

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). Clinical Ophthalmology 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. Clinical Ophthalmology 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. Clinical Ophthalmology 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, as
a **preloaded** relationship

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

MY SURGEON



BAUSCH+LOMB

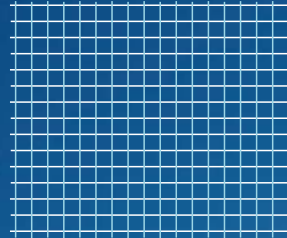
See better. Live better.

GLISTENING-FREE MATERIAL

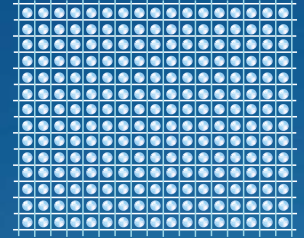
Trusight™ Optic - Glistening-free

Hydration to an equilibrium water content and then packaged in 0.9 % physiologic 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®	0.59 ± 0.63
Clareon® IOL (Alcon)	1.20 ± 1.16
MicroPure (PhysIOL)	2.45 ± 3.13

COMPRESSION FORCES

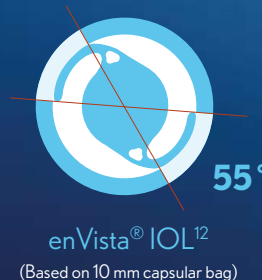
Accuset™ Haptics - designed for refractive predictability and stable centration^{8,9,11}

Large capsular bag contact



ISO 11979-3 model

- **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). Clinical Ophthalmology 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. Clinical Ophthalmology 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

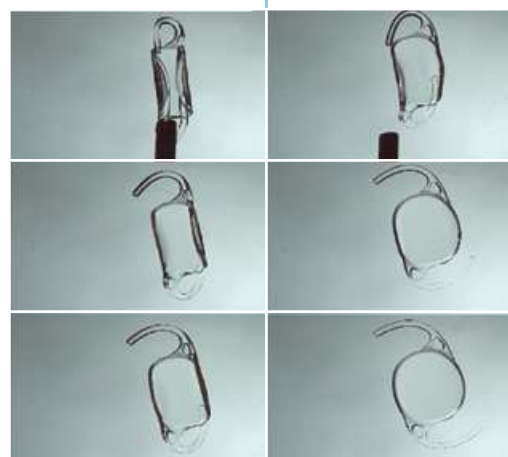
The Enhanced enVista® IOL material is made of the same polymers as its precursor, but their proportions have been modified to decrease the glass transition temperature (T_g) from 23°C to 15°C

