

enVista®
one-piece hydrophobic acrylic intraocular lens

BAUSCH+LOMB
SimplifEYE™
delivery system



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

More than 3 million eyes already enjoying
the enVista® experience worldwide¹

1. enVista® and Enhanced enVista® shipments extract 2013-Q1 2020



CATARACT



LASER



RETINA

BAUSCH+LOMB
See better. Live better.

enVista®

one-piece hydrophobic acrylic intraocular lens

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 Ophthalmol. 2018 Dec;41(10):899-903



CATARACT



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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...

MY SURGEON

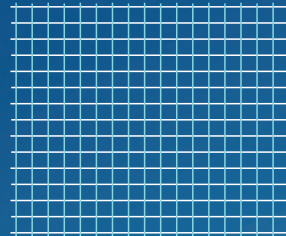


GLISTENING-FREE MATERIAL

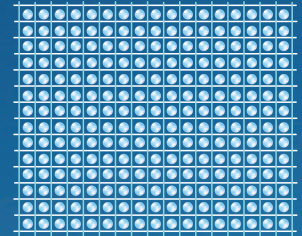
Trusight™ Optic - Glistening-free

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 evaluation¹⁰

IOL	Average Microvacuoles/mm ² ± 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

Accuset™ Haptics - designed for refractive predictability and stable centration^{8,9,11}

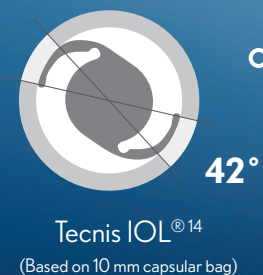
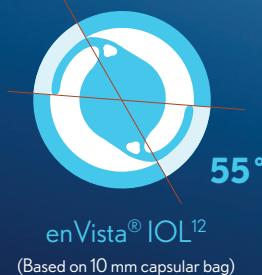


ISO 11979-3 model

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



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 DJ. IOL material quality study - David J Apple International 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 (T_g) from 23°C to 15°C.

