

This site is intended for Healthcare Professionals in EMEA only

ENVISTA® TORIC

Unique haptic design for maximum contact with the capsular bag

- › Hydrophobic acrylic material glistening-free^{1,2}
- › Designed for stable and predictable performance
- › Aberration-free aspheric optics
- › 56° contact angle between haptics and capsular bag
- › 360° posterior square designed to minimize the risk of PCO**
- › Polished surface

[Go to enVista® Toric Calculator](#)

PRODUCT INFORMATION



MATERIAL

- > Hydrophobic acrylic glistening-free
- > 4 % water volume
- > UV Filter
- > Refraction index: 1.54

DESIGN

- > Single piece aberration free aspheric optics
- > Modified C-loop haptics design
- > 360° posterior square edge
- > Haptics with fenestration holes
- > Optic diameter: 6.00 mm
- > Overall diameter: 12.5 mm

DIOPTRIC RANGE

- > From +6.00 D to +30.00 D

Cylinder power – IOL Plane:

- > +1.25 D / +2.00 D / +2.75 D / +3.50 D / +4.25 D / +5.00 D / +5.75 D

Cylinder power - Corneal plane:

- > +0.90 D / +1.40 D / +1.93 D / +2.45 D / +2.98 D / +3.50 D / +4.03 D

DELIVERY SYSTEM

- > Reusable 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 (wound assist technique)

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

14:8 629–635. 3. Packer M, Williams JJ, 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

Constants are estimates only. It is recommended that each surgeon develops their own values. Last update: August 2016

PCO: Posterior capsular opacification

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BAUSCH + LOMB

enVista™

one-piece hydrophobic acrylic toric intraocular lens

toric

en

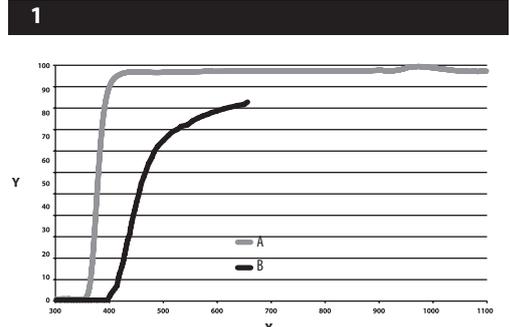
DEVICE DESCRIPTION

The enVista™ one-piece hydrophobic acrylic toric intraocular lens (enVista toric IOL) was developed to replace the natural crystalline lens in adult patients in whom the cataractous lens has been removed.

The enVista toric IOL has an aspheric optic that is designed to be free of spherical aberration through the incorporation of a proprietary spherical aberration-neutral optic design that does not influence the pre-surgical corneal spherical aberration profile. The optic is designed with the SureEdge™, posterior squared step edge to provide a 360-degree PCO barrier. The enVista toric IOL employs an Accuset™ haptic with a broad, modified C-loop design and optic-haptic offset to facilitate improved contact and stability within the capsular bag. The posterior located cylinder axis marks denote the meridian with the lowest power. The enVista material that makes up the TruSight™ optic has been assessed for glistening-free capacity and scratch resistance. Incorporated StableFlex™ technology allows for enhanced lens compliance for ease of loading, premium control through lens delivery, and efficient optical recovery following implantation.

PHYSICAL CHARACTERISTICS OF enVistaTORIC IOL MODEL MX60ET

Lens / Haptic Material	Hydrophobic acrylic (hydroxyethyl methacrylate (HEMA)-polyethylene glycol phenyl ether acrylate (poly(EGPEA)-styrene copolymer, crosslinked with ethylene glycol dimethacrylate)						
Material Characteristics	Index Of Refraction: 1.53 @ 35°C; Specific Gravity: 1.19 g/ml						
Optic Type / Powers	Aspheric / -6.0D to $+30.0\text{D}$ Diopters in 0.5D Dioptric Increments (SE – Spherical Equivalent)						
Cylinder Powers (CYL) – IOL Plane	1.25 D	2.00 D	2.75 D	3.50 D	4.25 D	5.00 D	5.75 D
Cylinder Powers (CYL) – Corneal Plane	0.90 D	1.40 D	1.93 D	2.45 D	2.98 D	3.50 D	4.03 D
Dimensions	Body Diameter: 6.0 mm; Overall Diameter: 12.5 mm; Haptic Angle: 0°						
Spectral Transmittance	Ultraviolet: UVB3 for $\lambda = 20.0$ diopter IOL. See Figure 1 with Chart X value = Wavelength (nm) and Y value = % Transmittance; chart compares the transmittance curve of an enVista Lens to a 53 Year Old Human Lens. A = $\lambda = 20$ Diopter enVista 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 Waller, J. R., "Transmission of the Ocular Media," Investigative Ophthalmology, 1:776-783, 1962						



INDICATIONS

The enVista one-piece hydrophobic acrylic toric IOL (Model MX60ET) is indicated for primary implantation in the capsular bag of the eye in adult patients for visual correction of aphakia and corneal astigmatism following removal of a cataractous lens for improved uncorrected distance vision.

