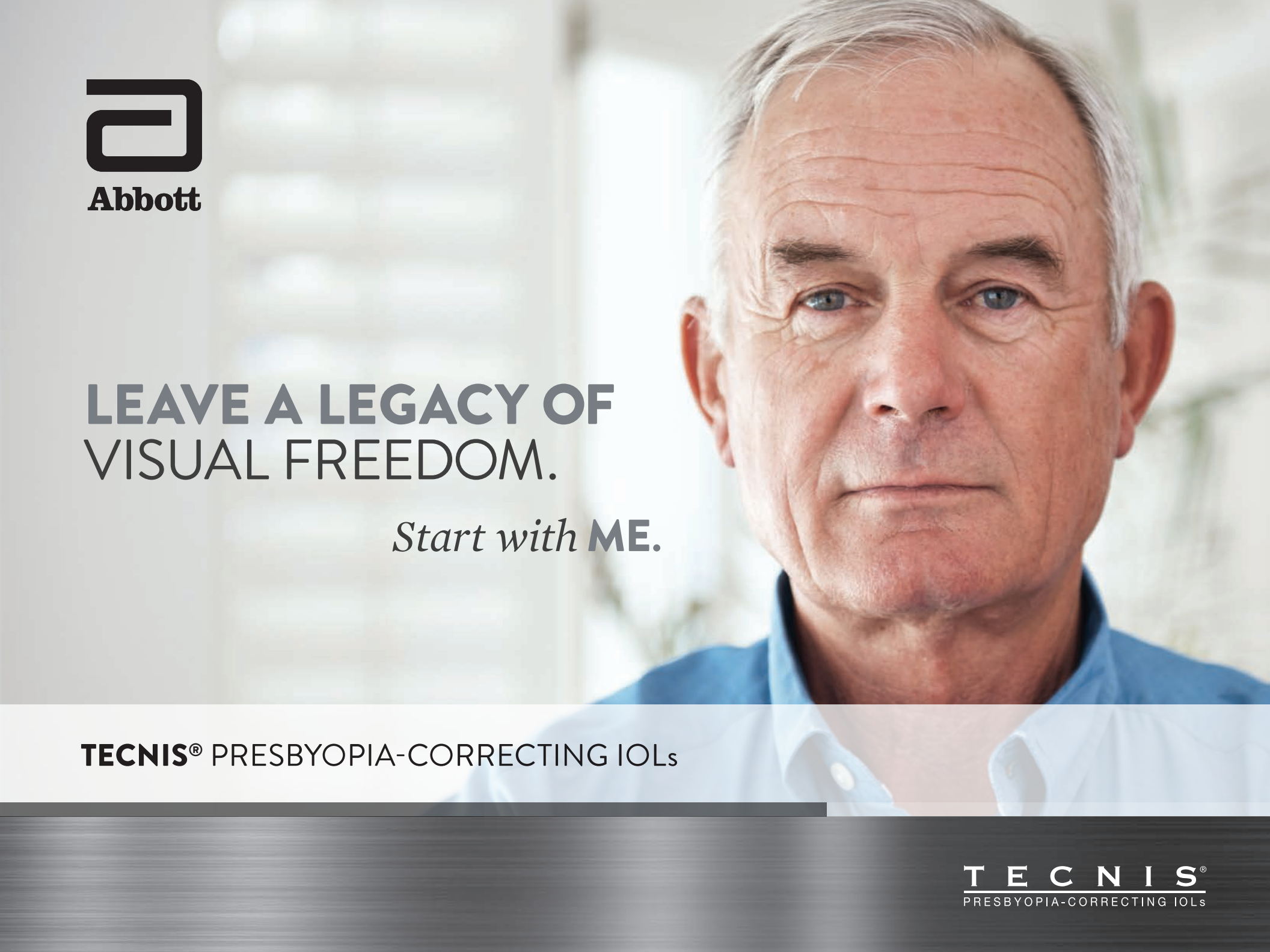
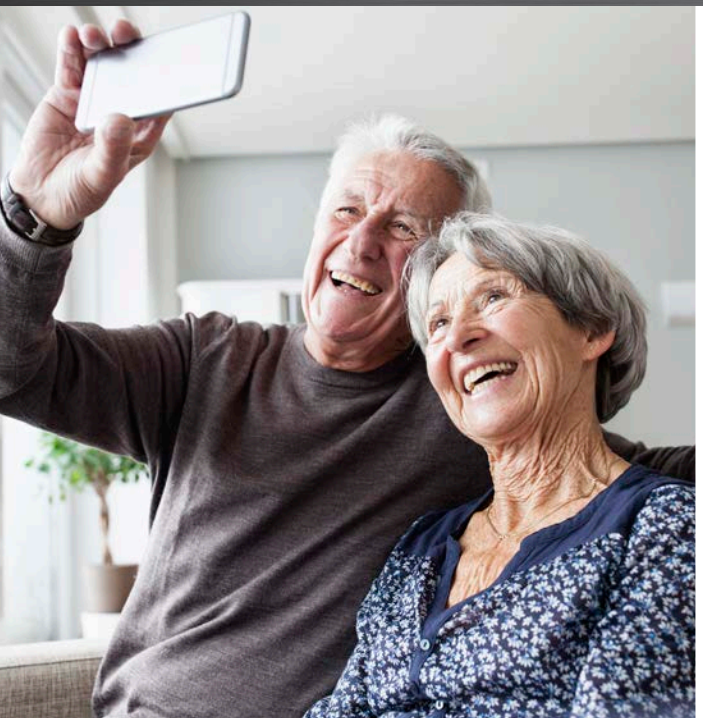
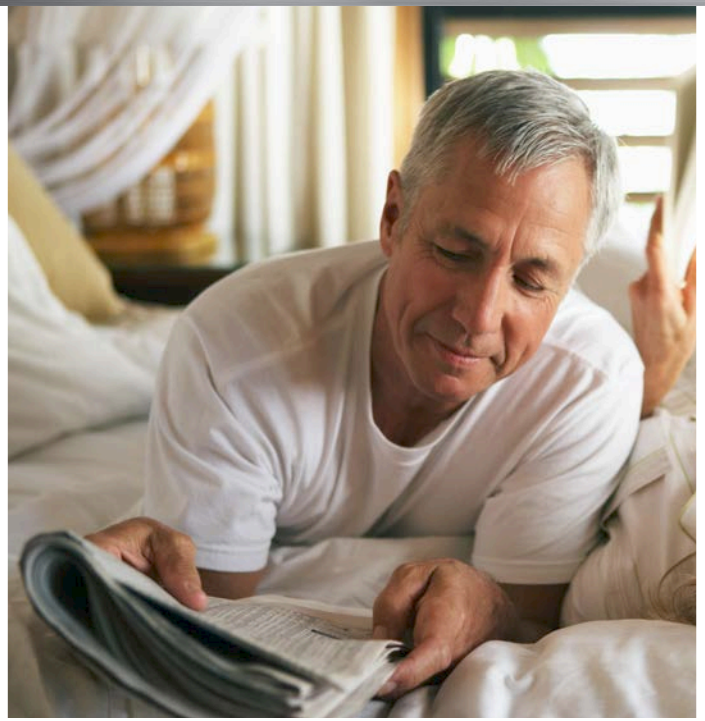

