BAUSCH + LOMB

enVista Aspire™

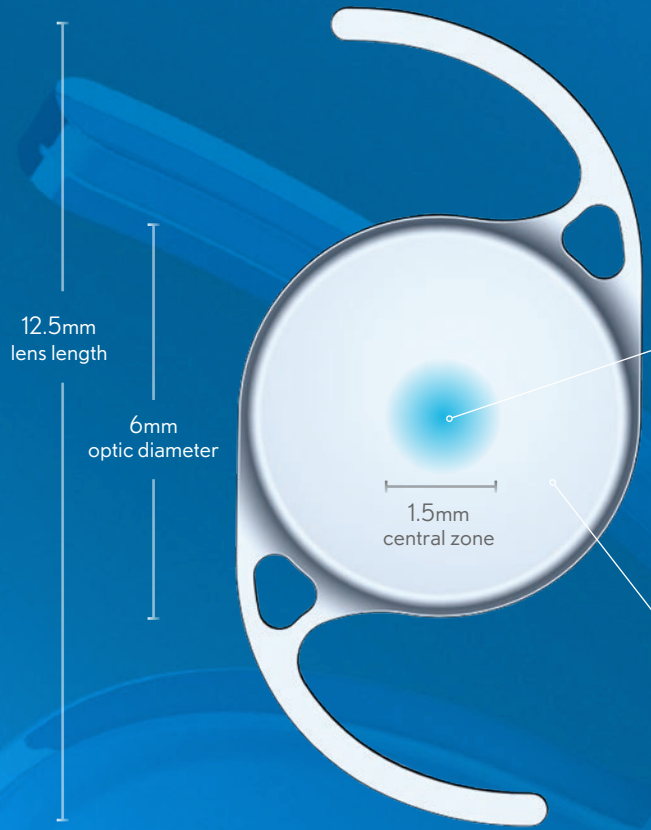
Intermediate Optimized monofocal IOLs


enVista ASPIRE™
ELEVATE THE EVERYDAY
Transcend the boundaries of standard monofocals and deliver your patients an IOL designed for the modern world – a fusion of uncompromised distance contrast sensitivity with an optic designed for a broader depth of focus.*1
*Based on optical bench testing – MTF study in ISO2 model cornea, comparison of MX60E and enVista Aspire™.

Built on innovative, Intermediate Optimized (IO) optics and harmonized with Controlled Curvature Change (3C) technology, enVista Aspire™ culminates a journey of astonishing possibilities for your patients as they **navigate their increasingly tech-infused lifestyles**.

- Novel optics built on a globally proven and trusted platform
- Over 5 million non-toric and 500,000+ toric implants worldwide
- Demonstrated a broader depth of focus* than enVista® AO monofocal IOLs
- Pioneering glistening-free optic material[2]

* Based on optical bench testing. Clinically meaningful extension of the depth of focus has not been demonstrated in clinical trials.



Central zone

enVista Aspire™ features an Intermediate Optimized (IO) central zone that uses higher-order aspheric coefficients on the posterior surface to create a broader depth of focus.[1]

Featuring 3C (Controlled Curvature Change) technology, enVista Aspire™ optics are designed to harmonize the geometric power profile outward between the central base power and power at the periphery.[3]

Optic power profile

enVista Aspire™ uses a unique optic to create a gradual transitional distribution of light energy from the center to the periphery, an optic feature designed to minimize dysphotopsias.[3]

*Based on optic design characteristics. Data on File.

Outstanding performance and optical engineering are built into the design of every enVista® lens

A monofocal IOL for the modern world

Patients navigate a more complex world than ever before. As their world gets more complicated, the standard of cataract care must keep pace. With the average adult spending more than 13 hours a day interacting with digital devices, the need for access to a broader range of vision is apparent.[4] enVista Aspire™ provides you, the cataract surgeon, the opportunity to deliver on modern expectations.

