



EXPERIENCE THE
DIFFERENCE

TECNIS
Eyhance® IOL
with TECNIS SIMPLICITY® Delivery System

TECNIS
Eyhance® Toric II IOL
with TECNIS SIMPLICITY® Delivery System
Toric II

Getting Started **GUIDE**

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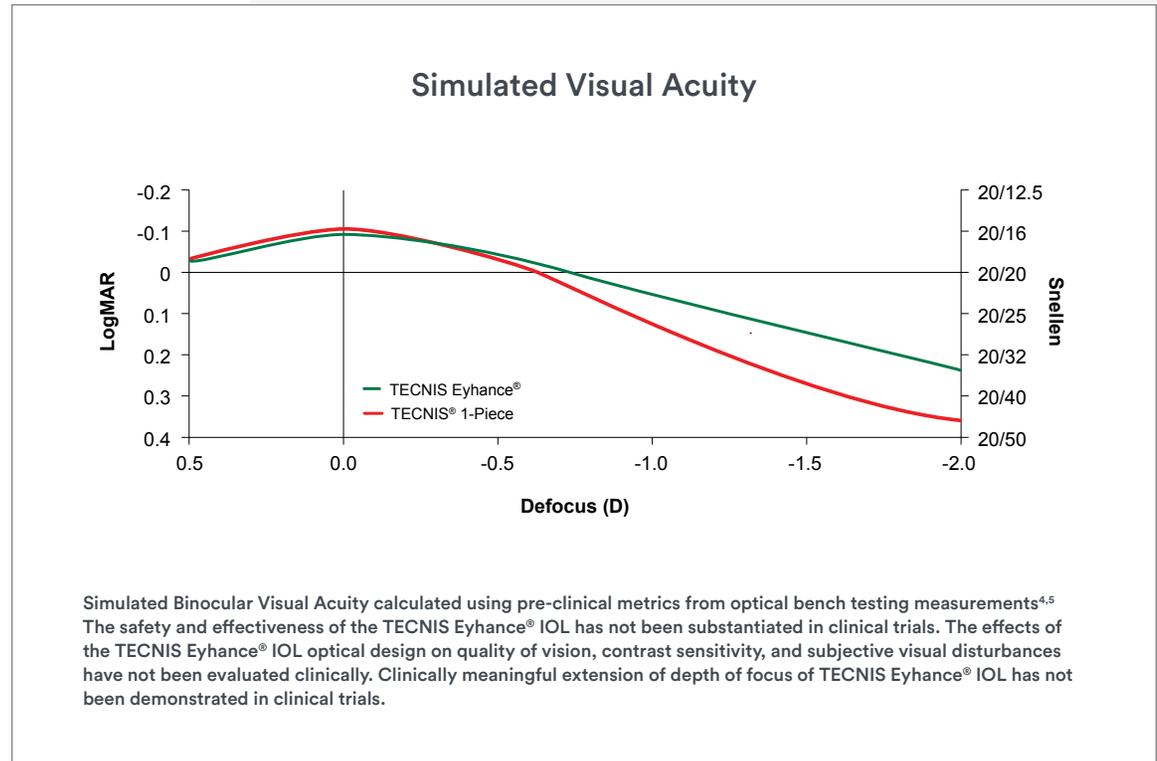
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INDICATIONS: The TECNIS Simplicity® Delivery System is used to fold and assist in inserting the TECNIS Eyhance® IOL for the visual correction of aphasia in adult patients in whom a cataractous lens has been removed by extracapsular cataract extraction. 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 aphasia 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.

BREAKTHROUGH DESIGN

The **TECNIS Eyhance® IOL** is the first monofocal lens designed to slightly extend the depth of focus.^{1,2,*}

Help your patients experience the difference. The breakthrough design of the TECNIS Eyhance® IOL delivers a different kind of monofocal experience.³ It's a modern monofocal IOL with a refractive surface designed to slightly extend the depth of focus.^{1,2,3,*}



*The TECNIS Eyhance® IOLs are designed to slightly extend the depth of focus compared to the TECNIS 1-Piece IOL, Model ZCB00 as measured in bench testing.

1. TECNIS Eyhance® IOL with TECNIS Simplicity® Delivery System, Model DIB - DFU US Z311524E Rev. A. Jan. 2021. REF2021CT4008.
2. TECNIS Eyhance® Toric II IOL with TECNIS Simplicity® Delivery System, Model DIU - DFU US Z311525E Rev. A. Jan. 2021. REF2021CT4007.
3. Data on File, Johnson & Johnson Surgical Vision, Inc. Design information of the TECNIS Eyhance® IOL. DOF2021CT4005. 2021.
4. Alarcon A, Cánovas C, Rosen R, et al. Preclinical metrics to predict through-focus visual acuity for pseudophakic patients. *Biomedical Optics Express*, 2016 Feb 16;7(5):1877-1888.
5. Alarcon A, Cánovas C, Koopman B, et al. Enhancing the intermediate vision of monofocal intraocular lenses using a higher order aspheric optic. *Journal of Refractive Surgery*, 2020;36(8):520-27.

