

# FOCUS ON VALUE



**TECNIS Symphony™ OptiBlue™ IOLs** build upon the benefits of the TECNIS™ platform to meet patient needs for quality of vision<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>

TECNIS® Toric II IOLs **deliver exceptional rotational stability**<sup>4,\*</sup>

Three proprietary technologies for the TECNIS™ platform now available for TECNIS Symphony™ OptiBlue™ IOL<sup>5,†</sup>



### Violet Light Filter

Designed to mitigate dysphotopsia, including halo, glare and starburst.<sup>6,7</sup>



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

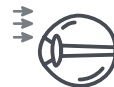
High-energy violet wavelengths **create more light scatter**, resulting in poor image quality. Blocking these wavelengths may reduce dysphotopsia.<sup>8-11</sup>

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>11,12</sup>



### High-resolution Echelette

Extends the depth of focus for a continuous range of vision.<sup>5</sup> Advanced lathing helps reduce light scatter and halo intensity.<sup>6</sup>



### Achromatic Technology

Achromatic design that corrects chromatic aberration to enhance image contrast, day and night.<sup>13,14</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.

† Proprietary technology in TECNIS Synergy™ IOLs and now available for TECNIS Symphony™ OptiBlue™ IOLs.

# Powered by InteliLight™, the TECNIS Symphony™ OptiBlue™ IOL is the next generation in clarity and sharpness<sup>15</sup>

Today's older adults lead active lifestyles, which may necessitate a variety of visual needs:<sup>16,17</sup>

Low level of disturbing visual symptoms<sup>16</sup>



Good vision in dim light/night driving<sup>16</sup>



Wide range of vision<sup>16</sup>

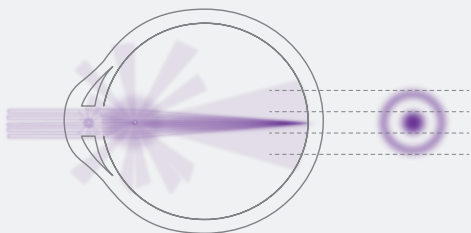


TECNIS Symphony™ OptiBlue™ IOLs, powered by InteliLight™, are **designed to mitigate dysphotopsia**<sup>18</sup>



Halo, glare, and starburst (i.e., dysphotopsia) not only **interfere with vision** but can **reduce visual contrast** and may impact a patient's ability to carry out certain activities.<sup>19,20</sup>

Violet light wavelengths can increase halos, especially at night<sup>20,\*</sup>

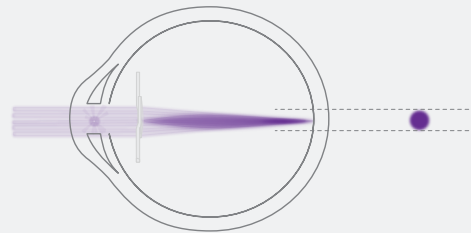


The violet light filter of the TECNIS Symphony™ OptiBlue™ IOL reduces light scatter:<sup>18,†</sup>

**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>18,21,\*</sup>



\* Artist rendition based on with and without TECNIS Symphony™ OptiBlue™ IOL Mechanism of Action. † Compared with TECNIS Symphony™ IOLs without violet light filter.

## TECNIS Symphony™ OptiBlue™ IOLs are designed to mitigate dysphotopsias to provide high-quality vision<sup>1,18</sup>

# TECNIS Symphony™ OptiBlue™ IOLs deliver high image contrast, day and night<sup>14,22</sup>

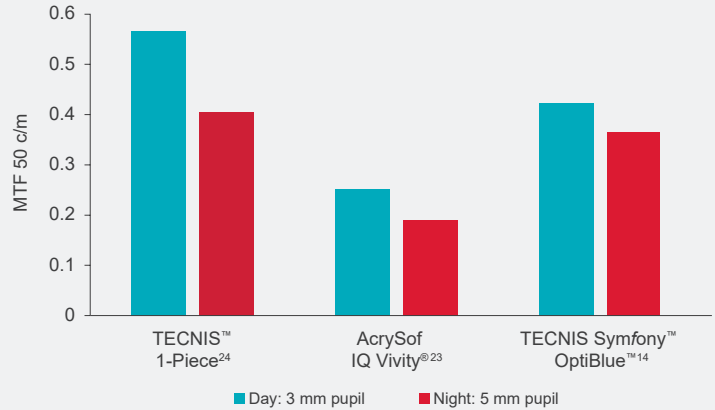
Image contrast provided by TECNIS Symphony™ OptiBlue™ IOLs was **more than 1.5x better than with AcrySof IQ Vivity®** and **comparable to TECNIS™ Monofocal 1-Piece IOL**<sup>14,23,24,\*</sup>



