

INDICATIONS: 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 and without presbyopia in whom a cataractous lens has been removed by extracapsular cataract extraction, and aphakia following refractive lensectomy in presbyopic adults, who desire useful vision over a continuous range of distances including far, intermediate and near, and increased spectacle independence. This device is intended to be placed in the capsular bag. The TECNIS® Multifocal 1-Piece Intraocular Lenses are indicated for primary implantation for the visual correction of [1] aphakia in adults in whom a cataractous lens has been removed and for Model ZMB00, [2] aphakia following refractive lensectomy in presbyopic adults who may benefit from useful near vision and reduced spectacle dependence across a range of distances. For Model ZKB00 and ZLB00, [2] aphakia following refractive lensectomy in presbyopic adults who desire improved uncorrected near, intermediate, and distance vision and increased spectacle independence across a range of distances. The intraocular lenses are intended to be placed in the capsular bag.

See page 15 for continued Indications and Important Safety Information.

TECNIS[®] Presbyopia-Correcting IOLs

See the Passion in Each Patient.

Johnson Johnson vision

The Passion to Exercise. The Vision to Excel

Understand Your Patients. Deliver Vision for Living.



Stay ahead of rising expectations with a complete portfolio designed to empower visual freedom in each patient's life — all from the leader in presbyopia-correcting IOLs.¹



Continuous range of highquality vision at all distances



Tailored clarity to meet each patient's lifestyle



The State of Sight.

Presbyopia is a progressive eye condition. While it can be treated with spectacles, presbyopiacorrecting IOLs may be a better alternative. Bifocal glasses have side effects due to limited depth of focus and loss of contrast.²

Modern Patients

Patients have higher expectations than ever before and see their golden years as a new chapter of possibility.³

Visual Demand³

People 50+



Largest growing demographic



Increasingly tech- and mobile-savvy

People 60+



60% are still in the workforce



71% see retirement as an opportunity to travel and explore other cultures

INDICATIONS: The TECNIS Symfony Toric Extended Range of Vision IOLs, models ZXT150, ZXT225, ZXT300, ZXT375, ZXT450, ZXT525, and ZXT600 are indicated for primary implantation for the visual correction of aphakia and pre-existing corneal astigmatism in adult patients with and without presbyopia in whom a cataractous lens has been removed by extracapsular cataract extraction, and aphakia following refractive lensectomy in presbyopic adults, who desire useful vision over a continuous range of distances including far, intermediate and near, a reduction of residual refractive cylinder, and increased spectacle independence. The model series ZXT IOLs are intended for capsular bag placement only.

See page 15 for continued Indications and Important Safety Information.

Modern Outcomes

Mitigating the effects of presbyopia surgically provides patients with vision for the modern lifestyle.



TECNIS Symfony®

Presbvopia and astigmatism management that seamlessly translate into brilliant. continuous vision





TECNIS® Multifocal IOLs

Outstanding, full-range vision optimized for spectacle independence at each patient's ideal distance



TECNIS Symfony® Extended Range of Vision IOIs

Drive Total Quality.

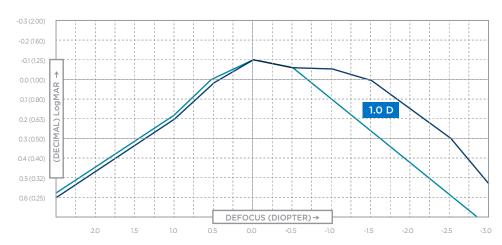
Deliver high-quality, continuous vision throughout the full range.



Seamless Brilliance

Extend the range of high-quality vision.

Bilateral Defocus 6-Month Adjusted Data⁴

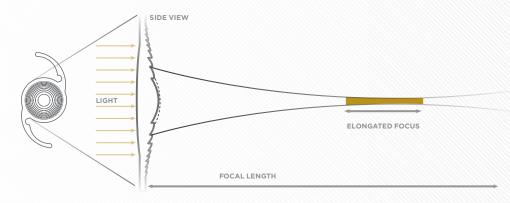


Increase patients' range of vision by 1.0 D across the defocus curve compared to a monofocal IOL.4





Proprietary Echelette Design



The proprietary diffractive echelette design creates an extended depth of focus, resulting in an extended range of vision.⁴

Uncorrected Visual Acuity⁴



20/25 at Distance

of patients



20/25 at Intermediate



20/32 at Near

of patients

Johnson Johnson vision

TECNIS Symfony IOLs

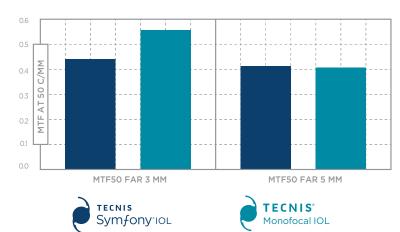
Strive for Brilliance.





