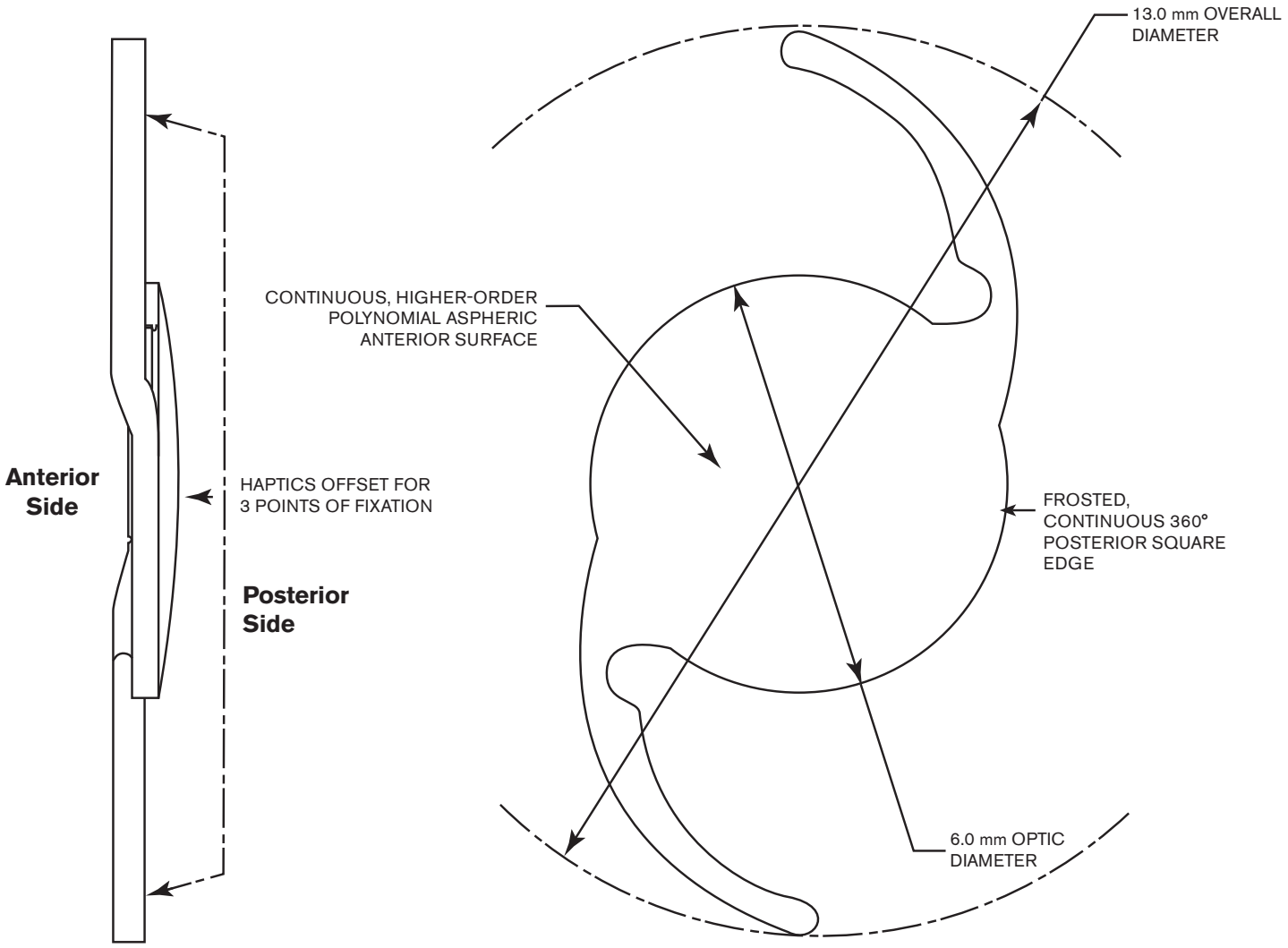
TECNIS

Eyhance™ IOL

with TECNIS SIMPLICITY® Delivery System

Model: DIB00

Defining the future of monofocals.



Johnson & Johnson VISION

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DESCRIPTION

OPTIC CHARACTERISTICS

Powers:	+5.0 D to +34.0 D in 0.5 diopter increments
Diameter:	6.0 mm
Shape:	Biconvex, continuous, higher-order polynomial aspheric anterior surface
Material:	UV-blocking hydrophobic acrylic
Refractive Index:	1.47 at 35° C
Edge Design:	**ProTEC** frosted, continuous 360° posterior square edge

OPTICAL BIOMETRY*

A-Constant (SRK/T):	119.3
AC Depth (HofferQ):	5.7 mm
Surgeon Factor (Holl.)[1]:	1.96 mm

APPLANATION ULTRASOUND BIOMETRY

A-Constant†:	118.8
Theoretical AC Depth:	5.4 mm
Surgeon Factor[1]:	1.68 mm

HAPTIC CHARACTERISTICS

Overall Diameter:	13.0 mm
Style:	C
Material:	UV-blocking hydrophobic acrylic
Design:	**Tri-Fix**, Haptics offset from optics, 1-piece lens

Preloaded **TECNIS Simplicity®** delivery system

* Values theoretically derived for a typical 22.0 D lens. Johnson & Johnson Vision 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.

INDICATIONS and IMPORTANT SAFETY INFORMATION for TECNIS Eyhance™ and TECNIS Eyhance™ Toric II IOLs with TECNIS Simplicity® Delivery System

Rx Only

INDICATIONS FOR USE: The TECNIS Simplicity™ Delivery System is used to fold and assist in inserting the TECNIS Eyhance™ IOL for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction. The lens is intended to be placed in the capsular bag. The TECNIS Simplicity® Delivery System is used to fold and assist in inserting the TECNIS Eyhance™ Toric II IOLs for the visual correction of aphakia and pre-existing corneal astigmatism of one diopter or greater in adult patients with or without presbyopia in whom a cataractous lens has been removed by phacoemulsification and who desire reduction in residual refractive cylinder. The lens is 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 Directions for Use that could increase complications or impact patient outcomes. The lens should be placed entirely in the capsular bag. Do not place the lens in the ciliary sulcus. 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: 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 (BSS) 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. **ADVERSE EVENTS:** The most frequently reported cumulative adverse event that occurred during the SENSAR® 1-Piece IOL clinical trial was cystoid macular edema which occurred at a rate of 3.3%.
ATTENTION: Reference the Directions for Use for a complete listing of Indications and Important Safety Information.

For precise results, utilize the **TECNIS®** Toric Calculator to determine the appropriate Toric model and power. Based on preoperative keratometry, biometry, and surgeon preferences, the calculator provides three IOL options, with residual astigmatism, to assist surgeons in accurate lens model selection and axis placement. www.TecnisToricCalc.com

References:
1. Holladay JT. International Intraocular Lens & Implant Registry 2003. J Cataract Refract Surg. 2003; 29:176-197. REF2016CT0151.

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