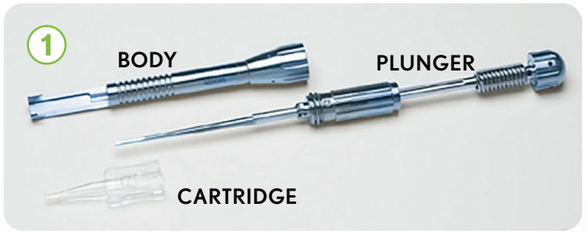
BLIS® Inserter

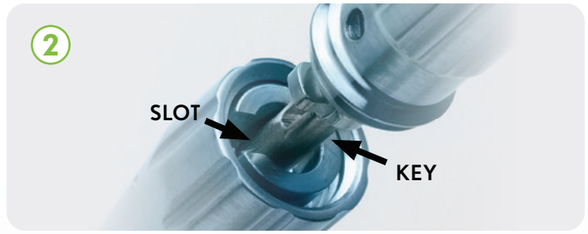
Loading Guide

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

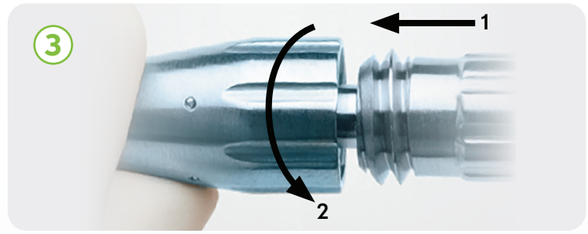
Use sterile garments and work in a sterile field when preparing Bausch + Lomb delivery systems and delivering IOLs.



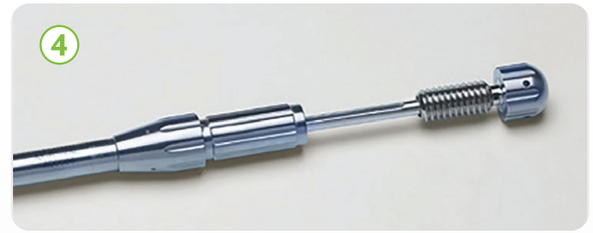
BLIS Injector System consists of a reusable hand piece (body and plunger) and a sterile single-use disposable cartridge. The reusable hand piece must be sterilized prior to use according to instructions provided in the Directions For Use.



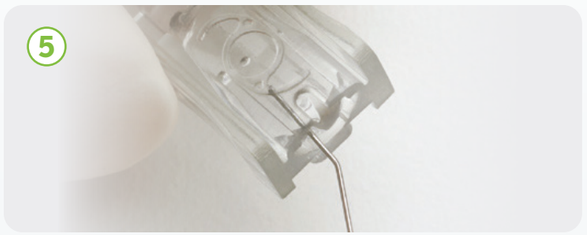
Insert the plunger into the hand piece body and align the protruding key on the plunger to the corresponding slot on the handpiece body.



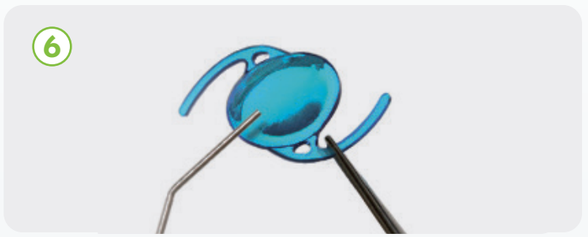
1 - Once the plunger is inserted into the handpiece body.
2 - Twist the retaining collar to firmly connect the two pieces.



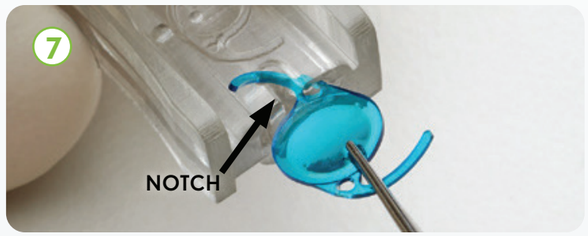
Retract the plunger all the way and place the handpiece in the sterile field.



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.

Note: IOL colored blue for visualization.

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

enVista ENVY HYDROPHOBIC ACRYLIC IOL | enVista ENVY TORIC HYDROPHOBIC ACRYLIC IOL

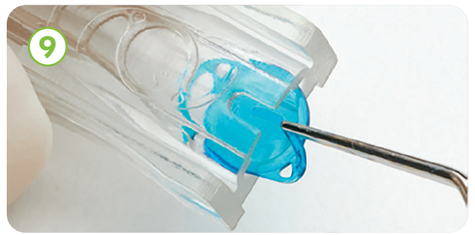
BAUSCH + LOMB

BLIS Inserter System

BLIS-R1

BLIS Inserter System

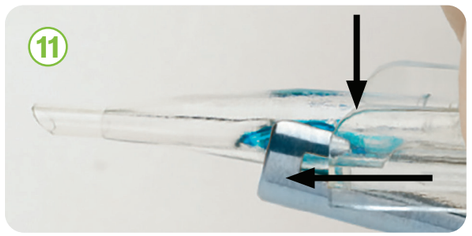
FOR INSERTING LENS MODEL EN & ETN
RECOMMENDED INCISION SIZE 2.2MM–2.4MM
TYPE OF ACTION Screw-type
COMMENTS Controlled delivery. Reusable. Sterilization required.



