

# Johnson & Johnson

## Introducing TECNIS PureSee™ IOL

# Pure Ease of Mind

## TECNIS PureSee™ IOL

### About the design

New purely refractive extended depth-of focus PCIOL<sup>1</sup>

### Range of vision

Excellent distance and intermediate vision with some near vision\*\*<sup>1</sup>

### Monofocal-like dysphotopsia

Monofocal-like visual disturbance profile<sup>1</sup>

### Excellent contrast

TECNIS PureSee™ IOL is the first and only EDOF IOL in the U.S. without a warning on loss of contrast sensitivity\*<sup>15</sup>

### Tolerance to refractive error

Providing pure ease of mind with high patient satisfaction<sup>9</sup>

Read Important Safety Information

\*In clinical evaluation, TECNIS PureSee™ IOL demonstrated contrast sensitivity comparable to a monofocal intraocular lens, with no clinically meaningful differences ( $\leq 0.3$  log units) versus monofocal controls across pupil sizes, while maintaining distance visual acuity and low levels of visual symptoms  
\*\*TECNIS PureSee™ IOL achieved a 1.5-line difference in mean monocular distance-corrected near VA at 6 months compared to TECNIS™ 1-Piece.

# Introducing OptiCurve™ technology the new purely refractive posterior surface design<sup>1</sup>

Taking proven TECNIS™ design principles to the next level offering more range & consistency

## Posterior optic

OptiCurve™ Technology: an advanced design with a smooth power profile, that extends depth-of-focus<sup>1</sup>

Providing **monofocal-like**:



Dysphotopsia Profile<sup>1</sup>



Distance visual acuity<sup>1</sup>

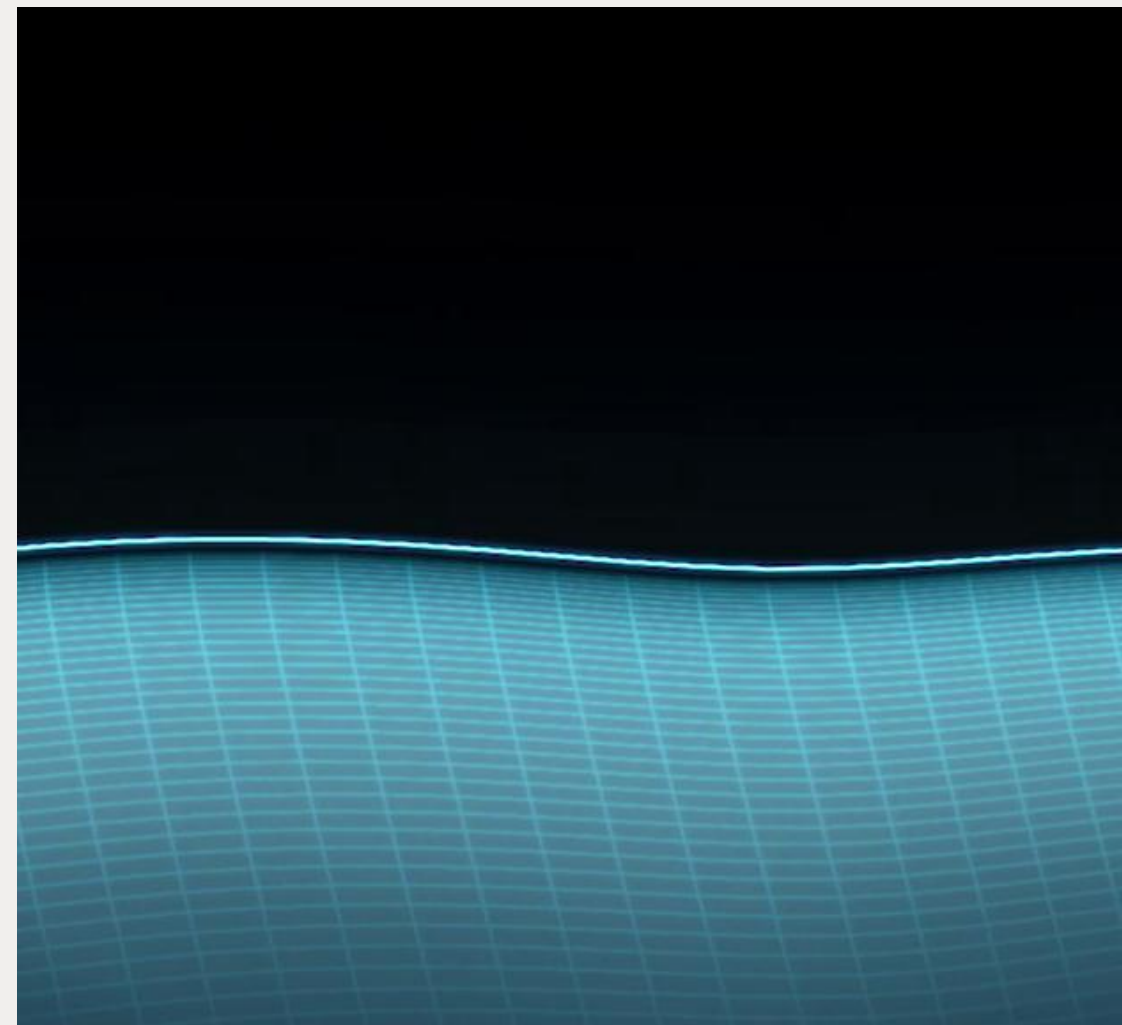


Contrast sensitivity<sup>1</sup>



Tolerance to refractive error<sup>9</sup>

With **significantly improved range of vision** as compared to a monofocal<sup>1</sup>



TECNIS PureSee™ posterior surface

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# The TECNIS™ platform enables new generation designs like TECNIS PureSee™ to work without compromising quality<sup>1</sup>

Think of TECNIS™ like a speed boat with a steel hull that maintains its high performance even in rough waters

