BAUSCH + LOMB

enVista Envy™

Full Range of Vision IOLs




enVista ENVY™
FLOURISH
AT EVERY STEP

Discover the **FULL RANGE OF VISION IOL** that launches a **new era of confidence** with **enviable outcomes**[1]



FULL RANGE OF VISION CORRECTION

ACCESSIBLE TO ALL CATARACT SURGEONS[1]

OUTSTANDING PERFORMANCE IN ALL LIGHTING CONDITIONS

WITH ACTIVSYNC - INTELLIGENT ENERGY DISTRIBUTION[4]

TREAT MORE ASTIGMATIC PATIENTS WITH MORE PRECISION[5]

EXCELLENT PATIENT TOLERANCE

TO GLARE, HALOS, AND STARBURSTS[2, 3]




A full range of vision comes with high expectations
enVista
HYDROPHOBIC ACRYLIC IOL
ENVY

A lens with an enviable tolerance to dysphotopsia[1, 2, 3*]

	enVista Envy[1, 2*]			
Types of dysphotopsia	% of patients with little to no bothersomeness		% of patients with severe disturbance	
Country	US (n=309)	Canada (n=110)	US (n=309)	Canada (n=110)
Glares	88%	96%	3%	0%
Halos	80%	88%	6%	6%
Starbursts	91%	94%	3%	1%

	PanOptix (n=127)[3*]	
Type of dysphotopsia	% of patients with little to no bothersomeness	% of patients with severe disturbance
Glares	73%	3%
Halos	73%	13%
Starbursts	72%	16%

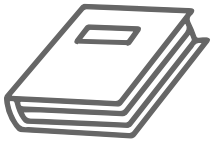
*Respective patient reported outcome data at 4–6 months post-op (non-head-to-head) from enVista Envy US clinical study (n=309), 4–6 months post-op enVista Envy Canadian clinical study (n=110) and 6-month post-op AcrySof PanOptix clinical study (n=127)

enVista Envy can enhance your patients' visual experience in their daily-life activities[2]



91%

LITTLE TO NO DIFFICULTY
READING MOBILE SCREEN[2]



94%

LITTLE TO NO DIFFICULTY
VIEWING CLOSE OBJECTS[2]

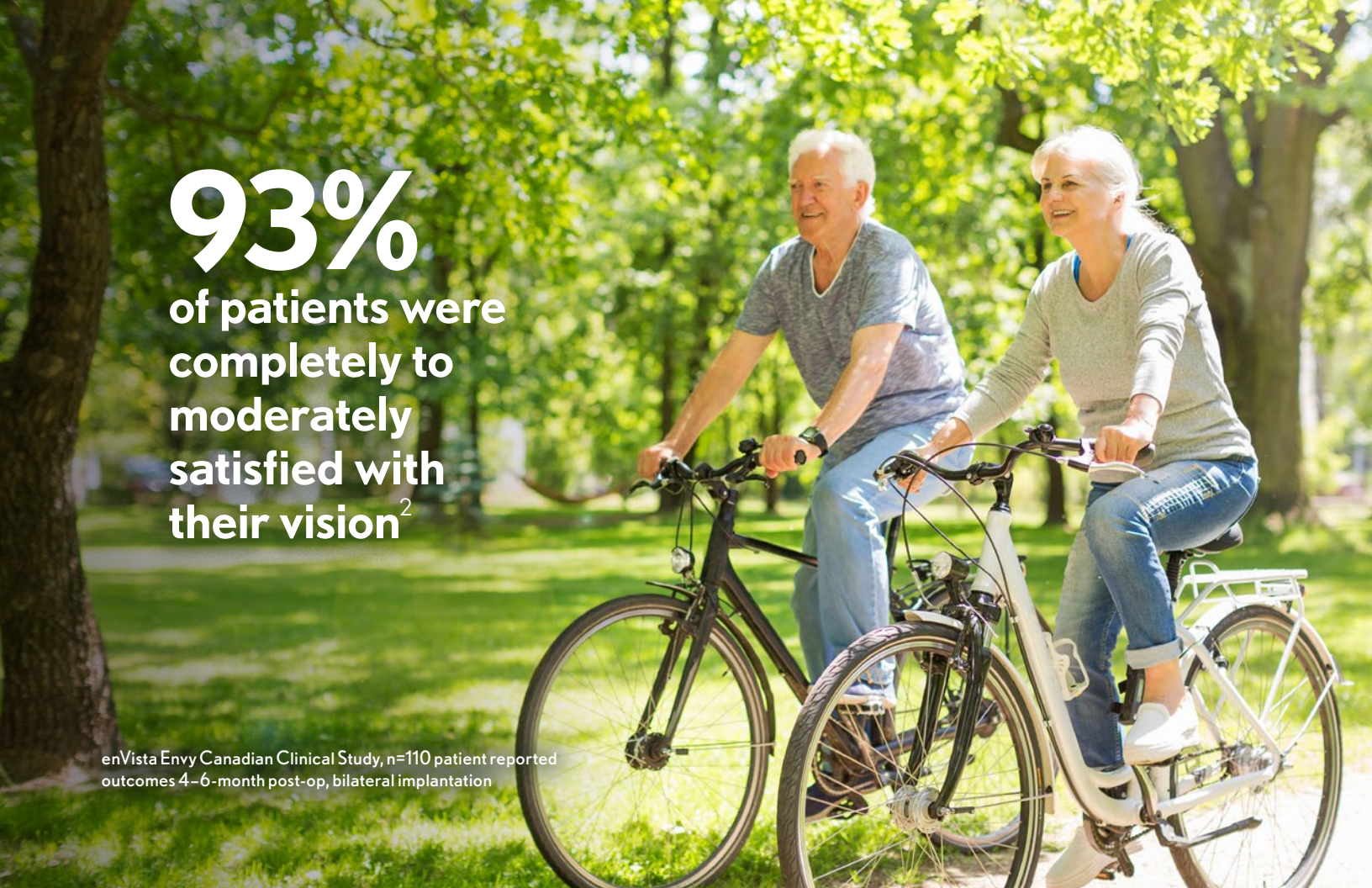


95%

LITTLE TO NO DIFFICULTY
READING COMPUTER SCREEN[2]