Focal point extended

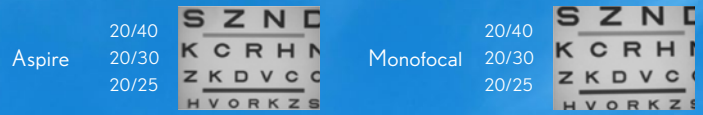
Unlike conventional spherical monofocal IOLs and low-order aspheric IOLs, enVista Aspire™ uses higher-order aspheric coefficients on the posterior surface of the lens. This means that the enVista Aspire™ optic design allows for a broader depth of focus compared to a standard monofocal IOL.*

Uncompromising distance

Bench testing for enVista Aspire™ (IO Optic) demonstrated similar visual contrast at distance when compared to the enVista® (AO Optic), with the average spherical aberration of the natural cornea.[1,5]*

* Based on optical bench testing[3] - MTF study in ISO2 (+0.28µm) model cornea.

Through Focus image at distance[3]†



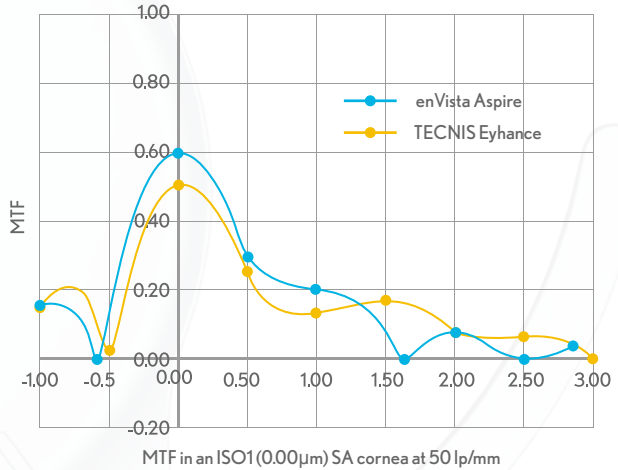
Obtained using an ISO1 (+0.00µm) SA cornea

†Images taken at 100cm.

Intermediate Optimized optic

enVista Aspire™ demonstrated a **120% increase** in continuous depth of focus **compared to enVista®.**[3]

enVista Aspire™ vs TECNIS Eyhance Through focus MTF[6]



* Based on optical bench testing – MTF study in ISO1 model cornea.
+ Based on bench testing.
DOF = Depth of Focus

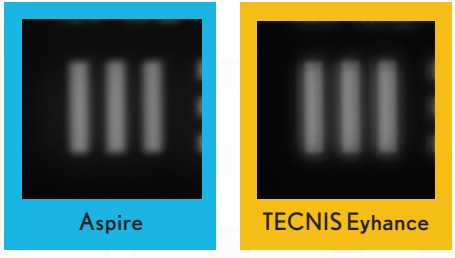
- enVista Aspire™ demonstrated 1.25D of continuous DOF[3*]
- enVista Aspire™ demonstrated similar DOF compared to TECNIS Eyhance[3+]

Excellent contrast sensitivity

Image analysis showed enVista Aspire™ demonstrated approximately 20% higher contrast across the entire through-focus range compared to TECNIS Eyhance.[6]

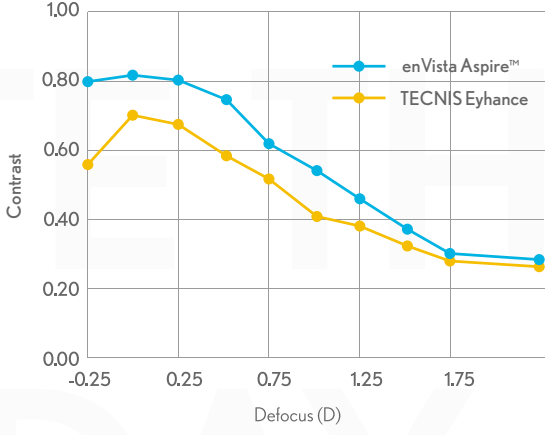
* Based on optical bench testing[3] - MTF study in ISO2 (+0.28µm) model cornea.
Evaluation of enhanced monofocal plus IOLs with extended depth of focus. ARVO Annual Meeting Abstract.

