enVista®
hydrophobic acrylic IOL

enVista® toric
One-piece Hydrophobic Acrylic Toric Intraocular Lens

The monofocal IOL that listened to your needs and gives a + to your patients

More than 5 million eyes already enjoying the enVista® experience worldwide[1]

1. enVista® and Enhanced enVista® shipments extract 2011-May 2022

CATARACT

LASER

RETINA

BAUSCH + LOMB
See better. Live better.

enVista®
hydrophobic acrylic IOL

I KNOW YOU...

...are in love with my **glistening free**[2,3] material

...are in love with my **resistance to tough conditions**[4]

...are in love with my **rotational and refractive stability**[2, 3, 5, 6]

...are in love with my **low PCO* rate**[2, 7]

MY SURGEON

***PCO: Posterior Capsular Opacification**

2. Parker et al. Safety and effectiveness of a glistening-free single-piece hydrophobic acrylic intraocular lens (enVista®). Clin Ophthalmol. 2013;7:1905–1912.
3. 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.
4. BAUSCH + LOMB data on file: rb_011216_081636_Enhanced enVista_Material Properties Testing
5. Parker et al. Prospective multicenter clinical trial to evaluate the safety and effectiveness of a new glistening-free one-piece acrylic toric intraocular lens. Clin Ophthalmol. 2018;12:1031-103.
6. Garzón N et al. Evaluation of Rotation and Visual Outcomes After Implantation of Monofocal and Multifocal Toric Intraocular Lenses. J. Refract. Surg.2015;31(2), 1-9.
7. Ton Van C, Tran THC. Incidence of posterior capsular opacification requiring Nd:YAG capsulotomy after cataract surgery and implantation of enVista® MX60 IOL. J Fr Ophtalmol. 2018 Dec;41(10):899-903

CATARACT

LASER

RETINA

BUT ALSO I KNOW...

...that sometimes you flirt with others with **quicker unfolding** than me, maybe I am a little bit shy

...you are looking for an easy solution for a preloaded , as a **preloaded** relationship

I promise that from now on, I will give you what you are looking for...

BAUSCH+LOMB
See better. Live better.

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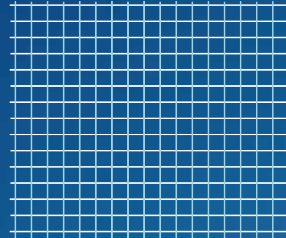
hydrophobic acrylic IOL

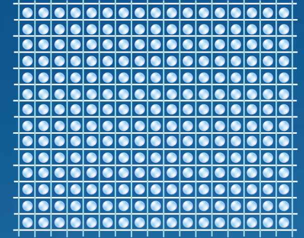
GLISTENING-FREE MATERIAL

Trusight™ Optic - Glistening-free

Hydrated to an equilibrium water content and then packaged in 0.9 % physiological saline solution to prevent glistening formation

No glistenings of any grade were reported for any subject at any visit[8, 9]

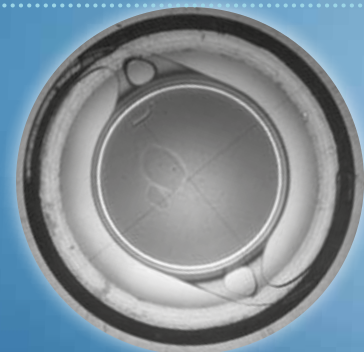

dry state


equilibrium wet state

Accelerated ageing in-vitro glistening evaluation[10]

IOL	Average Microvacuoles/mm² ± Standard Deviation
Enhanced enVista® (Bausch + Lomb)	0.59 ± 0.63
EyeCee® ONE (Bausch + Lomb)	1.05 ± 0.21
Clareon® IOL (Alcon)	1.20 ± 1.16
MicroPure (PhysIOL)	2.45 ± 3.13

COMPRESSION FORCES


ISO 11979-3 model

Accuset™ Haptics - designed for refractive predictability and stable centration[8, 9, 11]

Large capsular bag contact

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

enVista® IOL[12]
(Based on 10 mm capsular bag)

AcrySof IQ®[13]
(Based on 10 mm capsular bag)

Tecnis IOL®[14]
(Based on 10 mm capsular bag)

8. Parker et al. Safety and effectiveness of a glistening-free single-piece hydrophobic acrylic intraocular lens (enVista®). Clin Ophthalmol. 2013:7 1905-1912.
9. 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.
10. Auffarth G. Schickhardt S., Zhang L., Monroe D.J: IOL material quality study - David J Apple Internantional Laboratory- University-Eye Clinic Heidelberg_ August 2020
11. Garzon et al. Evaluation of Visual Outcomes After Implantation of Monofocal and Multifocal Toric Intraocular Lenses. J Refract Surg. 2015;31(2):90-97.
12. BAUSCH + LOMB data on file : Intraocular lens design verification report- July 2016.
13. BAUSCH + LOMB data on file: IOL competitive benchmarking study report_DEC 2009.
14. PMA P980040/S039: FDA Summary of Safety and Effectiveness Data_Tecnis Toric IOL.