The lower T_g 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

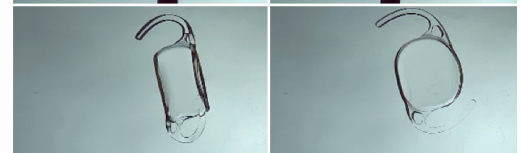
enVista®

Enhanced enVista®

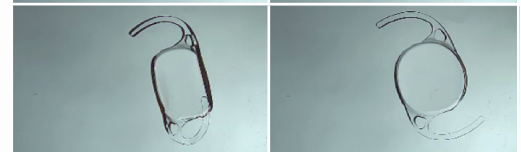
After 10 seconds



After 20 seconds

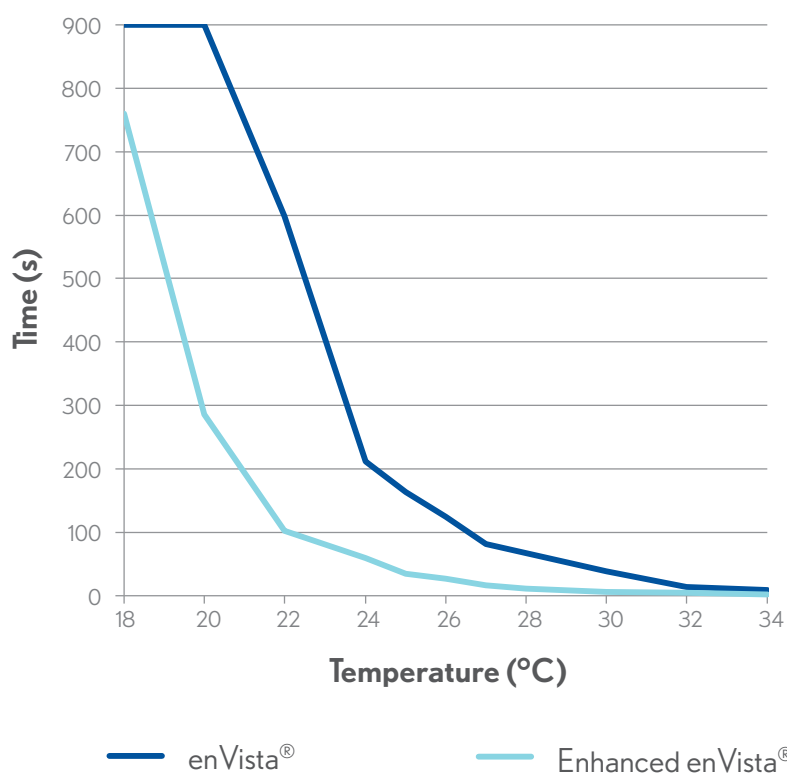


After 30 seconds

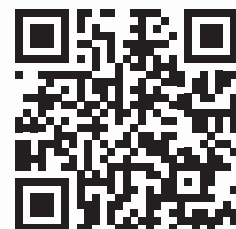


Images comparing the unfolding time between enVista® and Enhanced enVista®

Unfolding time according to temperature (laboratory testing)¹⁵



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

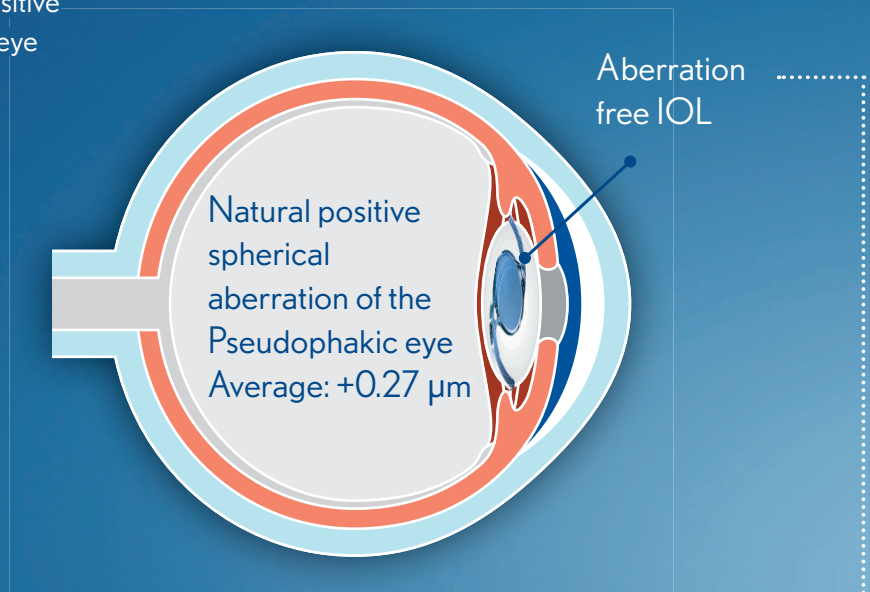


ABERRATION-FREE ASPHERIC OPTIC DESIGN

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: $+0.274 \pm 0.089 \mu\text{m}^{16}$



Depth of focus and residual spherical aberration

Maintaining a certain amount of positive spherical aberration after surgery can provide greater depth of focus¹⁷

- 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 focus¹⁸
- 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 IOLs¹⁹
- A randomized study reported a statistically significant lower distance-corrected near visual acuity with aspheric negative IOLs compared to the spherical version²⁰

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.

Simulation of visual acuity with depth of focus



USAF resolution test chart obtained by R+D laboratory testing at BAUSCH + LOMB²¹

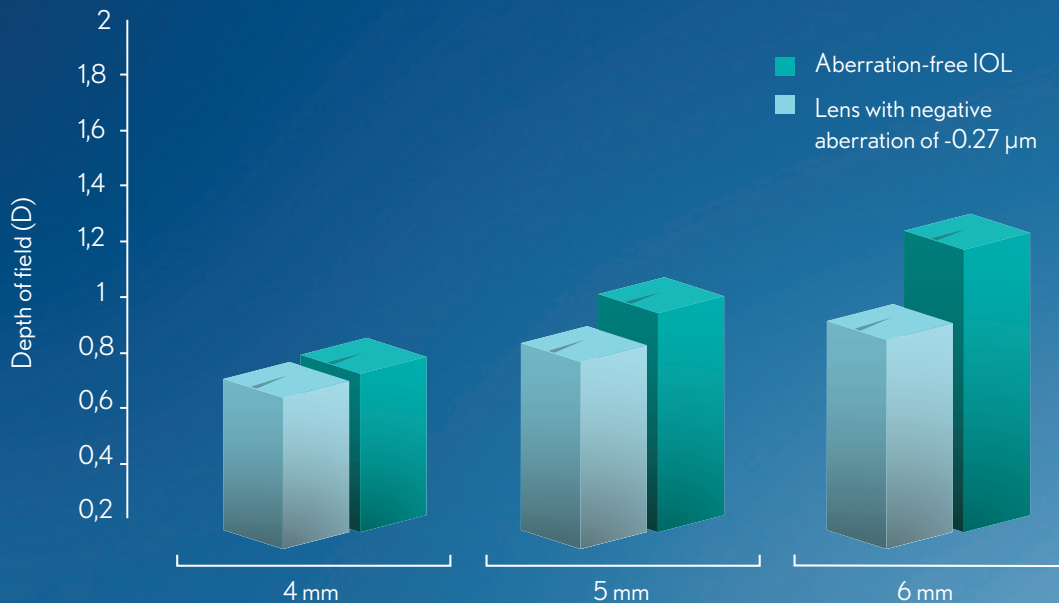
- The aberration-free IOL shows a 0.25 D to 0.30 D depth of focus increase (compared with negative spherical aberration IOL) based on the resolvability of the target of 20/20 or 20/30.

