TECNIS Eyhance™ IOL with TECNIS Simplicity™ Delivery System

Z311524E Rev. A
Revision Date: 01/2021

Rx Only

DEVICE DESCRIPTION:

The TECNIS Eyhance™ IOL with the TECNIS Simplicity™ Delivery System in Model DIB00, is an ultraviolet-light absorbing posterior chamber intraocular lens (IOL). It is designed to be positioned in the lens capsule to replace the optical function of the natural crystalline lens. This monofocal IOL contains a modified aspheric anterior surface when compared to the material and mechanical parent lens, the SENSAR® 1-Piece IOL, Model AAB00 and the monofocal analogue, the TECNIS® 1-Piece IOL, Model ZCB00. The lens compensates for corneal spherical aberrations. Accommodation will not be restored. The IOL contains a squared posterior optic edge that provides a 360-degree barrier. The edge of the optic has a frosted design to reduce potential edge glare effects.

The TECNIS Simplicity™ Delivery System Model DIB00 contains the TECNIS Eyhance™ IOL, which is a one-piece, foldable, posterior chamber lens with an overall diameter of 13.0 mm and an optic diameter of 6.0 mm. All IOL optical designs are associated with a certain amount of depth of focus. For monofocal IOLs, the amount of depth of focus is typically limited. The TECNIS Eyhance™ IOL uses an aspheric anterior surface that creates a small continuous increase in central lens power within the 1 mm diameter. The TECNIS Eyhance™ IOL is designed to slightly extend the dept of focus compared to the TECNIS® 1-Piece IOL, Model ZCB00 as measured in bench testing (see **Figure 1**). The power profile decreases towards the periphery outside the central 1 mm diameter in a manner comparable to the TECNIS® 1-Piece IOL, Model ZCB00, enabling the same correction of corneal spherical aberration and resulting in comparable distance image quality to the TECNIS® 1-Piece IOL, Model ZCB00 and the SENSAR® 1-Piece IOL, Model AAB00, for 3 mm pupil (see **Figure 2**). However, clinically meaningful extension of depth of focus has not been demonstrated in clinical trials. In general, extending the depth of focus negatively affects the quality of vision at far distances. Vision quality can be estimated using non-clinical testing (see **Figures 1 and 2**).

The TECNIS Simplicity™ Delivery System is designed to provide a sterile, controlled and touch-free method of delivering the lens into the eye. The lens is preloaded and preassembled in the delivery system. This reduces the number of steps required to prepare the IOL for insertion into the eye, when compared to a non-preloaded device. The lens with the delivery system is available in the full diopter range (5.0 D to 34.0 D) and is compatible with micro-incision surgical techniques. Sodium hyaluronate (HA) used in the cartridge coating is produced by a microbiological fermentation method.

LENS OPTIC:

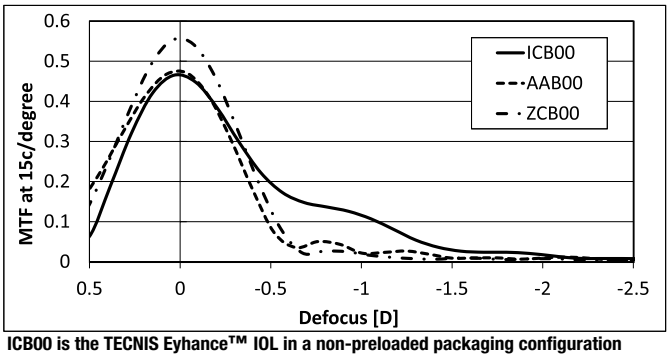
1. Optic Material: Optically clear, soft foldable hydrophobic acrylic with a covalently bound UV absorber. Full transmission of blue wavelength light for optimal scotopic sensitivity.
2. Power: +5.0 to +34.0 diopter powers in 0.5 diopter increments
3. Optic Center Thickness: 0.72 mm (+20.0D)
4. Optic Edge Design: PROTEC 360 square posterior edge
5. Index of Refraction: 1.47 at 35°C
6. Light Transmittance: UV cut-off at 10% T for a +5.0 diopter lens (thinnest) and a +34.0 diopter lens (thickest) are shown in **Figure 3**.

