

TECNIS[®]

Multifocal Toric II IOL

Toric II

Tailored Clarity to Meet Each Patient's Lifestyle.



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Multifocal Toric II IOL

+3.25 D

Toric II

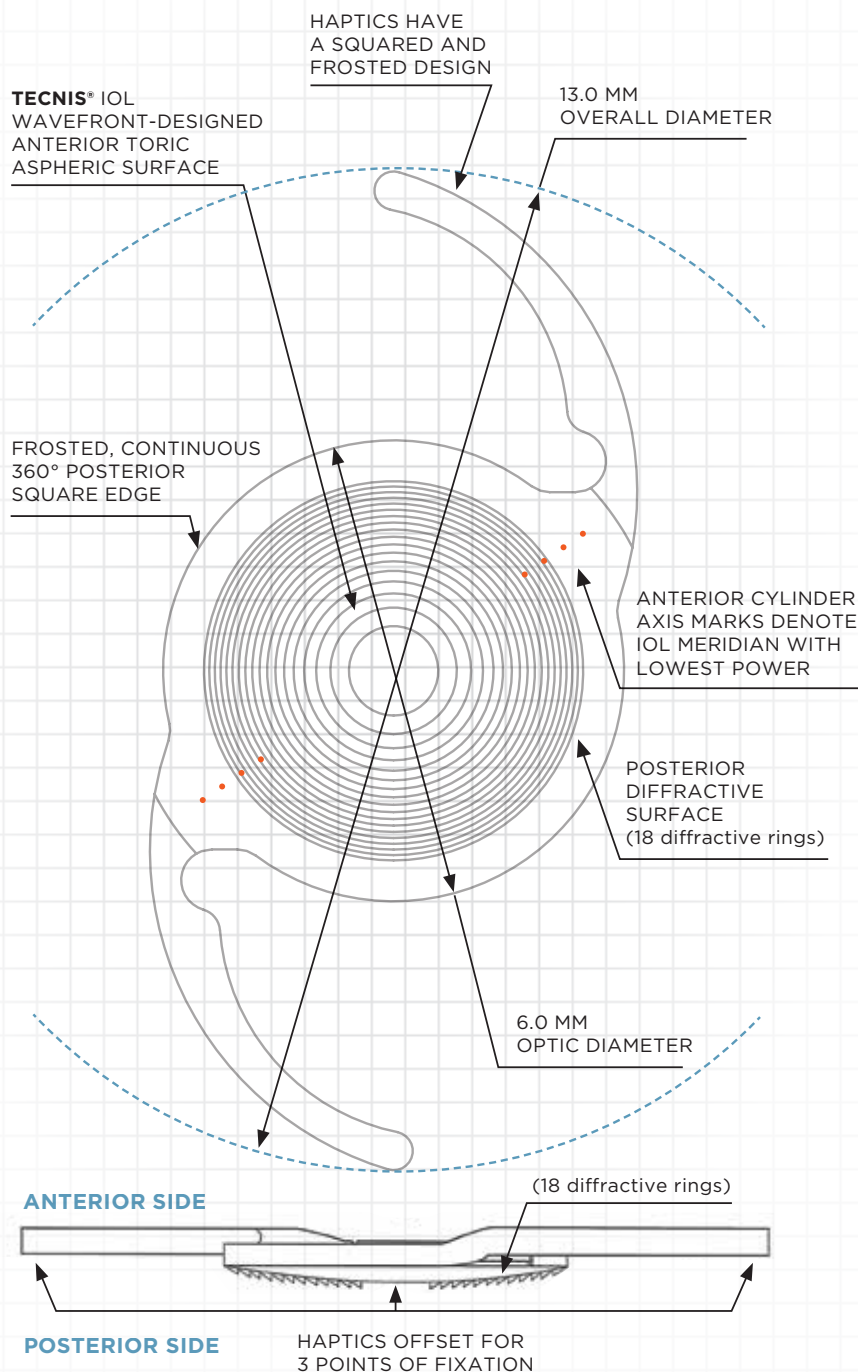
TECNIS[®]

MULTIFOCAL

TORIC II IOL +3.25 D

For Enhanced Performance at 42 cm (16 in)

(Theoretical Reading Distance)





