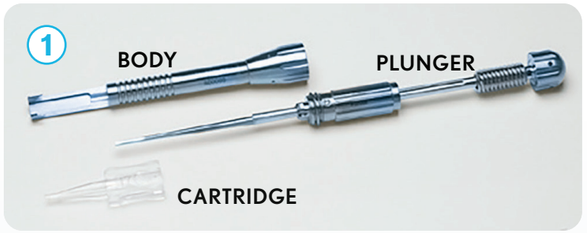
BLIS® Inserter

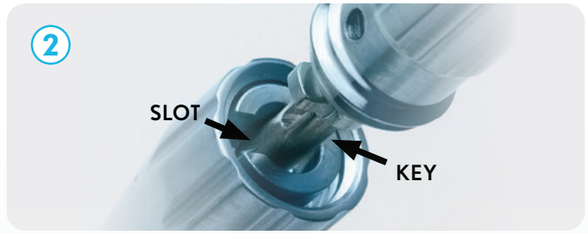
Loading Guide

enVista Aspire™ and
enVista Aspire™ Toric IOLs
with the BLIS Delivery System

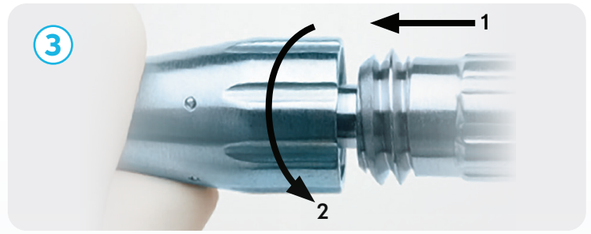
Use sterile garments and work in a sterile field when preparing Bausch + Lomb delivery systems and delivering IOLs.



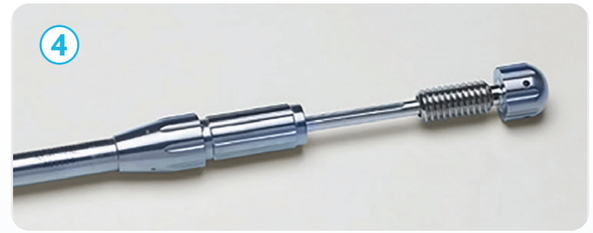
BLIS Injector System consists of a reusable hand piece (body and plunger) and a sterile single-use disposable cartridge. The reusable hand piece must be sterilized prior to use according to instructions provided in the Directions For Use.



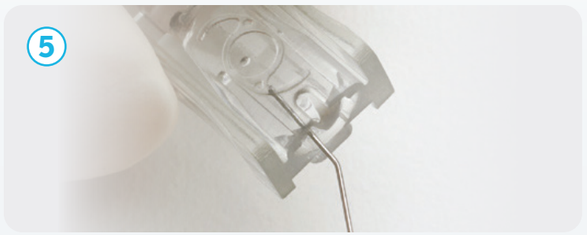
Insert the plunger into the hand piece body and align the protruding key on the plunger to the corresponding slot on the handpiece body.



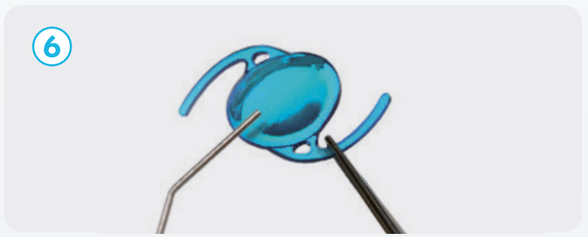
1 - Once the plunger is inserted into the handpiece body.
2 - Twist the retaining collar to firmly connect the two pieces.



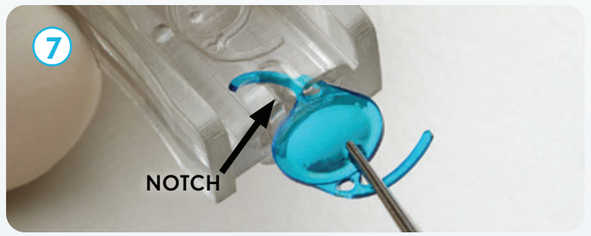
Retract the plunger all the way and place the handpiece in the sterile field.



