

# Vivinex™ Toric

UNPRECEDENTED CLARITY AND ROTATIONAL STABILITY

- 1 Glistening-free per Miyata scale; study result of the David J Apple International Laboratory for Ocular Pathology, University Hospital Heidelberg. Report on file.
  - 2 Pérez-Merino P, Marcos S. Effect of intraocular lens decentration on image quality tested in a custom model eye. J Cataract Refract Surg. 2018;44(7):889–896.
  - 3 Data on File of Study PHIV-101-SP2: Clinical Evaluation of the HOYA Vivinex IOL [2018].
  - 4 Schartmüller D, Schriefl S, Schwarzenbacher L, Leydolt C, Menapace R. True rotational stability of a single-piece hydrophobic intraocular lens. Br J Ophthalmol. 2018 Apr 17. pii: bjophthalmol-2017-311797. doi: 10.1136/bjophthalmol-2017-311797.
  - 5 Harrer et al. Variability in angle k and its influence on higher-order aberrations in pseudophakic eyes. J Cataract Refract Surg. 2017 Aug;43(8): 1015-1019.
  - 6 Abulafia A et al. New regression formula for toric intraocular lens calculations. J Cataract Refract Surg 2016; 42(5):663–671.
  - 7 Based on an average pseudophakic human eye.
  - 8 At IOL Plane.
- \* Trademarks are property of their respective owners.

The glistening-free hydrophobic Vivinex™ Toric IOL preloaded in the proven Vivinex™ iSert® injector offers unprecedented clarity of vision and outstanding rotational stability.

**HOYA**  
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# Vivinex™ Toric

## Unprecedented clarity and rotational stability

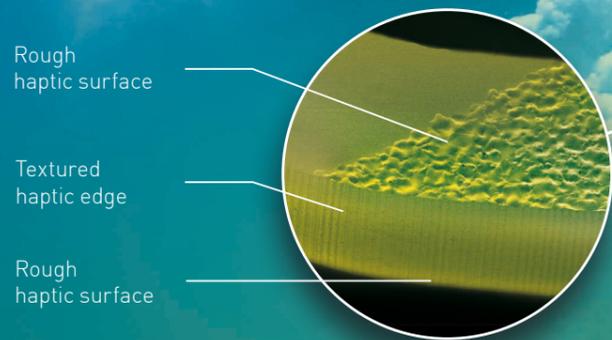
Designed for outstanding optical quality, Vivinex™ Toric has proven rotational stability for precise astigmatism correction and provides patients with unprecedented clarity of vision. Product quality, trust, dedication and attention to detail are deeply rooted in our Japanese heritage, and with 1 million lenses sold worldwide, surgeons' trust in Vivinex™ is proven.

### Vivinex™ Toric offers the following benefits:

- Glistening-free hydrophobic acrylic IOL material<sup>[1,3]</sup>
- Proprietary aspheric optic design for improved image quality<sup>[2]</sup>
- Active oxygen processing treatment and sharp optic edge to reduce PCO<sup>[3]</sup>
- Outstanding rotational stability<sup>[4]</sup>
- Median rotation 1.1° [range: 0.0°–5.0°]<sup>[4]</sup>

