BAUSCH + LOMB
SimplifEYE™

enVista®
hydrophobic acrylic IOL

HD QUALITY VISION PRELOADED

CATARACT LASER RETINA

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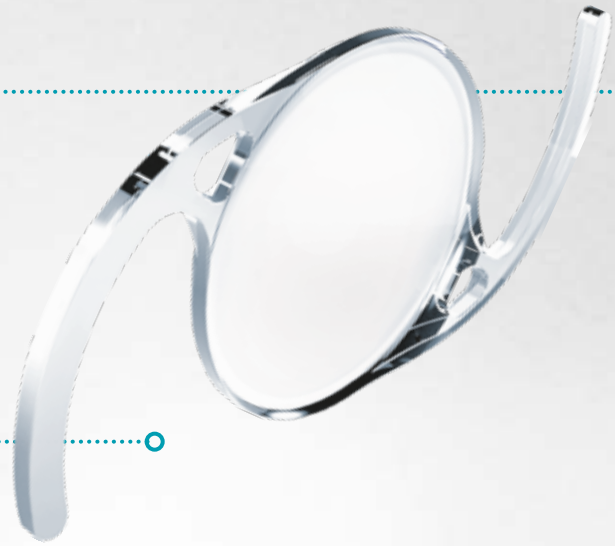
See better. Live better.

THE DESIGN IS DISTINCTIVE

Trusight™ optic: glistening-free

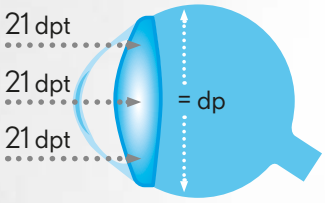
- The first glistening-free, single-piece hydrophobic acrylic IOL glistening- free[1,2]



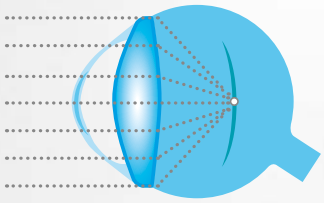
Advanced Optics technology: aberration-free aspheric optic design

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

- Neutral to the cornea
- Suitable for a broad range of patients regardless of their corneal profile
- Less sensitive to decentration[3]
- Preserves some degree of depth of field[4]



Uniform power from center to edge.[4]

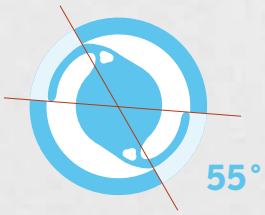


Aspheric anterior and posterior surfaces.[4]

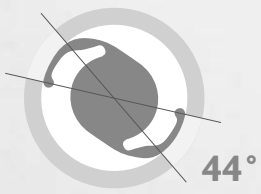
Aberration – free optic

AccuSet™ haptics: designed for refractive predictability and stable centration[2,5,6]

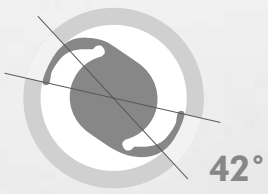
- **Fenestrated haptics** to prevent transfer of stress from the haptic to the optic
- **Haptics designed** to maximize the contact angle against the capsular bag



enVista IOL[7]
(Based on 10mm capsular bag)



AcrySof IQ[8]
(Based on 10mm capsular bag)



Tecnis IOL[9]
(Based on 10mm capsular bag)

CATARACT LASER RETINA

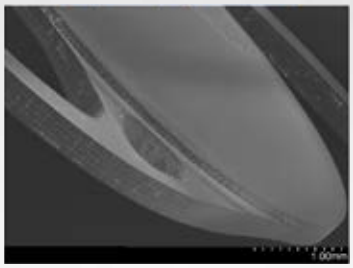
enVista®
hydrophobic acrylic IOL

THE OUTCOMES ARE CLEAR

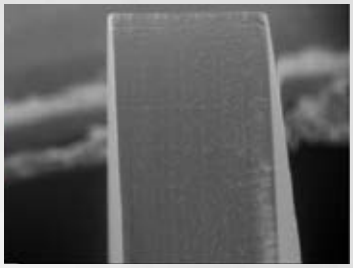
SureEdge™ design: continuous 360° posterior square edge to prevent PCO[10]

All images of 20D IOLs shown at same scale to aid comparison.
Posterior optic edge at top left of all images.

By courtesy of D. Spalton.[11]



A- Square edge continues at optic haptic junction.



