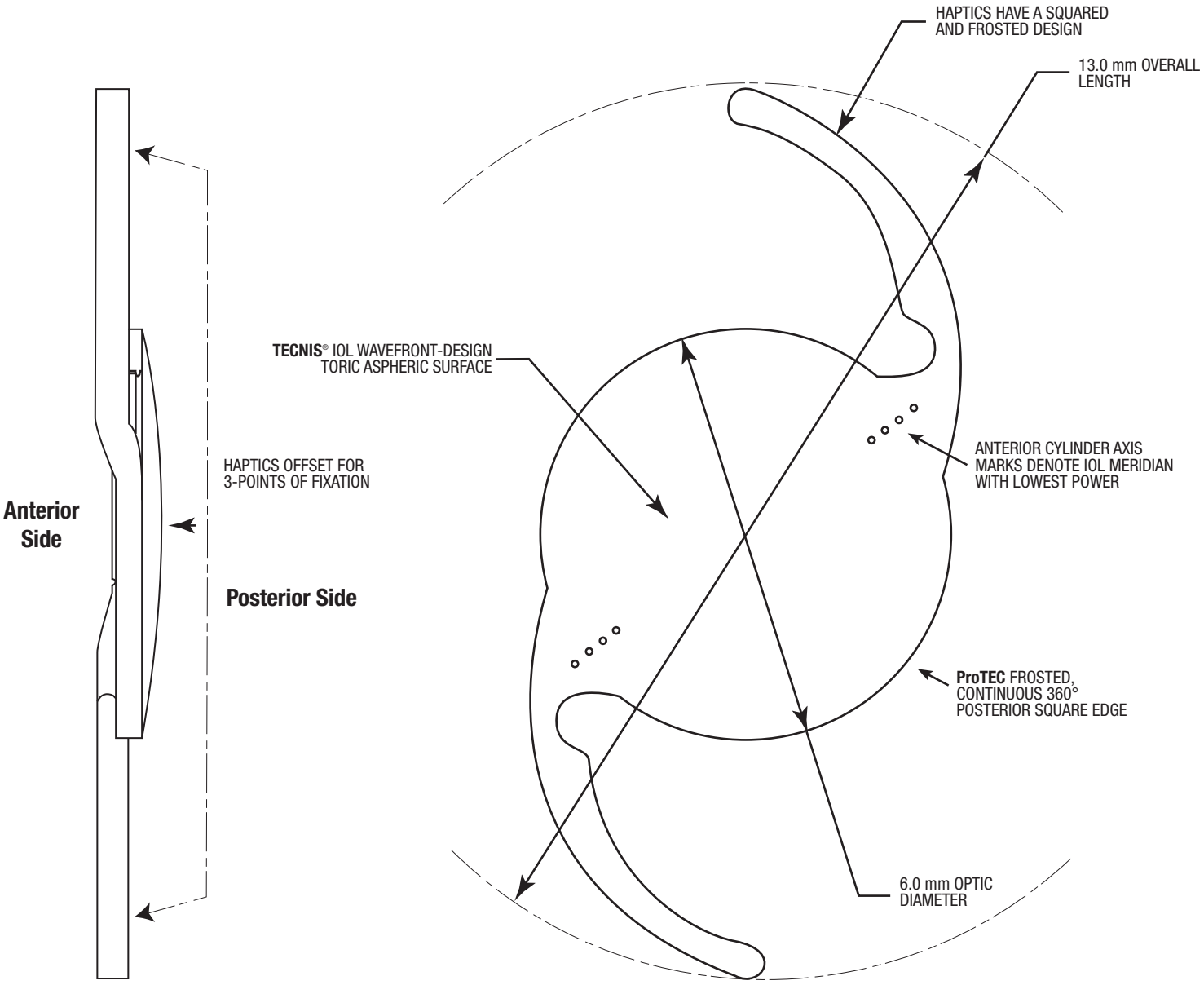
TECNIS®

Toric II 1-Piece IOL

Toric II

TECNIS® TORIC II 1-PIECE IOL | Hydrophobic Acrylic



Johnson & Johnson VISION

TECNIS®
Toric II 1-Piece IOL
Toric II

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**	**ZCU225**	**ZCU300**	**ZCU375**	**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
Diameter:				6.0 mm			
Shape:				Biconvex, anterior toric aspheric surface			
Material:				UV-blocking hydrophobic acrylic			
Refractive Index:				1.47 at 35° C			
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			

† 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'.
† 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).

INDICATIONS AND IMPORTANT SAFETY INFORMATION
Rx Only

ATTENTION
Reference the Directions for Use labeling for a complete listing of Indications and Safety Information.

INDICATIONS
The TECNIS® Toric II 1-Piece IOL 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.

WARNINGS
Physicians considering lens implantation should weigh the potential risk/benefit ratio for any circumstances described in the TECNIS® Toric II 1-Piece IOL Directions for Use that could increase complications or impact patient outcomes. The clinical study did not show evidence of effectiveness for the treatment of preoperative corneal astigmatism of less than one diopter. The TECNIS® Toric II 1-Piece IOL should not be placed in the ciliary sulcus. Rotation of the TECNIS® Toric II 1-Piece IOL away from its intended axis can reduce its astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder.

PRECAUTIONS
Accurate keratometry and biometry in addition to the use of the TECNIS® Toric Calculator (www.TecnisToricCalc.com) are recommended to achieve optimal visual outcomes. The safety and effectiveness of the toric intraocular lens have not been substantiated in patients with certain preexisting ocular conditions and intraoperative complications. Refer to the TECNIS® Toric II 1-Piece IOL Directions for Use for a complete description of the preexisting conditions and intraoperative complications. All preoperative surgical parameters are important when choosing a toric lens for implantation. Variability in any of the preoperative measurements can influence patient outcomes. All corneal incisions were placed temporally in the clinical study. When the insertion system is used improperly, the haptics of the TECNIS® Toric II 1-Piece IOL may become broken. Please refer to the specific instructions for use provided with the insertion instrument or system. Do not reuse, resterilize, or autoclave.

ADVERSE EVENTS
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).

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Reorder: TEC13-04

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