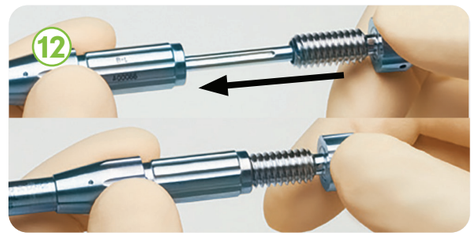
Push the optic down onto the base of the cartridge using non-serrated forceps then fold the trailing haptic on top of the optic and into the cartridge.

Note: IOL colored blue for visualization.

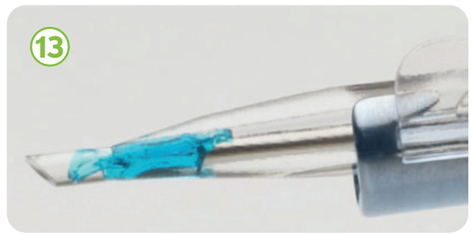
Release the trailing haptic. With non-serrated forceps advance the IOL past the marker line, to ensure that the IOL is held in a folded position, by pushing on the haptic junction. Once the IOL is past the line, ensure the IOL and haptics remain in place after retracting the forceps until it is ready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

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

INDICATIONS: The **enVista Envy™ hydrophobic acrylic IOL** is indicated for primary implantation in the capsular bag of the eye in adult patients for visual correction of aphakia with less than or equal to 1.0 D preoperative corneal astigmatism following removal of a cataractous lens to mitigate the effects of presbyopia by providing improved intermediate and near visual acuity, while maintaining comparable distance visual acuity to an aspheric monofocal IOL. The **enVista Envy™ toric hydrophobic acrylic 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 to mitigate the effects of presbyopia by providing improved intermediate and near visual acuity, while maintaining comparable distance visual acuity to an aspheric monofocal IOL.
WARNINGS/PRECAUTIONS: Physicians should weigh the potential risk/benefit ratio before implanting the enVista Envy lens under any of the circumstances or conditions outlined in the Instructions for Use labeling. Some visual disturbances may be expected due to the superposition of focused and unfocused multiple images. These may include some perceptions of halos or radial lines around point sources of light (starbursts) under nighttime conditions, glare, double vision, haziness and blurred vision. It is expected that, in a small percentage of patients, the observation of such phenomena will be annoying and may be perceived as a hindrance, particularly in low illumination conditions such as nighttime driving. As with other trifocal IOLs, there is a possibility that visual disturbances may be significant enough that the patient will request explant of the IOL. A reduction in contrast sensitivity as compared to a monofocal IOL may be experienced by some patients, therefore, patients implanted with trifocal IOLs should exercise caution when driving at night or in low light or poor visibility conditions. Care should be taken to achieve IOL centration as IOL decentration may result in patients experiencing visual disturbances or suboptimal vision under certain lighting conditions. The surgeon must target emmetropia to achieve optimal visual performance. Patients should be advised that unexpected outcomes could lead to continued spectacle dependence or the need for secondary surgical intervention (e.g., intraocular lens replacement or repositioning). Please provide a copy of the Patient Information Brochure, which can be found at www.bausch.com/IFU. Posterior capsule opacification (PCO) may significantly affect the vision of patients with multifocal IOLs earlier in its progression than patients with monofocal IOLs. This may be due to the reduced contrast sensitivity observed with multifocal IOLs.
Additional Precautions for Toric IOLs: The enVista Envy Toric IOL has not been evaluated in a clinical study. In general, astigmatism that is corrected with a higher cylinder power IOL can result in clinically significant residual astigmatism. The effect of residual astigmatism at distance, intermediate, and near was evaluated in a clinical study of patients who had been implanted with non-toric enVista Envy IOLs and were induced with cylinder power to simulate various levels of residual astigmatism. If a secondary surgical intervention is necessary to reposition the IOL, explantation should be considered as some patients may have recurrent or persistent issues related to rotational instability and misalignment.
CAUTION: Federal law restricts this device to sale by or on the order of a physician.
ATTENTION: See the Directions for Use for a complete listing of indications and important safety information.

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