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

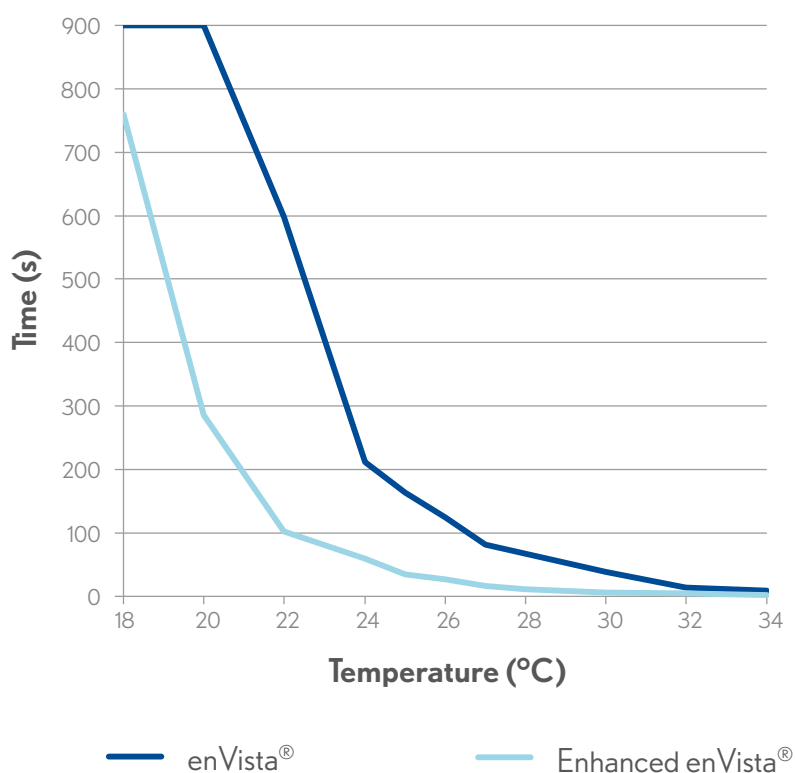
enVista®

Enhanced enVista®

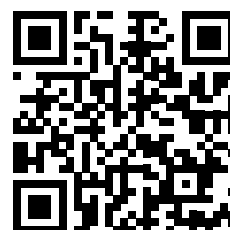


Images comparing the unfolding time between enVista® and Enhanced enVista®¹⁵

Unfolding time according to temperature (laboratory testing)¹⁵



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

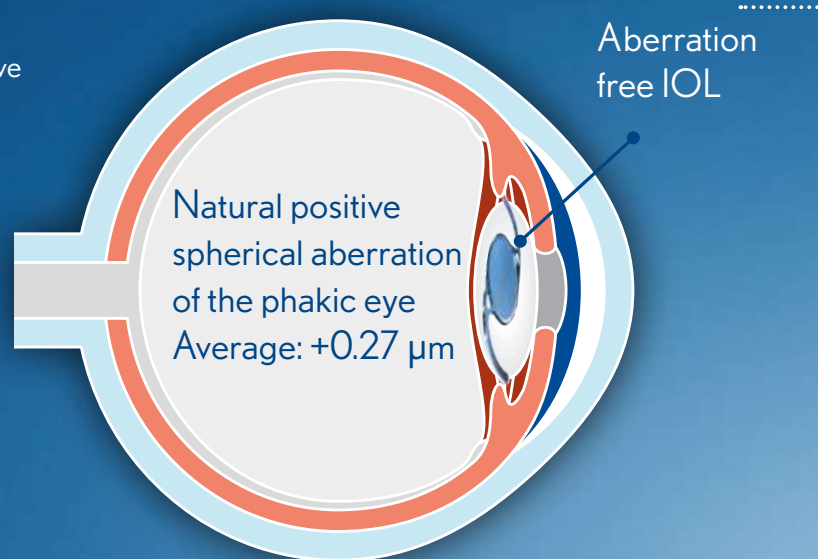


ABERRATION-FREE ASPHERIC OPTIC DESIGN

- 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 phakic eye with Enhanced enVista®

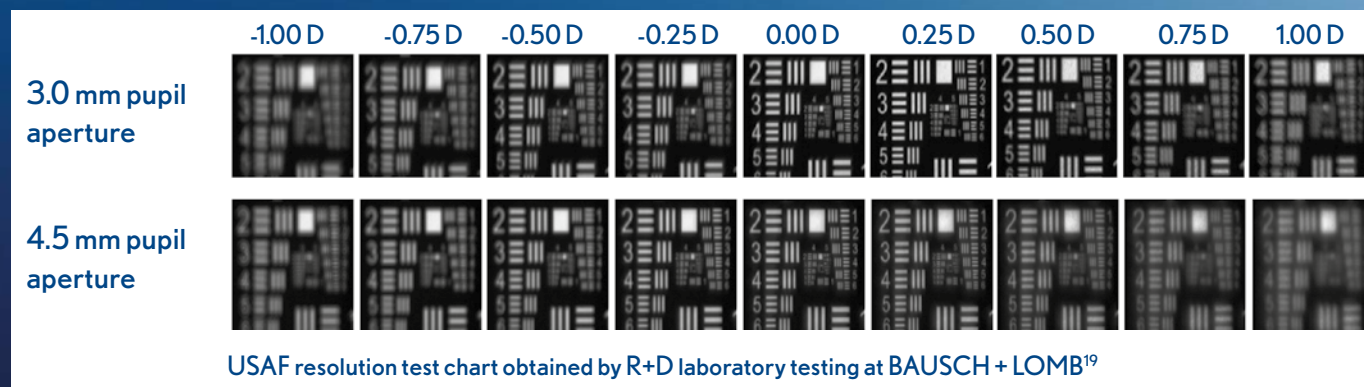
Average: $+0.274 \pm 0.089 \mu\text{m}^{16}$



Depth of focus and residual spherical aberration

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

- Many authors indicate that it is beneficial for vision quality to maintain residual spherical aberration¹⁸



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. McLellan JS, Marcos S, Prieto PM, Burns SA. Imperfect optics may be the eye's defence against chromatic blur. Nature. 2002 May;417(6885):174-6.