Abbott
LEAVE A LEGACY OF
VISUAL FREEDOM.
Start with ME.
TECNIS® PRESBYOPIA-CORRECTING IOLs
TECNIS®
PRESBYOPIA-CORRECTING IOLs

*The **TECNIS**® Portfolio of presbyopia-correcting IOLs empowers you to hand-select a lens that can deliver the visual freedom your patients need to live the life they desire.*

Now you can offer your patients, including those with astigmatism, a full range of high-quality vision that is as deliberate as the care you provide.


TECNIS®
PRESBYOPIA-CORRECTING IOLs





WHATEVER THEIR LIFESTYLE, CHOOSE TECNIS® IOLs TO DELIVER:

SHARPEST VISION

ENHANCED FUNCTIONALITY

LONG-TERM SUSTAINABILITY

INDICATIONS FOR USE : The **TECNIS** Sym*fony*® 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** Sym*fony*® 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. **INDICATIONS:** The **TECNIS**® Multifocal 1-Piece intraocular lenses are 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 phacoemulsification and who desire near, intermediate, and distance vision with increased spectacle independence. The intraocular lenses are intended to be placed in the capsular bag.

THE COMPLETE PORTFOLIO OF **LEADING IOLs.** **A FULL RANGE OF VISUAL FREEDOM** FOR YOUR PATIENTS.

*The **TECNIS**® portfolio of presbyopia-correcting IOLs. Enhanced performance you can depend on.*

FIRST & ONLY

NEW

EXTENDED DEPTH OF FOCUS IOLs

TECNIS Symfony® IOL

The first and only presbyopia-correcting IOL that delivers a full range of continuous high-quality vision.

TECNIS Symfony® TORIC IOL

The first and only presbyopia-correcting IOL that delivers a full range of continuous high-quality vision, now for patients with astigmatism.

MULTIFOCAL 1-PIECE IOLs

+4.0 D

Optimized for patients favoring activities such as reading or knitting.

+3.25 D

Optimized for patients favoring activities such as computer work or cooking.