enVista HYDROPHOBIC ACRYLIC IOL ENVY™

Canadian Clinical Study, enVista Envy n=110 patient reported outcomes 4–6-month post-op, bilateral implantation


93%
of patients were completely to moderately satisfied with their vision[2]
enVista Envy Canadian Clinical Study, n=110 patient reported outcomes 4–6-month post-op, bilateral implantation

ActivSync optic delivers intelligent energy distribution

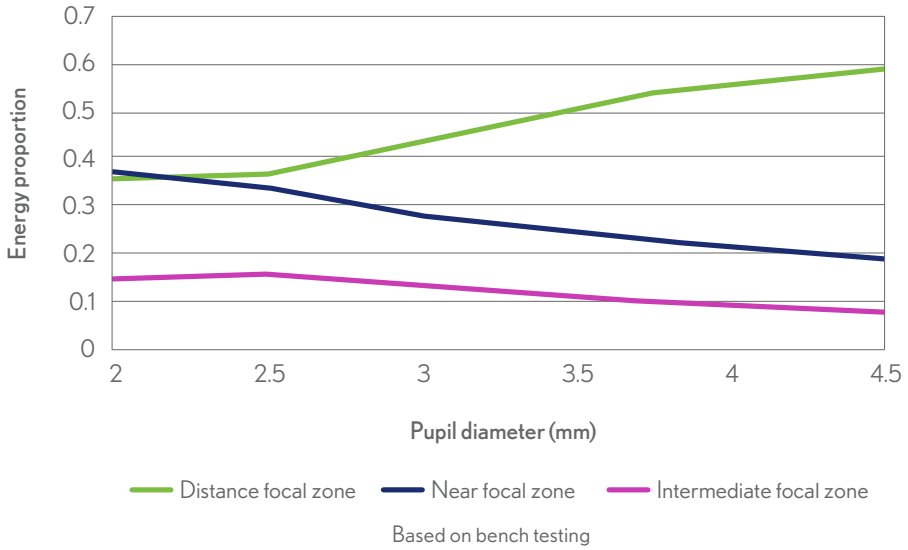
enVista
HYDROPHOBIC ACRYLIC IOL
ENVY™





The ActiveSync optic in enVista Envy is designed to **enhance image contrast** when patients need it most, evenly distributing light in photopic conditions and prioritizing distance in mesopic conditions.

enVista Envy energy distribution according to pupil size[4]

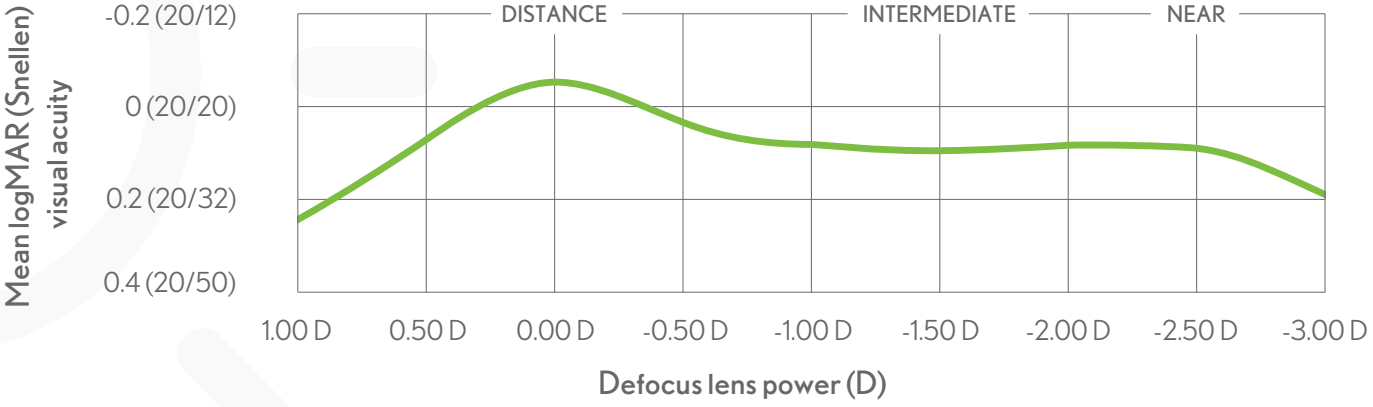


Based on bench testing

enVista Envy demonstrated excellent performance

In **photopic conditions**, ActivSync optic maintained excellent full range of vision for patients.[1,4]

enVista Envy defocus curve 3–4mm pupil size[1]



enVista HYDROPHOBIC ACRYLIC IOL ENVY

enVista Envy US Clinical Study, binocular implantation, 4–6-month post-op, n=42 eyes

...in all lighting conditions

In pupils larger than 4mm, ActivSync optic is able to prioritize light energy, which facilitates night vision.[1,4]

enVista Envy defocus curve >4mm pupil size[1]



enVista Envy US Clinical Study, binocular implantation, 4–6-month post-op, n=36 eyes

