

# FOCUS ON VALUE



## TECNIS Symphony™ OptiBlue® IOLs build upon the benefits of the TECNIS® platform to meet patients' needs<sup>1</sup>

TECNIS Symphony™ OptiBlue® IOLs are built on the strength of the TECNIS® platform

Correction of spherical aberration to virtually zero, resulting in **sharp quality of vision**<sup>2</sup>

Low induction of chromatic aberration and **high image contrast, day and night**<sup>3</sup>

Observe less capsular phimosis to **minimize decreased vision and IOL decentration**<sup>4</sup>

TECNIS® IOLs are **not associated with glistenings**<sup>5</sup>

Powered by **IntelliLight™**, an innovative combination of three proprietary technologies<sup>6,\*</sup>



### Violet Light Filter

Designed to mitigate dysphotopsia, including halo, glare and starburst.<sup>7,8</sup>



*Why filter violet (380-460 nm) but not blue (460-500 nm) light?*

High-energy violet wavelengths **create more light scatter**, resulting in poor image quality. Blocking these wavelengths may reduce dysphotopsia.<sup>9-12</sup>

Blue light transmission **aids image quality in low light**. Transmission decreases with age, which may reduce the ability to walk on uneven surfaces or read in dim light.<sup>12,13</sup>



### High-resolution Echelette

Extends the depth of focus for a continuous range of vision.<sup>6</sup> Advanced lathing helps reduce light scatter and halo intensity.<sup>7</sup>



### Achromatic Technology

Achromatic design that corrects chromatic aberration to enhance image contrast, day and night.<sup>14,15</sup>

\* Proprietary technology in TECNIS Synergy™ IOLs and now available for TECNIS Symphony™ OptiBlue® IOLs.

Johnson & Johnson VISION

Symphony™

OptiBlue® IOL

Powered by IntelliLight™

Symphony™

OptiBlue® IOL

Toric II

Powered by IntelliLight™

# Powered by InteliLight™, the TECNIS Symphony™ OptiBlue® IOL is the next generation in clarity and sharpness<sup>16</sup>

Older adults lead active lifestyles, which may necessitate a variety of visual needs:<sup>17,18</sup>

Low level of disturbing visual symptoms



Good vision in dim light



Wide range of vision

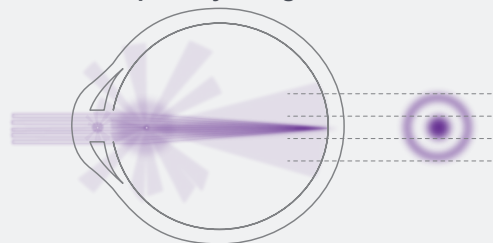


TECNIS Symphony™ OptiBlue® IOLs, powered by InteliLight™, are **designed to mitigate dysphotopsia**<sup>19</sup>



Halo, glare, and starburst (i.e., dysphotopsia) not only **interfere with vision** but can **reduce visual contrast** and impact a patient's ability to carry out certain activities.<sup>20,21</sup>

Violet light wavelengths can increase halos, especially at night<sup>21,\*</sup>

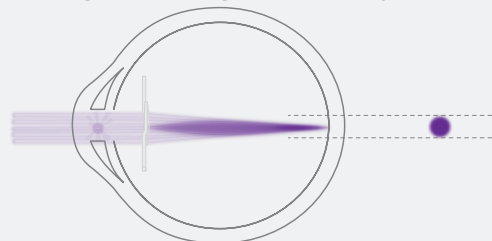


The violet light filter of the TECNIS Symphony™ OptiBlue® IOL reduces light scatter:<sup>19,†</sup>

**19%** improvement in straylight performance based on area under the curve (AUC) analysis of the straylight parameter.

**7-11%** improvement in straylight parameter based on a simulation study using a theoretical cornea eye model.

TECNIS Symphony™ OptiBlue® IOL blocks violet light, reducing halo intensity<sup>19,22,\*</sup>



\* Artist rendition based on TECNIS Symphony OptiBlue MOA (Mechanism of Action) Video – EMEA 2021 (PP2021CT5311). † Compared with TECNIS Symphony™ IOLs without violet light filter.