Give patients image contrast that's comparable to a monofocal IOL due to active chromatic aberration correction.⁵

MTF (50 c/mm) Day and Night⁵



Enhance image contrast not only by reducing chromatic aberration but also by correcting existing chromatic aberration of the phakic eye.⁴

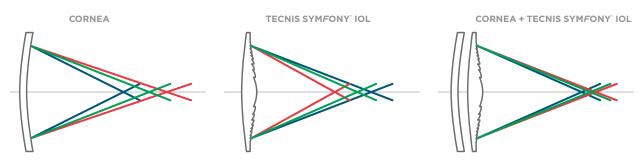
Chromatic Aberration⁶

TECNIS* Symfony* IOL:
1.28 D

Aphakic Eye: **1.69 D**

Proprietary Achromatic Technology

Only **TECNIS Symfony*** IOLs correct chromatic aberration at distance, intermediate and near to deliver a sharp image over the entire range of vision.^{4,6*}



*Based on feature comparison and data among PC IOL brands (AcrySof" IQ ReSTOR", Bausch and Lomb Crystalens, HOYA Acrylic IOLs) in the US.

Johnson Johnson Vision



Right on Track.

Deliver enduring performance that helps patients see more of life with improved focus.

Enduring Performance

Choose **TECNIS Symfony*** IOLs for excellent tolerance to astigmatism and decentration.^{7,8}

Maintain 20/20 visual acuity through 1.0 D of astigmatism.⁷

Maintain image quality throughout 0.75 mm of decentration.8*

^{*}Derived from theoretical calculations.



The Difference is Night and Day



Pupil-size independence enables patients to maintain their active lifestyles in all lighting conditions.⁴

Low Incidence of Visual Symptoms⁴













3.4% 1.4% Moderate Severe

Spontaneous Reports of Ocular Symptoms, 6 Months Postoperative

Mapping Results

In large, multi-center, multi-geographic clinical studies, > 1000 eyes have shown very low spontaneous reports of halo with the **TECNIS Symfony*** IOL.^{4,9,10}

TECNIS® Multifocal IOLs

Inspired Design.

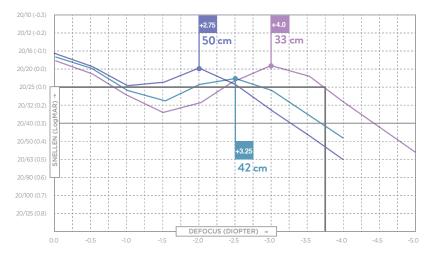
Tailor your patients' vision to meet their lifestyle needs.



Tailored Clarity

Personalize near visual acuity while delivering high-quality vision across the full range.

Binocular Defocus 6-Month Data¹¹







TECNIS° Multifocal IOL

+4.0 D data are historical from a separate clinical study using the same test methodology.

Full Palette

The models ZLB00 and ZKB00 have high spectacle independence in any lighting condition.11*

Tailor Selection Based on Patient Lifestyle

+4.0 D

Reading and knitting +3.25 D

Multimedia work

+2.75 D Grocery shopping

Patients Who Never or Only Sometimes Wear Glasses^{11**}







Ready for Life

Help your patients see life clearly — all day long.

More than 90% of patients experience no difficulty with **night vision** (+2.75 D data).11** Incidence of severe halos comparable to the TECNIS® Monofocal IOL (+2.75 D data).¹¹

The Difference is Night and Day



Pupil independence enables optimal performance in all lighting conditions.¹²

WARNINGS: Some visual effects associated with multifocal IOLs may be expected because of the superposition of focused and unfocused images. These may include a perception of halos/glare around lights under nighttime conditions. It is expected that, in a small percentage of patients, the observation of such phenomena will be annoying and may be perceived as a hindrance, particularly in low illumination conditions. On rare occasions, these visual effects may be significant enough that the patient will request removal of the multifocal IOL. Contrast sensitivity is reduced with a multifocal lens compared to a monofocal lens. Therefore, patients with multifocal lenses should exercise caution when driving at night or in poor visibility conditions.