Intelligent optic design meets exceptional engineering

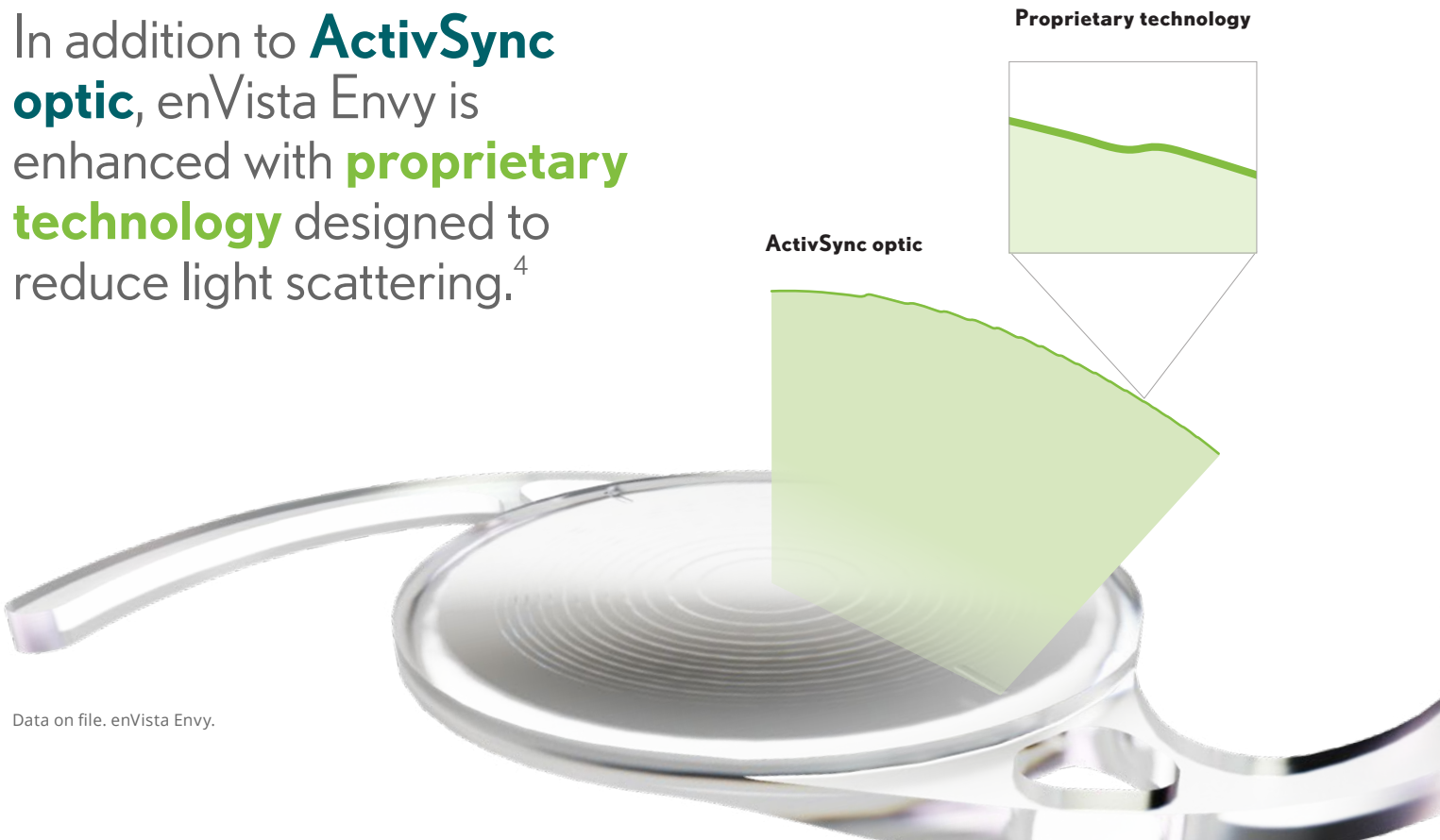
- Full range of vision diffractive anterior surface
- 1.2mm central zone
- 1.6 D intermediate and 3.1 D near adds
- Consistent -0.15µm SA profile across full diopter range



SA = spherical aberration

enVista
HYDROPHOBIC ACRYLIC IOL
ENVY

In addition to **ActivSync optic**, enVista Envy is enhanced with **proprietary technology** designed to reduce light scattering.[4]



Data on file. enVista Envy.


enVista Envy demonstrated exceptional visual outcomes[1]
enVista
HYDROPHOBIC ACRYLIC IOL
ENVY
enVista Envy US Clinical Study

enVista Envy performance is supported by a robust US clinical study

A multicenter, randomized, and controlled clinical trial which assessed the safety and effectiveness of the enVista Envy IOL included a one-year follow-up period and demonstrated excellent long-term outcomes.[1]