PATIENT SELECTION

The TECNIS Eyhance® IOL has the same indication as other monofocal IOLs. The lens may be used 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 Eyhance® IOL has a unique shape that is designed to slightly extend the depth of focus^{1,2*} and it provides better image contrast in low light compared to other monofocals.^{6,**}

Prior to surgery, ensure your patients have realistic expectations:

- Inform your patient of the possible risks and benefits they will experience with the implantation of a monofocal IOL.
- Provide a copy of the patient information brochure.
- Be sure patients understand that they will still need to wear glasses for some activities.

*The TECNIS Eyhance® IOLs are designed to slightly extend the depth of focus compared to the TECNIS® 1-Piece IOL, Model ZCB00 as measured in bench testing.

**30% improved image contrast compared to AcrySof IQ SN60WF at 5 mm.

6. Data on File, Johnson & Johnson Surgical Vision, Inc. 2021. TECNIS Eyhance® and monofocal competitor IOLs MTF data. Sept. 2018. DOF2021CT4002.



BIOMETRY

- Use an Optical Biometer and ensure that measurements are reliable
- Calibrate the device regularly
- Repeat measurements 3 - 5x
 - Proper fixation is essential. Have the patient look directly at the red light as instrument measures along the visual axis.
- Repeat axial length measurement if⁷:
 - Axial length < 22.0mm or > 25.0mm
 - Average corneal power < 40D or > 47D
 - Difference of corneal astigmatism between eyes is > 1D
 - Difference of axial length between eyes is > 0.3mm
 - Difference of calculated emmetropic IOL power is > 1D
- If uncertain with measurements, use another device and compare the results (i.e., IOLMaster and Lenstar).

7. ASM 2017 Canadian Biometry Session. How to achieve the best refractive outcomes. Screening criteria from Dr. Jack Holladay. PP2016OTH0603.



KERATOMETRY

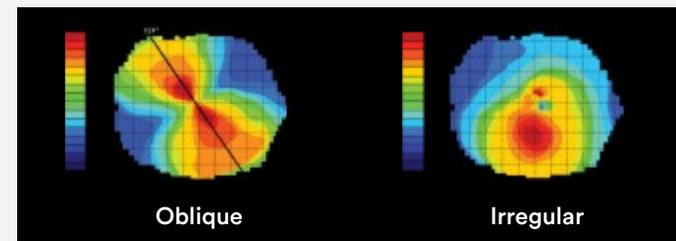
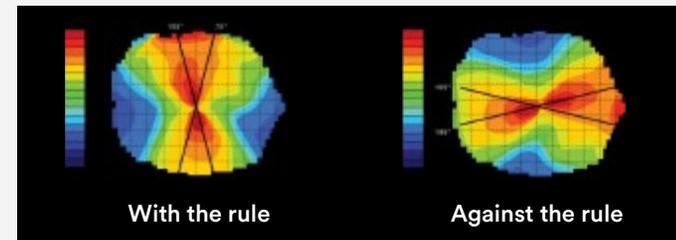
- Make sure that the surface of the cornea is stable prior to keratometry. Manage the ocular surface before biometry AND surgery.
- Perform the keratometry before any eye drops (anesthetic, cycloplegic, fluorescein) are instilled (except artificial tears).
- Ask patient to blink several times then take the measurement.
- 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.
- Repeat keratometry if:
 - K is not between 41D – 47D*
 - Difference of average corneal power > 1.0D between eyes*
 - Difference in corneal astigmatic power > 1.0D between consecutive measurements
 - Poor fixation (e.g., mature cataract, etc.)
 - Uncooperative or non-communicative patients

Note: Refractive outcomes are matched 1:1 with keratometry inaccuracy (If you're 1.0D off in your K readings, you will have a 1.0D refractive surprise).

*Outcome optimization with accurate biometry.

TOPOGRAPHY

- Topography can be used to identify irregular astigmatism.
- Depending on the device (e.g., Cassini, Pentacam, Galilei) it can also be used to directly measure posterior corneal astigmatism.



IOL CALCULATION FORMULA AND TARGET

TECNIS Eyhance® IOL is part of the TECNIS® 1-Piece family of products sharing the same mechanical properties and axial position in the eye.

- Initial A-constant suggested is the same as your optimized ZCB00 A-constant.
- Be sure to optimize the TECNIS Eyhance® A-constant after you have data for 30 eyes (see A-constant optimization below).
- Use a fourth-generation formula, such as the Barrett Universal II formula (other formulas include Hill-RBF, Olsen, Holladay II).
- When using a toric IOL, it is strongly recommended that a calculator be used that compensates for posterior corneal astigmatism such as the TECNIS® Toric Calculator (www.TecnisToricCalc.com).

