TECNIS PureSee™ IOL with TECNIS SIMPLICITY™ Delivery System
TECNIS PureSee™ Toric II IOL with TECNIS SIMPLICITY™ Delivery System
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Rx Only

DEVICE DESCRIPTION

The TECNIS PureSee™ IOL with TECNIS SIMPLICITY™ Delivery System in Model DEN00V, and the TECNIS PureSee™ Toric II IOL with TECNIS SIMPLICITY™ Delivery System in Models DET150, DET225, DET300 and DET375 are ultraviolet (UV) and violet light-filtering posterior chamber IOLs that are to be positioned in the lens capsule to replace the optical function of the natural crystalline lens. Accommodation will not be restored. In addition, the toric IOLs compensate for corneal astigmatism.

The TECNIS PureSee™ IOLs are extended depth of focus (EDF) IOLs used to mitigate the effects of presbyopia. Compared to the TECNIS™ monofocal IOL, Model ZCB00, the lens provides significantly improved intermediate vision while maintaining distance visual acuity, contrast sensitivity, and low levels of visual symptoms. The TECNIS PureSee™ IOLs also demonstrated pupil-independent lens performance among the pupil sizes tested. In addition, the parent toric IOLs achieved the ANSI Standard for Toric IOLs, Z80.30, rotational stability requirement (>90% of eyes having ≤5° axis change between consecutive visits).

The TECNIS PureSee™ IOLs use the purely refractive OptiCurve™ technology on the posterior optic of the lens to create a modulated power profile that extends the depth of focus. The biconvex optic also incorporates the proprietary TECNIS™ wavefront-designed aspheric or toric-aspheric anterior surface designed to compensate for spherical aberration. The combination of the OptiCurve™ technology and the anterior TECNIS™ surface enables the high-quality distance vision and pupil independence, maintaining distance visual acuity and contrast sensitivity at the level of a monofocal IOL. The lens has an overall diameter of 13.0 mm and an optic diameter of 6.0 mm. The lens consists of a soft acrylic material with UVAM (a supplemental UV light-absorbing material) and a proprietary violet light-filtering chromophore, which reduces transmittance of violet light wavelengths. The posterior edge of the anterior optic is squared to provide a 360-degree barrier and is frosted to reduce potential edge glare effects. In addition, the haptics of the TECNIS PureSee™ Toric II IOLs, Model Series DET, have a squared and frosted design. The anteriorly located cylinder axis marks on the toric-aspheric optic denote the meridian with the lowest power and are to be aligned with the steep corneal meridian.

The TECNIS SIMPLICITY™ Delivery System is designed to provide a sterile, controlled and touch-free method of delivering the lens into the eye. The lens is preloaded and preassembled in the delivery system. This reduces the number of steps required to prepare the IOL for insertion into the eye, when compared to a non-preloaded device. The lens with the delivery system is available in the full diopter range (5.0D to 34.0D) and is compatible with micro-incision surgical techniques. Sodium hyaluronate (HA) used in the cartridge coating is produced by a microbiological fermentation method.

TECHNICAL SPECIFICATIONS

A summary of technical specifications of the TECNIS PureSee™ IOLs is provided below.

Attribute	**TECNIS PureSee™ IOL, Model DEN00V**	**TECNIS PureSee™ Toric II IOLs, Models DET150-375**
Lens Configuration	1-piece lens	1-piece lens
Anterior Optic Profile	TECNIS™wavefront-designed aspheric surface	TECNIS™ wavefront-designed toric-aspheric surface
Posterior Optic Profile	Purely refractive OptiCurve™ Technology	
Lens Material	Soft foldable hydrophobic acrylic with UVAM and proprietary violet light-filtering chromophore*	
Index of Refraction	1.47 at 35°C	
Light Transmittance	UV cut-off at 10% T for a spherical equivalent (SE) +5.0 D lens (thinnest), SE +20.0 D lens and a SE +34.0 D lens (thickest) are shown in **Figure 1.**	
Optic Center Thickness	0.7 mm (+20.0 D)	
Optic Edge Design	PROTEC 360 square posterior edge	
Haptic Configuration	TRI-FIX design Modified C, integral with optic	TRI-FIX design Modified C, integral with optic
Haptic Thickness	0.46 mm	
Diopter Power Range	Spherical Equivalent (SE) Power: +5.0 D to +34.0 D in 0.5 D increments	Spherical Equivalent (SE) Power: +5.0 D to +34.0 D in 0.5 D increments Cylinder Power: Model DET150: 1.50 D Model DET225: 2.25 D Model DET300: 3.00 D Model DET375: 3.75 D (as measured at the IOL plane)

*The TECNIS PureSee™ IOLs may appear slightly blue on the anterior surface under slit lamp examination, which is not detectable by patients. The violet light filter has not been shown to provide retinal phototoxicity protection.

Conversion table for cylinder powers:

Model	Cylinder Power (D)	
	IOL Plane (Labeled)	Corneal Plane*
DET150	1.50	1.03
DET225	2.25	1.54
DET300	3.00	2.06
DET375	3.75	2.57

*The corresponding cylinder values at the corneal plane have been calculated based on the average pseudophakic eye.

INDICATIONS FOR USE

TECNIS PureSee™ IOL with TECNIS SIMPLICITY™ Delivery System, Model DEN00V

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.

TECNIS PureSee™ Toric II IOLs with TECNIS SIMPLICITY™ Delivery System, Models DET150, DET225, DET300, DET375

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.

CONTRAINDICATION

There are no known contraindications.

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) 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.

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.

<u>Before Surgery</u>

- 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

<u>During Surgery</u>

- 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

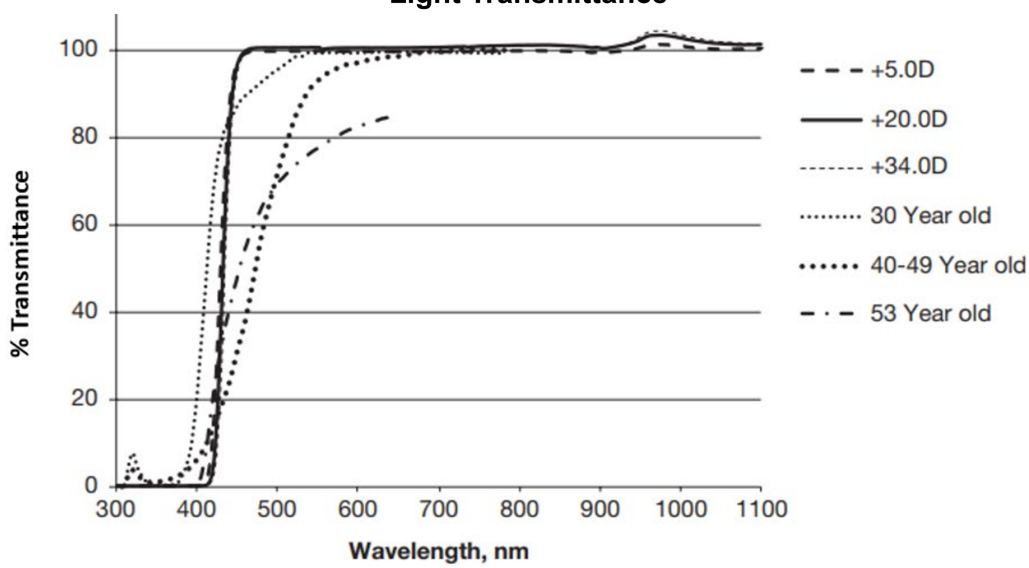
24. Potential complications generally associated with cataract surgery include, but are not limited to: endophthalmitis/intraocular infection, hypopyon, hyphema, IOL dislocation, persistent cystoid macular edema, pupillary block, retinal detachment/tear, persistent corneal stromal edema, persistent uveitis, 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.

WARNINGS

1. 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:
    a. Recurrent severe anterior or posterior segment inflammation of unknown etiology
    b. Posterior segment diseases of which monitoring or treatment ability may be limited by an intraocular lens
    c. 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)
    d. Compromised posterior capsule or zonules due to previous trauma or developmental defect in which appropriate support of the IOL is not possible
    e. Risk of damage to the endothelium during implantation
    f. Suspected microbial infection
    g. Congenital bilateral cataracts
    h. Previous history of, or a predisposition to, retinal detachment
    i. Potentially good vision in only one eye
    j. Medically uncontrollable glaucoma
    k. Corneal endothelial dystrophy
    l. Proliferative diabetic retinopathy.
2. 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.
3. 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.
4. Do not use if the cartridge of the delivery system is cracked or split prior to implantation.
5. Do not implant the lens if the rod tip does not advance the lens or if it is jammed in the delivery system.
6. Do not stop, reverse or advance the plunger too slowly (for example more than 1 second) during initial lens advancement (**Figure 12**). Doing so may result in improper folding of the lens.
7. Do not advance the lens from the Holding Position (**Figure 14**) 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.

8. 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.
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.

Figure 1
Light Transmittance



Legend:
Spectral transmittance curve of a typical 5-diopter IOL (thinnest). UV(420): UV cut-off at 10%T is 420 nm.
Spectral transmittance curve of a typical 20-diopter IOL. UV(424): UV cut-off at 10%T is 424 nm.
Spectral transmittance curve of a typical 34-diopter IOL (thickest). UV(426): UV cut-off at 10%T is 426 nm.
Spectral transmittance curve of crystalline lenses: 30 year old and 40-49 year old from Artigas, J.M., Felipe, A., Navea, A., Fandino, A., & Artigas, C. Spectral transmission of the human crystalline lens in adult and elderly persons: color and total transmission of visible light. Invest Ophthalmol Vis Sci (2012);53(7):4076-4084. 53 year old from Boettner, E.A., and Wolter J.R. Transmission of the Ocular Media. Investigative Ophthalmology. 1962;1:776-783.

CLINICAL STUDY RESULTS: TECNIS PURESEE™ IOL WITH TECNIS SIMPLICITY™ DELIVERY SYSTEM, MODEL DEN00V

A prospective, 6-month, multicenter, bilateral, randomized, evaluator- and subject-masked, clinical investigation was conducted at 9 investigative sites in the US to evaluate the safety and effectiveness of the TECNIS PureSee™ IOL with TECNIS SIMPLICITY™ Delivery System, Model DEN00V. The control IOL was the TECNIS™ 1-Piece IOL with TECNIS SIMPLICITY™Delivery System, Model DCB00. The primary effectiveness endpoints were (a) monocular, photopic, distance-corrected intermediate visual acuity at 66 cm, (b) monocular, photopic, distance-corrected depth of focus at 0.20 LogMAR, (c) monocular, photopic, best-corrected distance visual acuity at 4 m and (d) monocular, photopic, distance-corrected visual acuity at 100 cm. The primary safety endpoints were (a) monocular, photopic, best-corrected distance visual acuities at 4 m, (b) rates of adverse events vs. ISO Safety Performance and Effectiveness (SPE) rates, (c) monocular distance-corrected mesopic contrast sensitivity without glare, (d) incidence of Secondary Surgical Interventions (SSIs) related to optical properties of the lens, (e) incidence of all other non-SPE serious AEs and/or device-related adverse events for eyes in the TECNIS PureSee™ IOL lens group, and (f) investigator's assessment of his/her ability to visualize the fundus. All other measurements presented are pre-identified as other endpoints and considered supportive clinical information. The study was not designed for statistical comparison of these results and only descriptive statistics are presented for these endpoints.

Overall, as all primary safety and effectiveness endpoints success criteria were achieved, the study demonstrates the safety and effectiveness of the TECNIS PureSee™ IOL, Model DEN00V as an Extended Depth of Focus IOL. The Model DEN00V IOL provided improved intermediate vision and an increased depth of focus with visual acuity of 0.20 LogMAR or better compared to a monofocal IOL. The Model DEN00V achieved distance vision comparable to that of a monofocal IOL, maintained contrast sensitivity function and an optical/visual symptom profile similar to a monofocal IOL, and demonstrated a low incidence of adverse events with favorable comparisons to ISO SPE rates. These results provide adequate evidence of the safety and effectiveness of the investigational TECNIS PureSee™ IOL, Model DEN00V.

Additional pre-defined endpoints included near visual acuity and spectacle wear with descriptive results. Mean monocular distance-corrected near visual acuity at 6 months was 0.34 LogMAR for the TECNIS PureSee™ lens and 0.49 LogMAR for the control lens (a 1.5-line difference); For spectacle wear, 74.4% of subjects in the TECNIS PureSee™ group reported wearing glasses "None/A little of the time" with 50% of subjects in the control group reporting the same.

For the remainder of the clinical summary section, "TECNIS PureSee™" refers to the TECNIS PureSee™ IOL, Model DEN00V, and "control" refers to the TECNIS™ 1-Piece IOL, Model DCB00. NOTE: The Intent-To-Treat (ITT) Population was the primary analysis set for the primary effectiveness endpoints and the Safety Population (SP) was the primary analysis set for the primary safety endpoints and other endpoints. In addition, Per-Protocol (PP) Population was also the primary analysis set for the primary effectiveness BCDVA endpoint. All results presented are based on the SP with observed case (i.e., available data with no data imputation) unless specified otherwise. First eyes were- the primary eyes and presented in the monocular data tables, unless specified otherwise.

Subject Population

Of the 228 subjects enrolled and implanted in the study, 115 were in the TECNIS PureSee™ IOL group (115 bilaterally implanted) and 113 were in the control group (113 bilaterally implanted) in the SP. There was 1 subject who was randomized to the TECNIS PureSee™ IOL group but received the Control lens in both eyes; therefore, there were 116 TECNIS PureSee™ and 112 control subjects in ITT population. Subject demographics were similar between the TECNIS PureSee™ and control groups. The mean age was 69.0 ± 6.9 years for the TECNIS PureSee™ group and 68.0 ± 6.4 years for the control group. The majority of subjects in both lens groups were female (61.7% TECNIS PureSee™; 61.9% control), and most subjects in both lens groups were white (80.9% TECNIS PureSee™; 81.4% control). The remainder of subjects were African American (11.3% TECNIS PureSee™; 14.2% control), Asian (4.3% TECNIS PureSee™; 2.7% control), Native Hawaiian/Pacific Islander (0.9% TECNIS PureSee™ only), American Indian/ Alaska Native Asian including Indian (0.9%, control only), and Other Race (2.6% TECNIS PureSee™; 0.9% control). Similar demographic characteristics were observed for age, sex, race, ethnicity and iris color between lens groups.

IOL Power Selection and Postoperative Refractive Outcomes

Surgeons were instructed to select the IOL power to achieve emmetropia in both eyes (closest to plano spherical equivalent). Both the TECNIS PureSee™ and control first eyes had mean manifest refraction spherical equivalent outcomes at 6 months within emmetropia (±0.25D); although, the TECNIS PureSee™ group was slightly hyperopic (0.04D), and the control group was slightly myopic (−0.06D). There were no clinically meaningful differences in refractive outcomes between lens groups for first and second eyes. Mean refractive cylinder did not exceed 0.50D for first eyes in either lens group.

Distance Photopic Visual Acuity

Table 1 presents photopic (85 cd/m^2) uncorrected and distance corrected visual acuity results for the TECNIS PureSee™ and control IOLs at 6 months. Mean monocular first-eye best-corrected distance visual acuity (BCDVA) was both a primary effectiveness endpoint and primary safety endpoint. As a primary safety endpoint, mean monocular BCDVA was comparable between the TECNIS PureSee™ and control IOL groups in the Safety Population (SP), with mean Snellen equivalents of 20/18 and 20/16, respectively. The lower limit of the 2-sided 90% confidence interval (CL) of the mean difference in BCDVA was -0.06 LogMAR, exceeding the -0.10 LogMAR non-inferiority margin in the SP and meeting the statistical non-inferiority criterion. As a primary effectiveness endpoint, similar results were observed in both the PP and ITT populations, with a lower CL of -0.06 LogMAR, demonstrating that the TECNIS PureSee™ IOL was non-inferior to the control lens in BCDVA (**Table 2)**.

Table 1
Mean Distance Visual Acuity at 6 Months
Safety Population

		Monocular				Binocular			
Distance Visual Acuity	**Lens Group**	**N**	**Mean LogMAR**	**Snellen Equiv.**	**Line Change vs. Control[a]**	**N**	**Mean LogMAR**	**Snellen Equiv.**	**Line Change vs. Control[a]**
Best-Corrected[b]	TECNIS PureSee™	113	-0.04	20/18	**-0.4 lines**	113	-0.07	20/17	**-0.5 lines**
	Control	110	-0.08	20/16		110	-0.12	20/15	
Uncorrected	TECNIS PureSee™	113	0.05	20/22	**-0.5 lines**	113	-0.01	20/19	**-0.5 lines**
	Control	110	0.00	20/20		110	-0.06	20/17	

[a] Line difference (Control minus TECNIS PureSee™) was converted directly from LogMAR difference.
[b] Best-corrected distance visual acuity was a primary safety endpoint.

Table 2
Monocular Best-Corrected Distance Visual Acuity (LogMAR) at 6 Months
Intend-To-Treat (ITT) and Per-Protocol (PP) Population

Population	**Lens Group**	**N**	**Mean Monocular LogMAR**	**Monocular Snellen Equiv.**	**90% CI**
ITT[a]	TECNIS PureSee™	116	-0.04	20/18	(-0.05, -0.03)
	Control	112	-0.08	20/17	(-0.10, -0.07)
	Difference		-0.04	-0.4 lines [b]	(-0.06, -0.02)
PP	TECNIS PureSee™	111	-0.04	20/18	(-0.06, -0.03)
	Control	107	-0.08	20/16	(-0.10, -0.07)
	Difference		-0.04	-0.4 lines [b]	(-0.06, -0.02)

[a] Intent-to-Treat population was used with multiple imputation approach to handle missing data.
[b] Line difference (Control minus TECNIS PureSee™) was converted directly from LogMAR difference.
Non-inferiority margin of -0.10 LogMAR.

The distributions of monocular uncorrected and best-corrected distance visual acuities for TECNIS PureSee™ and control first eyes at 6 months are presented in **Table 3** and **Table 4**. The proportion of TECNIS PureSee™ first eyes, all eyes and best-case eyes achieving monocular BCDVA of 0.30 LogMAR (20/40 Snellen) or better (primary safety endpoint) was above the ISO Safety and Performance Endpoint (SPE) for BCDVA, therefore meeting the prespecified success criterion for the primary BCDVA safety endpoint. The distributions of binocular uncorrected and best-corrected distance visual acuity for TECNIS PureSee™ and control at 6 months are presented in **Table 5** and **Table 6**. Overall, distance visual acuity results demonstrated that the TECNIS PureSee™ lens provides comparable distance visual acuity to the monofocal control lens.