## TECNIS Symphony™ OptiBlue® IOLs are designed to mitigate dysphotopsias to provide high-quality vision<sup>1,19</sup>

# TECNIS Symphony™ OptiBlue® IOLs deliver high image contrast, day and night<sup>15,23</sup>

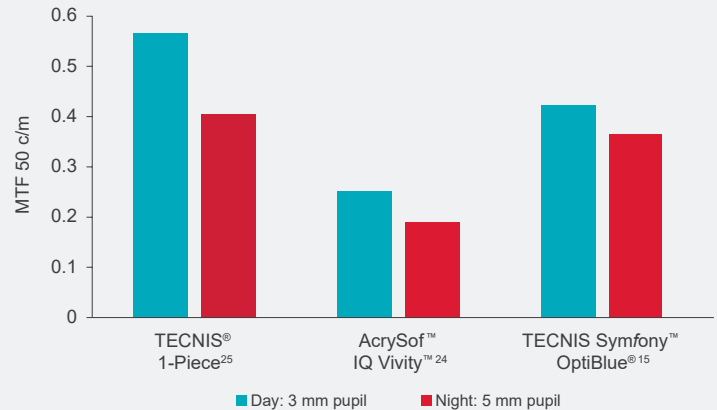
Image contrast provided by TECNIS Symphony™ OptiBlue® IOLs was **more than 1.5x better than with AcrySof™ IQ Vivity™** and **comparable to TECNIS® Monofocal 1-Piece IOL**<sup>15,24,25,\*</sup>



Contrast sensitivity loss contributes considerably to age-related visual decline, especially under dim light<sup>26</sup>

Optimizing contrast sensitivity may be an important consideration for patient safety and functioning<sup>27-29</sup>

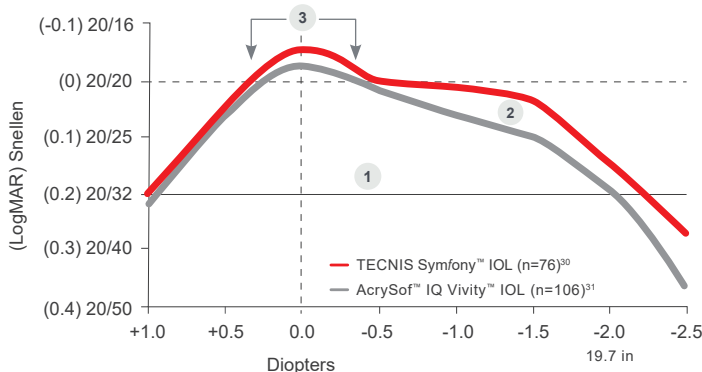
Image contrast performance (day and night)\*



\* Based on bench testing of the modulation transfer function (MTF), which has been measured for a set of lens models, in a similar manner, using the Average Cornea Eye (ACE) model in white light. The ACE model is designed to simulate the spherical and chromatic aberration of the average natural human cornea.<sup>15</sup>

## TECNIS Symphony™ OptiBlue® IOLs provide superior performance across every distance compared with AcrySof™ IQ Vivity™<sup>30,31,†</sup>

Binocular defocus curves demonstrate a wider range of continuous vision than AcrySof™ IQ Vivity™ IOL<sup>30,31,†,‡</sup>



- 1 Mean visual acuity of ~20/32 or better from infinity to <20 inches may allow patients to seamlessly move between different activities<sup>30</sup>
- 2 ~29% more AUC above 0.2 LogMAR (~20/32 Snellen) compared with AcrySof™ IQ Vivity™<sup>30,31,§</sup>
- 3 Tolerance to post-op refractive errors due to a large landing zone is a key factor for high patient satisfaction<sup>30,32</sup>