Hold the cartridge with the IOL diagram facing up. Fill the entire inside with a Bausch+Lomb recommended viscoelastic. Folding and compression of the lens should be initiated just prior to insertion and delivery into the eye. Avoid excess dwell time(> 3 minutes) between loading and lens insertion to minimize the potential for delivery complications including lens damage.



Rinse the entire IOL with sterile balanced salt solution or sterile normal saline. Examine the IOL thoroughly to ensure particles have not become attached to it, and examine the lens optical surfaces for other defects. The IOL may be soaked in sterile balanced salt solution until ready for implantation.



Grasp the edge of the IOL optic with non-serrated forceps and orient the IOL to match the diagram on the cartridge. Do not grasp the trailing haptic. As you advance the IOL into the cartridge, engage the leading haptic with the notch in the cartridge to fold the haptic on top of the optic.

Slowly advance the IOL into the cartridge to the edge of the trailing fenestration hole until the leading haptic is fully folded on top of the optic.

Please see Directions for Use for complete listing of indications, contraindications, warnings, precautions and use information.

enVista ASPIRE HYDROPHOBIC ACRYLIC IOL | enVista ASPIRE TORIC HYDROPHOBIC ACRYLIC IOL

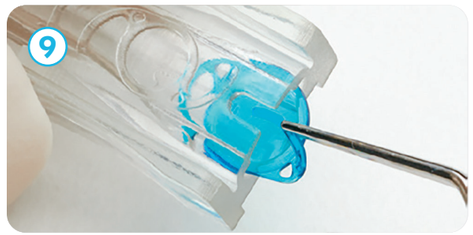
BAUSCH + LOMB

BLIS Inserter System

BLIS-R1

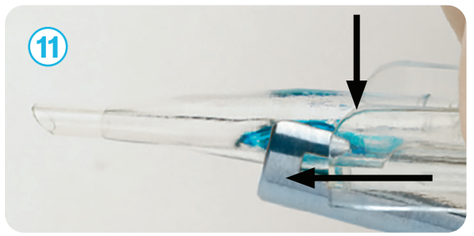
BLIS Inserter System

FOR INSERTING LENS MODEL EA & ETA
RECOMMENDED INCISION SIZE BLIS-X1 2.4MM OR LESS
TYPE OF ACTION Screw-type
COMMENTS Controlled delivery. Reusable. Sterilization required.

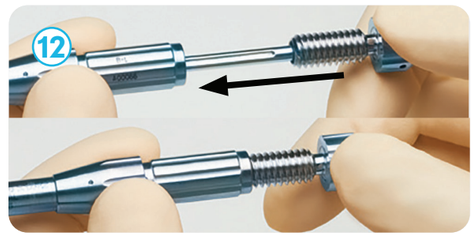


Push the optic down onto the base of the cartridge using non-serrated forceps then fold the trailing haptic on top of the optic and into the cartridge.

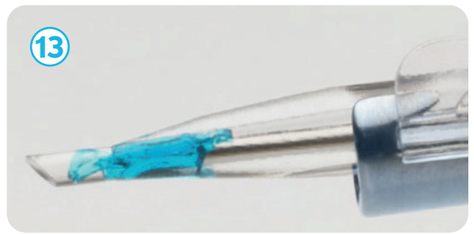
Release the trailing haptic. With non-serrated forceps advance the IOL past the marker line, to ensure that the IOL is held in a folded position, by pushing on the haptic junction. Once the IOL is past the line, ensure the IOL and haptics remain in place after retracting the forceps until it is ready to be delivered.



Before inserting the loaded cartridge into the hand piece, make sure the plunger is pulled all the way back.
1 - Insert the cartridge into the hand piece slots with the IOL diagram facing up and the tip bevel facing down.
2 - Push down firmly on the back end of the cartridge and all the way forward until it snaps securely into place.



Grasp the hand piece body with one hand and advance the plunger with the other hand. Visually confirm that the plunger tip correctly engages the IOL optic and continue to advance the plunger until it bottoms out (do not turn knob to engage threads). The IOL is now in the hand-off position.