Table 3
Monocular Distance (Far) Visual Acuity (Snellen) at 6 Months

Monocular Snellen Visual Acuity	TECNIS PureSee™				Control			
	Uncorrected N=113		Best-Corrected N=113		Uncorrected N=110		Best-Corrected N=110	
	n	%	n	%	n	%	n	%
$20/20^{-2}$ or better	66	58.4%	100	88.5%	78	70.9%	102	92.7%
$20/25^{-2}$ or better	93	82.3%	110	97.4%	98	89.1%	107	97.3%
$20/32^{-2}$ or better	104	92.0%	113	100.0%	106	96.4%	109	99.1%
$20/40^{-2}$ or better	111	98.2%	113	100.0%	109	99.1%	110	100.0%
Worse than $20/40^{-2}$	2	1.8%	0	0.0%	1	0.9%	0	0.0%

%=(n/N) * 100

Table 4
Monocular Distance (Far) Visual Acuity (LogMAR) at 6 Months

Monocular LogMAR Visual Acuity	TECNIS PureSee™				Control			
	Uncorrected N=113		Best-Corrected N=113		Uncorrected N=110		Best-Corrected N=110	
	n	%	n	%	n	%	n	%
0.00 or better	50	44.3%	91	80.5%	66	60.0%	97	88.2%
0.10 or better	82	72.6%	110	97.4%	96	87.3%	105	95.5%
0.20 or better	102	90.3%	112	99.1%	103	93.6%	108	98.2%
0.30 or better	109	96.5%	113	100.0%	109	99.1%	110	100.0%
Worse than 0.30	4	3.5%	0	0.0%	1	0.9%	0	0.0%

%=(n/N) * 100

Table 5
Binocular Distance (Far) Visual Acuity (Snellen) at 6 Months

Binocular Snellen Visual Acuity	TECNIS PureSee™				Control			
	Uncorrected N=113		Best-Corrected N=113		Uncorrected N=110		Best-Corrected N=110	
	n	%	n	%	n	%	n	%
$20/20^{-2}$ or better	88	77.9%	106	93.8%	98	89.1%	107	97.3%
$20/25^{-2}$ or better	103	91.2%	111	98.2%	105	95.5%	109	99.1%
$20/32^{-2}$ or better	113	100.0%	112	99.1%	110	100.0%	110	100.0%
$20/40^{-2}$ or better	113	100.0%	113	100.0%	110	100.0%	110	100.0%
Worse than $20/40^{-2}$	0	0.0%	0	0.0%	0	0.0%	0	0.0%

%=(n/N) * 100

Table 6
Binocular Distance (Far) Visual Acuity (LogMAR) at 6 Months

Binocular LogMAR Visual Acuity	TECNIS PureSee™ Uncorrected N=113		TECNIS PureSee™ Best-Corrected N=113		Control Uncorrected N=110		Control Best-Corrected N=110	
	n	%	n	%	n	%	n	%
0.00 or better	77	68.1%	104	92.0%	92	83.6%	107	97.3%
0.10 or better	99	87.6%	110	97.4%	101	91.8%	108	98.2%
0.20 or better	110	97.4%	112	99.1%	109	99.1%	110	100.0%
0.30 or better	113	100.0%	113	100.0%	110	100.0%	110	100.0%
Worse than 0.30	0	0.0%	0	0.0%	0	0.0%	0	0.0%

%=(n/N) * 100

Intermediate Photopic Visual Acuity

Intermediate visual acuities were tested at 66 cm under photopic (85 cd/m^2) lighting conditions. Mean uncorrected and distance-corrected intermediate visual acuities at 6 months for both the TECNIS PureSee™ and control IOL groups are presented in **Table 7**. Mean monocular first-eye distance-corrected intermediate visual acuity (DCIVA) was one of the primary effectiveness endpoints. There was a statistically significant improvement (p<0.0001) in mean monocular distance-corrected intermediate visual acuity (DCIVA) at 6 months in favor of the TECNIS PureSee™ lens in the ITT population, with an improvement of 1.5 lines (0.15 LogMAR), meeting the statistical success criterion. The mean and median monocular distance-corrected intermediate visual acuity at 6 months was 0.15 and 0.14 LogMAR for first eyes, which met the clinical success criteria of ≤0.20 LogMAR.

Table 7
Mean Intermediate Visual Acuity at 66 cm at 6 Months

Intermediate Visual Acuity	Lens Group	Monocular N	Monocular Mean LogMAR	Monocular Snellen Equiv.	Monocular Line Change vs. Control[b]	Binocular[c] N	Binocular[c] Mean LogMAR	Binocular[c] Snellen Equiv.	Binocular[c] Line Change vs. Control[b]
Distance-Corrected[a]	TECNIS PureSee™	116	0.15	20/28	**1.5 lines**	113	0.10	20/25	**1.0 lines**
	Control	112	0.31	20/40		110	0.19	20/30	
Uncorrected[c]	TECNIS PureSee™	113	0.17	20/29	**0.8 lines**	113	0.09	20/24	**0.4 lines**
	Control	110	0.25	20/35		110	0.13	20/26	

[a] Monocular distance corrected visual acuity was a primary effectiveness endpoint. Results were obtained from the Intent-to-Treat population with multiple imputation to handle missing data.
[b] Line difference (Control minus TECNIS PureSee™) is converted directly from LogMAR difference.
[c] Uncorrected and binocular visual acuities were other endpoints and Safety Population with observed case was used for the analysis.

The distributions of monocular uncorrected and distance-corrected intermediate visual acuities for TECNIS PureSee™ and control first eyes at 6 months are presented in **Table 8** and **Table 9**. Results favored TECNIS PureSee™, showing a difference of 52.3% between groups, with 82.3%

of TECNIS PureSee™ subjects achieving monocular DCIVA of 0.20 LogMAR (20/32 Snellen) or better compared to 30.0% of control subjects (**Table 9**). The distributions of binocular uncorrected and distance-corrected intermediate visual acuity for TECNIS PureSee™ and control at 6 months are presented in **Table 10** and **Table 11**. The intermediate visual acuity results demonstrated the TECNIS PureSee™ lens provides overall improved intermediate vision compared to the monofocal control lens.

Table 8
Monocular Intermediate Visual Acuity (Snellen) at 66 cm at 6 Months

Monocular Snellen Visual Acuity	TECNIS PureSee™				Control			
	Uncorrected N=113		Distance-Corrected N=113		Uncorrected N=110		Distance-Corrected N=110	
	n	%	n	%	n	%	n	%
$20/20^{-2}$ or better	13	11.5%	12	10.6%	8	7.3%	3	2.7%
$20/25^{-2}$ or better	58	51.3%	69	61.1%	27	24.6%	16	14.6%
$20/32^{-2}$ or better	90	79.7%	103	91.2%	55	50.0%	46	41.8%
$20/40^{-2}$ or better	109	96.5%	110	97.4%	82	74.6%	67	60.9%
$20/50^{-2}$ to $20/80^{-2}$	3	2.7%	2	1.8%	27	24.5%	41	37.3%
$20/100^{-2}$ or worse	1	0.9%	1	0.9%	1	0.9%	2	1.8%

%=(n/N) * 100

Table 9
Monocular Intermediate Visual Acuity (LogMAR) at 66 cm at 6 Months

Monocular LogMAR Visual Acuity	TECNIS PureSee™				Control			
	Uncorrected N=113		Distance-Corrected N=113		Uncorrected N=110		Distance-Corrected N=110	
	n	%	n	%	n	%	n	%
0.00 or better	5	4.4%	6	5.3%	3	2.7%	1	0.9%
0.10 or better	29	25.7%	36	31.9%	23	20.9%	9	8.2%
0.20 or better	78	69.0%	93	82.3%	47	42.7%	33	30.0%
0.30 or better	104	92.0%	109	96.5%	71	64.6%	56	50.9%
0.31 to 0.60	8	7.1%	2	1.8%	38	34.5%	48	43.6%
0.61 or worse	1	0.9%	2	1.8%	1	0.9%	6	5.5%

%=(n/N) * 100

Table 10
Binocular Intermediate Visual Acuity (Snellen) at 66 cm at 6 Months

Binocular Snellen Visual Acuity	TECNIS PureSee™				Control			
	Uncorrected N=113		Distance-Corrected N=113		Uncorrected N=110		Distance-Corrected N=110	
	n	%	n	%	n	%	n	%
$20/20^{-2}$ or better	38	33.6%	35	31.0%	33	30.0%	12	10.9%
$20/25^{-2}$ or better	89	78.8%	92	81.4%	65	59.1%	42	38.2%
$20/32^{-2}$ or better	109	96.5%	110	97.4%	90	81.8%	80	72.7%
$20/40^{-2}$ or better	112	99.1%	111	98.2%	106	96.4%	99	90.0%
$20/50^{-2}$ to $20/80^{-2}$	0	0.0%	1	0.9%	4	3.6%	11	10.0%
$20/100^{-2}$ or worse	1	0.9%	1	0.9%	0	0.0%	0	0.0%

%=(n/N) * 100

Table 111
Binocular Intermediate Visual Acuity (LogMAR) at 66 cm at 6 Months

Binocular LogMAR Visual Acuity	TECNIS PureSee™				Control			
	Uncorrected N=113		Distance-Corrected N=113		Uncorrected N=110		Distance-Corrected N=110	
	n	%	n	%	n	%	n	%
0.00 or better	21	18.6%	12	10.6%	20	18.2%	5	4.6%
0.10 or better	67	59.3%	68	60.2%	51	46.4%	29	26.4%
0.20 or better	106	93.8%	106	93.8%	83	75.5%	66	60.0%
0.30 or better	111	98.2%	111	98.2%	101	91.8%	92	83.6%
0.31 to 0.60	1	0.9%	1	0.9%	9	8.2%	18	16.4%
0.61 or worse	1	0.9%	1	0.9%	0	0.0%	0	0.0%

%=(n/N) * 100

Photopic Visual Acuity at 100 cm

Monocular distance-corrected visual acuity (DCVA) was also tested at 100 cm under photopic (85 cd/m^2) lighting conditions (**Table 12**). Mean monocular DCVA tested at 100 cm at 6 months was one of the primary effectiveness endpoints. TECNIS PureSee™ achieved a mean of 0.10 LogMAR for first eyes in the ITT population, meeting the success criteria of being ≤0.20 LogMAR.

Table 12
Mean Monocular Distance-Corrected Visual Acuity[a] at 100 cm at 6 Months
Intend-To-Treat (ITT) Population

Visual Acuity	Lens Group	N	Mean LogMAR	Snellen Equiv.	Line Difference vs. Control[b]
Distance-Corrected	TECNIS PureSee™	116	0.10	20/25	**0.6 lines**
	Control	112	0.16	20/29	

[a] Monocular distance-corrected visual acuity at 100cm was a primary effectiveness endpoint. Results were obtained from the Intent-to-Treat population with multiple imputation approach to handle missing data.

[b] Line difference (Control minus TECNIS PureSee™) wasconverted directly from LogMAR difference.

The distributions of monocular distance-corrected visual acuity tested at 100 cm for TECNIS PureSee™ and control first eyes at 6 months are presented in **Table 13** and **Table 14**. Results favored TECNIS PureSee™, with 88.5% of TECNIS PureSee™ subjects achieving monocular distance-corrected visual acuity at 100 cm of 0.20 LogMAR (20/32 Snellen) or better compared to 66.4% of control subjects (**Table 14**).

Overall, visual acuity results demonstrated the TECNIS PureSee™ provides improved vision compared to the monofocal control lens at 100 cm.

Table 13
Monocular Distance-Corrected Visual Acuity (Snellen) at 100 cm at 6 Months

Monocular Snellen Visual Acuity	TECNIS PureSee™ Distance-Corrected N=113		Control Distance-Corrected N=110	
	n	%	n	%
$20/20^{-2}$ or better	35	31.0%	21	19.1%
$20/25^{-2}$ or better	84	74.3%	54	49.1%
$20/32^{-2}$ or better	105	92.9%	80	72.7%
$20/40^{-2}$ or better	110	97.4%	100	90.9%
20/50 to 20/80	2	1.8%	10	9.1%
20/100 or worse	1	0.9%	0	0.0%

%=(n/N) * 100

Table 14
Monocular Distance-Corrected Visual Acuity (LogMAR) at 100 cm at 6 Months

Monocular LogMAR Visual Acuity	TECNIS PureSee™ Distance-Corrected N=113 n	%	Control Distance-Corrected N=110 n	%
0.00 or better	20	17.7%	13	11.8%
0.10 or better	68	60.2%	40	36.4%
0.20 or better	100	88.5%	73	66.4%
0.30 or better	108	95.6%	93	84.6%
0.31 to 0.60	4	3.5%	17	15.5%
0.61 or worse	1	0.9%	0	0.0%

%=(n/N) * 100

Near Photopic Visual Acuity

The study pre-identified some "additional endpoints" as supportive clinical information, including near photopic visual acuity. The study was not designed for statistical comparison of this endpoint. Therefore, only descriptive statistics are presented here. As one of the "additional endpoints," near vision data were collected at 40 cm under photopic (85 cd/m^2) lighting conditions. At 6 months, the mean monocular distance-corrected near visual acuity was 0.34 LogMAR for the TECNIS PureSee™ lens and 0.49 LogMAR for the control lens, with an observed mean difference of 1.5 lines between groups (**Table 15**).

Table 15
Mean Near Visual Acuity at 40 cm at 6 Months

Near Visual Acuity	Lens Group	Monocular N	Monocular Mean LogMAR	Monocular Snellen Equiv.	Monocular Line Change vs. Control[a]	Binocular N	Binocular Mean LogMAR	Binocular Snellen Equiv.	Binocular Line Change vs. Control[a]
Distance-Corrected	TECNIS PureSee™	113	0.34	20/43	**1.5 lines**	113	0.28	20/38	**1.1 lines**
	Control	110	0.49	20/61		110	0.39	20/49	
Uncorrected	TECNIS PureSee™	113	0.35	20/44	**1.2 lines**	113	0.25	20/35	**0.9 lines**
	Control	110	0.47	20/59		110	0.33	20/42	

[a] Line difference (Control minus TECNIS PureSee™) was converted directly from LogMAR difference.

The distributions of monocular uncorrected and distance corrected near visual acuities for TECNIS PureSee™ and control first eyes at 6 months are presented in **Table 16** and **Table 17**.

Table 16
Monocular Near Visual Acuity (Snellen) at 40 cm at 6 Months

Monocular Snellen Visual Acuity	TECNIS PureSee™ Uncorrected N=113 n	%	TECNIS PureSee™ Distance-Corrected N=113 n	%	Control Uncorrected N=110 n	%	Control Distance-Corrected N=110 n	%
$20/20^{-2}$ or better	0	0.0%	0	0.0%	1	0.9%	0	0.0%
$20/25^{-2}$ or better	2	1.8%	4	3.5%	1	0.9%	0	0.0%
$20/32^{-2}$ or better	28	24.8%	21	18.6%	6	5.5%	7	6.4%
$20/40^{-2}$ or better	63	55.8%	56	49.6%	29	26.4%	23	20.9%
$20/50^{-2}$ to $20/80^{-2}$	47	41.6%	55	48.7%	70	63.6%	70	63.6%
$20/100^{-2}$ or worse	3	2.7%	2	1.8%	11	10.0%	17	15.5%

%=(n/N) * 100

Table 17
Monocular Near Visual Acuity (LogMAR) at 40 cm at 6 Months

Monocular LogMAR Visual Acuity	TECNIS PureSee™ Uncorrected N=113 n	%	TECNIS PureSee™ Distance-Corrected N=113 n	%	Control Uncorrected N=110 n	%	Control Distance-Corrected N=110 n	%
0.00 or better	0	0.0%	0	0.0%	1	0.9%	0	0.0%
0.10 or better	0	0.0%	1	0.9%	1	0.9%	0	0.0%
0.20 or better	17	15.0%	13	11.5%	4	3.6%	2	1.8%
0.30 or better	41	36.3%	39	34.5%	19	17.3%	15	13.6%
0.31 to 0.60	68	60.2%	72	63.7%	70	63.6%	69	62.7%
0.61 or worse	4	3.5%	2	1.8%	21	19.1%	26	23.6%

%=(n/N) * 100

Table 18
Binocular Near Visual Acuity (Snellen) at 40 cm at 6 Months

Binocular Snellen Visual Acuity	TECNIS PureSee™ Uncorrected N=113 n	%	TECNIS PureSee™ Distance-Corrected N=113 n	%	Control Uncorrected N=110 n	%	Control Distance-Corrected N=110 n	%
$20/20^{-2}$ or better	1	0.9%	0	0.0%	0	0.0%	0	0.0%
$20/25^{-2}$ or better	28	24.8%	19	16.8%	7	6.4%	3	2.7%
$20/32^{-2}$ or better	62	54.9%	45	39.8%	42	38.2%	21	19.1%
$20/40^{-2}$ or better	93	82.3%	91	80.5%	63	57.3%	46	41.8%
$20/50^{-2}$ to $20/80^{-2}$	19	16.8%	21	18.6%	45	40.9%	60	54.5%
$20/100^{-2}$ or worse	1	0.9%	1	0.9%	2	1.8%	4	3.6%

%=(n/N) * 100

Table 19
Binocular Near Visual Acuity (LogMAR) at 40 cm at 6 Months

Binocular LogMAR Visual Acuity	TECNIS PureSee™ Uncorrected N=113		TECNIS PureSee™ Distance-Corrected N=113		Control Uncorrected N=110		Control Distance-Corrected N=110	
	n	%	n	%	n	%	n	%
0.00 or better	0	0.0%	0	0.0%	0	0.0%	0	0.0%
0.10 or better	11	9.7%	4	3.5%	3	2.7%	1	0.9%
0.20 or better	50	44.3%	33	29.2%	23	20.9%	11	10.0%
0.30 or better	81	71.7%	72	63.7%	55	50.0%	36	32.7%
0.31 to 0.60	31	27.4%	40	35.4%	50	45.5%	66	60.0%
0.61 or worse	1	0.9%	1	0.9%	5	4.6%	8	7.3%

%=(n/N) * 100

Mesopic Visual Acuity

Mesopic visual acuity was another pre-identified “additional endpoint” for supportive clinical information. The study was not designed for statistical comparison of this endpoint. Therefore, only descriptive statistics are presented here. Best-corrected distance (far) and distance-corrected intermediate (66 cm) visual acuities were tested under mesopic (3 cd/m^2) lighting conditions. Mean mesopic visual acuities at 6 months for both TECNIS PureSee™ and control groups are presented in **Table 20**. The difference in mean monocular mesopic BCDVA between lens groups was -0.05 LogMAR. The mean monocular mesopic DCIVA for the TECNIS PureSee™ lens was 0.32 LogMAR, showing a difference of 1.5 lines between the two groups. Differences in mesopic BCDVA and DCIVA between TECNIS PureSee™ and control are consistent in all lighting conditions tested (mesopic and photopic conditions). The distributions of mesopic BCDVA for both lens groups at 6 months are presented in **Table 21** and **Table 22**. The distributions of mesopic DCIVA for both lens groups at 6 months are presented in **Table 23** and **Table 24.**

Table 20
Mean Mesopic Distance (Far) and Intermediate (66 cm) Visual Acuity at 6 Months

Visual Acuity	Lens Group	Monocular N	Monocular Mean LogMAR	Monocular Snellen Equiv.	Monocular Line Change vs. Control[a]	Binocular N	Binocular Mean LogMAR	Binocular Snellen Equiv.	Binocular Line Change vs. Control[a]
Best-Corrected Distance	TECNIS PureSee™	113	0.11	20/25	**-0.5 lines**	113	0.07	20/23	**-0.7 lines**
	Control	110	0.06	20/22		110	0.00	20/20	
Distance-Corrected Intermediate	TECNIS PureSee™	113	0.32	20/41	**1.5 lines**	113	0.24	20/34	**1.5 lines**
	Control	110	0.47	20/59		110	0.39	20/39	

[a] Line difference (Control minus TECNIS PureSee™) was converted directly from LogMAR difference.