LENS CONSTANT OPTIMIZATION

- Measure the maximum plus (least minus) manifest refraction at the four-to-six-week post-operative visit.
- It will take at least 30 cases to calculate your personal constant at the outset.*
- Always use the same instruments and be sure to do every operation exactly the same.
- Lens constants may be optimized using stand-alone software or the software that comes with your biometer.

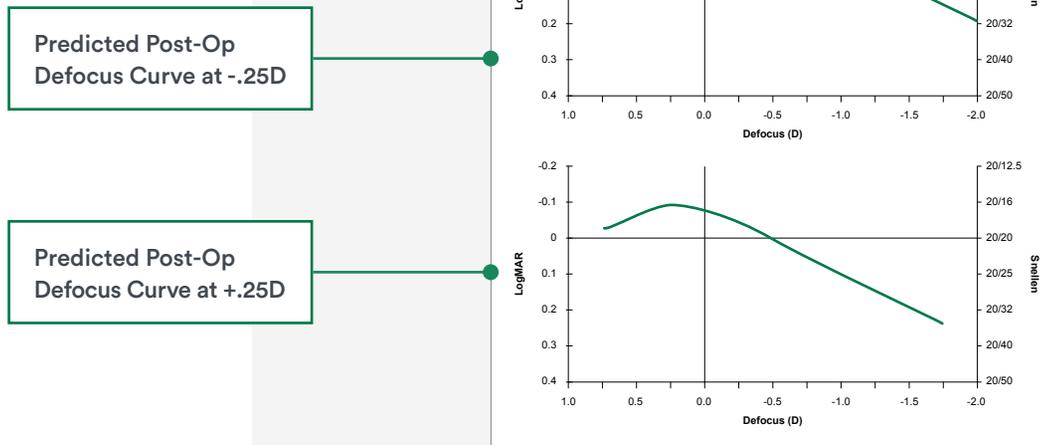
*A-constant optimization.

PRECAUTIONS: 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 multicenter 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.

REFRACTIVE TARGETING

Consider targeting for emmetropia in the first eye then adjust accordingly for the fellow eye depending on patient preference.

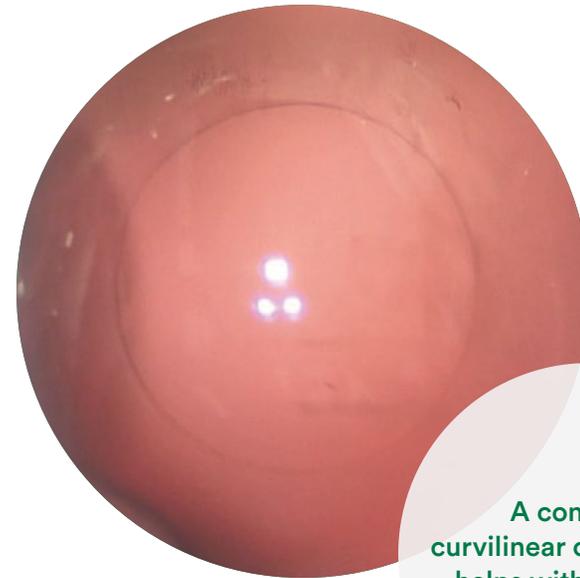
When targeting 1st minus, note that distance vision may be slightly compromised and near vision may be better.



Simulated Binocular Visual Acuity calculated using pre-clinical metrics from optical bench testing measurements.^{4,5} The safety and effectiveness of the TECNIS Eyhance® IOL has not been substantiated in clinical trials. The effects of the TECNIS Eyhance® IOL optical design on quality of vision, contrast sensitivity, and subjective visual disturbances have not been evaluated clinically. Clinically meaningful extension of depth of focus of TECNIS Eyhance® IOL has not been demonstrated in clinical trials.

OPERATIVE

- When using intraoperative aberrometry, if the system has not been optimized, do not choose the TECNIS Eyhance® lens from the IOL menu. Choose the ZCB00 to determine the spherical equivalent power.
- A consistent curvilinear capsulorhexis is critical for centration and accurate effective lens position.
- After implantation of the TECNIS Eyhance® IOL, remove all OVD including behind the IOL, then push posteriorly to aid in capsule capture.



A consistent curvilinear capsulorhexis helps with centration and lens position.

*Outcome optimization with accurate biometry.