FASTER UNFOLDING

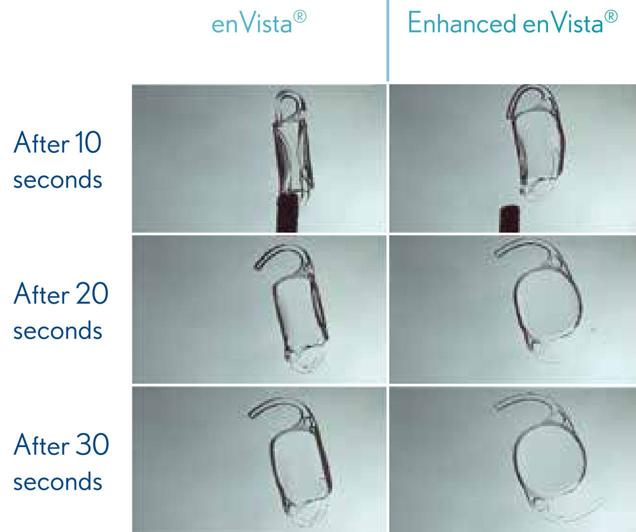
Stableflex™ Technology

Formulation updated for faster unfolding

The Enhanced enVista® IOL material is made of the same polymers as its precursor, but their proportions have been modified to decrease the glass transition temperature (Tg) from 23°C to 15°C.

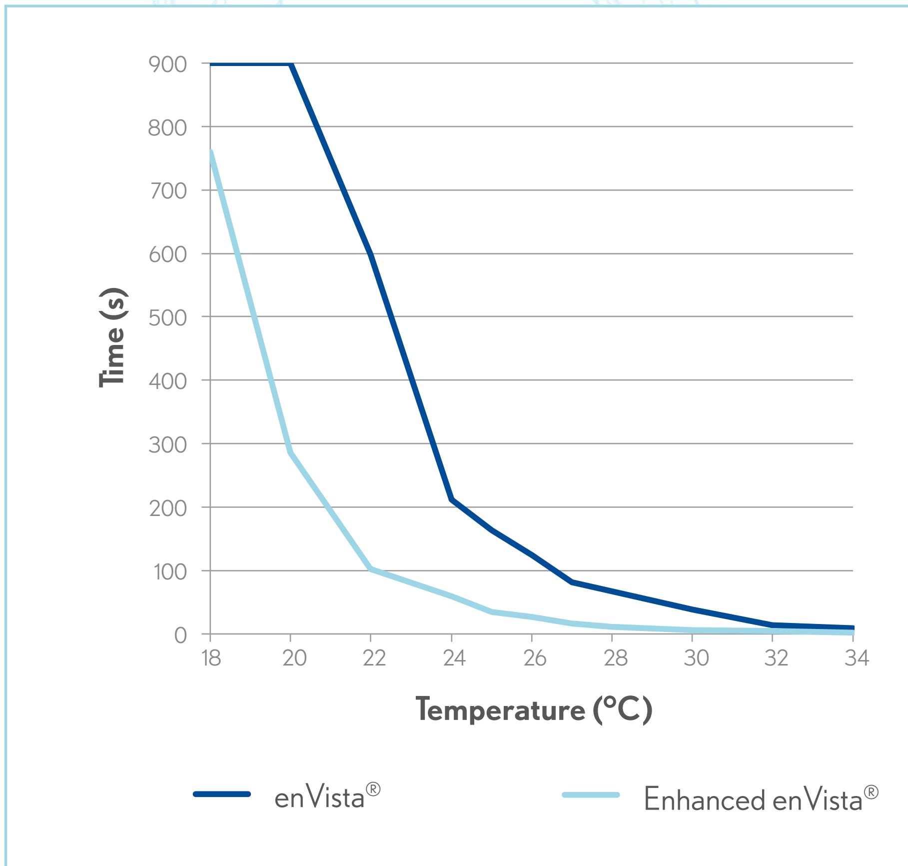
The lower Tg of the Enhanced enVista® allows better injectability, with faster and improved unfolding efficiency at lower temperatures (18°C to 30°C) compared to the enVista®.

+20.00 D Unfolding at 25°C

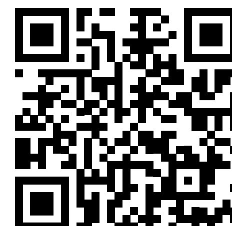


Images comparing the unfolding time between enVista® and Enhanced enVista®

Unfolding time according to temperature (laboratory testing)[15]