Table 21
Mesopic Best Corrected Distance Visual Acuity (Snellen) at 6 Months

Best-Corrected Distance Snellen Visual Acuity	TECNIS PureSee™				Control			
	Monocular N=113		Binocular N=113		Monocular N=110		Binocular N=110	
	n	%	n	%	n	%	n	%
$20/20^{-2}$ or better	29	25.7%	51	45.1%	59	53.6%	88	80.0%
$20/25^{-2}$ or better	82	72.6%	104	92.0%	93	84.6%	108	98.2%
$20/32^{-2}$ or better	107	94.7%	111	98.2%	106	96.4%	109	99.1%
$20/40^{-2}$ or better	111	98.2%	111	98.2%	107	97.3%	109	99.1%
Worse than $20/40^{-2}$	2	1.8%	2	1.8%	3	2.7%	1	0.9%

%=(n/N) * 100

Table 22
Mesopic Best Corrected Distance Visual Acuity (LogMAR) at 6 Months

Best-Corrected Distance LogMAR Visual Acuity	TECNIS PureSee™				Control			
	Monocular N=113		Binocular N=113		Monocular N=110		Binocular N=110	
	n	%	n	%	n	%	n	%
0.00 or better	13	11.5%	27	23.9%	35	31.8%	63	57.3%
0.10 or better	60	53.1%	82	72.6%	84	76.4%	99	90.0%
0.20 or better	99	87.6%	109	96.5%	104	94.6%	109	99.1%
0.30 or better	110	97.4%	111	98.2%	107	97.3%	109	99.1%
Worse than 0.30	3	2.7%	2	1.8%	3	2.7%	1	0.9%

%=(n/N) * 100

Table 23
Mesopic Distance-Corrected Intermediate Visual Acuity (Snellen) at 66 cm at 6 Months

Distance-Corrected Intermediate Snellen Visual Acuity	TECNIS PureSee™				Control			
	Monocular N=113		Binocular N=113		Monocular N=110		Binocular N=110	
	n	%	n	%	n	%	n	%
$20/20^{-2}$ or better	0	0.0%	1	0.9%	0	0.0%	0	0.0%
$20/25^{-2}$ or better	2	1.8%	13	11.5%	0	0.0%	3	2.7%
$20/32^{-2}$ or better	33	29.2%	71	62.8%	4	3.6%	11	10.0%
$20/40^{-2}$ or better	78	69.0%	104	92.0%	23	20.9%	46	41.8%
$20/50^{-2}$ to $20/80^{-2}$	33	29.2%	8	7.1%	77	70.0%	62	56.4%
$20/100^{-2}$ or worse	2	1.8%	1	0.9%	10	9.1%	2	1.8%

%=(n/N) * 100

Table 24
Mesopic Distance-Corrected Intermediate Visual Acuity (LogMAR) at 66 cm at 6 Months

Distance-Corrected Intermediate LogMAR Visual Acuity	TECNIS PureSee™				Control			
	Monocular N=113		Binocular N=113		Monocular N=110		Binocular N=110	
	n	%	n	%	n	%	n	%
0.00 or better	0	0.0%	1	0.9%	0	0.0%	0	0.0%
0.10 or better	2	1.8%	4	3.5%	0	0.0%	1	0.9%
0.20 or better	22	19.5%	47	41.6%	2	1.8%	6	5.5%
0.30 or better	60	53.1%	93	82.3%	11	10.0%	24	21.8%
0.31 to 0.60	50	44.2%	19	16.8%	84	76.4%	82	74.5%
0.61 or worse	3	2.7%	1	0.9%	15	13.6%	4	3.6%

%=(n/N) * 100

Depth of Focus

Mean monocular (first-eye) distance-corrected depth of focus was one of the primary effectiveness endpoints; measurements were plotted using the ITT population with the multiple imputation approach to handle missing data (**Figure 2**). The curves indicated that the TECNIS PureSee™ group maintained 0.20 LogMAR or better visual acuity from 0.0D to -1.77D and the control group from 0.0D to -1.13D. The depth of focus at the 0.20 LogMAR threshold (horizontal line) for the TECNIS PureSee™ group was 0.64D greater than that for the control, meeting the clinical success criterion of a between-lens difference of at least 0.50D. Binocular depth of focus (with 0.20 LogMAR or better) was maintained through -2.15D for the TECNIS PureSee™ group and through -1.54D for the control group, yielding a similar difference (0.61D), in favor of the TECNIS PureSee™ group (**Figure 3**).

Figure 2
Monocular Distance-Corrected Depth of Focus Curve at 6 Months
Intent-to-Treat Population with Multiple Imputation

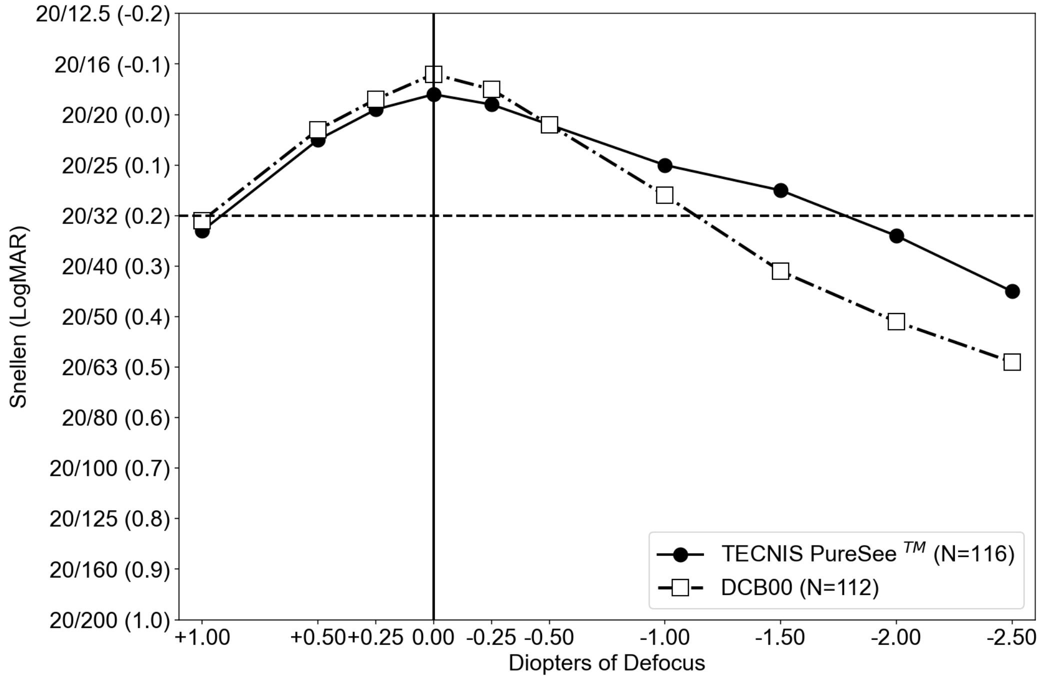
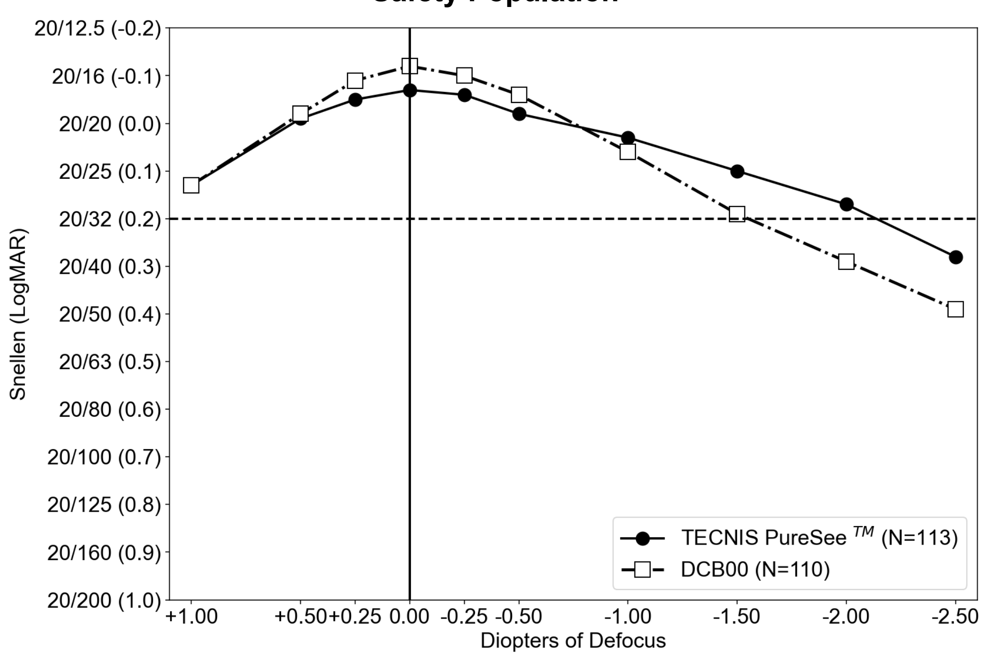
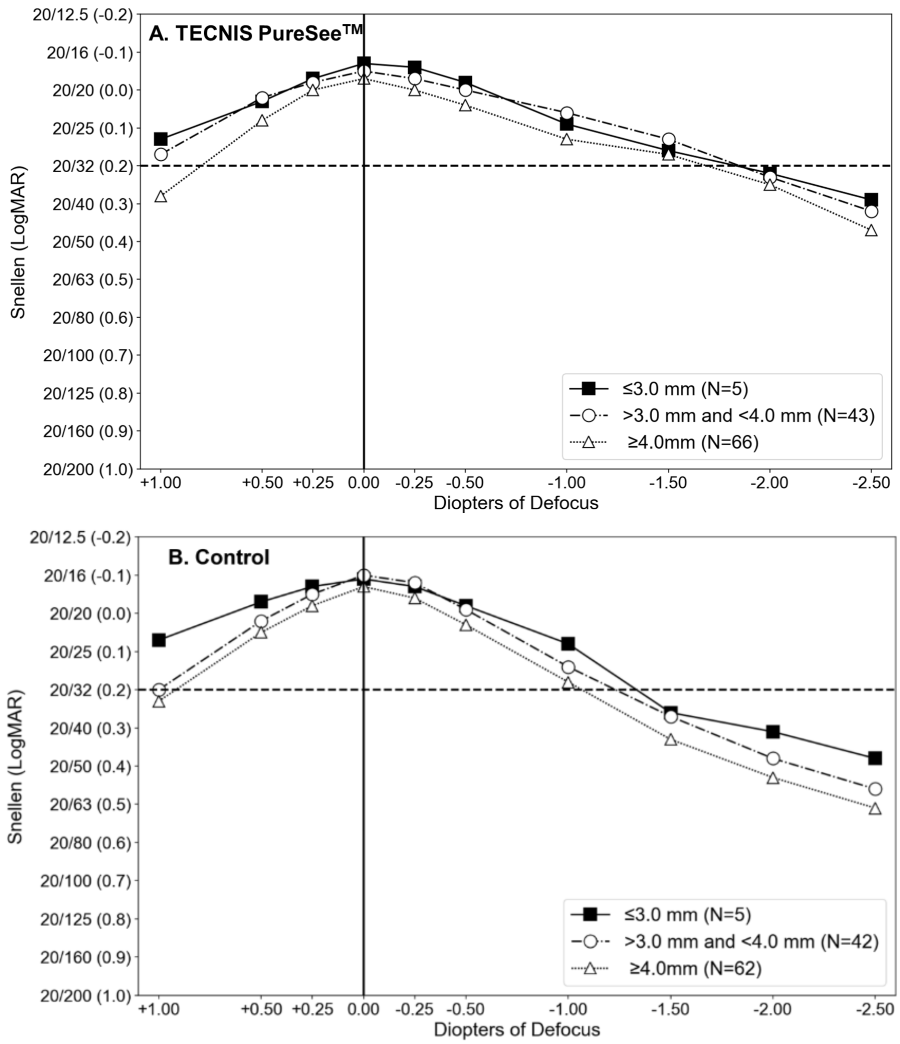


Figure 3
Binocular Distance-Corrected Depth of Focus Curve at 6 Months
Safety Population



Greater depth of focus was observed for the TECNIS PureSee™ group than the control group across all pupil size categories of "small" (≤ 3.0 mm), "medium" (>3.0 mm to <4.0 mm) or "large" (≥ 4.0 mm;), where pupil size was measured under photopic conditions (**Figure 4**). The curves indicate no noticeable effect of pupil size on TECNIS PureSee™ performance.

Figure 4
Monocular Distance-Corrected Depth of Focus Curve by Pupil Size at 6 Months Intent-to-Treat Population with Observed Case



Mesopic Contrast Sensitivity

The between-lens groups differences (**Table 25** and **Figure 5**) in mean monocular (first-eye) contrast sensitivity (CS) values under mesopic conditions without glare (primary safety endpoint) were ≤0.3 log units at all spatial frequencies, meeting the clinical success criterion of the primary safety endpoint according to ISO 11979-7:2024. Likewise, the median differences were ≤0.3 log units at all spatial frequencies. All subjects (100%) in both lens groups were able to see the reference pattern for the contrast sensitivity tests at all tested conditions.

Similar to the monocular mesopic without glare CS outcomes, the between-lens group mean and median differences in both monocular CS with glare (**Figure 5**) and binocular CS with and without glare (**Figure 6**) under mesopic conditions were ≤0.3 log units at all spatial frequencies.

Table 25
Monocular Best Corrected Distance Mesopic Contrast Sensitivity (Log Unit) at 6 Months

			Without Glare		With Glare	
Spatial Frequency	**Lens Model**	**N**	**Mean**	**Did not see reference pattern %**	**Mean**	**Did not see reference pattern %**
1.5 cpd	TECNIS PureSee™	113	1.95	0.0%	1.73	0.0%
	Control	110	1.91	0.0%	1.75	0.0%
	Difference		0.04		-0.02	
3.0 cpd	TECNIS PureSee™	113	2.00	0.0%	1.81	0.0%
	Control	110	2.01	0.0%	1.88	0.0%
	Difference		-0.01		-0.08	
6.0 cpd	TECNIS PureSee™	113	1.65	0.0%	1.50	0.0%
	Control	110	1.75	0.0%	1.70	0.0%
	Difference		-0.10		-0.20	
12.0 cpd	TECNIS PureSee™	113	0.98	0.0%	0.88	0.0%
	Control	110	1.11	0.0%	1.06	0.0%
	Difference		-0.13		-0.18	

Cpd = Cycles per degree

Figure 5
Mean (±1 SD) Monocular Best Corrected Distance Mesopic Contrast Sensitivity (Log Unit) at 6 Months

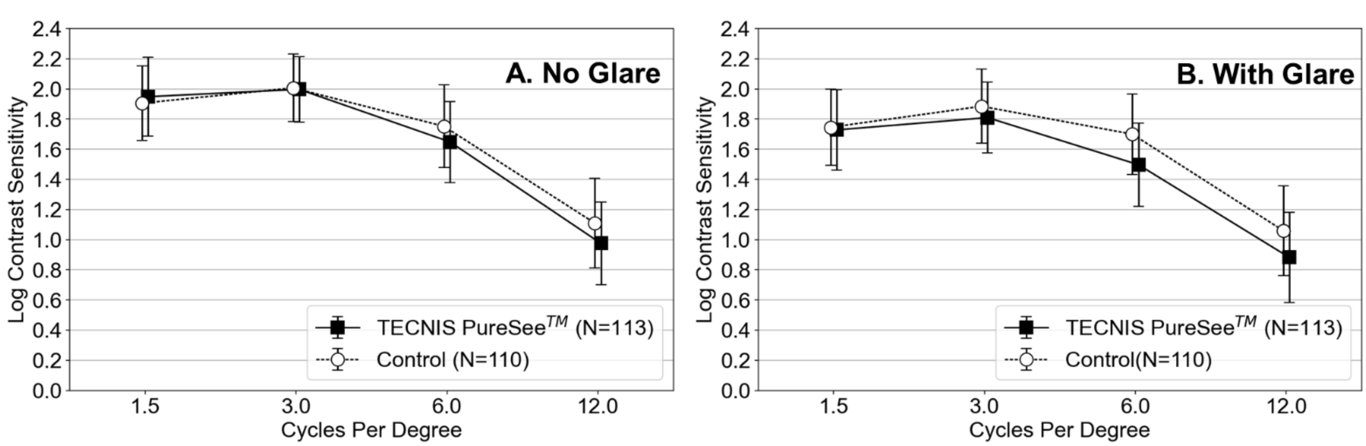
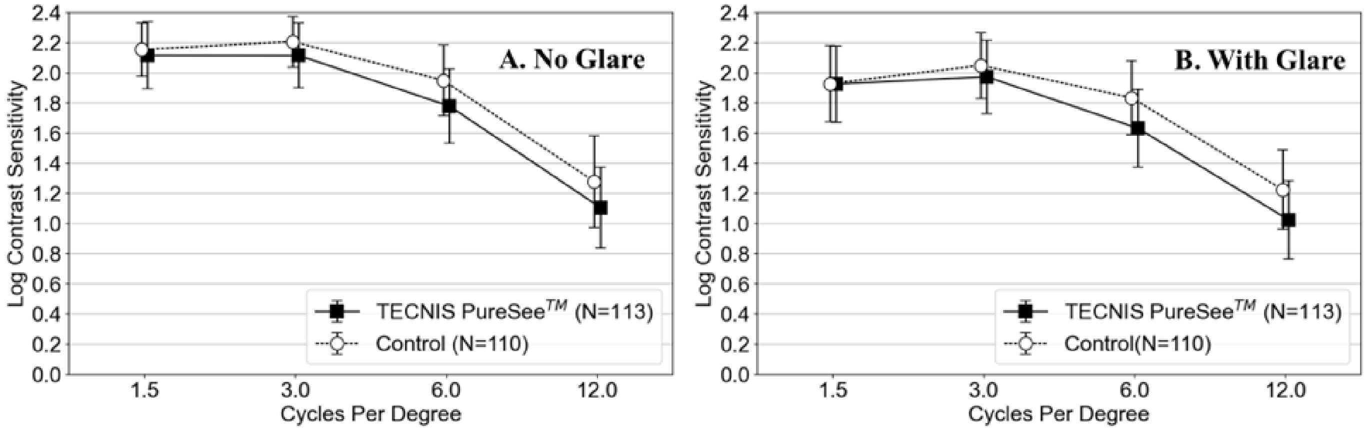


Figure 6
Mean (±1 SD) Binocular Best Corrected Distance Mesopic Contrast Sensitivity (Log Unit) at 6 Months



Monocular best corrected distance contrast sensitivity results were stratified by pupil size categories of □small□(≤3.0 mm), □medium□(>3.0 mm to <4.0 mm) or □large□(≥4.0 mm), where pupil size was measured under mesopic conditions. **Figure 7** and **Figure 8** show that the results for monocular mesopic contrast sensitivity without glare and with glare are consistent for all pupil size categories for the TECNIS PureSee™ and control group. There were no clinically meaningful differences (≤0.3 log units) between lens groups or pupil size categories.

