# Elevate the everyday





Intermediate
Optimized
monofocal IOLs



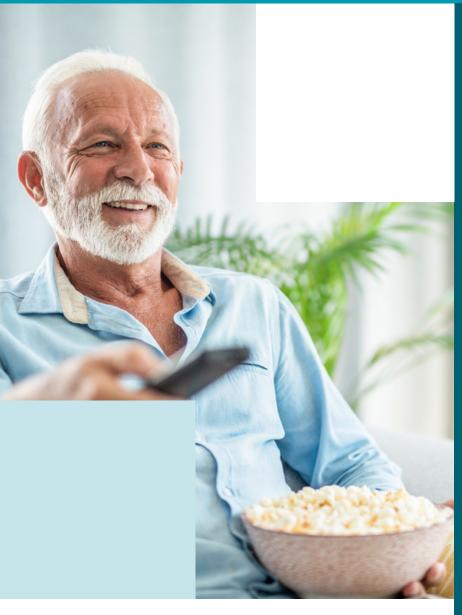
# enVista ASPIRE



# 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 vision with an optic designed for a broader depth of focus.

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



# A monofocal IOL for the modern world

Patients are navigating their world with more complexities than ever before. As the world progresses, so should their standard of cataract care. The need for broader range of vision is apparent, as adults spend more than 13 hours a day interacting with digital devices.¹ As a surgeon, enVista Aspire™ provides you with the opportunity to deliver modern expectations.

- Novel optics built on a proven platform that is trusted around the world with more than 8 million implantations<sup>2</sup>
- In optical bench testing, enVista Aspire<sup>™</sup> demonstrated a broader depth of focus compared to enVista<sup>™</sup> AO (Advanced Optics) monofocal IOLs<sup>³</sup>
- The original glistening-free optic material



## Outstanding performance and optical engineering are built into the design of every enVista<sup>TM</sup> lens

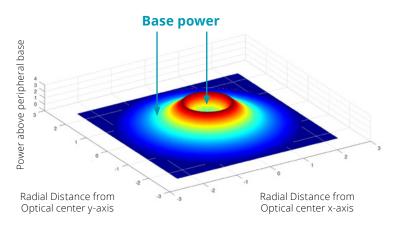
#### **Central zone**

enVista Aspire™'s Intermediate Optimized (IO) central zone, utilizes higher-order aspheric coefficients on the posterior surface to create a broader depth of focus.

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

enVist Aspire™ demonstrated 1.25 D of continuous depth of focus<sup>4</sup>

enVista Aspire™ IOL Power Surface Plot showing the power distribution on the posterior side of the Aspire IOL optic.



This image is not a topographical map of the lens, it is a power map of the lens

#### Optic power profile

The unique optic of enVista Aspire™ creates a gradual transitional distribution of light energy from center to the periphery.

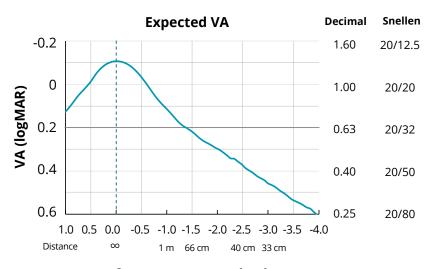




#### **Uncompromising distance vision**

In optical bench testing for enVista Aspire™ (Intermediate Optimized Optic) showed an Expected Visual Acuity (EVA) of 20/20 for distance vision<sup>5</sup>

enVista Aspire™ Expected Visual Acuity (EVA) at 3.00 mm pupil size, +0.27 µm corneal spherical aberration and 550 nm monochromatic light.



Defocus (D) - Spectacle plane

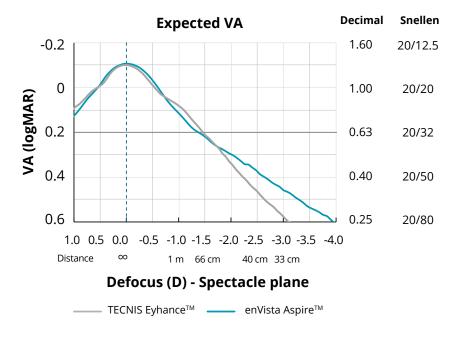
— enVista Aspire™



## Intermediate Optimized optic

Expected Visual Acuity at 3.00 mm pupil size, +0.27 µm corneal spherical aberration and 550 µm monochromatic light.