¹⁹. BAUSCH + LOMB data on file: AO Technology_V19-0981M_R&D report Sept 2019



The depth of focus should be greater with an aspherical IOL that does not induce aberration, in comparison with an aspheric IOL that induces negative aberration. Some studies found that the depth of focus was significantly greater^{20, 21}

Simulation of visual acuity with depth of focus



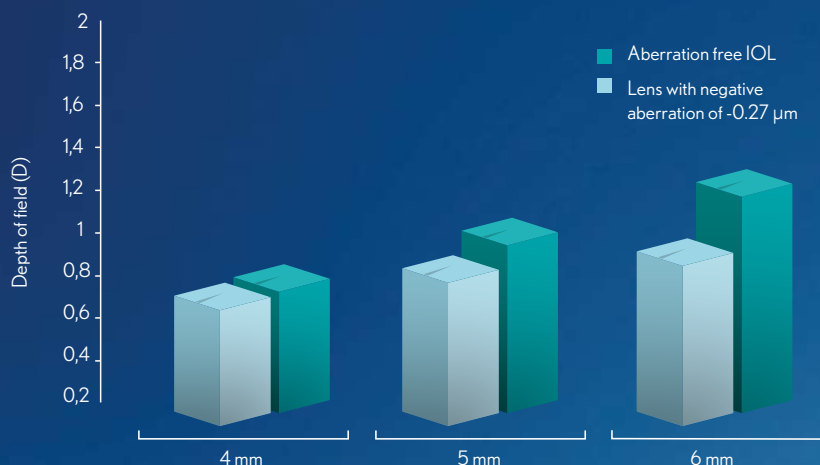
USAF resolution test chart obtained by R+D laboratory testing at BAUSCH + LOMB²²

- ▶ Using optical ray tracing simulations, the aberration free IOL demonstrated a wider range of improved image resolution when compared to a negative spherical aberration IOL.
- ▶ Aberration-free IOL shows a 0.25 D to 0.30 D depth of focus increase 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 + LOMB²²

20. 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.
 21. 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.
 22. Data on file: AO Technology_V19-098M_R&D report Sept 2019



Graph adapted from Johansson B et al. 2007. Diagram of boxes that assesses the average depth of field by the Strehl ratio with different sizes of pupil where the medians and 1st and 3rd quartile are shown²³

A multicentre study has shown that aspheric optics with Advanced Optics technology provide greater depth of field than aspheric optics with negative aberration, which could contribute to greater visual quality perception²³

Nomogram for targeting refractive error to balance residual spherical aberration after adjusting for pupil size when implanting an aberration-free IOL²⁴

Corneal spherical aberration (at 6.0 mm)		0.07 μm	0.17 μm	0.27 μm	0.37 μm	0.47 μm
Pupil Size	6 mm					
	5.5 mm					
	5 mm					
	4.5 mm					
	4 mm					
	3.5 mm					
	3 mm					

Balance against post-op modest hyperopic refraction

plano

-0.25 D

-0.50 D

²³ 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.

²⁴ George H.H. Beiko, BM, BCh, FRCSC. The fundamentals of spherical aberration. CRSToday Europe July 2012.

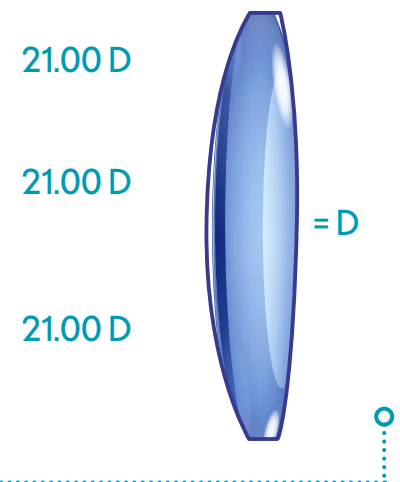


Tolerance to decentration

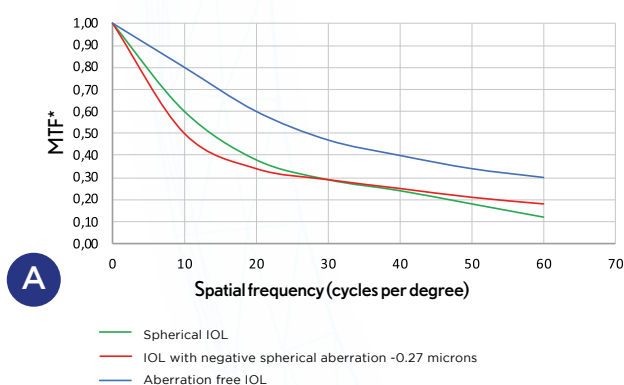
Decentration is much more frequent than one might think

In general, the average decentration after uncomplicated cataract surgery reported in studies is 0.30 ± 0.16 mm (Range 0 to 1.9 mm)²⁵