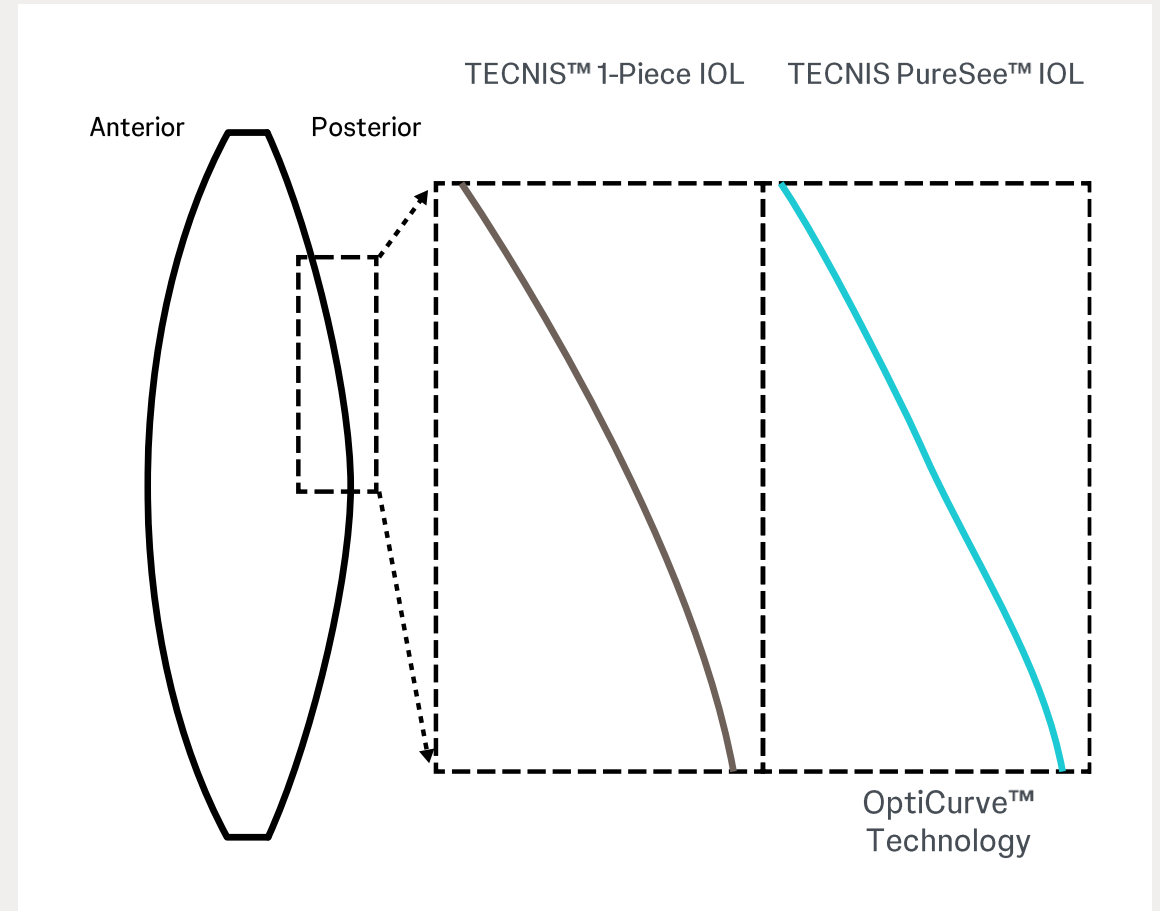
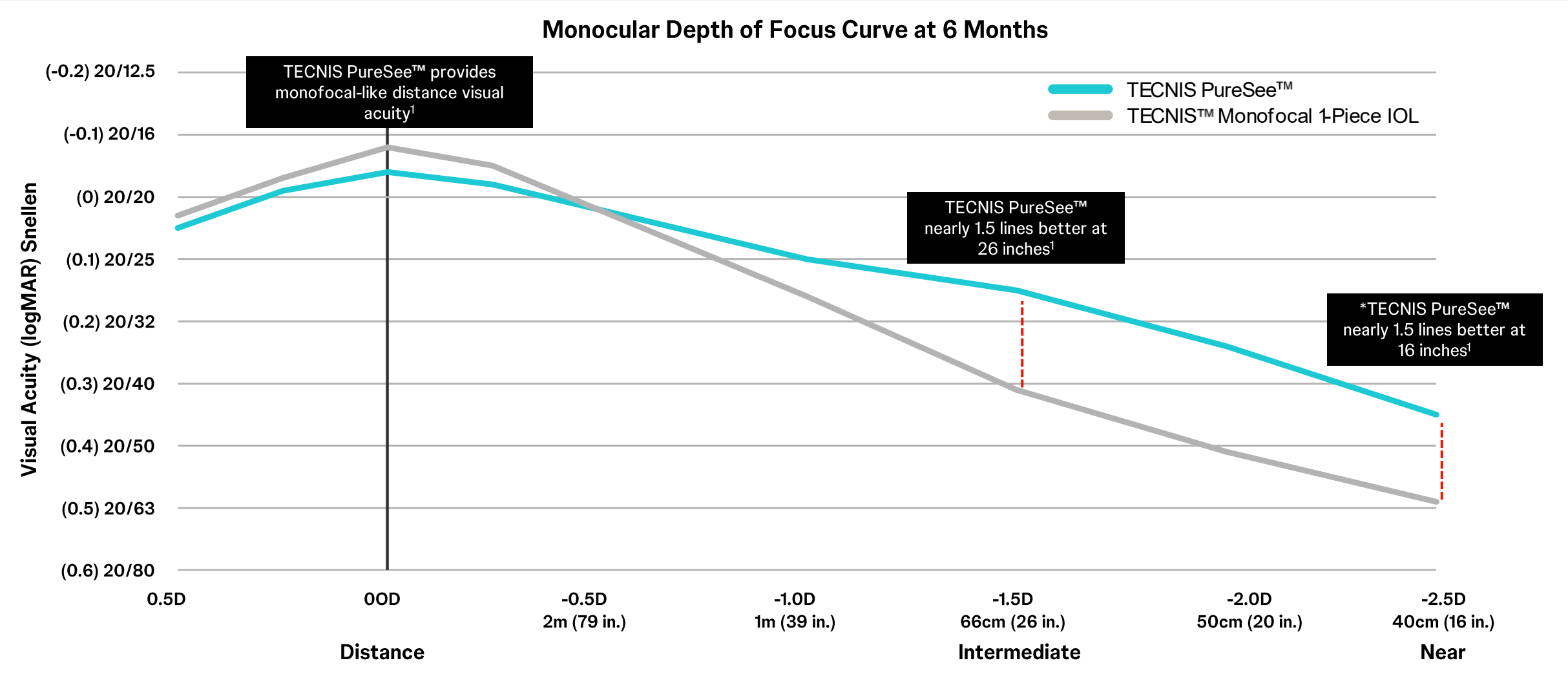