Figure 7
Mean Monocular Best Corrected Distance Mesopic Contrast Sensitivity Without Glare (Log Unit) by Pupil Size at 6 Months

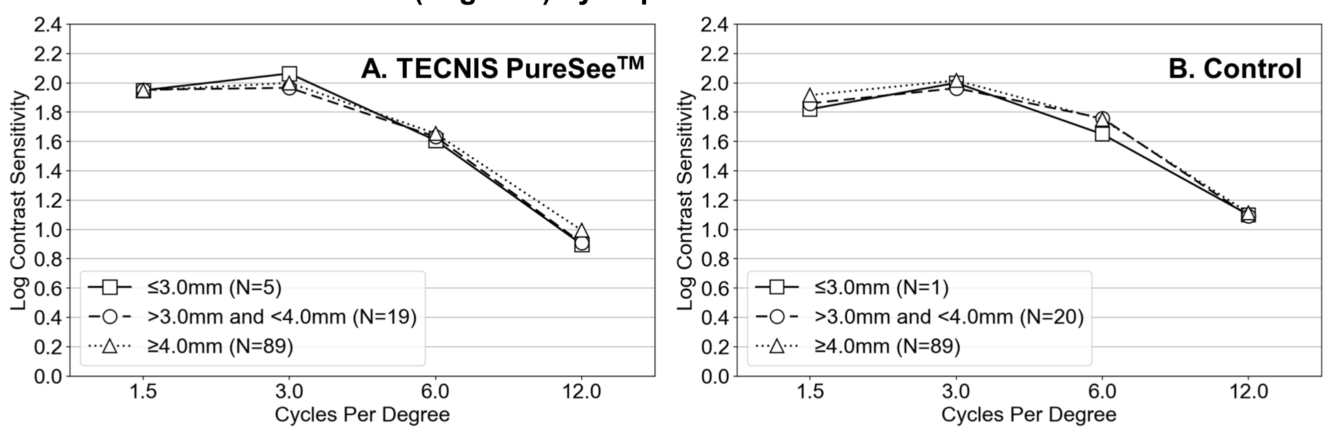
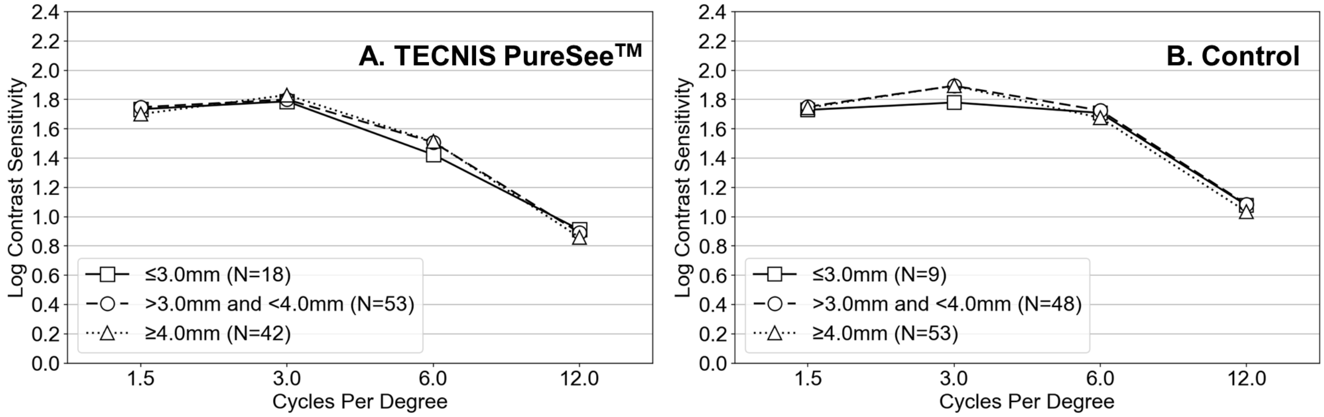


Figure 8
Mean Monocular Best Corrected Distance Mesopic Contrast Sensitivity With Glare (Log Unit) by Pupil Size at 6 Months



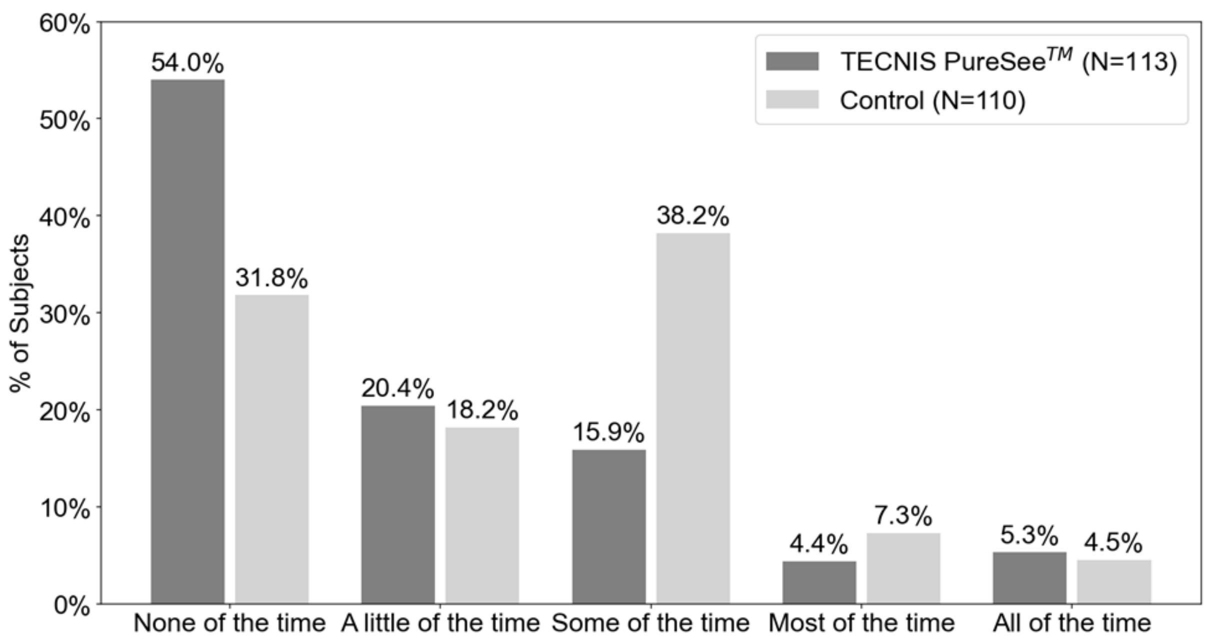
Spectacle Wear

Spectacle wear was another pre-identified “additional endpoint” for supportive clinical information. The study was not designed for statistical comparison of this endpoint. Therefore, only descriptive statistics are presented here. Spectacle wear and other related items were assessed by responses to a subject questionnaire, the Patient-Reported Spectacle Independence Questionnaire-v2 (PRSIQv2), which was developed and evaluated following the US FDA guidance document “Patient-Reported Outcomes Measures: Use in Medical Product Development to Support Labeling Claims” dated December 2009. In the questionnaire, patients were asked how often they wore glasses (or other visual correction) during the last 7 days for four categories: distance, intermediate, near and overall vision. **Table 26** presents the frequency of spectacle wear under each of these conditions. **Figure 9** presents the frequency of overall spectacle wear at 6 months for bilaterally implanted subjects. Reports of wearing glasses “None/ A little of the time” for overall spectacle wear was 74.4% of subjects in the TECNIS PureSee™ group and 50% of subjects in the control group.

Table 26
Frequency of Spectacle Wear for Distance, Intermediate, Near and Overall Vision

Condition	Frequency	TECNIS PureSee™ N=113		Control N=110	
		n	%	n	%
Distance Vision	None of the time	106	93.8%	96	87.3%
	A little of the time	0	0.0%	2	1.8%
	Some of the time	1	0.9%	6	5.5%
	Most of the time	2	1.8%	4	3.6%
	All of the time	4	3.5%	2	1.8%
Intermediate Vision	None of the time	88	77.9%	69	62.7%
	A little of the time	3	2.7%	5	4.5%
	Some of the time	9	8.0%	11	10.0%
	Most of the time	4	3.5%	13	11.8%
	All of the time	9	8.0%	12	10.9%
Near Vision	None of the time	30	26.5%	9	8.2%
	A little of the time	19	16.8%	10	9.1%
	Some of the time	18	15.9%	19	17.3%
	Most of the time	25	22.1%	24	21.8%
	All of the time	21	18.6%	48	43.6%
Overall Vision	None of the time	61	54.0%	35	31.8%
	A little of the time	23	20.4%	20	18.2%
	Some of the time	18	15.9%	42	38.2%
	Most of the time	5	4.4%	8	7.3%
	All of the time	6	5.3%	5	4.5%

Figure 9
Overall Spectacle Wear at 6 Months



Lens Findings

Lens findings was another pre-identified “additional endpoint” for supportive clinical information. The study was not designed for statistical comparison of this endpoint. Therefore, only descriptive statistics are presented here. There were no reports of any lens findings (e.g. lens instability, glistenings) at 6 months for TECNIS PureSee™ or control IOLs.

Fundus Visualization

Fundus visualization (primary safety endpoint) at 6 months was adequate for all first eyes (100.0%) and for the entire all-eyes group (first + second eye; 100.0%) in the study.

Ocular/ Visual Symptoms

The study pre-identified some "additional endpoints" as supportive clinical information, including ocular/visual symptoms. The study was not designed for statistical comparison of this endpoint. Therefore, only descriptive statistics are presented here. At 6 months, subjects in both lens groups spontaneously reported ocular/visual symptoms in response to the open-ended question, “Are you having any difficulties with your eyes or vision?” These subject-reported outcomes were documented for both lens groups (**Table 28**). The rates of optical/visual symptoms typically associated with presbyopia-correcting IOLs (i.e., halos, night glare and starbursts) were ≤5.3% for TECNIS PureSee™ and ≤4.5% for control, with none of the subjects in the TECNIS PureSee™ group and one subject (1/110, or 0.9%) in the control group reporting severe symptoms (**Table 27**).

Table 27
Spontaneous (Non-directed[a]) Reports of Ocular/Visual Symptoms (First Eyes) at 6 Months

	TECNIS PureSee™ N=113		Control N=110	
	n	**%**	**n**	**%**
Blurred Vision[b]				
Overall	5	4.4%	1	0.9%
Distance	3	2.7 %	0	0.0 %
Intermediate	3	2.7%	7	6.4%
Near	19	16.8%	22	20.0%
Decreased Vision[b]				
Overall	0	0.0%	0	0.0%
Distance	0	0.0%	0	0.0%
Intermediate	0	0.0%	0	0.0%
Near	1	0.9%	0	0.0%
Halos[b]	6	5.3%	5	4.5%
Mild	3	2.7%	4	3.6%
Moderate	3	2.7%	0	0.0%
Severe	0	0.0%	1	0.9%
Night Glare[b]	5	4.4%	2	1.8%
Mild	0	0.0%	1	0.9%
Moderate	5	4.4%	1	0.9%
Severe	0	0.0%	0	0.0%

Starbursts[b]	6	5.3%	1	0.9%
Mild	2	1.8%	1	0.9%
Moderate	4	3.5%	0	0.0%
Severe	0	0.0%	0	0.0%
Photophobia	8	7.1%	6	5.5%
Day glare	2	1.8%	1	0.9%
Night vision difficulty (overall)	2	1.8%	1	0.9%

% = (n/N)*100
Subjects may report multiple symptoms.
[a]Responses to the question, "Are you having any difficulties with your eyes or vision?"
[b]Severity collected in follow-up response.

In addition to spontaneous (non-directed) reports of visual symptoms, the validated Patient Reported Visual Symptoms Questionnaire (PRVSQv2) was included in the study as another "additional endpoint." The study was not designed for statistical comparison of this endpoint. Therefore, only descriptive statistics are presented here. Subjects were asked about seven specific visual symptoms in the PRVSQv2 that were defined. If they reported experiencing a particular symptom, they were then asked to rate how bothered they were by the symptom and if there was anything they had a lot of difficulty with, or did not do, because of the symptom. A subject may report multiple symptoms. In **Table 28** which presents the PRVSQv2 results, ≥70.8% of TECNIS PureSee™ subjects and ≥68.2% of control subjects reported that they did not experience halos, glare or starbursts. When reported, rates of very or extremely bothersome symptoms were ≤2.7% for TECNIS PureSee™ subjects and ≤5.5% for control subjects. The most common questionnaire-directed symptoms reported at 6 months were sensitivity to light and poor low light vision, with rates of "very" or "extreme" bother of ≤5.3% for TECNIS PureSee™ subjects and ≤3.6% for control subjects. At 6 months, difficulty with visual symptoms was reported with rates of ≤6.2% in the TECNIS PureSee™ group and of ≤7.3 % in the control group (**Table 29**).

Table 28
Experience/Bother With Visual Symptoms at 6 Months
(Directed Questionnaire)

		TECNIS PureSee™ N=113		Control N=110	
		n	%	n	%
Halos	Did not experience or NR	83	73.5%	75	68.2%
	Not at all bothered	10	8.8%	14	12.7%
	Slightly bothered	10	8.8%	13	11.8%
	Moderately bothered	7	6.2%	5	4.5%
	Very bothered	3	2.7%	3	2.7%
	Extremely bothered	0	0.0%	0	0.0%
Starbursts	Did not experience or NR	80	70.8%	81	73.6%
	Not at all bothered	8	7.1%	9	8.2%
	Slightly bothered	11	9.7%	12	10.9%
	Moderately bothered	11	9.7%	5	4.5%

	Very bothered	2	1.8%	3	2.7%
	Extremely bothered	1	0.9%	0	0.0%
Multiple or Double Vision	Did not experience or NR	97	85.8%	103	93.6%
	Not at all bothered	2	1.8%	0	0.0%
	Slightly bothered	7	6.2%	3	2.7%
	Moderately bothered	4	3.5%	2	1.8%
	Very bothered	3	2.7%	1	0.9%
	Extremely bothered	0	0.0%	1	0.9%
Sensitivity to Light	Did not experience or NR	62	54.9%	61	55.5%
	Not at all bothered	5	4.4%	3	2.7%
	Slightly bothered	28	24.8%	19	17.3%
	Moderately bothered	11	9.7%	20	18.2%
	Very bothered	6	5.3%	4	3.6%
	Extremely bothered	1	0.9%	3	2.7%
Glare Related to Scattered Light	Did not experience or NR	92	81.4%	91	82.7%
	Not at all bothered	2	1.8%	2	1.8%
	Slightly bothered	12	10.6%	10	9.1%
	Moderately bothered	4	3.5%	1	0.9%
	Very bothered	3	2.7%	6	5.5%
	Extremely bothered	0	0.0%	0	0.0%
Occlusions	Did not experience or NR	110	97.3%	109	99.1%
	Not at all bothered	1	0.9%	1	0.0%
	Slightly bothered	1	0.9%	0	0.0%
	Moderately bothered	1	0.9%	0	0.0%
	Very bothered	0	0.0%	1	0.9%
	Extremely bothered	0	0.0%	0	0.0%
Poor Low Light Vision	Did not experience or NR	62	54.9%	72	65.5%
	Not at all bothered	7	6.2%	8	7.3%
	Slightly bothered	31	27.4%	16	14.5%
	Moderately bothered	8	7.1%	11	10.0%
	Very bothered	4	3.5%	3	2.7%
	Extremely bothered	1	0.9%	0	0.0%

% = (n/N)*100
NR = Not Reported

Table 29
Difficulty With Activity Due to Visual Symptoms at 6 Months

(Directed Questionnaire)		TECNIS PureSee™ N=113		Control N=110	
		n	%	n	%
Halos	Did not experience or NR	83	73.5%	75	68.2%
	No	26	23.0%	34	30.9%
	Yes	4	3.5%	1	0.9%
Starbursts	Did not experience or NR	80	70.8%	81	73.6%
	No	28	24.8%	27	24.5%
	Yes	5	4.4%	2	1.8%
Multiple or Double Vision	Did not experience or NR	97	85.8%	103	93.6%
	No	12	10.6%	5	4.5%
	Yes	4	3.5%	2	1.8%
Sensitivity to Light	Did not experience or NR	62	54.9%	61	55.5%
	No	46	40.7%	42	38.2%
	Yes	5	4.4%	7	6.4%
Glare Related to Scattered Light	Did not experience or NR	92	81.4%	91	82.7%
	No	16	14.2%	15	13.6%
	Yes	5	4.4%	4	3.6%
Occlusions	Did not experience or NR	110	97.3%	109	99.1%
	No	3	2.7%	0	0.0%
	Yes	0	0.0%	1	0.9%
Poor Low Light Vision	Did not experience or NR	62	54.9%	72	65.5%
	No	44	38.9%	30	27.3%
	Yes	7	6.2%	8	7.3%

% = (n/N)*100
NR = Not Reported

Adverse Events

One of the co-primary safety endpoints was persistent and cumulative rates of ISO 11979-7 SPE adverse events (AEs) among first eyes and all eyes in the TECNIS PureSee™ lens group. This primary safety endpoint met the study success criteria because the rates were below or not statistically significantly higher than the ISO SPE rates (**Table 30 and Table 31**). Overall, there were 2 SAEs in first eyes and 3 SAEs in all eyes associated with ISO SPEs.