TECNIS® Multifocal Toric II IOL

+3.25 D
Toric II

MODEL:
1.50 D - ZLU150 3.00 D - ZLU300
2.25 D - ZLU225 3.75 D - ZLU375

OPTIC CHARACTERISTICS

Powers:	+5.0 D to 34.0 D in 0.5 diopter increments			
Diameter:	6.0 mm			
Model:	ZLU150	ZLU225	ZLU300	ZLU375
Cylinder Powers - IOL Plane:	1.50 D	2.25 D	3.00 D	3.75D
Cylinder Powers - Corneal Plane:	1.03 D	1.54 D	2.06 D	2.57D
Correction Range Based on Combined Corneal Astigmatism (Preoperative Kcyl ^a +SIA ^b) <i>This information is used for software set up and not as a guide for lens selection</i>	0.75 - 1.50 D	1.50 - 2.00 D	2.00 - 2.50 D	2.50 - 3.00 D
Shape:	Biconvex, anterior toric aspheric surface, posterior diffractive surface			
Add Power (IOL Plane):	+3.25 D			
Add Power (Spec Plane):	+2.37 D			
Material:	UV-blocking hydrophobic acrylic			
Refractive Index:	1.47 at 35°C			
Asphericity of Lens ¹ :	-0.27 um			
Chromatic Aberration (Abbe Number):	55			
Edge Design:	ProTEC frosted, continuous 360° posterior square edge			

BIOMETRY

	CONTACT ULTRASOUND	OPTICAL
A-Constant:	118.8*	119.3 [†]
Theoretical AC Depth:	5.40 mm	5.72 mm
Surgeon Factor ² :	1.68 mm	1.96 mm

HAPTIC CHARACTERISTICS

Overall Length:	13.0 mm
Style:	C
Material:	UV-blocking hydrophobic acrylic
Design:	Haptics offset from optic, Haptics have a squared and frosted design

RECOMMENDED INSERTION INSTRUMENTS UNFOLDER® Platinum 1 Series Screw-Style Inserter

MODEL

DK7796

UNFOLDER® Platinum 1 Series Cartridge

1MTEC30

^a Keratometric cylinder

^b Surgically induced Astigmatism

¹ Value theoretically derived for a typical 20.00 D lens. Johnson & Johnson Vision recommends that surgeons personalize their A-constant based on their surgical techniques and equipment, experience with the lens model and postoperative results. [†]Derived from clinical evaluation results of the **TECNIS®** 1-Piece Platform.

For optimal results, utilize the **TECNIS®** Toric IOL calculator at www.TecnisToricCalc.com to determine the appropriate Toric model and power.

INDICATIONS and IMPORTANT SAFETY INFORMATION for TECNIS® Multifocal Toric II IOLs

Rx ONLY

INDICATIONS FOR USE: The TECNIS® Multifocal Toric II lens models ZKU150, ZKU225, ZKU300, ZKU375 and ZLU150, ZLU225, ZLU300, ZLU375 are indicated for primary implantation for the visual correction of aphakia and for reduction of residual refractive astigmatism in adult patients with or without presbyopia, with greater than or equal to 1 diopter of preexisting corneal astigmatism, in whom a cataractous lens has been removed in order to provide near, intermediate and distance vision. The IOLs are intended for capsular bag placement only. **WARNINGS:** Physicians considering lens implantation should weight the potential risk/benefit ratio for any conditions described in the Directions for Use that could increase complications or impact patient outcomes. Multifocal IOL implants may be inadvisable in patients where central visual field reduction may not be tolerated, such as macular degeneration, retinal pigment epithelium changes, and glaucoma. The lens should not be placed in the ciliary sulcus. Inform patients about the possibility that a decrease in contrast sensitivity and an increase in visual disturbances may affect their ability to drive a car under certain environmental conditions, such as driving at night or in poor visibility conditions. The clinical study of the TECNIS Toric 1-Piece IOL did not show evidence of effectiveness for the treatment of preoperative corneal astigmatism of less than one diopter. The TECNIS® Multifocal Toric II IOLs should not be placed in the ciliary sulcus. Rotation of the TECNIS® Multifocal Toric II IOL away from its intended axis can reduce its astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. **PRECAUTIONS:** Prior to surgery, inform prospective patients of the possible risks and benefits associated with the use of this device and provide a copy of the patient information brochure to patient. Secondary glaucoma has been reported occasionally in patients with controlled glaucoma who received TECNIS® Multifocal IOL implants. The long term effects of intraocular lens implantation have not been determined. 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® Multifocal Toric II 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. Do not reuse, resterilize, or autoclave. **ADVERSE EVENTS:** Only the rate (3.3%) of surgical re-interventions, most of which were non-lens-related, in the ZLB00 (+3.25 D) lens group, was statistically higher than the FDA grid rate (for both first and second eyes). 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). **ATTENTION:** Reference the Directions for Use for a complete listing of Indications and Important Safety Information.

1. DOF2015OTH0005 Additivity of pseudophakic optical performance losses due to IOL (v1.0) - TECNIS: SA -0.27 and corneal SA +0.27. (p.2) Simulations show that the

TECNIS® IOL, that corrects 0.27 microns of SA and has an Abbe number of 55, provides improved image contrast rang

2. Holladay, et al, A threepart system for refining intraocular lens calculations. (v0.1) - Table 1:

Corresponding values for commonly used formula constants and the "surgeon factor" (p.2)