BAUSCH + LOMB
See better. Live better.

This site is intended for Healthcare Professionals in EMEA only

ENVISTA® PRELOADED / ENVISTA®

Trusight™ optic: glistening-free

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

StableFlex™ technology: controlled unfolding[3]

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.

- Neutral to the cornea
- Less sensitive to decentration4
- Preserves some degree of depth of field[5]
- 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]

RODUCT INFORMATION

ATERIAL

- Hydrophobic acrylic glistening-free
- 4 % water content
- UV Filter
- Refraction index: 1.53

ESIGN

- Monofocal optic, aspheric, aberration-free, biconvex
- Modified C-loop haptics design
- 360° posterior square edge
- Haptics with fenestration holes
- Optic diameter: 6.0 mm
- Overall diameter: 12.5 mm

IOPTER RANGE

- From 0.00 D to +10.00 D (1.00 D steps)
- 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)

ELIVERY SYSTEM

e-loaded SimplifEYE™ injection system

ecommended incision size ≥ 2,2 mm

ONSTANTS*

ptic Constant :

- SRK/T Constant A: 119.1
- ACD: 5.61
- Surgeon factor: 1.85
- Haigis: a0: 1.46 / a1: 0.40 / a2: 0.10

ltrasonic 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 udy. 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 esence 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 otics and Tecnis Z9000 intraocular lenses: Swedish multicenter study', Journal of Cataract & Refractive Surgery. 2007 September; Vol. 33. **6.** Garzon et al., 'Evaluation of sual 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 psular opacification requiring Nd:YAG capsulotomy after cataract surgery and implantation of envista®MX60 IOL. Journal francais d'ophtalmologie (2018) 41 : 899-903

BAUSCH + LOMB

enVista™

Hydrophobic Acrylic Intraocular Lens

4130802

EN

FOLDABLE HYDROPHOBIC ACRYLIC UV ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS

DEVICE DESCRIPTION

The enVista™ intraocular lens (IOL) is a single-piece ultra-violet absorbing posterior chamber intraocular lens developed to replace the natural crystalline lens in adult patients in whom the cataractous lens has been removed.

The enVista IOL has an aspheric optic and is designed to be free of spherical aberration.

PHYSICAL CHARACTERISTICS OF ENVISTA™ MODEL MX60E

Lens / Haptic Material	Hydrophobic acrylic (hydroxyethyl methacrylate (HEMA)-polyethylene glycol phenyl ether acrylate (poly(EG)PEA)-styrene copolymer, crosslinked with ethylene glycol dimethacrylate)
Material Characteristics	Index Of Refraction: 1.53 @ 35°C ; Specific Gravity: 1.19 g/ml
Optic Type	Aspheric
Powers	0.0 to +34.0 Diopters (0.0 to +10.0 in 1.0 Diopter increments, +10.0 to +30.0 in 0.5 Diopter increments, and +30.0 to +34.0 in 1.0 Diopter increments)
Dimensions	Body Diameter: 6.0 mm ; Overall Diameter: 12.5 mm ; Haptic Angle: 0°
Spectral Transmittance	**UV(364):** 10% transmittance for +20.0 diopter IOL See figure **1** with chart's **X** value = Wavelength (nm) and **Y** value = % Transmittance; chart compares the transmittance curve of an enVista MX60 Lens to a 53 Year Old Human Lens. **A** = + 20 Diopter enVista MX60 Lens and **B** = 53 Year Old Human Lens. **NOTE:** Light transmittance values for an IOL material may vary slightly depending on the method of measurement. **Reference:** 53 year old human lens data from Boettner, E.A. and Welter, J. R., "Transmission of the Ocular Media," Investigative Ophthalmology, 1:776-783, 1962

INDICATIONS

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

Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio:

1. Recurrent severe anterior or posterior segment inflammation or uveitis.
2. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment diseases.
3. Surgical difficulties at the time of cataract extraction, which might increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss).
4. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
5. Circumstances that would result in damage to the endothelium during implantation.
6. Suspected microbial infection.
7. Children under the age of 2 years are not suitable candidates for intraocular lenses.
8. Patients in whom neither the posterior capsule nor zonules are intact enough to provide support.

PRECAUTIONS

1. Do not attempt to resterilize the lens as this can produce undesirable side effects.
2. Do not use if product sterility or quality is thought to be compromised due to damaged packaging or signs of leakage (such as the loss of saline storage solution, or the presence of salt crystallization).
3. Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline.
4. Do not store the lens at a temperature greater than 43°C (110 °F). DO NOT FREEZE. Do not autoclave the intraocular lens.
5. Do not reuse the lens. It is intended for permanent implantation. If explanted, sterility and proper function cannot be assured.
6. The safety and effectiveness of the enVista IOL have not been substantiated in patients with preexisting ocular conditions and intraoperative complications (see below). 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 one or more of these conditions. Physicians considering lens implantation in such patients should explore the use of alternative methods of aphakic correction and consider lens implantation only if alternatives are deemed unsatisfactory in meeting the needs of the patient.
7. If this product is reprocessed and/or re-used, Bausch & Lomb cannot guarantee the functionality, material structure, or cleanliness or sterility of the product. Re-use could lead to illness, infection and/or injury to the patient or user and, in extreme incidents, death. This product is labeled as 'single use' which is defined as a device intended to be used once only for a single patient.

