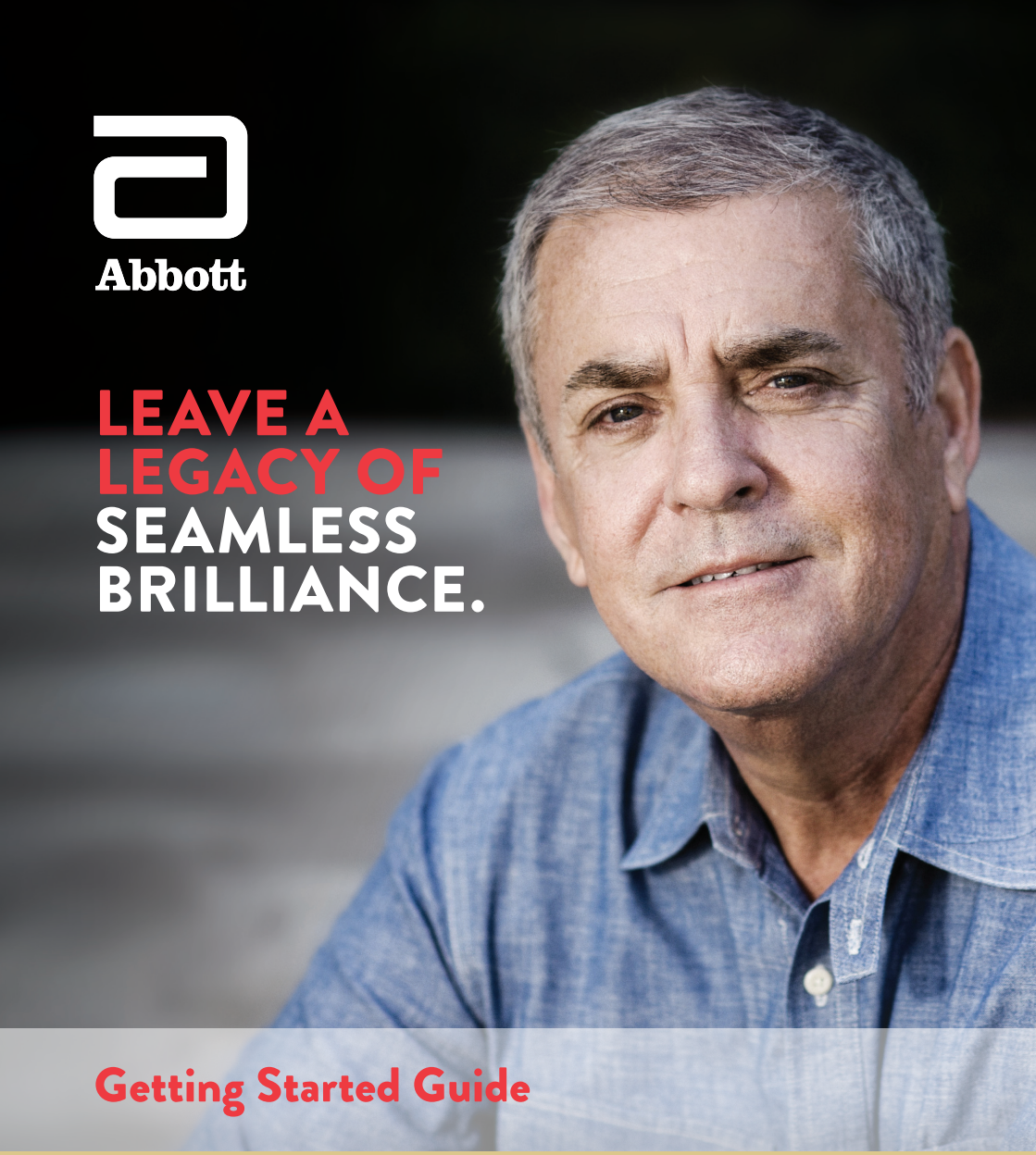


Getting Started Guide

TECNIS Symfony®
Extended Range of Vision IOL

This is a guide only. Please read the full directions for use (DFU).