332 ENVISTA ENVY (TEST GROUP)

664 number of eyes

169 ENVISTA (CONTROL GROUP)

338 number of eyes

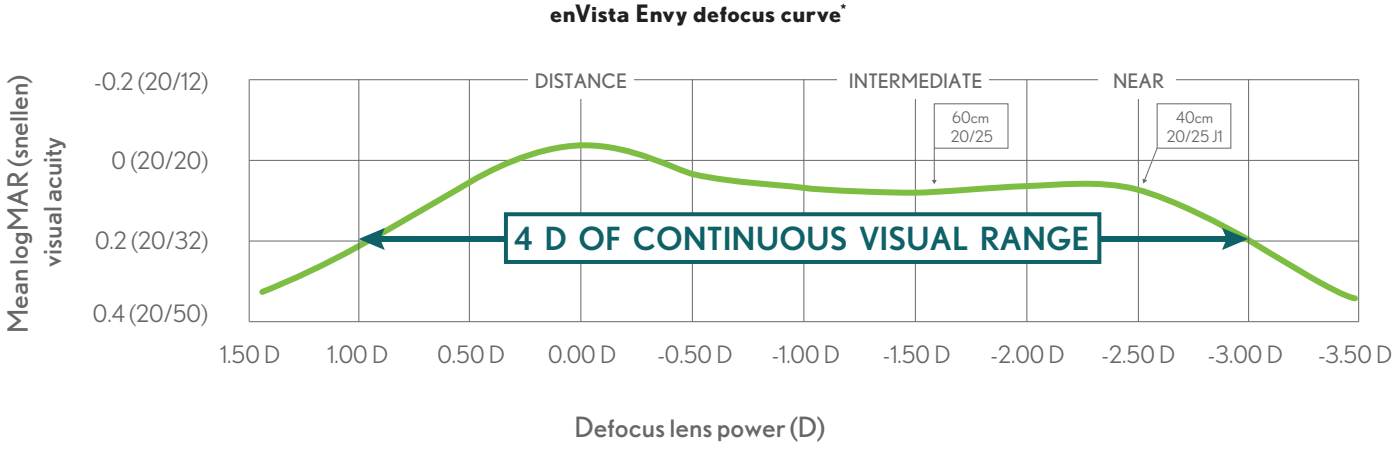
23 INVESTIGATION SITES

enVista Envy US Clinical Study

enVista Envy™ delivers excellent image contrast for low-light visual clarity[4]

enVista
HYDROPHOBIC ACRYLIC IOL
ENVY™

Help your patients achieve spectacle independence[1]



*enVista Envy US Clinical Study, n=53 patients reported outcomes 4–6-month post-op, bilateral

enVista Envy achieved excellent mean visual acuity results in a robust US clinical study[1]

Near



DCNVA Bilateral
Photopic Conditions

n=284

Intermediate



DCIVA Bilateral
Photopic Conditions

n=283

Distance



BCDVA Bilateral
Photopic Conditions

n=312

enVista
HYDROPHOBIC ACRYLIC IOL
ENVY™

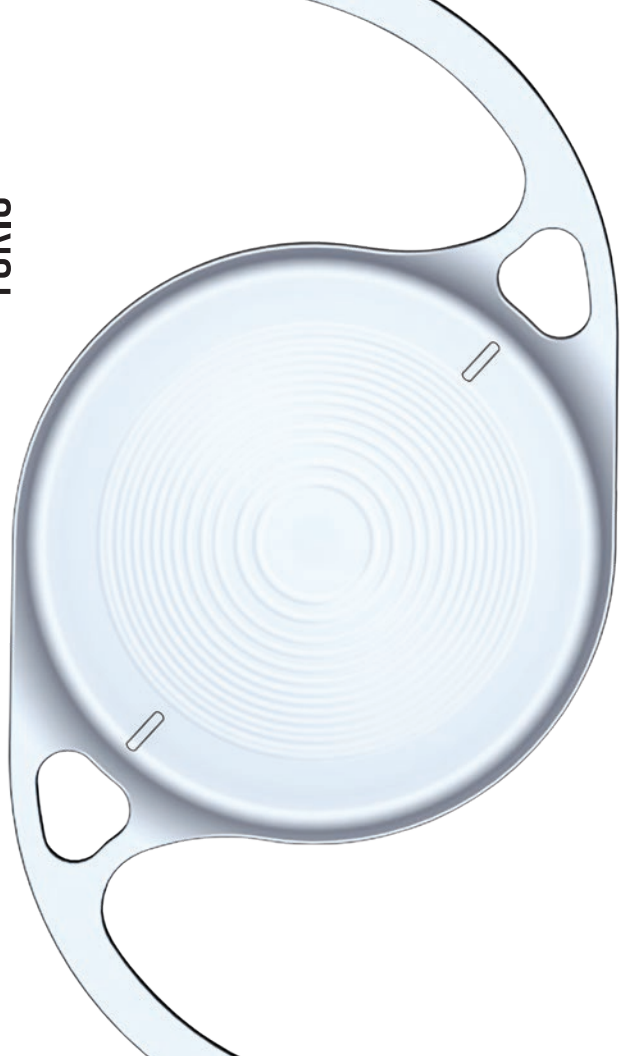
enVista Envy US Clinical Study, bilateral implantation, 4–6-month post-op



enVista ENVY™ TORIC

Spectacle independence is achievable

Studies have shown that patients who received a full range of vision IOL lens with >0.5 D of residual astigmatism see a significant reduction in their quality of distance vision.[6, 7, 9]



Correcting cataracts and astigmatism. **BOTH at the same time.**

Benefits of Toric IOLs

- Reduces the need for additional refractive correction procedures.
- Provides greater accuracy and range than corneal-incisional and limbal-relaxing procedures.[8]

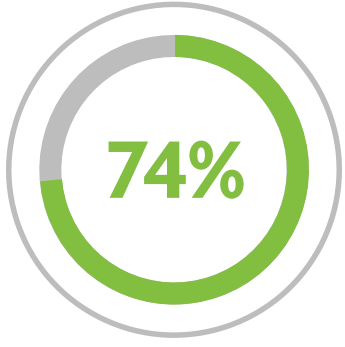
Low-Cyl technology expands premium options for low astigmatism treatment