HAPTICS:

1. Material: Soft foldable hydrophobic acrylic with a covalently bound UV absorber.
2. One-piece lens
3. Configuration: TRI-FIX design Modified C, integral with optic
4. Haptic thickness: 0.46 mm

Figure 1:

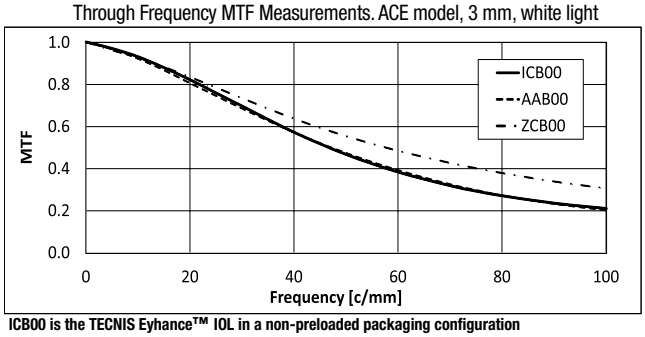
Through Focus MTF Measurements. ACE model, 3 mm, white light



ICB00 is the TECNIS Eyhance™ IOL in a non-preloaded packaging configuration

Figure 2:

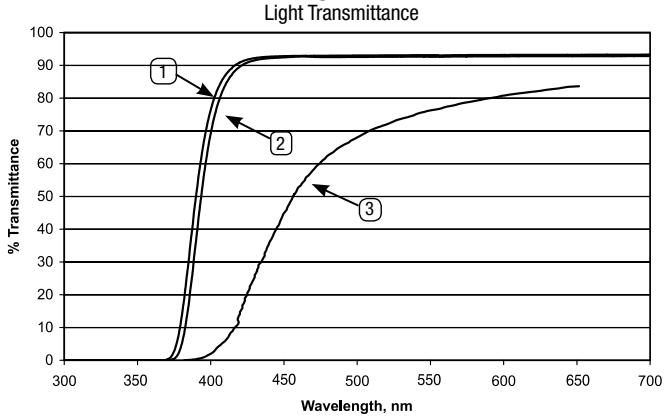
Through Frequency MTF Measurements. ACE model, 3 mm, white light



ICB00 is the TECNIS Eyhance™ IOL in a non-preloaded packaging configuration

Figure 3:

Light Transmittance



Legend:

Curve 1: Spectral transmittance curve of a typical 5 diopter IOL (thinnest), UV cut-off at 10% T is 375.4 nm.
Curve 2: Spectral transmittance curve of a typical 34 diopter IOL (thickest), UV-cut-off at 10% T is 380.4 nm.
Curve 3: Spectral transmittance curve corresponding to 53-year-old Phakic eye*.

Note: The cut-off wavelengths and the spectral transmittance curves represent the range of the transmittance values of IOLs (5-34 diopter) made with this material.

* Boettner, E.A., and Wolter J.R. Transmission of the Ocular Media. Investigative Ophthalmology. 1962; 1:776-783.

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.

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

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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. 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.
4. Do not use if the cartridge of the delivery system is cracked or split prior to implantation.
5. Do not implant the lens if the rod tip does not advance the lens or if it is jammed in the delivery system.
6. During initial lens advancement (**Figure 6**), 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.
7. After initial lens advancement (**Figure 6**) and the half turn rotation step (**Figure 7**), do not move the plunger forward until ready for lens implantation. Doing so may result in the lens being stuck in the cartridge.
8. 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.
9. 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.
10. 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.

PRECAUTIONS:

1. 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 (glare, halo, etc.) have not been evaluated clinically. MTF testing of the TECNIS Eyhance™ IOL (**Figures 1 and 2**) 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.

GENERAL ADVERSE EVENTS FOR IOLS:

Potential adverse events during or following cataract surgery with implantation of the IOL may include but are not limited to:

1. Endophthalmitis/intraocular infection
2. Hypopyon
3. Hyphema
4. IOL dislocation
5. Cystoid macular edema
6. Pupillary block
7. Retinal detachment/tear
8. Persistent corneal stromal edema
9. Persistent iritis
10. Persistent raised intraocular pressure (IOP) requiring treatment
11. Acute corneal decompensation
12. Secondary intraocular surgical intervention (including implant repositioning, removal, AC tap, or other surgical procedure)
13. Any other adverse event that leads to permanent visual impairment or requires surgical or medical intervention to prevent permanent visual impairment

CLINICAL STUDY RESULTS FOR THE SENSAR® 1-PIECE LENS, MODEL AAB00:

The material and mechanical parent lens of TECNIS Eyhance™ IOL with the TECNIS Simplicity™ Delivery System, Model DIB00, is the Model AAB00 lens. The difference between lens Model DIB00 and lens Model AAB00 is the wavefront designed aspheric anterior optic surface of lens Model DIB00. The clinical results of the Model AAB00 lens are applicable to Model DIB00 lens. The clinical trial was conducted between November 2005 and June 2007. The purpose of the study was to evaluate the safety and effectiveness of lens Model AAB00 in subjects who underwent cataract removal and intraocular lens implantation. Following routine cataract removal by phacoemulsification, all IOLs were implanted in the capsular bag with a continuous curvilinear capsulorhexis.