### Textured-rough haptic surface for better grip

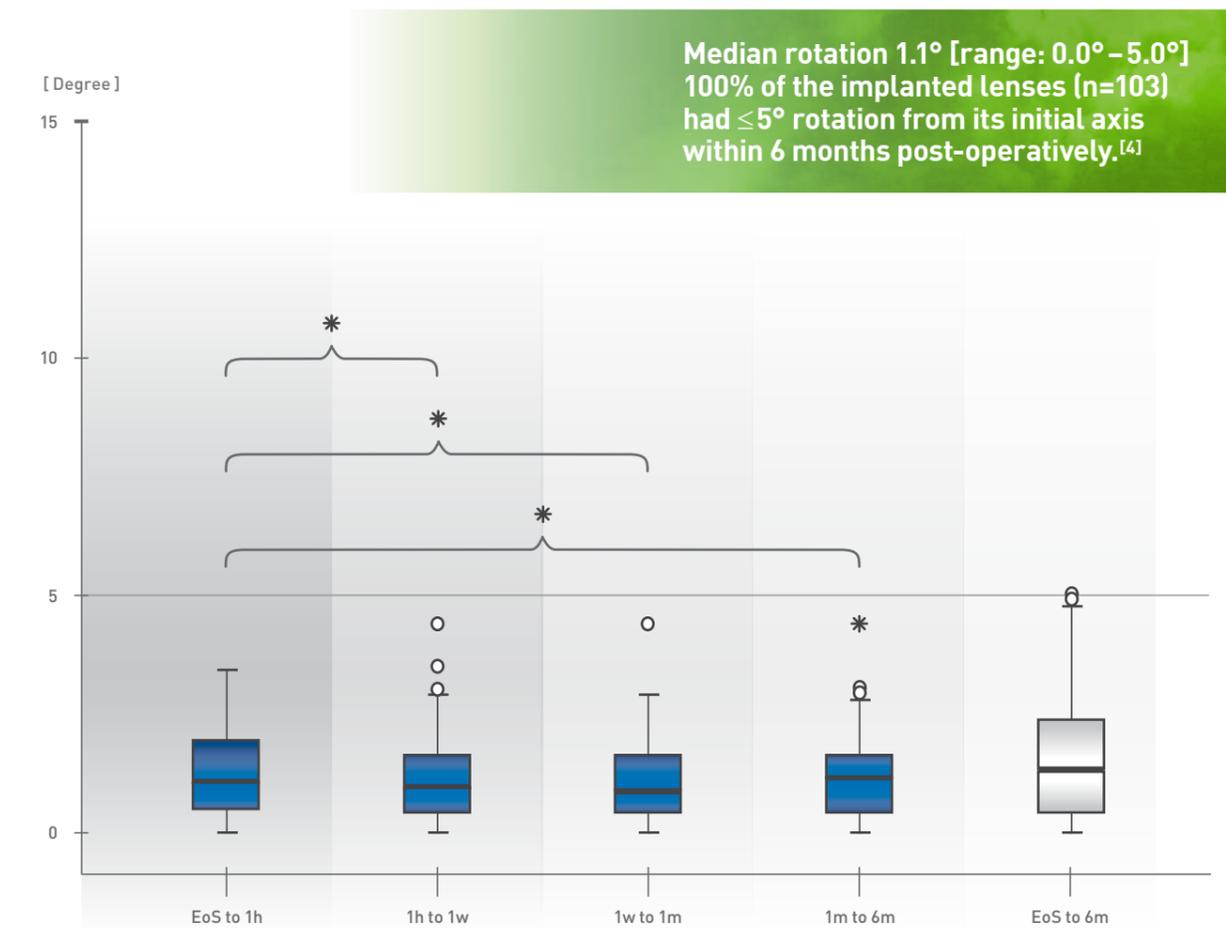
Designed to provide better grip inside the capsular bag and to reduce the potential for adhesion to the optic surface, Vivinex™ has two tread patterns applied to three surfaces.



## Reliable outcomes through outstanding rotational stability<sup>[4]</sup>

Early clinical results with the Vivinex™ preloaded IOL platform at the University of Vienna confirm unprecedented rotational stability. In a group of 103 eyes, no lens rotated more than 5 degrees from orientation at the end of surgery to 6 months postoperatively.

### Absolute Rotation in Degrees<sup>[4]</sup>



EoS = End of Surgery; 1h = 1 hour postop; 1w = 1 week postop; 6m = 6 months postop

**Within the first hour, the increase in rotation was statistically significant compared with all other time-points (p<0.001; one-way analysis of variance followed by least significant difference test).**

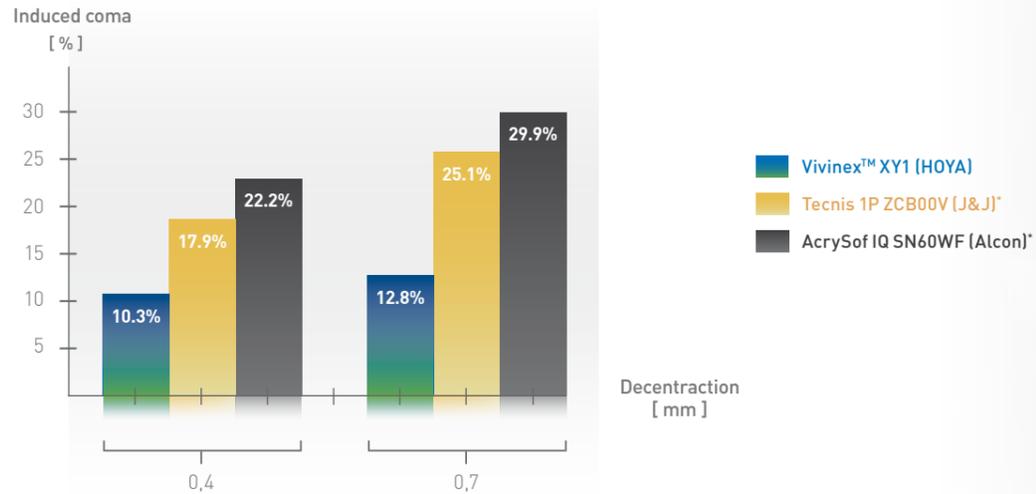
Most studies published about rotational stability of toric IOLs do not measure early rotation from the initial axis at end of surgery. The baseline for rotation measurements is often the axis of alignment at 1 day postoperative.<sup>[4]</sup>