To deliver the IOL, insert the cartridge tip into the incision with the IOL diagram facing up and the tip bevel facing down. Slowly rotate the plunger knob clockwise to advance the plunger. Ensure that the plunger tip engages the IOL , the haptics remain tucked, and the plunger remains behind the IOL throughout the entire delivery until the IOL is fully released into the eye.

1. enVista directions for use.
2. Altmann GE, Nichamin LD, Lane SS, Pepose JS. Optical performance of 3 intraocular lens designs in the presence of decentration. J Cataract Refract Surg. 2005 Mar;31(3):574-85
3. Packer M. enVista hydrophobic acrylic intraocular lens: glistening free. Expert Review of Ophthalmology. 2015; 10:5,415-420.

Indications & Important Safety Information for enVista Aspire™ and enVista Aspire™ Toric IOL

INDICATIONS: The enVista Aspire™ hydrophobic acrylic IOL (non-preloaded model EA) is indicated for primary implantation in the capsular bag of the eye in adult patients for the visual correction of aphakia following removal of a cataractous lens.

The enVista Aspire™ toric hydrophobic acrylic IOL (non-preloaded model ETA) is indicated for primary implantation in the capsular bag of the eye in adult patients for the visual correction of aphakia and corneal astigmatism following the removal of a cataractous lens for improved uncorrected distance vision.

DEVICE DESCRIPTION: The enVista Aspire and enVista Aspire toric IOLs use an optical modification of the posterior aspheric surface to create a small continuous increase in IOL power within the central 1.5 mm diameter to slightly extend the depth of focus. However, clinically meaningful extension of the depth of focus has not been demonstrated in clinical trials.

WARNINGS: enVista Aspire and enVista Aspire toric IOLs: Physicians considering IOL implantation under any of the following circumstances should weigh the potential risk/benefit ratio: (1) Recurrent severe anterior or posterior segment inflammation or uveitis; (2) Patients in whom the IOL may affect the ability to observe, diagnose, or treat posterior segment diseases; (3) Surgical difficulties at the time of cataract extraction, which might increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss); (4) A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible; (5) Circumstances that would result in damage to the endothelium during implantation; (6) Suspected microbial infection; (7) Patients in whom neither the posterior capsule nor zonules are intact enough to provide support. enVista Aspire toric IOL only: Rotation of the IOL away from the intended axis can reduce its astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. If necessary, IOL positioning should occur prior to capsule fibrosis and IOL encapsulation.

PRECAUTIONS: Neither the safety and effectiveness, nor the effects of the Aspire IOL optical design on depth of focus, contrast sensitivity, and subjective visual disturbances (glare, halo, etc.) have been evaluated clinically. MTF testing of the Aspire IOL optical design (used in model ETA) may aid the surgeon in understanding the theoretical image quality expected with the Aspire IOL compared to the enVista monofocal IOL MX60E. However, these do not fully assess all aspects of clinical difficulties under all conditions. Surgeons must weigh the potential benefits of the modified optical design of the Aspire IOL (model ETA) against the potential for risks associated with a degradation in vision quality and the lack of clinical data to characterize the impact of the Aspire IOL optical design on contrast sensitivity and subjective visual disturbance. These considerations may be especially relevant to patients with certain pre-existing ocular conditions (prior corneal refractive surgery, irregular corneal astigmatism, severe corneal dystrophy, macular disease, optic nerve atrophy, etc.) or intraoperative conditions (posterior capsular rupture, complications in which the IOL stability could be compromised, inability to place IOL in capsular bag, etc).

The safety and effectiveness of the IOL have not been substantiated in patients with pre-existing ocular conditions and intraoperative complications. Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting an IOL in a patient with one or more of these conditions. Physicians considering IOL implantation in such patients should explore the use of alternative methods of aphakic correction and consider IOL implantation only if alternatives are deemed unsatisfactory in meeting the needs of the patient.

Patients with preoperative problems, such as corneal endothelial disease, abnormal cornea, macular degeneration, retinal degeneration, glaucoma, and chronic drug miosis may not achieve the visual acuity of patients without such problems. The physician must determine the benefits to be derived from IOL implantation when such conditions exist.

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. 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 these devices to sale by or on the order of a physician.

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

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