The results achieved by 117 patients followed for one year provide the basis for the data supporting the use of this lens design for visual correction of aphakia. In the total study population (123 patients), 56.9% of the patients were female and 43.1% were male; 93.5% were Caucasian, 4.1% were Black and 2.4% were Asian. The best corrected distance visual acuity results for the "best case" patients at 1 year (330-420 days) postoperatively are provided in **Table 1**. In addition the data compared to the FDA Grid values (historical control) are presented in **Table 2**.

ADVERSE EVENTS:

The incidence of adverse events experienced during the clinical trial for material and mechanical parent model, Model AAB00 is similar to or less than those of the historic control population (FDA Grid for posterior chamber IOLs) as shown in **Table 3**.

DIRECTIONS FOR USE:

1. Prior to opening the outer box, examine the outer box label for lens model, dioptric power, proper configuration and expiration date.
2. After opening the outer box of the TECNIS Eyhance™ IOL with TECNIS Simplicity™ Delivery System, examine the device package for any damage, and verify that information on the device (lens model, dioptric power, and serial number) is consistent with the information on the outer box label.
3. Open the peel pouch and remove the delivery system in the tray. Place the tray on the sterile environment. Do not use the device if the pouch is damaged or the seal is broken. If the device is defective in any way, use another delivery system.
4. Use BSS or OVD as a hydration method using a cannula. Insert the cannula into the hydration port and fill the cartridge completely from cartridge tip to hydration port without filling the lens case (**Figures 4 and 5**). Proceed to step 5 once completed.
5. Carefully remove the delivery system from the tray. Do not touch the tip of the delivery system during removal as this may damage the tip. Inspect the tip to ensure that it is not damaged.
6. Quickly advance the plunger forward in a continuous motion (for example less than 1 second) until it stops at the threads (**Figure 6**). Do not stop or reverse while advancing the plunger.
7. Rotate the knob half a turn clockwise to place the lens in the holding position (**Figure 7**). Do not move the plunger forward until ready for lens implantation. Dwell the lens in this position for 0 to 10 minutes. To minimize haptic release time, a minimum of 3 minutes is recommended. If left for more than 10 minutes, then do not use device.
8. Proceed with the lens implantation by inserting the delivery system tip into the incision with the bevel of the tip oriented downwards. Rotate the knob of the plunger clockwise to slowly advance the lens forward. Lens must be delivered within 1 minute. Continue to rotate the plunger knob until the lens is fully released from the delivery system tip.
9. Rotate the knob of the plunger counter-clockwise to slowly retract the plunger.
10. Discard the device. Do not re-use the delivery system.
11. The physician should consider the following points:
    - The surgeon should target emmetropia, as this lens is designed for optimum visual performance when emmetropia is achieved.
    - Care should be taken to achieve centration of the intraocular lens.

CAUTION:

Do not use the TECNIS Simplicity™ Delivery System if the package has been damaged. The sterility of the lens may have been compromised.

LENS POWER CALCULATIONS:

Accurate keratometry and biometry are essential to successful visual outcomes. Preoperative calculation of the required dioptric power for this posterior chamber intraocular lens should be determined by the surgeon's experience, preference, and intended lens placement. The lens is designed for optimum visual performance when emmetropia is targeted. The A-constants listed on the outer label are presented as a guideline and serve as a starting point for implant power calculations. The physician should determine preoperatively the dioptric power of the lens to be implanted.

Physicians requiring additional information on lens power calculations may contact the local Johnson & Johnson Surgical Vision, Inc. representative. Lens power calculation methods are described in the following references:

1. Haigis W. "The Haigis formula". In: Shammas HJ, ed, Intraocular Lens Power Calculations. Thorofare, NJ, Slack, 2004; 41-57.
2. Hoffer K.J., "The Hoffer Q formula: a comparison of theoretic and regression formulas", J Cataract Refract Surg, 19, 700-712 (1993). Erratum in: J Cataract Refract Surg 1994;20:677. Erratum in: J Cataract Refract Surg 2007;33:2-3.
3. Holladay J.T., Prager T.C., Chandler T.Y., Musgrove K.H., Lewis J.W. and Ruiz R.S., "A three-part system for refining intraocular lens power calculations", J Cataract Refract Surg. 14,17-24 (1988).
4. Retzlaff J.A, Sanders D.R. and Kraff M.C., "Development of the SRK/T intraocular lens implant power calculation formula", J Cataract Refract Surg. 16, 333-340 (1990). Erratum in: J Cataract Refract Surg. 1990;16:528.
5. Olsen T. "The Olsen formula". In: Shammas HJ, ed, Intraocular Lens Power Calculations. Thorofare, NJ, Slack, 2004; 27-40.
6. Canovas C., Artal P. "Customized eye models for determining optimized intraocular lenses power". Biomed. Opt. Express 2011;2:1649-1662.

PATIENT REGISTRATION SECTION (FOR US):

Each patient who receives a TECNIS Eyhance™ IOL must be registered with Johnson & Johnson Surgical Vision, Inc. at the time of lens implantation.

Registration is accomplished by completing the Implant Registration Card that is enclosed in the lens package and mailing it to Johnson & Johnson Surgical Vision, Inc.. Patient registration is essential for Johnson & Johnson Surgical Vision's long-term patient follow-up program and will assist Johnson & Johnson Surgical Vision, Inc. in responding to adverse reaction reports and/or potentially sight-threatening complications.

PATIENT CARD:

An implant identification card, to be supplied to the patient, is included in the package. The patient should be instructed to keep the card as a permanent record of his/her implant and to show the card to any eye care practitioner he/she may see in the future.

REPORTING:

Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as lens-related and that were not previously expected in nature, severity, or rate of occurrence must be reported to Johnson & Johnson Surgical Vision, Inc.. This information is being requested from all surgeons in order to document potential long-term effects of IOL implantation, especially in younger patients.

Physicians are required to report these events to aid in identifying emerging or potential problems with posterior chamber lenses. These problems may be related to a specific lot of lenses or may be indicative of long-term problems associated with these lenses or with IOLs in general.

HOW SUPPLIED:

Each lens is supplied sterile and preloaded in the delivery system within a single aseptic transfer peel pouch. The aseptic transfer peel pouch is sterilized with ethylene oxide and should be opened only under sterile conditions. The pouch and product labels are enclosed in a shelf pack. The external surfaces of the pouch are not sterile. The recommended storage temperature is 25°C (77°F).

EXPIRATION DATE:

The use-by date on the TECNIS Simplicity™ Delivery System package is the sterility expiration date. The delivery system should not be used, and the lens should not be implanted after the indicated sterility expiration date.

RETURN/EXCHANGE POLICY:

Contact the local Johnson & Johnson Surgical Vision, Inc. representative for the return/exchange policy. Return the lens with proper identification and the reason for the return. Label the return as a biohazard. Do not attempt to resterilize the lens.

PATIENT INFORMATION:

Each patient should receive information regarding intraocular lenses prior to the decision to implant an intraocular lens.

SYMBOL/EXPLANATION:

SYMBOL	EXPLANATION
STERILE EO	Sterilized using ethylene oxide
	Do not re-use
	Use-by date (YYYY-MM-DD:Year-Month-Day)
	Consult instructions for use
	Manufacturer
STERILIZE	Do not resterilize
35°C (95°F) 5°C (41°F)	Upper limit of temperature
	Keep away from sunlight
	Date of manufacture (YYYY-MM-DD: Year-Month-Day)
	Do not use if package is damaged
REF	Catalogue number
SN	Serial number

Johnson & Johnson Surgical Vision, Inc.
1700 E. St. Andrew Place
Santa Ana, CA 92705 USA

For production site, refer to product label.

Table 1:
Best Corrected Distance Visual Acuity (Snellen Equivalent) at 1 Year
Best Case Subjects* (N = 110) for the SENSAR® 1-Piece IOL, Model AAB00

Age Group	N	20/20 or Better		20/25 to 20/40		20/50 to 20/100		20/125 or Worse	
		n	%	n	%	n	%	n	%
< 60	11	11	100.0	0	0.0	0	0.0	0	0.0
60-69	35	29	82.9	6	17.1	0	0.0	0	0.0
70-79	46	39	84.8	7	15.2	0	0.0	0	0.0
≥ 80	18	14	77.8	4	22.2	0	0.0	0	0.0
TOTAL†	**110**	**93**	**84.5**	**17**	**15.5**	**0**	**0.0**	**0**	**0.0**

