TECNIS®

Toric II 1-Piece IOL

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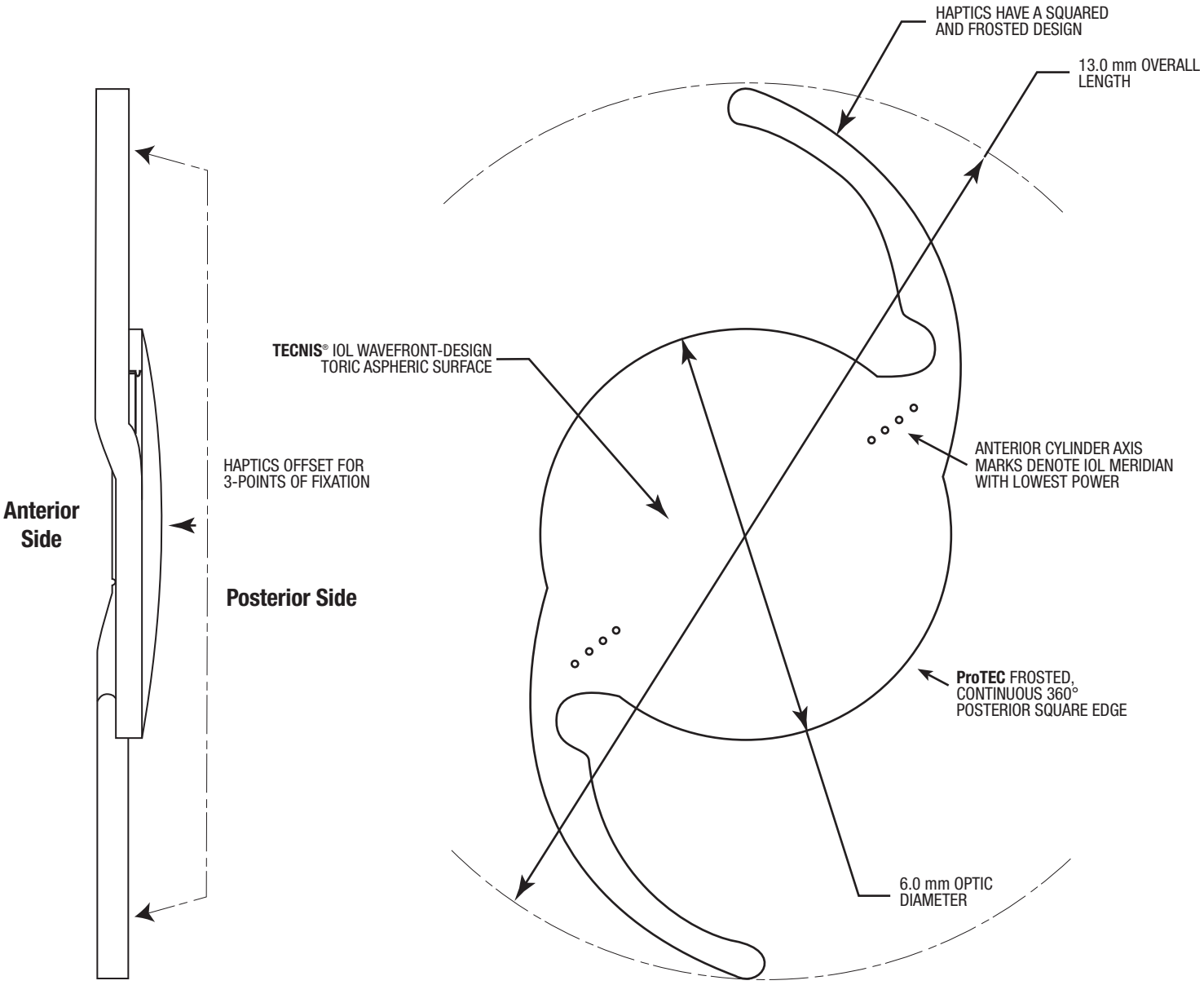
TECNIS® TORIC II 1-PIECE IOL | Hydrophobic Acrylic



Johnson & Johnson VISION

TECNIS®
Toric II 1-Piece IOL
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Models: ZCU150 ZCU225 ZCU300 ZCU375 ZCU450 ZCU525 ZCU600

