

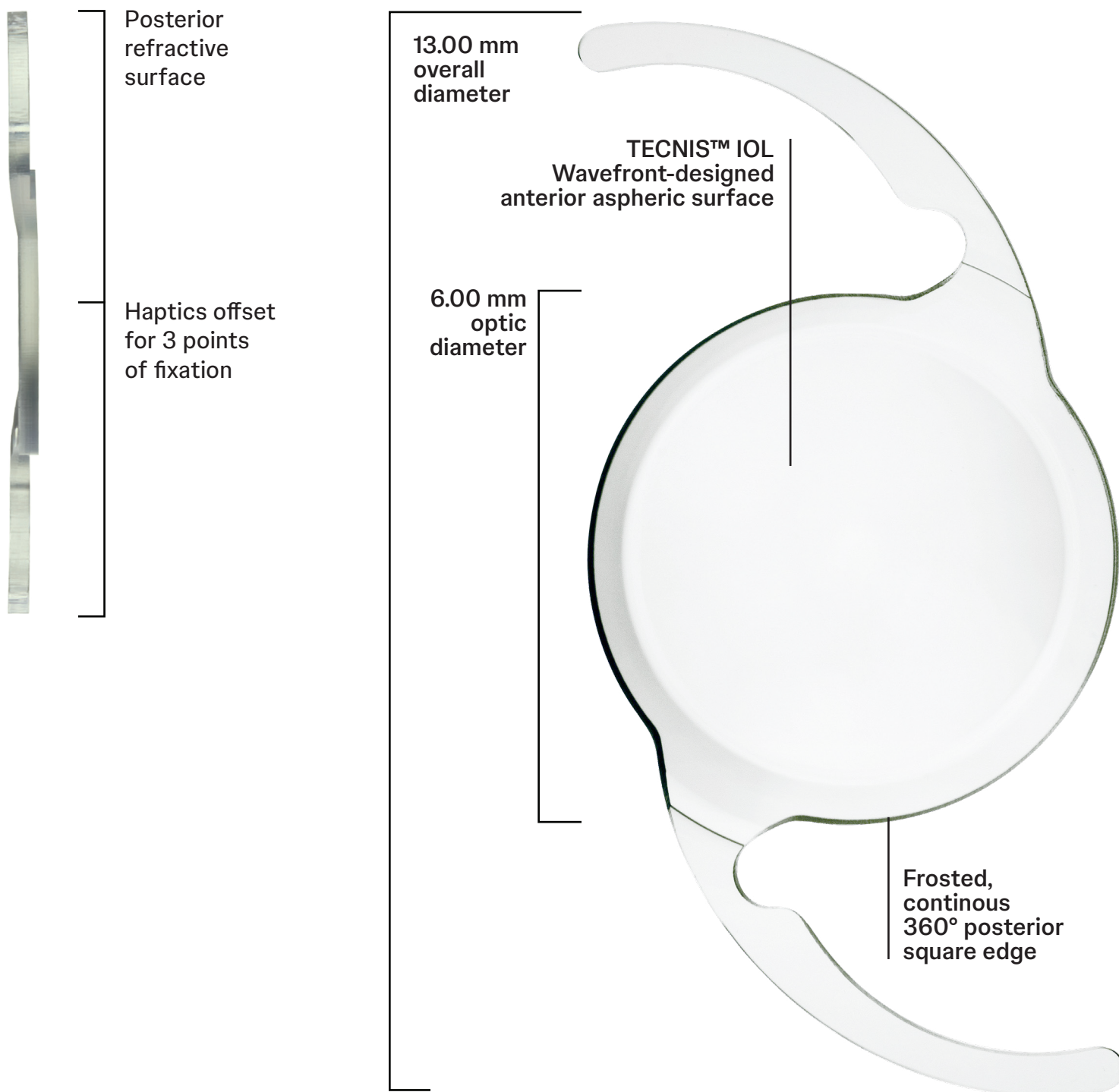
TECNIS PureSee™ IOL

Models DEN00V,
DET150-375

with TECNIS SIMPLICITY™ Delivery System



Anterior side



TECNIS PureSee™ IOL

with TECNIS SIMPLICITY™ Delivery System

Models DEN00V,
DET150–375

| Model | TECNIS PureSee™ IOL | TECNIS PureSee™ Toric II IOL | | | |
|--------------------------------|---|------------------------------|--------|--------|--------|
| | DEN00V | DET150 | DET225 | DET300 | DET375 |
| Cylinder powers: IOL plane | | 1.50 D | 2.25 D | 3.00 D | 3.75 D |
| Cylinder powers: Corneal plane | | 1.03 D | 1.54 D | 2.06 D | 2.57 D |
| Powers | +5.0 to +34.0 D in 0.5 D increments | | | | |
| Diameter | 6.00 mm | | | | |
| Center thickness | 0.7 mm (20.0 D) | | | | |
| Shape | Biconvex, wavefront-designed anterior aspheric surface, posterior refractive surface to increase the depth of focus | | | | |
| 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 | | | | |
| Delivery system | Preloaded TECNIS SIMPLICITY™ Delivery System | | | | |