Image to show posterior optic design

# Excellent distance and intermediate vision with some near\*<sup>1</sup>

TECNIS PureSee™ delivers monofocal-like distance visual acuity<sup>1</sup>

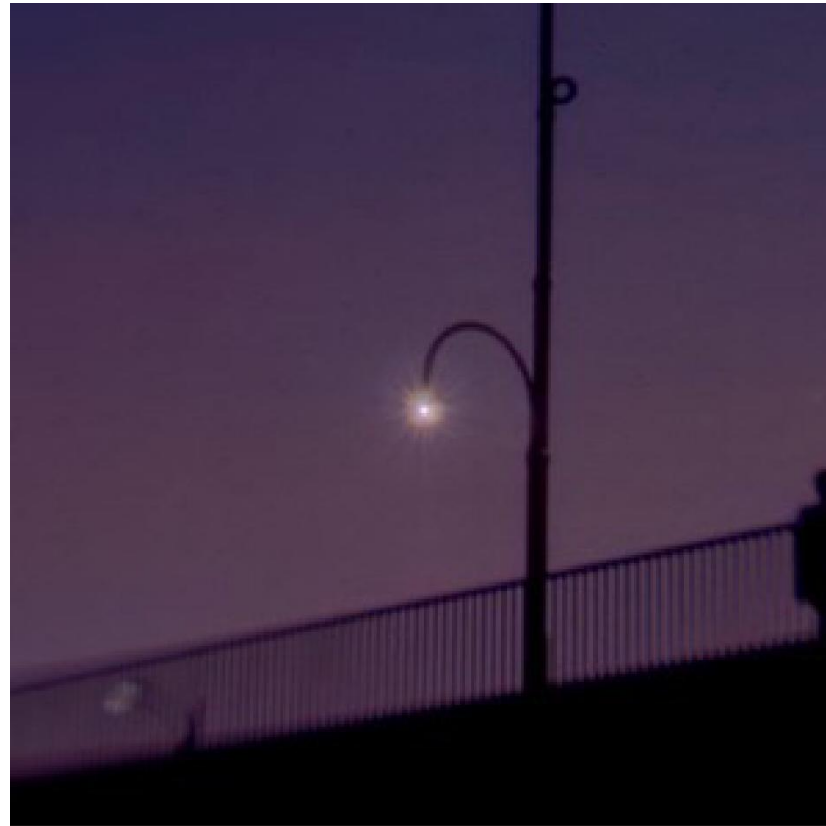


# The purely refractive design enables a monofocal-like dyphotopsia<sup>1</sup>

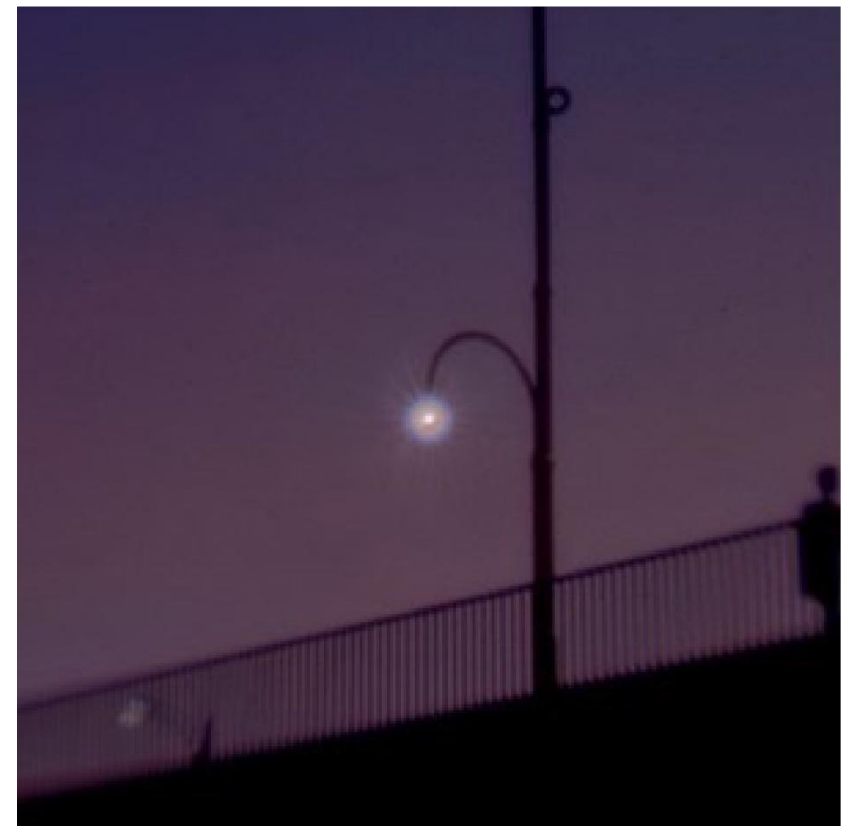
Even under defocus, leading to high patient satisfaction<sup>9</sup>

97%

Of TECNIS PureSee™ patients reported no very bothersome visual disturbances<sup>1</sup>