Estimation of through-focus contrast[6]



USAF target images (0.00µm) SA model cornea using 3mm aperture

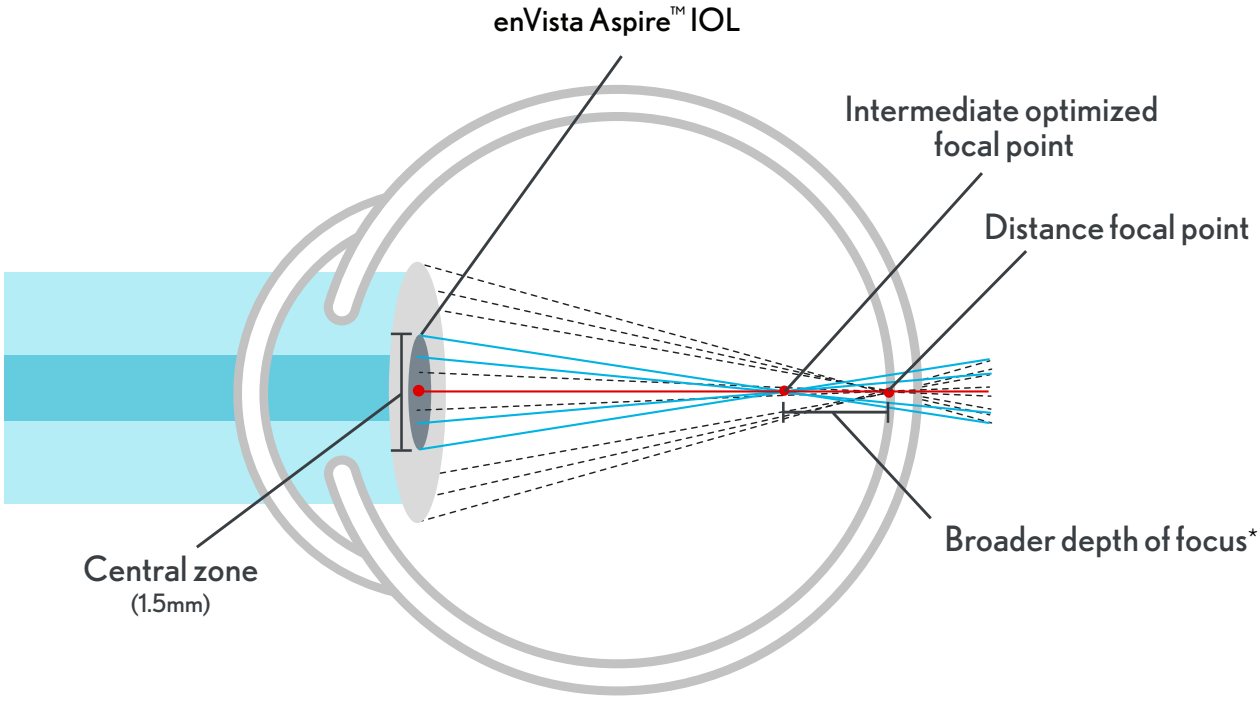
enVista Aspire™ vs TECNIS Eyhance Through Focus Contrast[6]



Monofocal for the modern world

All patients deserve vision that brings their world into focus. For your patients that may not be candidates for presbyopia-correcting IOLs, enVista Aspire™ IO optics provide an excellent monofocal option.

