



 **TECNIS PureSee™ IOL** can give you a continuous range of high-quality vision.²

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

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 preexisting corneal astigmatism, in whom a cataractous lens has been removed. The lens is intended to correct presbyopia by providing improved vision over a continuous range of distances including far, intermediate, and near, and decreased spectacle dependence. 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 IOL which is indicated for primary implantation for the visual correction of aphakia and pre-existing corneal astigmatism in adult patients with and without presbyopia in whom a cataractous lens has been removed. The lens is intended to correct presbyopia by providing improved vision over a continuous range of distances including far, intermediate, and near, a reduction of residual refractive cylinder, and decreased spectacle dependence. The lens is intended for capsular bag placement only.

WARNING: Physicians should weigh the potential risk/benefit ratio of IOL implantation in patients with any of the conditions described in the Directions for Use. These conditions are not specific to the design of the IOL and are attributed to cataract surgery and/or IOL implantation in general. The IOL should be placed entirely in the capsular bag. Do not place the IOL in the ciliary sulcus. Patients should be informed of the possibility of visual disturbances. The lens may cause a reduction in contrast sensitivity under certain conditions, compared to an aspheric monofocal IOL; fully inform the patient of this risk before implanting the lens. Special consideration should be made for patients with macular disease, amblyopia, corneal irregularities, or other ocular disease. Inform patients to exercise special caution when driving at night or in poor visibility conditions.

Rotation of the TECNIS PureSee™ Toric II IOL away from their intended axis can reduce their astigmatic correction. Misalignment greater than 30° may increase postoperative refractive cylinder. If necessary, IOL 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 use if the cartridge tip is cracked or split. Do not implant the IOL if the rod tip does not advance the IOL or if it is jammed in the delivery system. Do not advance the IOL from the Holding Position (located at the half turn rotation position for the initial advancement of the IOL into the cartridge) prior to fully hydrating the system and ready for implantation. A minimum of 1 minute at the Holding Position is required to fully hydrate the system to prevent sticking and a potential scratch or crack to the IOL. Interruptions during delivery may result in the IOL being scratched or cracked or stuck in the cartridge. Discard the device if the IOL has been advanced past the Holding Position but not delivered within 60 seconds. The IOL and delivery system should be discarded if the IOL has been folded within the cartridge for more than 10 minutes. Not doing so may result in the IOL being stuck in the cartridge.

PRECAUTIONS: Autorefractors may not provide optimal postoperative refraction of patients with the IOL. Manual refraction with maximum plus technique is strongly recommended. Recent contact lens usage may affect the patient's refraction; therefore, in contact lens wearers, surgeons should establish corneal stability without contact lenses prior to determining IOL power. Target emmetropia for optimum visual performance.

For the TECNIS PureSee™ Toric II IOL, variability in any preoperative surgical parameters (e.g., keratometric cylinder, incision location, estimated surgically induced astigmatism, or biometry) can influence patient outcomes. Carefully remove all viscoelastic and do not over-inflate the capsular bag at the end of the case, to avoid lens rotation.

This is a single use device, do not sterilize the lens or the delivery system. Do not store the device in direct sunlight or at a temperature under 5°C (41°F) or over 35°C (95°F). Do not autoclave the delivery system. Do not advance the lens unless ready for lens implantation. The contents are sterile unless the package is opened or damaged. The recommended temperature for implanting the lens is at least 17°C (63°F). The use of balanced salt solution or viscoelastics is required when using 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.

ADVERSE EVENTS: Potential adverse events during or following cataract surgery with implantation of the IOL may include but are not limited to: Endophthalmitis/intraocular infection, IOL dislocation, persistent cystoid macular edema, persistent corneal stromal edema, persistent raised intraocular pressure (IOP) requiring treatment, secondary surgical intervention (including implant repositioning, removal, AC tap, or other surgical procedure). Adverse events can lead to permanent visual impairment and may require secondary surgical intervention, including intraocular lens exchange or explanation.

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

As with any medical procedure, risks and potential complications may occur. Please consult your eye care specialist for detailed information and to discuss these possible risks and complications with you prior to the procedure.

References:

1. <https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/presbyopia>
2. TECNIS PureSee™ IOL with TECNIS SIMPLICITY™ Delivery System, Model DEN00V, DfU Z311989 Rev B. 3. DOF2023CT4011 – Simulations of visual symptoms under defocus for TECNIS PureSee™ IOL. 29 March 2023.

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| Vision



DO YOU WANT HIGH-QUALITY VISION AFTER CATARACT SURGERY?

Ask your doctor about **TECNIS PureSee™ IOL**

TECNIS
PureSee™ IOL
with TECNIS SIMPLICITY™ Delivery System

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| Vision



When undergoing cataract surgery, you may have the option to correct presbyopia, a normal age-related condition that makes it difficult to see things up close.

Everyone gets presbyopia as they get older—typically becomes noticeable after the age of 45—but it is possible to get uninterrupted, high-quality vision again with TECNIS PureSee™ IOL.^{1,2}

PURE QUALITY VISION

See every detail of life, day and night



When you get cataract surgery, your cataract isn't just removed—it is replaced by a small, soft lens called an *intraocular lens*—or *IOL* for short. You won't be able to feel or see the IOL, but it will stay inside your eye to help you see clearly.

TECNIS PureSee™ is a new IOL with continuous-power technology, designed to help you live an active life with high-quality vision.²

Unlike other lenses that provide focus at one or two points, the **TECNIS PureSee™** IOL can deliver uninterrupted clarity across your full range of vision, even in dim light.^{2,3}

PRESBYOPIA

Age

45

Typically becomes noticeable around the age of 45¹



Makes it difficult to focus on things up close (near vision)



Can be addressed with a presbyopia-correcting IOL



Other solutions include reading glasses, contacts or an additional surgery



With presbyopia



With **TECNIS PureSee™** IOL

These images are for illustrative purposes only and do not represent actual data derived from studies. These illustrative simulations are intended to help you better understand your vision in certain eye conditions.

BENEFITS OF TECNIS PURESEE™ IOL



Provides excellent distance vision for reading street signs and intermediate vision for the computer, with improved near vision.²



Supports continuous, crisp, high-contrast vision which can be helpful in low-light scenarios.^{2,3}



Gives you sharp, continuous vision day and night, with a low level of distracting visual symptoms. You may still need reading glasses for small print.²

Talk to your doctor about what you want to see more of, and find out if TECNIS PureSee™ IOLs are right for you.