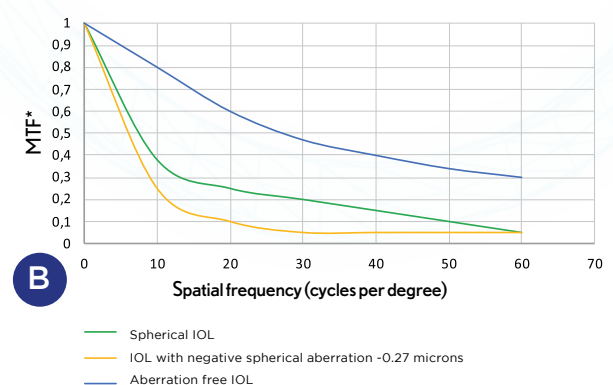
- ▶ The neutral aspherical design of both the anterior and posterior optical surfaces of the Enhanced enVista® lens allows for the constant power of the lens, from the centre to the periphery of its optic
- ▶ Enhanced enVista® lens is aberration-free and, therefore, it does not induce other aberrations in case of decentration, even with decentration of 1 mm or more²⁵



Performance of different IOLs based on decentration²⁶



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



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

Figure adapted from Altman GE, et al. 2005. Sensitivity to contrast in mesopic conditions (3 cd/m^2) in patients with Akreos® AO (pupils $4.01 \pm 0.45 \text{ mm}$) and Akreos® spherical Fit (pupil $4.04 \pm 0.41 \text{ mm}$)²⁶

*MTF: Modulation Transfer Function

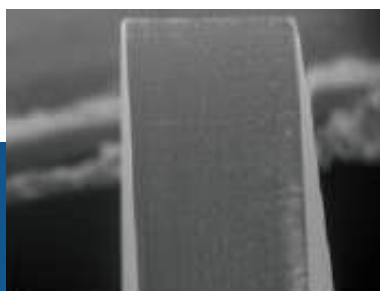
360° POSTERIOR OPTIC BARRIER

SureEdge™ Design - Continuous 360° posterior square edge

Implantation of the enVista® (MX60P) is associated with low, three-year cumulative incidence rates of PCO requiring Nd:YAG laser capsulotomy.



A- Square edge continues at optic haptic junction.



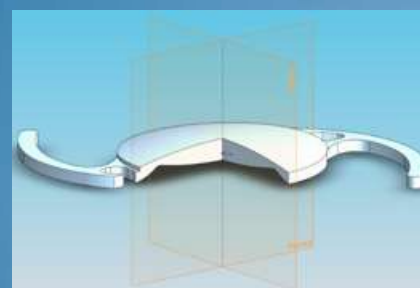
B- Edge profile. Radius of curvature <10µm.



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. 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

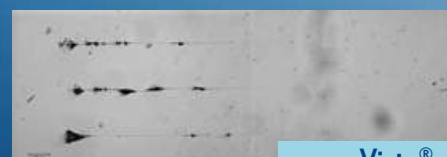


SCRATCH RESISTANCE²⁹

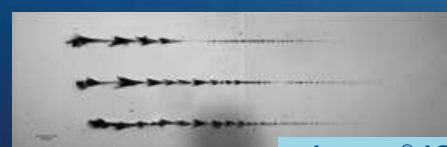
Nonoscratch Evaluation done by R+D laboratory testing at BAUSCH + LOMB:

Ramped load scratches were generated in 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, Iran 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

PRELOADED IOL

enVista® preloaded with the BAUSCH + LOMB SimplifEYE™ delivery system.

- ▶ **Less risk of IOL damage, cross-contamination and mishandling.**³⁰
- ▶ 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**³¹
- ▶ Recommended incision size ≥ 2.2 mm³²

12 supakuotas injektoriuje (preloaded) implantuojamas sukanč rankenėlė



^{30.} 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
^{31.} Marketscope 2019

^{32.} BAUSCH + LOMB memorandum: Calculated theoretical incision size for various injectors - September, 13 2019

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one-piece hydrophobic acrylic intraocular lens

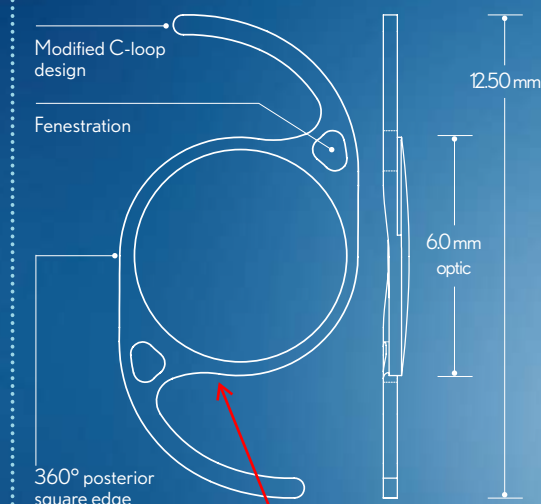
BAUSCH + LOMB
SimplifEYE™
delivery system

CLINICAL EXPERIENCES SINCE 2010 THE OUTCOMES ARE CLEAR

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

More than 3 million of implantations since 2013

enVista® lens specifications



*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

10 vienos dalies

13 be skylių optinėje dalyje
(skylių yra atraminiuose
elementuose ir turi jėgos
paskirstymo funkciją)



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www.bauschsurgical.eu

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BAUSCH + LOMB
See better. Live better.

