TECNIS Eyhance™ Toric II IOL with TECNIS Simplicity™ Delivery System

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Rx Only

DEVICE DESCRIPTION:

The TECNIS Eyhance™ Toric II IOL with the TECNIS Simplicity™ Delivery System in Models DIU150-600, are ultraviolet light-absorbing posterior chamber intraocular lenses (IOLs). They are designed to be positioned in the lens capsule to replace the optical function of the natural crystalline lens. These monofocal IOLs contain a modified aspheric toric anterior surface when compared to the material and mechanical parent lens, the SENSAR® 1-Piece IOL, Model AAB00 and the monofocal toric analogue, the TECNIS® Toric 1-Piece IOL, Model ZCT. The lens compensates for corneal spherical aberrations and corneal astigmatism. The benefits of aspheric compensation for corneal spherical aberrations are contingent upon full refractive correction of sphere and cylinder. Accommodation will not be restored. The IOL contains a squared posterior edge that provides a 360-degree barrier. The edge of the optic has a frosted design to reduce potential edge glare effects. In addition, compared to the TECNIS® Toric 1-Piece IOL, the haptics of the TECNIS Eyhance™ Toric II IOL has a squared and frosted design. The anteriorly located cylinder axis marks denote the meridian with the lowest power and is to be aligned with the steep corneal meridian.

The TECNIS Simplicity™ Delivery System Model DIU contains the TECNIS Eyhance™ Toric II IOL, which is a one-piece, foldable, posterior chamber lens with an overall diameter of 13.0 mm and an optic diameter of 6.0 mm. All IOL optical designs are associated with a certain amount of depth of focus. For monofocal IOLs, the amount of depth of focus is typically limited. The TECNIS Eyhance™ Toric II IOL use an aspheric anterior surface that creates a small continuous increase in central lens power within the 1 mm diameter.

The TECNIS Eyhance™ IOLs are designed to slightly extend the depth of focus compared to the TECNIS® 1-Piece IOL, Model ZCB00 as measured in bench testing (see **Figure 1**). The power profile decreases towards the periphery outside the central 1 mm diameter in a manner comparable to the TECNIS® 1-Piece IOL, Model ZCB00, enabling the same correction of corneal spherical aberration and resulting in comparable distance image quality to the TECNIS® 1-Piece IOL, Model ZCB00 and the SENSAR® 1-Piece IOL, Model AAB00, for a 3 mm pupil (see **Figure 2**). However, clinically meaningful extension of depth of focus has not been demonstrated in clinical trials. In general, extending the depth of focus negatively affects the quality of vision at far distances. Vision quality can be estimated using non-clinical testing (see **Figures 1 and 2**).

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 (5.0 D to 34.0 D) and is compatible with micro-incision surgical techniques. Sodium hyaluronate (HA) used in the cartridge coating is produced by a microbiological fermentation method.

LENS OPTIC:

1. Optic Material: Optically clear, soft foldable hydrophobic acrylic with a covalently bound UV absorber. Full transmission of blue wavelength light for optimal scotopic sensitivity.
2. Spherical Equivalent (SE) Power: +5.0 to +34.0 diopter powers in 0.5 diopter increments.
3. Cylinder Power: 1.50 diopters, 2.25 diopters, 3.00 diopters, 3.75 diopters, 4.50 diopters, 5.25 diopters and 6.00 diopters (as measured at the IOL plane).

Conversion table for cylinder powers:

	Cylinder Powers (D)						
Model	DIU150	DIU225	DIU300	DIU375	DIU450	DIU525	DIU600
IOL Plane (Labeled)	1.50	2.25	3.00	3.75	4.50	5.25	6.00
Corneal Plane*	1.03	1.54	2.06	2.57	3.08	3.60	4.11

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

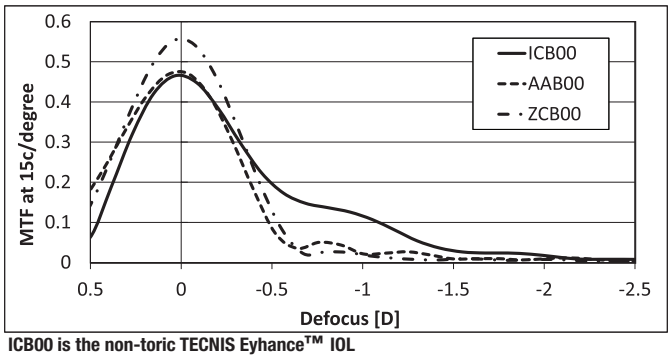
4. Optic Center Thickness: 0.72 mm (+20.0D)
5. Optic Edge Design: PROTEC 360 square posterior edge
6. Index of Refraction: 1.47 at 35°C
7. Light Transmittance: UV cut-off at 10% T for a +5.0 diopter lens (thinnest) and a +34.0 diopter lens (thickest) are shown in **Figure 3**

HAPTICS:

1. Material: Soft foldable hydrophobic acrylic with a covalently bound UV absorber
2. One-piece lens
3. Configuration: TRI-FIX design Modified C, integral with optic
4. Haptic thickness: 0.46 mm

Figure 1:

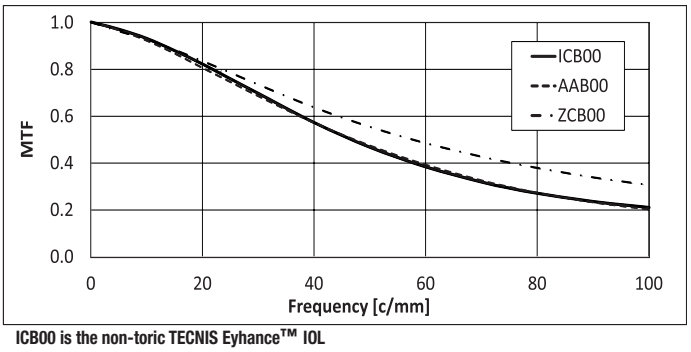
Through Focus MTF Measurements. ACE model, 3 mm, white light



ICB00 is the non-toric TECNIS Eyhance™ IOL

Figure 2:

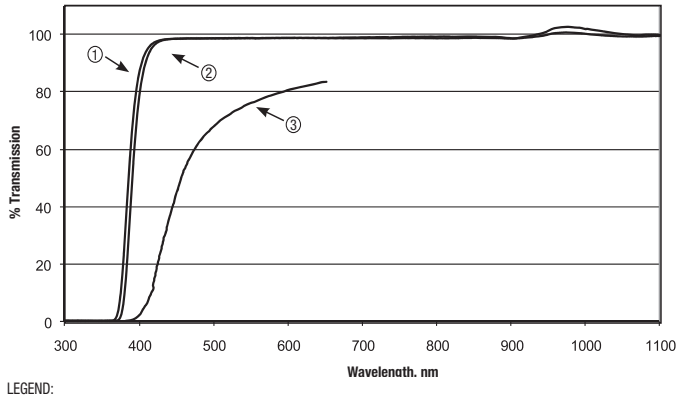
Through Frequency MTF Measurements. ACE model, 3 mm, white light



ICB00 is the non-toric TECNIS Eyhance™ IOL

Figure 3:

Light Transmittance



LEGEND:
Curve 1: Spectral Transmittance curve of a typical 5 diopter IOL (thinnest), UV cut-off at 10% T is 375nm
Curve 2: Spectral Transmittance curve of a typical 34 diopter IOL (thickest), UV cut-off at 10% T is 380nm
Curve 3: Spectral Transmittance (T) Curve* Corresponding to 53 year-old Phakic Eye

Note: The cut-off wavelengths and the spectral transmittance curves represent the range of the transmittance of IOLs (5-34 diopter) made with this material. Spectral transmission measurements were taken in water at room temperature.

*Boettner, E.A., and Wolter J.R. Transmission of the Ocular Media. Investigative Ophthalmology. 1962; 1:776-783.

2021-02-02

INDICATIONS FOR USE:

The TECNIS Simplicity™ Delivery System is used to fold and assist in inserting the TECNIS Eyhance™ Toric II IOLs for the visual correction of aphakia and pre-existing corneal astigmatism of one diopter or greater in adult patients with or without presbyopia in whom a cataractous lens has been removed by phacoemulsification and who desire reduction in residual refractive cylinder. The lens is intended to be placed in the capsular bag.

WARNINGS:

Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio:

1. Patients with any of the following conditions may not be suitable candidates for an intraocular lens because the lens may exacerbate an existing condition, may interfere with diagnosis or treatment of a condition or may pose an unreasonable risk to the patient's eyesight. These conditions are not specific to the design of the lens and are attributed to cataract surgery and IOL implantation in general:
   a. Patients with recurrent severe anterior or posterior segment inflammation or uveitis of unknown etiology, or any disease producing an inflammatory reaction in the eye.
   b. Patients in whom the intraocular lens may affect the ability to observe, diagnose or treat posterior segment diseases.
   c. Surgical difficulties at the time of cataract extraction, which may increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure or significant vitreous prolapse or loss).
   d. A compromised eye due to previous trauma or developmental defects in which appropriate support of the IOL is not possible.
   e. Circumstances that would result in damage to the endothelium during implantation.
   f. Suspected microbial infection.
   g. Patients in whom neither the posterior capsule nor the zonules are intact enough to provide support for the IOL.
   h. Congenital bilateral cataracts.
   i. Previous history of, or a predisposition to, retinal detachment.
   j. Patients with only one good eye with potentially good vision.
   k. Medically uncontrollable glaucoma.
   l. Corneal endothelial dystrophy.
   m. Proliferative diabetic retinopathy.
   n. Children under the age of 2 years are not suitable candidates for intraocular lenses.
2. The lens should be placed entirely in the capsular bag. Do not place the lens in the ciliary sulcus.
3. The clinical study for the TECNIS® Toric 1-Piece IOL did not show evidence of effectiveness for the treatment of preoperative corneal astigmatism of less than one diopter.
4. 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.
5. Do not use if the cartridge of the delivery system is cracked or split prior to implantation.
6. Do not implant the lens if the rod tip does not advance the lens or if it is jammed in the delivery system.
7. During initial lens advancement (**Figure 6**), quick advancement of the plunger is needed. Do not stop or reverse while advancing the plunger. Doing so may result in improper folding of the lens.
8. After initial lens advancement (**Figure 6**) and the half turn rotation step (**Figure 7**), do not move the plunger forward until ready for lens implantation. Doing so may result in the lens being stuck in the cartridge.
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. Rotation of the toric lens 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.
11. 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.
12. The reuse/resterilization/reprocessing of Johnson & Johnson Surgical Vision, Inc. single-use devices may result in physical damage to the medical device, failure of the medical device to perform as intended, and patient illness or injury due to infection, inflammation, and/or illness due to product contamination, transmission of infection, and lack of product sterility.