Intermediate Optimization optic design allows for a broader depth of focus

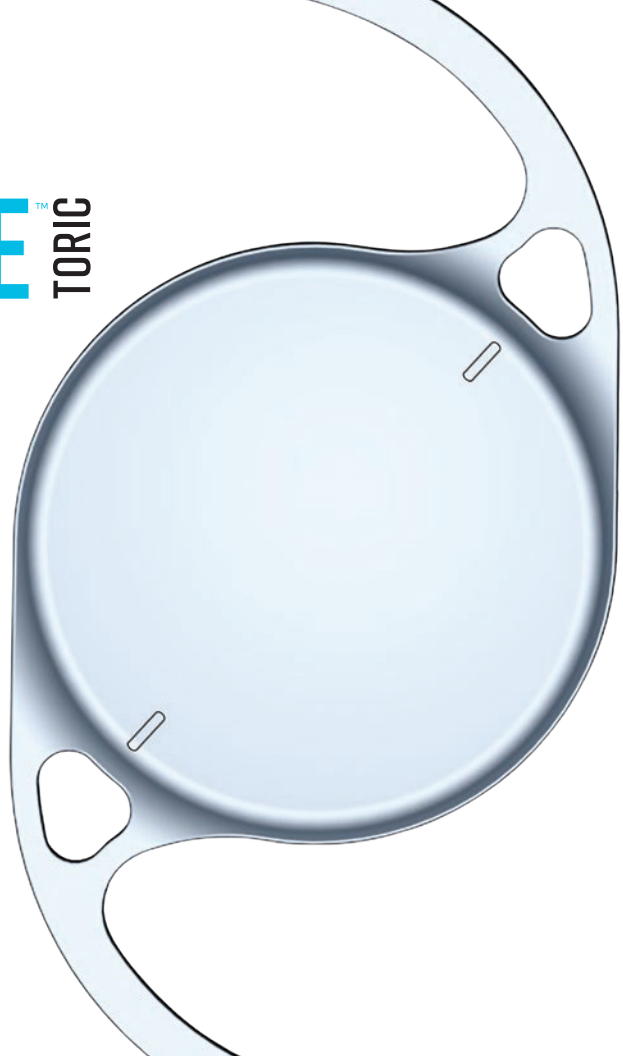


*Based on optical bench testing – MTF

enVista ASPIRE™ TORIC

Treat lower levels of astigmatism

Most cataract patients with more than 0.5 diopters of corneal astigmatism aim to achieve post-surgery spectacle independence.[9,10,26]



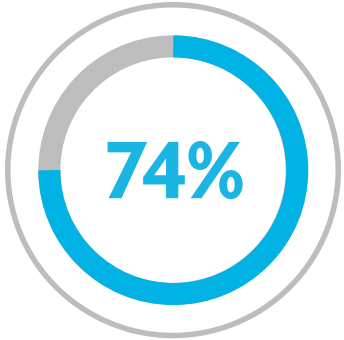
Correcting ametropia and astigmatism. Both at the same time.

Benefits of Toric IOLs

- Eliminates extra surgical procedures on the anterior of the eye.
- Provide greater accuracy and range than corneal-incisional and limbal-relaxing procedures. [11]

Low-Cyl correction technology equals more surgeon options for treating low astigmatism

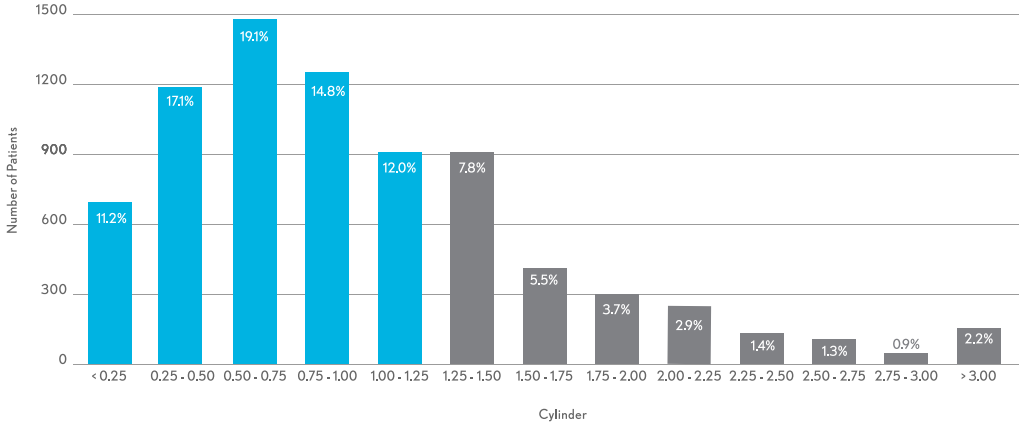
A significant number of patients today are not treated for astigmatism, despite the need. A small amount of astigmatism (as little as 0.50 D) has the potential to affect functional and low contrast visual acuity[12] and has an impact on the visual comfort of computer users.[12]



of cataract patients have less than 1.25D of corneal astigmatism.[9]