POST OPERATIVE

POST-OP MEDS/DROPS⁸

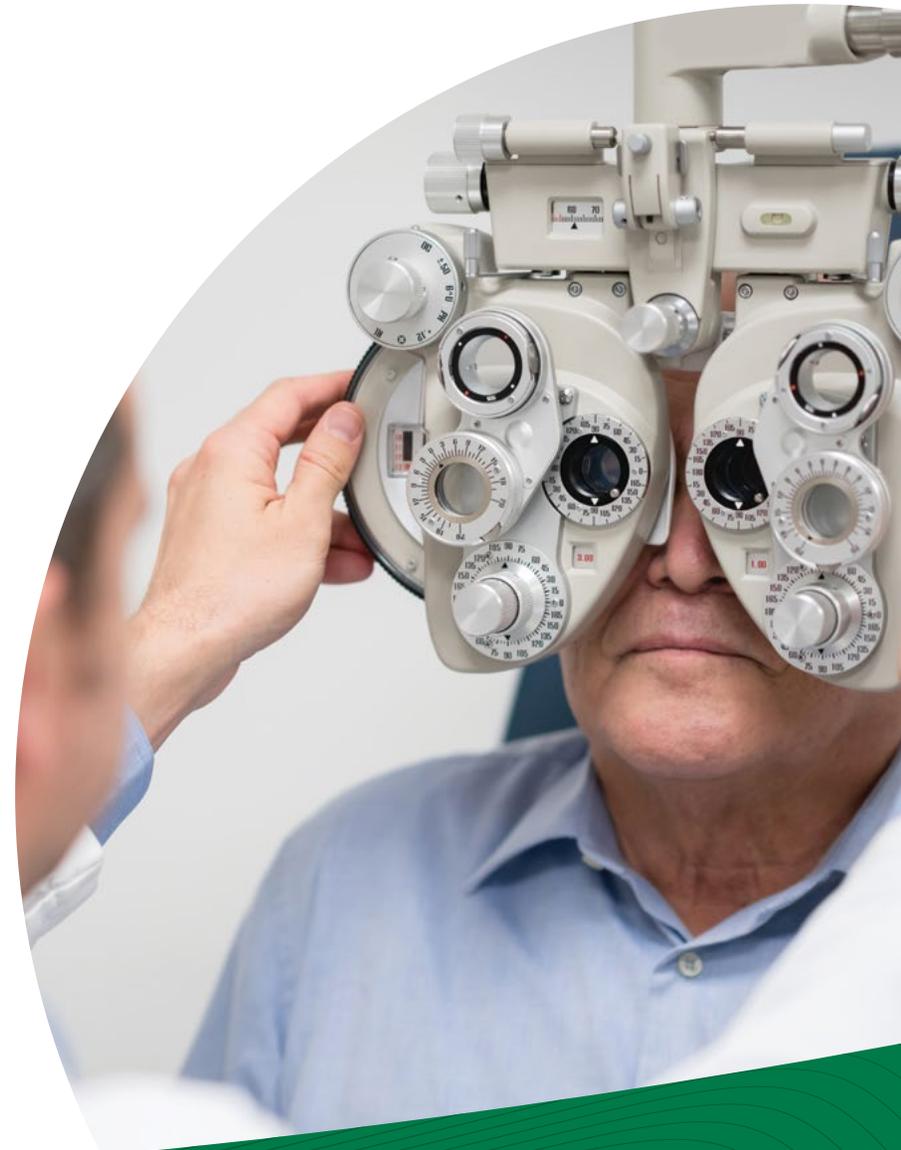
- Consider refraining from using generic ophthalmic drops. These medications may bring trade-offs in efficacy, safety and convenience.
- Continue to optimize the ocular surface and treat any symptomatic OSD, MGD and/or blepharitis.

MAXIMUM PLUS REFRACTION

Due to the elongated focus of the TECNIS Eyhance[®], refraction needs to be performed with care using the maximum plus refraction technique (“pushing plus”). This refractive outcome will be used to refine your personal lens constant.

PUSHING PLUS STEPS⁹

- 1**
Correct for distance and perform a Visual Acuity (VA) check.
- 2**
Add +1.00 D or until the patient can no longer see 2-3 lines higher than VA in Step 1 (e.g., the 20/40 line, if VA was 20/20 in Step 1) at distance.
- 3**
Add -0.25 D (+0.75 -> +0.50 -> +0.25 and so on), performing repeated VA checks.
- 4**
Maximum Plus (or Least Minus) has been achieved when ALL letters on the line can be read clearly for the first time, not necessarily where the letters are the clearest.