Scan here to watch a video of the faster unfolding with the Enhanced enVista®



15. BAUSCH + LOMB data on file: Enhanced enVista® Unfolding Study Report_ENG16-067S_August 2016

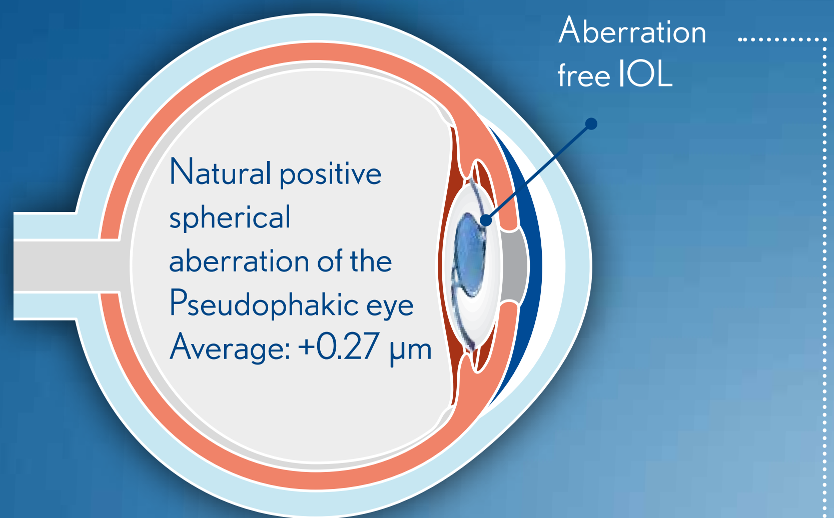
enVista®
hydrophobic acrylic IOL

ABERRATION-FREE ASPHERIC OPTIC DESIGN

Enhanced enVista® is designed to have no spherical aberrations. It is inherently **"aberration-free"**. The resultant pseudophakic eye has a natural amount of positive spherical aberration.

Residual spherical aberration = Natural positive spherical aberration of the Pseudophakic eye with Enhanced enVista®

Average: +0.274 ± 0.089 µm[16]



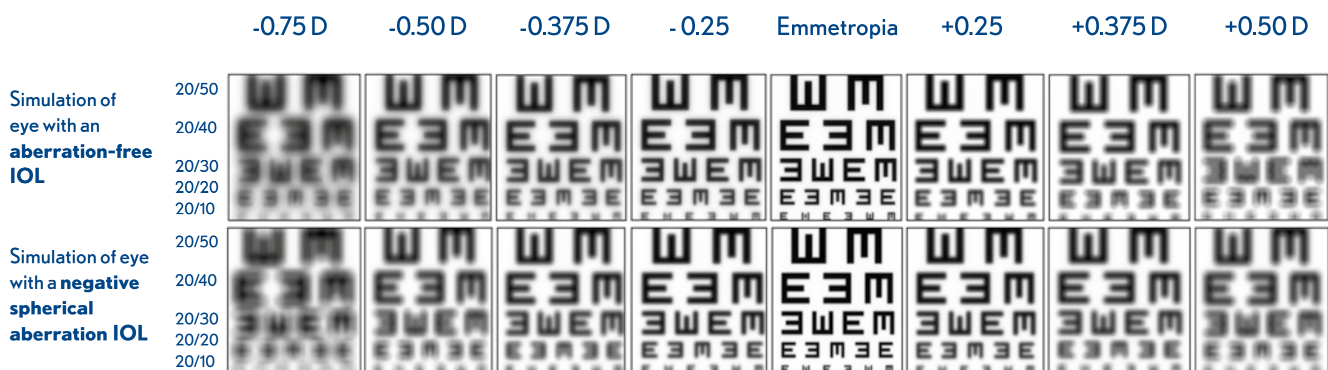
Depth of focus and residual spherical aberration

Maintaining a certain amount of positive spherical aberration after surgery can provide greater depth of focus[17]

- Using Adaptive Optic simulation, some authors reported that a slight residual amount of positive spherical aberration offers a good compromise between distance visual acuity and depth of focus[18]
- In an optical bench evaluation, aspheric IOLs designed to compensate the spherical aberrations demonstrated a lower tolerance to defocus with a significantly smaller depth of focus compared to spherical IOLs[19]
- A randomized study reported a statistically significant lower distance-corrected near visual acuity with aspheric negative IOLs compared to the spherical version[20]

16. Beiko, George H.H. BM, BCh, FRCS(C); Haigis, Wolfgang MS, PhD; Steinmueller, Andreas MS Distribution of corneal spherical aberration in a comprehensive ophthalmology practice and whether keratometry can predict aberration values, Journal of Cataract & Refractive Surgery. May 2007 - Volume 33 - Issue 5 - p 848-858 doi: 10.1016/j.jcrs.2007.01.035.
17. Nio YK, Jansonius NM, Fidler V, Geraghty E, Norrby S, Kooijman AC. Spherical and irregular aberrations are important for the optimal performance of the human eye. Ophthalmic Physiol Opt. 2002 Mar;22(2):103-12.
18. Ruiz-Alcocer J, Pérez-Vives C, Madrid-Costa D, García-Lázaro S, Montés-Micó R. Depth of focus through different intraocular lenses in patients with different corneal profiles using adaptive optics visual simulation. J Refract Surg. 2012 Jun;28(6):406-12. doi: 10.3928/1081597X-20120518-03. PMID: 22692522.
19. Marcos S, Barbero S, Jiménez-Alfaro I. Optical quality and depth-of-field of eyes implanted with spherical and aspheric intraocular lenses. J Refract Surg. 2005 May-Jun;21(3):223-35.
20. Rocha KM, Soriano ES, Chamon W, Chalita MR, Nosé W. Spherical aberration and depth of focus in eyes implanted with aspheric and spherical intraocular lenses: a prospective randomised study. Ophthalmology. 2007 Nov;114(11): 2050-4.

Using optical ray tracing simulations, the enVista® aberration-free IOL demonstrated a wider range of improved image resolution when compared to an IOL with a negative spherical aberration.



USAF resolution test chart obtained by R+D laboratory testing at BAUSCH + LOMB[21]

- The aberration-free IOL shows a 0.25 D to 0.30 D depth of focus increase (compared with negative spherical aberration IOL) based on the resolvability of the target of 20/20 or 20/30.