PRECAUTIONS:

1. The safety and effectiveness of the TECNIS Eyhance™ Toric II IOL has not been substantiated in clinical trials. The effects of the TECNIS Eyhance™ Toric II IOL optical design on quality of vision, contrast sensitivity, and subjective visual disturbances (glare, halo, etc.) have not been evaluated clinically. MTF testing of the TECNIS Eyhance™ IOL (**Figures 1 and 2**) may aid the Surgeon in understanding the theoretical image quality expected with the TECNIS Eyhance™ IOL compared to other JJSV monofocal IOLs (AAB00 and ZCB00). However, these do not fully assess all aspects of clinical difficulties under all conditions. Surgeons must weigh the potential benefits of the modified optical design of the TECNIS Eyhance™ IOL against the potential for risks and the lack of clinical data to characterize the impact of the TECNIS Eyhance™ IOL optical design on contrast sensitivity and subjective visual disturbance. These considerations may be especially relevant to patients with certain pre-existing ocular conditions (prior corneal refractive surgery, irregular corneal astigmatism, severe corneal dystrophy, macular disease, optic nerve atrophy, etc.) or intraoperative conditions (posterior capsular rupture, complications in which the IOL stability could be compromised, inability to place IOL in capsular bag, etc.).
2. 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.
3. Some autorefractors utilize only the central part of the IOL to calculate the refraction of the eye and that is the region where the TECNIS Eyhance™ deviates from the monofocal design which could result in a wrong estimation of the refraction. Manual refraction with maximum plus technique is strongly recommended.
4. Recent contact lens usage may affect the patient's refraction; therefore, for patients who wear contact lenses, surgeons should establish corneal stability without contact lenses prior to determining IOL power.
5. The lens is designed for optimum visual performance when emmetropia is targeted.
6. 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 and the preloaded inserter material without producing undesirable side effects.
7. Do not store the device in direct sunlight or at a temperature under 5°C (41°F) or over 35°C (95°F).
8. Do not autoclave the delivery system.
9. Do not advance the lens unless ready for lens implantation.
10. The contents are sterile unless the package is opened or damaged.
11. The recommended temperature for implanting the lens is at least 17°C (63°F).
12. The use of balanced salt solution (BSS) or viscoelastics is required when using the delivery system. For optimal performance when using OVD, use the HEALON® family of viscoelastics. The use of BSS with additives has not been studied for this product.
13. 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.
14. Do not leave the lens in a folded position more than 10 minutes.
15. 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 instructions for use provided.
16. Carefully remove all viscoelastic and do not over-inflate the capsular bag at the end of the case. Residual viscoelastic and/or over-inflation of the capsular bag may allow the lens to rotate, causing misalignment of the TECNIS Eyhance™ Toric II IOL with the intended axis of placement.

17. The use of methods other than the TECNIS® Toric Calculator to select cylinder power and appropriate axis of implantation were not assessed in the clinical study for the TECNIS® Toric 1-Piece IOLs and may not yield similar results. Accurate keratometry and biometry, in addition to the use of the TECNIS® Toric Calculator (www.TecnisToricCalc.com) are recommended to achieve optimal visual outcomes.
18. The safety and effectiveness of the TECNIS Eyhance™ Toric II IOLs have not been substantiated in patients with the following preexisting ocular conditions and intraoperative complications (see below). Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient with one or more of these conditions.

Before Surgery

- 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

During Surgery

- Excessive vitreous loss
- Capsulotomy by any technique other than a circular tear
- The presence of radial tears known or suspected at the time of surgery
- Situations in which the integrity of the circular tear cannot be confirmed by direct visualization
- Cataract extraction by techniques other than phacoemulsification or liquefaction
- Situations where the need for a large capsulotomy can be anticipated (e.g., diabetics, retinal detachment in the fellow eye, peripheral retinal pathology, etc.)
- Capsular rupture
- Significant anterior chamber hyphema
- Uncontrollable positive intraocular pressure
- Zonular damage

19. 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 a prospective clinical study and may yield results different from those in the TECNIS® Toric intraocular lens labeling. Please refer to the Johnson & Johnson Surgical Vision, Inc. Toric Calculator user manual for more information.
20. All preoperative surgical parameters are important when choosing a toric lens for implantation, including preoperative keratometric cylinder (magnitude and axis), incision location, 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.
21. All corneal incisions were placed temporally in the clinical study for the TECNIS® Toric 1-Piece IOLs. If the surgeon chooses to place the incision at a different location, outcomes may be different from those obtained in the clinical study. Note that the TECNIS® Toric Calculator incorporates the surgeon's estimated SIA and incision location when providing IOL options.

