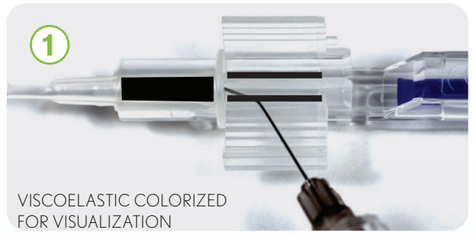
INJ100 Inserter

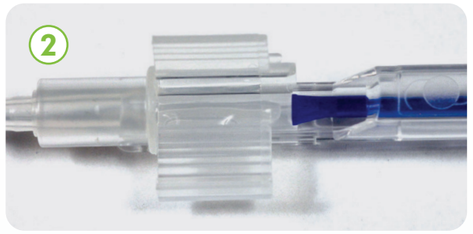
Loading Guide

enVista Envy™ and enVista Envy™ Toric IOL with the INJ100 Delivery System

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

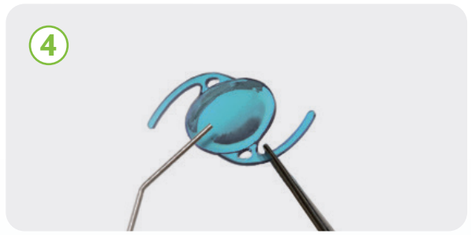


Entering from the side of the loading chamber, apply a recommended Bausch + Lomb viscoelastic directly into the conical tip. Then apply 2 thin lines into the lateral grooves within the loading chamber.

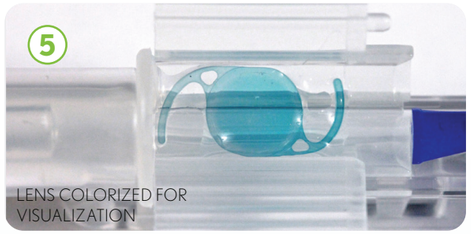


Advance the plunger tip to the outer edge of the cartridge wings as shown.

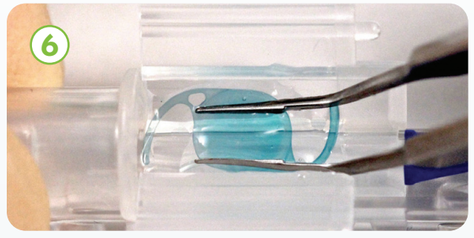
Open the vial containing the IOL and, using non-serrated forceps, remove the lens by grasping and carefully pulling it out vertically from the center slot at the top portion of the vial.



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.

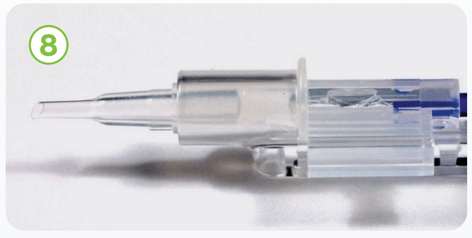


Position the lens in the middle of the loading chamber so that the anterior side is up and the lens is in a reverse-S orientation.

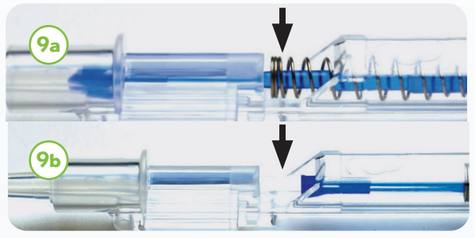


Apply slight downward pressure with the forceps to push the lens and haptics down to ensure they are properly seated under the grooves.

Slightly close the cartridge wings to hold the lens in place and then advance the plunger so that the haptics are compressed. The compression is correct when the haptic is pointing toward, but not touching, the optic.