TECNIS Symfony® Extended Range of Vision IOL

GIVE YOUR PATIENTS
A CONTINUOUS RANGE OF HIGH-QUALITY VISION

The TECNIS Symfony® IOL combines two complementary proprietary technologies to provide an extended range of continuous, high-quality vision[1]

In the US Pivotal study with 148 patients, the **TECNIS** Symfony® IOL showed:

- 20/20 mean uncorrected binocular visual acuity for distance
- 20/20 mean uncorrected binocular visual acuity for intermediate vision
- 20/25 mean uncorrected binocular near visual acuity

Indications for use

The **TECNIS** Symfony® Extended Range of Vision 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 Extended Range of Vision 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.

Patient selection basics

- Patient should be motivated to have improved visual acuity over the full range of vision: near, intermediate and distance
- Patient should understand overall spectacle wear will be reduced when compared to a monofocal, but glasses may still be needed for some up-close activities
- Abbott has produced tools that will help you talk to your patients about whether **TECNIS®** presbyopia-correcting IOLs are a good fit for their needs

  Refer to:

  - Patient Lifestyle Questionnaire
  - Vision Simulator
  - Patient Brochure

Please contact your Abbott representative for more information or to request these tools.

Every patient considering implantation of a presbyopia-correcting IOL needs to be aware that there are trade-offs associated with the technologies available

TECNIS Symfony® IOL

1. A full range of continuous, high-quality vision[1]
2. 85% of patients wore glasses none or a little bit of the time[1]
3. Low incidence of halo and glare[1]
4. Patients may require glasses for close, near tasks[1]

Refractive Targeting

When calculating IOL power with **TECNIS** Symfony® IOL, ensure the patient will end up as close to emmetropia as possible. Select the power that results in the least minus residual refraction.

TECNIS Symfony® IOL A-constant[1]

The **TECNIS** Symfony® IOL is part of the **TECNIS**® 1-Piece Family of products sharing the same mechanical properties and axial position in the eye as the rest of the **TECNIS**® 1-Piece Family of products. Optical behaviour has been analyzed for the **TECNIS** Symfony® IOL, and our A-constant recommendations are:

A-constant:	**118.8D**	**119.3D**
Theoretical AC Depth:	**5.4 mm**	**5.7 mm**
Surgeon Factor:[1]	**1.68 mm**	**1.96 mm**

As with all IOLs, the manufacturer's recommendations are a sound starting point. For best possible outcomes, surgeons should personalized their A-constant based on their refractive outcomes. For the **TECNIS** Symfony® IOL, it is essential to follow the post-operative refraction advice which can be found below.

Post-operative refraction[2,3]

The lens has an elongated focus so the "maximum plus" refraction technique is strongly recommended.

Maximum plus

Post-operatively, eyes implanted with a **TECNIS** Symfony® IOL should be refracted to the maximum plus (or least minus) diopter through which the best distance visual acuity is achieved. This will ensure that visual acuity for distance is optimized while maximizing the Extended Range of Vision available at intermediate and near distances.

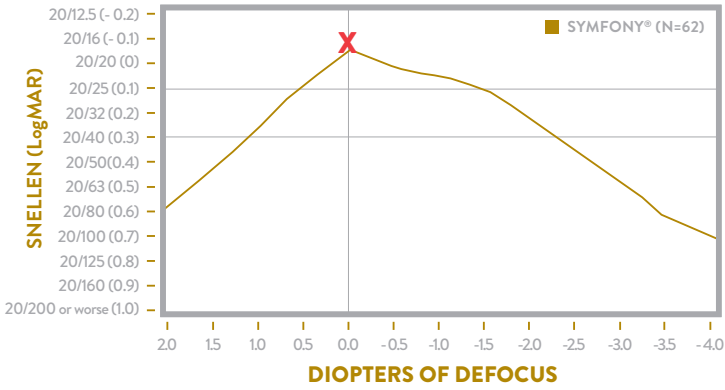
Due to its design, refraction on patients implanted with the **TECNIS** Symfony® IOL needs to be performed with care, especially if you are using these refractive outcomes to refine personal A-constants.