 In optical bench testing enVista Aspire™ demonstrated similar depth of focus compared to TECNIS Eyhance<sup>5</sup>



This expected Visual Acuity (EVA) is a pre-clinical metric, estimated using a formula from the through focus MTFa obtained with the 3.00 mm pupil size. 6,7 This MTFa results from the integration of MTF function in a range of spatial frequencies and has been shown to strongly correlate with average clinical visual acuity.<sup>7,8</sup>

The EVA provides a useful tool to predict the expected visual performance of a lens.

Juan Antonio Azor, Fidel Vega, Jesus Armengol, Maria S. Millan. Characterization of various presbyopia-correcting intraocular lenses on optical bench. Comparative study. Grupo de Optica Aplicada y Procesado de Imagen (GOAPI). Department of Optics and Optometry Universitat Politecnica de Catalunya BARCELONATECH
 Alarcon A, Canovas C, Rosen R, et al. Preclinical metrics to predict through-focus visual acuity for pseudophakic patients. Biomed Opt Express. 2016;7(5):1877-1888
 American National Standards Institute (ANSI) Z80.35-2018, "Extended depth of focus intraocular lenses"

<sup>8.</sup> Vega F., Met al "Visual acuity of pseudophakic patients predicted from in-vitro measurements of intraocular lenses with different design," Biomed. Opt. Express 9(10),4893–4906

# Monofocal for the modern world

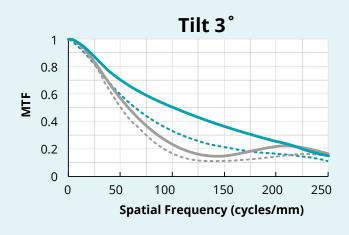
In optical bench testing enVista Aspire™ is less sensitive to tilt and decentration when compared with TECNIS Eyhance™

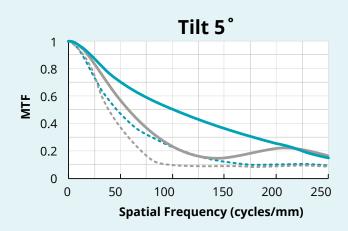


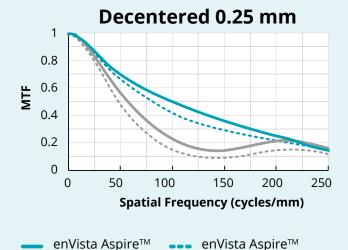
#### Decentration is much more frequent than one might think

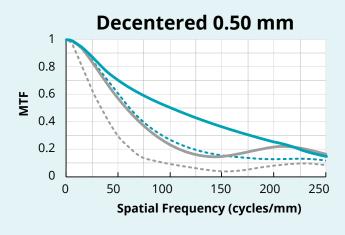
A large series of 395 eyes reported an average IOL decentration after uncomplicated cataract surgery of  $0.40 \pm 0.2$  mm (range 0 to 1.7 mm)<sup>9</sup>

Comparative MTF for tilt and decentration at 3.00 mm pupil size and +0.27 µm corneal spherical aberration<sup>5</sup>









— TECNIS Eyhance™

TECNIS Eyhance™ tilted or decentered

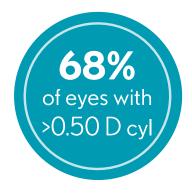
tilted or decentered

## Removing cataracts. Correcting astigmatism. Both at the same time.

#### Benefits of toric IOLs

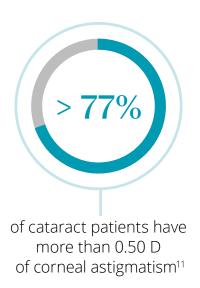
- Avoid the need to perform other procedures during cataract surgery
- Shown to provide greater accuracy and range of corrective power than corneal incisional and limbal relaxing procedures<sup>10</sup>

Thanks to our extended range of cyls and ultra low +0.90 D, enVista Aspire™ Toric covers 68 % of the cataract surgery population with > +0.50 D of corneal astigmatism<sup>11\*</sup>

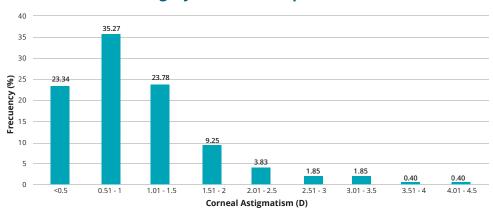


A significant number of patients today are not treated for astigmatism, despite the need.