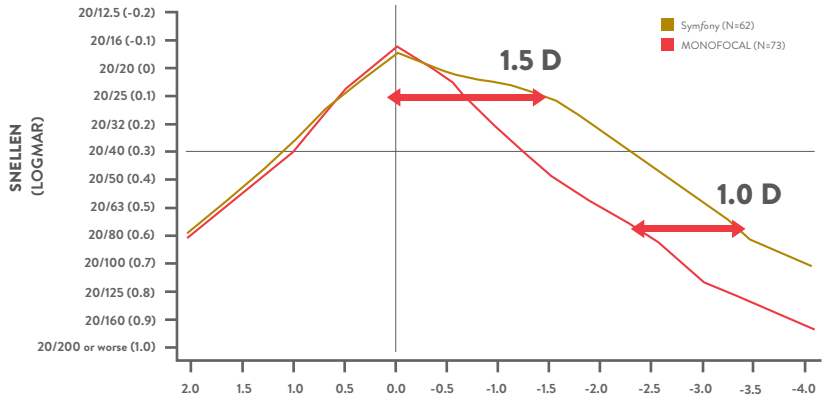
+2.75 D

Optimized for patients favoring activities such as golfing or grocery shopping.

SHARPEST VISION

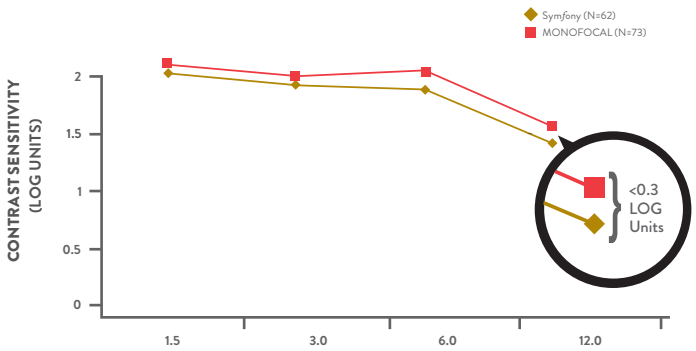
LEAVE A LEGACY OF **SEAMLESS BRILLIANCE.**
CONTINUOUS, HIGH-QUALITY VISION AT ALL DISTANCES.

BINOCULAR DEFOCUS CURVE AT 6 MONTHS[1]



Sustained mean visual acuity of 20/25 or better through 1.5 D of defocus. Increase of 1.0 D range of vision throughout the defocus curve compared to a monofocal IOL.[1]

CONTRAST SENSITIVITY MEASURED AT MULTIPLE SPATIAL FREQUENCIES MESOPIC WITHOUT GLARE[1]



None of the differences exceeded 0.3 log units at two or more spatial frequencies

TECNIS Symfony® IOL delivers contrast sensitivity with no clinically significant difference compared to a monofocal IOL.[1]

EXCELLENT MEAN BINOCULAR UNCORRECTED VISUAL AT ALL DISTANCES.[1]

20/25 NEAR (40cm)

20/20 INTERMEDIATE (66cm)

20/20 DISTANCE (4m)

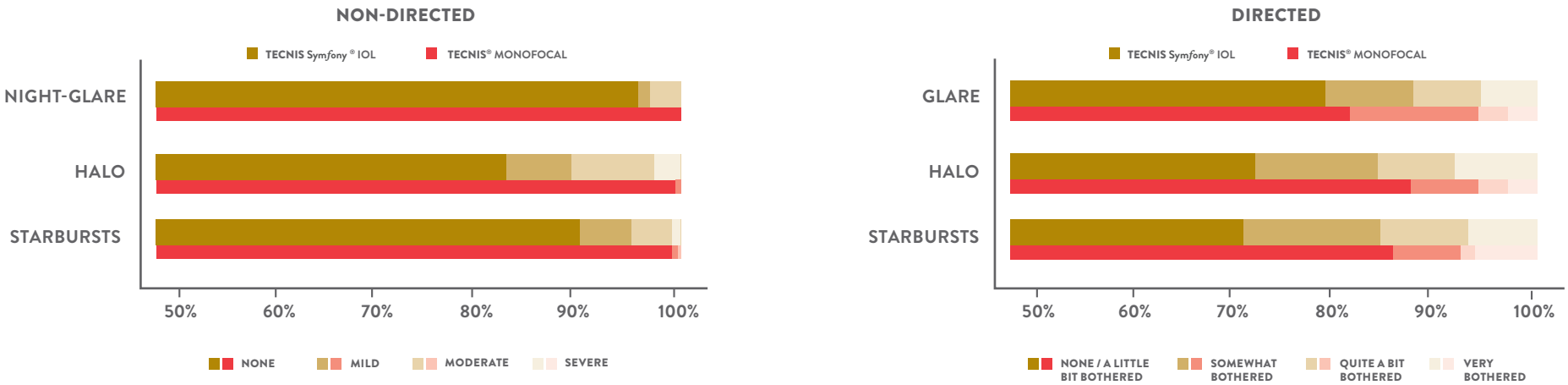
WARNING: The **TECNIS** Symfony® IOL may cause a reduction in contrast sensitivity under certain conditions, compared to an aspheric monofocal IOL. The physician should carefully weigh the potential risks and benefits for each patient, and should fully inform the patient of the potential for reduced 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. Patients implanted with the lens should be informed to exercise special caution when driving at night or in poor visibility conditions.

