TECNIS Symfony® Extended Range of Vision IOL

TECNIS Symfony® Extended Range of Vision IOL Toric

Getting Started GUIDE

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TECNIS Symfony® IOL and TECNIS Symfony® TORIC IOL

Johnson & Johnson VISION

IN THIS GUIDE

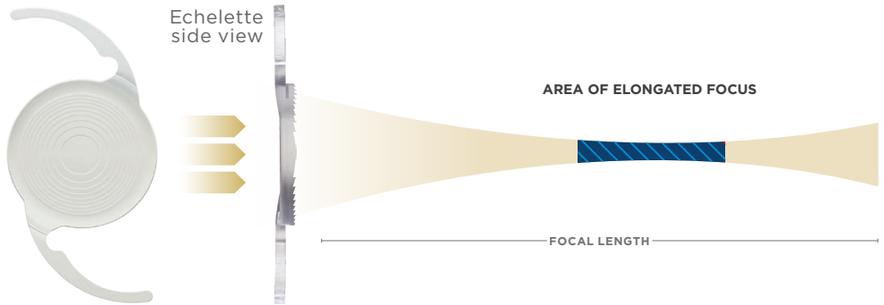
INDICATIONS FOR USE

The TECNIS Sym*f*ony® IOL, Model ZXR00, 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 lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The Model ZXR00 IOL is intended for capsular bag placement only.

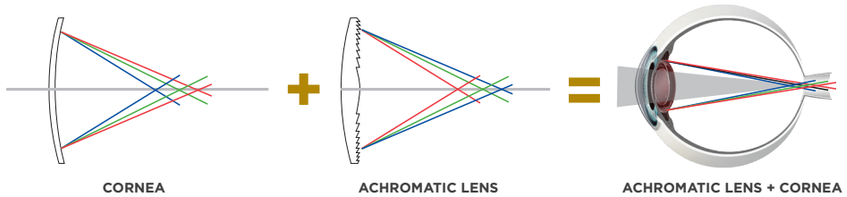
The TECNIS Sym*f*ony® Toric IOLs, Models ZXT150, ZXT225, ZXT300, and ZXT375, are indicated for primary implantation for the visual correction of aphakia and for reduction of residual refractive astigmatism in adult patients with greater than or equal to 1 diopter of preoperative corneal astigmatism, in whom a cataractous lens has been removed. The lens mitigates the effects of presbyopia by providing an extended depth of focus. Compared to an aspheric monofocal IOL, the lens provides improved intermediate and near visual acuity, while maintaining comparable distance visual acuity. The Model Series ZXT IOLs are intended for capsular bag placement only.

TECNIS Sym*f*ony® IOL combines two complementary and proprietary technologies to provide continuous high-quality vision at all distances.

Proprietary diffractive echelette design creates an **extended depth of focus** resulting in an extended range of vision.



Proprietary achromatic technology corrects chromatic aberration for **enhanced image contrast.**[1,2]



PRE-OPERATIVE:
Patient Selection

Careful medical judgment should be exercised in patients with the following conditions as the safety and effectiveness of the TECNIS Sym*f*ony® IOL has not been established in such cases:

- 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
- Pregnancy

WARNINGS: Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio described in the Directions for Use. 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: Patients with recurrent severe anterior or posterior segment inflammation or uveitis of unknown etiology, or any disease producing an inflammatory reaction in the eye. Patients in whom the intraocular lens may affect the ability to observe, diagnose or treat posterior segment diseases. See safety information continued on page 12.

PRE-OPERATIVE:
Managing Expectations

Patients considering implantation of a presbyopia-correcting IOL need to be aware that there are trade-offs associated with the technologies available.

- TECNIS Sym*f*ony® has been designed for high-quality, continuous vision at all distances with 20/25 or better visual acuity through 26 inches.[3]
- 85% of patients in the clinical trial wore glasses none or a little bit of the time
  - Inform patients that they may still need to wear glasses for some activities
- Inform patients that glare and visual disturbances may occur especially at night (i.e. spiderweb-like halo).[3]
- Ideally, choose patients with no corneal abnormalities.[4]

BIOMETRY

- Use an Optical Biometer and ensure that measurements are reliable.
- Calibrate the device regularly.
- Repeat measurements 3x-5x.
  - Proper fixation is essential. Have the patient look directly at the red light as instrument measures along the visual axis.
- Repeat axial length measurement if[5]:
  - Axial length <22.0mm or >25.0mm
  - Average corneal power <40D or >47D
  - Difference of corneal astigmatism between eyes is >1D
  - Difference of axial length between eyes is >0.3mm
  - Difference of calculated emmetropic IOL power is >1D
- If uncertain with measurements, use another device and compare the results (i.e. IOL Master and Lenstar).