With Low-Cyl technology:

Broaden the treatable astigmatism range in cataract surgery to as low as <1.0 D at the corneal plane.[10]

The first and only full range of vision toric platform available in the US

providing Low-Cyl toric technology (1.25 D at the IOL plane)

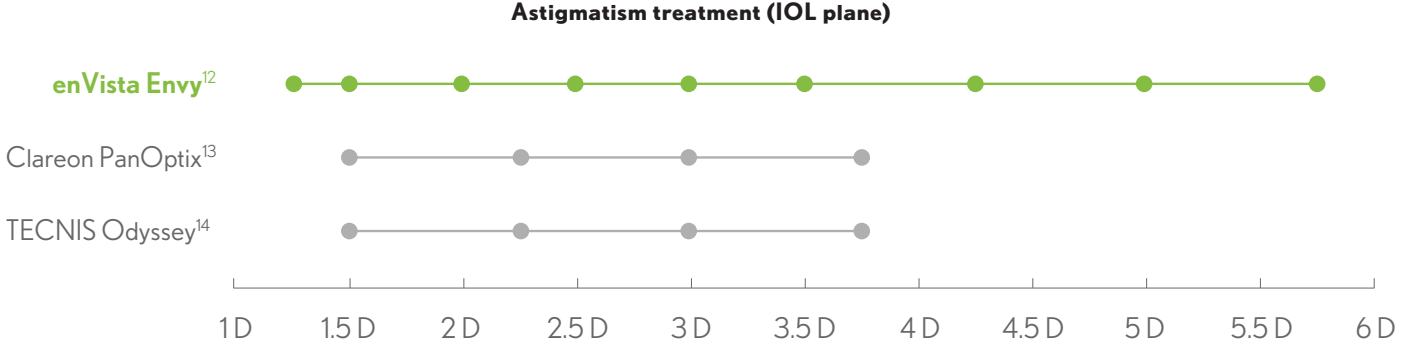


of cataract patients have less than 1.25 D of corneal astigmatism.[11]

enVista HYDROPHOBIC ACRYLIC IOL ENVY TORIC

Astigmatism treatment options for MORE patients with MORE precision[5]

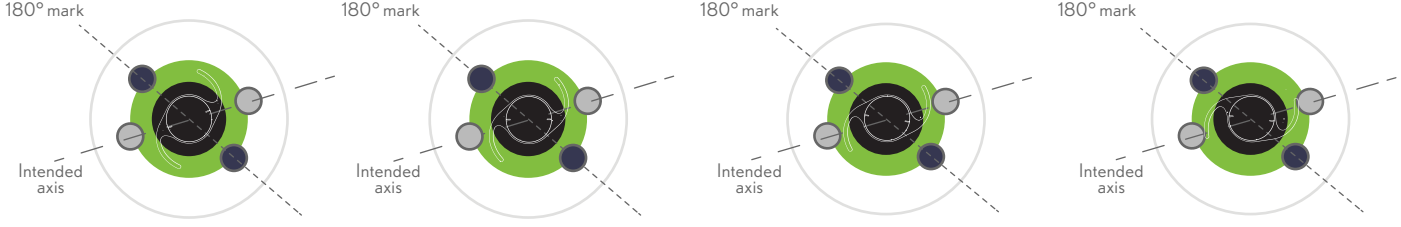
- **Lowest** available cylinder treatment: 1.25 D at IOL plane (<1 D at corneal plane)*
- **Highest** available cylinder treatment: 5.75 D at IOL plane*
- **Only** toric platform that treats half-step cylinders (up to 3.5 D at IOL plane)*



*Comparison to available multifocal toric platforms approved in the US

The enVista platform is tailored for EXCELLENT stability and toric outcomes

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



1° Lens Rotation
Effectiveness 96.7%[15]

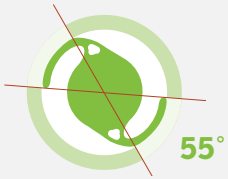
5° Lens Rotation
Effectiveness 83.5%[15]

10° Lens Rotation
Effectiveness 67%[15]

30° Lens Rotation
Effectiveness 1%[15]

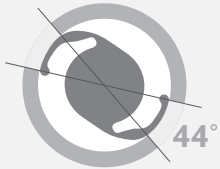
enVista HYDROPHOBIC ACRYLIC IOL ENVY TORIC

110° of capsular bag contact



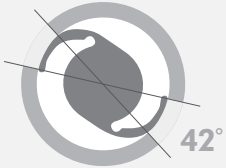
enVista toric platform[4]