	Depth of focus based on 20/20 vision	Depth of focus based on 20/30 vision
Aberration-free IOL	-0.5 D to +0.25 D, total 0.75 D	-0.75 D to +0.375 D, total 1.125 D

Data obtained by R+D laboratory testing at BAUSCH + LOMB[21]

21. Data on file: AO Technology_V19-098M_R&D report Sept 2019

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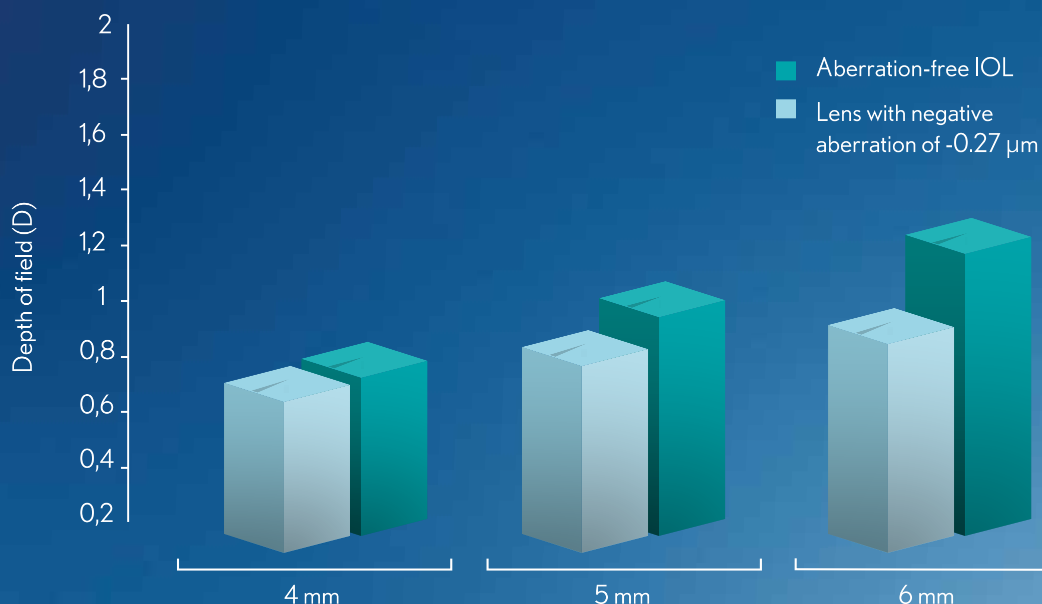
A multicentre study has shown that aspheric optics with Advanced Optics technology provide greater depth of field than aspheric optics with a negative aberration, which could contribute to greater visual quality perception[22]



Graph adapted from Johansson B et al. Average depth of field assessed by the Strehl ratio (adapted from the original box plot diagram with different pupil sizes)

Depth of focus and residual spherical aberration

In a recent prospective randomized study, the authors reported a significantly better DCNVA measured at 33 cm with enhanced enVista preloaded compared to Tecnis Monofocal 1-Piece

	Monocular	Enhanced enVista®	TECNIS® Monofocal 1-Piece
Rocha et al 2020[23]	DCNVA (33 cm)	0.29 ffl 0.16	0.42 ffl 0.24

- Aberration-free IOLs are likely to produce higher positive spherical aberration and better DCNVA than a negative spherical aberration IOL[23]

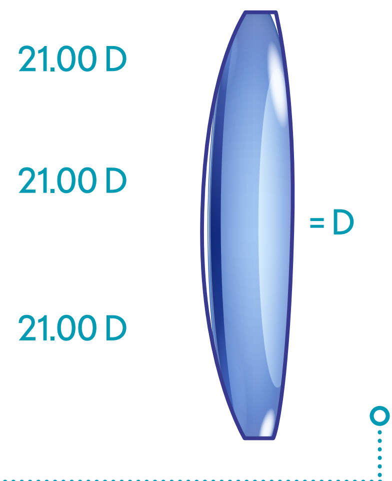
22. Johansson B, Sundelin S, Wikberg-Matsson A, Unsbo P, Behndig A. Visual and optical performance of the Akreos Adapt Advanced Optics and Tecnis Z9000 intraocular lenses: Swedish multicenter study. J Cataract Refract Surg. 2007. Sep;33(9):1565-72.
23. Karolinne Maia Rocha, Larissa Gouvea, George Oral Waring, Jorge Haddad. Static and Dynamic Factors Associated With Extended Depth of Focus in Monofocal Intraocular Lenses. American Journal of Ophthalmology Volume 216, 2020, Pages 271-282, ISSN 0002-9394, https://doi.org/10.1016/j.ajo.2020.04.014.