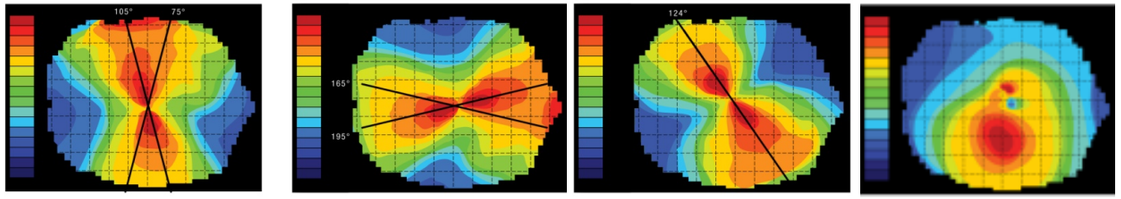
PRECAUTIONS: Prior to surgery, the surgeon must inform prospective patients of the possible risks and benefits associated with the use of this device and provide a copy of the patient information brochure to the patient. When performing refraction in patients implanted with the TECNIS Sym*f*ony® IOL, interpret results with caution when using autorefractors or wavefront aberrometers that utilize infrared light, or when performing a duochrome test. Confirmation of refraction with maximum plus manifest refraction technique is recommended.

KERATOMETRY

- Make sure that the surface of the cornea is stable prior to keratometry. Manage the ocular surface before biometry AND surgery.
- Perform the keratometry before any eye drops (anesthetic, cycloplegic, fluorescein) are instilled (except artificial tears).
- Ask patient to blink several times then take the measurement.
- 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. (reference: DFU)
- Repeat keratometry if:
  - K is not between 41D – 47D[6]
  - Difference of average corneal power > 1.0D between eyes[6]
  - Difference in corneal astigmatic power > 1.0D between consecutive measurements
  - Poor fixation e.g. mature cataract, etc.
  - Uncooperative or non-communicative patients
- Note: Refractive outcomes are matched 1:1 with keratometry inaccuracy (If you're 1.0D off in your K readings, you will have a 1.0D refractive surprise).

TOPOGRAPHY

- Topography can be used to identify irregular astigmatism.
- Depending on the device (e.g. Cassini, Pentacam, Galileil) it can also be used to directly measure posterior corneal astigmatism.



With the rule **Against the rule** **Oblique** **Irregular**

IOL CALCULATION FORMULA AND TARGET

TECNIS Sym*f*ony® IOL is part of the TECNIS® 1-Piece Family of products sharing the same mechanical properties and axial position in the eye.

- Initial A-constant suggested is the same as your optimized ZCB00 A-constant.
- Be sure to optimize the TECNIS Sym*f*ony® A-constant after you have data for 30 eyes (see A-constant optimization below).
- Use a fourth generation formula, such as the Barrett's Universal II formula (other formulas include RBF, Olsen, Holladay 2).
- When using a toric IOL, it is strongly recommended that a calculator be used that compensates for posterior corneal astigmatism such as the Tecnis Toric Calculator (www.TecnisToricCalc.com).

LENS CONSTANT OPTIMIZATION

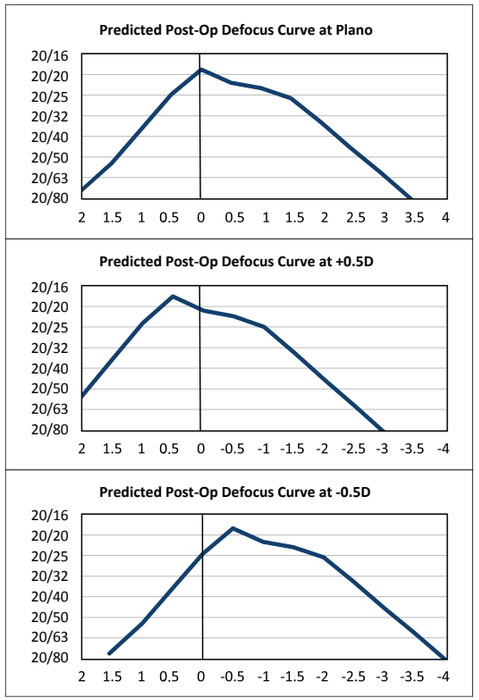
- Measure the maximum plus (least minus) refraction at the four-to-six-week follow-up visit.
- It will take at least 30 cases to calculate your personal constant at the outset.[7]
- Always use the same instruments and do everything exactly the same.
- Lens constants may be optimized using stand-alone software or the software that comes with your biometer or IOL Master.

PRECAUTIONS: 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 multicenter 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.