This site is intended for Healthcare Professionals in EMEA only

ENVISTA® PRELOADED / ENVISTA®

Trusight™ optic: glistening-free

vienos dalies, hidrofobinis

1 The single-piece hydrophobic acrylic IOL glistening-free^{1,2}

StableFlex™ technology: controlled unfolding³

For a smooth and controlled IOL delivery

Advanced Optics (AO) technology: aberration-free aspheric optic design

enVista®'s Advanced Optics (AO) technology has been designed to not induce any positive or negative spherical aberration.

5

nesukelia jokių teigiamų ar neigiamų sferinių aberacijų

➤ Neutral to the cornea 5

➤ Less sensitive to decentration⁴

➤ Preserves some degree of depth of field⁵

5 asferinis priekinis ir užpakalinis paviršius

➤ Aspheric anterior and posterior surfaces

AccuSet™ haptics: designed for predictability and stable centration^{1,2,6}

➤ Fenestrated haptics designed to prevent transference of stress from the haptic to the optic

➤ Haptics designed to maximize the contact angle against the capsular bag

SureEdge™ design: continuous 360° posterior squareedge to prevent PCO*⁷

5

360 laipsnių perimetru status.



MATERIAL

- Hydrophobic acrylic glistening-free
- 4 % water content turi 4% vandens
- UV Filter su UV filtru
- Refraction index: 1.53 Lūžio rodiklis 1.53

DESIGN

- Monofocal optic, aspheric, aberration-free, biconvex
- Modified C-loop haptics design C modifikacijos atraminiai elementai
- 360° posterior square edge 360 laipsnių perimetru status.
- Haptics with fenestration holes
- Optic diameter: 6.0 mm optinis diametras
- Overall diameter: 12.5 mm

DIOPTRIC RANGE

- From 0.00 D to +10.00 D (1.00 D steps) laužiamoji galia (dioptrijos)
- From 0.00 D to +34.00 D :
 - 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

re-loaded SimplifEYE™ injection system preloadintas, SimplifEYE - implanuojamas sukančią rankenėlę

Recommended incision size $\geq 2,2$ 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

Intrasonic Constant:

- Constant A: 118.7
- ACD: 5.37
- Surgeon factor: 1.62

M. Packer, L. Fry, K. Lavery, R. Lehmann, 'Safety and effectiveness of a glistening-free single-piece hydrophobic acrylic intraocular lens (enVista)'. Clin Ophthalmol. 13;7:1905-1912. **2.** P. Heiner et al. 'Safety and effectiveness of a single-piece hydrophobic acrylic intraocular lens' (enVista®) - results of a European and Asian-Pacific study. Clinical Ophthalmology 2014;8 629-635. **3.** R&D report ENG16-067S_ 08082016. **4.** G. Altmann, et al., 'Optical performance of 3 intraocular lens designs in the presence of decentration'. J Cataract Refract Surg. 2005 Mar; 31:574-85. **5.** B. Johansson, S. Sundelin et al., 'Visual and optical performance of the Akreos Adapt Advanced Optics and Tecnis Z9000 intraocular lenses: Swedish multicenter study', Journal of Cataract & Refractive Surgery. 2007 September; Vol. 33. **6.** Garzon et al., 'Evaluation of Visual Outcomes After Implantation of Monofocal and Multifocal Toric Intraocular Lenses.' J Refract Surg. 2015;31(2):90-97. **7.** Ton Van C., Tran T.H.C: Incidence of posterior capsular opacification requiring Nd:YAG capsulotomy after cataract surgery and implantation of envista®MX60 IOL. Journal francais d'ophtalmologie (2018) 41 : 899-903

DDITIONAL PRODUCT INFORMATION

- [enVista Brochure](#)
 - [enVista Loading Guide](#)
-

BAUSCH Health

DESCRIPTION: enVista MX60PL DFU / GBL / CLW

PART No.: 4135500 **SPEC No. or SPEC DIMENSIONS:** 45104 / C-68754

SPECIAL INSTRUCTIONS: n/a

PRINT SUPPLIERS: Please refer to Bausch Health's *Print Supplier Guidelines*

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