   Before Surgery
   - Retinal conditions or predisposition to retinal conditions, previous history of, or a predisposition to, retinal detachment or proliferative diabetic retinopathy, in which future treatment may be compromised by implanting this lens.
   - Amblyopia
   - Clinically severe corneal dystrophy (e.g., Fuchs')
   - Rubella, congenital, traumatic or complicated cataracts
   - Extremely shallow anterior chamber, not due to swollen cataract
   - Recurrent anterior or posterior segment inflammation of unknown etiology, or any disease producing an inflammatory reaction in the eye (e.g. iritis or uveitis).
   - Aniridia
   - Iris neovascularization
   - Glaucoma (uncontrolled or controlled with medication)
   - Microphthalmos or macrophthalmos
   - Optic nerve atrophy
   - Previous corneal transplant
   - Pre-existing ocular conditions which may negatively impact stability of the implant.

   During Surgery
   - Mechanical or surgical manipulation required to enlarge the pupil
   - Vitreous loss (significant)
   - Anterior chamber bleeding (significant)
   - Uncontrollable positive intraocular pressure
   - Complications in which the IOL stability could be compromised
8. Patients with preoperative problems such as corneal endothelial disease, abnormal cornea, macular degeneration, retinal degeneration, glaucoma, and chronic drug miosis may not achieve the visual acuity of patients without such problems. The physician must determine the benefits to be derived from lens implantation when such conditions exist.
9. A high level of surgical skill is required for intraocular lens implantation. The surgeon should have observed and/or assisted in numerous implantations and successfully completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses.
10. 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. Secondary surgical interventions include, but are not limited to: lens repositioning, lens replacement, vitreous aspiration or iridectomy for pupillary block, wound leak repair, and retinal detachment repair.
11. Care should be taken to remove all viscoelastic from the anterior and posterior surfaces of the lens.

MODE OF ACTION

enVista IOLs are intended to be folded and placed in the posterior chamber of the eye after the cataractous crystalline lens has been removed.

CALCULATION OF LENS POWER

The recommended A-constant listed on the lens carton is intended for use with axial length measurements obtained by optical biometry. Use of axial length measurements by other techniques (e.g. Applanation A-scan) will normally require a different lens constant. This number is a guideline only and is based on an evaluation of clinical data obtained using the IOL Master.

The physician should determine preoperatively the power of the lens to be implanted. Lens power calculation methods are described in the following references:

- Hoffer K J. The Hoffer Q formula: a comparison of theoretic and regression formulas, Journal of Cataract and Refractive Surgery Vol. 19, pp. 700-712, 1993; ERRATA, Vol. 20, pp. 677, 1994.
- Holladay JT, Musgrove KH, Prager TC, Lewis JW, Chandler TY, Ruiz RS. A three-part system for refining intraocular lens power calculations. Journal of Cataract and Refractive Surgery, Vol. 14, pp. 17-24, 1988.
- Norrby NES. Unfortunate Discrepancies, Letter to the Editor and Reply by Holladay JT. Journal of Cataract and Refractive Surgery, Vol. 24, pp. 433-434, 1998.
- Olsen T, Olesen H, Thim K, and Corydon L. Prediction of pseudophakic anterior chamber depth with the newer IOL calculation formulas. Journal of Cataract and Refractive Surgery, Vol. 18, pp. 280-285, 1992.
- Retzlaff JA, Sanders DR, Kraff MC. Development of the SRK/T intraocular lens implant power calculation formula. Journal of Cataract and Refractive Surgery, Vol. 16, pp. 333-340, 1990; ERRATA, Vol. 16, pp. 528, 1990.
- Haigis W: The Haigis Formula. In: Intraocular lens power calculations. H. John Shammas (eds), Slack Incorporated, Thorofare, NJ, USA, pp. 39-57, 2004.