REFRACTIVE TARGETING

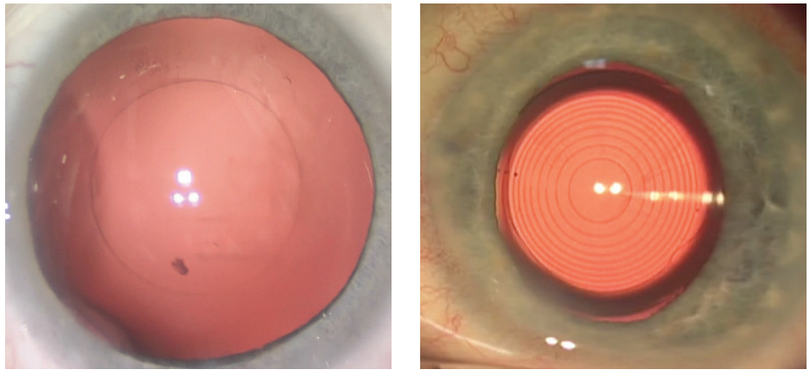
Consider targeting for emmetropia in the first eye then adjust accordingly for the fellow eye depending on patient preference.

- When targeting 1st minus, note that distance vision may be slightly compromised and near vision will be better.
- When targeting the 1st plus, patients may have better distance vision and slightly less near vision.



OPERATIVE:

- When using intraoperative aberrometry, if the system has not been optimized, do not choose the TECNIS Sym*f*ony® lens from the IOL menu. Choose the ZCB00 to determine the spherical equivalent power.
- A consistent curvilinear capsulorhexis is critical for centration and accurate effective lens position.
- After implantation of the TECNIS Sym*f*ony® IOL, remove all OVD including behind the IOL, then push posteriorly to aid in capsule capture.
- While patient is fixating on the single coaxial microscope light, center the first diffractive ring on the first Purkinje image. If angle kappa is large (> 0.5 mm), center the first diffractive ring in between the pupil center and the first Purkinje image.[6] This will effectively center the TECNIS Sym*f*ony® lens at the midpoint of the angle kappa.
- For TECNIS Sym*f*ony® Toric implantation, please refer to TECNIS® Toric Tips and Pearls by Dr. Daniel Chang.



A consistent curvilinear capsulorhexis helps with centration and lens position.

POST OPERATIVE:

POST-OP MEDS/DROPS[8]

- Refrain from using generic ophthalmic drops. These medications may bring trade-offs in efficacy, safety and convenience.
- Continue to optimize the ocular surface and treat any symptomatic OSD, MGD and/or blepharitis.

AUTO REFRACTIONS WILL NOT BE ACCURATE WITH THIS LENS

- Due to the chromatic aberration compensation inherent in the TECNIS Sym*f*ony® lens, auto-refractors (including aberrometers) may yield erroneous refractive results.

MAXIMUM PLUS REFRACTION

- Due to the elongated focus of the TECNIS Sym*f*ony®, refraction needs to be performed with care using the maximum plus refraction technique (“push plus”). This refractive outcome will be used to refine your personal lens constant.
- Start with a **+1.50D** sphere and assess visual acuity.
- Start reducing in **-0.25D** steps until patient sees the most number of letters with the least amount of minus. (THIS WILL BE THE MAXIMUM PLUS REFRACTION)
- Affirm by reducing another **-0.25D** or two and VA should remain the same.

1. DOF2015CT0023_Chromatic Aberration of the TECNIS Sym*f*ony® IOL
2. DOF2015CT0018_Chromatic Aberration of the TECNIS Sym*f*ony® IOL
3. TECNIS Sym*f*ony IOL Directions For User
4. CRSTEuro Sym*f*ony Pearls Article
5. Screening Criteria, Jack Holladay, PP2016OTH0603
6. Outcome Optimization with Accurate Biometry
7. A constant optimization
8. Brand v. Generic- Donnenfeld Article

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR TECNIS SYM*F*ONY® AND TECNIS SYM*F*ONY® TORIC EXTENDED RANGE OF VISION IOLs