ENHANCED FUNCTIONALITY

OUTSTANDING VISIBILITY IN ANY LIGHTING CONDITION.

TECNIS Symfony® IOL demonstrated a low incidence of visual symptoms.[1]

VISUAL SYMPTOMS AT 6 MONTHS[1]



TECNIS Symfony® IOL PUPIL INDEPENDENCE ENABLES OPTIMAL PERFORMANCE IN ALL LIGHTING CONDITIONS.[1]

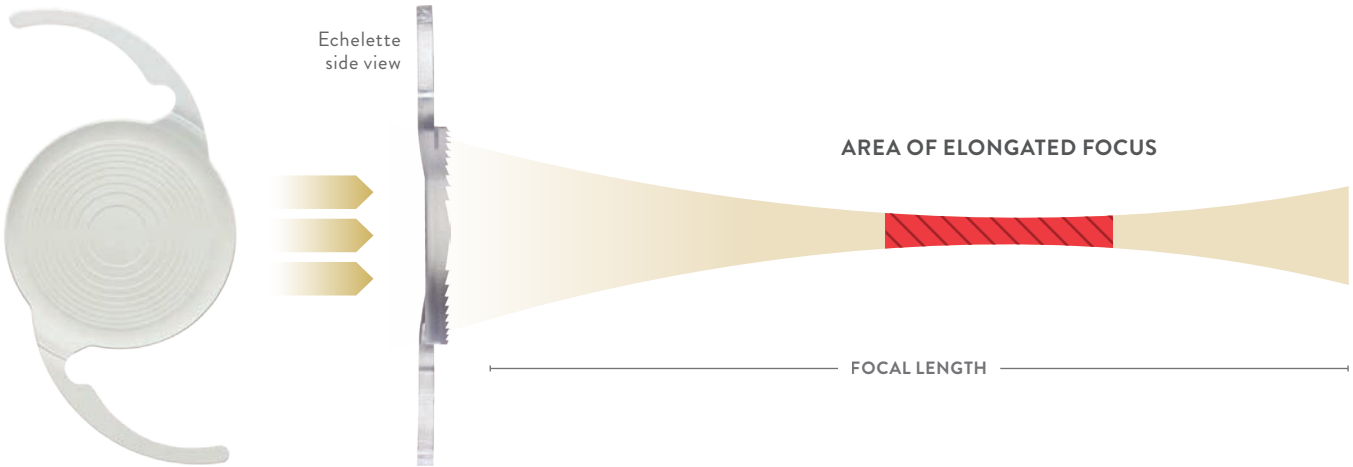
85% OF PATIENTS WORE GLASSES NONE OR A LITTLE BIT OF THE TIME.[1*]

*Although the questionnaire was not determined to be a psychometrically valid assessment of the concept of spectacle independence, data showed that the Symfony IOL achieved the secondary effectiveness endpoint of reduced overall spectacle wear compared to the control monofocal IOL.

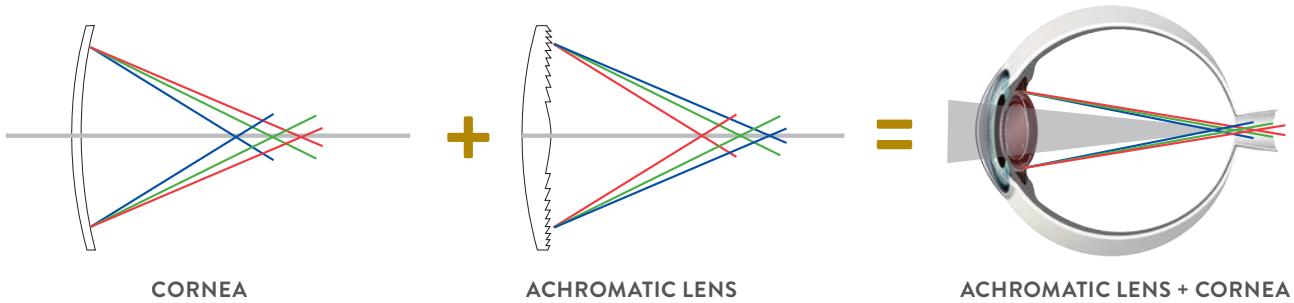
WARNING: Some visual effects associated with the **TECNIS** Symfony® IOL may be expected due to the lens design that delivers elongation of focus. These may include a perception of halos, glare, or starbursts around lights under nighttime conditions. The experience of these phenomena will be bothersome 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. See page 17 for more safety information.

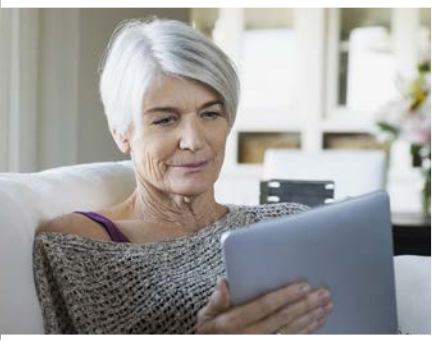
ORCHESTRATING LIGHT FOR BETTER VISION
THROUGH ADVANCED TECHNOLOGY YOU CAN SEE.