* Excludes subjects with macular degeneration at any time during the study
† Includes three subjects who experienced a Nd:YAG posterior capsulotomy

Table 2:
Best Corrected Distance Visual Acuity (Snellen Equivalent) at 1 Year
Best Case Subjects* (N = 110) for the SENSAR® 1-Piece IOL, Model AAB00 vs. FDA Grid

AGE DECADE	TOTAL		VISUAL ACUITY 20/40 OR BETTER		FDA GRID
	N	%	N	%	%
< 60	11	10.0	11	100.0	98.5
60 - 69	35	31.8	35	100.0	96.5
70 - 79	46	41.8	46	100.0	97.5
> 80	18	16.4	18	100.0	94.8
TOTAL†	**110**	**100.0**	**110**	**100.0**	**96.7**

* Excludes subjects with macular degeneration at any time during the study
† Includes three subjects who experienced a Nd:YAG posterior capsulotomy

Table 3:
Adverse Events for the SENSAR® 1-Piece IOL, Model AAB00
All Subjects (N = 123)

Adverse Events	Cumulative		Persistent at 1 Year		FDA Grid /ISO SPE	
	N	%	N	%	CUM%	PER%
Persistent Corneal Edema	-	-	0	0.0	-	0.3
Cystoid Macular Edema (CME)	4	3.3*	1	0.9†	3.0	0.5
Endophthalmitis	0	0.0	-	-	0.1	-
Hyphema	0	0.0	-	-	2.2	-
Hypopyon	0	0.0	-	-	0.3	-
Persistent Iritis	-	-	0	0.0	-	0.3
Secondary Surgical Intervention – Pars Plana Vitrectomy with Membrane Peel	1	0.8	-	-	0.8	-
Lens Dislocation	0	0.0	-	-	0.1	-
Pupillary Block	0	0.0	-	-	0.1	-
Retinal Detachment	0	0.0	-	-	0.3	-
Persistent Raised IOP Requiring Treatment	-	-	0	0.0	-	0.4
Lens Exchange – Torn Haptic related to improper loading technique	1	0.8	-	-	-	-

* This rate is not statistically significantly higher than the FDA Grid cumulative rate for posterior chamber IOLs of 3.0% (p=0.5060).

† This rate is not statistically significantly higher than the FDA Grid rate for posterior chamber IOLs of 0.5% (p=0.4437).

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Figure 4:

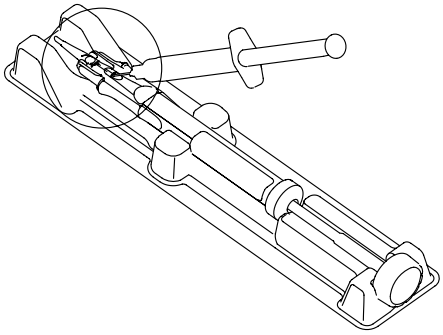


Figure 5:

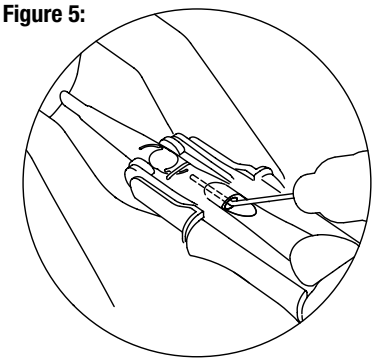


Figure 6:

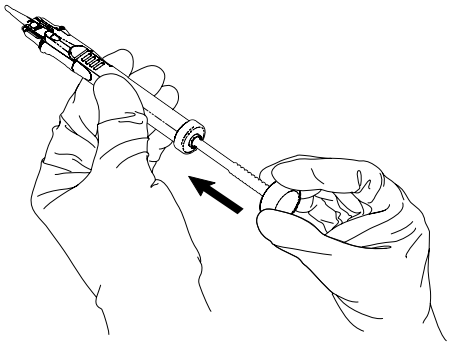
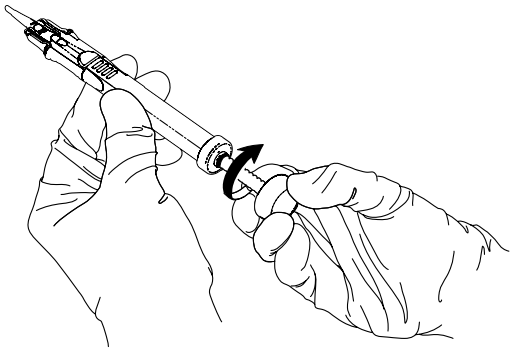


Figure 7:



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