| Biometry* | Contact ultrasound | Optical |
|-----------------------------|--------------------|---------|
| A-Constant | 118.8 | 119.3 |
| AC depth | 5.4 mm | 5.7 mm |
| Lens factor | 1.78 | 2.04** |
| Surgeon factor ² | 1.68 mm | 1.96 mm |

| Haptic characteristics ¹ | |
|-------------------------------------|---|
| Overall diameter | 13.00 mm |
| Thickness | 0.46 mm |
| Style | C |
| Material | UV-absorbing hydrophobic acrylic with violet light filter |
| Design | TRI-FIX, Haptics offset from optic; 1-piece lens |

*Value theoretically derived for a typical 22.0 D lens.

**This lens factor is based on our manufacturer a-constant. For Barrett optimized lens factor please refer to the Barrett Universal website.

Johnson & Johnson Surgical Vision, Inc. recommends that surgeons personalize their A-constant based on their surgical techniques and equipment, experience with the lens model and postoperative results

References:

1. TECNIS PureSee™ with TECNIS SIMPLICITY™ Delivery System, Model DEN00V, US DFU Z312075E Rev B
2. Calculated based on Holladay I formula - Holladay JT. International Intraocular Lens and Implant Registry 2003. J Cataract Refract Surg 2003;29:176-197 REF2016CT0151.

INDICATIONS and IMPORTANT SAFETY INFORMATION for TECNIS PureSee™ IOL and TECNIS PureSee™ Toric II IOLs with TECNIS SIMPLICITY™ Delivery System

Rx Only

INDICATIONS FOR USE: The TECNIS SIMPLICITY™ Delivery System is used to fold and assist in inserting the TECNIS PureSee™ 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 lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the TECNIS PureSee™ IOL provides improved intermediate visual acuity, while maintaining comparable distance visual acuity. The lens is intended for capsular bag placement only.

The TECNIS SIMPLICITY™ Delivery System is used to fold and assist in inserting the TECNIS PureSee™ Toric II IOLs, which 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. The lenses mitigate the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the TECNIS PureSee™ Toric II IOLs provide improved intermediate visual acuity, while maintaining comparable distance visual acuity. The lenses are intended for capsular bag placement only.

WARNINGS: Physicians should weigh the potential benefit/risk ratio of IOL implantation in patients with any of the conditions listed in the Directions for Use, as intraocular lenses may exacerbate an existing condition or may pose an unreasonable risk to the eyesight of patients.

Rotation of the TECNIS PureSee™ Toric II IOLs 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.

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. Do not implant the lens if the rod tip does not advance the lens or if it is jammed in the delivery system. The lens and delivery system should be discarded if the lens has been folded within the cartridge for more than 10 minutes.

PRECAUTIONS: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient. Potential risks for cataract surgery may include but are not limited to infection, inflammation, retinal detachment, increased eye pressure, hyphema, hypopyon, and posterior capsular opacification. 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. Autorefractors may not provide optimal postoperative refraction of patients with the IOL. Manual refraction with maximum plus technique is strongly recommended. This is a single-use device. Do not resterilize the lens or the delivery system. Do not store the device in direct sunlight or at a temperature under 41°F (5°C) or over 95°F (35°C). Do not autoclave the delivery system. Do not use if the delivery system has been dropped or if any part was inadvertently struck while outside the shipping box. The sterility of the delivery system and/or the lens may have been compromised. The recommended temperature for implanting the lens is at least 63°F (17°C). Do not advance the lens unless ready for lens implantation. Do not leave the lens in a folded position more than 10 minutes. The use of balanced salt solution or ophthalmic viscosurgical devices (OVDs) is required when using the delivery system. The lens should be placed entirely in the capsular bag. The lens should not be placed in the ciliary sulcus.

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

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For healthcare professionals only. Please reference the Instructions for Use for a complete list of Indications and Important Safety Information and contact our specialists in case of any question.

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