Prevalance of corneal astigmatism prior to cataract surgery[9]

n = 6,000 | Warren E. Hill, MD | Keratometry Database



Lower astigmatism is common in patients seeking cataract surgery.[9]

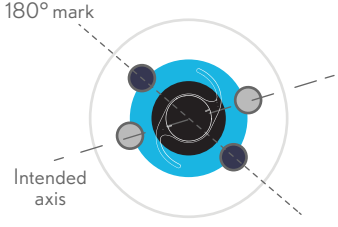
With Low-Cyl technology:
Broaden the treatable astigmatism range in cataract surgery to as low as <1.0D.[1]

The first and only...
Low-Cyl toric (1.25D) below 1.5D at the IOL plane commercially available in the US

Trust a platform tailored for toric

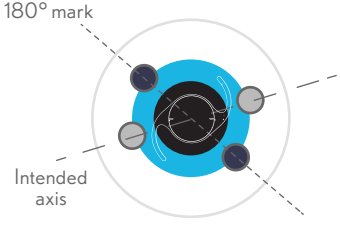
Leveraging the enVista® platform's stability, the unique material and design perform exceptionally for astigmatic patients.

Toric alignment and rotational stability are vital for patient satisfaction and visual outcomes.



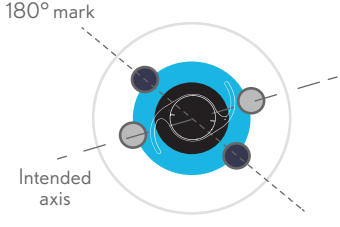
1° Lens Rotation

Effectiveness 96.7%[13]



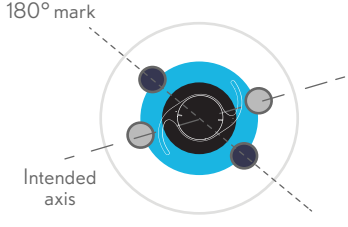
5° Lens Rotation

Effectiveness 83.5%[13]



10° Lens Rotation

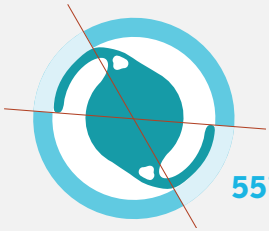
Effectiveness 67%[13]



30° Lens Rotation

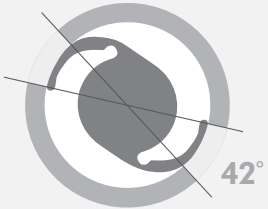
Effectiveness 1%[13]

110°
of capsular bag contact



enVista® Toric platform[14]

84°
of capsular bag contact

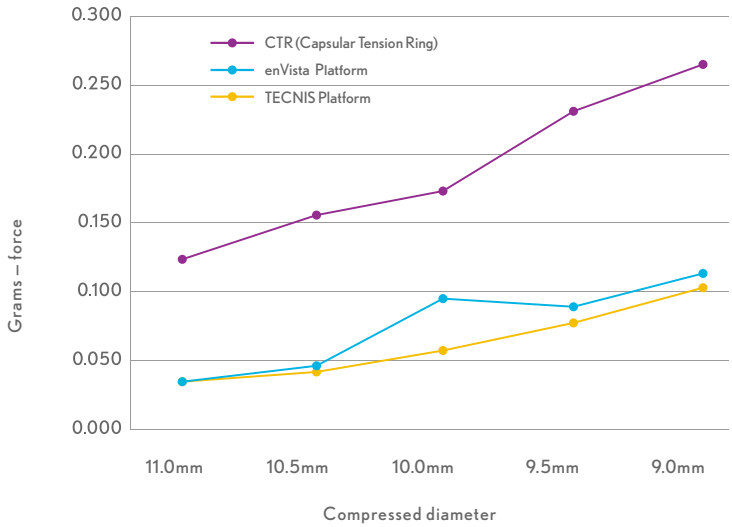


TECNIS toric platform[14]