## Proprietary aspheric optic design for improved image quality

In presence of decentration coma is less in HOYA Vivinex™ as compared with other leading competitor IOLs at 4.0 mm pupil diameter.<sup>[2]</sup>

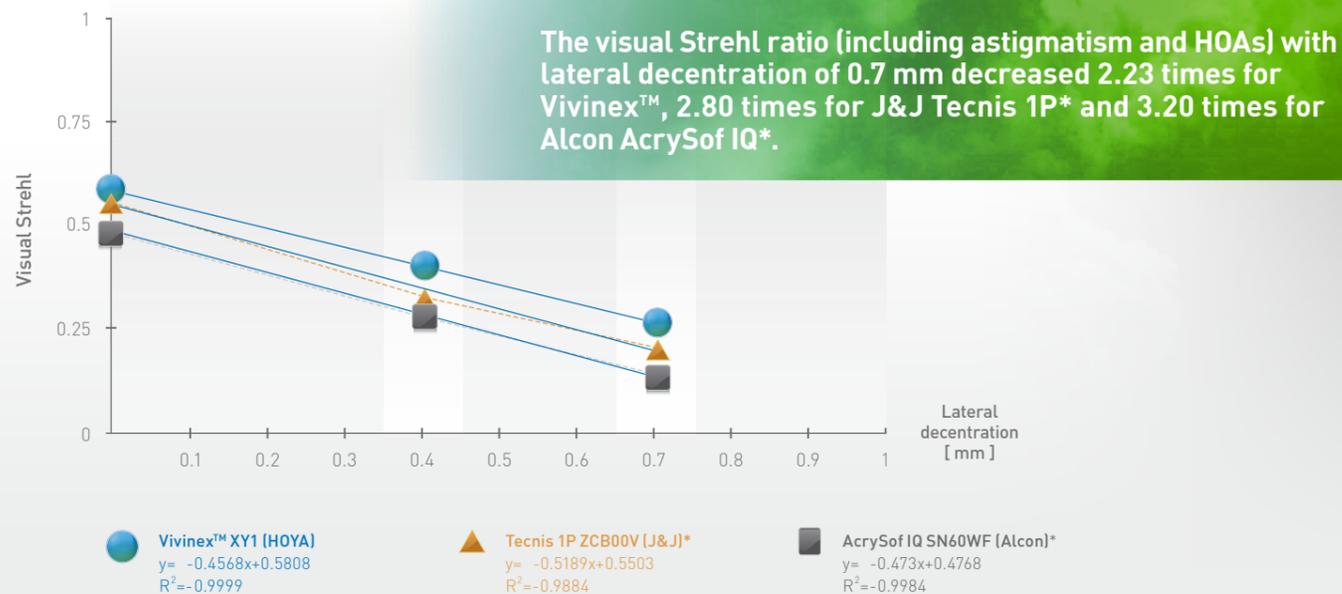
Studies have shown that the mean decentration of an IOL following cataract surgery is  $0.4 \pm 0.2$  mm with a range up to 1.7 mm.<sup>[5]</sup>

### Reduced coma caused by off-axis alignment



### Reduced impact on optical quality caused by off-axis alignment<sup>[2]</sup>

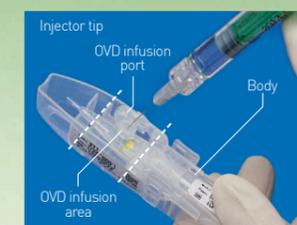
Vivinex™ also showed the highest absolute optical quality for a centered IOL.



