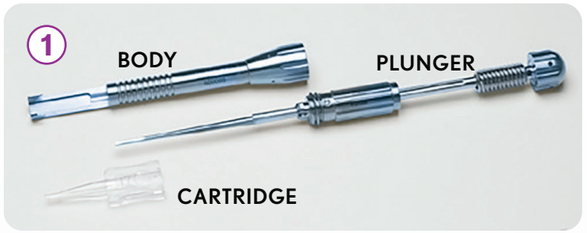
BLIS® Inserter

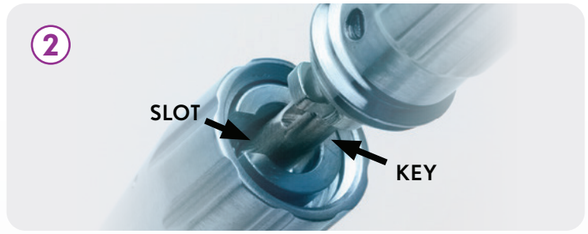
Loading Guide

enVista IOL with the
BLIS Delivery System

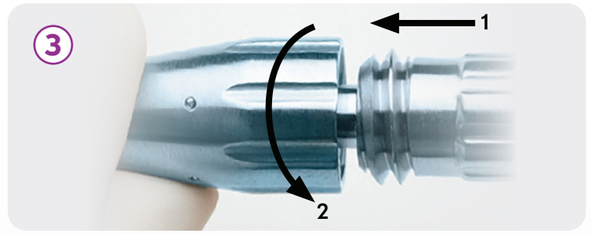
Use sterile garments and work in a sterile field when preparing Bausch + Lomb delivery systems and delivering IOLs.



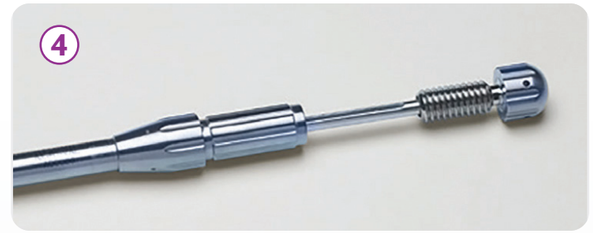
BLIS Injector System consists of a reusable hand piece (body and plunger) and a sterile single-use disposable cartridge. The reusable hand piece must be sterilized prior to use according to instructions provided in the Directions For Use.



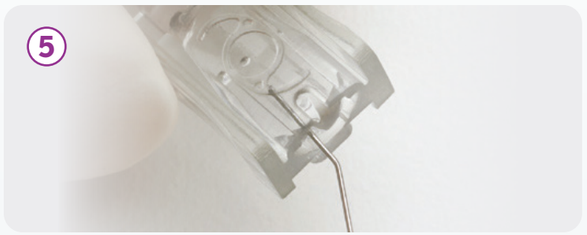
Insert the plunger into the hand piece body and align the protruding key on the plunger to the corresponding slot on the handpiece body.



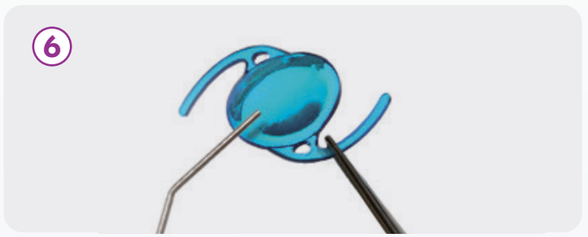
1 - Once the plunger is inserted into the handpiece body.
2 - Twist the retaining collar to firmly connect the two pieces.



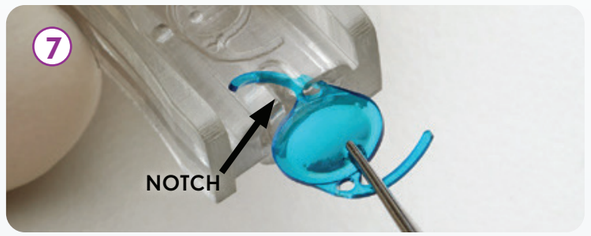
Retract the plunger all the way and place the handpiece in the sterile field.



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® HYDROPHOBIC ACRYLIC IOL | enVista® TORIC HYDROPHOBIC ACRYLIC IOL

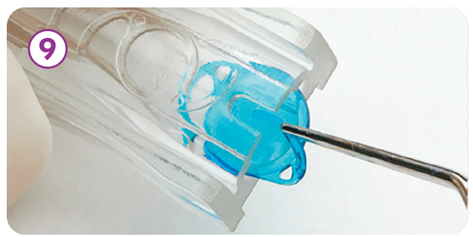
BAUSCH + LOMB

BLIS Inserter System

BLIS-R1

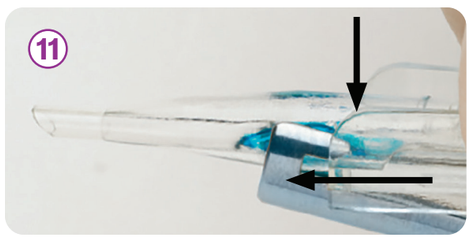
BLIS Inserter System

FOR INSERTING LENS MODEL MX60E & MX60ET
RECOMMENDED INCISION SIZE BLIS-X1 2.4MM OR LESS
TYPE OF ACTION Screw-type
COMMENTS Controlled delivery. Reusable. Sterilization required.

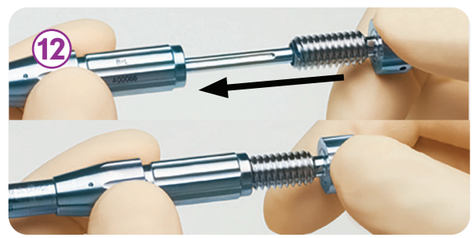


Push the optic down onto the base of the cartridge using non-serrated forceps then fold the trailing haptic on top of the optic and into the cartridge.

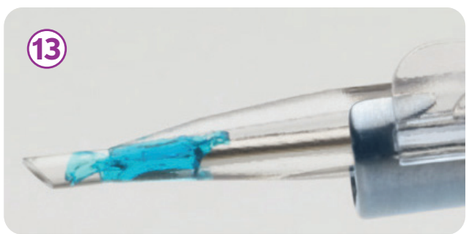
Release the trailing haptic. With non-serrated forceps advance the IOL past the marker line, to ensure that the IOL is held in a folded position, by pushing on the haptic junction. Once the IOL is past the line, ensure the IOL and haptics remain in place after retracting the forceps until it is ready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

INDICATIONS: The enVista one-piece hydrophobic acrylic IOL is indicated for primary implantation in the capsular bag of the eye in adult patients for visual correction of aphakia following removal of a cataractous lens for improved uncorrected distance vision. The enVista one-piece hydrophobic acrylic toric IOL is indicated for primary implantation in the capsular bag of the eye in adult patients for visual correction of aphakia and corneal astigmatism following removal of a cataractous lens for improved uncorrected distance vision

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 intra ocular lens by any method. Do not use if the packaging is damaged or if there are signs of leakage. Do not store lenses or inserter at temperatures over 43°C (109°F) or lower than 0°C (32°F). Do not reuse the lens or inserter. Safety and effectiveness of the enVista IOL and the enVista toric IOL have not been substantiated in patients with conditions and intraoperative complications as outlined in the 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, acute corneal decompensation, toxic anterior segment syndrome (TASS), 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.

BAUSCH + LOMB