enVista Aspire™ Toric

Hydrophobic Acrylic IOL

IO MONOFOCAL TORIC

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

IO INTERMEDIATE-OPTIMIZED **OPTIC**

BROADER
DEPTH OF FOCUS
COMPARED TO THE AO MONOFOCAL OPTIC [1]

AVAILABLE TO TREAT
< 1D OF ASTIGMATISM
AT THE CORNEAL PLANE[2]

3C (controlled curvature change) Technology. Uncompromised distance contrast sensitivity compared to the AO monofocal optic.[1]

Unique AccuSet™ Haptic Design (110 degrees of capsular bag contact) provides exceptional rotational stability.[3]

The original glistening-free optic material.[4]

enVista ASPIRE TORIC
HYDROPHOBIC ACRYLIC IOL

BAUSCH + LOMB

enVista ASPIRE™ TORIC

HYDROPHOBIC ACRYLIC IOL

ETA order number ETAU CCC+XXX

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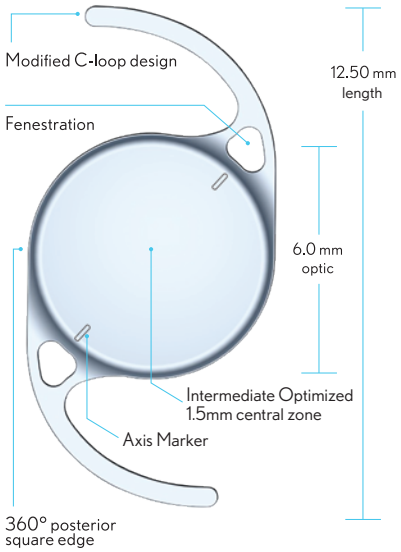

MODEL NUMBER	ETA (non-preload)
OPTIC DESIGN	One-piece Aspheric, biconvex Posterior high-order aspheric surface Posterior toricity
OPTIC SIZE	6mm
LENGTH	12.5mm
HAPTICS	Modified C, fenestrated
OPTICAL BIOMETRY SUGGESTED A-CONSTANT ACD-CONSTANT SURGEON FACTOR	119.1 1.85mm 5.61mm
OTHER FEATURES	Glistening 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

Storz® BLIS Inserter System

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

c represents the cylinder, x represents the diopter

1. enVista Aspire Directions for Use, Bausch & Lomb.
2. enVista Toric Directions for Use, Bausch & Lomb.
3. Data on File, Bausch & Lomb.
4. enVista Directions for Use, Clinical Data [May 2017].

storz® Ophthalmic Instruments by Bausch+Lomb

Find B+L IOL surgical equipment online at **www.StorzEye.com**

Indications and Important Safety Information for enVista Aspire™ Toric IOL

INDICATIONS: 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 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: 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; (8) 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 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

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