Rx Only

WARNINGS: 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), a compromised eye due to previous trauma or developmental defects in which appropriate support of the IOL is not possible circumstances that would result in damage to the endothelium during implantation, suspected microbial infection, patients in whom neither the posterior capsule nor the zonules are intact enough to provide support for the IOL, children under the age of 2 years are not suitable candidates for intraocular lenses, congenital bilateral cataracts, previous history of, or a predisposition to, retinal detachment, patients with only one good eye with potentially good vision, medically uncontrollable glaucoma, corneal endothelial dystrophy, proliferative diabetic retinopathy. The TECNIS Sym*f*ony® IOL should not be placed in the ciliary sulcus. Patients with a predicted postoperative astigmatism greater than 1.0 diopter may not be suitable candidates for implantation with the TECNIS Sym*f*ony® and TECNIS Sym*f*ony® Toric IOLs, Models ZXR00, ZXT150, ZXT225, ZXT300, and ZXT375, as they may not obtain the benefits of reduced spectacle wear or improved intermediate and near vision seen in patients with lower astigmatism.
The effectiveness of TECNIS Sym*f*ony® Toric IOLs in reducing postoperative residual astigmatism in patients with preoperative corneal astigmatism < 1.0 diopter has not been demonstrated. Rotation of TECNIS Sym*f*ony® Toric IOLs away from their intended axis can reduce their 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. Johnson & Johnson Surgical Vision, Inc. IOLs are single-use devices only. Do not reuse this IOL.

PRECAUTIONS: The ability to perform some eye treatments (e.g. retinal photocoagulation) may be affected by the TECNIS Sym*f*ony® IOL optical design. 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. Do not resterilize the lens. Most sterilizers are not equipped to sterilize the soft acrylic material without producing undesirable side effects. Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline. Do not store the lens in direct sunlight or at a temperature greater than 113°F (45°C). Do not autoclave the intraocular lens. The surgeon should target emmetropia as this lens is designed for optimum visual performance when emmetropia is achieved. Care should be taken to achieve IOL centration, as lens decentration may result in a patient experiencing visual disturbances under certain lighting conditions. When the insertion system is used improperly, TECNIS Sym*f*ony® IOLs may not be delivered properly (i.e., haptics may be broken). Please refer to the specific instructions for use provided with the insertion instrument or system. The safety and effectiveness of TECNIS Sym*f*ony® IOLs have not been substantiated in patients with preexisting ocular conditions and intraoperative complications (see below for examples). Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in a patient with one or more of these conditions: Before Surgery: Pupil abnormalities, prior corneal refractive or intraocular surgery, choroidal hemorrhage, chronic severe uveitis, concomitant severe eye disease, extremely shallow anterior chamber, medically uncontrolled glaucoma microphthalmos, non-age-related cataract, proliferative diabetic retinopathy (severe), severe corneal dystrophy, severe optic nerve atrophy, irregular corneal astigmatism, amblyopia Macular disease, pregnancy. During Surgery: Excessive vitreous loss, non-circular capsulotomy/capsulorhexis, the presence of radial tears known or suspected at the time of surgery, Situations in which the integrity of the circular capsulotomy/capsulorhexis cannot be confirmed by direct visualization, cataract extraction by techniques other than phacoemulsification or liquefaction, capsular rupture, Significant anterior chamber hyphema, uncontrollable positive intraocular pressure, zonular damage. Carefully remove all viscoelastic and do not over-inflate the capsular bag at the end of the case. Residual viscoelastic and/or overinflation of the capsular bag may allow the lens to rotate, causing misalignment of the TECNIS Sym*f*ony® Toric IOL with the intended axis of placement. The use of methods other than the Tecnis Toric Calculator to select cylinder power and appropriate axis of implantation were not assessed in the parent 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 Calculator (www.TecnisToricCalc.com), are recommended to achieve optimal visual outcomes for the TECNIS Sym*f*ony® Toric IOL. All preoperative surgical parameters are important when choosing a TECNIS Sym*f*ony® Toric IOL 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. All corneal incisions were placed temporally in the parent 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 in the clinical study for the parent Tecnis Toric IOL. Note that the Tecnis Toric Calculator incorporates the surgeon's estimated SIA and incision location when providing IOL options. Potential adverse effects (e.g., complications) associated with the use of the device include the following:Infection (endophthalmitis), Hypopyon, IOL dislocation, Cystoid macular edema, Corneal edema, Pupillary block, Iritis, Retinal detachment/tear, Raised IOP requiring treatment, Visual symptoms requiring lens removal, Tilt and decentration requiring repositioning, Residual refractive error resulting in secondary intervention. Secondary surgical interventions include, but are not limited to: Lens repositioning (due to decentration, rotation, subluxation, etc.), Lens replacement, Vitreous aspirations or iridectomy for pupillary block, Wound leak repair, Retinal detachment repair, Corneal transplant, Lens replacement due to refractive error, Unacceptable optical/visual symptoms, Severe inflammation.

SERIOUS ADVERSE EVENTS: The most frequently reported serious adverse events that occurred during the clinical trial of the TECNIS Sym*f*ony® lens were cystoid macular edema (2 eyes, 0.7%) and surgical reintervention (treatment injections for cystoid macular edema and endophthalmitis, 2 eyes, 0.7%). One eye was reported with pupillary capture and the eye that had endophthalmitis also had a small hypopyon. No other serious adverse events and no lens-related adverse events occurred during the trial.

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