Contrast sensitivity loss contributes considerably to age-related visual decline, especially under dim light<sup>25</sup>

Optimizing contrast sensitivity may be an important consideration for patient safety and functioning<sup>26-28</sup>

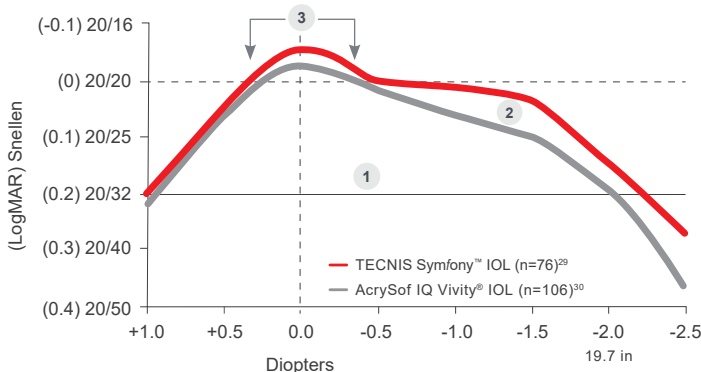
Image contrast performance (day and night)\*



\* 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>14</sup>

## TECNIS Symphony™ OptiBlue™ IOLs provide superior performance across every distance compared with AcrySof IQ Vivity®<sup>29,30,†</sup>

Binocular defocus curves demonstrate a wider range of continuous vision than AcrySof IQ Vivity® IOL<sup>29,30,†,‡</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>29</sup>
- 2 ~29% more AUC above 0.2 LogMAR (~20/32 Snellen) compared with AcrySof IQ Vivity®<sup>29,30,§</sup>
- 3 Tolerance to post-op refractive errors due to a large landing zone is a key factor for high patient satisfaction<sup>29,31</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>32</sup> ‡ Direct comparisons of defocus curves provide a detailed comparison of visual acuity at every level of defocus.<sup>33</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>34</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>1,35,36</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>36</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>38</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>39</sup>



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

Older individuals value active lifestyles and have a need for options that **optimize uncompromised vision for their preferred activities**<sup>37</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>40</sup>
- Exceptional rotational stability (**mean rotation of 0.94° at 3 months post surgery**)<sup>4,\*</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>41,42</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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## INDICATION AND IMPORTANT SAFETY INFORMATION for the TECNIS Symfomy™ OptiBlue™ Extended Range of Vision IOL with TECNIS Simplicity™ Delivery System and TECNIS Symfony™ Toric II OptiBlue™ Extended Range of Vision IOL with TECNIS Simplicity™ Delivery System

### Rx Only

### INDICATIONS

The TECNIS Simplicity™ Delivery System is used to fold and assist in inserting the TECNIS Symfomy™ OptiBlue™ Extended Range of Vision IOL, which 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 lens is intended for capsular bag placement only.

The TECNIS Simplicity™ Delivery System is used to fold and assist in inserting the TECNIS Symfomy™ Toric II OptiBlue™ Extended Range of Vision IOLs that 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 lenses 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. The lens 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 for 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.

Rotation of the TECNIS Symfony™ Toric II OptiBlue™ 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.

Do not attempt to disassemble, modify or alter the delivery system or any of its components, as this can significantly affect the function and/or structural integrity of the design. Do not implant the lens if the rod tip does not advance the lens or if it is jammed in the delivery system. The lens and delivery system should be discarded if the lens has been folded within the cartridge for more than 10 minutes.

### PRECAUTIONS

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 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 II OptiBlue™ IOL, variability in any preoperative surgical parameters (e.g., keratometric cylinder, incision location, estimated surgically induced astigmatism, or biometry) can influence patient outcomes. Carefully remove all viscoelastic and do not over-inflate the capsular bag at the end of the case, to avoid lens rotation.

This is a single use device, do not resterilize the lens or the delivery system. Do not store the device in direct sunlight or at a temperature under 5°C (41°F) or over 35°C (95°F). Do not autoclave the delivery system. Do not advance the lens unless ready for lens implantation. The contents are sterile unless the package is opened or damaged. The recommended temperature for implanting the lens is at least 17°C (63°F). The use of balanced salt solution or viscoelastics is required when using the delivery system. Do not use if the delivery system has been dropped or if any part was inadvertently struck while outside the shipping box.

### SERIOUS ADVERSE EVENTS

The most frequently reported serious adverse events during the clinical trial of the TECNIS Symfomy™ 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. Overall, 2.7% (4/148) of TECNIS Symfomy™ subjects experienced serious adverse events during the study and 0% (0/148) experienced device-related or unanticipated events.

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

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