Getting Started

GUIDE

TECNIS Symfony® IOL and
TECNIS Symfony® TORIC IOL
TECNIS Symfony® 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.

INDICATIONS FOR USE
The Tecnis Symfony® 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 Symfony® 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.
PRE-OPERATIVE: 

**Patient Selection**

Careful medical judgment should be exercised in patients with the following conditions as the safety and effectiveness of the Symfony 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

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.

- Symfony has been designed for high-quality, continuous vision at all distances with 20/25 or better visual acuity through 26 inches.1
- 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. spider web like halo).1
- Ideally, choose patients with no corneal abnormalities.2

**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.

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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 if axial length measurement is out of range:
  - Axial length <22.0mm or >25.0mm
  - Average corneal power <40D or >47D
  - Difference of corneal astigmatism between eyes >1D
  - Difference of axial length between eyes >0.3mm
  - Difference of calculated emmetropic IOL power >1D
- If uncertain with measurements, use another device and compare the results (i.e. IOL Master and Lenstar).

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.
- Wet cornea with lubricants if the eye is dry or if measurements are inconsistent.
- 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
  - Difference of average corneal power > 1.0D between eyes
  - 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, Galilei) can also be used to directly measure posterior corneal astigmatism.
TECNIS Symfony® 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 Symfony 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.9
- 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.

**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.

**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 AMO Toric Calculator user manual for more information.
**OPERATIVE:**

- When using intraoperative aberrometry, if the system has not been optimized, do not choose the Symfony lens from the IOL menu. Chose 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 Symfony 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. This will effectively center the Symfony lens at the midpoint of the angle kappa.
- For Symfony Toric implantation, please refer to TECNIS® Toric Tips and Pearls by Dr. Daniel Chang.

**POST OPERATIVE:**

**POST-OP MEDS/DROPS**
- 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 Symfony lens, auto-refractors (including aberrometers) may yield erroneous refractive results.

**MAXIMUM PLUS REFRACTION**
- Due to the elongated focus of the Symfony, 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.
SERIOUS ADVERSE EVENTS: The most frequently reported serious adverse events that occurred during the clinical trial of the Tecnis Symfony 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.