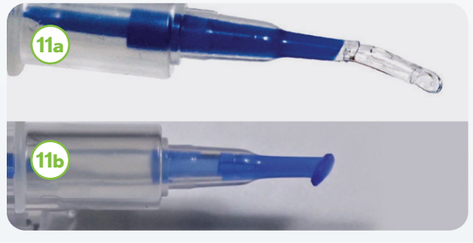


Next, close the cartridge wings together until the click-lock mechanism engages.



a) Push the lens into the conical tip by advancing the plunger until the spring contacts the outer edge of the cartridge wing.
b) Pull the plunger back all the way to visually confirm that the lens remains in the conical tip.

Push the plunger forward again to engage the lens. The lens is now ready for injection.



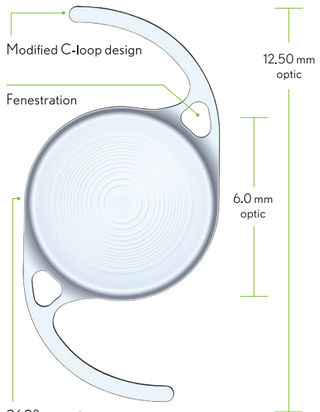
a) With the conical tip bevel facing down, inject the lens by applying continuous pressure on the plunger until the lens is fully expressed from the tip. Clockwise injector rotation will compensate for any lens rotation.
b) NB: Avoid advancing the plunger tip past the end of the cartridge tip in order to avoid 'mushrooming' of the silicone sponge inside the wound.

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

INJ100 Inserter System

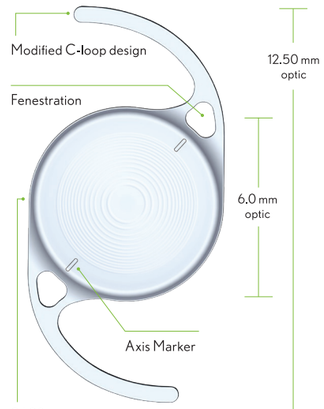


MODEL NUMBER	EN (non-preload)
MATERIAL	Hydrophobic Acrylic
OPTIC DESIGN	One-piece Aspheric, biconvex Anterior apodized diffractive Posterior refractive Posterior aspheric surface 1.6 D intermediate 3.1 D near
OPTIC SIZE	6mm
LENGTH	12.5mm
OPTIC EDGE DESIGN	Sharp 360° square posterior edge
HAPTICS	Modified C, fenestrated
REFRACTIVE INDEX	1.53 at 35° C
UV CUTOFF	389nm at 10% transmittance
OPTICAL BIOMETRY Optical A-constant* ACD Surgeon Factor	 119.5 5.84mm 2.06mm
APPLANATION BIOMETRY Applanation A-constant* ACD Surgeon Factor	 119.2 5.60mm 1.89mm
OTHER FEATURES	Glistening free
DIOPTER RANGE	+6 D to +10 D (1.0 D increments) +10 D to +34 D (0.5 D increments)

* A-constant values are suggested as a guideline. Physicians should calculate lens power based on optimization of their experience and preference with IOL technology.

INJ100 Inserter

FOR INSERTING LENS MODEL EN & ETN
RECOMMENDED INCISION SIZE 2.2mm-2.6mm
TYPE OF ACTION Silicone tip push-type
COMMENTS Single-handed delivery. Disposable.



MODEL NUMBER	ETN (non-preload)
MATERIAL	Hydrophobic Acrylic
OPTIC DESIGN	One-piece Aspheric, biconvex Anterior apodized diffractive Posterior refractive Posterior toricity 1.6 D intermediate 3.1 D near
OPTIC SIZE	6mm
LENGTH	12.5mm
OPTIC EDGE DESIGN	Sharp 360° square posterior edge
HAPTICS	Modified C, fenestrated
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OTHER FEATURES	Glistening free
DIOPTER RANGE	+6 D to +34 D (0.5 D increments)
CYLINDER POWERS IOL PLANE	1.25, 1.50, 2.00, 2.50, 3.00, 3.50, 4.25, 5.00, 5.75 D

* A-constant values are suggested as a guideline. Physicians should calculate lens power based on optimization of their experience and preference with IOL technology.

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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