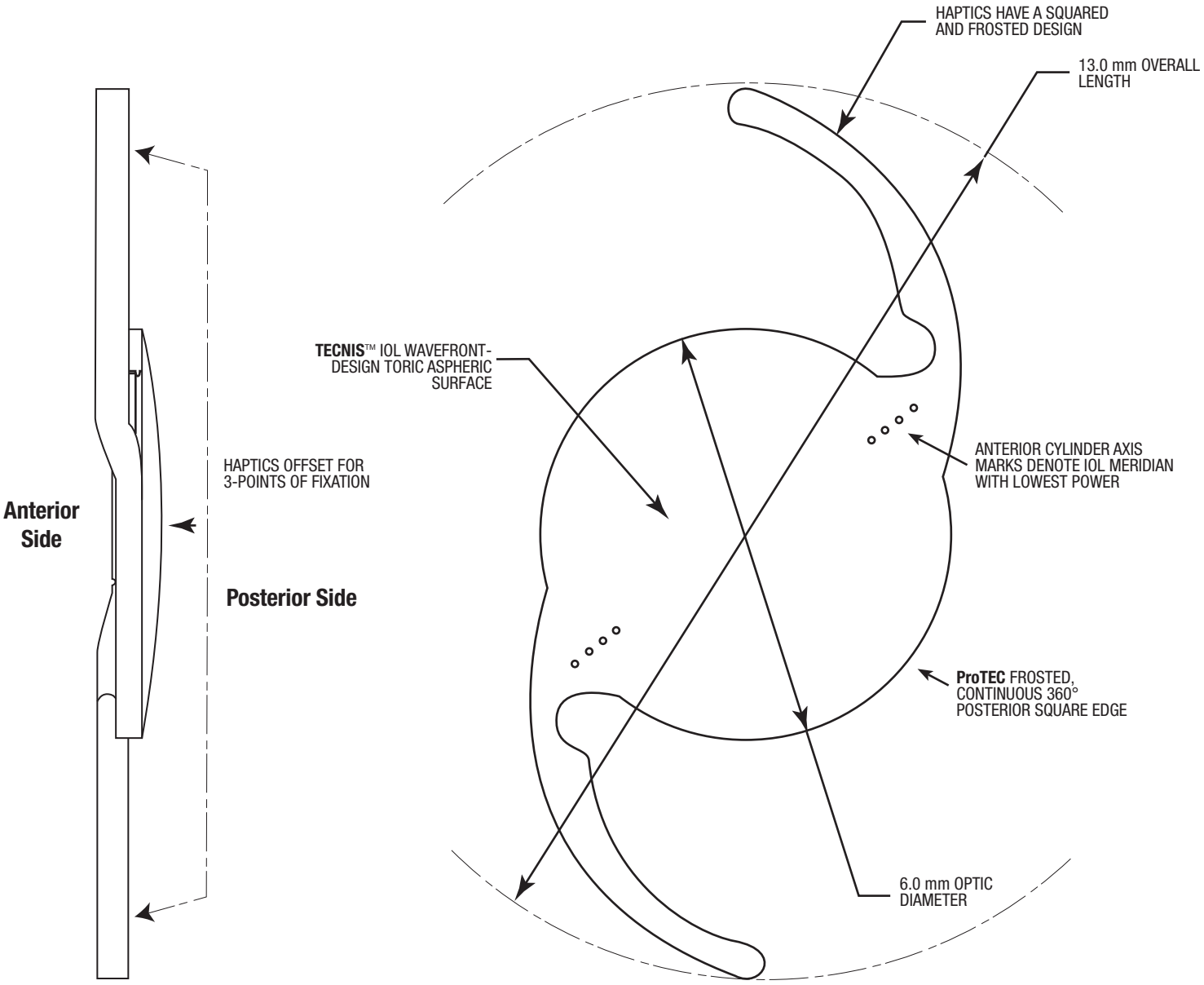
TECNIS™

Toric II 1-Piece IOL

Toric II

TECNIS™ TORIC II 1-PIECE IOL | Hydrophobic Acrylic



Johnson&Johnson

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
Correction Range Based on Combined Corneal Astigmatism (Preoperative Kcyl[a]+SIA[b]) This information is used for software set up and not as a guide for lens selection	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	DK7796
The **UNFOLDER**™ Platinum 1 Series Cartridge	1MTEC30

[a] Keratometric cylinder
[b] Surgically induced Astigmatism
[†] 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'.
‡ Derived from clinical evaluation results of the 1-Piece IOL Platform for optical biometry.
§ A-Constant theoretically derived for ultrasound biometry.