Proprietary diffractive echelette design creates an **extended depth of focus** resulting in an extended range of vision.[1]



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





"With the **TECNIS** Sym*fony*® IOL platform, I can confidently offer a full range of vision to more patients than ever before. The **TECNIS** Sym*fony*® TORIC IOL in particular is a game changer."

— Daniel Chang, MD
Empire Eye & Laser Center
Bakersfield, CA

"My **TECNIS**® presby-correcting family just got bigger with the addition of the Sym*fony*® EDOF lenses to the already high-performing **TECNIS**® low-add Multifocals. Now I can customize the focus to fit each patient's unique lifestyle."

— Keith Walter, MD
Wake Forest, NC

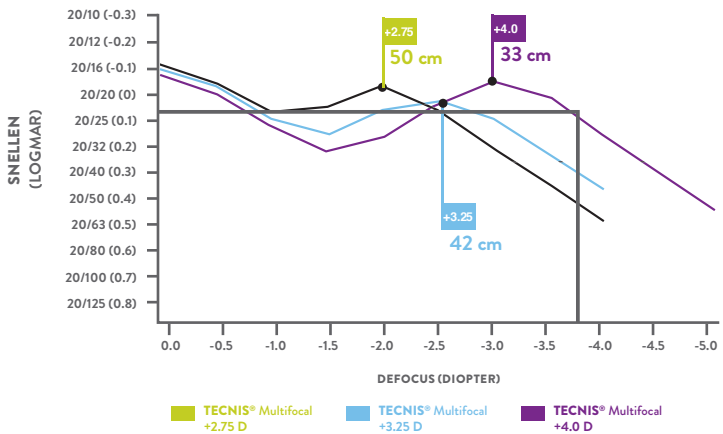
SHARPEST VISION

LEAVE A LEGACY OF **TAILORED CLARITY.**

OUTSTANDING VISION WITH ENHANCED FOCUS WHERE EACH PATIENT NEEDS IT MOST.

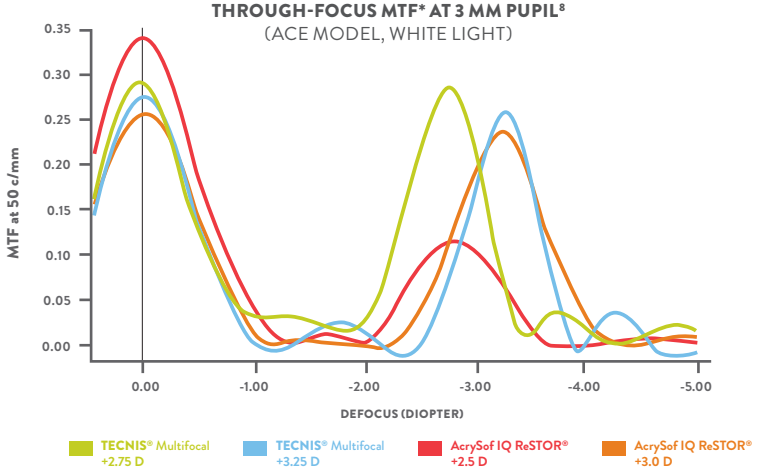
***TECNIS®** Multifocal IOLs deliver up to 4x greater image contrast at near distance than other leading multifocal lenses.*[8]

BINOCULAR DEFOCUS CURVE AT 6 MONTHS[7]

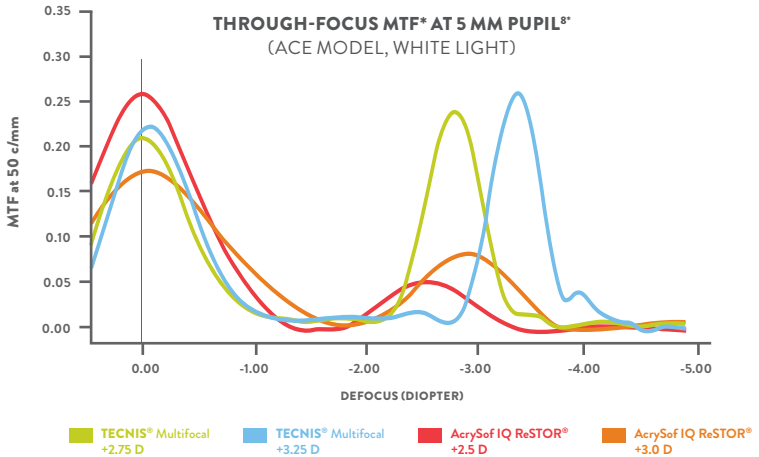


Distances (cm) in the graph are approximate.+4.0 D data are historical from a separate clinical study using the same test methodology.

