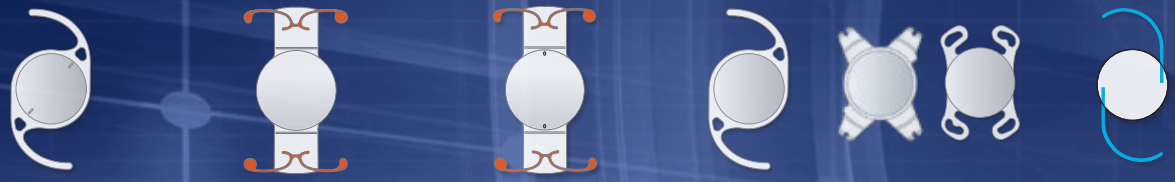
BAUSCH + LOMB

U.S. IOL PRODUCT CATALOG

enVista® TORIC | CRYSTALENS® AO | Trulign® TORIC | enVista® | AKREOS® | SOFPORT®AO



SURGICAL EQUIPMENT

STANDARD MONOFOCAL IOLS AND INSERTERS

PREMIUM IOLS AND INSERTERS

INSTRUMENTS

BAUSCH + LOMB VISCOELASTICS

TABLE OF CONTENTS

enVista® TORIC IOL

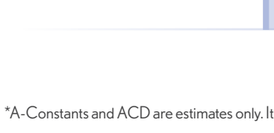
- Complete cylinder offerings to expand your reach – 7 cylinder powers, including sub 1D at the corneal plane[1]
- 300% more radial compression force than traditional hydrophobic acrylic[2]
- 100% ≤5° rotation[3]
- 1.1° mean rotation[3]*

*Between form 3-4

enVista TORIC IOL:

Lens Design	Model Number	Optic Design	Optic Size	Length	Optical Biometry Suggested A-constant ACD-constant*	Other Features	Diopter Range	Cylinder Powers IOL Plane
	MX60T	Aspheric, aberration-free, biconvex, posterior-surface toric	6mm	12.5mm	119.1 5.61mm	Glistening-free hydrophobic acrylic material Refractive index: 1.54 at 35° C UV absorbing Sharp 360° square posterior edge	+6 D to +30 D in 0.5-D increments	1.25, 2.00, 2.75, 3.50, 4.25, 5.00, 5.75

enVista TORIC INSERTERS:

Inserter Design	Product Number	For Inserting Lens Model	Recommended Incision Size	Type of Action	Comments
	BLIS-R1 (Handpiece) BLIS-X1 (Cartridge) BLIS-X0 (Cartridge)	MX60T +10 to +30 D with X1 cartridge +6 to +30 D with X0 cartridge	2.2mm-2.6mm	Twist Mechanism	Reusable, twist mechanism designed for controlled delivery Sterilization required
	INJ100	MX60T	2.2mm-2.6mm	Plunger	Single-handed delivery Disposable

TORIC MARKERS:

Inserter Design	Product Number	Overall Length	Material	Comments
Storz Toric Bubble Marker 	E2431	99mm, 3.9 inches	Stainless Steel	During the "clean" portion of the procedure, the bubble level is positioned below the cornea while the exterior of the ring is aligned to the limbus. The marker provides marks at the horizontal axis and at 90°. Not available in Canada.
Whitman Axis Marker 	E2430	81mm, 3.2 inches	Stainless Steel	Marked with a sterile marking pen, these blades are aligned under the microscope with limbal markings made pre-operatively at the 180° axis, or 3 and 9 o'clock. The instrument is pressed onto the eye surface, leaving two long, radial marks in the mid periphery of the cornea. The toric alignment markings on the IOL can then be aligned with these radial marks. Not available in Canada.

*A-Constants and ACD are estimates only. It is recommended that each surgeon develop his or her own values.

CRYSTALENS® AO IOL

- Crystalens AO is an accommodating IOL for presbyopia correction
- Crystalens delivers:
  - 100% of the light, 100% of the time for excellent contrast sensitivity and minimized issues with halos and glare[4,5]
  - Statistically significant superiority in uncorrected intermediate visual acuity over other multifocal lenses[6]

CRYSTALENS AO IOLs:

Lens Design	Model Number	Optic Design	Optic Size	Length	Optical Biometry Suggested A-constant ACD-constant*	Other Features	Diopter Range
	AO1UV	Aspheric, aberration-free, biconvex	5.0mm	11.5mm	119.1 5.61mm	Silicone material Refractive index at 35°C: 1.43	+17 to +22 D in 0.25-D increments +22.5 to +33 D in 0.50-D increments
	AO2UV	Aspheric, aberration-free, biconvex	5.0mm	12.0mm	119.1 5.61mm	Silicone material Refractive index at 35°C: 1.43	+4 to +10 D in 1.0-D increments +10.5 to +24 D in 0.50-D increments

CRYSTALENS INSERTERS:

Inserter Design	Product Number	Recommended Incision Size	Type of Action	Comments
	CI-28	2.8mm-3.0mm	Syringe	Single-handed delivery Disposable
	CI-26	2.6mm	Syringe	Single-handed delivery Disposable

*A-Constants and ACD are estimates only. It is recommended that each surgeon develop his or her own values.

TRULIGN® TORIC IOL

- The first lens to correct astigmatism and presbyopia in one procedure
- Provides for a broad range of vision[6]
- Excellent stability[7]
  - Rotation of ≤5° in 96.1% of eyes[7]
- Trulign Toric delivers:
  - 100% of light, 100% of the time[5] for minimized halos and glare[7]
  - 99.2% of patients reported no significant visual disturbances[7]

TRULIGN TORIC IOL:

Lens Design	Model Number	Optic Design	Optic Size	Length	Optical Biometry Suggested A-constant ACD-constant*	Other Features	Diopter Range	Cylinder Powers IOL Plane
	BL1UT	Aspheric, aberration-free, biconvex toric posterior surface	5.0mm	11.5mm	119.1 5.61mm	Silicone with UV protection 10% UV cutoff at 400nm 360° posterior square edge Refractive index at 35°C: 1.43	+4 to +10 D in 1.0-D increments +10 to +33 D in 0.5-D increments	1.25, 2.00, 2.75 D

TRULIGN TORIC INSERTERS:

Inserter Design	Product Number	Recommended Incision Size	Type of Action	Comments
	CI-28	2.8mm-3.0mm	Syringe	Single-handed delivery Disposable
	CI-26	2.6mm	Syringe	Single-handed delivery Disposable

TORIC MARKERS:

Inserter Design	Product Number	Overall Length	Material	Comments
Storz Toric Bubble Marker 	E2431	99mm, 3.9 inches	Stainless Steel	During the "clean" portion of the procedure, the bubble level is positioned below the cornea while the exterior of the ring is aligned to the limbus. The marker provides marks at the horizontal axis and at 90°. Not available in Canada.
Whitman Axis Marker 	E2430	81mm, 3.2 inches	Stainless Steel	Marked with a sterile marking pen, these blades are aligned under the microscope with limbal markings made pre-operatively at the 180° axis, or 3 and 9 o'clock. The instrument is pressed onto the eye surface, leaving two long, radial marks in the mid periphery of the cornea. The toric alignment markings on the IOL can then be aligned with these radial marks. Not available in Canada.

*A-Constants and ACD are estimates only. It is recommended that each surgeon develop his or her own values.

enVista® IOL

- The enVista IOL had no glistenings reported at any time in controlled clinical study[9,10]
- Features a defocus tolerant, advanced aberration-free optic which enables predictability in achieving desired refractive outcomes[8,10,11]
  - Aberration-free optic provides a desirable compromise between depth of field and image quality[12]
  - Optic is not sensitive to misalignment or decentration[13]
- Potential for increased resistance to scratching or abrasions[14]

enVista IOL:

Lens Design	Model Number	Optic Design	Optic Size	Length	Haptics	Applanation Suggested A-constant ACD-constant Surgeon Factor*	Optical Biometry Suggested A-constant ACD-constant Surgeon Factor*	Other Features	Diopter Range
	MX60E	Aspheric, aberration-free, biconvex	6mm	12.5mm	Modified C, fenestrated	118.7 5.37mm 1.62mm	119.1 5.61mm 1.85mm	Glistening-free hydrophobic acrylic material Refractive index: 1.54 UV absorbing Sharp 360° square posterior edge	0 to +10 D in 1.0-D increments +10 to +30 D in 0.5-D increments +30 to +34 D in 1.0-D increments

enVista IOL LENS POSITIONER:

Positioner Design	Product Number	Overall Length	Comments
	E4926	112mm	Designed specifically to position the enVista IOL into the BLIS-X1 cartridge for delivery Once enVista lens is placed into the BLIS-X1 cartridge with the leading haptic tucked on top of the optic, the lens positioner can be used to catch the rear optic and advance the lens forward

enVista INSERTERS:

Inserter Design	Product Number	For Inserting Lens Model	Recommended Incision Size	Type of Action	Comments
	BLIS-R1 (Handpiece) BLIS-X1 (Cartridge)	MX60E 0 to +34 D with X1 cartridge	2.2mm-2.6mm	Twist Mechanism	Reusable, twist mechanism designed for controlled delivery Sterilization required
	INJ100	MX60E	2.2mm-2.6mm	Plunger	Single-handed delivery Disposable

*A-Constants and ACD are estimates only. It is recommended that each surgeon develop his or her own values.

