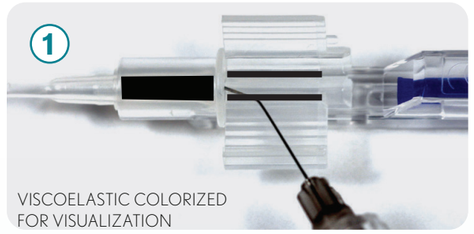
INJ100® Inserter

Loading Guide

enVista® and enVista® Toric IOL with the INJ100 Delivery System

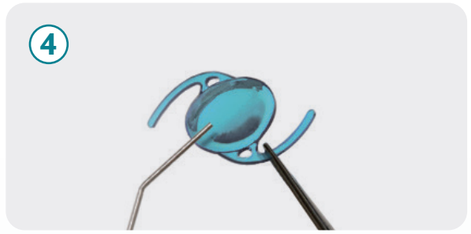
Use sterile garments and work in a sterile field when preparing Bausch + Lomb delivery systems and delivering IOLs.



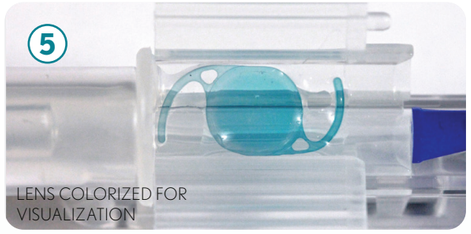
Entering from the side of the loading chamber, apply a recommended Bausch + Lomb viscoelastic directly into the conical tip. Then apply 2 thin lines into the lateral grooves within the loading chamber.

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

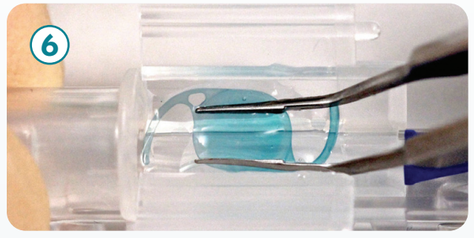
Open the vial containing the IOL and, using non-serrated forceps, remove the lens by grasping and carefully pulling it out vertically from the center slot at the top portion of the vial.



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.

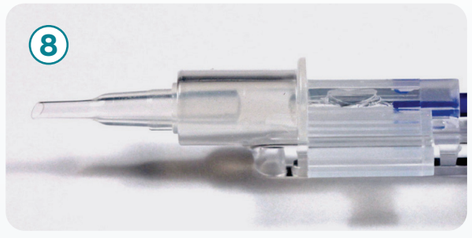


Position the lens in the middle of the loading chamber so that the anterior side is up and the lens is in a reverse-S orientation.

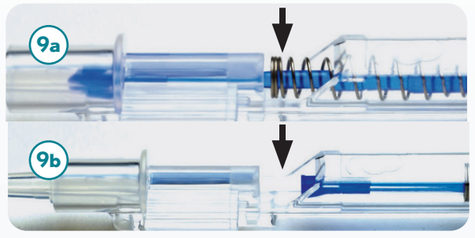


Apply slight downward pressure with the forceps to push the lens and haptics down to ensure they are properly seated under the grooves.

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.

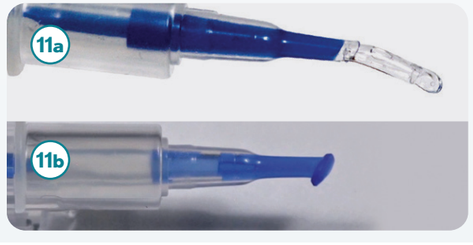


Next, close the cartridge wings together until the click-lock mechanism engages.



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® HYDROPHOBIC ACRYLIC IOL | enVista® TORIC HYDROPHOBIC ACRYLIC IOL

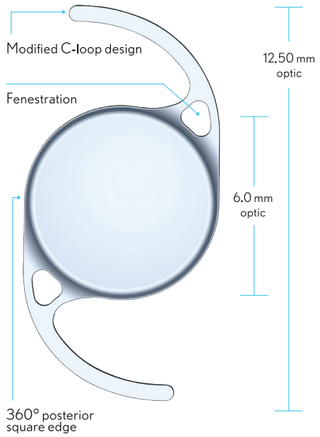
BAUSCH + LOMB

INJ100® Inserter System

VIEW VIDEO LOADING GUIDE

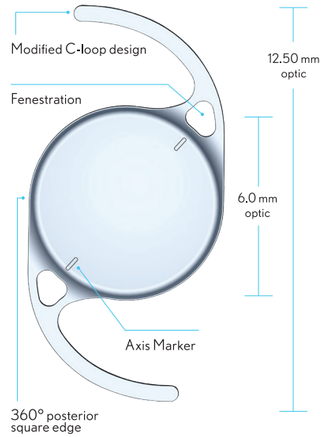
INJ100 Inserter

FOR INSERTING LENS MODEL EE & ETE
RECOMMENDED INCISION SIZE 2.2mm-2.6mm
TYPE OF ACTION Push-type
COMMENTS Silicone soft-tip. Single-handed delivery. Disposable.



MODEL NUMBER	EE (non-preload)
OPTIC DESIGN	One-piece Hydrophobic acrylic Aspheric, aberration-free, biconvex
OPTIC SIZE	6mm
LENGTH	12.5mm
HAPTICS	Modified C, fenestrated
OPTICAL BIOMETRY Optical A-constant* ACD Surgeon Factor	119.1 5.61mm 1.85mm
APPLANATION BIOMETRY Applanation A-constant* ACD Surgeon Factor	118.7 5.37mm 1.62mm
OTHER FEATURES	Glistening free Refractive index: 1.53 UV absorbing Sharp 360° square posterior edge
DIOPTER RANGE	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

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



MODEL NUMBER	ETE (non-preload)
OPTIC DESIGN	One-piece Hydrophobic acrylic Aspheric, aberration-free, biconvex, posterior-surface toric
OPTIC SIZE	6mm
LENGTH	12.5mm
HAPTICS	Modified C, fenestrated
OPTICAL BIOMETRY Optical A-constant* ACD Surgeon Factor	119.1 5.61mm 1.85mm
APPLANATION BIOMETRY Applanation A-constant* ACD Surgeon Factor	118.7 5.37mm 1.62mm
OTHER FEATURES	Glistening free Refractive index: 1.53 at 35° C UV absorbing Sharp 360° square posterior edge
DIOPTER RANGE	+6 D to +30 D in 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

* 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 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.

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