Tolerance to decentration

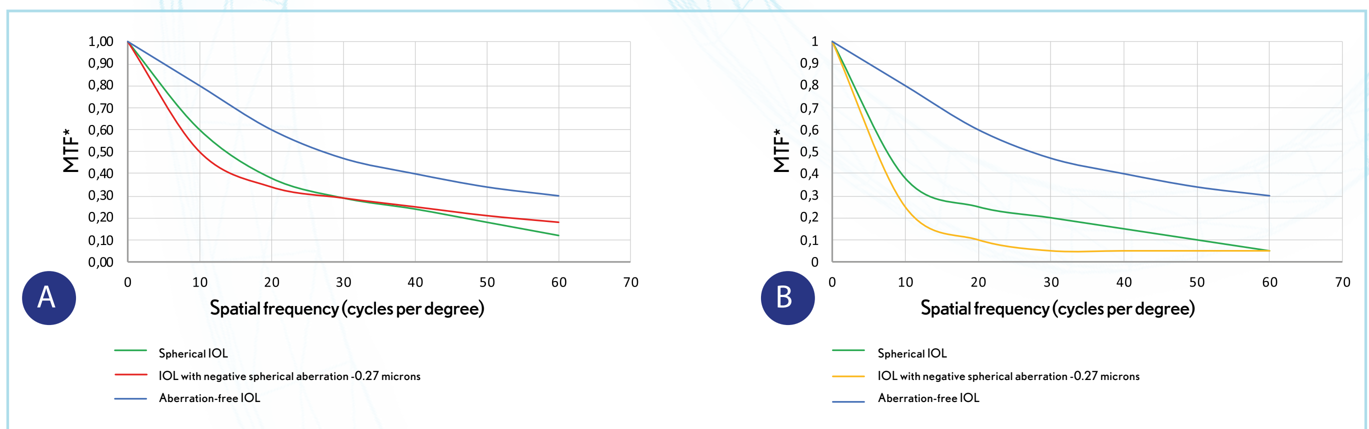
Decentration is much more frequent than one might think

A large series of 395 eyes reported an average IOL decentration after uncomplicated cataract surgery of 0.40 ± 0.2 mm (range 0 to 1.7 mm) [24]

- The neutral aspherical design of both the anterior and posterior optical surfaces of the Enhanced enVista® lens allows for the constant power of the lens, from the centre to the periphery of its optic
- Enhanced enVista® lens is aberration-free, and therefore, it is more robust to decentration[25,26]



Performance of different IOLs based on decentration[25]



A. The IOLs are decentered 0.5 mm. Induction of asymmetrical HOAs degraded the performances of both the spherical IOL and the one inducing a negative spherical aberration, causing the MTF curves to droop and separate.

B. The IOLs are decentered 1.0 mm, further degrading the performance of the spherical IOL and the one inducing a negative spherical aberration but not the aberration-free IOL.

Figure adapted from Altman GE, et al.2005. obtained with the B+L Sofport IOL, having the same AO technology aberration free optic. For a 4 mm pupil diameter. (S= sagittal T= tangential).
*MTF: Modulation Transference Function

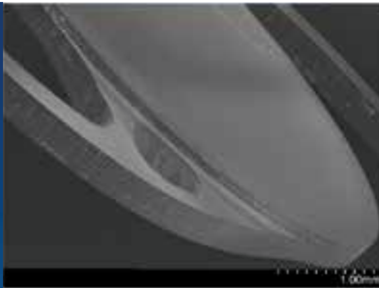
24. Harrer A., Hirnschall N., Tabernero J et al : Variability in angle k and its influence on higher-order aberrations in pseudophakic eyes J Cataract Refract Surg 2017; 43:1015-1019
25. Altmann GE, Nichamin LD, Lane SS, Pepose JS. Optical performance of 3 intraocular lens designs in the presence of decentration. J Cataract Refract Surg. 2005Mar;31(3):574-85.
26. McKelvie J, McArdle B, McGhee C. The influence of tilt, decentration, and pupil size on the higher-order aberration profile of aspheric intraocular lenses. Ophthalmology. 2011 Sep;118(9):1724-31. doi: 10.1016/j.ophtha.2011.02.025. Epub 2011 Jun 12. PMID: 21665282.

enVista®
hydrophobic acrylic IOL

360° POSTERIOR OPTIC BARRIER

SureEdge™ Design - Continuous 360° posterior square edge

Implantation of the enVista® (MX60) is associated with low, three-year cumulative incidence rates of PCO requiring Nd:YAG laser capsulotomy.



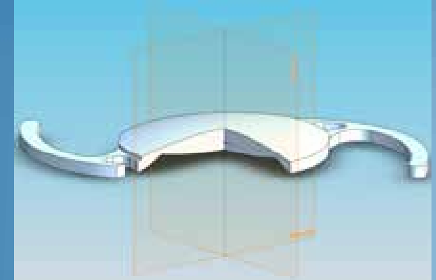
A- Square edge continues at optic haptic junction.

B- Edge profile. Radius of curvature <10µm.

C- Edge profile at Optic-haptic junction. Radius of curvature <10µm.

All images of +20.00 D IOLs shown at same scale to aid comparison. Posterior optic edge at top left of all images. By courtesy of D. Spalton[27]

The enVista® IOL has step-vaulted haptics that translate the optic posteriorly for direct contact with the capsular bag, which owing to its hydrophobic surfaces, leads to a reduction in PCO.[28]

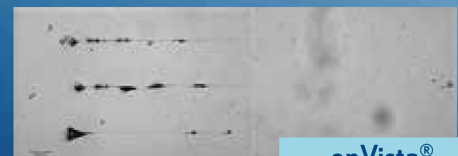


SCRATCH RESISTANCE[29]

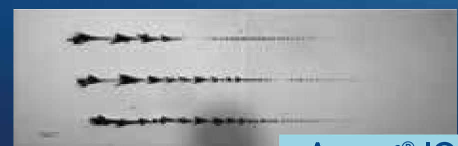
Nanoscratch Evaluation done by R+D laboratory testing at BAUSCH + LOMB:

Ramped load scratches were generated in the 0.3-80 mN range using a 8 micron radius, 60 degree conical diamond stylus while submerged in saline solution.

