TECNIS

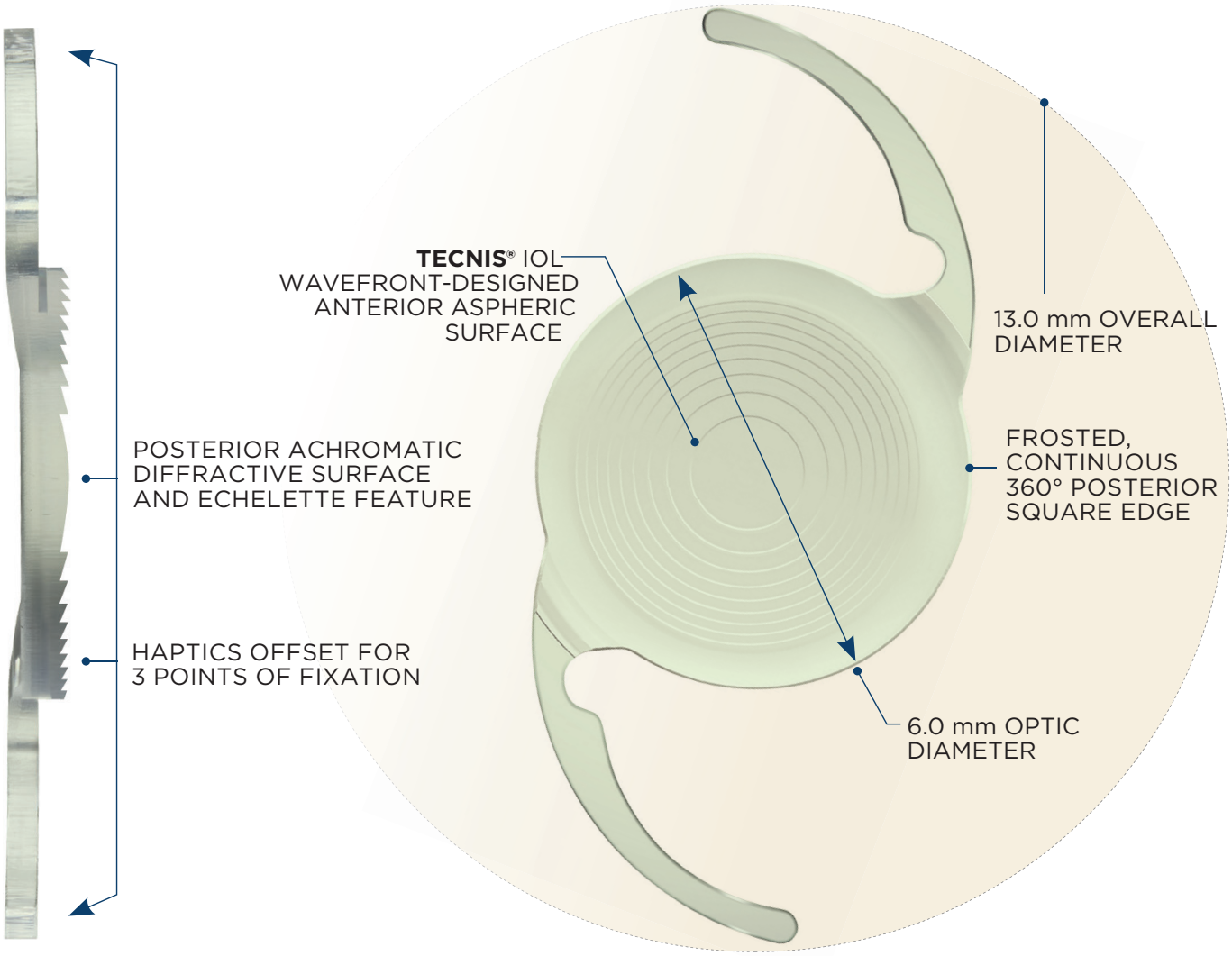
Symfony™

OptiBlue® IOL

Powered by **InteliLight™**

Model DXR00V

Anterior Side



Johnson & Johnson VISION

TECNIS

Symfony™

OptiBlue® IOL

Powered by **InteliLight™**

Model: DXR00V

OPTICAL CHARACTERISTICS[1]	
Model Number:	DXR00V
Powers:	+5.0 D to +34.0 D in 0.5 diopter increments
Diameter:	6.0 mm
Center Thickness:	0.7 mm (20.0 D)
Shape:	Biconvex, wavefront-designed anterior aspheric surface, posterior achromatic diffractive surface designed to reduce chromatic aberration for improved image contrast and echelette feature to extend the range of vision.
Material:	UV-absorbing hydrophobic acrylic with violet light filter
Refractive Index:	1.47 at 35º C
Edge Design:	**ProTEC** frosted, continuous 360° posterior square edge

BIOMETRY*	CONTACT ULTRASOUND†	OPTICAL††
A-constant:	118.8	119.3
AC Depth:	5.4 mm	5.7 mm
Surgeon Factor:[2]	1.68 mm	1.96 mm

HAPTIC CHARACTERISTICS[1]	
Overall Diameter:	13.0 mm
Thickness:	0.46 mm
Style:	C
Material:	UV-absorbing hydrophobic acrylic with violet light filter
Design:	**TRI-FIX,** Haptics offset from optic; 1-piece lens

Preloaded TECNIS SIMPLICITY® Delivery System