AKREOS® IOLs

- Akreos AO provides quality of vision with advanced optics[15-17]
  - Manufactured to have a high degree of flexibility to allow for an incision size as small as 1.8 mm[18]
  - Three lengths for excellent fit[19] and four-point haptic design for excellent centration and stability[19,20]
  - An equi-biconvex design which has been shown in other IOLs to minimize reflected light compared to an unequal biconvex design[21]

AKREOS® MICS IOL:

Lens Design	Model Number	Optic Design	Optic Size	Length	Haptics	Applanation Suggested A-constant ACD-constant Surgeon Factor*	Optical Biometry Suggested A-constant ACD-constant Surgeon Factor*	Other Features	Diopter Range
	MI60L	Aspheric, aberration-free, biconvex	5.6mm 22.5 to 30.0 D 6.0mm 15.5 to 22.0 D 6.2mm 0.0 to 15.0 D	10.5mm 22.5 to 30.0 D 10.7mm 15.5 to 22.0 D 11.0mm 0.0 to 15.0 D	4 haptics	118.4 5.20mm 1.45mm	119.1 5.61mm 1.85mm	Hydrophilic acrylic material Refractive index: 1.46 UV absorbing 360° posterior square edge	0 to +9 D in 1.0-D increments +10 to +30 D in 0.5-D increments

AKREOS MICS IOL INSERTER:

Inserter Design	Product Number	For Inserting Lens Model	Recommended Incision Size**	Type of Action	Comments
	VIS100	MI60L	1.8mm-2.4mm	Plunger	Single-handed delivery Disposable

AKREOS AO IOL:

Lens Design	Model Number	Optic Design	Optic Size	Length	Haptics	Applanation Suggested A-constant ACD-constant Surgeon Factor*	Optical Biometry Suggested A-constant ACD-constant Surgeon Factor*	Other Features	Diopter Range
	AO60	Aspheric, aberration-free, biconvex	6.0mm 10.0 to 30.0 D 6.2mm 0.0 to 9.0 D	10.5mm 22.5 to 30.0 D 10.7mm 15.5 to 22.0 D 11.0mm 0.0 to 15.0 D	4 haptics	118.0 4.96mm 1.22mm	118.5 5.26mm 1.51mm	Hydrophilic acrylic material Refractive index: 1.46 UV absorbing 360° posterior square edge	0 to +9 D in 1.0-D increments +10 to +30 D in 0.5-D increments

AKREOS AO IOL INSERTERS:

Inserter Design	Product Number	For Inserting Lens Model	Recommended Incision Size**	Type of Action	Comments
	VIS100	AO60	1.8mm-2.4mm	Plunger	Single-handed delivery Disposable
	AI-28	AO60	2.8mm-3.0mm	Plunger	Single-handed delivery Disposable
	INJ100	AO60	2.2mm-2.6mm	Plunger	Single-handed delivery Disposable

*A-Constants and ACD are estimates only. It is recommended that each surgeon develop his or her own values.
**Incision sizes are estimates. Actual sizes may vary due to incision construction, location, and any stretching that may have occurred.

SOFPORT® SYSTEM

- Unfolds gently and controllably within the eye[22]
- SofPort AO is neutral to the induction of positive or negative spherical aberrations and does not induce significant high-order aberrations[23]
- SofPort AO optic is less sensitive to the effects of misalignment or decentration than non-AO lenses[23]
- Designed with a sharp 360° square posterior edge, a feature that has been shown to result in reduced PCO compared to round edged IOLs[24]

SOFPORT® IOLs:

Lens Design	Model Number	Optic Design	Optic Size	Length	Haptics	Applanation Suggested A-constant ACD-constant Surgeon Factor*	Optical Biometry Suggested A-constant ACD-constant Surgeon Factor*	Other Features	Diopter Range
	LI61AO	Aspheric, aberration-free, biconvex	6.0mm	13.0mm	Modified C 5° angle	118.0 5.0mm 1.22mm	118.7 5.40mm 1.62mm	360° square edge Blue PMMA haptics Refractive index: 1.43	0 to +4 D in 1.0-D increments +5 to +30 D in 0.5-D increments +31 to +34 D in 1.0-D increments
	LI61SE	Biconvex	6.0mm	13.0mm	Modified C 5° angle	118.0 5.0mm 1.22mm	118.7 5.40mm 1.62mm	360° square edge Blue PMMA haptics Refractive index: 1.43	0 to +4 D in 1.0-D increments +5 to +30 D in 0.5-D increments

SOFPORT SYSTEM INSERTERS:

Inserter Design	Product Number	For Inserting Lens Model	Recommended Incision Size**	Type of Action	Comments
	EZ-28V	LI61AO LI61SE	2.8mm-3.0mm	Syringe	Single-handed delivery Disposable
	EZ-24	LI61AO LI61SE	2.4mm-2.6mm	Syringe	Single-handed delivery Disposable

SINGLE-PIECE PMMA IOLS:

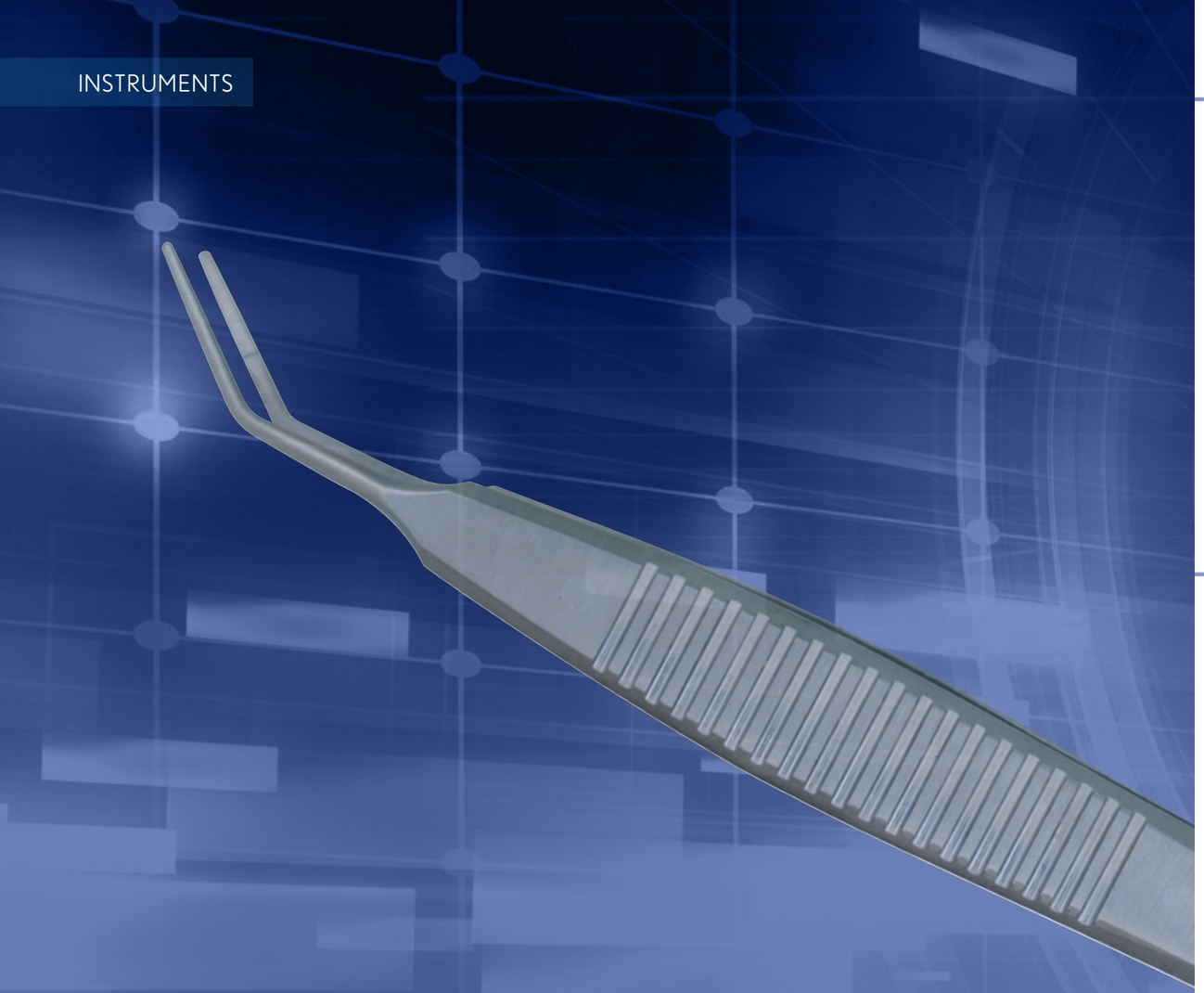
Posterior Chamber

Lens Design	Model Number	Optic Design	Optic Size	Length	Haptics	Applanation Suggested A-constant ACD-constant*	Other Features	Diopter Range
	P359UV	Spherical, equiconvex	5.5mm	12.25mm	Modified C Double-flat Step-vaulted 2.4° angle	118.0 4.96mm	EZE-FIT Extended diopter range available	0 to +45 D in 1.0-D increments +10 to +30 D in 0.5-D increments
	EZE-60	Spherical, equiconvex	6.0mm	12.75mm	Modified C Double-flat Step-vaulted 3° angle	118.1 5.02mm	EZE-FIT	+10 to +30 D in 0.5-D increments

Anterior Chamber

Lens Design	Model Number	Optic Design	Optic Size	Length	Haptics	Applanation Suggested A-constant ACD-constant*	Other Features	Diopter Range
	S122UV	Spherical, equiconvex	6.0mm	12.50mm	Modified S Step-vaulted 4.4° angle	115.8 3.68mm	4-point fixation White-to-white range 10.0mm to 11.49mm	+5 to +30 D in 0.5-D increments
	L122UV	Spherical, equiconvex	6.0mm	13.75mm	Modified S Step-vaulted 3.7° angle	115.8 3.68mm	4-point fixation White-to-white range 11.5mm to 12.25mm	+5 to +30 D in 0.5-D increments

*A-Constants and ACD are estimates only. It is recommended that each surgeon develop his or her own values.
**Incision sizes are estimates. Actual sizes may vary due to incision construction, location, and any stretching that may have occurred.



INSTRUMENTS

Bausch + Lomb designs, manufactures, and distributes a full array of world-renowned Storz® ophthalmic instruments. To view the online catalog of Storz Ophthalmics products, visit www.storzeye.com.

storz®
Ophthalmic
Instruments

INSERTER LOADING FORCEPS:

Product	Tip Detail	Product Number	Description
		E1815 AB	**Bechert-McPherson angled tying forceps** Angled 45° shafts with 10mm tying platform Serrated handle with dull finish Overall length: 83mm, 3.3 inches
		SUE04	**McPherson tying forceps** Angled jaws and 4.0mm tying platform May be used for IOL cartridge loading Packaged sterile; 8 per box. Single-use. Overall length: 98mm, 3.8 inches
		ET2912	**enVista IOL Loading Forceps** This instrument is designed to load the enVista® IOL into the lens cartridge of the Bausch + Lomb Injector System (BLIS). Polished tips designed to protect the lens surface from scratching. Overall length: 114mm, 4.5 inches Materials: Titanium