- Scratch velocity of 5 mm/minute and a loading rate of 199.25 mN/minute.
- Optical microscope to examine scratch morphologies and determine the onset of cracking/material damage.



enVista®

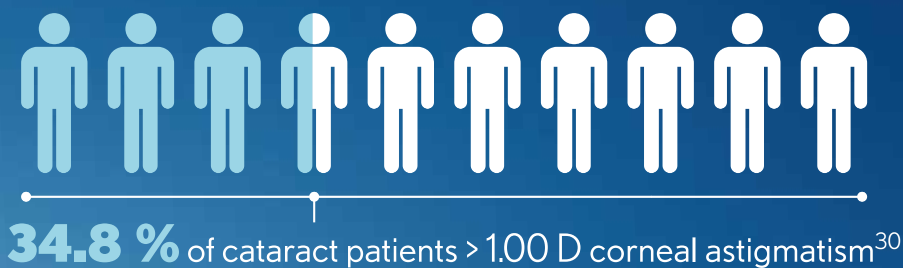


Acrysof® IQ

27. Anish Dhital, David Spalton, Jimmy Boyce: enVista square edge evaluation_Saint Thomas Hospital _2011
28. Ton Van C, Tran THC. Incidence of posterior capsular opacification requiring Nd:YAG capsulotomy after cataract surgery and implantation of enVista® MX60 IOL. J Fr Ophtalmol. 2018 Dec;41(10):899-903.
29. . BAUSCH + LOMB data on file: rb_011216_081636_Enhanced enVista_Material Properties Testing

THE CLINICAL NEED FOR ASTIGMATISM CORRECTION

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



34.8 % of cataract patients > 1.00 D corneal astigmatism[30]

52.8 % Market potential for Toric IOLs[31]

But **7 %** of all IOL procedures are toric IOLs[31]

Small amount of astigmatism has the potential to affect functional and low-contrast visual acuity[32], and has an impact on the visual confort of computer users[33]

30. Teresa Ferrer-Blasco, Robert Montés-Micó, Sofia C. Peixoto-de-Matos, José M. González-Méijome, Alejandro Cerviño. Prevalence of corneal astigmatism before cataract surgery. Journal of Cataract & Refractive Surgery, Volume 35, Issue 1, 2009.
31. Market Scope 2019
32. Miller A, Kris M, Griffiths A. Effect of small focal errors on vision. Opt Vis Sci. 1997;74(7):521-526
33. Rosenfield M. Computer vision syndrome: a review of ocular causes and potential treatments. Ophthalmic Physiol Opt. 2011 Sep;31(5):502-15. doi: 10.1111/j.1475-1313.2011.00834.x. Epub 2011 Apr 12. PMID: 21480937.

enVista® toric
One-piece Hydrophobic Acrylic Toric Intraocular Lens

UNIQUE HAPTICS ARE DESIGNED TO SECURE A PREDICTABLE ASTIGMATISM CORRECTION

Lock in rotational stability you can rely on

enVista® toric is the ideal combination of stable performance and predictability.

Enhanced enVista® is designed to have no spherical aberrations. It is inherently **"aberration-free"**. The resultant pseudophakic eye has a natural amount of positive spherical aberration.

Residual spherical aberration = Natural positive spherical aberration of the Pseudophakic eye with Enhanced enVista®

Average: +0.274 ± 0.089 μm[16]

Unique fenestrated, step-vaulted haptics with 55° contact angle are designed to maximize stability

- **100 %** of patients had ≤5° from visit 1-2 months to visit 4-6 months[34]
- enVista® toric showed 4-6 months after surgery, mean UDVA of 0.11 logMAR (20/25 Snellen), with **94.5 % of the eyes achieveing functional UDVA ≥ 20/40**[35]
- **No secondary surgical interventions** were required for any clinical study participants (n=108)[35]

ENHANCED ENVISTA® TORIC FOR A BROAD POPULATION OF PATIENTS

The corneal astigmatism correction ranges of Enhanced enVista® toric IOLs.

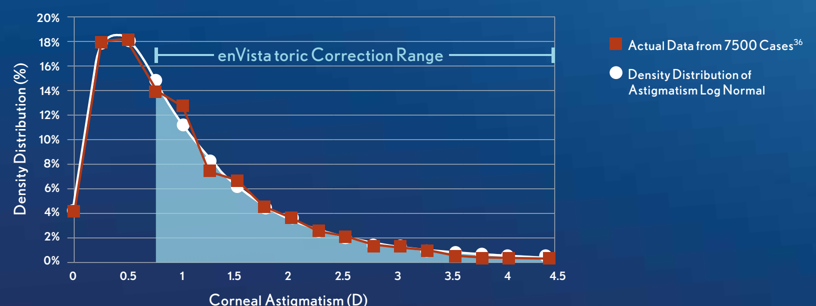


Figure adapted from Hoffer KJ. Biometry of 7,500 cataractous eyes

Enhanced enVista® toric is available as low as **1.25 D**

Enhanced enVista® toric corrects **< 1.00 D** of astigmatism at the corneal plane