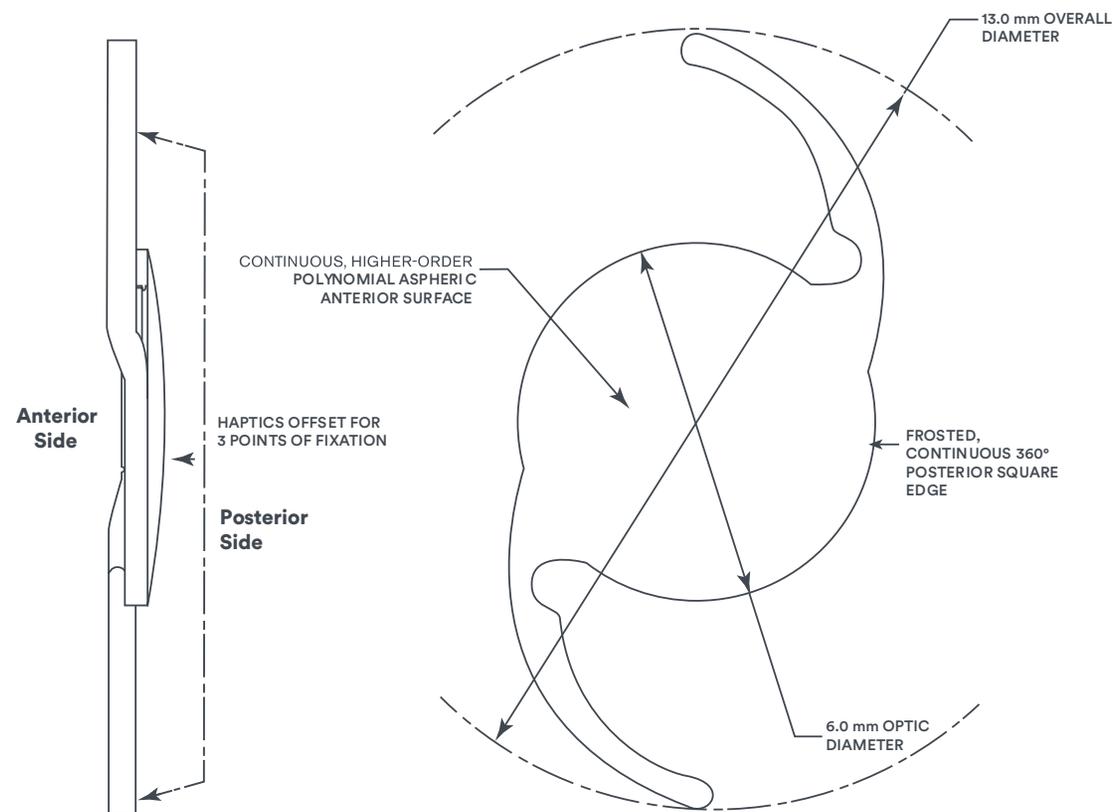
8. Guttman Krader C, Donnenfield ED, Lane SS, et al. Brand vs. generic: Which is best cataract surgery medicine? Ophthalmology Times. Jan. 2017:1-5.

9. Wilkinson, ME. General Refraction Techniques (1 of 7): Plus cylinder subjective refraction techniques for technicians. UIHC Department of Ophthalmology and Visual Sciences. January 2016:1-7.

TECNIS Eyhance® IOL

with TECNIS SIMPLICITY® Delivery System

Model DIB00



Preloaded in the
TECNIS
Simplicity[®]
 Delivery System



MODEL DIB00 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:	119.3
AC Depth:	5.7 mm
Surgeon Factor: ¹⁰	1.96 mm

APPLANATION ULTRASOUND BIOMETRY

A-Constant: [†]	118.8
Theoretical AC Depth:	5.4 mm
Surgeon Factor: ¹⁰	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

*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.

