of adverse events experienced during the clinical trial was comparable to or lower than the incidence reported in the historic control ("FDA grid") population. As with any surgical procedure, risk is involved. Vaulting is a post-operative adverse event where the TRULIGN® Toric IOL optic hinges move into and remain in a displaced configuration. If vaulting occurs, please see Directions for Use for a detailed listing of symptoms, information regarding diagnosis, potential causes, and sequelae. Physicians should consider the characteristics of each individual vaulting case prior to determining the appropriate treatment. Data on long-term follow-up after treatment of vaulting is notavailable.

ATTENTION: Refer to the Directions for Use labeling for a complete listing of indications, warnings and precautions, clinicaltrial information, etc.

CAUTION: Federal (USA) law restricts this device to the sale by or on the order of a physician

INDICATIONS AND IMPORTANT SAFETY INFORMATION
enVista® IOL (Model MX60 and Model MX60E)

INDICATIONS: Indicated for primary implantation for the visual correction of aphakia in adult patients in whom the cataractous lens has been removed. The lens is intended for placement in the capsular bag.

WARNINGS: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient.

PRECAUTIONS: Do not resterilize this intraocular lens by any method. Do no use if the packaging is damaged or if there are signs of leakage. Do not store lenses at temperatures over 43°C (109°F) or lower than 0°C (32°F). Do not reuse the lens. Safety and effectiveness of the enVista IOL have not been substantiated in patients with conditions and intraoperative complications as outlined in the enVista IOL Directions for Use.

ADVERSE EVENTS: As with any surgical procedure, there is risk involved. Potential complications accompanying cataract or implant surgery may include, but are not limited to the following: corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon transient or persistent glaucoma, and secondary surgical intervention.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

ATTENTION: Reference the Directions for Use labeling for a complete listing of indications and important safety information.

INDICATIONS AND IMPORTANT SAFETY INFORMATION
enVista® toric IOL (Model MX60T and Model MX60ET)

INDICATIONS: Indicated for primary implantation in the capsular bag of the eye in adult patients for the visual correction of aphakia and corneal astigmatism following removal of a cataractous lens for improved uncorrected distance vision.

WARNINGS: Physicians considering lens implantation in patients with pre-existing conditions, or in the event of surgical difficulties at the time of cataract extraction, should weigh the potential risk/benefit ratio. Rotation of enVista® toric IOL away from the intended axis can reduce the astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder.

PRECAUTIONS: Do not attempt to resterilize this lens. Do not use if the packaging is damaged or if there are signs of leakage. Do not store lenses at temperatures over 43°C (109°F) or lower than 0°C (32°F). Do not reuse the lens. Safety and effectiveness of the enVista toric IOL have not been substantiated in patients with conditions and intraoperative complications as outlined in the enVista toric IOL Directions for Use.

ADVERSE EVENTS: As with any surgical procedure, risk is involved. Potential adverse events accompanying cataract or implant surgery may include, but are not limited to, the following: corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon, transient or persistent glaucoma, acute corneal decompensation, toxic anterior segment syndrome (TASS). Secondary surgical interventions include, but are not limited to: lens repositioning, lens replacement, vitreous aspiration or iridectomy for pupillary block, wound leak repair, and retinal detachment repair.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

ATTENTION: This is not all you need to know. Please refer to the Directions For Use labeling for a complete listing of indications, full risk and safety information, clinical study information, etc.

INDICATIONS AND IMPORTANT SAFETY INFORMATION
Stellaris Elite® and Accessories

INDICATIONS: The Bausch + Lomb Stellaris Elite® vision enhancement system is intended for the emulsification and removal of cataracts, anterior and posterior segment vitrectomy. The system is designed for use in both anterior and posterior segment surgeries. It provides capabilities for phacoemulsification, coaxial and bimanual irrigation/aspiration, bipolar coagulation, vitrectomy, viscous fluid injection/removal and air/fluid exchange operations. The Stellaris Elite® Vision Enhancement System configured with the laser module is additionally intended for retinal photocoagulation and laser trabeculoplasty.