Visit the TECNIS™ Toric calculator at www.TecnisToricCalc.com

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 IOLs 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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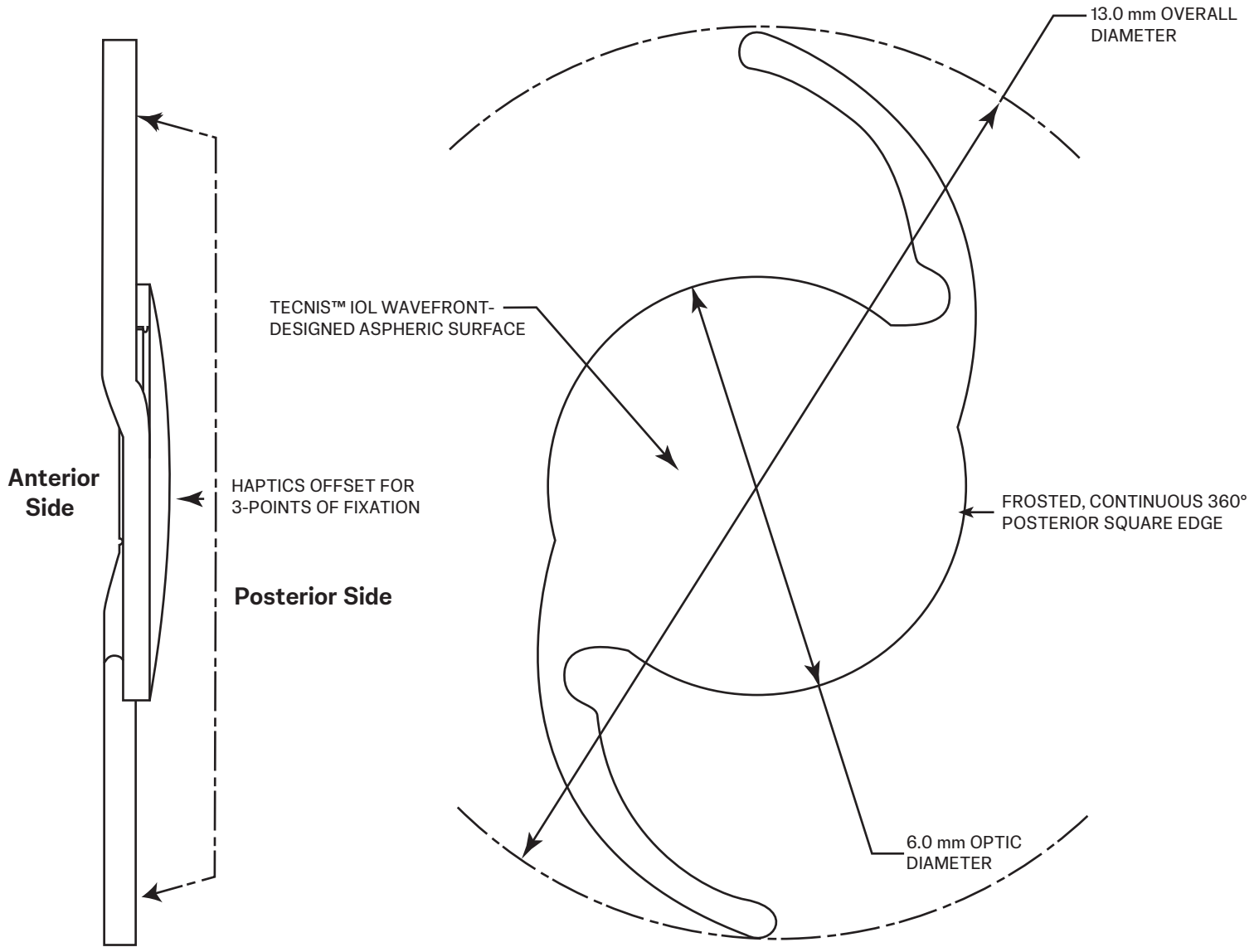
TECNIS™
Monofocal IOLs

