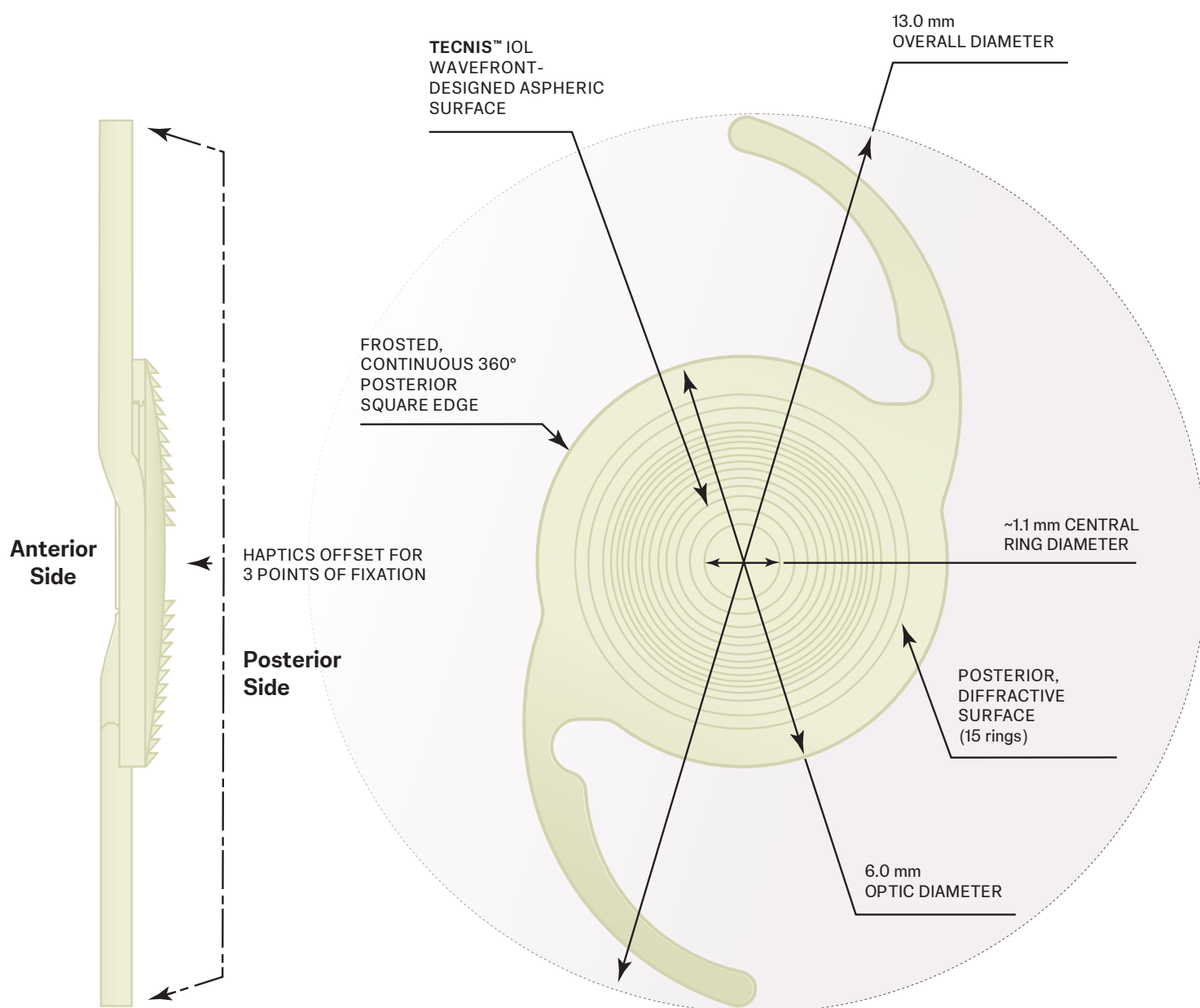


TECNIS
Odyssey™ IOL
with TECNIS SIMPLICITY™ Delivery System

Model DRN00V





OPTICAL CHARACTERISTICS¹

Model Number:	DRN00V
Powers:	+5.0 D to +34.0 D in 0.5 diopter increments
Diameter:	6.0 mm
Center Thickness:	0.7 mm (20.0 D)
Shape:	Biconvex, wavefront-designed anterior aspheric surface, proprietary posterior diffractive surface to provide a full range of vision²
Material:	UV-absorbing hydrophobic acrylic with violet-light filter
Refractive Index:	1.47 at 35° C
Edge Design:	ProTEC frosted, continuous 360° posterior square edge
Achromatic Technology:	Proprietary technology for chromatic aberration correction to enhance contrast

BIOMETRY¹

CONTACT ULTRASOUND†

OPTICAL††

A-constant:	118.8	119.3
AC Depth:	5.4 mm	5.7 mm
Surgeon Factor:³	1.68 mm	1.96 mm

HAPTIC CHARACTERISTICS¹

Overall Diameter:	13.0 mm
Thickness:	0.46 mm
Style:	C
Material:	UV-absorbing hydrophobic acrylic with violet-light filter
Design:	TRI-FIX , Haptics offset from optics; 1-piece lens

Preloaded TECNIS SIMPLICITY™ Delivery System

* Values theoretically derived for a typical 20.0 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.