GENERAL ADVERSE EVENTS FOR IOLS:

Potential adverse events during or following cataract surgery with implantation of an IOL may include but are not limited to:

1. Endophthalmitis/intraocular infection
2. Hypopyon
3. Hyphema
4. IOL dislocation
5. Cystoid macular edema
6. Pupillary block
7. Retinal detachment/tear
8. Persistent corneal stromal edema
9. Persistent iritis
10. Persistent raised intraocular pressure (IOP) requiring treatment
11. Acute corneal decompensation
12. Secondary intraocular surgical intervention (including implant repositioning, removal, AC tap, or other surgical procedure)
13. Any other adverse event that leads to permanent visual impairment or requires surgical or medical intervention to prevent permanent visual impairment

CLINICAL STUDY RESULTS FOR THE TECNIS® TORIC 1-PIECE LENSES, MODELS ZCT150, ZCT225, ZCT300 AND ZCT400:

The TECNIS® Toric 1-Piece IOLs are the mechanical parent lenses of the TECNIS Eyhance™ Toric II IOLs. The clinical results related to the toric design of the TECNIS® Toric 1-Piece IOLs are also applicable to the TECNIS Eyhance™ Toric II IOLs. A clinical investigation was conducted in the United States and Canada with the TECNIS® Toric 1-Piece IOLs, Models ZCT150, ZCT225, ZCT300 and ZCT400. The clinical investigation was designed to evaluate the safety and effectiveness, including the ability to reduce astigmatism, of the TECNIS® Toric 1-Piece lenses. This was a pivotal, prospective, multicenter, two-armed, bilateral, six month study conducted at 14 investigational sites. The first arm of the study was a randomized, comparative, double-masked (subject and technician) evaluation of the TECNIS® Toric 1-Piece IOL, Model ZCT150 with the TECNIS® 1-Piece IOL, Model ZCB00 as the control lens; referred to as the Randomized Control Arm (RCA). The second arm of the study was an open-label, non-comparative clinical trial of the TECNIS® Toric 1-Piece IOLs, Models ZCT225, ZCT300, and ZCT400; referred to as the Open Label Arm (OLA).

The four TECNIS® Toric 1-Piece IOL models investigated in this clinical study and their corresponding cylinder powers are listed below in **Table 1**. The corresponding cylinder values at the corneal plane have been calculated based on the average pseudophakic eye. The corneal astigmatism correction ranges are for the combined corneal astigmatism based on a vector sum of preoperative corneal astigmatism (preop Kcyl) and the predicted effect of SIA.

In order to facilitate toric IOL selection and axis placement, a web-based, proprietary TECNIS® Toric Calculator was used to determine the appropriate TECNIS® Toric IOL model and axis of placement for each eye.

The results achieved by the subjects followed to six months postoperatively demonstrate that the TECNIS® Toric 1-Piece IOL, Models ZCT150, ZCT225, ZCT300 and ZCT400, are safe and effective for the visual correction of aphakia. The following clinical results demonstrate 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 experienced improved uncorrected distance visual acuity compared to control values. Additionally, subjects implanted with lenses ZCT225, ZCT300 and ZCT400 were shown to have increased levels of spectacle independence at distance.

TECNIS® TORIC 1-PIECE IOL CLINICAL STUDY PATIENT POPULATION:

A total of 269 subjects were enrolled in the study; 197 were in the RCA and 72 in the OLA. Of the 197 in the RCA, 95 were implanted in the first eye with the control ZCB00 lens and 102 with a ZCT150 toric 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. The 6 month study results are presented for all study groups.

The subject population implanted with the ZCT150 lens in the RCA consisted of 53.9% females to 46.1% males, and subjects implanted with the ZCB00 control lens consisted of 57.9% females and 42.1% males. The OLA arm of the study consisted of 55.6% females and 44.4% males. 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:

Percent reduction in cylinder was calculated as the ratio of achieved postoperative refractive cylinder to the target refractive cylinder, adjusted for preoperative keratometric cylinder. Specifically, the difference between postoperative refractive cylinder and preoperative keratometric cylinder was divided by the difference between the target refractive cylinder and preoperative keratometric cylinder to calculate the percent reduction in cylinder. The target refractive cylinder is a combination of preoperative keratometric cylinder, SIA from the cataract incision and the toric IOL. The calculation was performed similarly for all eyes; in the RCA, the target refractive cylinder for ZCB00 eyes was calculated as if the control subjects were receiving a ZCT150 IOL.

As shown in **Table 2**, 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 six months postoperative. Additionally, the mean percent reduction in cylinder for OLA first eyes at six 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 (SD=59.29).

The TECNIS® Toric Calculator utilizes preoperative keratometry and surgeon-estimated SIA to calculate the expected postoperative keratometry and provides 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 0.32 D (with a median value of 0.25 D 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 0.20 D to 0.83 D for magnitude[Zadnik,Visser] and up to 20° for axis[Visser]) and any potential errors in surgeon-estimated SIA are contributing factors to prediction errors of postoperative keratometry.