Table 30
6-Month Persistent Adverse Events vs. ISO 11979-7 SPE[a] Rates
TECNIS PureSee™ Group

	ISO SPE Rate	First Eyes N=113		All Eyes N=226	
Persistent Medical Complication/Adverse Event	**%**	**n (%)**	**Lower Limit of 1-sided 95% CI**	**n (%)**	**Lower Limit of 1-sided 95% CI**
Corneal edema	0.3	0 (0.0%)	0.00	0 (0.0%)	0.00
Cystoid macular edema	0.5	1 (0.9%)	0.05	2 (0.9%)	0.16
Iritis	0.3	0 (0.0%)	0.00	0 (0.0%)	0.00
Raised IOP requiring treatment	0.4	0 (0.0%)	0.00	0 (0.0%)	0.00

[a] SPE: Safety and Performance Endpoint.
Confidence intervals were calculated using the Clopper-Pearson method.

Table 31
6-Month Cumulative Adverse Events vs. ISO 11979-7 SPE[a] Rates
TECNIS PureSee™ Group

	ISO SPE Rate	First Eyes N=115		All Eyes N=230	
Cumulative Medical Complication/Adverse Event	**%**	**n (%)**	**1-sided 95% Lower CI**	**n (%)**	**1-sided 95% Lower CI**
Cystoid macular edema[b]	3.0	1 (0.9%)	0.04	3 (1.3%)	0.36
Hypopyon	0.3	0 (0.0%)	0.00	0 (0.0%)	0.00
Endophthalmitis	0.1	0 (0.0%)	0.00	0 (0.0%)	0.00
Lens dislocated from posterior chamber	0.1	0 (0.0%)	0.00	0 (0.0%)	0.00
Pupillary block	0.1	0 (0.0%)	0.00	0 (0.0%)	0.00
Retinal detachment	0.3	0 (0.0%)	0.00	0 (0.0%)	0.00
Eyes with secondary surgical intervention[c]	0.8	1 (0.9%)	0.04	1 (0.4%)	0.02
○ Device related	-	0 (0.0%)	0.00	0 (0.0%)	0.00
○ Not device related	-	1 (0.9%)	0.04	1 (0.4%)	0.02

% = (n/N) *100
[a] SPE: Safety and Performance Endpoint.
[b] All incidence of cystoid macular edema reported per ISO, regardless of clinical significance as defined by Masket et al. AAO Task Force criteria.
[c] Excluding wound burp.
Confidence intervals were calculated using the Clopper-Pearson method.

Another co-primary safety endpoint was secondary surgical interventions (SSIs) related to the optical properties of the IOL. During the pivotal trial there were zero SSIs related to the optical properties of the IOL (e.g., no device related SSIs) (**Table 32**). SSIs that were unrelated to the optical properties of the IOL, including non-ISO SPE SSIs procedures (such as tap, wound burp, and paracentesis) are listed in **Table 32**.

Table 32
Secondary Surgical Interventions by IOL Group

	TECNIS PureSee™				Control			
	First Eyes N=115		All Eyes N=230		First Eyes N=113		All Eyes N=226	
	n	%	n	%	n	%	n	%
Secondary Surgical Interventions (SSIs)								
○ Anterior chamber washout for retained lens material	1	0.9%	1	0.4%	0	0.0%	0	0.0%
○ Wound burp	0	0.0%	2	0.9%	2	1.8%	3	1.3%
○ Pars plana vitrectomy for vitreous in the anterior chamber	0	0.0%	0	0.0%	0	0.0%	1	0.4%
○ Related to Optical Properties	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Total Eyes with SSIs	**1**	**0.9%**	**3**	**1.3%**	**2**	**1.8%**	**4**	**1.8%**

% = (n/N) *100

The incidence of all other non-SPE serious AEs and/or device-related adverse events for eyes in the test lens group was also a co-primary safety endpoint (**Table 33 and Table 34**). In the TECNIS PureSee™ group, the incidence rates of non-SPE ocular serious and/or device-related adverse events (AEs; primary safety endpoint) were 4.3% (5/115) for first eyes and 4.8% (11/230) for all eyes.

- Non-SPE SAEs: 1.7% (2/115) of TECNIS PureSee™ first eyes and 2.6% (6/230) of all eyes experienced increased intraocular pressure (IOP), deemed as serious but non-device related; all events were resolved without sequelae.

- Non-SPE ADEs: 2.6% (3/115) of TECNIS PureSee™ first eyes and 2.2% (5/230) of all eyes reported undesirable optical phenomena (or inadequate visual clarity) deemed device-related but non-serious; of these, 4 (from 2 subjects) from the all-eyes set were ongoing at study end. Only 1 (0.9%) subject in the TECNIS PureSee™ group reported optical phenomena to cause bother or difficulty that interfered with daily activity for more than 3 months.

Table 33
Ocular Non-SPE Related Serious and/or Device-Related Adverse Events
Safety Population - First Eyes

	TECNIS PureSee™ N=115		Control N=113	
Adverse Event	**n (%)**	**95% CI**	**n (%)**	**95% CI**
Inadequate visual clarity	1 (0.9)	(0.02, 4.75)	0 (0.0)	(0.00, 3.21)
Increased IOP	2 (1.7)	(0.21, 6.14)	3 (2.7)	(0.55, 7.56)
Undesirable optical phenomena	2 (1.7)	(0.21, 6.14)	3 (2.7)	(0.55, 7.56)
Total[a]	5 (4.3)	(1.43, 9.85)	6 (5.3)	(1.97, 11.20)

Confidence intervals are calculated using the Clopper-Pearson method.
[a] Total represents the number of unique eyes with at least 1 event.

Table 34
Ocular Non-SPE Related Serious and/or Device-Related Adverse Events
Safety Population - All Eyes

	TECNIS PureSee™ N=230		Control N=226	
Adverse Event	**n (%)**	**95% CI**	**n (%)**	**95% CI**
Inadequate visual clarity	2 (0.9)	(0.11, 3.11)	0 (0.0)	(0.00, 1.62)
Increased IOP	6 (2.6)	(0.96, 5.59)	4 (1.8)	(0.48, 4.47)
Undesirable optical phenomena	3 (1.3)	(0.27, 3.76)	6 (2.7)	(0.98, 5.69)
Total[a]	11 (4.8)	(2.41, 8.40)	10 (4.4)	(2.14, 7.99)

Confidence intervals are calculated using the Clopper-Pearson method.
[a] Total represents the number of unique eyes with at least 1 event.

Additional safety measurements based on the modified consensus definitions as set forth by the American Academy of Ophthalmology's Task Force (Masket et al. Ophthalmology 2017) are shown in **Table 35**.

Table 35
Ocular Adverse Events Based on a Modified Version of the AAO Task Force Consensus (Masket, et al 2017 reference)

	First Eyes		All Eyes		Subjects	
Adverse Event	**TECNIS PureSee™ N=115 n (%)**	**Control N=113 n (%)**	**TECNIS PureSee™ N=230 n (%)**	**Control N=226 n (%)**	**TECNIS PureSee™ N=115 n (%)**	**Control N=113 n (%)**
Increased IOP	3 (2.6)	7 (6.2)	7 (3.0)	9 (4.0)	6 (5.2)	8 (7.1)
Chronic anterior uveitis	2 (1.7)	0 (0.0)	3 (1.3)	0 (0.0)	3 (2.6)	0 (0.0)
Clinically significant cystoid macular edema	0 (0.0)	1 (0.9)	0 (0.0)	2 (0.9)	0 (0.0)	2 (1.8)
Corneal edema	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Toxic anterior segment syndrome	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Endophthalmitis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Mechanical pupillary block	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Rhegmatogenous RD	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Secondary IOL intervention	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Exchange	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Removal	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Reposition	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

% = n/N
Adverse Events are presented in descending order by the incidence rate of TECNIS PureSee™ first eyes.
n=Number of unique eyes or unique subject.

Visual Acuity Related Primary Safety Endpoints

Another co-primary safety endpoint was the percentage of eyes achieving BCDVA 0.30 logMAR or better acuity in the test lens group, as described in ISO 11979-7:2024, at the 6-month visit. The success criterion for the primary safety endpoint was achieved, as 100% of first eyes and all eyes in safety population and 100% of first eyes in best-case population achieved BCDVA 0.30 LogMAR (**Table 36**).

Table 36
Monocular Best-Corrected Distance Visual Acuity of 0.30 LogMAR or Better at 6 Months vs ISO 11979-7 SPE[a] Rates

Analysis Population	Cohort	LogMAR Threshold	ISO SPE (%)	n (%)	Upper bound of 1-sided 95% CI
Safety Population	First Eyes (N=113)	┤ 0.30	92.5	113 (100.0)	100.00
	All Eyes (N=226)	┤ 0.30	92.5	226 (100.0)	100.00
Best Case Population	First Eyes (N=112)	┤ 0.30	96.7	112 (100.0)	100.00

[a] SPE: Safety and Performance Endpoint.
Confidence intervals are calculated using the Clopper-Pearson method.

Mean monocular photopic BCDVA at 4 meters (first eyes and all eyes) in the test lens group is non-inferior to the control lens group by 0.10 logMAR margin, at the 6-month visit, was also a co-primary safety endpoint. Among first eyes in the SP at 6 months, the difference in mean monocular BCDVA between lens groups was -0.04 LogMAR. The lower limit of the 2-sided 90% CI of the mean difference was -0.06, which was greater than the -0.10 LogMAR non-inferiority margin; thus, the statistical success criterion of this primary safety endpoint was met. Similar to the first-eye results, for all eyes in the SP at 6 months, the difference in mean monocular (all-eye) BCDVA between lens groups was -0.04 LogMAR. The lower limit of the 2-sided 90% CI of the mean difference was -0.05, which was greater than the -0.10 LogMAR non-inferiority margin; thus, the statistical success criterion of this primary safety endpoint was also met (**Table 37**).

Table 37
Monocular Best-Corrected Distance Visual Acuity at 4 m at 6 Months
Safety Population

Cohort	Lens Group	N	Mean Monocular LogMAR	Monocular Snellen Equiv.	90% CI
First Eyes	TECNIS PureSee™	113	-0.04	20/18	(-0.05, -0.03)
	Control	110	-0.08	20/16	(-0.09, -0.06)
	Difference		-0.04	-0.4 lines [a]	(-0.06, -0.02)
All Eyes	TECNIS PureSee™	226	-0.04	20/18	(-0.05, -0.03)
	Control	220	-0.08	20/16	(-0.09, -0.07)
	Difference		-0.04	-0.4 lines [a]	(-0.05, -0.03)

[a] Line difference (Control minus TECNIS PureSee™) converted directly from LogMAR difference.
Non-inferiority margin of -0.10 LogMAR.

Finally, monocular (first eyes) mesopic contrast sensitivity (CS) without glare at 6 months was another co-primary safety endpoint. The between-lens groups differences in mean monocular CS values under mesopic conditions without glare were ┤ 0.3 log units at all spatial frequencies, meeting the clinical success criterion of the primary safety endpoint. The median differences (50th percentile) were ┤ 0.3 log units at all spatial frequencies. Notably, all subjects in both lens groups were able to detect the threshold CS pattern for first eyes under mesopic conditions without glare. Overall, results were comparable between lens groups (**Table 25**).

RELATED CLINICAL STUDIES

The TECNIS PureSee™ IOL, Model DEN00V and Toric II IOLs, Models DET150, DET225, DET300, and DET375 incorporate the same posterior design, so the same parent IOL studies are applicable to both. The data from other relevant clinical studies are included to support the safety and effectiveness of the TECNIS PureSee™ IOLs:

1. The TECNIS PureSee™ Toric II IOLs incorporate the same toric feature on the anterior optic surface found on their toric parent TECNIS™ Toric 1-Piece IOLs, Models ZCT150, ZCT225, ZCT300 and ZCT400 approved under P980040/S039. Due to the potential for an interaction between the toric and extended depth-of-focus (EDF) components of the toric device models, DET150, DET225, DET300 and DET375, an optical-bench study examining image quality was conducted with the highest toric power model IOL, DET 375, to demonstrate that the EDF effect of the TECNIS PureSee™ Toric II IOLs is maintained in the presence of misalignment (i.e., clinically-relevant amounts of tilt, decentration and rotation). Therefore, the clinical study results for the TECNIS™ Toric 1-Piece IOLs apply to the TECNIS PureSee™ Toric II IOLs, Models DET150, DET225, DET300 and DET375.

2. The TECNIS PureSee™ IOLs share the same 1-piece platform as the clinically studied mechanical parent, the SENSAR™ 1-Piece IOL, Model AAB00 approved under P980040/S015. Therefore, the clinical results for the SENSAR™ 1-Piece IOL, Model

AAB00 apply to the TECNIS PureSee™ IOL, Model DEN00V and the TECNIS PureSee™ Toric II IOLs, Models DET150, DET225, DET300 and DET375.

3. The TECNIS PureSee™ IOLs are made of the same soft acrylic material of the clinically studied TECNIS™ 3-Piece OptiBlue™ IOL, Model ZV9003 approved under P980040/S035. Therefore, the clinical results for the TECNIS™ 3-Piece OptiBlue™ IOL, Model ZV9003 apply to the TECNIS PureSee™ IOL, Model DEN00V and the TECNIS PureSee™ Toric II IOLs, Models DET150, DET225, DET300 and DET375.

CLINICAL STUDY RESULTS: TECNIS ™ TORIC 1-PIECE IOLS, MODELS ZCT150, ZCT225, ZCT300, AND ZCT400

A clinical investigation of the TECNIS™ Toric 1-Piece IOLs, Models ZCT150, ZCT225, ZCT300 and ZCT400, was conducted at 14 sites in the United States and Canada between March 2010 and September 2011. This pivotal, prospective, multicenter, two-armed, bilateral, 6-month clinical study was designed to evaluate the safety and effectiveness, including the ability to reduce astigmatism, of the TECNIS™ Toric 1-Piece lenses. The first arm of the study, referred to as the Randomized Control Arm (RCA), was a randomized, comparative, subject and technician-masked evaluation of the TECNIS™ Toric 1-Piece IOL, Model ZCT150, compared to a monofocal control, the TECNIS™ 1-Piece IOL, Model ZCB00. The second arm of the study, referred to as the Open Label Arm (OLA), was an open-label, non-comparative clinical trial of the TECNIS™ Toric 1-Piece IOL, Models ZCT225, ZCT300, and ZCT400. In order to facilitate toric IOL selection and axis placement, a web-based, proprietary TECNIS™ Toric IOL Calculator was used to determine the appropriate TECNIS™ Toric IOL model and axis of placement for each eye.

The 6-month results demonstrated that the TECNIS™ Toric 1-Piece IOLs, Models ZCT150, ZCT225, ZCT300 and ZCT400, are safe and effective for the visual correction of aphakia. The results demonstrated that the TECNIS™ Toric 1-Piece IOLs exhibit minimal rotation with sound rotational stability, leading to a significant reduction or elimination of residual refractive cylinder in most cases. As a result, subjects implanted with the TECNIS™ Toric 1-Piece IOLs experienced improved uncorrected distance visual acuity compared to control values. In the data summary, all results presented are for the safety population of all treated subjects.

Subject Population

A total of 269 subjects were enrolled and implanted: 197 were in the RCA and 72 in the OLA. Of the 197 in the RCA, 102 were implanted in the first eye with a Model ZCT150 toric lens and 95 were implanted in the first eye with the control lens. Of the 72 in the OLA, 17 were implanted with the ZCT225 lens in the first eye and 55 with either ZCT300 or ZCT400. Overall, 174 first eyes were implanted with a TECNIS™ Toric 1-Piece IOL.

In the RCA, the ZCT150 population consisted of 53.9% females and ZCB00 control population consisted of 57.9% females; in the OLA, the study population consisted of 55.6% females. Stratifying by race, the ZCT150 population consisted of 94.1% Caucasian, 3.9% African American, and 2.0% Asian; the ZCB00 control population consisted of 95.8% Caucasian, 3.2% African

American and 1.1% Asian; and the OLA group consisted of 94.4% Caucasian, 4.2% African American and 1.4% Asian. The mean ages were 69.9 years for the ZCT150 population, 71.3 years for the ZCB00 control population and 68.8 years for the OLA population.

Reduction in Cylinder

No statistically significant differences were observed in preoperative keratometric cylinder or target refractive cylinder between ZCT150 toric and ZCB00 control eyes in the RCA; however, statistically significant differences were observed for mean refractive cylinder and the mean percent reduction in cylinder in favor of the ZCT150 lens group compared to the ZCB00 control at 6 months postoperative (**Table 38**). Additionally, the mean percent reduction in cylinder for OLA first eyes at 6 months was statistically significantly higher than the target value of 25%. For all toric first eyes in the RCA and OLA safety populations combined (N=171), the mean percent reduction in cylinder was 75.24 (standard deviation [SD]=59.29).

Table 38
Mean Cylinder and Percent Reduction in Cylinder at Six Months
First Eyes[a] – Randomized Control Arm and Open Label Arm

VARIABLE	Randomized Control Arm Lens Model	N[a]	Mean	SD	P-Value	Open Label Arm Lens Model	N[a]	Mean	SD	P-Value
Preop Keratometric Cylinder (K_{cyl}; D)	Control	91	1.11	0.24	0.3436	Pooled	70	2.16	0.66	N/A
	ZCT150	101	1.08	0.28		ZCT225	17	1.58	0.28	
						ZCT300	24	1.91	0.46	
						ZCT400	29	2.70	0.55	
Target Refractive Cylinder (D)	Control	91	0.26	0.18	0.6267	Pooled	70	0.26	0.30	N/A
	ZCT150	101	0.25	0.17		ZCT225	17	0.12	0.10	
						ZCT300	24	0.19	0.12	
						ZCT400	29	0.41	0.40	
Refractive Cylinder (D)	Control	91	0.85	0.57	**<0.0001**	Pooled	70	0.67	0.47	N/A
	ZCT150	101	0.45	0.41		ZCT225	17	0.49	0.37	
						ZCT300	24	0.62	0.43	
						ZCT400	29	0.82	0.52	
Percent Cylinder Reduction[b]	Control	91	31.61	78.73	**<0.0001**	Pooled	70	76.27	33.09	**<0.0001[c]**
	ZCT150	101	74.53	72.25		ZCT225	17	73.78	27.17	
						ZCT300	24	72.03	38.57	
						ZCT400	29	81.23	31.78	

[a] Eyes with both preoperative and postoperative data
[b] Percent Reduction ANSI Formula=(Postop Ref. Cyl. minus Preop K. Cyl.)/(Target Ref. Cyl. minus Preop K. Cyl.); ANSI formula used except for a few eyes in the RCA with very small denominators (within ±0.1); for these eyes the ANSI formula was used but without the target value.
[c] Versus OLA target of 25% reduction

The TECNIS™ Toric IOL Calculator utilizes preoperative keratometry and a surgeon estimated surgically induced astigmatism (SIA) value to calculate the expected postoperative keratometry and provide options for toric IOL selection. An analysis of the errors in the calculation of postoperative keratometry was performed using vector arithmetic. Results showed that error in magnitude prediction was on average 0.32D (with a median value of 0.25D due to bias toward lower values) and error in meridian prediction was on average 16° (with a median value of 8°, again with bias toward lower values). It is important to note that measurement noise in keratometry (estimated from 0.20D to 0.8D for magnitude[1,2] and up to 20□for axis[2]) and any potential errors in surgeon-estimated SIA are contributing factors to prediction errors of postoperative keratometry.