† IOL constants have been theoretically derived for contact ultrasound.

†† IOL constants have been derived from clinical evaluation results of the 1-Piece IOL Platform.

References: 1. TECNIS Odyssey™ IOL with TECNIS SIMPLICITY™ Delivery System, Model DRN00V- DFU Z311926E, Rev B 07/2023 2024REF4544 2. Data On File, Johnson & Johnson Surgical Vision, Inc. 2023. DOF2023CT4023. 3. Holladay JT. International Intraocular Lens & Implant Registry 2003. *J Cataract Refract Surg.* 2003; 29:176-197. REF2016CT0151.

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR TECNIS ODYSSEY™ IOL WITH TECNIS SIMPLICITY™ DELIVERY SYSTEM, MODEL DRN00V AND TECNIS ODYSSEY™ TORIC II IOL WITH TECNIS SIMPLICITY™ DELIVERY SYSTEM, MODELS DRT150, DRT225, DRT300, DRT375

Rx Only

INDICATIONS:

The TECNIS SIMPLICITY™ Delivery System is used to fold and assist in inserting the TECNIS Odyssey™ IOL, which is indicated for primary implantation for the visual correction of aphakia in adult patients, with less than 1 diopter of pre-existing corneal astigmatism, in whom a cataractous lens has been removed. The TECNIS SIMPLICITY™ Delivery System is used to fold and assist in inserting the TECNIS Odyssey™ Toric II IOLs that are indicated for primary implantation for the visual correction of aphakia and for reduction of refractive astigmatism in adult patients with greater than or equal to 1 diopter of preoperative corneal astigmatism, in whom a cataractous lens has been removed. Compared to an aspheric monofocal lens, the TECNIS Odyssey™ IOLs mitigate the effects of presbyopia by providing improved visual acuity at intermediate and near distances to reduce eyeglass wear, while maintaining comparable distance visual acuity. The lens is intended for capsular bag placement only.

WARNINGS

Intraocular lenses may exacerbate an existing condition, may interfere with diagnosis or treatment of a condition or may pose an unreasonable risk to the eyesight of patients. Patients should have well-defined visual needs and be informed of possible visual effects (such as a perception of halo, starburst or glare around lights), which may be expected in nighttime or poor visibility conditions. Patients may perceive these visual effects as bothersome, which, on rare occasions, may be significant enough for the patient to request removal of the IOL. The physician should carefully weigh the potential risks and benefits for each patient. Patients with a predicted postoperative residual astigmatism greater than 1.0 diopter, with or without a toric lens, may not fully benefit in terms of reducing spectacle wear. Rotation of the TECNIS Odyssey™ Toric II IOL 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. The lens and delivery system should be discarded if the lens has been folded within the cartridge for more than 10 minutes. Not doing so may result in the lens being stuck in the cartridge. Do not attempt to disassemble, modify, or alter the delivery system or any of its components, as this can significantly affect the function and/or structural integrity of the design.

PRECAUTIONS

Interpret results with caution when using autorefractors or wavefront aberrometers that utilize infrared light, or when performing a duochrome test. Confirmation of refraction with maximum plus manifest refraction technique is strongly recommended. The ability to perform some eye treatments (e.g., retinal photocoagulation) may be affected by the IOL optical design. The surgeon should target emmetropia, as this lens is designed for optimum visual performance when emmetropia is achieved. The TECNIS Odyssey™ IOLs should not be placed in the ciliary sulcus. 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 Odyssey™ Toric II IOL. All preoperative surgical parameters are important when choosing a TECNIS Odyssey™ Toric II IOL for implantation, including preoperative keratometric cylinder (magnitude and axis), incision location, the 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. The effectiveness of TECNIS Odyssey™ Toric II IOLs in reducing postoperative residual astigmatism in patients with preoperative corneal astigmatism < 1.0 diopter has not been demonstrated. Patients with a predicted postoperative astigmatism greater than 1.0 D may not be suitable candidates for implantation with the TECNIS Odyssey™ IOLs, as they may not obtain the benefits of reduced spectacle wear or improved intermediate and near vision seen in patients with lower predicted postoperative astigmatism.

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

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