## More than 7 million HOYA preloaded IOLs sold worldwide

Proven Vivinex™ iSert® injector preloaded with the Vivinex™ IOL offers the following features:

- Injector tip outer diameter of 1.70 mm
- Uni-directional slider advancement
- Screw injector with constant length



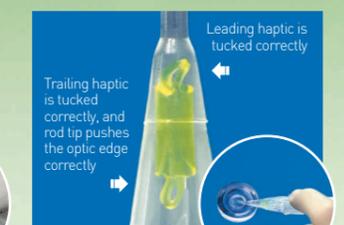
**Step A**  
 Infuse the OVD into the injector through the infusion port. Fill up the area indicated by dotted lines.



**Step B**  
 Press the release tabs, lift up and remove the cover from the case.



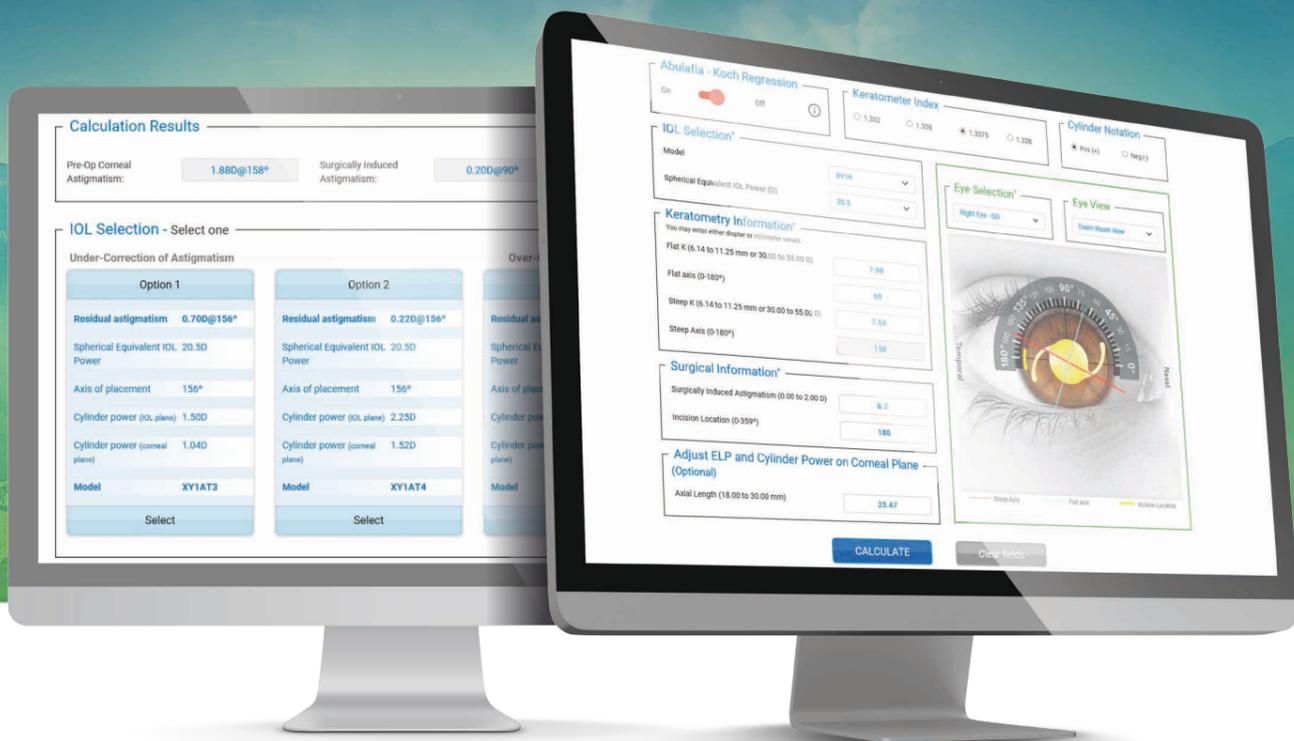
**Step C**  
 Hold body with thumb and push the slider slowly forward until it stops. Remove the injector from the case.