34. 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
35. enVista toric Directions for Use

Calculating toric IOL power with Enhanced enVista®

The enVista® toric calculator integrates the Emmetropia Verifying Optical (EVO) Toric Formula, an advanced IOL formula for cataract surgery.[37]

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[38]:

- A residual astigmatism prediction error ≤ 1.0 D in 87.2 % of eyes
- In 77 % of eyes the EVO Toric Calculator predicted orientation matched the theoretical post-operative refractive astigmatism
- Arithmetic mean residual astigmatism prediction error was 0.59 D ± 0.36 D
- The Barrett Toric Calculator and EVO Toric Calculator had similar performance with regards to their astigmatism prediction accuracy

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CE
enVista toric
enVista Toric Calculator
User Agreement | New Lens Calculation | Help | Contact Us

SURGEON AND PATIENT INFORMATION
Clear Inputs
Surgeon Name:
Patient Name:
Date of Birth (Optional) (dd/mm/yyyy):
Import Data: Browse...
Additional Notes (Optional):

INPUT PARAMETERS
Toric Lens Model: Select One...
Eye Selection: OD (Right) OS (Left)
Keratometry Units: Diopters Millimeters
K-Index: 1.3375 1.3320
Axial Length (mm): (20.00-35.00)
Flat K1 (D): (35.00-50.00)
Flat Axis: (0°-180°)
Steep K2 (D): (35.00-50.00)
Steep Axis: (0°-180°)
ACD (mm): (1.00-5.00)
Lens Thickness (mm): (2.00-6.00)
CCT (µm): (200-700)
A-Constant: 119.10 (118.60-119.60)
Target Refraction (D): 0 (-2.00-1.00)
SIA (D): (0-1.00)
Incision Location: (0°-360°)

INPUT VERIFICATION
Confirm Inputs

Access to the enVista® toric calculator now

envista.toriccalculator.com

36. Hoffer KJ. Biometry of 7,500 cataractous eyes. Am J Ophthalmology. 90:360-368, 1980
37. https://evoiolcalculator.com/start.aspx
38. Pantanelli SM, Sun A, Kansara N, Smits G. Comparison of Barrett and Emmetropia Verifying Optical Toric Calculators. Clin Ophthalmol. 2022;16:177-182https://doi.org/10.2147/OPTH.S346925

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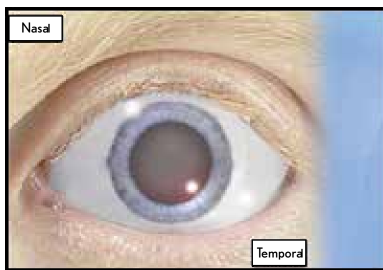
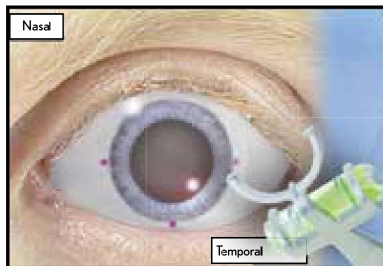
SURGICAL MARKING GUIDE FOR TORIC IOL

Tips endorsed by Dr. Álvaro Rodríguez-Ratón (Spain)

0º - 180º reference marks with bubble marker

- Mark the patient seated
- Instill anesthetic eye drops
- Paint the bubble marker with a marker pen. With the patient facing forward and making the bubble arranged between the two marks of the level, touch the eye with the marker making it coincide with the orientation 0º - 180º.



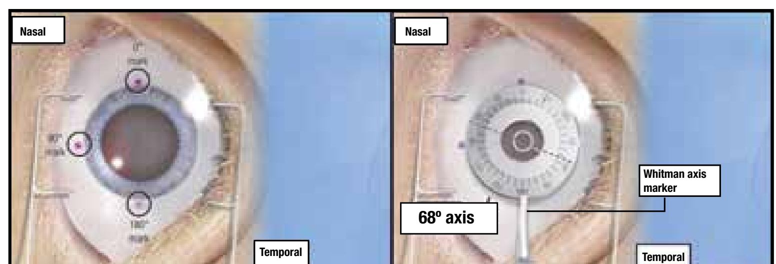


HOW TO MAKE THE MARKS WITH A SLIT LAMP:
Patient seated and with the head perfectly placed in the chin. Matching the lighting arm with the arm of observation on the same line, rotate the orientation of the light beam to position it horizontally, coinciding with the 0º - 180º axis, and dial with the 0º - 180º axis and mark.

Intraoperative markers with Whitman marker or with Mendez ring

1. With the patient lying down.
2. Place the Whitman marker matching its shaft (handle) with the previous marks at 0º - 180º. Turn the inner ring of the Whitman marker looking the orientation of the axis to which the lens will position intraocular
3. With the Mendez ring we can dial directly the orientation of the axis on the ocular surface.