88° of capsular bag contact



AcrySof IQ/CLAREON[4] toric platform

84° of capsular bag contact

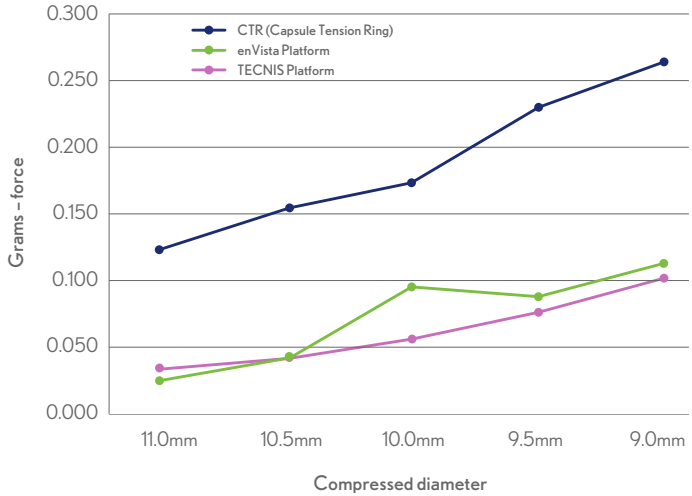


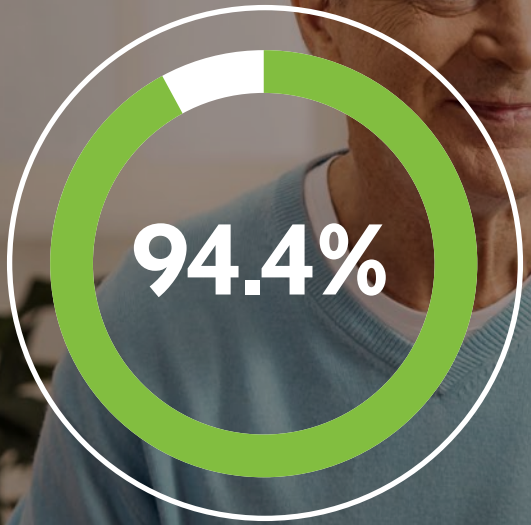
TECNIS toric platform[4]

Achieve reliable rotational stability for precise astigmatism correction

- 110° of capsular bag contact
- Delivers 300% more radial compression force than traditional hydrophobic IOLs[16]
- Demonstrated higher outward radial force compared to the TECNIS IOL toric platform[16]

Radial compression force - IOL platforms[17]





The enVista toric platform delivers proven rotational stability through **180 days post-surgery**[4]

Percent of eyes ≤ 5° rotation *(n=108)*

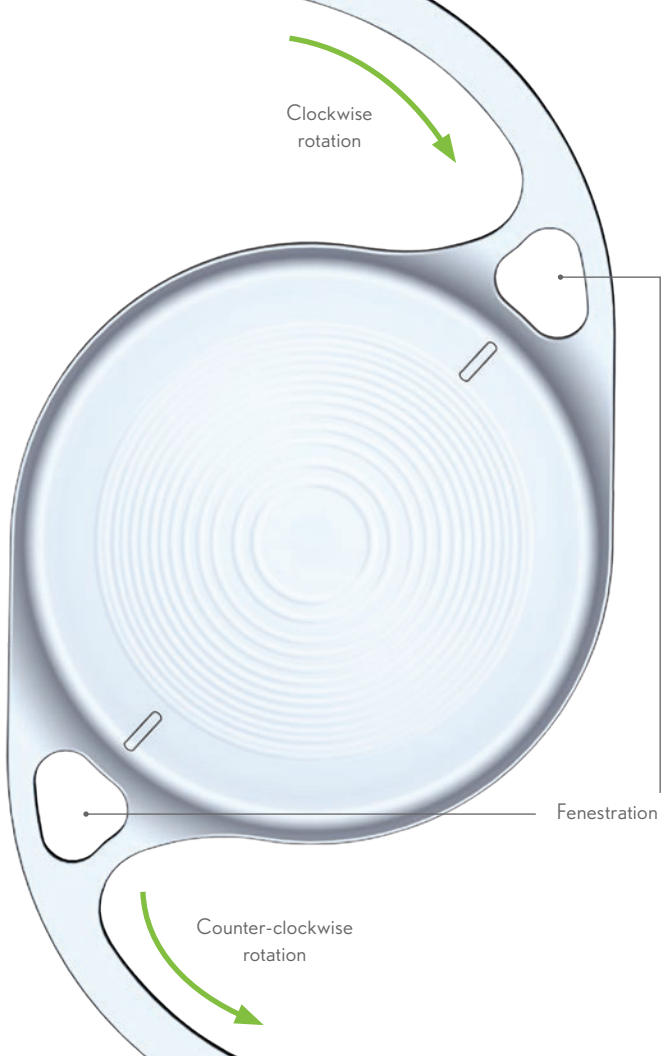
enVista Toric MX60ET US Clinical Study

enVista HYDROPHOBIC ACRYLIC IOL ENVY TORIC

Simplified intraoperative lens manipulation

The unique fenestration holes of enVista Envy Toric simplify lens manipulation during surgery,[26] 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.[18]

Using the EVO formula:

- Around 80% of patients achieve a targeted range of 0 to 0.5 D, surpassing traditional vergence formulas.[19]
- The proportion of eyes with a refractive astigmatism of ≤ 1.0 D is statistically superior compared to the Kane formula.[25]
- Improved alignment between predicted and actual refractive astigmatism compared to legacy formulas.[18]

The EVO formula includes posterior corneal astigmatism (PCA) modeling and IOL geometry considerations[1] to determine spherical equivalent refractive error, and the suitable IOL power, based on biometry.