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

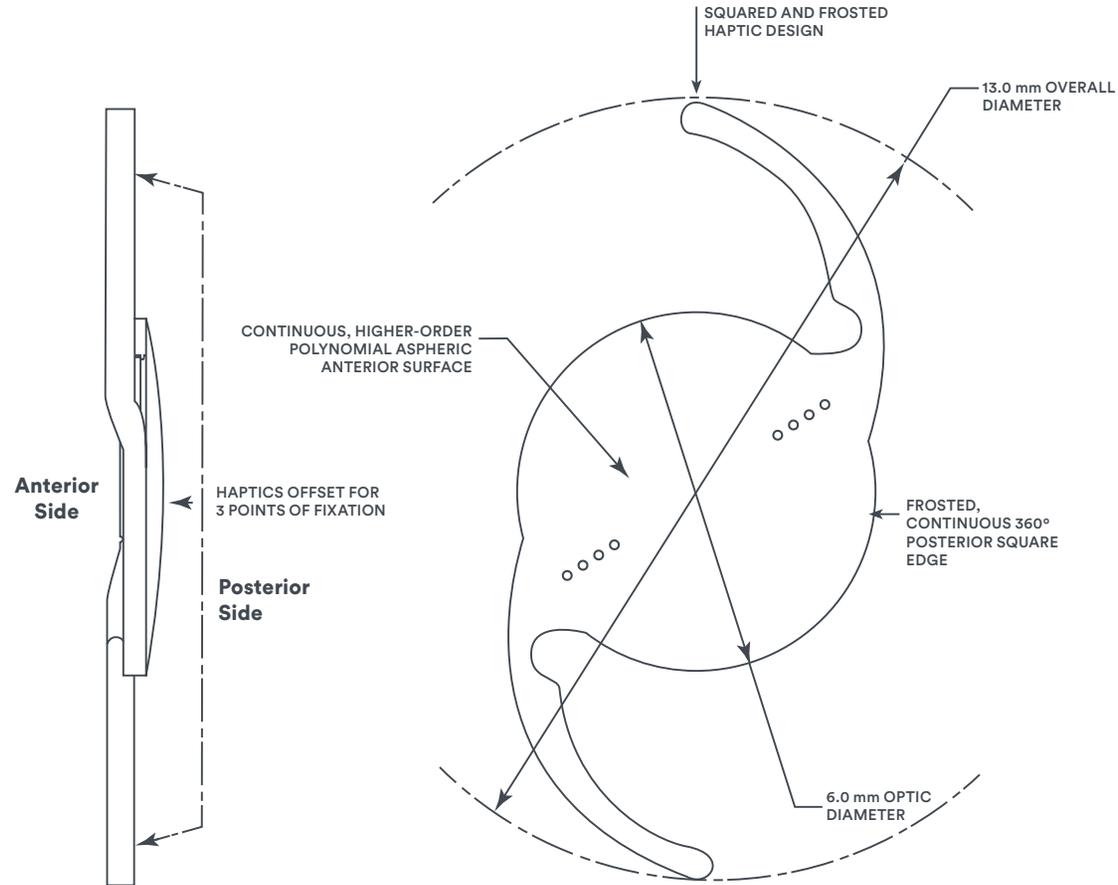
TECNIS

Eyhance® Toric II IOL

with TECNIS SIMPLICITY® Delivery System

Toric II

Model DIU150-DIU600



Preloaded in the
TECNIS
Simplicity[®]
Delivery System

MODEL DIU150-DIU600 DESCRIPTION

OPTIC CHARACTERISTICS²

Powers:	+5.0 D to +34.0 D in 0.5 diopter increments						
Model Numbers:	DIU150	DIU225	DIU300	DIU375	DIU450	DIU525	DIU600
Cylinder Powers - IOL Plane	1.50 D	2.25 D	3.00 D	3.75 D	4.50 D	5.25 D	6.00 D
Cylinder Powers - Corneal Plane	1.03 D	1.54 D	2.06 D	2.57 D	3.08 D	3.60 D	4.11 D
Diameter:	6.0 mm						
Shape:	Biconvex, continuous, higher-order polynomial aspheric anterior surface						
Material:	UV-light absorbing, 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
AC Depth:	5.4 mm	5.7 mm
Surgeon Factor: ¹⁰	1.68 mm	1.96 mm

HAPTIC CHARACTERISTICS²

Overall Diameter:	13.0 mm
Thickness:	0.46 mm
Style:	C, TRI-FIX haptics offset from optic; 1-piece lens
Material:	Soft, Foldable, UV-light absorbing, hydrophobic acrylic
Design:	Squared and frosted haptic design

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

*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.

Greater predictability
by accounting for
posterior corneal
astigmatism (PCA).¹¹

Get started at
TecnisToricCalc.com.



PRECAUTIONS: 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 IOL labeling. Please refer to the Johnson & Johnson Surgical Vision, Inc. Toric Calculator user manual for more information.

11. Koch DD, Ali SF, Shirayama M, Wang L. Contribution of posterior corneal astigmatism to total corneal astigmatism. J Cataract Refract Surg.2012;38(12):2080-2087.

TECNIS Eyhance® IOL

with TECNIS SIMPLICITY® Delivery System

Model DIB00

TECNIS Eyhance® Toric II IOL

with TECNIS SIMPLICITY® Delivery System

Toric II

Model DIU150-DIU600

Watch a video
demonstrating
how to use the
TECNIS® Simplicity
Delivery System



Enlarged Knob

More surgeon control

Ergonomic Design

Sturdy, comfortable grip; better grasp¹²

Lens Case

Preloaded with TECNIS Eyhance® IOLs

Hydration Port

For BSS or OVD

Beveled Tip

For a 2.2 - 2.4 mm incision

12. Data on file, Johnson & Johnson Surgical Vision, Inc. Delta IOL System Validation Report. JVC-DEL_S1.
December 12, 2018.

PATIENT INFORMATION

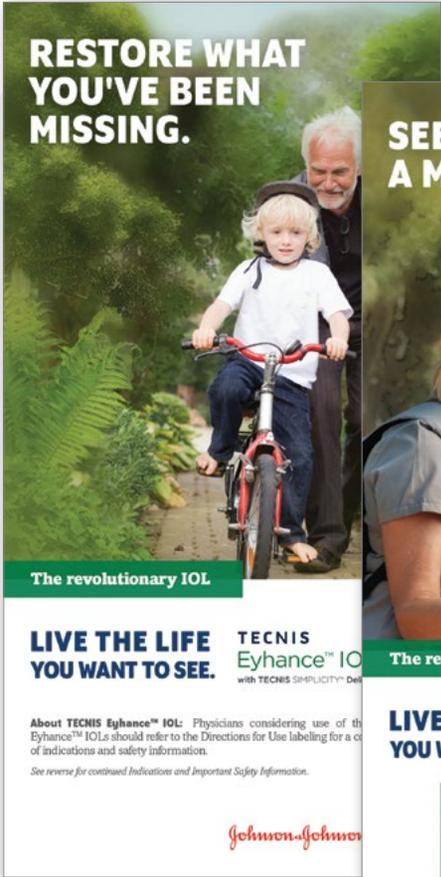
Use the links below as resources for your patients. They offer useful information to help educate and inform your patients' decisions.