- Autorefractors using infrared light, wavefront sensors, as well as infrared photorefractors, may not give reliable results
- When performing refraction in patients implanted with the **TECNIS** Symfony® 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

Achieving maximum plus[2,3]

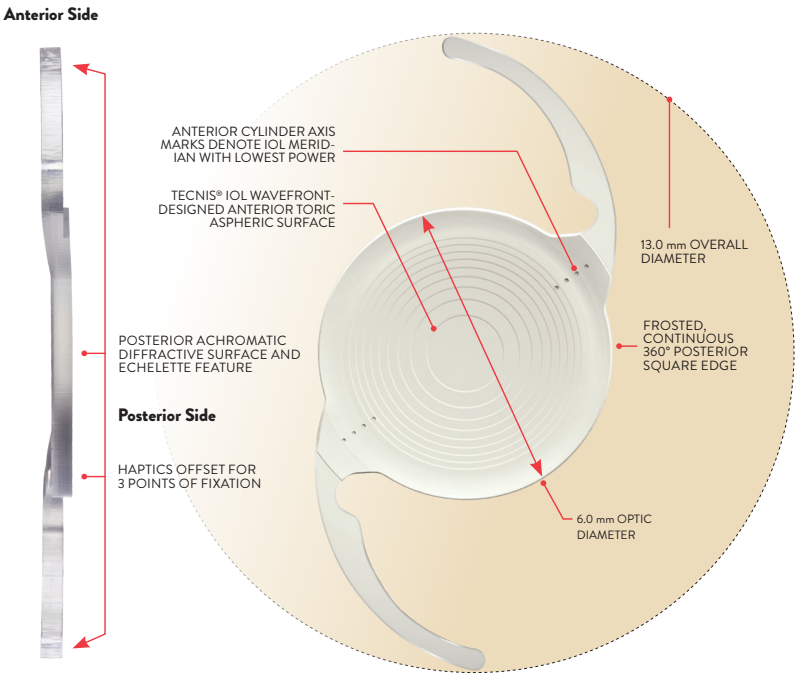
- The elongated focus of the **TECNIS** Symfony® IOL creates a defocus curve with a unique plateau shape.[1]
- To provide the ideal refractive outcome and the fullest range of vision possible for the patient, the left-hand edge of the plateau **X** should be focused on the retina for uncorrected distance vision.
- When refracting **TECNIS** Symfony® IOL patients, rather than assuming that the end result has been obtained when an additional 0.25 D creates a slight loss of crispness, patients should be refracted using the "maximum plus" or "least minus" technique to ensure that point **X** has been reached. This is particularly important when collecting data on which to personalize the surgeon's A-constant for the lens.

BINOCULAR UNCORRECTED DEFOCUS CURVE AT 6 MONTHS[1]



TECNIS Symfony® TORIC IOL

- Use consistent method for K reading measurements.
- Identify corneal irregularities using topography.
- Utilise the **TECNIS** Toric IOL calculator to determine the appropriate toric model and power.
- Print calculator results for reference in the OR.



Intra-operative considerations

- Use the **TECNIS** Toric IOL Calculator printout to verify the **TECNIS** Toric IOL model, power, and desired axis placement.
- Identify and mark the steep axis of the cornea using an axis gauge of your choice and the pre-operative reference marks.
- After IOL implantation, align the anterior surface markings of the IOL (four small dots) with the steep axis markings of the cornea for optimal correction of cylinder error.

