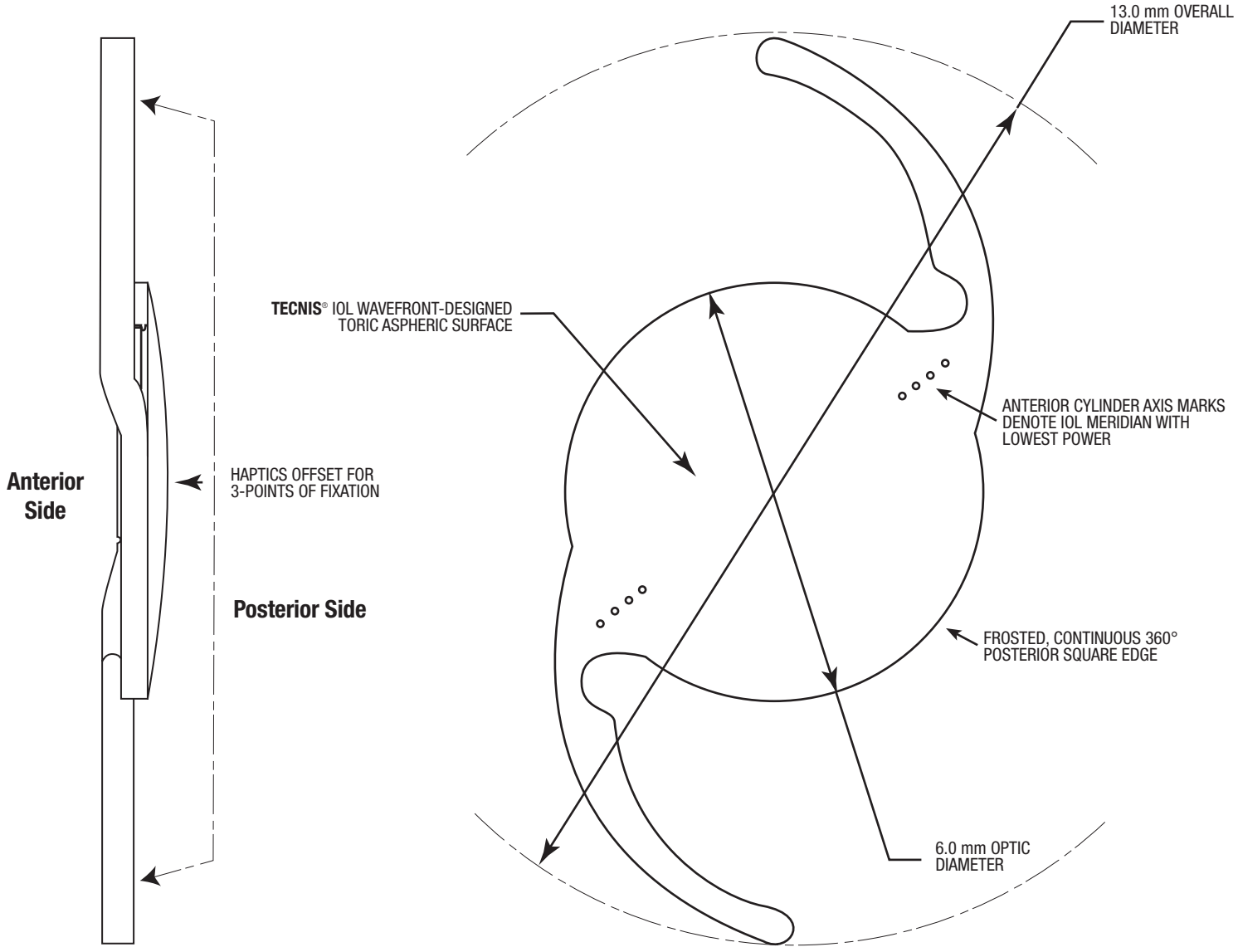
TECNIS® Toric 1-Piece Aspheric IOL

Hydrophobic Acrylic



TECNIS® TORIC ASPHERIC IOL

Abbott
A Promise for Life

TECNIS® Toric Aspheric IOL

TORIC

Models: 1.50 D – ZCT150 • 2.25 D – ZCT225 • 3.00 D – ZCT300 • 4.00 D – ZCT400

DESCRIPTION

OPTIC CHARACTERISTICS

Powers:	+5.0 D to +34.0 D in 0.5 diopter increments			
Cylinder Powers – IOL Plane:	1.50 D	2.25 D	3.00 D	4.00 D
Cylinder Powers – Corneal Plane:*	1.03 D	1.55 D	2.06 D	2.74 D
Corneal Astigmatism Correction Range† (Preop Kcyl+SIA)	0.75-1.50 D	1.50-2.00 D	2.00-2.75 D	2.75-3.62 D
Diameter:	6.0 mm			
Shape:	Biconvex, anterior toric aspheric surface			
Material:	UV-blocking hydrophobic acrylic			
Refractive Index:	1.47			
Edge Design:	**ProTEC** frosted, continuous 360° posterior square edge			