^{*}Compared to TECNIS* Multifocal IOL models (ZKB00 and ZLB00) and TECNIS* Monofocal IOL (ZCB00).

^{**}The questionnaire was not determined to be a psychometrically valid assessment of the concept of spectacle independence. Subjects ranked night vision metrics on a scale of 1-7.



TECNIS Symfony®

- Continuous range of high-quality vision at all distances4
- High image contrast due to active chromatic aberration correction⁴
- Low visual symptoms⁴

TECNIS®

Multifocal IOLs

- Tailored clarity to meet each patient's lifestyle
- High image contrast5*
- The models ZLB00 and ZKB00 have high spectacle independence in any lighting condition^{11**}

Put your patients first with the leader in presbyopia-correcting IOLs.

*Compared to ReSTOR 2.5 and ReSTOR 3.0 in the US.

Compared to **TECNIS* Multifocal IOL models (ZKB00 and ZLB00) and TECNIS' Monofocal IOL (ZCB00)

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Indications & Important Safety Information

TECNIS SYMFONY EXTENDED RANGE OF VISION IOL

WARNINGS: Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio. 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, 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 Symfony* IOL should be placed entirely in the capsular bag and should not be placed in the ciliary sulcus. The TECNIS Symfony* IOL may cause a reduction in contrast sensitivity under certain conditions, compared to an aspheric monofocal IOL. The physician should carefully weigh the potential risks and benefits for each patient, and should fully inform the patient of the potential for reduced contrast sensitivity before implanting the lens in patients. Special consideration of potential visual problems should be made before implanting the lens in patients with macular disease, amblyopia, corneal irregularities, or other ocular disease which may cause present or future reduction in acuity or contrast sensitivity. Because the TECNIS Symfony* IOL may cause a reduction in contrast sensitivity compared to a monofocal IOL, patients implanted with the lens should be informed to exercise special caution when driving at night or in poor visibility conditions. Some visual effects associated with the **TECNIS Symfony**® IOL may be expected due to the lens design that delivers elongation of focus. These may include a perception of halos, glare, or starbursts around lights under nighttime conditions. The experience of these phenomena will be bothersome or very bothersome in some people, particularly in low-illumination conditions. On rare occasions, these visual effects 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* IOL, models ZXROO, as they may not obtain the benefits of reduced spectacle wear or improved intermediate and near vision seen in patients with lower astigmatism. IOLs are singleuse devices only. Do not reuse this IOL.

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 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. The ability to perform some eye treatments (e.g., retinal photocoagulation) may be affected by the **TECNIS Symfony*** 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 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 Symfony* 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 Symfony* 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. 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 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.

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



Indications & Important Safety Information Continued

TECNIS' MULTIFOCAL FAMILY OF 1-PIECE IOLS

WARNINGS: Physicians considering lens implantation under any of the conditions described in the Directions for Use should weigh the potential risk/benefit ratio prior to implanting a lens. Some visual effects associated with multifocal IOLs may be expected because of the superposition of focused and unfocused images. These may include a perception of halos/glare around lights under nighttime conditions. It is expected that, in a small percentage of patients, the observation of such phenomena will be annoying and may be perceived as a hindrance, particularly in low illumination conditions. On rare occasions, these visual effects may be significant enough that the patient will request removal of the multifocal IOL. Contrast sensitivity is reduced with a multifocal lens compared to a monofocal lens. Therefore, patients with multifocal lenses should exercise caution when driving at night or in poor visibility conditions. Patients with a predicted postoperative astigmatism >1.0D may not be suitable candidates for multifocal IOL implantation since they may not fully benefit from a multifocal IOL in terms of potential spectacle independence. Care should be taken to achieve centration, as lens decentration may result in patients experiencing visual disturbances particularly in patients with large pupils under mesopic conditions. Multifocal IOL implants may be inadvisable in patients where central visual field reduction may not be tolerated, such as macular degeneration, retinal pigment epithelium changes, and glaucoma. Patients with certain medical conditions may not be suitable candidates for IOLs. Consult the Directions for Use for more information.