Zadnik K, Mutti D, Adams A. The repeatability of measurement of the ocular components. Invest Ophthalmol Vis Sci. 1992 Jun; 33(7): 2325-33

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

The absolute difference between refractive cylinder at six months vs. the target is presented in **Table 3**. In the RCA, 72.3% (73/101) of ZCT150 eyes compared to 49.5% (45/91) of ZCB00 eyes were within 0.50 D of target refractive cylinder; additionally, 94.1% (95/101) of ZCT150 eyes compared to 70.3% (64/91) of ZCB00 eyes were within 1.00 D of target refractive cylinder. In the OLA, 52.9% (37/70) were within 0.50 D and 84.3% (59/70) were within 1.00 D of target refractive cylinder.

SUBGROUP ANALYSIS:

Results in the RCA were stratified by preoperative Kcyl alone and by predicted Kcyl (i.e., vector sum of preoperative Kcyl, magnitude and axis, SIA, and incision axis) in 0.25 D increments as shown in **Tables 4, 5, and 6**.

ROTATIONAL STABILITY:

The degree of lens axis rotation between time points was measured using a direct photographic method. **Table 7** presents the change in axis rotation between stability time points (one to three months and three to six months) for toric first eyes. The TECNIS® Toric 1-Piece IOLs achieved the ANSI Standard for Toric IOLs, Z80.30 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 8 presents axis change for toric eyes between baseline (day 1) and six months. Of toric first eyes, 97% had <10° of axis change between baseline and six months.

Table 9 presents mean axial rotation between stability time points (one to three months and three to six months) as well as overall (baseline to six months). Mean axial rotation was minimal (<3°) whether taking direction of axis shift into account or regardless of direction (absolute value).

ADVERSE EVENTS:

The incidence rates of cumulative events for the TECNIS® Toric 1-Piece IOL first eyes in the clinical study compared to ISO SPE rates are presented in **Table 10**. The incidence rates for the TECNIS® Toric ZCT IOL first eyes compared favorably to the ISO SPE rates. Only the rate of surgical re-intervention (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 repositioning procedures (2.3%; 4/175) alone was not statistically significantly higher than the ISO SPE rate for surgical re-intervention. 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 re-interventions (two retinal repair procedures; 1.1%, 2/174) was not statistically significantly higher than the ISO SPE rate for surgical re-intervention.

There were no persistent medical complications present at six months for toric first eyes in comparison to the ISO SPE rates for persistent complications. Additionally, no adverse events occurred in toric second eyes (0%; 0/149) or for any ZCB00 control eyes.

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) that underwent IOL repositioning procedures in the study. 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 six months vs. following the repositioning procedures.

CLINICAL STUDY RESULTS FOR THE SENSAR® 1-PIECE LENS, MODEL AAB00:

The material and mechanical parent lens of the TECNIS Eyhance™ Toric II IOL with the TECNIS Simplicity™ Delivery System, Model DIU, is the Model AAB00 lens. The difference between lens Model DIU and lens Model AAB00 is the modified prolate anterior optic surface of lens Model DIU. The clinical results of the Model AAB00 lens are applicable to Model DIU lens.The clinical trial was conducted between November 2005 and June 2007. The purpose of the study was to evaluate the safety and effectiveness of lens Model AAB00 in subjects who underwent cataract removal and intraocular lens implantation. Following routine cataract removal by phacoemulsification, all IOLs were implanted in the capsular bag with a continuous curvilinear capsulorhexis.

The results achieved by 117 subjects followed for one year provide the basis for the data supporting the use of this lens design for visual correction of aphakia. In the total study population (123 subjects), 56.9% of the subjects were female and 43.1% were male; 93.5% were Caucasian, 4.1% were African American and 2.4% were Asian. The best corrected distance visual acuity results for the "best case" subjects at 1 year (330-420 days) postoperatively are provided in **Table 11**. In addition, the data compared to the FDA Grid/ISO SPE values (historical control) are presented in **Table 12**.

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/ISO SPE rates for posterior chamber IOLs) as shown in **Table 13**.

LENS POWER CALCULATIONS:

Accurate keratometry and biometry are essential to successful visual outcomes. Preoperative calculation of the required spherical equivalent and cylinder power for this posterior chamber intraocular lens should be determined by the surgeon's experience, preference, and intended lens placement. The lens is designed for optimum visual performance when emmetropia is targeted. The A-constants listed on the outer label are presented as a guideline and serve as a starting point for implant power calculations. The physician should determine preoperatively the dioptric (SE) and cylinder power of the lens to be implanted. Use of the Johnson & Johnson Surgical Vision, Inc. provided toric calculator tool is recommended for determining the appropriate toric IOL model, optimal axis of the IOL placement and IOL cylinder 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:

1. Haigis W. "The Haigis formula". In: Shammas HJ, ed, Intraocular Lens Power Calculations. Thorofare, NJ, Slack, 2004; 41-57.
2. Hoffer K.J., "The Hoffer Q formula: a comparison of theoretic and regression formulas", J Cataract Refract Surg, 19, 700-712 (1993). Erratum in: J Cataract Refract Surg 1994;20:677. Erratum in: J Cataract Refract Surg 2007;33:2-3.
3. Holladay J.T., Prager T.C., Chandler T.Y., Musgrove K.H., Lewis J.W. and Ruiz R.S., "A three-part system for refining intraocular lens power calculations", J Cataract Refract Surg. 14,17-24 (1988).
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SELECTION AND PLACEMENT OF THE TECNIS Eyhance™ Toric II 1-Piece IOL:

The astigmatism to be corrected should be determined from keratometry and biometry data 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 of postoperative corneal astigmatism as well as the respective axis. In order to facilitate IOL selection and axis placement, Johnson & Johnson Surgical Vision, Inc. provides a web-based proprietary tool, the TECNIS® Toric Calculator (www.TecnisToricCalc.com) for the surgeon. The corneal astigmatism to be corrected at the time of surgery is calculated by the TECNIS® Toric 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. Journal of Cataract and Refractive Surgery. 1988; 14:17-24). This yields an individual calculation instead of using a fixed ratio based on average ocular parameters.