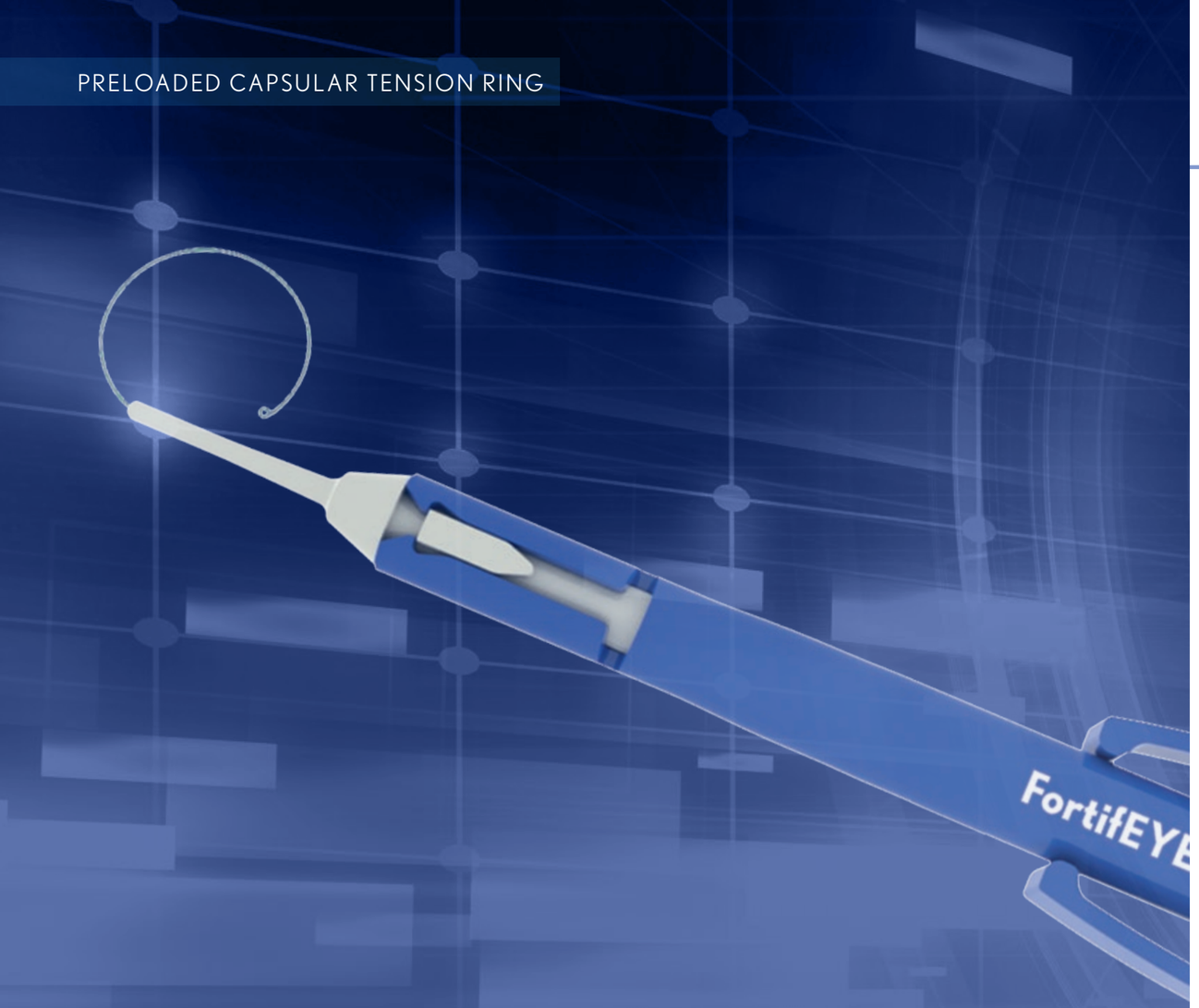
IOL MANIPULATORS:

Product	Tip Detail	Product Number	Description
		E4926	Designed specifically to position the enVista IOL into the BLIS-X1 cartridge for delivery. Once enVista lens is placed into the BLIS-X1 cartridge with the leading haptic tucked on top of the optic, the lens positioner can be used to catch the rear optic and advance the lens forward. Overall length: 112mm, 4.4 inches
		E0545	**Sinskey iris and IOL hook** 0.2mm hook with straight shaft and flat serrated handle Used to mark the visual axis Polished finish Overall length: 118mm, 4.6 inches
		E0571	**Lester lens manipulator** Straight shaft with 0.2mm hourglass shape tip Round knurled handle with dull finish Overall length: 115mm, 4.5 inches
		E0579	**Maloney no-hole manipulator** Teardrop-shaped tip with post Round knurled handle with dull finish Overall length: 124mm, 4.75 inches
		E0572	**Fenzl insertion hook** Angled 45°, 10mm shaft with 0.2mm tip Round knurled handle with dull finish Overall length: 117mm, 4.6 inches

CAPSULEGUARD® IA HANDPIECE:

Product	Tip Detail	Product Number	Description
		85912ST	**CapsuleGuard I/A Handpiece Stellaris® System Straight** This instrument features a flexible straight-tip design for effective cortical removal. Recommended for use in a 2.2 to 2.8mm incision, the smooth irrigation and aspiration ports eliminate sharp edges for reduced risk of capsule rupture. The silicone tip design facilitates cortex removal, capsule polishing, viscoelastic removal, and IOL manipulation in the capsular bag, and the semitransparent silicone sleeve provides enhanced visualization.