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 patient. There were no patients 21 years old or younger included in the clinical studies; therefore there are insufficient clinical data to demonstrate safety and effectiveness in this age group. The central one millimeter area of the lens creates a far image focus, therefore patients with abnormally small pupils (-1mm) should achieve, at a minimum, the prescribed distance vision under photopic conditions; however, because this multifocal design has not been tested in patients with abnormally small pupils, it is unclear whether such patients will derive any near vision benefit. Autorefractors may not provide optimal postoperative refraction of multifocal patients; manual refraction is strongly recommended. In contact lens wearers, surgeons should establish corneal stability without contact lenses prior to determining IOL power. Care should be taken when performing wavefront measurements as two different wavefronts are produced (one will be in focus (either far or near) and the other wavefront will be out of focus); therefore incorrect interpretation of the wavefront measurements is possible. The long-term effects of intraocular lens implantation have not been determined; therefore implant patients should be monitored postoperatively on a regular basis. Secondary glaucoma has been reported occasionally in patients with controlled glaucoma who received lens implants. The intraocular pressure of implant patients with glaucoma should be carefully monitored postoperatively. Do not resterilize or autoclave. Use only sterile irrigating solutions such as balanced salt solution or sterile normal saline. Do not store in direct sunlight or over 45°C. Emmetropia should be targeted as this lens is designed for optimum visual performance when emmetropia is achieved. Please refer to the specific instructions for use provided with the insertion instrument or system for the amount of time the IOL can remain folded before the IOL must be discarded. When the insertion system is used improperly, the haptics of the IOL may become broken. Please refer to the specific instructions for use provided with the insertion instrument or system.

ADVERSE EVENTS: The most frequently reported adverse event that occurred during the clinical trials of the **TECNIS*** Multifocal lenses was surgical re-intervention, most of which were non-lens-related. Lens-related re-interventions occurred at a rate of 0.6% to 1.0%. Other surgical re-interventions included lens exchanges (for incorrect IOL power), retinal repair, ruptured globe repair, macular hole repair, removal of retained lens material, treatment injections for cystoid macular edema and iritis, and blepharoplasty.

TECNIS' MONOFOCAL 1-PIECE IOLs

INDICATIONS: TECNIS* 1-Piece Lenses are indicated for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction. These devices are intended to be placed in the capsular bag. IMPORTANT SAFETY INFORMATION: Physicians considering lens implantation under any of the conditions described in the Directions for Use should weigh the potential risk/benefit ratio prior to implanting a lens that could increase complications or impact patient outcomes. Do not place the lens in the ciliary sulcus. The most commonly reported adverse events of cataract surgery with the 1-piece IOL included macular edema.

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

References

1. Freeman R. Market Scope 2017 – IOL Report: A Global Market Analysis for 2016 to 2022. P. 79. REF2018MLT4002. 2. Lord SR, et al. A Multifocal Glasses Impair Edge-Contrast Sensitivity and Dept Perception and Increase the Risk of Falls in Older People. *J Am Geriatrics Soc.* 2002;50(11):1760-1766. REF2018OTH0044. 3. Project Ageless: Meet the Healthy Ager – Insights into Their Journey of Aging. Abbott Nutrition. REF2018CT4084. 4. TECNIS Symfony* IOL DfU – Z311036 – Rev 02 – Sep 2016 – US. REF2017CT0015. 5. DOF2017CT0006 – MTF of the TECNIS Symfony* IOL and other lens models – Weeber H. 23 June 2017. 6. DOF2018CT4007 – Chromatic aberration of the TECNIS Symfony* IOL – Weeber H. May 24, 2018. 7. Carones F. Residual Astigmatism Threshold and Patient Satisfaction with Bifocal, Trifocal and Extended Range of Vision Intraocular Lenses (IOLs). *Open J Ophthalmol.* 2017;7(01):1-7. REF2017OTH0102. 8. DOF2016CT0023 – Tolerance to IOL decentration of the TECNIS Symfony* IOL – Piers P, Weeber H. 30 June 2016. 9. Cochener B, et al. Clinical outcomes of a new extended range of vision intraocular lens: International Multicenter Concerto Study. *J Cataract Refract Surg* 2016; 42(9):1268-1275. REF2016CT0489. 10. Data on File 166 – Clinical Investigation of a Design Extension of the TECNIS* 1-Piece Intraocular Lens (Model XRA03) – Key results from primary study phase (New Zealand) – Feb. 2014. REF2014CT0018. 11. TECNIS* MIOL DfU – ZMB00, ZKB00 and ZLB00 – Z310970 – Rev 02 – 10 Dec 2014 – US. REF2014CT0623.

Not actual patient. Images for illustrative purposes only.

TECNIS[®] Presbyopia-Correcting IOLs

Bring Vision to Life.

For healthcare professionals only. Please read the Directions for Use and consult our specialists if you have any questions.

Johnson Johnson vision

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