OPTICAL BIOMETRY‡

A-constant:	119.3

ULTRASOUND BIOMETRY§

A-constant:	118.8

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

RECOMMENDED INSERTION INSTRUMENTS	MODEL
UNFOLDER Platinum 1 Series Screw-Style Inserter	DK7796
UNFOLDER Platinum 1 Series Cartridge	1MTEC30

* Based on average pseudophakic human eye.
†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 **TECNIS**® 1-Piece platform.
§Value theoretically derived for a typical 20.0 D lens. AMO recommends that surgeons personalize their A-constant based on their surgical techniques and equipment, experience with the lens model, and postoperative results.

MICRO-IMPLANTATION CATARACT SUITE

Indications: The TECNIS® Toric 1-Piece posterior chamber lenses are 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 1-Piece IOL Directions for Use that could increase complications or impact patient outcomes. These circumstances include recurrent severe anterior or posterior segment inflammation or uveitis; 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 clinical study for 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® Toric 1-Piece IOL should not be placed in the ciliary sulcus. Rotation of the TECNIS® Toric 1-Piece IOL away from its intended axis can reduce its astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. If necessary, lens repositioning should occur as early as possible prior to lens encapsulation. **Precautions:** Prior to surgery, the surgeon must 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 the patient. Do not soak or rinse with any solution other than sterile balanced salt solution or sterile normal saline. Do not store in direct sunlight or at greater than 113°F (45°C). Carefully remove all viscoelastic and do not over-inflate the capsular bag at the end of the case. Residual viscoelastic and/or over-inflation of the capsular bag may allow the lens to rotate, causing misalignment of the TECNIS® Toric 1-Piece IOL with the intended axis of placement. When the insertion system is used improperly, the haptics of the TECNIS® Toric 1-Piece IOL may become broken. Please refer to the specific instructions for use provided with the insertion instrument or system. The use of methods other than the TECNIS Toric Calculator to select cylinder power and appropriate axis of implantation were not assessed in the clinical study and may not yield similar results. 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. Preexisting conditions include: choroidal hemorrhage, chronic severe uveitis, concomitant severe eye disease, extremely shallow anterior chamber, medically uncontrolled glaucoma, microphthalmos, non-age-related cataract, proliferative diabetic retinopathy (severe), severe corneal dystrophy, severe optic nerve atrophy, or irregular corneal astigmatism. Intraoperative conditions include: excessive vitreous loss, capsulotomy by any technique other than a circular tear, the presence of radial tears known or suspected at the time of surgery, situations in which the integrity of the circular tear cannot be confirmed by direct visualization, cataract extraction by techniques other than phacoemulsification or liquefaction, situations where the need for a large capsulotomy can be anticipated (e.g., diabetics, retinal detachment in the fellow eye, peripheral retinal pathology, etc.), capsular rupture, significant anterior chamber hyphema, uncontrollable positive intraocular pressure, and zonular damage. All preoperative surgical parameters are important when choosing a toric lens for implantation, including preoperative keratometric cylinder (magnitude and axis), incision location, surgeon's estimated surgically induced astigmatism (SIA) and biometry. Variability in any of the preoperative measurements can influence patient outcomes and the effectiveness of treating eyes with lower amounts of preoperative corneal astigmatism. All corneal incisions were placed temporally in the clinical study. If the surgeon chooses to place the incision at a different location, outcomes may be different from those obtained in the clinical study. Note that the TECNIS Toric Calculator incorporates the surgeon's estimated SIA and incision location when providing IOL options. Do not reuse, resterilize, or autoclave. **Adverse Events:** Potential adverse events during or following cataract surgery with implantation of an IOL may include but are not limited to: endophthalmitis/intraocular infection, hypopyon, pupillary block, retinal detachment, IOL dislocation, persistent corneal stromal edema, persistent cystoid macular edema, or secondary surgical intervention (including implant repositioning, removal, or other surgical procedure). The most frequently reported adverse event that occurred during the clinical trial of the TECNIS® Toric 1-Piece IOL was surgical reintervention, which occurred at a rate of 3.4% (lens repositioning procedures and retinal repair procedures). Other reported events included macular edema, which occurred at a rate of 2.9%, and retinal detachment, which occurred at a rate of 0.6%. **Caution:** Federal law restricts this device to sale by or on the order of a physician.

Abbott Medical Optics