OPTIC CHARACTERISTICS							
Powers:				+5.0 D to +34.0 D in 0.5 diopter increments			
MODEL	**ZCU150[c]**	**ZCU225[c]**	**ZCU300**	**ZCU375[d]**	**ZCU450**	**ZCU525**	**ZCU600**
Cylinder Powers – IOL Plane:	1.50 D	2.25 D	3.00 D	3.75 D	4.50 D	5.25 D	6.00 D
Cylinder Powers – Corneal Plane*:	1.03 D	1.54 D	2.06 D	2.57 D	3.08 D	3.60 D	4.11 D
Correction Range Based on Combined Corneal Astigmatism (Preoperative Kcyl[a]+SIA[b])	0.75 - 1.50 D	1.50 - 2.00 D	2.00 - 2.50 D	2.50 - 3.00 D	3.00 - 3.50 D	3.50 - 4.00 D	4.00 - 4.75 D
Diameter:				6.0 mm			
Shape:				Biconvex, anterior toric aspheric surface			
Material:				UV-blocking hydrophobic acrylic			
Refractive Index:				1.47 at 35° C			
ABBE:				55			
Asphericity of Lens:				-0.27 um			
Edge Design:				**ProTEC** frosted, continuous 360° posterior square edge			
OPTICAL BIOMETRY[‡]							
A-Constant:				119.3			
AC Depth:				5.7 mm			
Surgeon Factor:				1.96 mm			
APPLANATION ULTRASOUND BIOMETRY[§]							
A-Constant:				118.8			
Theoretical AC Depth:				5.4 mm			
Surgeon Factor[†]:				1.68 mm			
HAPTIC CHARACTERISTICS							
Overall Length:				13.0 mm			
Configuration:				**Tri-Fix** design, modified C, integral with optic			
Material:				UV-blocking hydrophobic acrylic			
Design:				Haptics offset from optic Haptics have a squared and frosted design			
RECOMMENDED INSERTION INSTRUMENTS				**MODEL**			
The **UNFOLDER®** Platinum 1 Series Handpiece The **UNFOLDER®** Platinum 1 Series Cartridge				DK7796 1MTEC30			

[a] Keratometric cylinder
[b] Surgically induced astigmatism
[c] IOL Model is not being used in this study
[d] ZCT375 will be used in place of the ZCT400 model following FDA-approval
[†] Calculated based on Holladay I formula: Holladay JT, Prager TC, Chandler TY, Musgrove KH, Lewis JW, Ruiz RS. A three-part system for refining intraocular lens power calculations. *J Cataract Refract Surg.* 1988;14(1):17-24 and Holladay, J.T. International Intraocular Lens & Implant registry 2003. *J Cataract Refract Surg.* 2003; 29:176-197.
* Based on average pseudophakic human eye and 'Holladay et al. A three-part system for refining intraocular lens power calculations. *J Cataract Refract Surg.* 1988;14(1):17-24'.
[b] Based on a vector sum of preoperative corneal astigmatism (preop Kcyl) and the predicted effect of surgically induced astigmatism (SIA).
[‡] Derived from clinical evaluation results of the 1-Piece IOL Platform for optical biometry.
[§] A-Constant theoretically derived for ultrasound biometry.

To learn more and to view important safety information, please review the TECNIS® Toric II IOL Directions For Use (DFU).

About TECNIS Toric II IOL

Physicians considering use of the TECNIS® Toric II OLs should refer to the Directions for Use labeling for a complete list of indications and safety information.

The TECNIS® Toric II 1-Piece posterior chamber lens is indicated for the visual correction of aphakia and pre-existing corneal astigmatism of one diopter or greater in adult patients with or without presbyopia in whom a cataractous lens has been removed by phacoemulsification and who desire improved uncorrected distance vision, reduction in residual refractive cylinder, and increased spectacle independence for distance vision. The device is intended to be placed in the capsular bag.

Important Safety Information: The most frequently reported cumulative adverse event that occurred during the TECNIS® Toric 1-Piece IOL clinical trial was surgical re-intervention which occurred at a rate of 3.4% (lens repositioning procedures and retinal repair procedures). Rotation of these IOLs away from its intended axis can reduce its astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. Variability in any of the preoperative measurements can influence patient outcomes. Physicians should weigh the potential risk/benefit ratio for circumstances described in the Directions for Use that could increase complications or impact patient outcomes. Federal law restricts this device to sale, distribution and use by or on the order of a physician.

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