TECNIS™ Monofocal 1-Piece IOL



TECNIS PureSee™ IOL

<sup>1</sup>Optical Bench Testing DOF2023CT4012

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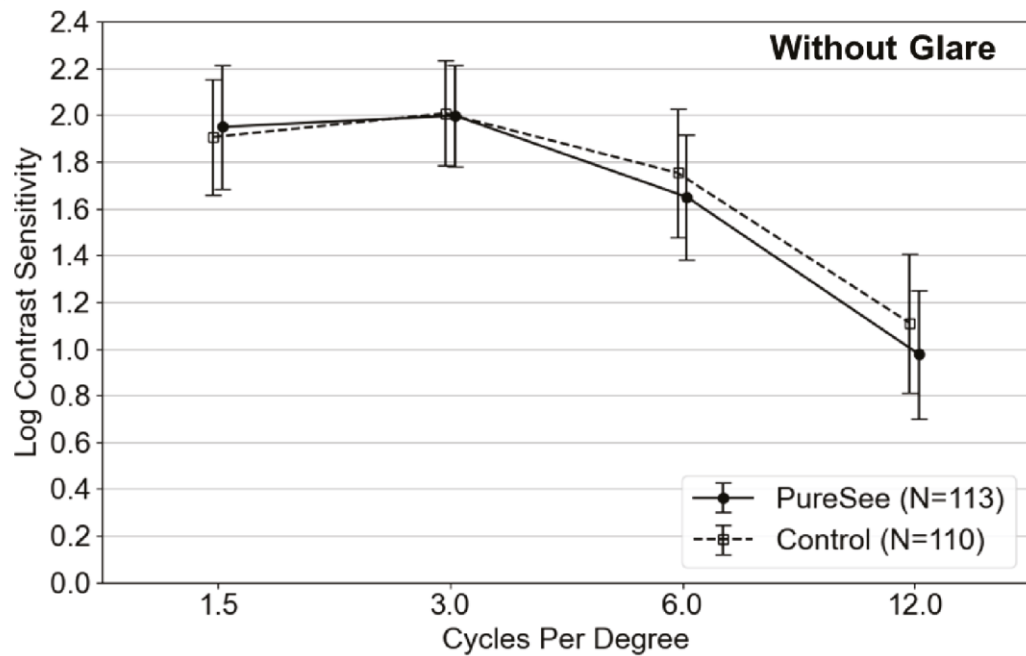
Excellent contrast

Tolerance to refractive  
error

# TECNIS PureSee™ IOL is the first and only EDOF IOL in the U.S. without a warning on loss of contrast sensitivity\*<sup>1,15</sup>

## Contrast Sensitivity

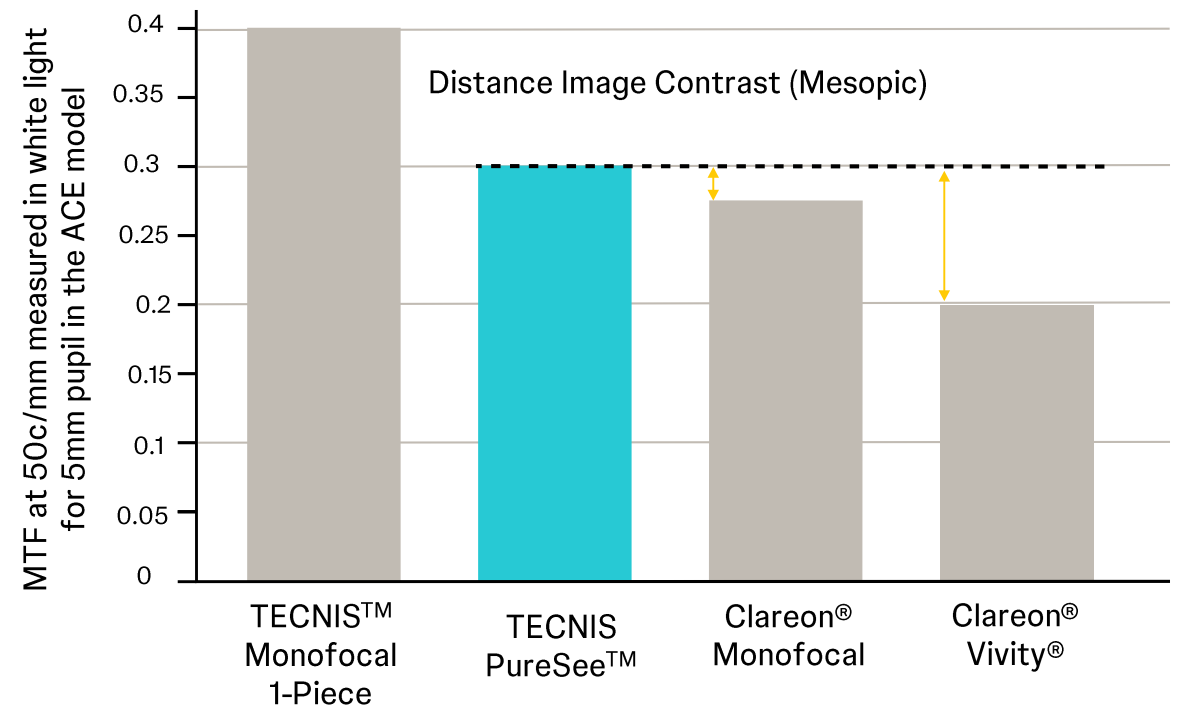
First and only EDOF maintaining contrast sensitivity comparable to an aspheric monofocal\*<sup>1</sup>



\*In clinical evaluation, TECNIS PureSee™ IOL demonstrated contrast sensitivity comparable to an aspheric monofocal intraocular lens, with no clinically meaningful differences ( $\leq 0.3$  log units) versus aspheric monofocal controls across pupil sizes, while maintaining distance visual acuity and low levels of visual symptoms.