CONTRAINDICATIONS

- All Systems: Use of accessories not designated by Bausch + Lomb for use with this equipment may result in serious permanent patient injury, adverse surgical outcome,or damage to theequipment.
- Systems with Laser Module: Photocoagulation is not indicated for patients without pigmentation (albino eyes). In addition, Laser Indirect Ophthalmoscope (LIO) is not indicated for cases involving laser photocoagulation within the arcades.

WARNINGS

- All Systems:
  - Implantable defibrillators present a risk of injury if triggered by a fibrillatory event during intraocular surgery.
  - Electromagnetic interaction between the phacoemulsification (phaco) handpiece and an implanted cardiac pacemaker is unlikely but cannot be ruled out.
- Systems with LaserModule:
  - All support personnel who are present during laser treatment must wear appropriate laser protective eyewear.
  - **DO NOT** look directly into the aiming or treatment laserbeam.
  - Use of unapproved delivery devices may cause inaccurate laser delivery which could result in serious permanent patient injury.
- When using the VITESSE® handpiece:
  - Use only the Entry Site Alignment (ESA) devices provided with the VITESSE® Handpiece Pack (yellow trocar caps). Do not use any ESA with metal components to avoid particulate in the eye.
- When using the FREEFLOW™ infusion line:
  - Do not attempt to administer intraocular gases or viscous fluids using this device.
  - The infusion line loop should be created in the horizontal plane.

GENERAL CAUTIONS FOR SINGLE USE ACCESSORIES:

- Do not re-sterilize or reuse any single use accessories.
- Do not use if package integrity / sterile barrier has been breached or compromised.
- Do not use or attempt to repair damaged single use products.

This is not all you need to know. Systems with Laser Module: Misuse of the laser system may lead to dangerous situations and severe injuries. All Systems: See the appropriate Operator Manual for detailed directions, proper use, and full risk and safety information. See individual product instructions for use for detailed information on the use of the VITESSE® Handpiece, vitrectomy packs and cutters, and the FREEFLOW™ infusion line.

CAUTION: Federal (U.S.) Law restricts these devices to sale, by or on the order of a physician.

INDICATIONS AND IMPORTANT SAFETY INFORMATION
SofPort® IOL

INDICATIONS: The LI61AO and LI61SE SofPort® lenses are intended to be used for primary implantation for the visual correction of aphakia in adult patients where a cataractous lens has been removed by extracapsular cataract extraction methods (see WARNINGS). They are intended for placement in the ciliary sulcus or capsular bag. NOTE: Implantation of intraocular lenses should not be performed in patients under 18 years of age.

WARNINGS: Before implanting LI61AO and LI61SE SofPort® IOLs in patients, preoperative evaluation should be performed by a surgeon to consider the potential benefit/risk ratio. As with any surgical procedure, there is risk involved. The safety and efficacy of these posterior chamber lenses have not been established if placed in the anterior chamber. The long-term effects of intraocular lens implantation have not been determined. The safety of intraocular lenses has not been substantiated in patients with pre-existing ocular conditions.

PRECAUTIONS: Do not resterilize these lenses by any method. Do not store lenses at temperatures over 45°C. Use only sterile intraocular irrigating solutions, e.g., balanced salt or normal saline solution, to rinse and/or soak lenses. The lens should be handled carefully. The lens must be discarded if it remains in the folding instrument longer than 15 minutes. Lens can be inserted flat with forceps, or with an approved injector.

ADVERSE EVENTS: The most frequently reported adverse events that occurred during the clinical trial of the SofPort® were hypopyon, intraocular infection and acute corneal decompensation all of which occurred at a rate of <0.5%. Other reported events occurring in less than 1% of patients were secondary surgical interventions.

ATTENTION: Refer to the Directions for Use labeling for a complete listing of indications, warnings and precautions, clinical trial information, etc.