The Johnson & Johnson Surgical Vision, Inc. TECNIS® Toric 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 DD 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 surgeon's estimated surgically induced corneal astigmatism are used as inputs for the TECNIS® Toric 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 Eyhance™ Toric II 1-Piece IOL models. In eyes with low levels of corneal astigmatism, the predicted residual refractive astigmatism for implantation of a TECNIS® 1-Piece lens, Model ZCB00, will be displayed for evaluation by the surgeon to determine the clinically meaningful benefit of implanting a toric IOL.

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 TECNIS Eyhance™ Toric II optic. These "indentations", or axis marks, form an imaginary line representing the plus cylinder axis (note: IOL cylinder steep meridian is 90° away). The TECNIS Eyhance™ Toric II IOL 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 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 Eyhance™ 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. Special care should be taken to ensure proper positioning of the TECNIS Eyhance™ 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 Eyhance™ 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® Toric II 1-Piece IOL axis during surgery, an unanticipated surgically induced change in the cornea, or physical rotation of the TECNIS Eyhance™ 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 or surgery.

DIRECTIONS FOR USE:

1. Prior to opening the outer box, examine the outer box label for lens model, dioptric spherical equivalent (SE) and cylinder power, proper configuration and expiration date.
2. After opening the outer box of the TECNIS Eyhance™ Toric II IOL with TECNIS Simplicity™ Delivery System, examine the device package for any damage, and verify that information on the device (lens model, dioptric (SE) and cylinder power, and serial number) is consistent with the information on the outer box label.
3. Open the peel pouch and remove the delivery system in the tray. 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 delivery system.
4. Use BSS 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 (**Figures 4 and 5**). Proceed to step 5 once completed.
5. Carefully remove the delivery system from the tray. Do not touch the tip of the delivery system during removal as this may damage the tip. Inspect the tip to ensure that it is not damaged.
6. Quickly advance the plunger forward in a continuous motion (for example less than 1 second) until it stops at the threads (**Figure 6**). Do not stop or reverse while advancing the plunger.
7. Rotate the knob half a turn clockwise to place the lens in the holding position (**Figure 7**). Do not move the plunger forward until ready for lens implantation. Dwell the lens in this position for 0 to 10 minutes. To minimize haptic release time, a minimum of 3 minutes is recommended. If left for more than 10 minutes, then do not use device.
8. Proceed with the lens implantation by inserting the delivery system tip into the incision with the bevel of the tip oriented downwards. Rotate the knob

of the plunger clockwise to slowly advance the lens forward. Lens must be delivered within 1 minute. Continue to rotate the plunger knob until the lens is fully released from the delivery system tip.

9. Rotate the knob of the plunger counter-clockwise to slowly retract the plunger.
10. Discard the device. Do not re-use the delivery system.
11. The physician should consider the following points:
    - The surgeon should target emmetropia, as this lens is designed for optimum visual performance when emmetropia is achieved.
    - Care should be taken to achieve centration of the intraocular lens.
    - Carefully remove all viscoelastic from the capsular bag and align the lens with the intended axis of placement.

Factors to consider in deciding whether to implant a toric lens: effectiveness of implanting a toric lens 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. Based on the tolerances set in the ANSI standard Z80.30, cylinder power variation may cause the intended correction at the corneal plane to vary by up to 16%.

CAUTION:

Do not use the TECNIS Simplicity™ Delivery System if the package has been damaged. The sterility of the lens may have been compromised.

PATIENT REGISTRATION SECTION (For US):

Each patient who receives a TECNIS Eyhance™ Toric II 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 Reaction Reports and/or potentially sight-threatening complications.

PATIENT CARD:

An implant identification card, to be supplied to the patient, is included in the package. 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 intraocular lens implantation, especially in younger patients.

Physicians are required to report these events in order to aid in identifying emerging or potential problems with posterior chamber lenses. 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 intraocular lenses in general.

HOW SUPPLIED:

Each lens is supplied sterile and preloaded in the delivery system within a single aseptic transfer peel pouch. The 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 25°C (77°F).

EXPIRATION DATE:

The use-by date on the TECNIS Simplicity™ Delivery System package is the sterility expiration date. The delivery system should not be used, and the lens should 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 lens with proper identification and the reason for the return. Label the return as a biohazard. Do not attempt to resterilize the lens.

PATIENT INFORMATION:

Each patient should receive information regarding intraocular lenses prior to the decision to implant an intraocular lens.