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

enVista HYDROPHOBIC ACRYLIC IOL ENVY TORIC

Delivery systems

Available for enVista Envy and enVista Envy Toric IOLs





BLIS® (reusable solution)

- Quality engineering and built from high-grade titanium.
- Requires a small incision size of 2.2mm to 2.4mm, for smooth lens deliveries.[20]

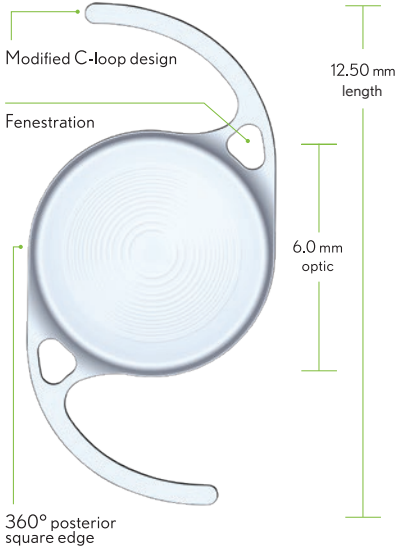
EyeGility™ (singe-use solution)

- Silicone soft-tip plunger supports reliable delivery of the IOL into the eye.[21]
- Push type delivery enables convenient one-handed operation.[21]

enVista ENVY

HYDROPHOBIC ACRYLIC IOL

EN order number ENUXXXX
EC24N order number EC24NUXXXX



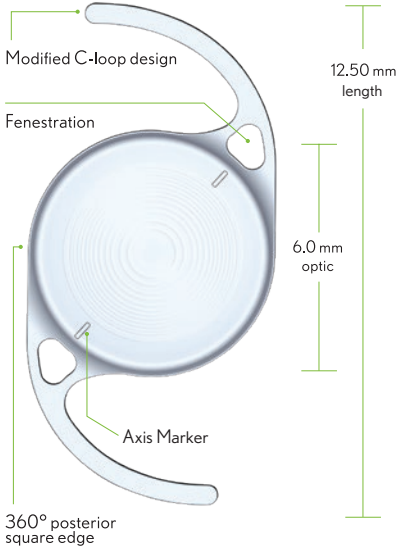
	EN (non-preload)	EC24N
MODEL NUMBER		
MATERIAL	Hydrophobic Acrylic	Hydrophobic Acrylic
OPTIC DESIGN	One-piece Aspheric, biconvex Anterior apodized diffractive Posterior refractive Posterior aspheric surface 1.6 D intermediate 3.1 D near	One-piece Aspheric, biconvex Anterior apodized diffractive Posterior refractive Posterior aspheric surface 1.6 D intermediate 3.1 D near
OPTIC SIZE	6mm	6mm
LENGTH	12.5mm	12.5mm
OPTIC EDGE DESIGN	Sharp 360° square posterior edge	Sharp 360° square posterior edge
HAPTICS	Modified C, fenestrated	Modified C, fenestrated
REFRACTIVE INDEX	1.53 at 35° C	1.53 at 35° C
UV CUTOFF	389nm at 10% transmittance	389nm at 10% transmittance
OPTICAL BIOMETRY (OPTIMIZED) Optical A-constant* ACD Surgeon Factor	 119.24 5.788mm 1.981mm	 119.24 5.788mm 1.981mm
OTHER FEATURES	Glistening free	Glistening free
DIOPTER RANGE	+6 D to +10 D (1.0 D increments) +10 D to +34 D (0.5 D increments)	+10D to +30D (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 ENVY™ TORIC

HYDROPHOBIC ACRYLIC IOL

ETN order number ETNU CCC+XXX
ETPN order number ETPNU CCC+XXX



C represents cylinder, X represents diopter

MODEL NUMBER	ETN (non-preload)	ETPN (preloaded)
MATERIAL	Hydrophobic Acrylic	Hydrophobic Acrylic
OPTIC DESIGN	One-piece Aspheric, biconvex Anterior apodized diffractive Posterior refractive Posterior toricity 1.6 D intermediate 3.1 D near	One-piece Aspheric, biconvex Anterior apodized diffractive Posterior refractive Posterior toricity 1.6 D intermediate 3.1 D near
OPTIC SIZE	6mm	6mm
LENGTH	12.5mm	12.5mm
OPTIC EDGE DESIGN	Sharp 360° square posterior edge	Sharp 360° square posterior edge
HAPTICS	Modified C, fenestrated	Modified C, fenestrated
REFRACTIVE INDEX	1.53 at 35° C	1.53 at 35° C
UV CUTOFF	389nm at 10% transmittance	389nm at 10% transmittance
OPTICAL BIOMETRY (OPTIMIZED) Optical A-constant* ACD Surgeon Factor	 119.24 5.788mm 1.981mm	 119.24 5.788mm 1.981mm
OTHER FEATURES	Glistening free	Glistening free
DIOPTER RANGE	+6 D to +10 D (1.0 D increments) +10 D to +34 D (0.5 D increments)	+10D to +30D (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.

Indications and Important Safety Information for enVista Envy™ IOL

INDICATIONS: The enVista Envy hydrophobic acrylic IOL is indicated for primary implantation in the capsular bag of the eye in adult patients for visual correction of aphakia with less than or equal to 1.0 D preoperative corneal astigmatism following removal of a cataractous lens to mitigate the effects of presbyopia by providing improved intermediate and near visual acuity, while maintaining comparable distance visual acuity to an aspheric monofocal IOL.