CAUTION: Federal (USA) law restricts this device to the sale by or on the order of a physician.

INDICATIONS AND IMPORTANT SAFETY INFORMATION
OcuCoat® Viscoelastic

INDICATIONS: OcuCoat® viscoelastic is indicated for use as an ophthalmic surgical aid in anterior segment surgical procedures, including cataract extraction and intraocular lens implantation. OcuCoat® maintains a deep chamber during anterior segment surgery and there by allows for more efficient manipulation with less trauma to the corneal endothelium and other ocular tissues.

PRECAUTIONS: For intraocular use only. Discard unused contents of OcuCoat® syringe after each use. Do not resterilize.

Precautions are limited to those normally associated with the ophthalmic surgical procedure being performed. There may be transient increased intraocular pressure following surgery because of pre-existing glaucoma or due to the surgery itself. For these reasons, the following precautions should be considered:

- OcuCoat® should be removed from the anterior chamber at the end of surgery
- If the post-operative intraocular pressure increases above expected values, appropriate therapy should be administered

ADVERSE EVENTS: Clinical testing of OcuCoat® showed it to be extremely well tolerated after injection into the human eye. A transient rise in intraocular pressure postoperatively has been reported in some cases. Rarely, postoperative inflammatory reactions (iritis, hypopyon), as well as incidents of corneal edema and corneal decompensation, have been reported with viscoelastic agents. Their relationship to OcuCoat® has not been established.

ATTENTION: Refer to the Directions for Use labeling for a complete listing of indications, warnings and precautions, clinical trial information,etc.

CAUTION: Federal (USA) law restricts this device to the sale by or on the order of a physician.

INDICATIONS AND IMPORTANT SAFETY INFORMATION
VICTUS® femtosecond laser platform

The VICTUS® femtosecond laser platform is indicated for use for:
The creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea
For anterior capsulotomy during cataract surgery
The creations of cuts / incisions in the cornea of patients undergoing cataract surgery or other ophthalmic treatment requiring cuts / incisions in the cornea
Laser-assisted lens fragmentation of nuclear cataracts during cataract surgery, not for posterior subcapsular (PSC) and cortical cataracts

SAFETY INFORMATION

The VICTUS® femtosecond laser platform emits an invisible class 3B laser beam that may injure the retina of the eyes or burn the skin. Never look directly into the laser source.

Misuse of the laser system may lead to dangerous situations and severe injuries. See the Operator Manual for detailed directions, proper use, and full risk and safety information.

Contraindications
General contraindications for using the VICTUS® femtosecond laser platform include, but are not limited to, the following: pediatric surgery, hypotony or glaucoma, retinal disorders, rheumatic diseases, occlusion of retinal vessels, pellucid marginal degeneration, existing corneal implant, heavy vascularization of the ocular tissue, epilepsy. Conditions that would cause inadequate clearance between the intended capsulotomy cut and the corneal endothelium. Valid exclusion criteria that complicate the docking procedure. Subjects with corneal disease or pathology that precludes applanation of the cornea or transmission of laser wavelength or distortion of laser light, who show signs of suspected or diagnosed keratoconus, who are pregnant or nursing, who are blind in the fellow eye, patients with any cornea disease in the eye that requires treatment (recurrent corneal erosion, severe basement membrane disease), difference of more than 5D between minimum and maximum K-values of the central 3mm zone on a keratometric map of the cornea, or maximum K-value of more than 60D, or minimum K-value of less than 37D

Potential Complications
Potential general complications resulting from VICTUS procedures include, but are not limited to corneal abrasion or defect, pain, bleeding, inflammation, and elevated intraocular pressure.

Please see the Operator Manual for detailed potential procedure-specific complications and contraindications for anterior capsulotomy, corneal cuts / incisions, flaps used in LASIK, and lens fragmentation. Potential complications are not limited to those included in the User Manual.

CAUTION: Federal (U.S.) Law restricts this device to sale, by or on the order of a physician.

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