The absolute difference between refractive cylinder at 6 months vs. the target is presented in **Table 39**. In the RCA, 72.3% (73/101) of ZCT150 eyes compared to 49.5% (45/91) of ZCB00 eyes were within 0.50D of target refractive cylinder; additionally, 94.1% (95/101) of ZCT150 eyes compared to 70.3% (64/91) of ZCB00 eyes were within 1.00D of target refractive cylinder. In the OLA, 52.9% (37/70) were within 0.50D and 84.3% (59/70) were within 1.00D of target refractive cylinder.

Table 39
Absolute Difference between Refractive Cylinder at Six Months vs. Target First Eyes – Randomized Control Arm and Open Label Arm

Diopter Group	Randomized Control Arm				Open Label Arm		All Toric Eyes[a]	
	ZCT150 N=101		ZCB00 Control N=93		ZCT225, ZCT300, ZCT400 N=71		ZCT150, ZCT225, ZCT300, ZCT400 N=172	
	n	%	n	%	n	%	n	%
>2.0	0	0.0	0	0.0	0	0.0	0	0.0
1.51-2.00	1	1.0	6	6.6	2	2.9	3	1.8
1.01-1.50	5	5.0	21	23.1	9	12.9	14	8.2
(≤1.00)	**95**	**94.1**	**64**	**70.3**	**59**	**84.3**	**154**	**90.0**
0.51-1.00	22	21.8	19	20.9	22	31.4	44	25.7
(≤0.50)	**73**	**72.3**	**45**	**49.5**	**37**	**52.9**	**110**	**64.3**
Total Tested	101	100.0	91	100.0	70	100.0	171	100.0
Not Reported	0		2		1		1	

%=n/Total Tested

[a] As control eyes had ≤1.5 D of preoperative K_{cyl} only, results for all toric eyes pooled are not to be compared to control values

Subgroup Analysis

Cylinder outcomes in the RCA were stratified by preoperative K_{cyl} alone and by predicted K_{cyl} (i.e., vector sum of preoperative K_{cyl}, magnitude and axis, SIA, and incision axis) in 0.25D increments as shown in **Table 40**, **Table 41**, and **Table 42**.

[1] Zadnik K K, Mutti D, Adams A. The repeatability of measurement of the ocular components. Invest Ophthalmol Vis Sci. 1992 Jun; 33(7): 2325-33.
[2] Visser N, Berendschot T, Verbakel F, de Brabander J, Nuijts R. Comparability and repeatability of corneal astigmatism measurements using different measurement technologies. J. Cataract Refract Surg. 2012 Oct; 38(1): 1764-70.

Table 40
Achieved Cylinder Reduction as a Percentage of Intended Reduction (Percent Reduction in Cylinder ANSI Formula) at 6 Months Stratified by Keratometric Cylinder First Eyes Randomized Control Arm ZCT150 and ZCB00

Model	Preoperative Keratometric Cylinder (D)	N	Percent Reduction in Cylinder (ANSI)[a] Mean	SD	Predicted Keratometric Cylinder (D)[b] (Preop K_{cyl} + SIA)	N	Percent Reduction in Cylinder (ANSI)[a] Mean	SD
ZCB00	<0.75	4	-45.26	80.51	<0.75	13	-1.28	136.54
ZCT150		5	-79.77	51.59		16	78.20	122.83
ZCB00	0.75-0.99	22	32.32	111.09	0.75-0.99	23	7.39	48.81
ZCT150		30	69.20	87.53		21	55.38	58.57
ZCB00	1.00-1.24	34	41.06	68.41	1.00-1.24	31	43.44	59.77
ZCT150		38	94.88	52.09		36	61.88	49.80
ZCB00	1.25-1.49	27	32.31	60.95	1.25-1.49	20	45.09	73.00
ZCT150		22	74.82	45.78		26	100.27	63.21
ZCB00	≥1.50	4	19.43	17.23	≥1.50	4	118.57	50.01
ZCT150		6	99.88	32.32		2	139.43	31.58
ZCB00	**All**	91	31.61	78.73	**All**	91	31.61	78.73
ZCT150		101	74.53	72.25		101	74.53	72.25

[a] Percent Cylinder Reduction (ANSI Formula)=(Postop Ref. Cyl. minus Preop K_{cyl})/(Target Ref. Cyl. minus Preop K_{cyl}); Percent cylinder reduction (ANSI formula) adjusted for eyes (3) with small denominators (±0.10) where target value was not used.

[b] Predicted keratometric cylinder is the vector combination of preoperative keratometric cylinder (magnitude and axis), estimated SIA and incision axis.

Table 41
Residual Refractive Cylinder at 6 Months Stratified by Keratometric Cylinder First Eyes Randomized Control Arm ZCT150 and ZCB00

Model	Preoperative Keratometric Cylinder (D)	N	Residual Refractive Cylinder (D) Mean	SD	Predicted Keratometric Cylinder (D)[a] (Preop K_{cyl} + SIA)	N	Residual Refractive Cylinder (D) Mean	SD
ZCB00	<0.75	5	0.85	0.42	<0.75	14	0.77	0.49
ZCT150		5	0.91	0.14		16	0.55	0.43
ZCB00	0.75-0.99	22	0.56	0.50	0.75-0.99	23	1.03	0.51
ZCT150		30	0.50	0.40		21	0.43	0.33
ZCB00	1.00-1.24	34	0.80	0.55	1.00-1.24	31	0.84	0.68
ZCT150		38	0.36	0.36		36	0.48	0.45
ZCB00	1.25-1.49	27	1.09	0.59	1.25-1.49	21	0.84	0.52
ZCT150		22	0.48	0.49		26	0.39	0.43
ZCB00	≥1.50	5	1.35	0.28	≥1.50	4	0.43	0.42
ZCT150		6	0.34	0.44		2	0.38	0.18
ZCB00	**All**	93	0.86	0.57	**All**	93	0.86	0.57
ZCT150		101	0.45	0.41		101	0.45	0.41

[a] Predicted keratometric cylinder is the vector combination of preoperative keratometric cylinder (magnitude and axis), estimated SIA and incision axis.

Table 42
Change in Absolute Cylinder[a] at Six Months Stratified by Keratometric Cylinder First Eyes Randomized Control Arm ZCT150 and ZCB00

Model	Preoperative Keratometric Cylinder (D)	N	Reduction >0.50 D n	Reduction >0.50 D %	Absolute Cylinder Change ≤ +/-0.50 D[b] n	Absolute Cylinder Change ≤ +/-0.50 D[b] %	Increase >0.50 D n	Increase >0.50 D %	Predicted Keratometric Cylinder (D)[c] (Preop K_{cyl} + SIA)	N	Reduction >0.50 D n	Reduction >0.50 D %	Absolute Cylinder Change ≤ +/-0.50 D[b] n	Absolute Cylinder Change ≤ +/-0.50 D[b] %	Increase >0.50 D n	Increase >0.50 D %
ZCB00	<0.75	5	0	0.00	4	80.00	1	20.0	<0.75	14	2	14.29	10	71.43	2	14.29
ZCT150		5	0	0.00	4	80.00	1	20.0		16	5	31.25	9	56.25	2	12.50
ZCB00	0.75-0.99	22	7	31.82	13	59.09	2	9.09	0.75-0.99	23	2	8.70	18	78.26	3	13.04
ZCT150		30	10	33.33	19	63.33	1	3.33		21	15	71.43	6	28.57	0	0.00
ZCB00	1.00-1.24	34	12	35.29	19	55.88	3	8.82	1.00-1.24	31	12	38.71	17	54.84	2	6.45
ZCT150		38	29	76.32	9	23.68	0	0.00		36	22	61.11	14	38.89	0	0.00
ZCB00	1.25-1.49	27	9	33.33	16	59.26	2	7.41	1.25-1.49	21	10	47.62	10	47.62	1	4.76
ZCT150		22	18	81.82	4	18.18	0	0.00		26	19	73.08	7	26.92	0	0.00
ZCB00	≥1.50	5	1	20.00	4	80.00	0	0.00	≥1.50	4	3	75.00	1	25.00	0	0.00
ZCT150		6	6	100.0	0	0.00	0	0.00		2	2	100.0	0	0.00	0	0.00
ZCB00	**All**	93	29	31.18	56	60.22	8	8.60	**All**	93	29	31.18	56	60.22	8	8.60
ZCT150		101	63	62.38	36	35.64	2	1.98		101	63	62.38	36	35.64	2	1.98

[a] Change in Absolute Cylinder=Postop Ref. Cyl minus Preop K_{cyl}
[b] Not all eyes were targeted for a reduction in absolute cylinder greater than 0.50 D; therefore, some eyes that achieved the intended cylinder change will be included in the ± 0.50 D column
[c] Predicted keratometric cylinder is the vector combination of preoperative keratometric cylinder (magnitude and axis), estimated SIA and incision axis.

Distance Visual Acuities

In the RCA, a statistically significant improvement (p=0.0009) in mean monocular UCDVA at 6 months was found in favor of ZCT150 (0.10 LogMAR, SD 0.14; Snellen equivalent 20/25) over the ZCB00 control group (0.16 LogMAR, SD 0.16; Snellen equivalent 20/29) by 0.6 lines. In the OLA, mean UCDVA was 0.11 LogMAR (SD 0.12; Snellen equivalent 20/26). For all toric eyes in the RCA and OLA combined (N=172), mean UCDVA was 0.10 LogMAR (SD 0.13; Snellen equivalent 20/25).

In the RCA, statistically significant differences in the distribution of monocular UCDVA results were observed at 6 months group with higher proportions of ZCT150 eyes achieving 20/20 or better (43.6%; p=0.0026) and 20/40 or better (97.0%; p=0.0092) vs. ZCB00 control eyes (23.7% and 87.1%, respectively). In the OLA, a statistically significantly (p<0.0001) greater proportion of eyes achieved UCDVA of 20/20 or better (38.0%) vs. target (6%); additionally, 97.2% of OLA eyes achieved UCDVA of 20/40 or better.

At 6 months, 100% of all toric first eyes and 100% of best-case toric first eyes in the RCA and OLA combined achieved BCDVA of 20/40 or better, exceeding the ISO BCDVA Safety and Performance Endpoint (SPE) rates for overall (92.5%) and best-case (96.7%). Additionally, 88.4% of all toric eyes achieved BCDVA of 20/20 or better.

Rotational Stability

The degree of lens axis rotation between time points was measured using a direct photographic method. **Table 43** presents the change in axis rotation between stability time points (1 to 3 months and 3 to 6 months) for toric first eyes. The TECNIS™ Toric 1-Piece IOLs achieved the Z80.30 ANSI Standard for Toric IOLs, rotational stability requirement (>90% of eyes having ≤5° axis change between consecutive visits approximately three months apart) as ≥93% of toric first eyes had a change in axis of ≤5° between stability visits approximately three months apart.

Table 43
Absolute Difference in Axis Alignment Between Visits
First Eyes – All Toric ZCT150, ZCT225, ZCT300, ZCT400 Pooled

Axis Shift (degrees)	Toric Eyes: Consistent Cases[a]				Toric Eyes with Data at Two or More Consecutive Visits[b]			
	1 Month vs. 3 Months		3 Months vs. 6 Months		1 Month vs. 3 Months		3 Months vs. 6 Months	
	n	%	n	%	n	%	n	%
>30	0	0.0	0	0.0	0	0.0	0	0.0
16-30	0	0.0	0	0.0	0	0.0	0	0.0
10-15	2	1.4	3	2.0	2	1.3	3	2.0
(<10)	146	98.6	145	98.0	154	98.7	149	98.0
6-9	9	6.1	6	4.1	9	5.8	6	3.9
0-5	**137**	**92.6[c]**	**139**	**93.9[c]**	**145**	**92.9[c]**	**143**	**94.1[c]**
Total	**148**	**100.0**	**148**	**100.0**	**156**	**100.0**	**152**	**100.0**

[a]Eyes with photographic axis data at all visits through six months.
[b]Eyes with photographic axis data at two or more consecutive visits but not necessarily all visits.
[c] Results achieved the ANSI Standard for Toric IOLs, Z80.30 rotational stability requirements (>90% of eyes having ≤5° axis change between consecutive visits approximately three months apart)

Table 44 presents the axis change for toric eyes between the baseline (1-day) and 6-month visits. Of toric first eyes, 97% had <10° of axis change between baseline and six months.

Table 44
Absolute Difference in Axis Alignment between 1 Day and 6 Months
First Eyes – All Toric ZCT150, ZCT225, ZCT300, ZCT400 Pooled

Axis Shift (degrees)	Toric Eyes: Consistent Cases[a]		Toric Eyes with Data at One Day and Six Months	
	1 Day vs. 6 Months		1 Day vs. 6 Months	
	n	%	N	%
>30	2[b]	1.4	2[b]	1.3
16-30	3[c,d]	2.0	3[c,d]	1.9
10-15	0	0.0	0	0.0
(<10)	**143**	**96.6**	**151**	**96.8**
6-9	4	2.7	4	2.6
0-5	139	93.9	147	94.2
Total	**148**	**100.0**	**156**	**100.0**

[a] Eyes with photographic axis data at all visits through six months
[b] Two ZCT400 eyes with calculated rotation of 40° and 45° underwent repositioning procedures
[c] Two ZCT300 eyes with calculated rotation of 18° and 21° underwent repositioning procedures
[d] One ZCT150 eye with calculated lens rotation 24° was not repositioned.

Table 45 presents mean axial rotation between stability time points (1 to 3 months and 3 to 6 months) as well as overall (baseline to 6 months). Mean axial rotation was minimal (<3°) whether taking direction of axis shift into account or regardless of direction (absolute value).

Table 45
Mean Change Axis
Difference Taking Direction into Account (±Sign Included)
And Degree Shift Regardless of Direction (Absolute Value)
First Eyes – All Toric ZCT150, ZCT225, ZCT300, ZCT400 Pool

Change in Axis Between Visits	Toric Eyes: Consistent Cases[a]			Toric Eyes with Data at Two or More Visits[b]		
	N	Mean (degrees)	SD	N	Mean (degrees)	SD
1 Month vs. 3 Month	148	0.24	2.82	156	0.25	2.77
3 Month vs. 6 Month	148	-0.06	2.94	152	-0.09	2.9 6
Baseline (1 Day) vs. 6 Month	148	-1.35	6.13	156	-1.33	5.99
Abs. Value: 1 Month vs. 3 Month	148	1.82	2.17	156	1.79	2.12
Abs. Value: 3 Month vs. 6 Month	148	1.85	2.28	152	1.89	2.27
Abs. Value: Baseline (1 Day) vs. 6 Month	148	2.74	5.65	156	2.70	5.51

[a] Eyes with photographic axis data at all visits through six months
[b] Eyes with photographic axis data at two or more visits but not necessarily all visits

Adverse Events

The cumulative adverse event incidence rates for the TECNIS™ Toric ZCT IOL first eyes compared favorably to the ISO SPE rates (**Table 46**). The rate of secondary surgical interventions (SSIs, 3.4%; 6/174) was statistically significantly higher than the ISO SPE rate of 0.8%. Four lens-related repositioning procedures were performed in toric eyes to correct a rotated IOL; however, the rate for lens-related SSIs (2.3%; 4/175) was not statistically significantly higher than the ISO SPE rate for SSIs. The lens repositioning procedures occurred in ZCT300 and ZCT400 first eyes only (7.3%; 4/55); no ZCT300 or ZCT400 second eyes underwent lens repositioning procedures, thereby yielding an overall rate of 4.7% (4/85) for all ZCT300 and ZCT400 eyes. The rate of non-lens-related SSIs (two retinal repair procedures; 1.1%, 2/174) was not statistically significantly higher than the ISO SPE rate for surgical re-intervention.

Table 46
Cumulative Adverse Events through 6 Months
TECNIS™ Toric ZCT First Eyes: ZCT150, ZCT225, ZCT300 and ZCT400

Cumulative Adverse Event	ZCT Eyes N=174		ISO SPE[a] Rate
	n	%	%
Cystoid macular edema	5	2.9	3.0
Hypopyon	0	0.0	0.3
Endophthalmitis	0	0.0	0.1
Lens dislocation	0	0.0	0.1
Pupillary block	0	0.0	0.1
Retinal detachment	1	0.6[b]	0.3
Secondary Surgical Intervention	6	3.4[c]	
○ Lens-related: repositioning procedures	4	2.3[d]	0.8
○ Not lens-related: retinal repair procedures	2	1.1[e]	

[a] ISO 11979-7 Safety and Performance Endpoint (SPE).
[b] p=0.4071 compared to cumulative ISO SPE rate of 0.3%
[c] **p=0.0030** compared to cumulative ISO SPE rate of 0.8%
[d] p=0.0521 compared to cumulative ISO SPE rate of 0.8%
[e] p=0.4059 compared to cumulative ISO SPE rate of 0.8%

There were no persistent complications/adverse events present at 6 months for toric first eyes (0%; 0/174) in comparison to the ISO SPE rates for persistent complications/adverse events.

IOL rotation was noted by investigators at one day postoperatively in four toric first eyes; these were the four eyes (two ZCT300 and two ZCT400) mentioned above that underwent IOL repositioning procedures. IOL rotation at one day was estimated by the investigators to be 10° in both ZCT300 eyes, 35° in one ZCT400 eye, and 40° in the other ZCT400 eye. The repositioning procedures were performed early in the postoperative period, between the 1-day and 1-month study visits. Photographic analyses showed good lens stability following the repositioning procedures with only 2° to 5° of calculated rotation at 6 months vs. following the repositioning procedures.

Ocular/Visual Symptoms

Table 47 presents the degree of bother/trouble with ocular/visual symptoms at 6 months as collected from a questionnaire. Overall, most toric and ZCB00 control subjects reported "no trouble at all" for most items, including those that may be related to a toric IOL (things appearing distorted, judging distances when going up or down steps, objects appearing tilted, floors or flat surfaces appearing curved). Reports of ocular symptoms for toric eyes with >2.0D of cylinder correction at the corneal plane (ZCT300 and ZCT400) did not appear different from the lower cylinder models, indicating no impact on the ocular/visual profile with higher cylinder correction.