WARNINGS/PRECAUTIONS: Physicians should weigh the potential risk/benefit ratio before implanting the enVista Envy lens under any of the circumstances or conditions outlined in the Instructions for Use labeling. Some visual disturbances may be expected due to the superposition of focused and unfocused multiple images. These may include some perceptions of halos or radial lines around point sources of light (starbursts) under nighttime conditions, glare, double vision, haziness and blurred vision. It is expected that, in a small percentage of patients, the observation of such phenomena will be annoying and may be perceived as a hindrance, particularly in low illumination conditions such as nighttime driving. As with other trifocal IOLs, there is a possibility that visual disturbances may be significant enough that the patient will request explant of the IOL. A reduction in contrast sensitivity as compared to a monofocal IOL may be experienced by some patients, therefore, patients implanted with trifocal IOLs should exercise caution when driving at night or in low light or poor visibility conditions. Care should be taken to achieve IOL centration as IOL decentration may result in patients experiencing visual disturbances or suboptimal vision under certain lighting conditions. The surgeon must target emmetropia to achieve optimal visual performance. Patients should be advised that unexpected outcomes could lead to continued spectacle dependence or the need for secondary surgical intervention (e.g., intraocular lens replacement or repositioning). Please provide a copy of the Patient Information Brochure, which can be found at www.bausch.com/IFU. Posterior capsule opacification (PCO) may significantly affect the vision of patients with multifocal IOLs earlier in its progression than patients with monofocal IOLs. This may be due to the reduced contrast sensitivity observed with multifocal IOLs.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

ATTENTION: See the Directions for Use for a complete listing of indications and important safety information.

enVista
HYDROPHOBIC ACRYLIC IOL
ENVY™

Indications and Important Safety Information for enVista Envy™ Toric IOL

INDICATIONS: The enVista Envy toric hydrophobic acrylic IOL is indicated for primary implantation in the capsular bag of the eye in adult patients for visual correction of aphakia and corneal astigmatism following removal of a cataractous lens to mitigate the effects of presbyopia by providing improved intermediate and near visual acuity, while maintaining comparable distance visual acuity to an aspheric monofocal IOL.

WARNINGS/PRECAUTIONS: Physicians should weigh the potential risk/benefit ratio before implanting the enVista Envy lens under any of the circumstances or conditions outlined in the Instructions for Use labeling. Some visual disturbances may be expected due to the superposition of focused and unfocused multiple images. These may include some perceptions of halos or radial lines around point sources of light (starbursts) under nighttime conditions, glare, double vision, haziness and blurred vision. It is expected that, in a small percentage of patients, the observation of such phenomena will be annoying and may be perceived as a hindrance, particularly in low illumination conditions such as nighttime driving. As with other trifocal IOLs, there is a possibility that visual disturbances may be significant enough that the patient will request explant of the IOL. A reduction in contrast sensitivity as compared to a monofocal IOL may be experienced by some patients, therefore, patients implanted with trifocal IOLs should exercise caution when driving at night or in low light or poor visibility conditions. Care should be taken to achieve IOL centration as IOL decentration may result in patients experiencing visual disturbances or suboptimal vision under certain lighting conditions. The surgeon must target emmetropia to achieve optimal visual performance. Patients should be advised that unexpected outcomes could lead to continued spectacle dependence or the need for secondary surgical intervention (e.g., intraocular lens replacement or repositioning). Please provide a copy of the Patient Information Brochure, which can be found at www.bausch.com/IFU. Posterior capsule opacification (PCO) may significantly affect the vision of patients with multifocal IOLs earlier in its progression than patients with monofocal IOLs. This may be due to the reduced contrast sensitivity observed with multifocal IOLs. The enVista Envy Toric IOL has not been evaluated in a clinical study. In general, astigmatism that is corrected with a higher cylinder power IOL can result in clinically significant residual astigmatism. The effect of residual astigmatism at distance, intermediate, and near was evaluated in a clinical study of patients who had been implanted with non-toric enVista Envy IOLs and were induced with cylinder power to simulate various levels of residual astigmatism. If a secondary surgical intervention is necessary to reposition the IOL, explantation should be considered as some patients may have recurrent or persistent issues related to rotational instability and misalignment.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

ATTENTION: See the Directions for Use for a complete listing of indications and important safety information.

enVista HYDROPHOBIC ACRYLIC IOL ENVY TORIC

Advanced enVista IOL platform features

TruSight® technology

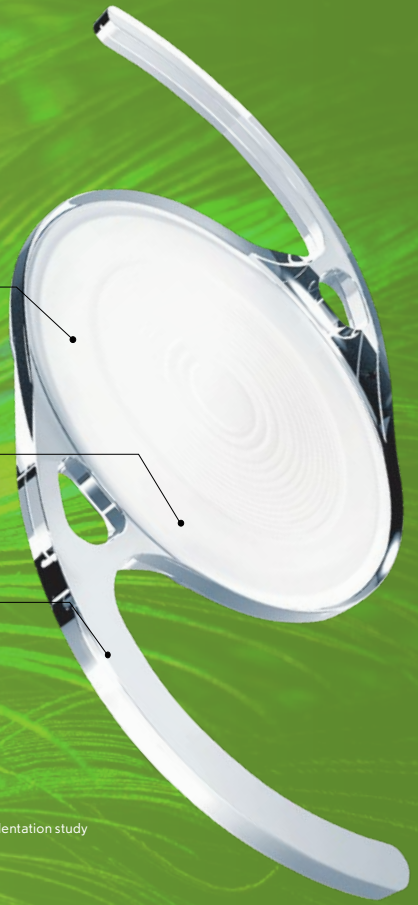
Glistening-free material* with improved scratch resistance and 25x the hardness of traditional hydrophobic acrylic IOLs.[22,**]

StableFlex® technology

Efficient lens unfolding, ensuring excellent optic recovery.[12]

SureEdge® design

Outstanding defense against Posterior Capsular Opacification (PCO).[12, 24]



*Glistenings are observed by ophthalmologists at the slit lamp as backscatter. There has been no established correlation between these backscatter observations and what patients observe.

**Based on nanoindentation study

References

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3. Alcon AcrySof PanOptix Clinical Study.
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