## Image Contrast

36% higher image contrast vs. Clareon® Vivity®<sup>11,19</sup>

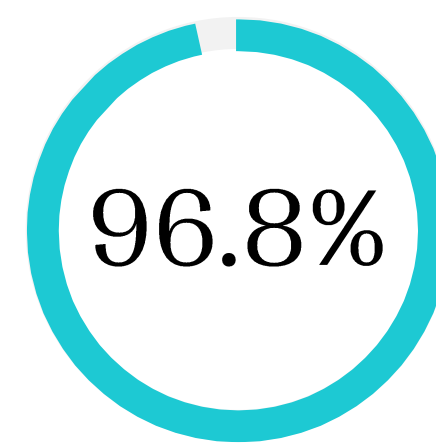
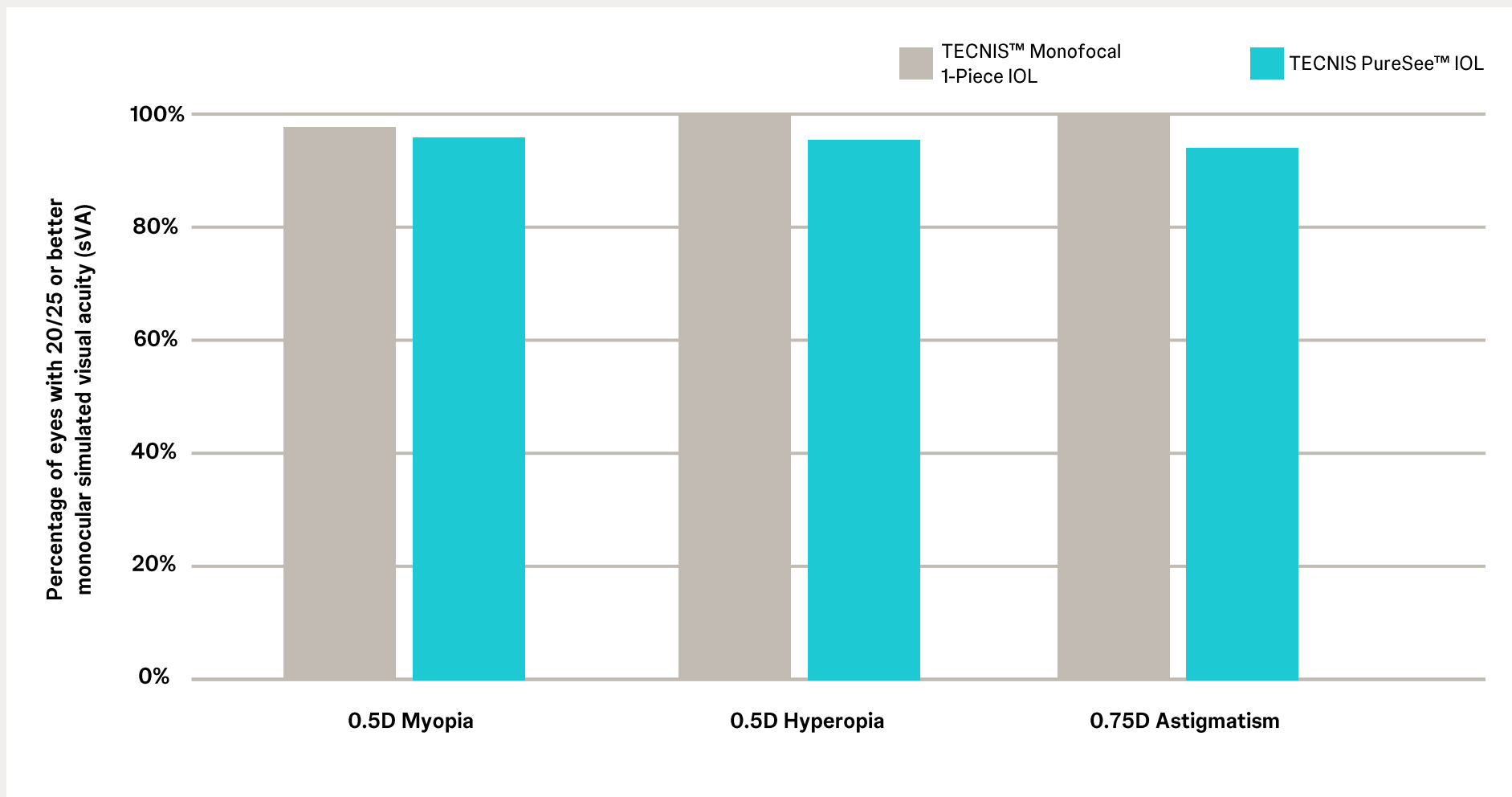


The Average Corneal Eye (ACE) model measures in white light with corneal aberrations of the average eye) MTF; modulation transfer function. This measures the ratio of object contrast to image contrast. Higher MTF means more contrast transfer, enhancing the perceived image

Learn more about the ACE MTF model.



# Tolerance to refractive error providing *Pure Ease of Mind*<sup>9</sup>



Of patients with ametropia achieved 20/25 or better binocular UCDVA<sup>9</sup>

**TECNIS PureSee™ IOL**

Mean spherical equivalent	0.36±0.19D logMAR
Absolute cylinder	0.47±0.30D logMAR
Mean monocular CDVA	-0.06±0.07D logMAR
Mean binocular UDVA	-0.03±0.08D logMAR

Based on hybrid study including pre-clinical simulated visual acuity and prospective randomized evaluation of patients bilaterally implanted with TECNIS PureSee™



# A series of clinical studies showed high patient satisfaction<sup>1,2</sup>

90%

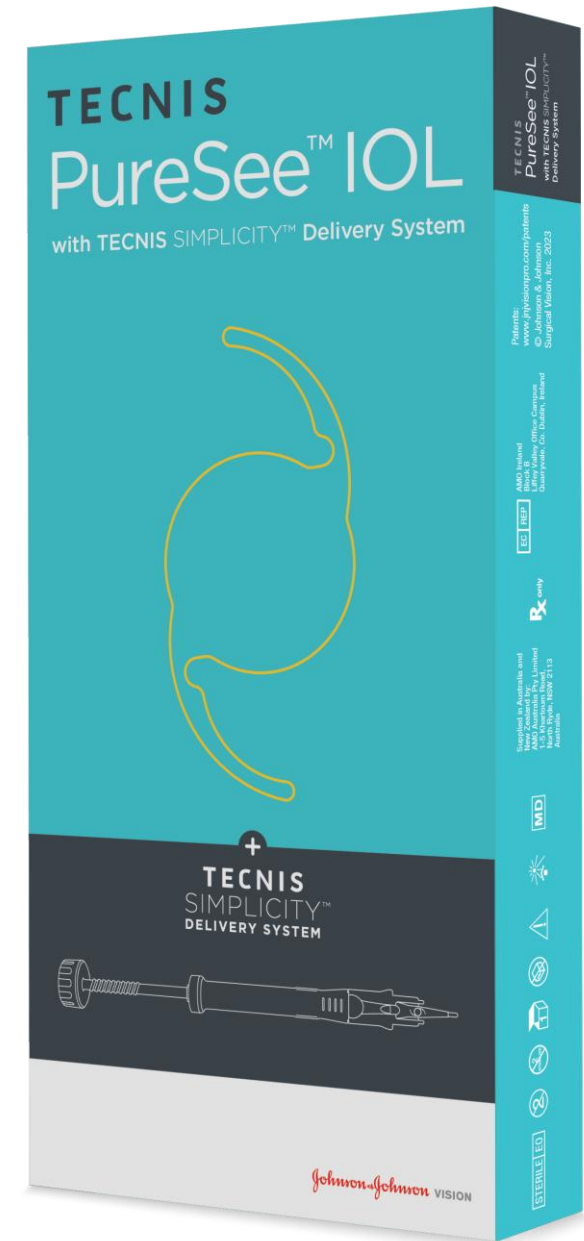
Of patients occasionally or never wore glasses\*<sup>1</sup>