* Value theoretically derived for a typical 22.0 D lens. Johnson & Johnson Surgical Vision, Inc. 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.

References:

1. **TECNIS Symfony™ OptiBlue®** with **TECNIS SIMPLICITY®** Delivery System, Models DXR00V/DXW100-375, Z311520P, Rev. A, May 2021. REF2021CT4162.
2. Calculated based on Holladay I formula - Holladay JT, et al. A three-part system for refining intraocular lens power calculations. *J Cataract Refract Surg* 1988;14(1):17-24. REF2014CT0092.

INDICATIONS and IMPORTANT SAFETY INFORMATION for TECNIS SYMFONY™ OPTIBLUE® and TECNIS SYMFONY™ TORIC II OPTIBLUE® EXTENDED RANGE OF VISION IOLs with TECNIS SIMIPLICITY® DELIVERY SYSTEM

Rx Only

INDICATIONS: The TECNIS SIMPLICITY® Delivery System is used to fold and assist in inserting the TECNIS Symfony™ 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 Symfony™ 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 Symfony™ lens were cystoid macular edema (2 eyes, 0.7%) and surgical reintervention (treatment injections for cystoid macular edema and endophthalmitis, 2 eyes, 0.7%). No lens-related adverse events occurred during the trial. Overall, 2.7% (4/148) of TECNIS Symfony™ 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.