WARNINGS

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

- Recurrent severe anterior or posterior segment inflammation or uveitis.
- Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment diseases.
- 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).
- A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
- Circumstances that would result in damage to the endothelium during implantation.
- Suspected microbial infection.
- Patients in whom neither the posterior capsule nor zonules are intact enough to provide support.
- Rotation of enVista toric IOL away from the intended axis can reduce their astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. If necessary, lens positioning should occur prior to capsule fibrosis and lens encapsulation.

PRECAUTIONS

- Do not attempt to resterilize the lens as this can produce undesirable side effects.
- 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).
- Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline.
- Do not store the lens at a temperature greater than 43°C (109°F) or lower than 0°C (32°F). Do not autoclave the intraocular lens.
- Do not re-use the lens. It is intended for permanent implantation. If explanted, sterility and proper function cannot be assured.
- The safety and effectiveness of the enVista toric IOL have not been substantiated in patients with pre-existing 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.

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
- 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.
 - 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.
 - Care should be taken to remove all viscoelastic from the anterior and posterior surfaces of the lens, to minimize the possibility of lens rotation causing misalignment of enVista toric IOL from the intended axis placement.
 - Effectiveness of implanting a toric lens in reducing postoperative astigmatism is affected by many factors, including the following:
 - The degree of mismatch between the postoperative magnitude of corneal astigmatism and effective IOL power in the corneal plane.
 - Misalignment between the intended axial position and final IOL axial orientation.
 - Error in prediction of the postoperative corneal cylinder axis and power. Error in prediction of cylinder axis is greatest for lower levels of preoperative corneal astigmatism.
 - Manufacturing variation in power and axis markings can influence intended correction.

MEDICAL DEVICE RE-USE STATEMENT

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.

ADVERSE EVENTS

The incidence of adverse events experienced during the clinical trial was comparable to or lower than the incidence reported in the historic control ("FDA grid") population. The enVista toric IOL demonstrated favorable safety compared with the Control IOL and the historical control (cf. ISO 11979-7 SPE) population, with no increase in incidence or severity of adverse events (AEs) compared with the Control IOL and no serious adverse events (SAEs) in the study eye. Overall, no safety signals were associated with the toric IOLs during this study. As with any surgical procedure, risk is involved. Potential adverse events 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, acute corneal decompensation, toxic anterior segment syndrome (TASS), 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.

SELECTION AND PLACEMENT OF enVista TORIC IOL

Keratometry and biometry data should be used in place of refractive data to determine targeted amount of astigmatism correction. Incision size and location influence amount of postoperative corneal astigmatism and its respective axis. It is recommended that surgeons customize their surgically induced corneal astigmatism values based upon individual surgical technique and past results. To facilitate IOL selection and axis placement, B+L provides a web-based proprietary tool, the enVista toric Calculator (<http://envista.toriccalculator.com>) for the surgeon. Preoperative keratometry and biometry data, incision location, spherical equivalent IOL power, and the surgeon's estimated surgically induced corneal astigmatism are used as inputs for the enVista toric Calculator. These inputs are used to determine the axis of placement in the eye and the predicted residual refractive astigmatism for up to three different enVista toric IOL models. In eyes with low levels of corneal astigmatism, the predicted residual refractive astigmatism for implantation of the enVista toric IOL will be displayed for evaluation by the surgeon to determine the clinically meaningful benefit of implanting a toric IOL. Prior to surgery the operative eye should be marked in the following manner: With the patient sitting upright, precisely mark the twelve o'clock and/or the six o'clock position with a T marker, a surgical skin marker, or a marking pencil indicated for ophthalmic use. Using these marks as reference points, an axis marker can be used immediately prior to or during surgery to mark the axis of lens placement. Input from the enVista toric calculator can be used to determine optimal axis of placement. Toric axis markings at the haptic-optic junction identify the flat meridian of the enVista toric IOL and represent an imaginary line of the plus cylinder axis. After the lens is inserted in the capsular bag, precisely align the axis markings on the enVista toric IOL with the marked axis of lens placement. Be sure to remove all viscoelastic from the capsular bag. Reconfirm proper alignment of the enVista toric IOL following viscoelastic removal and/or inflation of the capsular bag at the end of the surgical case. Residual viscoelastic and/or over-inflation of the bag may cause lens rotation away from the intended axis of placement. Deviation from the intended axis of placement may compromise effectiveness of astigmatic correction. Inaccurate astigmatism measurements, errors in corneal markings, inaccurate placement of the enVista toric IOL axis during surgery, unanticipated surgically induced changes in the cornea, or physical rotation of the lens after implantation may also limit the desired effect of the toric IOL on correction of corneal astigmatism.