Table 47
Degree of Bother/Trouble with Key Ocular/Visual Symptoms at 6 Months from a Directed Questionnaire
Bilateral Subjects[a] in the Randomized Control Arm and the Open Label Arm

During the past month, how bothered have you been by each of the following, using correction if needed?		Randomized Control Arm ZCT150 N=72	Randomized Control Arm ZCB00 Control N=78	Open Label Arm ZCT225 N=17	Open Label Arm ZCT300/ ZCT400[c] N=54	All Toric Subjects[b] ZCT150, ZCT225, ZCT300, ZCT400 N=143
Changes in your vision during the day	No trouble at all	93.1%	80.8%	94.1%	87.0%	90.9%
	A little trouble	5.6%	19.2%	5.9%	11.1%	7.7%
	Moderate trouble	1.4%	0.0%	0.0%	1.9%	1.4%
	Severe trouble	0.0%	0.0%	0.0%	0.0%	0.0%
Glare (reflections off shiny surfaces, snow)	No trouble at all	68.1%	50.0%	58.8%	51.9%	60.8%
	A little trouble	22.2%	33.3%	29.4%	27.8%	25.2%
	Moderate trouble	9.7%	14.1%	5.9%	20.4%	13.3%
	Severe trouble	0.0%	2.6%	5.9%	0.0%	0.7%
Things looking different out of one eye vs. the other	No trouble at all	84.7%	70.5%	100.0%	70.4%	81.1%
	A little trouble	12.5%	19.2%	0.0%	18.5%	13.3%
	Moderate trouble	2.8%	9.0%	0.0%	7.4%	4.2%
	Severe trouble	0.0%	1.3%	0.0%	3.7%	1.4%
Seeing in dim light	No trouble at all	84.7%	65.4%	70.6%	63.0%	74.8%
	A little trouble	15.3%	29.5%	23.5%	22.2%	18.9%
	Moderate trouble	0.0%	5.1%	5.9%	13.0%	5.6%
	Severe trouble	0.0%	0.0%	0.0%	1.9%	0.7%
Your depth perception	No trouble at all	98.6%	85.9%	82.4%	90.7%	93.7%
	A little trouble	1.4%	10.3%	17.6%	5.6%	4.9%
	Moderate trouble	0.0%	2.6%	0.0%	3.7%	1.4%
	Severe trouble	0.0%	1.3%	0.0%	0.0%	0.0%
Things appearing distorted	No trouble at all	97.2%	93.6%	94.1%	96.3%	96.5%
	A little trouble	1.4%	1.3%	0.0%	3.7%	2.1%
	Moderate trouble	1.4%	5.1%	5.9%	0.0%	1.4%
	Severe trouble	0.0%	0.0%	0.0%	0.0%	0.0%
Judging distance when going up or down steps (stairs, curbs)	No trouble at all	90.3%	87.2%	100.0%	88.9%	90.9%
	A little trouble	8.3%	9.0%	0.0%	9.3%	7.7%
	Moderate trouble	1.4%	2.6%	0.0%	1.9%	1.4%
	Severe trouble	0.0%	1.3%	0.0%	0.0%	0.0%
Objects appearing tilted	No trouble at all	100.0%	98.7%	100.0%	98.1%	99.3%
	A little trouble	0.0%	1.3%	0.0%	1.9%	0.7%
	Moderate trouble	0.0%	0.0%	0.0%	0.0%	0.0%
	Severe trouble	0.0%	0.0%	0.0%	0.0%	0.0%
Floors or flat surfaces appearing curved	No trouble at all	97.2%	100.0%	100.0%	98.1%	97.9%
	A little trouble	2.8%	0.0%	0.0%	1.9%	2.1%
	Moderate trouble	0.0%	0.0%	0.0%	0.0%	0.0%
	Severe trouble	0.0%	0.0%	0.0%	0.0%	0.0%

[a] Subjects bilaterally implanted with either toric or control lenses and with ≥0.75 D preoperative K_{cyl} in second eyes
[b] As control subjects had ≤1.5 D of preoperative K_{cyl}, results for all toric subjects pooled are not to be compared to control values
[c] ZCT IOL models with >2.0 D of cylinder correction at corneal plane presented separately

CLINICAL STUDY RESULTS FOR THE SENSAR IOL, MODEL AAB00

The acrylic SENSAR™ 1-Piece IOL, Model AAB00 was clinically studied in a US multicenter, unilateral, open-label, non-comparative clinical trial between November 2005 and June 2007. The purpose of the study was to evaluate the safety and effectiveness of SENSAR™ 1-Piece IOL, Model AAB00 in subjects undergoing cataract removal and intraocular lens implantation. The 1-year results demonstrated that the SENSAR™ 1-Piece IOL, Model AAB00, is safe and effective for the visual correction of aphakia.

Study Population

A total of 123 subjects were enrolled and implanted with the SENSAR™ 1-Piece IOL, Model AAB00. In the study population, 56.9% of subjects were female and 43.1% were male; 93.5% were Caucasian, 4.1% were Black and 2.4% were Asian.

Adverse Events

The incidence of adverse events experienced during the clinical trial for Model AAB00 is similar to or less than those of the historic control population (FDA Grid for Posterior Chamber IOLs) as shown in **Table 48**.

Table 48
SENSAR Model AAB00 IOL (upon which TECNIS PureSee™ IOL is based): Adverse Events All Subjects

Adverse Events	Cumulative		Persistent at 1 Year		FDA Grid	
	N	%	N	%	Cumulative %	Per %
Persistent Corneal Edema	-	-	0	0.0	-	0.3
Cystoid Macular Edema (CME)	4	3.3[a]	1	0.9[b]	3.0	0.5
Endophthalmitis	0	0.0	-	-	0.1	-
Hyphema	0	0.0	-	-	2.2	-
Hypopyon	0	0.0	-	-	0.3	-
Persistent Iritis	-	-	0	0.0	-	0.3
Secondary Surgical Intervention						
○ Pars Plana Vitrectomy with Membrane Peel	1	0.8	-	-	0.8	-
Lens Dislocation	0	0.0	-	-	0.1	-
Pupillary Block	0	0.0	-	-	0.1	-
Retinal Detachment	0	0.0	-	-	0.3	-
Persistent Raised IOP Requiring Treatment	-	-	0	0.0	-	0.4
Lens Exchange						
○ Torn Haptic related to improper loading technique	1	0.8	-	-	-	-

[a] This rate is not statistically significantly higher than the FDA Grid cumulative rate for posterior chamber IOLs of 3.0% (p=0.5060).
[b] This rate is not statistically significantly higher than the FDA Grid rate for posterior chamber IOLs of 0.5% (p=0.4437).

CLINICAL STUDY RESULTS FOR THE TECNIS™ OPTIBLUE™ IOL, MODEL ZV9003

A multi-center, bilateral and double-masked study compared the clinical outcomes of the TECNIS™ OptiBlue™ IOL, Model ZV9003 and the control, TECNIS™ Foldable Acrylic IOL, Model ZA9003. The mean best-corrected distance visual acuity, mean binocular contrast sensitivity, and color vision data were comparable between subjects implanted with the Model ZV9003 lens and those implanted with the control lens. Statistically significant improvements were observed 4-6 months and one year postoperatively in favor of the Model ZV9003 lens in subjective ratings for reduced difficulty with daytime driving.

A total of 250 subjects (ZV9003 lens group=126, control lens group=124) were enrolled. The subject population consisted of more females than males in both lens groups, with 61.9% females in the test group and 54.8% females in the control group. The subjects in the ZV9003 group were slightly older (mean age=73.3 years) than those in the control group (mean age=71.5 years). Majority of subjects were Caucasian in both lens groups (96.0% in the ZV9003 group, 96.8% in the control group). The remainder of subjects were Black (2.4% in the ZV9003 group, 2.4% in the control group), Asian (0.0% in the ZV9003 group, 0.8% in the control group), and "Other" (1.6% in the ZV9003 group, 0.0% in the control group).

Best-Corrected Distance Visual Acuity

At one year, 100% of ZV9003 first eyes and 99.2% of ZV9003 second eyes were 20/40 or better for best-corrected distance visual acuity, exceeding the FDA grid rate of 92.5%. At one year, all best-case ZV9003 first eyes achieved a best-corrected visual acuity of 20/40 or better, exceeding the FDA grid rate of 96.7%. The postoperative best-corrected distance visual acuity results for the best-case patients at one year are provided in **Table 49**. In addition, the data compared to the FDA grid values (historical control) are presented in **Table 50**.

Table 49
Best-Corrected Distance Visual Acuity (Snellen Equivalent) at 1 Year
ZV9003 First Eyes, Best-Case Subjects[a] (N=113)

Age Group	N	20/20 or Better		20/25 to 20/40		20/50 to 20/100		20/125 or Worse	
		n	%	n	%	n	%	n	%
<60	4	4	100.0	0	0.0	0	0.0	0	0.0
60 to 69	32	30	93.8	2	6.3	0	0.0	0	0.0
70 to 79	51	41	80.4	10	19.6	0	0.0	0	0.0
>80	26	18	69.2	8	30.8	0	0.0	0	0.0
Total	**113**	**93**	**82.3**	**20**	**17.7**	**0**	**0.0**	**0**	**0.0**

[a] Best-case was defined as eyes without clinically significant preoperative pathology, sulcus implantation, contralateral implantation, macular degeneration at any time, or other significant macular pathology (e.g., macular hole).

Table 50
Best-Corrected Distance Visual Acuity (Snellen Equivalent) at 1 Year
ZV9003 Best-Case Subjects[a] (N=113) vs. FDA Grid

	Total		20/40 or Better		FDA Grid
Age Decade	N	%	N	%	%
< 60	4	3.54%	4	100.0	98.5
60 to 69	32	28.32%	32	100.0	96.5
70 to 79	51	45.13%	51	100.0	97.5
> 80	26	23.01%	26	100.0	94.8
Total	**113**	**100.0**	**110**	**100.0**	**96.7**

[a] Best-case was defined as eyes without clinically significant preoperative pathology, sulcus implantation, contralateral implantation, macular degeneration at any time, or other significant macular pathology (e.g., macular hole).

Color Vision

As part of the inclusion criteria, all subjects underwent binocular color vision testing using the Ishihara color test and the Farnsworth-Munsell D-15 color vision test. Farnsworth-Munsell D-15 color testing was performed again at the 4-6 month and one-year postoperative visits. At 4-6 months, 98.3% (119/121) of subjects implanted with the ZV9003 lens and 99.2% (118/119) of subjects implanted with the control lens passed the color vision test. At one year, 99.2 (118/119) of subjects implanted with the ZV9003 lens and 95.8% (115/120) of subjects implanted with the control lens passed the color vision test (**Table 51**).

Table 51
Farnsworth-Munsell D-15 Color Vision Test at 4-6 Months and One Year

	ZV9003		Control	
Color Vision Test	4-6 Months (N=121)	One Year (N=119)	4-6 Months (N=119)	One Year (N=120)
Pass	98.3%	99.2%	99.2%	95.8%
Perfect (no errors)	95.0%	97.5%	93.2%	96.5%
Not Perfect (1 major error and minor errors)	5.0%	2.5%	6.8%	3.5%
Fail (≥2 major errors)	1.7%	0.8%	0.8%	4.2%

A statistically significant difference was observed between lens groups for driving during the day at 4-6 months (p=0.0044) and at one year (p=0.0330). Subjects implanted with ZV9003 reported less difficulty driving during the day, compared to subjects implanted with the control lens (**Table 52**).

Table 52
Subject Assessment of Driving During Daytime, 4-6 Months and One Year Directed Responses to a Subjective Questionnaire

Driving During Daytime	4 to 6 Months[a]		One Year[b]	
	ZV9003 N=121	Control N=120	ZV9003 N=119	Control N=120
No difficulty at all	100.0%	92.9%	98.1%	91.7%
A little difficulty	0.0%	5.4%	0.9%	8.3%
Moderate difficulty	0.0%	1.8%	0.0%	0.0%
Extreme difficulty	0.0%	0.0%	0.9%[c]	0.0%

[a] Statistically significant difference (p=0.0044) at 4-6 months, based on Wilcoxon Rank-Sum test
[b] Statistically significant difference (p=0.0330) at one year, based on Wilcoxon Rank-Sum test
[c] One subject implanted with ZV9003 had difficulty driving during the daytime preoperatively and at one year, which may not be lens-related. The subject's visual acuity was excellent at the one-year visit, and there were no other issues.

Adverse Events

The incidence of adverse events reported during the clinical trial for the TECNIS™ OptiBlue™ IOL is similar to or less than that of the historic control population (FDA Grid for posterior chamber IOLs) as shown in **Table 53** and **Table 54**. There were no persistent adverse events reported during the study. The incidence rates for the Model ZV9003 lens compared favorably to the specified FDA rates.

Table 53
Adverse Events, TECNIS™ OptiBlue™ IOL, Model ZV9003, First Eyes (N=126)

Cumulative Adverse Event	Study Eyes		FDA Grid Rate
	n	%	%
Subjects with no Adverse Events	**126**	**100.0**	**N/A**
Subjects with Adverse Events	**0**	**0.0**	**N/A**
○ Cystoid Macular Edema (CME)	0	0.0	3.0
○ Secondary Surgical Intervention	0	0.0	0.8
○ Endophthalmitis	0	0.0	0.1
○ Hyphema	0	0.0	2.2
○ Hypopyon	0	0.0	0.3
○ Lens Dislocation	0	0.0	0.1
○ Pupillary Block	0	0.0	0.1
○ Retinal Detachment	0	0.0	0.3

Table 54
Adverse Events, TECNIS™ OptiBlue™ IOL, Model ZV9003, Second Eyes (N=126)

Cumulative Adverse Event	Study Eyes n	Study Eyes %	FDA Grid Rate %
Subjects with no Adverse Events	**125**	**99.2**	**N/A**
Subjects with Adverse Events	**1**	**0.8**	**N/A**
○ Cystoid Macular Edema (CME)	0	0.0	3.0
○ Secondary Surgical Intervention	1	0.8	0.8
○ Endophthalmitis	0	0.0	0.1
○ Hyphema	0	0.0	2.2
○ Hypopyon	0	0.0	0.3
○ Lens Dislocation	0	0.0	0.1
○ Pupillary Block	0	0.0	0.1
○ Retinal Detachment	0	0.0	0.3

Best-Case Best-Corrected Distance Visual Acuity

The best-corrected distance visual acuity results for the "best-case" subjects at 1-year postoperatively are provided in **Table 55**. In addition, the results compared to the FDA Grid values (historical control) are presented in **Table 56**.

Table 55
SENSAR Model AAB00 IOL (upon which TECNIS PureSee™ IOL is based):
Best-Corrected Distance Visual Acuity (Snellen Equivalent) at 1 Year
Best-Case Subjects[a] (N=110)

Age Group	N	20/20 or Better		20/25 to 20/40		20/50 to 20/100		20/125 or Worse	
		n	%	N	%	n	%	n	%
< 60	11	11	100.0	0	0.0	0	0.0	0	0.0
60-69	35	29	82.9	6	17.1	0	0.0	0	0.0
70-79	46	39	84.8	7	15.2	0	0.0	0	0.0
≥ 80	18	14	77.8	4	22.2	0	0.0	0	0.0
TOTAL[b]	**110**	**93**	**84.5**	**17**	**15.5**	**0**	**0.0**	**0**	**0.0**

[a] Excludes subjects with macular degeneration at any time during the study.
[b] Includes three subjects who experienced a Nd:YAG posterior capsulotomy.

Table 56
SENSAR Model AAB00 IOL (upon which TECNIS PureSee™ IOL is based): Best-Corrected Distance Visual Acuity (Snellen Equivalent) at 1 Year Best-Case Subjects[a] (N=110) vs. FDA Grid

Age Group	Total		Visual Acuity 20/40 or Better		FDA Grid
	N	%	N	%	%
<60	11	10.0	11	100.0	98.5
60 to 69	35	31.8	35	100.0	96.5
70 to 79	46	41.8	46	100.0	97.5
>80	18	16.4	18	100.0	94.8
TOTAL[b]	**110**	**100.0**	**110**	**100.0**	**96.7**

[a] Excludes subjects with macular degeneration at any time during the study.
[b] Includes three subjects who experienced a Nd:YAG posterior capsulotomy.

LENS POWER CALCULATIONS

Accurate keratometry and biometry are essential for obtaining successful visual outcomes. Preoperative calculation of the required spherical equivalent lens power for posterior chamber intraocular lenses should be determined by the surgeon's experience, preference, and intended lens placement. Emmetropia should be targeted. Accuracy of IOL power calculation is particularly important for toric IOLs, as reduced eyeglass wear is the goal of IOL implantation. A-constants listed on the outer label are presented as a guideline and serve as a starting point for power calculations. The physician should preoperatively determine the spherical equivalent and cylindrical power of the lens to be implanted.

For TECNIS PureSee™ Toric II IOLs: Use of the TECNIS™ Toric IOL Calculator tool provided by Johnson & Johnson Surgical Vision, Inc. is recommended for determining the appropriate IOL model, optimal axis of IOL placement and cylinder power. The TECNIS PureSee™ Toric II IOLs are labeled with the IOL distance spherical equivalent power. Physicians requiring additional information on lens power calculations may contact the local Johnson & Johnson Surgical Vision, Inc. representative.

Lens power calculation methods are described in the following references:

- Barrett, Graham D. “An improved universal theoretical formula for intraocular lens power prediction.” Journal of Cataract & Refractive Surgery 19.6 (1993): 713-720.
- Canovas, Carmen, and Pablo Artal. “Customized eye models for determining optimized intraocular lenses power.” Biomedical optics express 2.6 (2011): 1649-1662.
- Haigis Wolfgang. “The Haigis Formula.” Shammas, H. John. Intraocular Lens Power Calculations. Slack Incorporated, 2004.
- Hoffer, Kenneth J. “The Hoffer Q formula: a comparison of theoretic and regression formulas.” Journal of Cataract & Refractive Surgery 19.6 (1993): 700-712.
- Holladay, Jack T., et al. “A three-part system for refining intraocular lens power calculations.” Journal of Cataract & Refractive Surgery 14.1 (1988): 17-24.