THROUGH-FOCUS MTF* AT 3 MM PUPIL[8]
(ACE MODEL, WHITE LIGHT)



THROUGH-FOCUS MTF* AT 5 MM PUPIL[8*]
(ACE MODEL, WHITE LIGHT)



20/25

OR BETTER VISUAL ACUITY THROUGH THE FULL RANGE OF VISION.[7**]

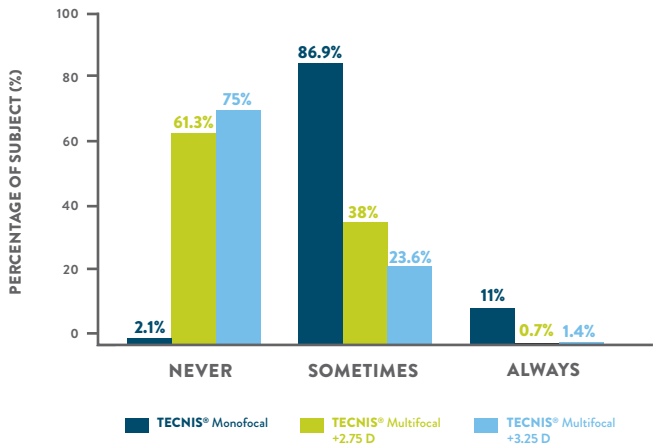
* Modular Transfer Function (MTF) is a measure of the amount of contrast transferred by the optics in a visual system. The higher the MTF value, the more contrast transferred to the image, resulting in higher image contrast.

** The **TECNIS®** Multifocal Family of 1-piece IOLs delivers 20/25 or better visual acuity through the full range of vision.

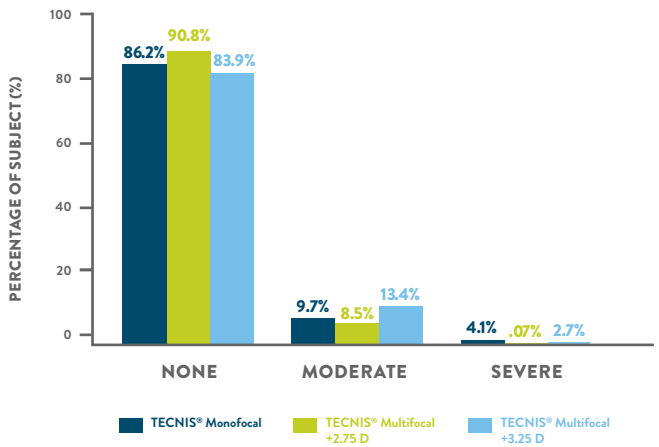
ENHANCED FUNCTIONALITY

HIGH-PERFORMANCE IOLs.
DESIGNED TO PROVIDE OUTSTANDING **VISIBILITY IN ANY LIGHTING CONDITION.**

HOW OFTEN DO YOU WEAR GLASSES?[7]



DEGREE OF DIFFICULTY WITH NIGHT VISION[7]
(WITH GLASSES IF YOU NEED THEM)*



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. Patients with a predicted postoperative astigmatism > 1.0 D 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. See Indications and Important Safety Information continued on page 18.

*On a scale of 1-7. The questionnaire was not determined to be a psychometrically valid assessment of the concept of spectacle independence.

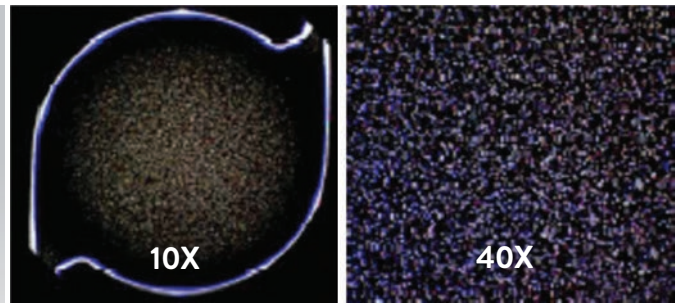
LONG-TERM SUSTAINABILITY

A COMPLETE PORTFOLIO WITH THE TECHNOLOGY TO DELIVER MORE.

TECNIS® IOLs are manufactured utilizing a sophisticated material that is NOT associated with glistenings, unlike another leading IOL.[4]

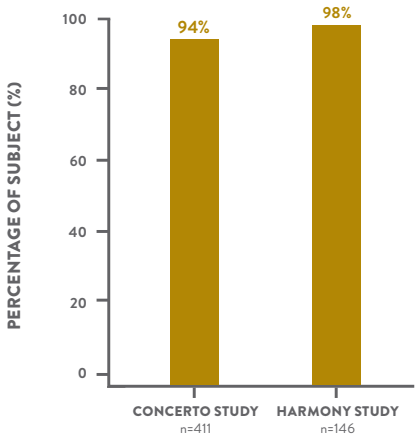
GLISTENINGS CAUSE LIGHT SCATTER

Which can result in a reduction in image contrast.[5,6]