† Based on comparison of defocus curves; not a head-to-head study. Note that TECNIS Symphony™ OptiBlue® IOL provides equivalent range of vision and tolerance to TECNIS Symphony™ IOL.<sup>33</sup>  
 ‡ Direct comparisons of defocus curves provide a detailed comparison of visual acuity at every level of defocus.<sup>34</sup> § The AUC metric provides an overview of visual range, accounting for the level of visual acuity within the range as well as the range itself. It represents the subjective experience better than intermediate and near visual acuities alone.<sup>35</sup>

TECNIS Symphony™ IOL technology delivers continuous vision across the entire range<sup>1</sup>

# TECNIS Symfony™ OptiBlue® IOLs may provide value

## TECNIS Symfony™ OptiBlue® IOLs may reduce spectacle needs, potentially offering patients long-term cost savings<sup>1,36,37</sup>



### Estimated indirect cost of monofocal vs. presbyopia-correcting IOLs

The average US cost per patient was calculated based on indirect cost components estimated to occur over the remaining lifetime after cataract surgery.

Cost Component	Presbyopia-correcting IOLs	Monofocal IOLs
Time spent during clinic visits and traveling	\$1,318.62	\$1,600.61
Transportation to and from clinics (car, bus, etc.)	\$128.49	\$420.21
Visit to correct visual acuity	\$93.07	\$418.82
Clean spectacles (sprays, cloths, etc.)	\$18.58	\$83.17
Spectacles (including replacement over time)	\$621.63	\$2,794.90
<b>Average Cost per Patient (in USD)</b>	<b>\$2,180.39</b>	<b>\$5,317.72</b>

Note: This study was based on data for Alcon's ReSTOR® IOLs. The average US cost per patient was calculated by: 1) Taking a straight average of the cost components reported across four countries.<sup>37</sup> 2) Inflating the cost estimate from 2006 to 2021 Euros using the European Central Bank. HICP – Indices breakdown by purpose of consumption. 1.6 – Health.<sup>39</sup> 3) Converting the average costs in Euros to USD using an exchange rate of 1 Euro = 1.1934 USD (2021 YTD average as of Oct 25, 2021).<sup>40</sup>



**Presbyopia-correcting IOLs should be presented as an option**

Older individuals value active lifestyles and have a need for options that **optimize vision for their preferred activities**<sup>38</sup>

## Additional features and benefits of TECNIS Symfony™ OptiBlue® IOLs



**TECNIS Symfony™ OptiBlue® IOLs are preloaded and preassembled in the single-use, fully disposable TECNIS Simplicity® Delivery System<sup>1</sup>**

- Provides a sterile, controlled, touch-free method of IOL delivery
- Reduces the number of steps required to prepare the IOL for insertion (compared with non-preloaded IOLs)



**TECNIS Symfony™ OptiBlue® IOLs are available on the TECNIS® Toric II Platform<sup>1</sup>**

- Squared and frosted haptic design for increased friction in the capsular bag<sup>41</sup>
- Exceptional rotational stability (**mean rotation of 0.94° at 3 months post surgery**)<sup>42,\*</sup>
- Toric IOL implantation was shown to be cost effective in patients with astigmatism as a result of reduced spectacle needs after cataract surgery<sup>43,44</sup>

\* Based on data from 200 eyes after 3 months postoperative follow-up in a postmarket prospective, multicenter, single-arm, open-label study of the TECNIS® Toric II 1-Piece IOL conducted in the US. Outcomes differ from the pivotal investigation data in the product labeling and were collected using different measurement methods, study design and clinical conditions.

**When choosing an IOL,  
consider the quality of the patient's vision for life**

# References, Indications, and Important Safety Information

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## INDICATIONS and IMPORTANT SAFETY INFORMATION for TECNIS SYMFONY™ OPTIBLUE® and TECNIS SYMFONY™ TORIC II OPTIBLUE EXTENDED RANGE OF VISION IOLs.

### Rx Only

**INDICATIONS:** The TECNIS Symfony™ OptiBlue® Extended Range of Vision IOL, Model ZXR00V, 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 ZXR00V IOL is intended for capsular bag placement only. The TECNIS Symfony™ Toric II OptiBlue® Extended Range of Vision IOLs, Models ZXW150, ZXW225, ZXW300, ZXW375, 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 ZXW IOLs are intended for capsular bag placement only.