SYMBOL/EXPLANATION:

SYMBOL	EXPLANATION
STERILE EO	Sterilized using ethylene oxide
	Do not re-use
	Use-by date (YYYY-MM-DD:Year-Month-Day)
	Consult instructions for use
	Manufacturer
STERILIZE	Do not resterilize
35°C (95°F) 5°C (41°F)	Upper limit of temperature
	Keep away from sunlight
	Date of manufacture (YYYY-MM-DD: Year-Month-Day)
	Do not use if package is damaged
REF	Catalogue number
SN	Serial number

Johnson & Johnson Surgical Vision, Inc.
1700 E. St. Andrew Place
Santa Ana, CA 92705 USA

For production site, refer to product label.

Table 1:
TECNIS® Toric 1-Piece IOLs

IOL Model	Cylinder Power		Correction ranges based on combined corneal astigmatism (preop Kcyl + SIA)
	IOL Plane	Corneal Plane	
ZCT150	1.50	1.03	0.75 – 1.50 D
ZCT225	2.25	1.54	1.50 – 2.00 D
ZCT300	3.00	2.06	2.00 – 2.75 D
ZCT400	4.00	2.74	2.75 – 3.62 D

Table 2:
Mean Cylinder and Achieved Cylinder Reduction as a Percentage of Intended Reduction (Percent Cylinder Reduction) at Six Months
First Eyes[a] - Randomized Control Arm and Open Label Arm
Safety Population

	Randomized Control Arm					Open Label Arm				
VARIABLE	Lens Model	N[a]	Mean	Std. Dev.	P-Value	Lens Model	N[a]	Mean	Std. Dev.	P-Value
PreopKeratometric Cylinder (Kcyl; D)	ZCB00	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)	ZCB00	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)	ZCB00	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]	ZCB00	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

Table 3:
Absolute Difference Between Refractive Cylinder at Six Months vs. Target
First Eyes - Randomized Control Arm and Open Label Arm
Safety Population

	Randomized Control Arm				Open Label Arm		All Toric Eyes[a]	
Diopter Group	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 Kcyl, results for all toric eyes pooled are not to be compared to control values

2021-02-02

Table 4:
Achieved Cylinder Reduction as a Percentage of Intended Reduction (Percent Reduction in Cylinder ANSI formula[a]) at 6 Months Stratified by Keratometric Cylinder
First Eyes Randomized Control Arm ZCT150 and ZCB00
Safety Population

Model	Preoperative Keratometric Cylinder (D)	N	Percent Reduction in Cylinder (ANSI)[a] Mean	Std Dev	Predicted Keratometric Cylinder (D)[b] (Preop Kcyl + SIA)	N	Percent Reduction in Cylinder (ANSI)[a] Mean	Std Dev
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 Kcyl)/(Target Ref. Cyl. minus Preop Kcyl); 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 5:
Residual Refractive Cylinder at 6 Months Stratified by Keratometric Cylinder
First Eyes Randomized Control Arm ZCT150 and ZCB00
Safety Population

Model	Preoperative Keratometric Cylinder (D)	N	Residual Refractive Cylinder (D) Mean	Std Dev	Predicted Keratometric Cylinder (D)[a] (Preop Kcyl + SIA)	N	Residual Refractive Cylinder (D) Mean	Std Dev
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 6:
Change in Absolute Cylinder[a] at Six Months Stratified by Keratometric Cylinder
First Eyes Randomized Control Arm ZCT150 and ZCB00
Safety Population

Model	Preoperative Keratometric Cylinder (D)	N	Absolute Cylinder Change: Reduction >0.50 D n	%	≤±0.50 D[b] n	%	Increase >0.50 D n	%	Predicted Keratometric Cylinder (D)[c] (Preop Kcyl + SIA)	N	Absolute Cylinder Change: Reduction >0.50 D n	%	≤±0.50 D[b] n	%	Increase >0.50 D n	%
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 Kcyl
[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.

Table 7:
Absolute Difference in Axis Alignment Between Visits
First Eyes - All Toric ZCT150, ZCT225, ZCT300, ZCT400 Pooled
Safety Population

Axis Shift (degrees)	Toric Eyes: Consistent Cases[a] 1 Month vs. 3 Months n	%	3 Months vs. 6 Months n	%	Toric Eyes with Data at Two or More Consecutive Visits[b] 1 Month vs. 3 Months n	%	3 Months vs. 6 Months 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 8:
Absolute Difference in Axis Alignment Between One Day and Six Months
First Eyes - All Toric ZCT150, ZCT225, ZCT300, ZCT400 Pooled
Safety Population

Axis Shift (degrees)	Toric Eyes: Consistent Cases[a] 1 Day vs. 6 Months n	%	Toric Eyes with Data at One Day and Six Months 1 Day vs. 6 Months n	%
>30	2[b]	1.4	2[b]	1.3
20-30	2[c,d]	1.4	2[c,d]	1.3
(<20)	144	97.3	152	97.4
16-19	1[e]	0.7	1[e]	0.6
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] One ZCT300 eye with calculated rotation of 21° underwent are positioning procedure.
[d] One ZCT150 eye with calculated lens rotation of 24° was not repositioned.
[e] One ZCT300 eye with calculated rotation of 18° underwent are positioning procedure.