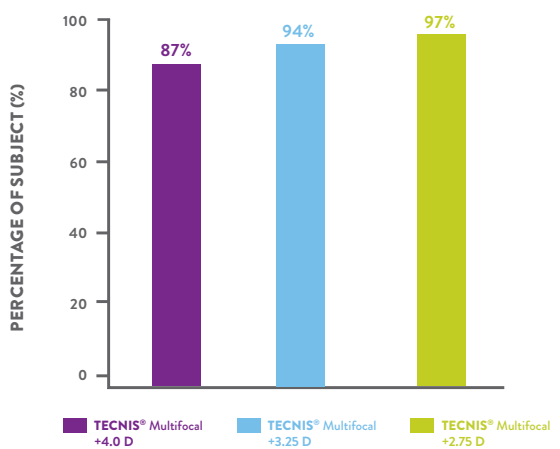


DELIVERING HIGH PATIENT SATISFACTION.

PATIENTS WHO WOULD RECOMMEND TECNIS Symfony® IOLs TO FRIENDS AND FAMILY[9,10]



PERCENT OF PATIENTS WHO WOULD ELECT TO HAVE THE SAME IOL AGAIN[7*]



*The questionnaire was not determined to be a psychometrically valid assessment of the concept of spectacle independence

TECNIS Symfony® IOLs[1]

- Continuous range of high-quality vision at all distances.
- High image contrast due to active correction of chromatic abberation.
- Low incidence of halo and glare.
- Available for patients with and without astigmatism.

TECNIS® MULTIFOCAL 1-PIECE IOLs

- Tailored clarity to meet each patient's lifestyle.
- Improved image contrast compared to other leading multifocal lenses.
- The best spectacle independence in any lighting condition.[7]

TECHNICAL SPECIFICATIONS

OPTICAL CHARACTERISTICS	TECNIS Symfony® IOL		TECNIS Symfony® TORIC IOL	
SE Powers:	+5.0 D to +34.0 D in 0.5 diopter increments		+5.0 D to +34.0 D in 0.5 diopter increments	
Model Numbers:	ZXR00		ZXT150 ZXT225 ZXT300 ZXT375	
Cylinder Powers - IOL Plane	NA		1.50 D 2.25 D 3.00 D 3.75 D	
Cylinder Powers - Corneal Plane	NA		-1.03 D 1.54 D 2.06 D 2.57 D	
Diameter:	6.0 mm		6.0 mm	
Center Thickness:	0.7 mm (20.0 D)		0.7 mm (20.0 D)	
Shape:	Biconvex, wavefront-designed anterior aspheric surface, posterior achromatic diffractive surface designed to reduce chromatic aberration for enhanced image contrast and echelette feature to extend the range of vision.		Biconvex, wavefront-designed anterior toric aspheric surface. Biconvex posterior achromatic diffractive surface to enhance image contrast and echelette feature to extend the range of vision.	
Material:	UV-blocking hydrophobic acrylic		UV-blocking hydrophobic acrylic	
Refractive Index:	1.47 at 35° C		1.47 at 35° C	
Edge Design:	**ProTEC** frosted, continuous 360° posterior square edge		**ProTEC** frosted, continuous 360° posterior square edge	
BIOMETRY*	**CONTACT ULTRASOUND†**	**OPTICAL††**	**CONTACT ULTRASOUND†**	**OPTICAL††**
A-constant:	118.8	119.3	118.8	119.3
AC Depth:	5.4 mm	5.7 mm	5.4 mm	5.7 mm
Surgeon Factor:[1]	1.68 mm	1.96 mm	1.68 mm	1.96 mm
HAPTIC CHARACTERISTICS				
Overall Diameter:	13.0 mm		13.0 mm	
Thickness:	0.46 mm		0.46 mm	
Style:	C		C	
Material:	Soft, Foldable, UV-blocking hydrophobic acrylic		Soft, Foldable, UV-blocking hydrophobic acrylic	
Design:	**TRI-FIX**, Haptics offset from optic; 1-piece lens		**TRI-FIX**, Haptics offset from optic; 1-piece lens	

RECOMMENDED INSERTION INSTRUMENTS

UNFOLDER® Platinum 1 Series Screw-Style Inserter (DK7796)
UNFOLDER® Emerald-AR Inserter (EMERALDAR)
ONE SERIES Ultra Syringe-Style Inserter (DK7786)
UNFOLDER® Platinum 1 Series Cartridge (1MTEC30)
UNFOLDER® Emerald-AR Cartridge (1CART30)
ONE SERIES Ultra Cartridge (1VIPR30)

TECNIS Symfony® Extended Range of Vision IOL

TECNIS Symfony® TORIC Extended Range of Vision IOL

* Value theoretically derived for a typical 22.0 D lens. AMO recommends that surgeons personalize their A-constant based on their surgical techniques and equipment, experience with the lens model and postoperative results.