Axis alignment phases

1. **Viscoelastic removal.** During OVD removal with preferred technique, take care not to allow the IOL to rotate beyond the calculated position.
3. **Final alignment.** Using your preferred technique, rotate the IOL clockwise until it is precisely aligned with the final calculated position.

Access highly accurate calculations at www.tecnistoriccalc.com

The **TECNIS** Toric IOL calculator is a single-use software application that helps you select the most appropriate **TECNIS** Toric IOL for your patient. The calculator takes into account surgeon preferences accepting the spherical equivalent IOL power as an input for each patient. This allows the surgeons to use the power calculation method and formula of their choice.

The **TECNIS** Toric IOL calculator then calculates cylinder IOL power options for you, as well as the orientation in which the IOL should be implanted to achieve optimum results. In addition, predicted post-operative residual astigmatism is calculated for each cylinder IOL power suggested.

TECNIS Symfony®
Extended Range of Vision IOL

References

1. TECNIS Symfony® IOL Directions for Use.
2. Kretz F. Top Tips for Premium IOL Refraction. *The Ophthalmologist* 2015;28-31 REF2015CT0128.
3. Bennett AG, Rabbetts RB - *Clinical Visual Optics,* 2nd edition, p. 128 - Butterworth Heinemann 1989. REF2015OTH0142.

INDICATIONS and IMPORTANT SAFETY INFORMATION for TECNIS SYMFONY and TECNIS SYMFONY TORIC EXTENDED RANGE OF VISION IOLs

Rx Only

INDICATIONS FOR USE

The TECNIS Symfony Extended Range of Vision 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 Extended Range of Vision 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.

WARNINGS

Patients with any of the conditions described in the Directions for Use 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. Lenses should not be placed in the ciliary sulcus. May cause a reduction in contrast sensitivity under certain conditions, compared to an aspheric monofocal IOL; fully inform the patient of this risk before implanting the lens. Special consideration should be made in patients with macular disease, amblyopia, corneal irregularities, or other ocular disease. Inform patients to exercise special caution when driving at night or in poor visibility conditions. Some visual effects may be expected due to the lens design, including: a perception of halos, glare, or starbursts around lights under nighttime conditions. These will be bothersome or very bothersome in some people, particularly in low-illumination conditions, and on rare occasions, may be significant enough that the patient may request removal of the IOL.

Patients with a predicted postoperative astigmatism greater than 1.0 diopter may not be suitable candidates for implantation with the TECNIS Symfony and TECNIS Symfony 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. Rotation of the Tecnis Symfony Toric IOLs away from their intended axis can reduce their astigmatic correction, and misalignment ⍰30° may increase postoperative refractive cylinder. If necessary, lens repositioning should occur as early as possible prior to lens encapsulation.

PRECAUTIONS

Interpret results with caution when refracting 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. The ability to perform some eye treatments (e.g. retinal photocoagulation) may be affected by the optical design. Target emmetropia for optimum visual performance. Care should be taken to achieve IOL centration, as lens decentration may result in a patient experiencing visual disturbances under certain lighting conditions.

For the Tecnis Symfony Toric IOL, variability in any preoperative surgical parameters (e.g. keratometric cylinder, incision location, surgeon's estimated surgically induced astigmatism and biometry) can influence patient outcomes. Carefully remove all viscoelastic and do not over-inflate the capsular bag at the end of the case to prevent lens rotation. Accurate keratometry and biometry, in addition to the use of the TECNIS Toric Calculator (HYPERLINK "http://www.TecnisToricCalc.com"www.TecnisToricCalc.com), are recommended to achieve optimal visual outcomes for the TECNIS Symfony Toric IOL. Note that the TECNIS Toric Calculator incorporates the surgeon's estimated SIA and incision location when providing IOL options.

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%). No lens-related adverse events occurred during the trial.

ATTENTION: Reference the Directions for Use for a complete listing of Indications and Important Safety Information.