- Holladay, Jack T. “Standardizing constants for ultrasonic biometry, keratometry, and intraocular lens power calculations.” Journal of Cataract & Refractive Surgery 23.9 (1997): 1356-1370.
- Norrby, Sverker NE. “Unfortunate discrepancies.” Journal of Cataract & Refractive Surgery 24.4 (1998): 433.
- Olsen T. “The Olsen formula.” Shammas, H. John. Intraocular Lens Power Calculations. Slack Incorporated, 2004.
- Retzlaff, John A., Donald R. Sanders, and Manus C. Kraff. “Development of the SRK/T intraocular lens implant power calculation formula.” Journal of Cataract & Refractive Surgery 16.3 (1990): 333-340.
- Barrett, Graham D. “An improved universal theoretical formula for intraocular lens power prediction.” Journal of Cataract & Refractive Surgery 19.6 (1993): 713-720.
- Canovas, Carmen, and Pablo Artal. “Customized eye models for determining optimized intraocular lenses power.” Biomedical optics express 2.6 (2011): 1649-1662.
- Haigis Wolfgang. “The Haigis Formula.” Shammas, H. John. Intraocular Lens Power Calculations. Slack Incorporated, 2004.
- Hoffer, Kenneth J. “The Hoffer Q formula: a comparison of theoretic and regression formulas.” Journal of Cataract & Refractive Surgery 19.6 (1993): 700-712.
- Holladay, Jack T., et al. “A three-part system for refining intraocular lens power calculations.” Journal of Cataract & Refractive Surgery 14.1 (1988): 17-24.

- Holladay, Jack T. “Standardizing constants for ultrasonic biometry, keratometry, and intraocular lens power calculations.” Journal of Cataract & Refractive Surgery 23.9 (1997): 1356-1370.
- Norrby, Sverker NE. “Unfortunate discrepancies.” Journal of Cataract & Refractive Surgery 24.4 (1998): 433.
- Olsen T. “The Olsen formula.” Shammas, H. John. Intraocular Lens Power Calculations. Slack Incorporated, 2004.
- Retzlaff, John A., Donald R. Sanders, and Manus C. Kraff. “Development of the SRK/T intraocular lens implant power calculation formula.” Journal of Cataract & Refractive Surgery 16.3 (1990): 333-340.

SELECTION AND PLACEMENT OF THE TECNIS PURESEE™ TORIC II IOL (MODELS DET150, DET225, DET300 AND DET375)

The astigmatism to be corrected should be determined from keratometry and biometry rather than refractive data since the presence of lenticular astigmatism in the crystalline lens to be removed may influence results. The size and location of the surgical incision may affect the amount and axis of corneal astigmatism. To facilitate IOL selection and placement, Johnson & Johnson Surgical Vision, Inc. provides a web-based proprietary tool, the TECNIS™ Toric IOL Calculator (www. TecnisToricCalc.com) for the surgeon. The corneal astigmatism to be corrected at the time of surgery is calculated by the TECNIS™ Toric IOL Calculator using vector summation of the preoperative corneal astigmatism and the expected surgically induced astigmatism. The cylinder IOL power calculation is based on the Holladay 1 formula (Holladay JT, Musgrove KH, Prager TC, Lewis JW, Chandler TY, and Ruiz RS. A three-part system for refining intraocular lens power calculations. J Cataract Refract Surg, 1988; 14:17-24). This yields an individual calculation instead of a fixed ratio based on average ocular parameters.

The TECNIS™ Toric IOL Calculator also provides an option for including the Posterior Corneal Astigmatism (PCA) (where available). The predetermined value for posterior corneal astigmatism can be included in the calculation by checking the box labeled Include Posterior Corneal Astigmatism (PCA). The option to include the predetermined value of PCA is based on an algorithm that combines published literature (Koch, et al. Contribution of posterior corneal astigmatism to total corneal astigmatism. J Cataract Refract Surg. 2012 Dec;38(12):2080-7) with a retrospective analysis of existing clinical data.

For optimal toric IOL calculations, it is recommended that surgeons customize their surgically induced corneal astigmatism values based upon individual surgical technique and past results. An example of this calculation can be found within the following reference (Holladay JT, Cravy TV, Koch DD. Calculating the surgically induced refractive change following ocular surgery. J Cataract Refract Surg, 1992; 18:429-43).

Preoperative keratometry and biometry data, incision location, spherical equivalent IOL power, and the surgeons estimated surgically induced corneal astigmatism are used as inputs for the TECNIS™ Toric IOL Calculator. These inputs are used to determine the axis of placement in the eye and the predicted residual refractive astigmatism for up to three different TECNIS PureSee™ Toric II IOL models. In eyes with low levels of corneal astigmatism, the predicted residual refractive astigmatism for implantation of a TECNIS PureSee™ IOL, Model DEN00V, will be displayed for evaluation by the surgeon to determine the clinically meaningful benefit of implanting a TECNIS PureSee™ Toric II IOLs.

For optimal results, the surgeon must ensure the correct placement and orientation of the lens within the capsular bag. The anterior surface of the IOL is marked with indentations (four at opposite sides) at the haptic/optic junction that identify the flat meridian of the toric IOL optic. These “indentations,” or axis marks, form an imaginary line representing the meridian with least power (note: IOL cylinder steep meridian is 90° away). The TECNIS PureSee™ Toric II IOLs cylinder axis marks should be aligned with the post-incision steep corneal meridian (intended axis of placement). Prior to surgery the operative eye should be marked in the following manner:

With the patient sitting upright, precisely mark the twelve o’clock and/or the six o’clock Position with a T marker, a surgical skin marker, or a marking pencil indicated for ophthalmic use. Using these marks as reference points, an axis marker can be used immediately prior to or during surgery to mark the axis of lens placement following the use of the web based TECNIS™ Toric IOL Calculator, www.TecnisToricCalc.com, to determine the optimal axis of placement.

After the lens is inserted, precisely align the axis marking indentations on the TECNIS PureSee™Toric II IOL with the marked axis of lens placement. Carefully remove all viscoelastic from the capsular bag. This may be accomplished by manipulating the IOL optic with the I/A tip and using standard irrigation/aspiration techniques to remove all viscoelastic from the eye. Bimanual techniques may be used, if preferred, to ensure removal of viscoelastic from behind the lens implant. Special care should be taken to ensure proper positioning of the TECNIS PureSee™

Toric II IOL at the intended axis following viscoelastic removal and/or inflation of the capsular bag at the end of the surgical case. Residual viscoelastic and/or over-inflation of the bag may allow the lens to rotate, causing misalignment of the TECNIS PureSee™ Toric II IOL with the intended axis of placement.

Misalignment of the axis of the lens with the intended axis of placement may compromise its astigmatic correction. Such misalignment can result from inaccurate keratometry or marking of the cornea, inaccurate placement of the TECNIS PureSee™ Toric II IOL axis during surgery, an unanticipated surgically induced change in the cornea, or physical rotation of the TECNIS PureSee™ Toric II IOL after implantation. In order to minimize this effect, the surgeon should be careful to ensure that preoperative keratometry and biometry is accurate and that the IOL is properly oriented prior to the end of surgery.

DIRECTIONS FOR USE

1. Prior to opening, examine the outer box and tamper evident seal for damage. Do not use if package is damaged.
2. Prior to opening the outer box, examine the outer box label for lens model, diopter power or spherical equivalent (SE) and cylinder (CYL) power, proper configuration and expiration date.
3. Break the tamper evident seal and remove the peel pouch.
4. After opening the outer box of the TECNIS SIMPLICITY™ Delivery System, examine the device package for any damage, and verify that information on the device (lens model, diopter power or spherical equivalent (SE) and cylinder (CYL) power, and serial number) is consistent with the information on the outer box label.
5. Open the peel pouch and remove the tray containing the delivery system. Place the tray on the sterile environment. Do not use the device if the pouch is damaged or the seal is broken. If the device is defective in any way, use another TECNIS SIMPLICITY™ Delivery System.
6. Use balanced salt solution or OVD as a hydration method using a cannula. Insert the cannula into the hydration port and fill the cartridge completely from cartridge tip to hydration port without filling the lens case (**Figure 10** and **Figure 11**). Proceed to step 7 once completed.
7. Carefully remove the TECNIS SIMPLICITY™ Delivery System from the tray. Do not touch the tip of the TECNIS SIMPLICITY™ Delivery System during removal as this may damage the tip. Inspect the tip to ensure that it is not damaged.
8. Quickly advance the plunger forward in a continuous motion (for example less than 1 second) until it stops at the threads (**Figure 12**). Do not stop or reverse while advancing the plunger.
9. Rotate the knob half a turn clockwise (**Figure 13**) to place the lens in the **correct** Holding Position (**Figure 14**). A representative **incorrect** Holding Position is provided in **Figure 15**. Keep the lens in the Holding Position for at least 1 minute to allow the system to hydrate in order to prevent sticking and a potential scratch or crack to the lens. To minimize haptic release time, a minimum of 3 minutes is recommended. Do not use the device if left for more than 10 minutes. Do not move the plunger forward until ready for lens implantation.
10. Proceed with the lens implantation by inserting the TECNIS SIMPLICITY™ Delivery System tip into the incision with the bevel of the tip oriented downwards. Rotate the knob of the plunger clockwise to continuously and smoothly advance the lens forward without pausing until the

lens is fully released from the delivery system tip. Discard the device if the lens has been advanced past the Holding Position but not delivered within 60 seconds.

11. Rotate the knob of the plunger counter-clockwise to slowly retract the plunger.
12. Discard the device. Do not re-use the TECNIS SIMPLICITY™ Delivery System.
13. The physician should consider the following points:
    - The surgeon should target emmetropia as this lens is designed for optimum visual performance when emmetropia is targeted.
14. Carefully remove all viscoelastic from the capsular bag. Align the lens with the intended axis of placement, following the recommendations provided in the "Selection and Placement" section for the TECNIS PureSee™ Toric II IOLs.

Factors to consider in deciding whether to implant a TECNIS PureSee™ Toric II IOL:

Effectiveness of implanting a toric IOL in reducing postoperative astigmatism is affected by many factors, including the following:

- The degree of mismatch between the postoperative magnitude of corneal astigmatism and effective IOL power in the corneal plane.
- Misalignment between the intended axial position and final IOL axial orientation.
- Error in prediction of the postoperative corneal cylinder axis and power. Error in prediction of cylinder axis is greatest for lower levels of preoperative corneal astigmatism.
- Manufacturing variation in power and axis markings can influence intended correction.
- The clinical data presented in **Table 39** represent outcomes that include the sources of variation listed above.

Caution:

Do not use the device if the package has been damaged. The sterility of the device may have been compromised.

PATIENT REGISTRATION (U.S. ONLY)

Each patient who receives a TECNIS PureSee™ IOL must be registered with Johnson & Johnson Surgical Vision, Inc. at the time of lens implantation. Registration is accomplished by completing the Implant Registration Card that is enclosed in the lens package and mailing it to Johnson & Johnson Surgical Vision, Inc. Patient registration is essential for Johnson & Johnson Surgical Vision's long term patient follow-up program and will assist Johnson & Johnson Surgical Vision, Inc. in responding to adverse event reports and/or potentially sight-threatening complications.

PATIENT CARD

An implant identification card is included in the package and should be supplied to the patient. The patient should be instructed to keep the card as a permanent record of his/her implant and to show the card to any eye care practitioner he/she may see in the future.

REPORTING

Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as lens-related and that were not previously expected in nature, severity, or rate of occurrence must be reported to Johnson & Johnson Surgical Vision, Inc. This information is being requested from all surgeons in order to document potential long-term effects of IOL implantation, especially in younger patients. Physicians are required to report these events to aid in identifying emerging or potential problems with posterior chamber IOLs. These problems may be related to a specific lot of lenses or may be indicative of long-term problems associated with these lenses or with IOLs in general.

HOW SUPPLIED

Each IOL is supplied sterile and preloaded in the delivery system within a single aseptic transfer peel pouch. The single aseptic transfer peel pouch is sterilized with ethylene oxide and should be opened only under sterile conditions. The pouch and product labels are enclosed in a shelf pack. The external surfaces of the pouch are not sterile. The recommended storage temperature is 77°F (25°C).

EXPIRATION DATE

The use-by date on the device is the sterility expiration date. The delivery system shall not be used, and the IOL shall not be implanted after the indicated sterility expiration date.

RETURN / EXCHANGE POLICY

Contact the local Johnson & Johnson Surgical Vision, Inc. representative for the return/exchange policy. Return the IOL with proper identification and the reason for the return. Label the return as a biohazard. Do not attempt to resterilize the IOL.

PATIENT INFORMATION

Each patient should receive information regarding IOLs, including information on different IOL options available to them, prior to the decision to implant an IOL.

SYMBOLS GLOSSARY

SYMBOL	TITLE	DESCRIPTION	TITLE OF STANDARD	STANDARD REFERENCE
STERILE EO	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	Medical devices — Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements	ISO 15223-1:2021 Reference #5.2.3 FDA Recognition # 5-134
	Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.	Medical devices — Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements	ISO 15223-1:2021 Reference #5.2.8 FDA Recognition # 5-134
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.	Medical devices — Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements	ISO 15223-1:2021 Reference #5.4.3 FDA Recognition # 5-134
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	Medical devices — Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements	ISO 15223-1: 2021 Reference 5.3.7 FDA Recognition # 5-134
REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	Medical devices — Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements	ISO 15223-1:2021 Reference #5.1.6 FDA Recognition # 5-134
	Keep away from sunlight	Indicates a medical device that needs protection from light sources.	Medical devices — Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements	ISO 15223-1:2021 Reference #5.3.2 FDA Recognition # 5-134
	Do not re-use	Indicates a medical device that is intended for one single use only.	Medical devices — Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements	ISO 15223-1:2021 Reference #5.4.2 FDA Recognition # 5-134
	Do not resterilize	Indicates a medical device that is not to be resterilized.	Medical devices — Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements	ISO 15223-1:2021 Reference #5.1.6 FDA Recognition # 5-134
SN	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	Medical devices — Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements	ISO 15223-1:2021 Reference #5.1.7 FDA Recognition # 5-134
	Use-by date	Indicates the date after which the medical device is not to be used. Date format is YYYY-MM-DD: Year-Month-Day.	Medical devices — Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements	ISO 15223-1:2021 Reference #5.1.4 FDA Recognition # 5-134
	Manufacturer	Indicates the medical device manufacturer.	Medical devices — Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements	ISO 15223-1:2021 Reference #5.1.1 FDA Recognition # 5-134
	Date of manufacture	Indicates the date when the medical device was manufactured. Date format is YYYY-MM-DD: Year-Month-Day. The use of this symbol precludes the use of 'Country of manufacture' with a date of manufacture.	Medical devices — Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements	ISO 15223-1:2021 Reference #5.1.3 FDA Recognition # 5-134

	Country of manufacture	To identify the country of manufacture of products In the application of this symbol, the "CC" shall be replaced by either the two-letter country code or the three letter country code defined in ISO 3166-1 (i.e., NL for The Netherlands and US for The United States). The date of manufacture may be added adjacent to this symbol. The use of this symbol with a date of manufacture precludes the use of symbol 'Date of manufacture'.	Medical devices — Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements	ISO 15223-1:2021 Reference #5.1.11 FDA Recognition # 5-134
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	Medical devices — Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements	ISO 15223-1:2021 Reference #5.4.4 FDA Recognition # 5-134
	Packaging unit	The number inserted in the symbol to indicate the number of pieces in the package.	Graphical symbols for use on equipment.	ISO 7000 Reference #2794 FDA Recognition # 5-124
MD	Medical device	Indicates the item is a medical device.	Medical devices — Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements	ISO 15223-1:2021 Reference #5.7.7 FDA Recognition # 5-134
UDI	Unique device identifier	Indicates a carrier that contains unique device identifier information	Medical devices — Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements	ISO 15223-1:2021 Reference #5.7.10 FDA Recognition # 5-134
D	Diopter	Indicates the diopter power of the IOL	Ophthalmic implants – Intraocular lenses – Part 4: Labelling and information	ISO 11979-4:2008 Reference #10
$\varnothing_T$	Overall diameter	Indicates the overall diameter of the IOL	Ophthalmic implants – Intraocular lenses – Part 4: Labelling and information	ISO 11979-4:2008 Reference #11
$\varnothing_B$	Body diameter	Indicates the body diameter of the IOL	Ophthalmic implants – Intraocular lenses – Part 4: Labelling and information	ISO 11979-4:2008 Reference #12
	1-10 minutes (minimum time: 1 minute I maximum time: 10 minutes)	Indicates the required hydration time of the IOL at the Holding Position	Not applicable	Not applicable

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For production site, refer to box label.

Figure 10

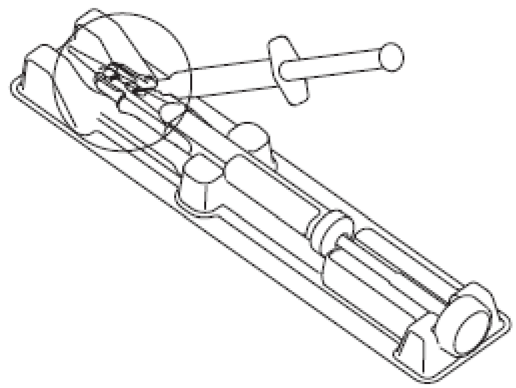

Figure 11

Figure 12

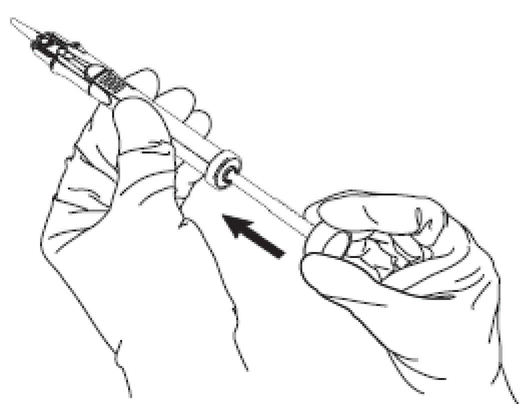

Figure 13

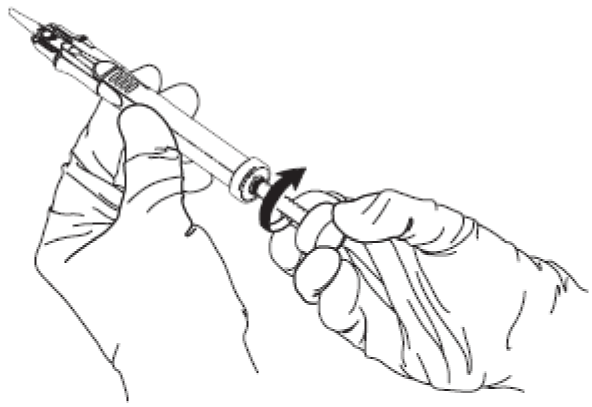

Figure 14

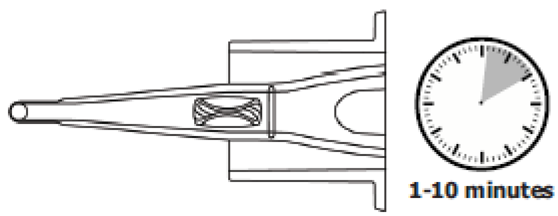

Figure 15