Exceptionally reliable rotational stability

- 110° of capsular bag contact
- Delivers 300% more radial compression force than traditional hydrophobic IOLs[15]
- Demonstrated higher outward radial force compared to the TECNIS IOL platform[15]

Radial compression force - IOL platforms[16]



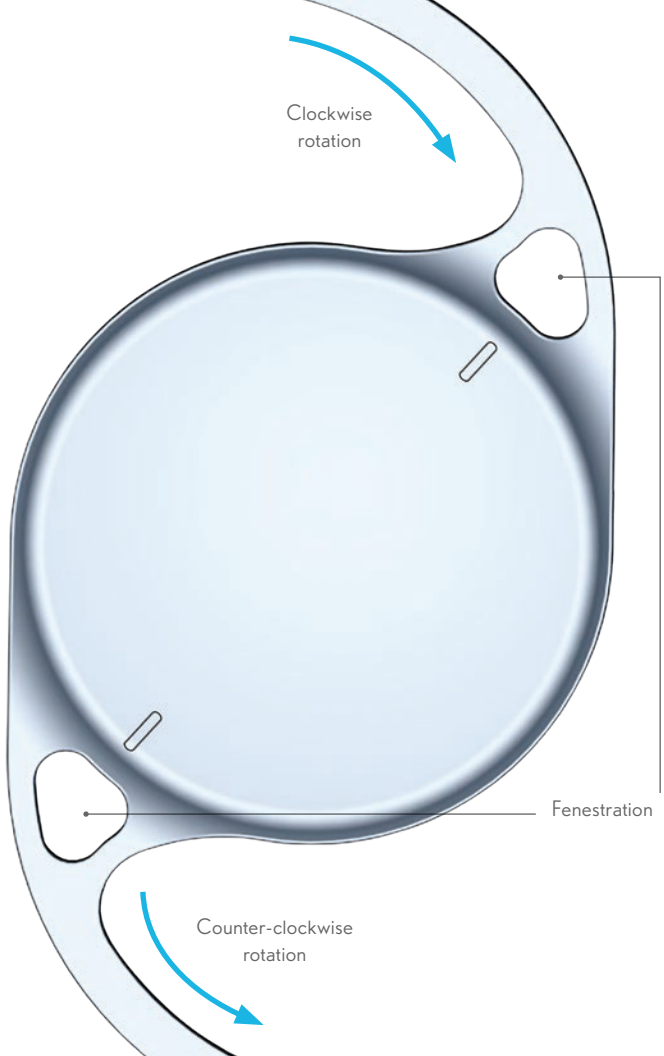
The enVista® toric platform delivers proven rotational stability through **180 days post-surgery.**[17]

94.4% of eyes ≤ 5° rotation *(n=108)*

Intraoperative lens manipulation: Simplified

The unique fenestration holes of enVista Aspire™ Toric simplify lens manipulation during surgery,[18] allowing both clockwise and counterclockwise positioning in the capsular bag.

The fenestrated haptics also reduce haptic-to-optic stress, ensuring lens integrity during capsular bag contraction.



The enVista® Toric Calculator
Your partner in accuracy

Powered by the advanced Emmetropia Verifying Optical (EVO) formula, the enVista® Toric Calculator sets the new standard for predicting spherical equivalence and providing data for low astigmatism cases.[19]

The EVO formula incorporates a theoretical model for posterior corneal astigmatism (PCA) and accounts for different IOL geometries.[14] The data it provides helps you determine the spherical equivalent refractive error, as well as which IOL power should be used based on biometry.