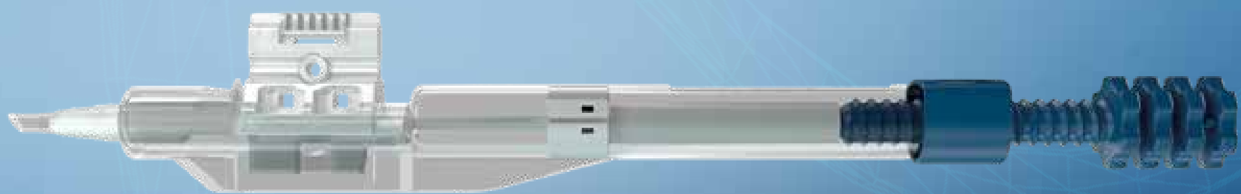
Whitman marker
Mendez ring



PRELOADED IOL

Enhanced enVista® is also available preloaded with the BAUSCH + LOMB SimplifEYE™ delivery system.

- **Less risk of IOL damage and mishandling**[37]
- It is thought that during the next several years, the use of **preloaded** IOLs is expected to **grow** and may well represent the **industry's future**[38]
- Recommended incision size ≥ 2.2 mm[39]



37. Chung B, Lee H, Choi M, Seo KY, Kim EK, Kim TI. Preloaded and non-preloaded intraocular lens delivery system and characteristics: human and porcine eyes trial. Int J Ophthalmol. 2018;11(1):6-11
38. Marketscope 2021
39. BAUSCH + LOMB Memorandum: Calculated theoretical incision size for various injectors - October 30, 2020

enVista hydrophobic acrylic IOL

enVista toric One-piece Hydrophobic Acrylic Toric Intraocular Lens

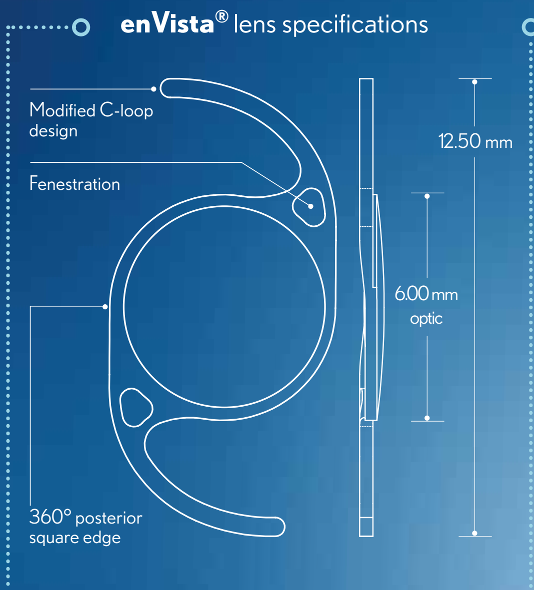
BAUSCH + LOMB SimplifEYE™ delivery system

CLINICAL EXPERIENCES SINCE 2010
THE OUTCOMES ARE CLEAR

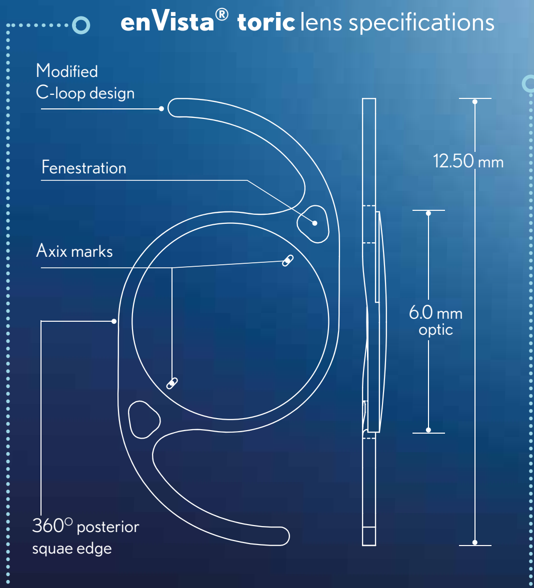
Aberration-free optic | Glistening-free performance | Predictable outcomes

More than 3 million implantations since 2013

enVista® lens specifications



enVista® toric lens specifications



Optic design	Aspheric, aberration-free, biconvex
Optic diameter	6.00 mm
Overall diameter	12.50 mm
Haptics	Modified C-loop, fenestrated, Step Vaulted
Optic constant	SRK/T Constant A: 119.1 ACD: 5.61 Surgeon factor: 1.85 Haigis: a_0: 1.46 / a_1: 0.40 / a_2: 0.10
Ultrasonic constant	Constant A: 118.7 ACD: 5.37 Surgeon factor: 1.62
Other features	Glistening-free hydrophobic acrylic material Abbe number: 42 Refractive index: 1.53 at 35°C UV absorbing Sharp 360° posterior square edge
Diopter range **Enhanced enVista®**	From 0.00 D to +10.00 D (1.00 D steps) From +10.00 D to +30.00 D (0.50 D steps) From +30.00 D to +34.00 D (1.00 D steps)
Diopter range **Enhanced enVista® toric**	Sphere powers: From +6.00 D to +30.00 D (0.50 D steps) Cylinder powers: **IOL Plane:** +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 **Corneal Plane:** +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	Preloaded BAUSCH + LOMB SimplifEYE™ delivery system Recommended incision size ≥ 2.2 mm Reuseable injector BLIS-R1 Single use cartridge BLIS-X1: from +10.0 D to +34.0 D (10 Units/box) Single use injector INJ100 (10 Units/box) Recommended incision size: 2.2 mm

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

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