 | PP2021OTH6078

Johnson & Johnson VISION

TECNIS

Symfony™

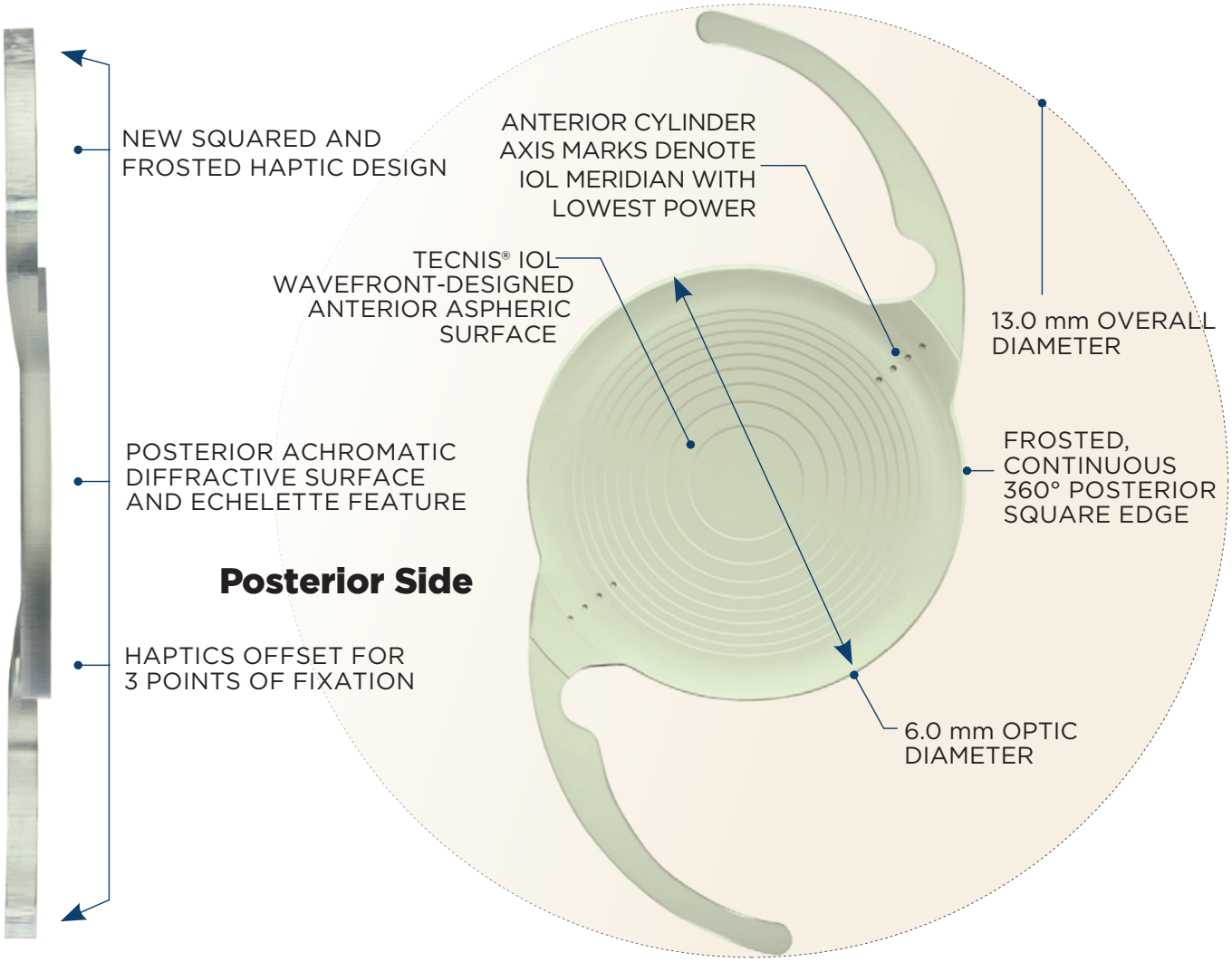
OptiBlue® IOL

Toric II

Powered by **InteliLight**™

Model: DXW150, DXW225, DXW300 and DXW375

Anterior Side



Johnson & Johnson VISION

TECNIS Symfony™ OptiBlue® IOL Toric II Powered by IntelliLight™

Model: DXW150, DXW225, DXW300 and DXW375

OPTICAL CHARACTERISTICS

SE Powers:	+5.0 D to +34.0 D in 0.5 diopter increments			
Model Numbers:	DXW150	DXW225	DXW300	DXW375
Cylinder Powers - IOL Plane	1.50D	2.25D	3.00D	3.75D
Cylinder Powers - Corneal Plane	1.03D	1.54D	2.06D	2.57D
Diameter:	6.0 mm			
Center Thickness:	0.7 mm (20.0 D)			
Shape:	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 with violet light filter			
Refractive Index:	1.47 at 35º C			
Edge Design:	**ProTEC** frosted, continuous 360° posterior square edge			

BIOMETRY*	CONTACT ULTRASOUND†	OPTICAL††
A-constant:	118.8	119.3
AC Depth:	5.4 mm	5.7 mm
Surgeon Factor:[1]	1.68 mm	1.96 mm

HAPTIC CHARACTERISTICS

Overall Diameter:	13.0 mm
Thickness:	0.46 mm
Style:	C
Material:	UV-blocking hydrophobic acrylic with violet light filter
Design:	**Squared and frosted haptic design.** **TRI-FIX,** Haptics offset from optic; 1-piece lens

Preloaded TECNIS SIMPLICITY® Delivery System

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

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