97%

Of patients would recommend the lens to friends or relatives\*\*<sup>2</sup>

97%

Of patients reported no very bothersome visual disturbances<sup>1</sup>



\*Overall spectacle wear at 6 months, none/a little/some of the time  
\*\*Prospective, randomized, multi-center 6-month clinical study. N=66

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Range of vision

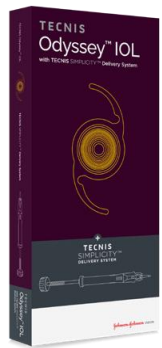
Monofocal-like dysphotopsia

Excellent contrast

Tolerance to refractive error

# TECNIS™ Portfolio of Presbyopia-Correcting IOLs

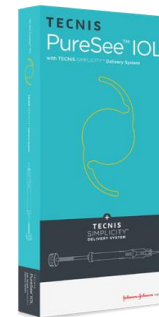
The TECNIS™ Family of IOLs is proud to offer two distinct presbyopia-correcting IOLs available for different patient needs.



### For patients that:

- Prioritize spectacle independence and minimal dependence on glasses<sup>\*18</sup>
- Want a full range of vision<sup>‡§10</sup>, particularly at near<sup>†20</sup>
- Understand there is some potential for dysphotopsia<sup>16</sup>

**TECNIS Odyssey™** is chosen for its broad, continuous<sup>§</sup> vision across near- to-distance tasks.<sup>\*\*10,18</sup>



### For patients that:

- Prioritize excellent distance and intermediate with some near vision<sup>^</sup>
- Understand glasses may be needed for fine print
- Are sensitive about potential risk of dysphotopsia

**TECNIS PureSee™** is chosen for its extended range of vision, and monofocal-like dysphotopsia.<sup>1</sup>

\*Individual results will vary. Some TECNIS Odyssey™ patients may require spectacles post-surgery. Consult your doctor to determine the lens options that are right for you.

\*\*Based on 1-month postoperative data from a multicenter, retrospective, real world clinical study in the U.S. evaluating visual and patient-reported outcomes from subjects bilaterally implanted with TECNIS Odyssey™ IOL (n=96).

^ TECNIS PureSee™ IOL achieved a 1.5-line difference in mean monocular distance-corrected near VA at 6 months compared to TECNIS™ 1-Piece.

† Near 40cm

‡ Based on bench testing compared to a leading competitor trifocal IOL

§ continuous 20/25 or better

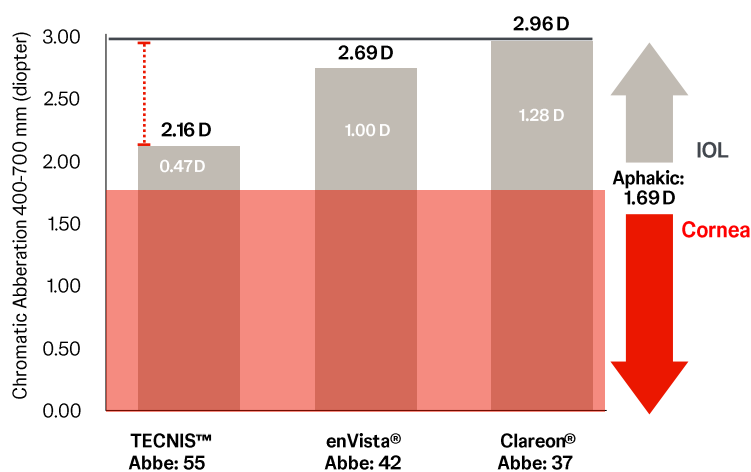


# High Quality Vision Starts with TECNIS™

Experience the strength of a proven 25+ year platform.

## Unmatched image contrast, day and night.<sup>3</sup>

TECNIS™ material induces the least amount of chromatic aberration.



## Sharp quality of vision.<sup>4</sup>

TECNIS™ IOLs are the first and only IOLs that correct spherical aberration (SA) to essentially zero.

	TECNIS™	Clareon®	enVista®
Average Corneal SA	+0.27	+0.27	+0.27
Lens SA <sup>‡</sup>	-0.27	-0.20	0.00
Total Residual SA	0.00	+0.07	-0.27
20/20 ≠ 20/happy	<b>E</b>	<b>E</b>	<b>E</b>

Increasing Asphericity<sup>†</sup>

## Sustained optical clarity and stability.<sup>5-6,8</sup>

TECNIS™ design and material lead to low rates of PCO and capsular phimosis<sup>7</sup>

TECNIS™ IOL material is not associated with glistenings.<sup>8</sup>

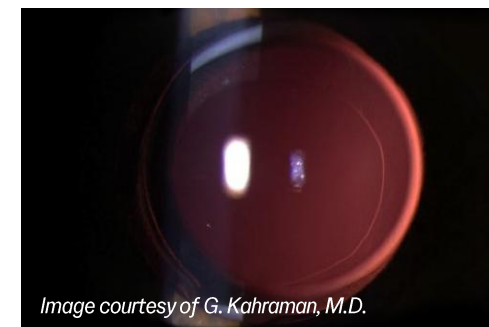


Image courtesy of G. Kahraman, M.D.

Clear anterior capsule (ACO grade 0) and no signs of fibrosis was observed at 5-year follow up.<sup>7</sup>

<sup>†</sup>Compared to Clareon® and enVista® IOL platforms.

<sup>‡</sup>SA correction of lens at corneal plane. Images simulated using Zemike Tool, 6mm aperture, created by George Dai, PhD.