View the TECNIS Eyhance® brochure.

[View Brochure](#)

For people with astigmatism View the TECNIS Eyhance® Toric II brochure.

[View Brochure](#)



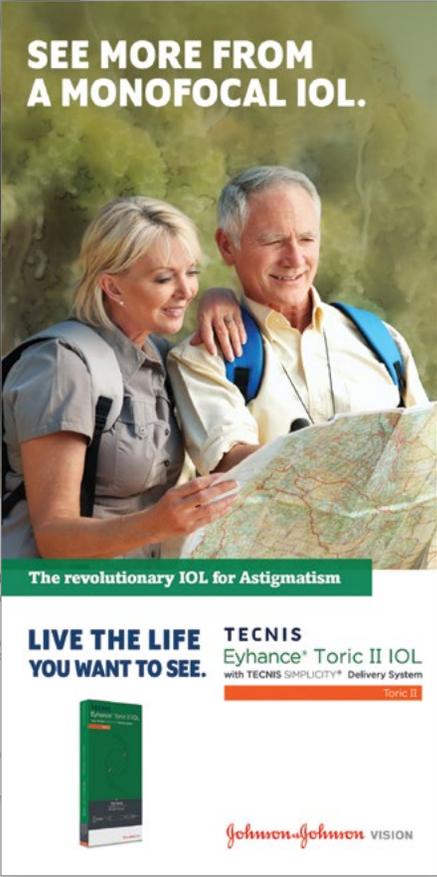
RESTORE WHAT YOU'VE BEEN MISSING.

The revolutionary IOL

LIVE THE LIFE YOU WANT TO SEE. TECNIS Eyhance™ IOL with TECNIS SIMPLICITY™ Delivery System

About TECNIS Eyhance™ IOL: Physicians considering use of the Eyhance™ IOLs should refer to the Directions for Use labeling for a complete list of indications and safety information. See reverse for continued Indications and Important Safety Information.

Johnson & Johnson



SEE MORE FROM A MONOFOCAL IOL.

The revolutionary IOL for Astigmatism

LIVE THE LIFE YOU WANT TO SEE. TECNIS Eyhance® Toric II IOL with TECNIS SIMPLICITY™ Delivery System



Johnson & Johnson VISION

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 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. These conditions are not specific to the design of the lens and are attributed to cataract surgery and IOL implantation in general:
 - 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. Congenital bilateral cataracts.
 - i. Previous history of, or a predisposition to, retinal detachment.
 - j. Patients with only one good eye with potentially good vision.
 - k. Medically uncontrollable glaucoma.
 - l. Corneal endothelial dystrophy.
 - m. Proliferative diabetic retinopathy.
 - n. Children under the age of 2 years are not suitable candidates for intraocular lenses.
2. The lens should be placed entirely in the capsular bag. Do not place the lens in the ciliary sulcus.
3. Johnson & Johnson Surgical Vision, Inc. single-use medical devices are labeled with instructions for use and handling to minimize exposure to conditions which may compromise the product, patient, or the user. When used according to the directions for use, the delivery system minimizes the risk of infection and/or inflammation associated with contamination.
4. The reuse/resterilization/reprocessing of Johnson & Johnson Surgical Vision, Inc. single-use devices may result in physical damage to the medical device, failure of the medical device to perform as intended, and patient illness or injury due to infection, inflammation, and/or illness due to product contamination, transmission of infection, and lack of product sterility.
5. The clinical study for the TECNIS® Toric 1-Piece IOL did not show evidence of effectiveness for the treatment of preoperative corneal astigmatism of less than one diopter.

6. Rotation of the toric lens from its intended axis can reduce its 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.
7. 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.
8. Do not use if the cartridge of the delivery system is cracked or split prior to implantation.
9. Do not implant the lens if the rod tip does not advance the lens or if it is jammed in the delivery system.
10. During initial lens advancement, quick advancement of the plunger is needed. Do not stop or reverse while advancing the plunger. Doing so may result in improper folding of the lens.
11. After initial lens advancement and the half turn rotation step, do not move the plunger forward until ready for lens implantation. Doing so may result in the lens being stuck in the cartridge.
12. The lens and delivery system should be discarded if the lens has been folded within the cartridge for more than 10 minutes. Not doing so may result in the lens being stuck in the cartridge.