† IOL constants have been theoretically derived for contact ultrasound.

†† IOL constants have been derived from clinical evaluation results of the 1-Piece IOL Platform.

1. Calculated based on Holladay I formula (Holladay JT, Prager TC, Chandler TY, Musgrove KH, Lewis JW, Ruiz RS. A three-part system for refining intraocular lens power calculations. J Cataract Refract Surg. 1988;14(1):17-24).

For precise results, utilize the Abbott **TECNIS®** Toric IOL calculator at www.TecnisToricCalc.com to determine the appropriate Toric model and power.

REFERENCES

1. **TECNIS** Symfony® DFU.
2. DOF2015CT0020 MTF of **TECNIS** Symfony® IOL and other lens models.
3. DOF2015CT0023_Chromatic Aberration of the **TECNIS** Symfony® IOL.
4. DOF, Abbott Medical Optics Inc., 2013.
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6. Nagata M, et al. Clinical evaluation of the transparency of hydrophobic acrylic intraocular lens optics. J Cataract Refract Surg. 2010 Dec;36(12):2056-60.
7. **TECNIS®** Multifocal DFU.
8. Data on File, **TECNIS®** Multifocal and AcrySof ReSTOR® through focus curve.
9. DOF2016CT0024 Concerto Study Report.
10. DOF2015OTH0009 **TECNIS** Symfony® Harmony Observational Study.

TECHNICAL SPECIFICATIONS

OPTIC CHARACTERISTICS		
Powers:	+5.0 D to +34.0 D in 0.5 D increments	
Diameter:	6.0 mm	
Shape:	Biconvex, anterior aspheric surface, posterior diffractive surface	
Add Power (IOL Plane):	**+2.75 D** (ZKB00) **+3.25 D** (ZLB00) **+4.0 D** (ZMB00)	
Add Power (Spec Plane):	**+2.01 D** (ZKB00) **+2.37 D** (ZLB00) **+3.0 D** (ZMB00)	
Material:	UV-blocking hydrophobic acrylic	
Refractive Index:	1.47 at 35° C	
Edge Design:	**ProTEC** frosted, continuous 360° posterior square edge	
BIOMETRY†	**CONTACT ULTRASOUND**	**OPTICAL**
A-Constant:	118.8†	119.3††
Theoretical AC Depth:	5.40 mm	5.72 mm
Surgeon Factor:[10]	1.68 mm	1.96 mm
HAPTIC CHARACTERISTICS		
Overall Length:	13.0 mm	
Style:	C	
Material:	UV-blocking hydrophobic acrylic	
Design:	Haptics offset from optic	

†Value theoretically derived for a typical 20.0 D lens. AMO recommends that surgeons personalize their A-constant based on their surgical techniques and equipment, experience with the lens model and postoperative results.

††Derived from clinical evaluation results of the **TECNIS®** 1-Piece platform.


LEAVE A LEGACY OF
VISUAL FREEDOM.
Start with ME.
TECNIS®
PRESBYOPIA-CORRECTING IOLs

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR TECNIS Symfony® AND TECNIS Symfony® TORIC EXTENDED RANGE OF VISION IOLS

Rx Only

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 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** 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. The effectiveness of **TECNIS** Symfony® Toric IOLs in reducing postoperative residual astigmatism in patients with preoperative corneal astigmatism < 1.0 diopter has not been demonstrated. Rotation of **TECNIS** Symfony® 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. AMO IOLs are single-use 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 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** 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. 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** Symfony® 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** Symfony® Toric IOL. All preoperative surgical parameters are important when choosing a **TECNIS** Symfony® 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** 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.

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR THE TECNIS® MULTIFOCAL 1-PIECE IOLs

Rx Only

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 > 1.0 D 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 patients. 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 (~1 mm) 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 45ºC (113ºF). 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. **ATTENTION:** Reference the Directions for Use for a complete listing of Indications and Important Safety Information.

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR THE TECNIS® MONOFOCAL 1-PIECE IOL

Rx Only

INDICATIONS: The **TECNIS**® 1-Piece Lens is indicated for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extra capsular cataract extraction. These devices are intended to be placed in the capsular bag. **WARNINGS:** Physicians considering lens implantation should weigh the potential risk/benefit ratio for any conditions described in the **TECNIS**® 1-Piece IOL Directions for Use that could increase complications or impact patient outcomes. The **TECNIS**® 1-Piece IOL should not be placed in the ciliary sulcus. **PRECAUTIONS:** Do not reuse, resterilize, or autoclave. **ADVERSE EVENTS:** In 3.3% of patients, reported adverse events of cataract surgery with the **TECNIS**® 1-Piece IOL included macular edema. Other reported reactions occurring in less than 1% of patients were secondary surgical intervention (pars plana vitrectomy with membrane peel) and lens exchange (due to torn lens haptic). **ATTENTION:** Reference the Directions for Use for a complete listing of Indications and Important Safety Information.

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