PRELOADED CAPSULAR TENSION RING



FortifEYE® CTR

- Simplifies capsular tension ring (CTR) implantation by preloading the implant eyelet into the device, allowing for safe, immediate preparation and use
- Sterile, non-optical implants made up of one continuous piece of polymethyl methacrylate (PMMA), available in both clockwise (right-handed) and counterclockwise (left-handed) implantation options
- For cataract patients with conditions associated with weak or partially absent zonules, such as:[25]
  - Primary zonular weakness (e.g., Marfan's Syndrome)
  - Secondary zonular weakness (e.g., trauma or vitrectomy)
  - Zonulysis
  - Pseudoexfoliation
  - Marchesani's Syndrome (or Weill-Marchesani's Syndrome)

FortifEYE CTR:

Injector Design	Type	Size (expanded, compressible)	Bulbus Lenth	Material
	CTR10R	12.3mm, 10.0mm	< 28mm	PMMA
	CTR10L	12.3mm, 10.0mm	< 28mm	PMMA
	CTR11R	13.0mm, 11.0mm	24 – 28mm	PMMA
	CTR11L	13.0mm, 11.0mm	24 – 28mm	PMMA
	CTR12R	14.5mm, 12.0mm	> 28mm	PMMA
	CTR12L	14.5mm, 12.0mm	> 28mm	PMMA

AMVISC® PLUS AND OCUCOAT VISCOELASTIC

- Amvisc Plus features viscosity 38% greater than Amvisc at 1/sec shear rate; cohesive properties ensure continuous space maintenance while providing corneal endothelial cell protection[26]
- Amvisc is a general-purpose, high-viscosity viscoelastic that enables excellent chamber maintenance during lens insertion and removal[26]
- OcuCoat delivers excellent protection of endothelial cells, an unobstructed view of the surgical field, and is easily removed from the anterior chamber[27]

BAUSCH + LOMB VISCOELASTICS:

AMVISC PLUS: FOR ALL STAGES OF CATARACT SURGERY

Product Number	Description	Dispensed
60081L	1.6% sodium hyaluronate (HA) concentration 0.8-mL preloaded sterile glass syringe with finger grip for comfort 27-gauge disposable cannula, 32° angle Syringe requires assembly of the cannula only Not made with natural rubber latex	Singles

Right for Combination Procedures

AMVISC: THE GENERAL-PURPOSE VISCOELASTIC

Product Number	Description	Dispensed
59081L	High-viscosity, 1.2% sodium hyaluronate (HA) concentration 0.8-mL preloaded sterile glass syringe with finger grip for comfort 27-gauge disposable cannula, 32° angle Syringe requires assembly of the cannula only Not made with natural rubber latex	Singles

Ideal for High-Volume, Small-Incision Surgery

OCUCOAT: EXCELLENT LUBRICATION QUALITIES

Product Number	Description	Dispensed
CC050S	2% hydroxypropyl methylcellulose (HPMC) viscoelastic solution 1.0-mL preloaded sterile glass syringe with finger grip for comfort 25-gauge disposable cannula, 32° angle Syringe requires assembly of the cannula only Not made with natural rubber latex	Singles
CC065S	2% hydroxypropyl methylcellulose (HPMC) viscoelastic solution 1.0-mL preloaded sterile glass syringe with finger grip for comfort 25-gauge disposable cannula, 32° angle Syringe requires assembly of the cannula only Not made with natural rubber latex	6 per box

Notes

TRULIGN® Toric Posterior Chamber Intraocular Lenses

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. 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 outlined in 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 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.

Crystalens® Posterior Accommodating Intraocular Lenses

INDICATIONS FOR USE: The Crystalens® Posterior 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:** 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. 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). 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 outlined in the Crystalens AO 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 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.

enVista® Toric Intraocular Lenses

INDICATIONS: Indicated for primary implantation in the capsular bag of the eye in adult patients for the visual correction of aphakia in adult patients 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 weight 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 (110°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. **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.

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

enVista® Intraocular Lenses

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 benefit/risk ratio before implanting a lens in a patient. **PRECAUTIONS:** Do not resterilize this intraocular lens by any method. Do not store lenses at temperatures over 43°C (110°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 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. **ATTENTION:** Reference the Directions for Use labeling for a complete listing of indications and important safety information.

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

Akreos® Intraocular Lens 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.

SofPort® Intraocular Lenses

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 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 lens 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.