	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	-0.75D to +0.375 D, total 1.125 D

Data obtained by R+D laboratory testing at BAUSCH + LOMB²¹

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

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 perception²²



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 ± 0.16	0.42 ± 0.24

Aberration-free IOLs are likely to produce higher positive spherical aberration and better DCNVA than a negative spherical aberration IOL²³

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.

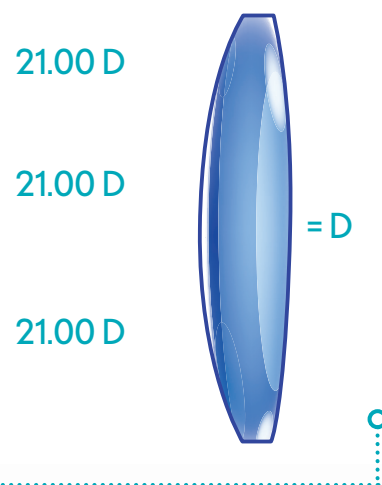
23. Karolinne Maia Rocha, Larissa Gouvea, George Oral Waring, Jorge Haddad. Static and Dynamic Factors Associated With Extended Depth of Focus in Monofocal Intraocular Lenses. American Journal of Ophthalmology Volume 216, 2020, Pages 271-282, ISSN 0002-9394, <https://doi.org/10.1016/j.ajo.2020.04.014>.

Tolerance to decentration

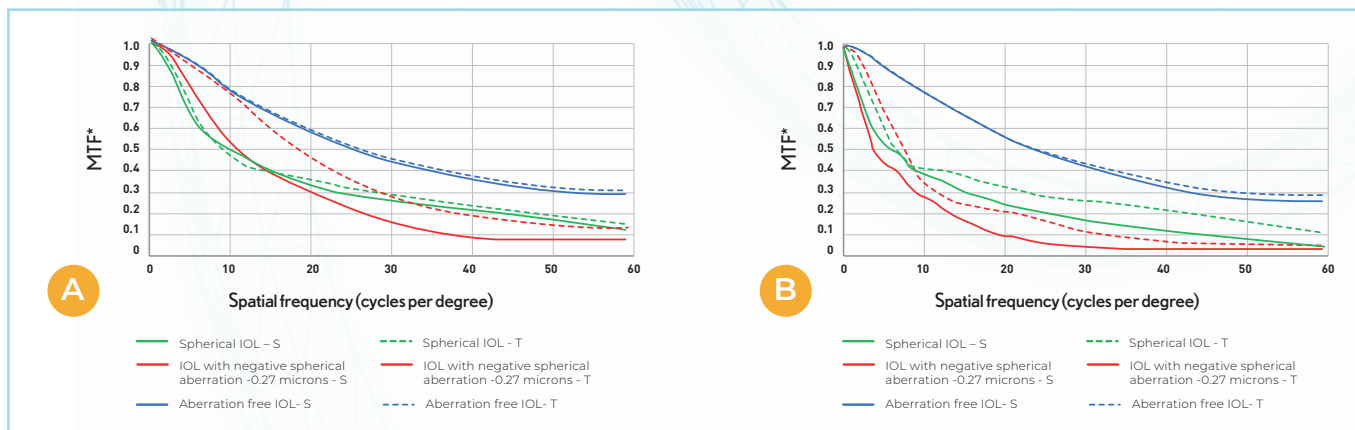
Decentration is much more frequent than one might think

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 decentration²⁵



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. Sensitivity to contrast in mesopic conditions (3 cd/m²) in patients with Akreos[®] AO (pupils 4.01 ± 0.45 mm) and Akreos[®] spherical Fit (pupil 4.04 ± 0.41 mm)²⁵

*MTF: Modulation Transference Function

24. Harrer A, Hirschschall 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

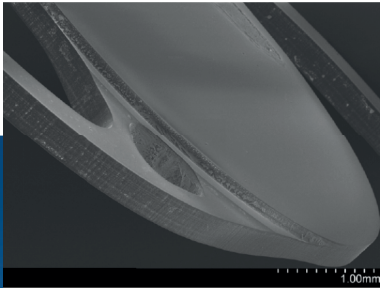
25. Altman GE, Nichamin LD, Lane SS, Pepose JS. Optical performance of 3 intraocular lens designs in the presence of decentration. J Cataract Refract Surg. 2005Mar;31(3):574-85.

