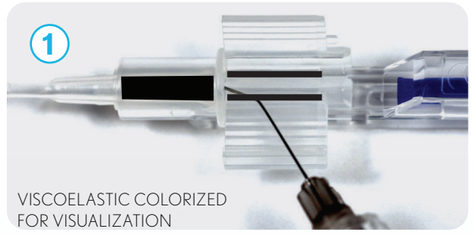
INJ100® Inserter

Loading Guide

enVista Aspire™ and
enVista Aspire™ Toric IOLs
with the INJ100 Delivery System

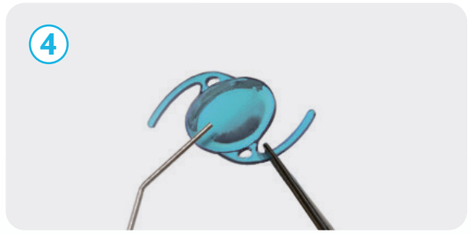
Use sterile garments and work in a sterile field when preparing Bausch + Lomb delivery systems and delivering IOLs.



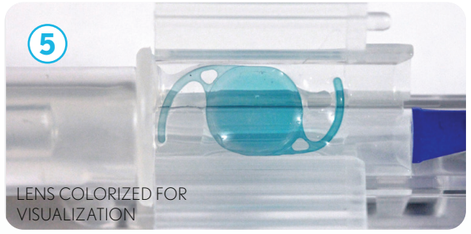
Entering from the side of the loading chamber, apply a recommended Bausch + Lomb viscoelastic directly into the conical tip. Then apply 2 thin lines into the lateral grooves within the loading chamber.

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

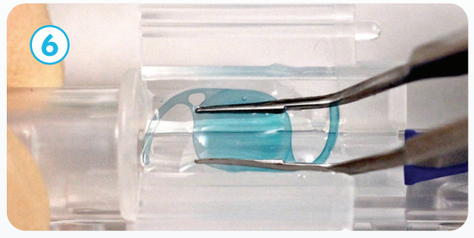
Open the vial containing the IOL and, using non-serrated forceps, remove the lens by grasping and carefully pulling it out vertically from the center slot at the top portion of the vial.



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.

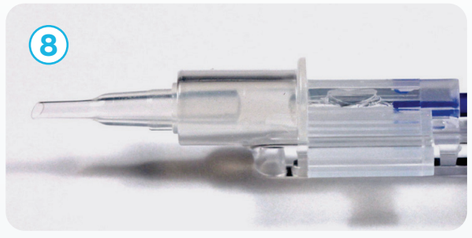


Position the lens in the middle of the loading chamber so that the anterior side is up and the lens is in a reverse-S orientation.

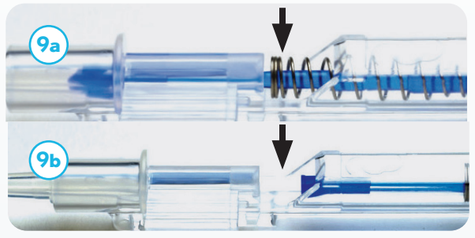


Apply slight downward pressure with the forceps to push the lens and haptics down to ensure they are properly seated under the grooves.

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.

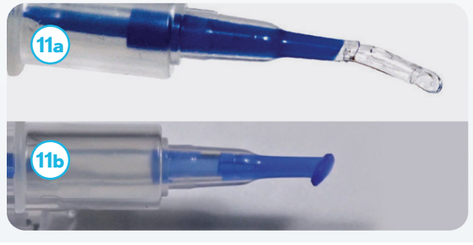


Next, close the cartridge wings together until the click-lock mechanism engages.



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.

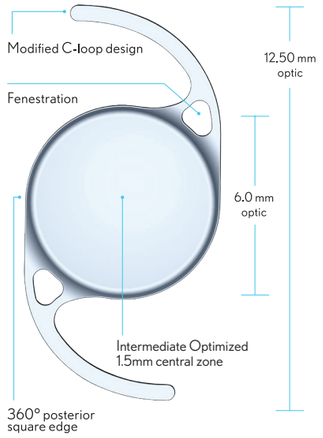
Please see Directions for Use for complete listing of indications, contraindications, warnings, precautions and use information.

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

BAUSCH + LOMB

INJ100® Inserter System

VIEW VIDEO LOADING GUIDE

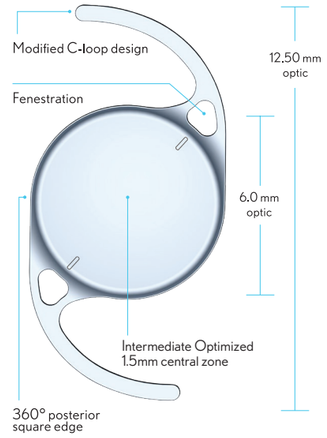


MODEL NUMBER	EA (non-preload)
OPTIC DESIGN	One-piece Aspheric, biconvex Posterior high-order aspheric surface
OPTIC SIZE	6mm
LENGTH	12.5mm
HAPTICS	Modified C, fenestrated
OPTICAL BIOMETRY Optical A-constant* ACD Surgeon Factor	119.1 5.61mm 1.85mm
APPLANATION BIOMETRY Applanation A-constant* ACD Surgeon Factor	118.7 5.37mm 1.62mm
OTHER FEATURES	Glistening free Refractive index: 1.53 UV absorbing Sharp 360° square posterior edge
DIOPTER RANGE	+6 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 EA & ETA
RECOMMENDED INCISION SIZE 2.2mm-2.6mm
TYPE OF ACTION Push-type
COMMENTS Silicone soft-tip. Single-handed delivery. Disposable.



MODEL NUMBER	ETA (non-preload)
OPTIC DESIGN	One-piece Aspheric, biconvex Posterior high-order aspheric surface Posterior toricity
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	+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

* 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 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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