**WARNINGS:** Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio: 1. 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: a) Patients with recurrent severe anterior or posterior segment inflammation or uveitis of unknown etiology, or any disease producing an inflammatory reaction in the eye. b) Patients in whom the intraocular lens may affect the ability to observe, diagnose or treat posterior segment diseases. c) 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). d) A compromised eye due to previous trauma or developmental defects in which appropriate support of the IOL is not possible. e) Circumstances that would result in damage to the endothelium during implantation. f) Suspected microbial infection. g) Patients in whom neither the posterior capsule nor the zonules are intact enough to provide support for the IOL. h) Children under the age of 2 years are not suitable candidates for intraocular lenses. i) Congenital bilateral cataracts. j) Previous history of, or a predisposition to, retinal detachment. k) Patients with only one good eye with potentially good vision. l) Medically uncontrollable glaucoma. m) Corneal endothelial dystrophy. n) Proliferative diabetic retinopathy. 2. The TECNIS Symfony™ OptiBlue® IOL should be placed entirely in the capsular bag and should not be placed in the ciliary sulcus. 3. The TECNIS Symfony™ OptiBlue® 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, and patients implanted with the lens should be informed to exercise special caution when driving at night or in poor visibility conditions. 4. Some visual effects associated with the TECNIS Symfony™ OptiBlue® 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. 5. Patients with a predicted postoperative astigmatism greater than 1.0 diopter may not be suitable candidates for implantation with the TECNIS Symfony™ OptiBlue® and TECNIS Symfony™ Toric II OptiBlue® IOLs, Models ZXR00V, ZXW150, ZXW225, ZXW300, and ZXW375, as they may not obtain the benefits of reduced spectacle wear or improved intermediate and near vision seen in patients with lower astigmatism. 6. The effectiveness of TECNIS Symfony™ Toric II OptiBlue® IOLs in reducing postoperative residual astigmatism in patients with preoperative corneal astigmatism < 1.0 diopter has not been demonstrated. 7. Rotation of TECNIS Symfony™ Toric II OptiBlue® 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. 8. Johnson & Johnson Surgical Vision, Inc. IOLs are single use devices only. Do not reuse this IOL.

**PRECAUTIONS:** 1. 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. 2. When performing refraction in patients implanted with the TECNIS Symfony™ OptiBlue® 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. 3. The ability to perform some eye treatments (e.g., retinal photocoagulation) may be affected by the TECNIS Symfony™ OptiBlue® IOL optical design. 4. 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. 5. Do not sterilize the lens. Most sterilizers are not equipped to sterilize the soft acrylic material without producing undesirable side effects. 6. Do not soak or rinse the intraocular lens with any solution other than sterile balanced salt solution or sterile normal saline. 7. Do not store the lens in direct sunlight or at a temperature greater than 45°C (113°F). Do not autoclave the intraocular lens. 8. The surgeon should target emmetropia as this lens is designed for optimum visual performance when emmetropia is achieved. 9. Care should be taken to achieve IOL centration, as lens decentration may result in a patient experiencing visual disturbances under certain lighting conditions. 10. When the insertion system is used improperly, TECNIS Symfony™ OptiBlue® 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. 11. The safety and effectiveness of TECNIS Symfony™ OptiBlue® 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 phacemulsification or liquefaction • Capsular rupture • Significant anterior chamber hypohemia • Uncontrollable positive intraocular pressure • Zonular damage. 12. Carefully remove all viscoelastic and do not over-inflate the capsular bag than the phase 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 II OptiBlue® IOL with the intended axis of placement. 13. The TECNIS® Toric IOL Calculator includes a feature that accounts for posterior corneal astigmatism (PCA). 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 multi-center 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. 14. 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 II IOL. 15. All preoperative surgical parameters are important when choosing a TECNIS Symfony™ Toric II OptiBlue® IOL for implantation, including preoperative keratometric cylinder (magnitude and axis), incision location, surgeons 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. 16. 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. 17. 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.

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

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