DIRECTIONS FOR USE

1. Prior to implanting, examine the lens package for type, power, and proper configuration.
2. Open the peel pouch and remove the vial in a sterile environment.
3. Remove the lid from the vial.
4. With a pair of smooth forceps, remove the lens from the vial by gently grasping the lens haptic.
5. Rinse the entire lens with sterile balanced salt solution or sterile normal saline.
6. Examine the lens thoroughly to ensure particles have not become attached to it, and examine the lens optical surfaces for other defects.
7. The lens may be soaked in sterile balanced salt solution until ready for implantation.
8. *Amvisc*, *Amvisc Plus*, or *OcuCoat* viscoelastic should be used for lubrication of the delivery system when inserting the lens.
9. Bausch + Lomb recommends using a Bausch + Lomb approved delivery system.
10. There are various surgical procedures that can be utilized, and the surgeon should select a procedure that is appropriate for the patient. Surgeons should verify that appropriate instrumentation is available prior to surgery.

OVERVIEW OF CLINICAL STUDIES

Clinical studies have been conducted on the enVista single-piece IOL (model MX60) and the parent xact X-60 three-piece IOL (model X-60). The results of clinical investigations provide reasonable assurance that the Model MX60 IOL is safe and effective for the visual correction of aphakia following cataract extraction.

For the enVista MX60 clinical study, all subjects in the safety analysis set were evaluated for IOL glistenings at Form 3 and Form 4 visits. IOL glistenings were evaluated via retroillumination slit lamp examination utilizing a photographic grading scale provided in the protocol. The grading scale consisted of (in order of severity), "none, grade 0 (trace), grade 1, 2, 3, or 4." No glistenings of any grade were reported for any subject at any visit in the clinical study.

HOW SUPPLIED

The lens is individually packaged in a sterile vial (containing a 0.9% saline solution), within a peel pouch, and should only be opened under sterile conditions. A patient card and self-adhesive labels are supplied to provide traceability of the lens. The package is sterilized by gamma irradiation.

EXPIRATION DATE

Sterility is guaranteed unless the pouch is damaged or opened. The expiration date on the lens package is the sterility expiration date. This lens should not be implanted after the indicated sterility expiration date.

ADVERSE EVENT REPORTING

Adverse events and/or potentially sight threatening complications that may be regarded as lens related and that were not previously expected in nature, severity or degree of incidence should be reported within five (5) days to Bausch + Lomb. This information is being requested from all surgeons in order to document potential long-term effects of intraocular lens implantation. Physicians are encouraged to report these events in order to aid in identifying emerging or potential problems with intraocular lenses. These problems may be related to a specific lot of lenses or may be indicative of long-term effects associated with these lenses or with IOLs in general. If you wish to report a problem, please call Bausch + Lomb at 1-800-338-2020.

PATIENT REGISTRATION INSTRUCTIONS AND REPORTING REGISTRATION

Each patient who receives an enVista IOL must be registered with Bausch + Lomb at the time of lens implantation. Registration is accomplished by completing the Implant Registration Card that is enclosed in the lens package and mailing it to Bausch + Lomb. Patient registration is essential and will assist Bausch + Lomb in responding to adverse reaction reports and/or potentially sight-threatening complications. An implant identification card is supplied in the lens package and must be given to the patient.

RETURNED GOODS POLICY

All lenses being returned must be accompanied by a returned goods authorization number issued by Bausch + Lomb Customer Service. Call 1-800-338-2020 for return authorization and full policy information.

WARRANTY

Bausch & Lomb Incorporated warrants that the intraocular lens, when delivered, will conform to all applicable laws and the manufacturer's then current version of the published specifications for such intraocular lens in all material respects and will be free from defects in material and workmanship.

BAUSCH & LOMB INCORPORATED DISCLAIMS ALL OTHER WARRANTIES, EXPRESS, IMPLIED OR BY OPERATION OF LAW, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. BAUSCH & LOMB INCORPORATED SHALL NOT BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT OR EXEMPLARY DAMAGES OF ANY KIND, DIRECTLY OR INDIRECTLY ARISING FROM THE PURCHASE OR USE OF THIS PRODUCT EVEN IF BAUSCH & LOMB INCORPORATED HAD BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS, DAMAGE OR EXPENSE.

SYMBOLS USED ON LABELING

Symbol	Description	Symbol	Description
PC	Posterior Chamber	$Ø_a$	Body Diameter (Optic Diameter)
UV	Ultraviolet	$Ø_l$	Overall Diameter (Overall Length)
D	Diopter	SN	Serial Number
	Member Green Dot Scheme	℞ ONLY	Caution: Federal (US) law restricts this device to sale by or on the order of a physician

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609 USA

EC REP Bausch & Lomb GmbH,
Brunsbütteler Damm 165-173, 13581 Berlin, Germany

Manufacturing Site: Bausch & Lomb Incorporated, 21 Park Place Blvd. North, Clearwater, FL 33759 USA

U.S. Patents: 6281319 and 6635731. ®/™ are trademarks of Bausch & Lomb Incorporated or its affiliates.

℞ ONLY | STERILE R | 2 STERILIZE | 43°C 110°F | 0°C 32°F

CE 0197

Date of issue: 2018-12
1800425 / 4130802 / P1EMENA03