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# Exceptional rotational stability

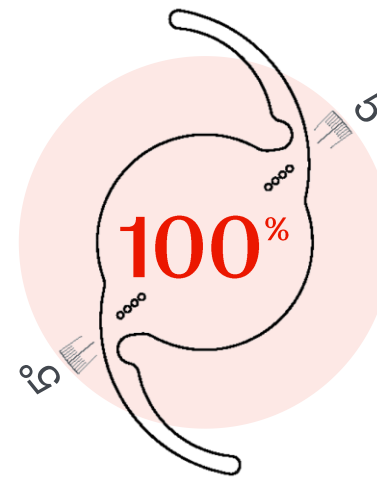
TECNIS™ Toric II IOLs have the lowest likelihood of needing repositioning\*\*13



Advanced squared, frosted haptic design engineered for increased friction.<sup>12,13</sup>



TECNIS PureSee™ is available  
DET150, 225, 300, and 375  
cylinder correction



of TECNIS™ Toric II IOLs  
rotated  $\leq 5^\circ$  at 1-month  
and 3-months post-op\*13

Outstanding mean  
rotational stability  
at post-op:\*13

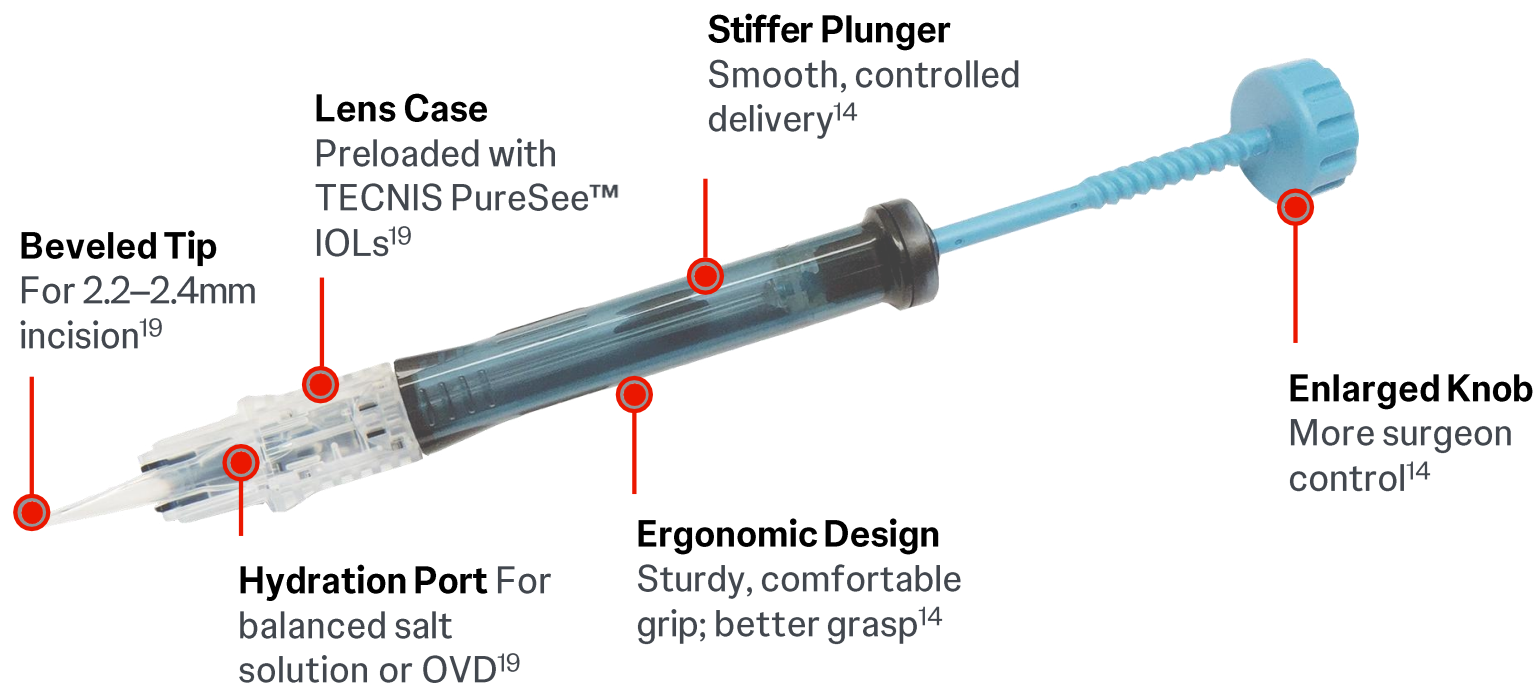
Day 1	0.82°
Month 3	0.94°

\*Based on data from 200 eyes after 3 months postoperative follow-up in a postmarket prospective, multicenter, single-arm, open-label study of the TECNIS™ Toric II 1-Piece IOL conducted in the US. Outcomes differ from the pivotal investigation data in the product labeling and were collected using different measurement methods, study design and clinical conditions

\*\*Compared to AcrySof® Toric, enVista® Toric, and TECNIS™ Toric IOLs based on a retrospective chart review that looked at the rate of surgical IOL repositioning due to clinically significant IOL rotation comparing case records for 993 eyes implanted with TECNIS™ Toric II (n=308), AcrySof® Toric (n=362), enVista® Toric IOLs (n=270), or TECNIS™ Toric (n=53).

# Extraordinary Simplicity

Simplify lens delivery with TECNIS SIMPLICITY™ preloaded delivery system.



## Improved efficiency

Simple 3-step process: hydrate, advance and deliver<sup>14</sup>

## Enhanced safety

Minimize risk of infection associated with contamination<sup>19</sup>

## Smooth & controlled delivery

Designed to safely place the IOL into the capsular bag<sup>14,19</sup>

## Flexibility

Hydrate with balanced salt solution or OVD<sup>19</sup>

# TECNIS PureSee™ IOL

## 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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# TECNIS PureSee™ IOL

## 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 below, as intraocular lenses may exacerbate an existing condition or may pose an unreasonable risk to the eyesight of patients. The following conditions are not specific to the design of the IOL and are attributed to cataract surgery and/or IOL implantation in general:
  - Recurrent severe anterior or posterior segment inflammation of unknown etiology
  - Posterior segment diseases of which monitoring or treatment ability may be limited by an intraocular lens
  - Surgical difficulties at the time of cataract extraction and/or intraocular lens implantation that might increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss)
  - Compromised posterior capsule or zonules due to previous trauma or developmental defect in which appropriate support of the IOL is not possible
  - Risk of damage to the endothelium during implantation
  - Suspected microbial infection
  - Congenital bilateral cataracts
  - Previous history of, or a predisposition to, retinal detachment
  - Potentially good vision in only one eye
  - Medically uncontrollable glaucoma
  - Corneal endothelial dystrophy
  - Proliferative diabetic retinopathy
- Rotation of the toric lens 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 use if the cartridge of the delivery system is cracked or split prior to implantation.
- Do not implant the lens if the rod tip does not advance the lens or if it is jammed in the delivery system.
- Do not stop, reverse or advance the plunger too slowly (for example more than 1 second) during initial lens advancement. Doing so may result in improper folding of the lens.
- Do not advance the lens from the Holding Position prior to fully hydrating the system. 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 lens.
- Do not advance the lens from the Holding Position until ready for implantation. Interruptions during delivery may result in the lens being scratched or cracked or stuck in the cartridge. Discard the device if the lens has been advanced past the Holding Position but not delivered within 60 seconds.