Table 9:
Mean Change in Axis
Difference Taking Direction into Account (+/- Sign Included)
and Degree Shift Regardless of Direction (Absolute Value)
First Eyes - All Toric ZCT150, ZCT225, ZCT300, ZCT400 Pooled
Safety Population

Change in Axis Between Visits	Toric Eyes: Consistent Cases[a] N	MEAN (degrees)	STD. DEV.	Toric Eyes with Data at Two or More Visits[b] N	MEAN (degrees)	STD. DEV.
1 Mon. vs. 3 Mon.	148	0.24	2.82	156	0.25	2.77
3 Mon. vs. 6 Mon.	148	-0.06	2.94	152	-0.09	2.96
Baseline (1 Day) vs. 6 Mon.	148	-1.35	6.13	156	-1.33	5.99
Abs. Value-1 Mon. vs 3 Mon.	148	1.82	2.17	156	1.79	2.12
Abs. Value-3 Mon. vs 6 Mon.	148	1.85	2.28	152	1.89	2.27
Abs. Value-Baseline (1 Day) vs. 6 Mon.	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

Table 10:
Cumulative Adverse Events through Six Months
TECNIS® Toric ZCT First Eyes: ZCT150, ZCT225, ZCT300 and ZCT400

Cumulative Adverse Event	ZCT Eyes N=174 n	%	ISO SPE[a] Rate %
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
Surgical re-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%

Table 11:
Best Corrected Distance Visual Acuity (Snellen Equivalent) at 1 Year
Best Case Subjects* (N = 110) for the SENSAR® 1-Piece IOL, Model AAB00

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†	**110**	**93**	**84.5**	**17**	**15.5**	**0**	**0.0**	**0**	**0.0**

* Excludes subjects with macular degeneration at any time during the study
† Includes three subjects who experienced a Nd:YAG posterior capsulotomy

Table 12:
Best Corrected Distance Visual Acuity (Snellen Equivalent) at 1 Year
Best Case Subjects * (N=110) for the SENSAR® 1-Piece IOL, Model AAB00 vs. FDA Grid

Age Decade	Total		Visual Acuity 20/40 or Better		FDA Grid /ISO SPE
	N	%	N	%	%
< 60	11	10.0	11	100.0	98.5
60 – 69	35	31.8	35	100.0	96.5
70 – 79	46	41.8	46	100.0	97.5
> 80	18	16.4	18	100.0	94.8
TOTAL†	**110**	**100.0**	**110**	**100.0**	**96.7**

* Excludes subjects with macular degeneration at any time during the study
† Includes three subjects who experienced a Nd:YAG posterior capsulotomy

Table 13:
Adverse Events for the SENSAR® 1-Piece IOL, Model AAB00
All Subjects (N = 123)

Adverse Events	Cumulative		Persistent at 1 Year		FDA Grid /ISO SPE	
	N	%	N	%	CUM%	PER%
Persistent Corneal Edema	-	-	0	0.0	-	0.3
Cystoid Macular Edema (CME)	4	3.3*	1	0.9†	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	-	-	-	-

* This rate is not statistically significantly higher than the FDA Grid cumulative rate for posterior chamber IOLs of 3.0% (p=0.5060).

† This rate is not statistically significantly higher than the FDA Grid rate for posterior chamber IOLs of 0.5% (p=0.4437).

Figure 4:

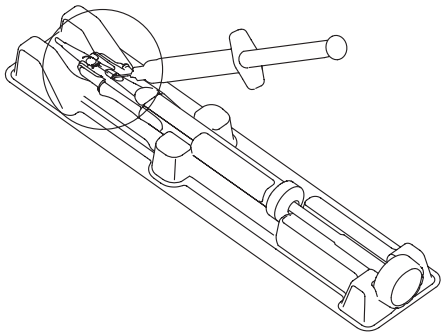


Figure 5:

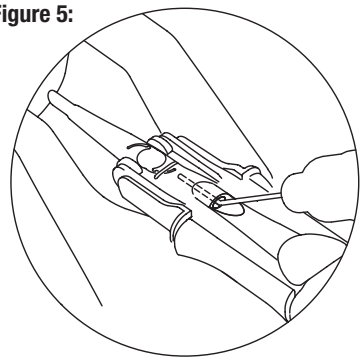


Figure 6:

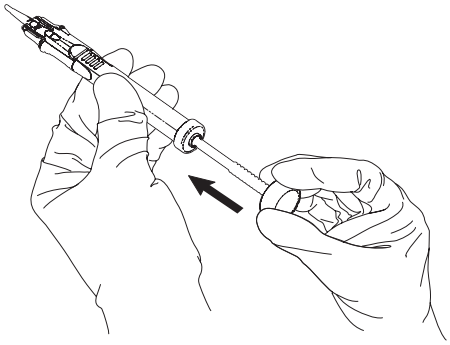
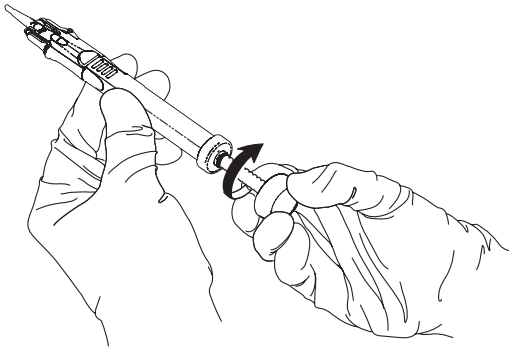


Figure 7:



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