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

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

StableFlex™ technology: controlled unfolding[12]

SimplifEYE™ preloaded delivery system

New

BAUSCH + LOMB SimplifEYE™

- Full diopter range preloaded
- Ease of use
- 2.2mm incision size (WAT)
- Single-use

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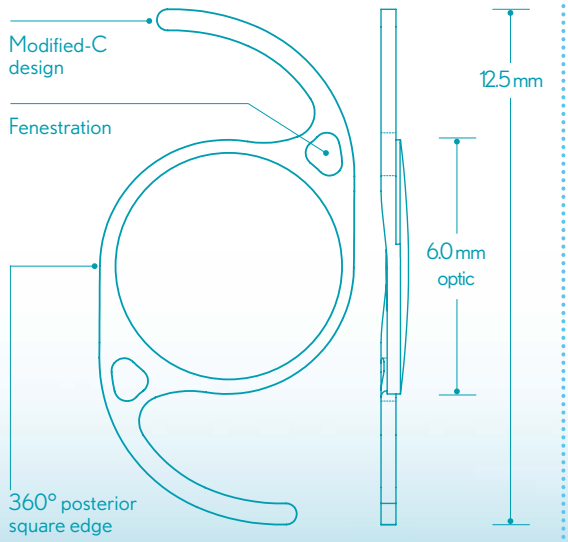
CLINICAL EXPERIENCE SINCE 2010
THE OUTCOMES ARE CLEAR

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

enVista®
hydrophobic acrylic IOL

Optic Design	Aspheric, aberration-free, biconvex
Optic Size	6 mm
Length	12.5 mm
Haptics	Modified C, fenestrated, Step Vaulted
US Applanation* A-constant (SRK/T) ACD (Hoffer Q) Surgeon Factor (Holladay I)	 118.7 5.37 mm 1.62 mm
Optical Biometry* A-constant (SRK/T) ACD (Hoffer Q) Surgeon Factor (Holladay I) a0 ; a1 ; a2 (Haigis) Lens Factor (Barrett) Design Factor (Barrett)	 119.1 5.61 mm 1.85 mm a0: 1.46 ; a1: 0.40 ; a2: 0.10 1.94 -0.5
Other Features	Glistening-free hydrophobic acrylic material Abbe index: 41.0 Refractive index: 1.53 at 35°C UV absorbing Sharp 360° posterior square edge Preloaded
Diopter Range	0.0 D to +10.0 D (1.0 D steps) +10.0 D to +30.0 D (0.5 D steps) +30.0 D to +34.0 D (1.0 D steps)

enVista Lens Specifications



EMEA_SU_B_ENVISTAP_19_001

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*Constants are estimates only. It is recommended that each surgeon develop his or her own values.

1. Bausch+Lomb Internal data, enVista direction for use. **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.** 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. **4.** 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. **5.** Garzon et al., 'Evaluation of Visual Outcomes After Implantation of Monofocal and Multifocal Toric Intraocular Lenses.' J Refract Surg. 2015;31(2):90-97. **6.** M. Packer, L. Fry, K. Lavery, R. Lehmann, 'Safety and effectiveness of a glistening-free single-piece hydrophobic acrylic intraocular lens (enVista)'. Clin Ophthalmol. 2013;7:1905-1912. **7.** B+L data on file : Intraocular lens design verification report- July 2016 **8.** B+L data on file_ IOL competitive benchmarking study report_DEC 2009 **9.** PMA P980040/S039: FDA Summary of Safety and Effectiveness Data_Tecnis Toric IOL **10.** 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 français d'ophtalmologie (2018) 41: 899-903 **11.** MA Nanavaty, DJ. Spalton, J.Boyce, A. Brain, J. Marshall, 'Edge profile of commercially available square-edged intraocular lenses'. J Cataract Refract Surg. 2008 Apr; 34(4):677-86. **12.** R&D report ENG16-067S_08082016.

INDICATIONS FOR USE: Indicated for primary implantation for the visual correction of aphakia in adult patients in whom the cataractous lens has been removed. The lens is intended for placement in the capsular bag. **WARNINGS:** Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk / benefit ratio before implanting a lens in a patient. **PRECAUTIONS:** : Do not resterilize this intraocular lens by any method. Do not store lenses at temperatures over 43°C (110°F). Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient with conditions as outlined in the enVista IOL Directions for use. **ADVERSE EVENTS:** As with any surgical procedure, there is risk involved. Potential complications accompanying cataract or implant surgery may include, but are not limited to the following: corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon transient or persistent glaucoma, and secondary surgical intervention. **ATTENTION:** Reference the Directions for Use labeling for a complete listing of indications and important safety information. **CAUTION:** Federal law restricts this device to sale by or on the order of a physician.

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