

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<sup>1,2</sup>
- 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

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## 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

### Cylindrical power – IOL Plane:

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

### Cylindrical 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

- Reuseable 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 glistering-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**



one-piece hydrophobic acrylic toric intraocular lens

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## DEVICE DESCRIPTION

## PHYSICAL CHARACTERISTICS OF enVistaTORIC IOL MODEL MX60ET

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## WARNINGS

3. 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. Patients in whom neither the posterior capsule nor zonules are intact enough to provide support.
8. 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

- ### 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

## MEDICAL DEVICE RE-USE STATEMENT

## ADVERSE EVENTS

## SELECTION AND PLACEMENT OF enVista TORIC IOL

## CALCULATION OF LENS POWER

## 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.

- ## OVERVIEW OF CLINICAL STUDIES

## enVista MX60T CLINICAL TRIAL STUDY RESULTS

## HOW SUPPLIED

**EXPIRATION DATE**

## ADVERSE EVENT REPORTING

## PATIENT REGISTRATION INSTRUCTIONS AND REPORTING REGISTRATION

## RETURNED GOODS POLICY

## WARRANTY

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

 **Bausch & Lomb GmbH**  
Brunsbütteler Damm 165/173  
13581 Berlin, Germany

 **0197**

[www.bausch.com/symbols](http://www.bausch.com/symbols)

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## ОПИСАНИЕ НА ИЗДЕЛИЕТО

Еднокомпонентната хидрофобна акрилна торична вътрешна леща enVista™ (торична BOUL enVista) е разработена, за да замени естествената кристална леща при възрастни пациенти, при които катарактната леща е била премахната. Торичната BOUL enVista има асферична оптика, която е проектирана да няма сферична аберация чрез включването на вътрешнофирмена сферична аберационно-неутрална оптична конструкция, която не влияе на профила на предхирургичната сферична аберация на роговицата. Оптиката е конструирана със SureEdge™, заден стъпков ръб с квадратно сечение, който да осигури 360-градусова PCO барьера. Торичната BOUL enVista използва халтика Accuset™ с широк, модифициран C-образен контур и оптично-халпично отнемане 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 TrueSight™, е оценен за липса на отблясъци и устойчивост на надраскване. Вградената технология StableFlex™ позволява подобро съответствие на лещата за лесно поставяне, отличен контрол по време на