26. McKeivie 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.

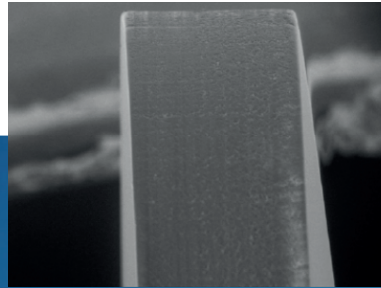
360° POSTERIOR OPTIC BARRIER

SureEdge™ Design - Continuous 360° posterior square edge

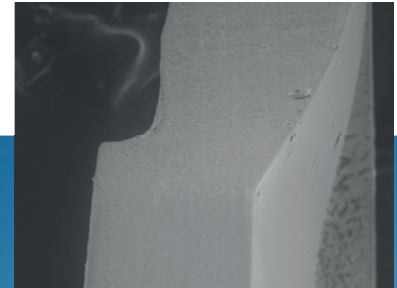
Implantation of the enVista® (MX60) is associated with low, three-year cumulative incidence rates of PCO requiring Nd:YAG laser capsulotomy.



A- Square edge continues at optic haptic junction.



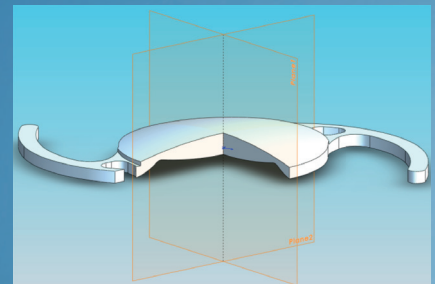
B- Edge profile.
Radius of curvature $<10\mu\text{m}$.



C- Edge profile at Optic-haptic junction. Radius of curvature $<10\mu\text{m}$.

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. Spalton²⁷

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

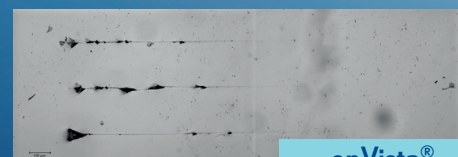


SCRATCH RESISTANCE²⁹

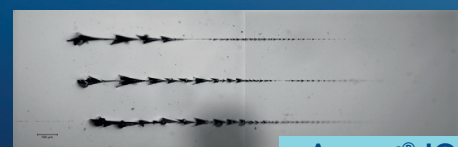
Nanoscratch Evaluation done by R+D laboratory testing at BAUSCH + LOMB:

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 Ophthalmol. 2018 Dec;41(10):899-903.

²⁹. BAUSCH + LOMB data on file: rb_011216_081636_Enhanced enVista_Material Properties Testing

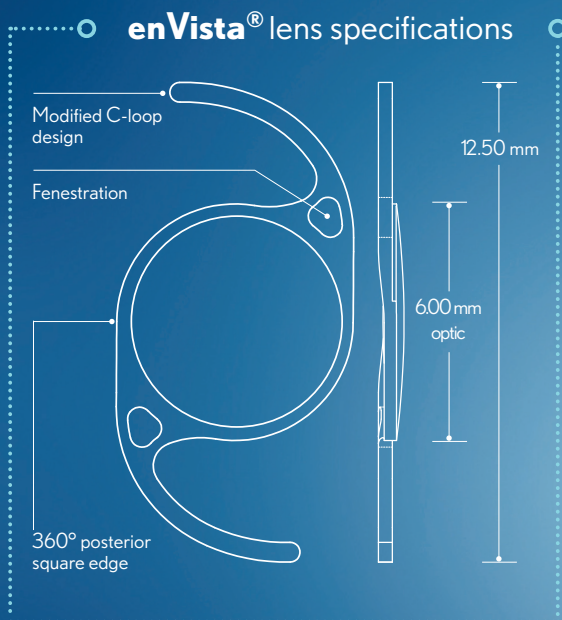
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SimplifEYE[™]
delivery system

CLINICAL EXPERIENCES SINCE 2010 THE OUTCOMES ARE CLEAR

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

More than 3 million implantations since 2013



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

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	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)
Delivery system	BAUSCH + LOMB SimplifEYE [™] delivery system Recommended incision size \geq 2.2 mm

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