Model: ZCB00

TECNIS™ 1-Piece Aspheric IOL
Hydrophobic Acrylic



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TECNIS™
Monofocal IOLs

Model: ZCB00

DESCRIPTION		
OPTIC CHARACTERISTICS		
Powers:	+5.0 D to +34.0 D in 0.5 diopter increments	
Diameter:	6.0 mm	
Shape:	Biconvex, anterior aspheric surface, square optic edge	
Material:	UV-blocking hydrophobic acrylic	
Refractive Index:	1.47 at 35˚ C	
Edge Design:	***ProTEC*** frosted, continuous 360° posterior square edge	
BIOMETRY	**CONTACT ULTRASOUND**	**OPTICAL**
A-constant:	118.8†	119.3*
Theoretical AC Depth:	5.4 mm	5.7 mm*
Lens Factor:	1.78	2.04** **This lens factor is based on our manufacturer a-constant. For Barrett optimized lens factor please refer to the Barrett Universal website.
Surgeon Factor:[1]	1.68 mm	1.96 mm*
HAPTIC CONSIDERATIONS		
Overall Length:	13.0 mm	
Style:	C	
Material:	UV-blocking hydrophobic acrylic	
Design:	Haptics offset from optic	
RECOMMENDED INSERTION INSTRUMENTS	**MODEL**	
UNFOLDER™ Platinum 1 Series Implantation System ***UNFOLDER***™ Platinum 1 Series Cartridge	DK7796 1MTEC30	

* Derived from clinical evaluation of the TECNIS™ 1-Piece platform.

† Value theoretically derived for a typical 20.0 D lens. Johnson & Johnson recommends that surgeons personalize their A-constant based on their surgical techniques and equipment, experience with the lens model, and postoperative results.

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR TECNIS™ 1-Piece IOL
Rx Only

INDICATIONS
TECNIS™ 1-piece lenses are indicated for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction. These devices are intended to be placed in the capsular bag.

PRECAUTIONS
Do not resterilize the lens. Most sterilizers are not equipped to sterilize the soft acrylic material without producing undesirable side effects. 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 in direct sunlight or at a temperature greater than 113°F (45°C). Do not autoclave the intraocular lens. Please refer to the specific instructions for use provided with the insertion instrument or system for the amount of time the IOL can remain folded before the IOL must be discarded. When the insertion system is used improperly, the haptics of the TECNIS™ 1-piece lens may become damaged.

WARNINGS
Physicians considering lens implantation should weigh the potential risk/benefit ratio for any conditions described in the TECNIS™ 1-Piece IOL Directions for Use that could increase complications or impact patient outcomes. These conditions include 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 may increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure or significant vitreous prolapse or loss); a compromised eye due to previous trauma or developmental defects in which appropriate support of the IOL is not possible; circumstances that would result in damage to the endothelium during implantation; suspected microbial infection; or patients in whom neither the posterior capsule nor the zonules are intact enough to provide support for the IOL. Children under the age of 2 years are not suitable candidates for intraocular lenses. The TECNIS™ 1-Piece IOL should not be placed in the ciliary sulcus.

ADVERSE EVENTS
In 3.3% of patients, reported adverse events of cataract surgery with the TECNIS™ 1-Piece IOL included macular edema. Other reported reactions occurring in less than 1% of patients were secondary surgical intervention (pars plana vitrectomy with membrane peel) and lens exchange (due to torn lens haptic).

ATTENTION
Reference the Directions for Use for a complete listing of indications and important safety information.

1. 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).

TECNIS™ 1-piece lenses are indicated for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction. These devices are intended to be placed in the capsular bag.

ATTENTION: For a complete listing of indications, precautions, warnings, and adverse events, refer to the package insert.

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