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# TECNIS PureSee™ IOL

9. 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.
10. Johnson & Johnson Surgical Vision, Inc., single-use medical devices are labeled with instructions for use and handling to minimize exposure to conditions which may compromise the product, patient, or the user. When used according to the directions for use, the delivery system minimizes the risk of infection and/or inflammation associated with contamination.
11. The reuse/resterilization/reprocessing of Johnson & Johnson Surgical Vision, Inc. single-use medical devices may result in physical damage to the medical device, failure of the medical device to perform as intended, and patient illness or injury due to infection, inflammation, and/or illness due to product contamination, transmission of infection, and lack of product sterility.

## PRECAUTIONS

1. 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.
2. Autorefractors may not provide optimal postoperative refraction of patients with the IOL. Manual refraction with maximum plus technique is strongly recommended.
3. This is a single-use device. Do not resterilize the lens or the delivery system. Most sterilizers are not equipped to sterilize the soft acrylic material of the IOL and the preloaded inserter material without producing undesirable side effects.
4. Do not store the device in direct sunlight or at a temperature under 41°F (5°C) or over 95°F (35°C).
5. Do not autoclave the delivery system.
6. The contents are sterile unless the package is opened or damaged.
7. 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.
8. The recommended temperature for implanting the lens is at least 63°F (17°C).
9. Do not advance the lens unless ready for lens implantation.
10. Do not leave the lens in a folded position more than 10 minutes.
11. When the delivery system is used improperly, the lens may not be delivered properly (i.e., haptics may be broken). Please refer to the specific Directions For Use section provided.
12. The use of balanced salt solution or ophthalmic viscosurgical devices (OVDs) is required when using the delivery system. For optimal performance when using OVD, use the HEALON™ family of OVDs. The use of balanced salt solution with additives has not been studied for this product.
13. The lens should be placed entirely in the capsular bag. The lens should not be placed in the ciliary sulcus.
14. 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 toric lens with the intended axis of placement.
15. Do not reuse.
16. 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.
17. The IOL is designed for optimum visual performance when emmetropia is targeted.
18. The TECNIS™ Toric IOL Calculator includes a feature that accounts for posterior corneal astigmatism (PCA). The PCA is based on an algorithm that combines published literature (Koch, et al., 2012) and a retrospective analysis of data from a TECNIS™ Toric multi-center clinical study. The PCA algorithm for the selection of appropriate cylinder power and axis of implantation was not assessed in the prospective TECNIS™ Toric IOL U.S. IDE study and may yield results different from those in the TECNIS PureSee™ Toric II IOL labeling. Please refer to the TECNIS™ Toric IOL Calculator user manual for more information.
19. The use of methods other than the TECNIS™ Toric IOL Calculator to select cylinder power and appropriate axis of implantation were not assessed in the TECNIS™ Toric IOL U.S. IDE study and may not yield similar results. Accurate keratometry and biometry, in addition to the use of the TECNIS™ Toric IOL Calculator ([www.TecnisToricCalc.com](http://www.TecnisToricCalc.com)) are recommended to achieve optimal visual outcomes for the TECNIS PureSee™ Toric II IOLs.
20. All preoperative surgical parameters are important when choosing a toric lens 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 the toric lens in reducing postoperative residual astigmatism in patients with preoperative corneal astigmatism less than 1.0 diopter has not been demonstrated.

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21. All corneal incisions were placed temporally in the TECNIS™ Toric IOL U.S. IDE study. If the surgeon chooses to place the incision at a different location, outcomes may be different from those obtained for the TECNIS™ Toric IOL. Note that the TECNIS™ Toric IOL Calculator incorporates the surgeon's estimated SIA and incision location when providing IOL options.
22. Children under the age of 2 years are not suitable candidates for intraocular lenses.
23. The safety and effectiveness of the TECNIS PureSee™ IOLs have not been substantiated in pregnant women, patients under the age of 22 or those with preexisting ocular conditions and intraoperative complications, including those specified in the Warnings and 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 with one or more of these conditions.

### Before Surgery

- Pupil abnormalities
- Prior corneal refractive or intraocular surgery
- 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
- Irregular corneal astigmatism
- Amblyopia
- Macular disease

### During Surgery

- Excessive vitreous loss
- Non-circular capsulotomy/capsulorhexis
- The presence of radial tears known or suspected at the time of surgery
- Situations in which the integrity of the circular capsulotomy/ capsulorhexis cannot be confirmed by direct visualization
- Cataract extraction by techniques other than phacoemulsification or liquefaction
- Capsular rupture
- Significant anterior chamber hyphema
- Uncontrollable positive intraocular pressure
- Zonular damage

24. Potential complications generally associated with cataract surgery include, but are not limited to: endophthalmitis/intraocular infection, hypopyon, hyphema, IOL dislocation, persistent cystoid macular edema, pupillary block, retinal detachment/tear, persistent corneal stromal edema, persistent uveitis, persistent raised intraocular pressure (IOP) requiring treatment (e.g., AC tap), retained lens material, or toxic anterior segment syndrome, or any other adverse event that leads to permanent visual impairment or requires surgical or medical intervention to prevent permanent visual impairment.

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# References

1. TECNIS PureSee™ IOL, Model DEN00V, US DFU Z312075E rev B.
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About the design

Range of vision

Monofocal-like  
dysphotopsia

Excellent contrast

Tolerance to refractive  
error