PRECAUTIONS

1. The safety and effectiveness of the TECNIS Eyhance® IOL and TECNIS Eyhance® Toric II IOL has not been substantiated in clinical trials. The effects of the TECNIS Eyhance® IOL optical design on quality of vision, contrast sensitivity, and subjective visual disturbances (glare, halo, etc.) have not been evaluated clinically. MTF testing of the TECNIS Eyhance® IOL may aid the Surgeon in understanding the theoretical image quality expected with the TECNIS Eyhance® IOL compared to other JJSV monofocal IOLs (AAB00 and ZCB00). However, these do not fully assess all aspects of clinical difficulties under all conditions. Surgeons must weigh the potential benefits of the modified optical design of the TECNIS Eyhance® IOL against the potential for risks and the lack of clinical data to characterize the impact of the TECNIS Eyhance® IOL optical design on contrast sensitivity and subjective visual disturbance. These considerations may be especially relevant to patients with certain pre-existing ocular conditions (prior corneal refractive surgery, irregular corneal astigmatism, severe corneal dystrophy, macular disease, optic nerve atrophy, etc.) or intraoperative conditions (posterior capsular rupture, complications in which the IOL stability could be compromised, inability to place IOL in capsular bag, etc.).
2. 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.
3. Some autorefractors utilize only the central part of the IOL to calculate the refraction of the eye and that is the region where the TECNIS Eyhance® deviates from the monofocal design which could result in a wrong estimation of the refraction. Manual refraction with maximum plus technique is strongly recommended.
4. Recent contact lens usage may affect the patient's refraction; therefore, for patients who wear contact lenses, surgeons should establish corneal stability without contact lenses prior to determining IOL power.
5. The lens is designed for optimum visual performance when emmetropia is targeted.
6. This is a single use device, do not resterilize the lens or the delivery system. Most sterilizers are not equipped to sterilize the soft acrylic material and the preloaded inserter material without producing undesirable side effects.
7. Do not store the device in direct sunlight or at a temperature under 5°C (41°F) or over 35°C (95°F).
8. Do not autoclave the delivery system.
9. Do not advance the lens unless ready for lens implantation.
10. The contents are sterile unless the package is opened or damaged.
11. The recommended temperature for implanting the lens is at least 17°C (63°F).

12. The use of balanced salt solution (BSS) or viscoelastics is required when using the delivery system. For optimal performance when using OVD, use the HEALON® family of viscoelastics. The use of BSS with additives has not been studied for this product.
13. Do not use if the delivery system has been dropped or if any part was inadvertently struck while outside the shipping box. The sterility of the delivery system and/or the lens may have been compromised.
14. Do not leave the lens in a folded position more than 10 minutes.
15. When the delivery system is used improperly, the lens may not be delivered properly (i.e., haptics may be broken). Please refer to the specific instructions for use provided.
16. Carefully remove all viscoelastic and do not over-inflate the capsular bag at the end of the case. Residual viscoelastic and/or over-inflation of the capsular bag may allow the lens to rotate, causing misalignment of the TECNIS Eyhance® Toric II IOL with the intended axis of placement.
17. The use of methods other than the TECNIS® Toric Calculator to select cylinder power and appropriate axis of implantation were not assessed in the clinical study for the TECNIS® Toric 1-Piece IOLs. 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.
18. The safety and effectiveness of the TECNIS Eyhance® Toric II IOLs have not been substantiated in patients with the following preexisting ocular conditions and intraoperative complications (see below). 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

- 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

During Surgery

- Excessive vitreous loss
- Capsulotomy by any technique other than a circular tear
- The presence of radial tears known or suspected at the time of surgery
- Situations in which the integrity of the circular tear cannot be confirmed by direct visualization
- Cataract extraction by techniques other than phacoemulsification or liquefaction
- Situations where the need for a large capsulotomy can be anticipated (e.g., diabetics, retinal detachment in the fellow eye, peripheral retinal pathology, etc.)
- Capsular rupture
- Significant anterior chamber hyphema
- Uncontrollable positive intraocular pressure
- Zonular damage

19. 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.

20. All preoperative surgical parameters are important when choosing a toric lens 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.
21. All corneal incisions were placed temporally in the clinical study for the TECNIS® Toric 1-Piece IOLs. If the surgeon chooses to place the incision at a different location, outcomes may be different from those obtained in the clinical study. Note that the TECNIS® Toric Calculator incorporates the surgeon's estimated SIA and incision location when providing IOL options.

ADVERSE EVENTS

Potential adverse events during or following cataract surgery with implantation of an IOL may include but are not limited to: endophthalmitis/intraocular infection, hypopyon, hyphema, IOL dislocation, cystoid macular edema, pupillary block, retinal detachment/tear, persistent corneal stromal edema, persistent iritis, persistent raised IOP (intraocular pressure) requiring treatment, acute corneal decompensation, secondary surgical intervention (including implant repositioning, removal, or other surgical procedure) and any other adverse event that leads to permanent visual impairment or requires surgical or medical intervention to prevent permanent visual impairment. 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%. Other reported events included secondary surgical intervention (pars plana vitrectomy with membrane peel) which occurred at a rate of 0.8% and lens exchange (torn haptic related to improper loading technique) which occurred at a rate of 0.8%. The most frequently reported cumulative adverse event that occurred during the TECNIS® Toric 1-Piece IOL clinical trial was surgical re-intervention which occurred at a rate of 3.4% (lens repositioning procedures and retinal repair procedures). Other reported events included cystoid macular edema which occurred at a rate of 2.9% and retinal detachment which occurred at a rate of 0.6%.

ATTENTION:

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

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