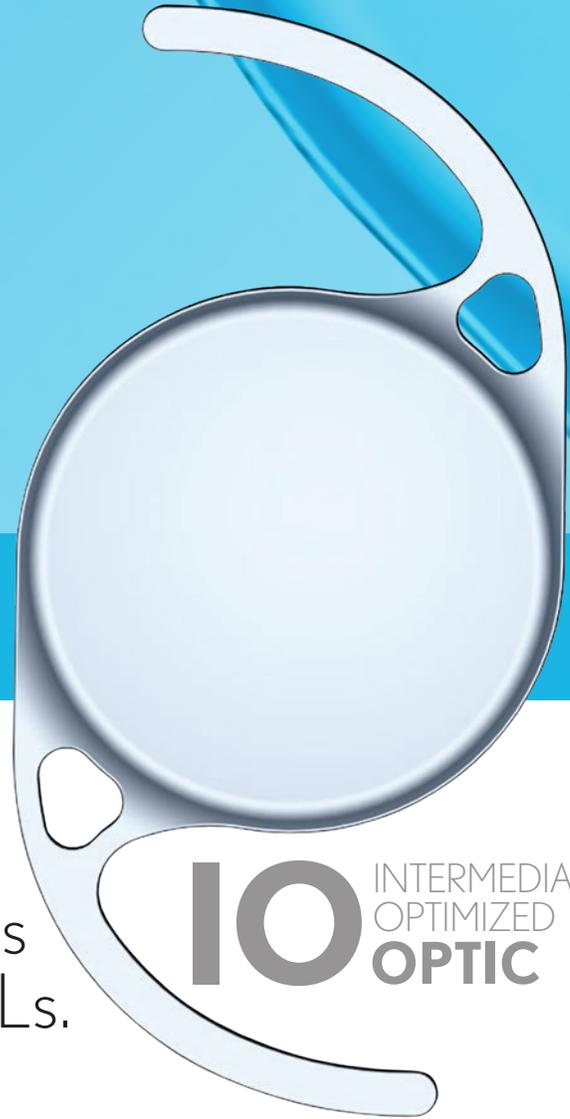


# enVista Aspire™

Hydrophobic Acrylic IOL

IO MONOFOCAL



Elevate the everyday.  
Transcend the boundaries  
of standard monofocal IOLs.

**IO** INTERMEDIATE-  
OPTIMIZED  
**OPTIC**

BROADER  
**DEPTH  
OF FOCUS**  
COMPARED TO THE AO MONOFOCAL OPTIC<sup>1</sup>

**3C** CONTROLLED  
CURVATURE  
CHANGE  
**TECHNOLOGY**

Uncompromised distance  
contrast sensitivity compared to  
the AO monofocal optic.<sup>1</sup>

A 1.5mm central zone on the  
posterior surface designed to  
create a broader depth of focus.<sup>1</sup>

The original glistening-free  
optic material.<sup>2</sup>

enVista **ASPIRE™**  
HYDROPHOBIC ACRYLIC IOL

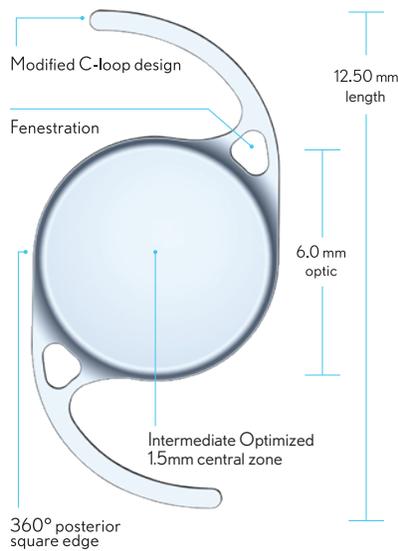
**BAUSCH + LOMB**

# enVista ASPIRE™

## HYDROPHOBIC ACRYLIC IOL

EA order number EAUXXXX

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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 SUGGESTED A CONSTANT ACD-CONSTANT SURGEON FACTOR	119.1 5.61mm 1.85mm
APPLANATION SUGGESTED A CONSTANT ACD-CONSTANT SURGEON FACTOR	118.7 5.37mm 1.62mm
OTHER FEATURES	Glistening free Refractive index: 1.53 UV absorbing Sharp 360° square posterior edge
DIOPTRER RANGE	+6 D to +34 D (0.5 D increments)

### Storz® BLIS Inserter System



FOR INSERTING LENS MODEL EA; +6 D to +34 D with X1 cartridge  
 RECOMMENDED INCISION SIZE 2.2mm–2.4mm  
 TYPE OF ACTION Screw-type  
 COMMENTS Controlled delivery. Reusable. Sterilization required.

### INJ100 Inserter



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

1. enVista Aspire Directions for Use, Bausch & Lomb.
2. enVista Directions for Use, Clinical Data [May 2017].



Find B+L IOL surgical equipment  
 online at [www.StorzEye.com](https://www.StorzEye.com)

## Indications and Important Safety Information for enVista Aspire™ 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.

**DEVICE DESCRIPTION:** The Aspire IOL uses 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:** As with any surgical procedure, there is risk involved. 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.

**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 this device to sale by or on the order of a physician. **ATTENTION:** This is not all you need to know. Please refer to the Directions For Use labeling for a complete listing of indications, full risk and safety information, clinical study information, etc.