CALCULATION OF LENS POWER

SUGGESTED A-CONSTANT: 119.1 (OPTICAL BIOMETRY)

The recommended A-Constant of 119.1 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.

DIRECTIONS FOR USE

- Prior to implanting, examine the lens package for type, power, and proper configuration.
- Open the peel pouch and remove the vial in a sterile environment.
- Remove the lid from the vial.
- With a pair of smooth forceps, remove the lens from the vial by gently grasping the lens haptic.
- Rinse the entire lens with sterile balanced salt solution or sterile normal saline.

- Examine the lens thoroughly to ensure particles have not become attached to it, and examine the lens optical surfaces for other defects.
- The lens may be soaked in sterile balanced salt solution until ready for implantation.
- Amvisc™, Amvisc Plus™, or OcuCoat™ viscoelastic should be used for lubrication of the delivery system when inserting the lens.
- Bausch + Lomb recommends using a Bausch + Lomb approved delivery system.
- 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

The results of the clinical study provide reasonable assurance that the Model MX60T IOL is safe and effective for the visual correction of aphakia and corneal astigmatism following cataract extraction.

The data support a significant dioptric reduction in cylinder and reduction in absolute cylinder, rotational stability of the lens, and improvement of both best corrected and uncorrected visual acuity at distance following implantation of the enVista toric IOL.

The enVista hydrophobic acrylic intraocular lens, Model MX60, is the parent lens of the MX60ET. 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.

enVista MX60T CLINICAL TRIAL STUDY RESULTS

The US clinical trial of the enVista toric intraocular lens was conducted in 191 subjects (191 eyes). The dioptric power range was 16.0 to 27.0 D with cylindrical powers at the lens plane of 1.25 D, 2.00 D, and 2.75 D for the MX60T.

HOW SUPPLIED

The enVista IOL (Model MX60ET) 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 Incorporated. 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 product 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 product, when delivered, will conform to all applicable laws and the manufacturer's then current version of the published specifications for such product in all material respects and will be free from defects in material and workmanship.

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SYMBOLS AND ABBREVIATIONS USED ON LABELING

Symbol or Abbreviation	Symbol or Abbreviation Title	Symbol or Abbreviation	Symbol or Abbreviation Title
SE	Spherical Equivalent	D	Diopter
CYL	Cylinder power	\varnothing_B	Body Diameter (Optic Diameter)
UV	Ultraviolet	\varnothing_T	Overall Diameter (Overall Length)

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ОПИСАНИЕ НА ИЗДЕЛИЕТО

Еднокомпонентната хидрофобна акрилна торична вътреочна леща enVista™ (торична ВОЛ enVista) е разработена, за да замени естествената кристална леща при възрастни пациенти, при които катарактната леща е била премахната. Торичната ВОЛ enVista има асферична оптика, която е проектирана да няма сферична aberация чрез включването на вътрешнофирмена сферична aberационно-неутрална оптична конструкция, която не влияе на профила на предхирургичната сферична aberация на роговицата. Оптиката е конструирана със SureEdge™, заден стъпков ръб с квадратно сечение, който да осигури 360-градусова PCO бариера. Торичната ВОЛ enVista използва хаптика Accuset™ с широк, модифициран C-образен контур и оптично-хаптично отнемване за улесняване на подобрения контакт и стабилност в капсулния сак. Постериорно разположената маркировка на оста на цилиндъра обозначава меридиана с най-ниската мощност. Материалът enVista, който съставя оптичната система TruSight™, е оценен за липса на отблясъци и устойчивост на надраскване. Вградената технология StableFlex™ позволява по-добро съответствие на лещата за лесно поставяне, отличен контрол по време на