With the EVO formula:

- Approximately 80% of patients are in the 0 to 0.5 D targeted range – a higher percentage of patients compared with traditional vergence formulas[20]
- The proportion of eyes with an absolute refractive astigmatism of ≤1.0 D was statistically superior to the Kane formula[21]
- The proportion of eyes in which the orientation of the predicted refractive astigmatism matched the actual refractive astigmatism was statistically significantly improved versus the legacy formula[19]

Scan to access
the enVista® Toric Calculator
https://envista.toriccalculator.com/

Aspire delivery systems

BLIS®

Available with both enVista Aspire™ and enVista Aspire™ Toric

- Quality engineering and built from high-grade titanium
- Reduce medical waste with the reusable instrumentation
- Requires a small incision size of 2.2mm to 2.4mm, for smooth lens deliveries[22]

INJ100

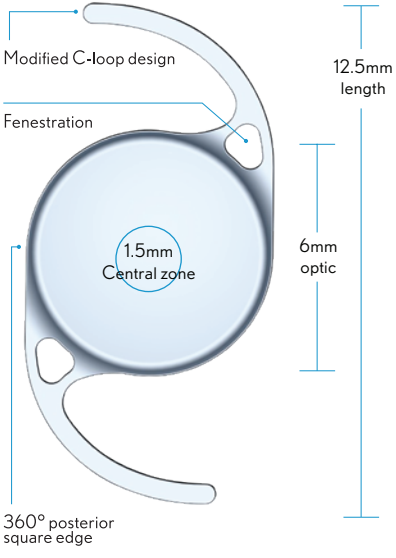
Available with both enVista Aspire™ and enVista Aspire™ Toric

- Disposable
- Uses a silicone soft-tip to deliver consistent lens folding – reproducible and reliable delivery into the capsular bag[23]
- Requires a small incision size of 2.4mm to 2.6mm, for smooth lens deliveries[23]

enVista ASPIRE™

HYDROPHOBIC ACRYLIC IOL

EA order number EAUXXXX



X represents diopter

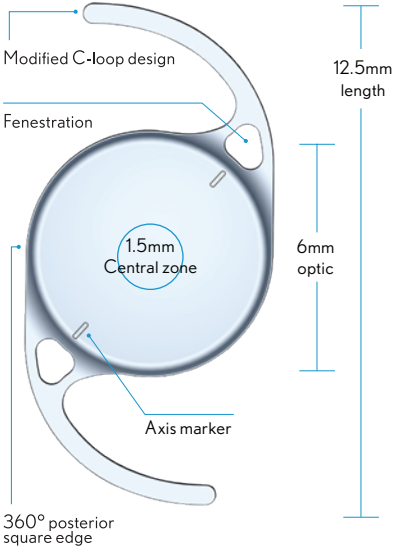
MODEL NUMBER	EA (non-preload)
OPTIC DESIGN	One-piece Aspheric, biconvex Posterior high-order aspheric surface
OPTIC SIZE	6mm
LENGTH	12.5mm
HAPTICS	Modified C, fenestrated
OPTICAL BIOMETRY Optical A-constant* ACD Surgeon Factor	 119.1 5.61mm 1.85mm
APPLANATION BIOMETRY Applanation A-constant* ACD Surgeon 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.

enVista ASPIRE™ TORIC

HYDROPHOBIC ACRYLIC IOL

ETA order number ETAU CCC+XXX



C represents cylinder, X represents diopter

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 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 1.5mm 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:

1. 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).
2. 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.
3. 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.

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 1.5mm 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:

1. 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).
2. 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.
3. 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.

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enVista® IOL platform technologies

TruSight® optic

Glistening-free material with improved scratch resistance and 25x the hardness of traditional hydrophobic acrylic IOLs.*[24]

StableFlex® technology

Efficient lens unfolding, ensuring excellent optic recovery.[1]

SureEdge® design

Outstanding defense against Posterior Capsular Opacification (PCO).[1,25]

*Based on nanoindentation study

1. enVista Aspire™ Directions for Use.
2. enVista® Directions for Use, Bausch & Lomb – Clinical Results. May 2017.
3. Data on file. enVista Aspire™.
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