A small amount of astigmatism (as little as 0.50 D) has the potential to affect functional and low contrast visual acuity<sup>12</sup> and has an impact on the visual comfort of computer users.<sup>12</sup>



#### Prevalence of corneal astigmatism before cataract surgery in Caucasian patients11



Corneal astigmatism distribution in 0.50 D steps in the entire sample (757 eyes).

Calculation from the Bernardo histogram Figure 1. Assuming a Linear interpolation of the area under the curve of the range of cylinders

<sup>10.</sup> Lake JC, Victor G, Clare G, et al. Toric intraocular lens versus limbal relaxing incisions for corneal astigmatism after phacoemulsification. Cochrane Database Syst Rev. 2019;12(12):CD012801. doi: 10.1002/14651858. CD012801.pub2

<sup>21.</sup> De Bernardo M, Zeppa L, Cennamo M, Iaccarino S, Zeppa L, Rosa N. Prevalence of Corneal Astigmatism before Cataract Surgery in Caucasian Patients. European Journal of Ophthalmology. 2014;24(4):494-500. doi:10.5301/ejo.5000415

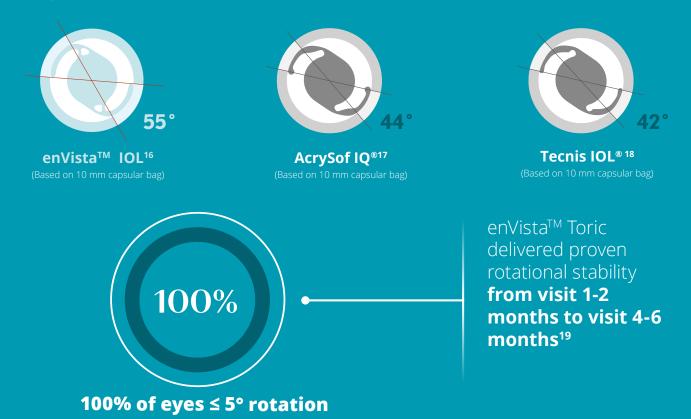
12. Miller AD, Kris MJ, Griffiths AC. Effect of small focal errors on vision. Optom Vis Sci. 1997;74(7):521-526. Novis C. Astigmatism and Toric Intraocular Lenses. Current Opinion in Ophthalmology 2000; Vol. 11, Issue 1: 47-50.

# Lock in rotational stability you can count on



Accuset™ Haptics - designed for refractive predictability and stable centration¹³-¹5

- Fenestrated haptics to prevent transfer of stress from the haptic to the optic
- Haptics designed to maximize the contact angle against the capsular bag



<sup>13.</sup> Parker et al. Safety and effectiveness of a glistening-free single-piece hydrophobic acrylic intraocular lens (enVista). Clin Ophthalmol. 2013:7 1905–1912.
14. P. Heiner et al. Safety and effectiveness of a single-piece hydrophobic acrylic intraocular lens (enVista®) – results of a European and Asian-Pacific study. Clin Ophthalmol. 2014:8 629–635.

<sup>15.</sup> Garzon et al. Evaluation of Visual Outcomes After Implantation of Monofocal and Multifocal Toric Intraocular Lenses. J Refract Surg. 2015;31(2):90-97

<sup>16.</sup> BAUSCH + LOMB data on file: Intraocular lens design verification report- July 2016

BAUSCH + LOMB data on file: IOL competitive benchmarking study report\_DEC 2009.

<sup>18.</sup> PMA P980040/S039: FDA Summary of Safety and Effectiveness Data\_Tecnis Toric IOL

<sup>19.</sup> enVista Toric data (MX60T). Packer M, Williams JI, Feinerman G, Hope RS. Prospective multicenter clinical trial to evaluate the safety and effectiveness of a new glistening-free one-piece acrylic toric intraocular lens. Clinical Ophthalmology 2018:12 1031-1039

## The enVista<sup>TM</sup> Toric Calculator

#### Your partner in accuracy

The enVista<sup>™</sup> Toric calculator integrates the Emmetropia Verifying Optical (EVO) Toric Formula, an advanced IOL formula for cataract surgery.<sup>20</sup>

It is based on the theory of emmetropization and generates an 'emmetropia factor' for each eye. As a thick lens formula, it takes into account of the optical dimensions of the eye, and can handle different IOL geometry and powers.