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UV Absorbing Posterior Chamber Intraocular Lenses

INDICATIONS: Bausch + Lomb ultraviolet absorbing lenses are indicated for primary implantation for the visual correction of aphakia with adult patients where a cataractous lens has been removed by extracapsular extraction methods. **WARNINGS:** Before implanting UV Absorbing Posterior Chamber 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 of intraocular lens implantation has not been substantiated in patients with pre-existing ocular conditions. Physicians should therefore consider lens implantation only if alternatives are deemed unsatisfactory to meet the needs of the patient. The long-term effects of intraocular lens implantation have not been determined. The safety and effectiveness of this lens, if placed in the anterior chamber, has not been established. **PRECAUTIONS:** Do not store the lens in direct sunlight or at temperatures greater than 110° F. Do not soak or rinse lenses in solutions other than balanced salt solution or equivalent. Do not resterilize. **ADVERSE EVENTS:** Possible complications accompanying IOL implantation may occur, but are not limited to the following: Hypopyon, intraocular infection, acute corneal decompression, lens removal with or without replacement, lens repositioning. **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.

Anterior Chamber Intraocular Lenses

INDICATIONS: Lenses in the Bausch + Lomb Surgical Model 122UV series are intended to be used for the visual correction of aphakia with adult patients where a cataractous lens has been removed by: Primary intracapsular cataract extraction, primary extracapsular cataract extraction, primary extracapsular cataract extraction when there is a structural reason where the anterior chamber lens would be the preferred one, prior surgery such that a secondary implant procedure is required. **WARNINGS:** Before implanting Anterior Chamber 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. Potential complications may include, but are not limited to lens dislocation and corneal endothelial damage. Some adverse events have been associated with the implantation of intraocular lenses including but not limited to hypopyon and acute corneal compensation. The safety of intraocular lens implantation has not been substantiated in patients with pre-existing ocular conditions. Physicians should therefore consider lens implantation only if alternatives are deemed unsatisfactory to meet the needs of the patient. The long-term effects of intraocular lens implantation have not been determined. **PRECAUTIONS:** Do not store the lens in direct sunlight or at temperatures greater than 110° F. Do not soak or rinse lenses in solutions other than balanced salt solution or equivalent. Do not resterilize. **ADVERSE EVENTS:** Possible complications accompanying IOL implantation may occur, but are not limited to the following: Hypopyon, intraocular infection, acute corneal decompensation, repair retinal detachment, reposition lens, resuture graft, corneal transplant, vitrectomy. **ATTENTION:** Refer to the Directions for Use labeling for a complete listing of indications, warnings and precautions, clinical trial information, etc.

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FortifEYE® CTR

INDICATIONS: For the stabilization of the crystalline lens capsule in the presence of weak or partially absent zonules in adult patients undergoing cataract extraction with intraocular lens implantation. Conditions associated with weak or partially absent zonules may include primary zonular weakness (e.g., Marfan syndrome), secondary zonular weakness (e.g., trauma or vitrectomy), cases of zonulysis, cases of pseudoexfoliation, and cases of Marchesani's syndrome. **CONTRAINDICATIONS:** The capsular tension ring should not be used in children 12 years of age or younger since this device is contraindicated in eyes still growing. The FortifEYE® CTR is contraindicated for patients with perforated or damaged capsules. **WARNINGS:** The effect of the capsular tension ring on the progression of zonular instability over time is unknown at this date. Eyes with pseudoexfoliation syndrome and decreased anterior chamber depth exhibit a greater likelihood of zonular instability at the time of surgery and an increased probability of intraoperative complications. Since the number of eyes with zonular dehiscence greater than 50% was very low (13/316, 4%), no scientific conclusions can be drawn regarding the probable visual outcome in this population, especially in the presence of other preoperative pathologies. The physician should use his/her own discretion in utilizing the FortifEYE® CTR in these cases. **PRECAUTIONS:** Do not use the Bausch + Lomb FortifEYE® CTR if the sterilized package is open or damaged. The capsular tension ring should not be used after the expiration date indicated. Do not re-sterilize the implant or the injector by any method. Do not reuse the implant or the injector. Rinse the implant only with sterile intraocular rinsing solutions such as sterile Ringer's solution or sterile balanced salt solution. Store only at room temperature. Do not expose to extreme temperatures. The injector must only be used with the implant provided with it. **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.

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, 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 from freezing. **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.

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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 thereby allows for more efficient manipulation with less trauma to the corneal endothelium and other ocular tissues. **PRECAUTIONS:** Discard unused contents of OcuCoat syringe after each use. Do not resterilize. 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:** 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. **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.

IOLs AND INSERTION SYSTEMS

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Phone: 1-800-338-2020 (5:00 AM to 5:00 PM Pacific Time)
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