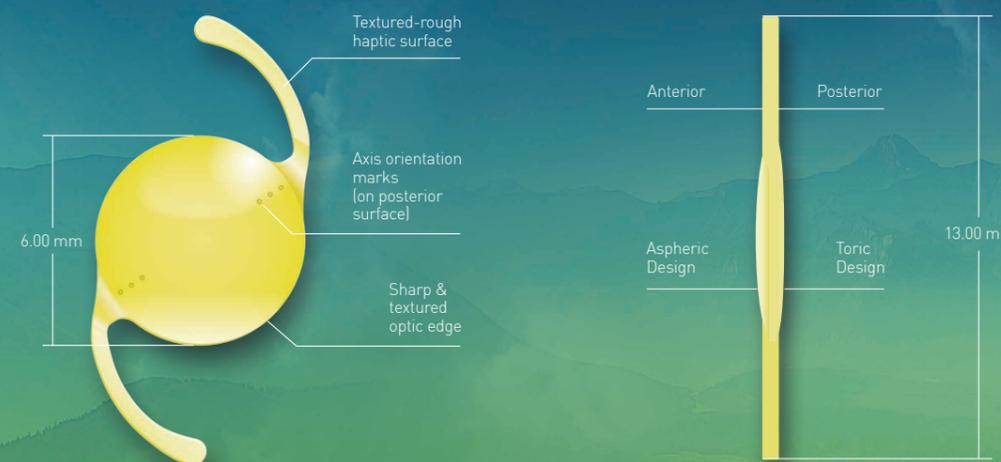
**Step D**  
 Carefully insert the injector tip into the eye through the incision, keeping the slit of the tip in a downward position. Slowly rotate the injector knob clockwise, to inject the lens into the capsular bag.

The handling shown above illustrates in summary the product application and does not replace the Instruction For Use.

# Precise calculation of cylinder power with the new HOYA Toric Calculator 4.1



# Technical characteristics



According to several studies, standard toric IOL calculations tend to result in undercorrection of eyes with against-the-rule astigmatism (ATR) and overcorrection of eyes with with-the-rule astigmatism (WTR).<sup>[6]</sup>

The new HOYA Toric Calculator (HTC) 4.1 can take account of posterior corneal astigmatism in the calculation by giving the option to apply the Abulafia-Koch Regression formula.

The Abulafia-Koch Regression, applied to a clinical patient cohort, has been shown to improve predictability of TIOL refractive outcomes.<sup>[6]</sup>

## The HTC 4.1 at a glance

- Choice of three different cylinder power options allows the doctor to select the most suitable IOL model based on residual astigmatism and axis
- Optional Abulafia-Koch Regression formula can account for the added astigmatic effect of the posterior cornea when measured by standard keratometry of the anterior corneal surface
- Option to display calculation results as plus (+) or minus (-) cylinder
- Option to select the used keratometer index, if flat and steep K are entered in diopters
- Optional axial length data entry to adjust the cylinder power of the toric IOL at the corneal plane
- Numerous different print and export options are available with customized orientation of the printed eye image

Vivinex™ Toric				
Model Name	XY1A			
Optic Design	Biconvex with sharp textured optic edge Anterior: Aspheric Design Posterior: Toric Design			
Optic & Haptic Materials	Hydrophobic acrylic Vivinex™ with UV- and blue light filter			
Haptical Design	Textured-rough haptic surface			
Dimensions (Optic/OAL)	6.00 mm / 13.00 mm			
Power	+10.00 to +30.00 D (in 0.50 D increments)			
Cylinder Power <sup>[7]</sup>	1.00 to 6.00 D (T2 to T9) T2 to T3 in 0.50 D increments T3 to T9 in 0.75 D increments			
Nominal A-Constant**	118.9			
Optimized Constants***	Haigis	a0 = -0.278	a1 = 0.215	a2 = 0.201
	Hoffer Q	pACD = 5.71		
	Holladay 1	sf = 1.94		
	SRK/T	A = 119.2		
Front injector tip outer diameter	1.70 mm			
Injector	Vivinex™ iSert® preloaded			

Model XY1A	Cylinder Power at IOL Plane	Cylinder Power at Corneal Plane <sup>[8]</sup>
T2	1.00 D	0.69 D
T3	1.50 D	1.04 D
T4	2.25 D	1.56 D
T5	3.00 D	2.08 D
T6	3.75 D	2.60 D
T7	4.50 D	3.12 D
T8	5.25 D	3.64 D
T9	6.00 D	4.17 D

\*\* The mentioned A-Constant is presented as a guideline only for lens power calculations. It is recommended that the A-Constant measurement be customized based on the surgeon's experience and measuring equipment.

\*\*\* Source: <https://iolcon.org> Calculated from 911 patient data for Vivinex™ Model XY1/XC1 as of August 17, 2018.