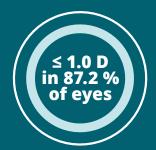
When calculating toric IOLs, it combines:

#### Theoretical posterior cornea astigmatism prediction

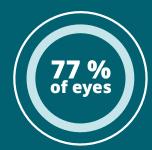
#### Thick lens modelling

#### Dynamically interconnected prediction of IOL power and toricity

A retrospective evaluation of EVO Toric Formula performed in a multi-centered clinical trial including 10 surgeons, based on 109 eyes implanted with enVista™ toric<sup>21</sup>:



Residual astigmatism prediction error



Calculator predicted orientation matched the theoretical postoperative refractive astigmatism



Arithmetic mean residual astigmatism prediction error

The Barrett Toric Calculator and EVO Toric Calculator had similar performance with regards to their astigmatism prediction accuracy.

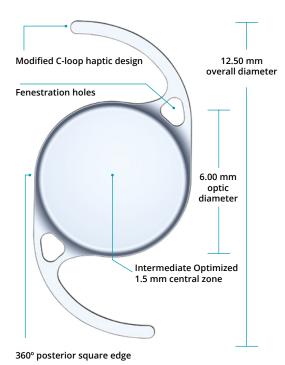


Scan to access the EVO toric calculator https://www.evoiolcalculator.com

## enVista ASPIRE

#### HYDROPHOBIC ACRYLIC IOL

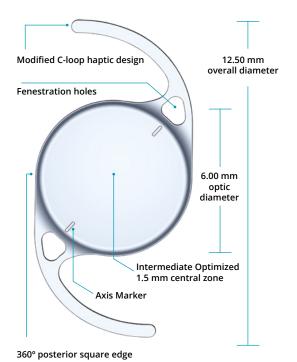
#### **SKU** EAXXXX



## enVista ASPIRE

#### HYDROPHOBIC ACRYLIC IOL

#### **SKU** ETAXXX+XXX



#### **MATERIAL**

- · Hydrophobic acrylic glistening-free
- UV filter (10 % cut-off wavelength: 389 nm)
- Refractive index: 1.53 at 35°C

#### **DESIGN**

- Intermediate Optimized Toric IOL with posterior high order aspheric surface
- · One piece, biconvex
- Modified C-loop haptic design
- 360° posterior square edge
- Haptic with fenestration holes
- Optic diameter: 6.00 mm
- · Overall diameter: 12.50 mm

#### **DIOPTER RANGE**

#### enVista Aspire™

From +6.00 D to +34.00 D (0.50 D steps)

#### enVista Aspire™ TORIC

Spherical equivalent power:

From +6.00 D to +34.00 D (0.50 D steps)

**Cylinder power - IOL Plane:** 0.90 D / +1.25 D / +1.50 D / +2.00 D / +2.50 D / +3.00 D / +3.50 D / +4.25 D / +5.00 D / +5.75 D

**Cylinder power - Corneal plane:** +0.64 D / +0.90 D / +1.06 D / +1.40 D / +1.76 D / +2.11 D / +2.45 D / +2.98 D / +3.50 D / +4.03 D

#### **DELIVERY SYSTEM**

#### Non-preloaded

BLIS (screw type, controlled delivery) reusable inserter and single use cartridge

Inserter: BLIS-R1 (1 Unit/box)
Cartridge: BLIS-X1 (10 Units/box)
Recommended incision size ≥ 2.2 mm

INJ100 (Silicone tip, push type single handed) Single-use inserter: INJ100 (10 Units/box) Recommended incision size ≥ 2.2 mm



#### **CONSTANTS\***

#### **OPTIC CONSTANT**

SRK/T Constant A: 119.1 ACD: 5.61

Surgeon factor: 1.85

Haigis: a0: 1.46 / a1: 0.40 / a2: 0.10

#### **ULTRASONIC CONSTANT**

Constant A: 118.7 ACD: 5.37

Surgeon factor: 1.62

\* Constants are estimates only. It is recommended that each surgeon develops their own values.



Transcend the boundaries of standard monofocals and deliver your patients an IOL designed for the modern world.



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**CATARACT GLAUCOMA** REFRACTIVE **RETINA VISUALIZATION**