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ISO 13485 Registered Company

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Tetraflex HD

STERILE STERILIZE Rx only

CE 2797

UDI
Tetraflex HD: 08443690TETRAFLEXHD86

PI32 Rev 11
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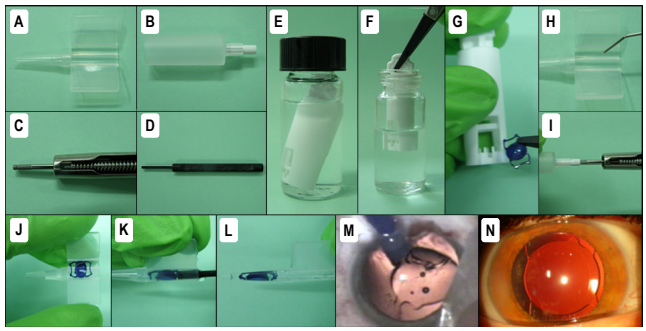
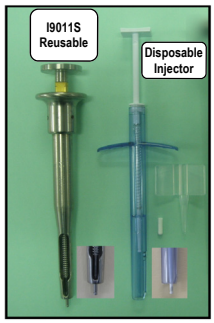


O	Labeled Power	Increments (D)	Claim Tolerances (D)
Tetraflex HD™	+5.0 to +14.5	0.5	±0.25
	+15.0 to +25.0	0.25	±0.11
	+25.5 to +30.0	0.5	±0.25
	+31.0 to +36.0	1.0	±0.5



I9011S Reusable Injector
LC16
Cart45S
+5.0D to +26.0D

LC24
+5.0D to +36.0D

Disposable Injector
LC16I
+5.0D to +26.0D

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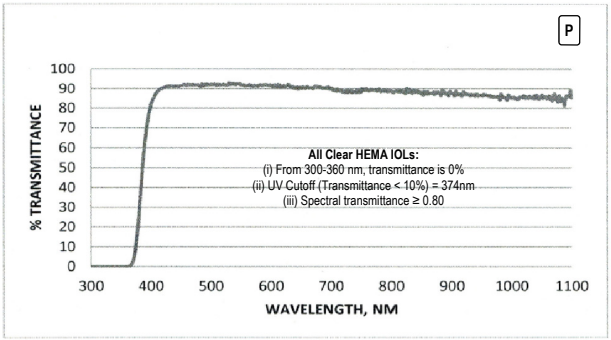

INSTRUCTIONS FOR USE

IMPORTANT NOTICE
It is highly recommended that the surgeon adhere to the recommendations, contraindications and warnings outlined in these instructions.

DEVICE DESCRIPTION
The Lenstec Tetraflex™ HD Accommodating Posterior Chamber Intraocular Lens is a single piece intraocular lens with 'Closed' loop haptics. The Lenstec Tetraflex™ HD intraocular lens is manufactured from a medical grade co-polymer of Hydrophilic Acrylic, with a polymerisable UV blocker.

INTENDED USE
The Tetraflex™ HD Accommodating Posterior Chamber Intraocular Lens (IOL) is indicated for treatment of aphakia with or without presbyopia. Patients meeting all of the following criteria should be considered suitable for implantation:

- 18 years or older
- Male or Female
- Any race
- Able to provide written informed consent

The lenses are indicated for primary implantation when a cataractous lens has been removed by phacoemulsification with circular tear capsulotomy and the posterior capsule intact.

CONTRAINDICATIONS
Outside of general contraindications for ocular surgery, the following specific contraindications apply:
Uncontrolled glaucoma, microphthalmia, chronic severe uveitis, retinal tear/detachment, corneal decompensation, diabetic retinopathy, iris atrophy, perioperative complications, potential foreseeable postoperative complications and other conditions which an ophthalmic surgeon might identify based on their experience.

CLINICAL BENEFITS
The primary benefits for clinical management and patient health include the treatment of:

- Aphakia
- Cataract
- Myopia
- Hyperopia

The duration of the treatment effect is anticipated to be permanent.

PERFORMANCE CHARACTERISTICS
The intended benefit of the Tetraflex™ HD Accommodating Posterior Chamber IOL is to provide enhanced distance and near vision with an increased independence from corrective lens wear.

RISKS
The potential risks of implanting the Lenstec Tetraflex™ HD Accommodating Posterior Chamber IOL is as follows:
Endophthalmitis, Toxic anterior segment syndrome (TASS), Anterior capsule fibrosis, Anterior capsule opacification, Posterior capsule opacification, Anterior corneal spherical aberration, Corneal astigmatism, Uveitis glaucoma hyphaema syndrome, Iritis, Pupillary capture, Cystoid macular edema, Corneal stromal edema, Posterior capsular contraction & lens deformation, Capsular bag damage, IOL decentration/dislocation, Elevated IOP, Concomitant surgery, Implant material clouding

Individuals in the following health categories may be at a higher risk of experiencing secondary IOL calcification (surface deposits on the lens):

- Diabetes
  - ♦ Associated:
    - ∗ Retinal detachment
    - ∗ Vitreous detachment
    - ∗ Vitrectomy
    - ∗ Diabetic retinopathy
    - ∗ Diabetic maculopathy
- Glaucoma
- Underwent DMEK or DSEK (multiple procedures further increase the risk)
- Hypertension
- High cholesterol

WARNINGS

- Some patients may still require glasses to perform certain tasks.
- There is no clinical data to support placing this lens in the ciliary sulcus.
- The effect of vitrectomy on accommodation is unknown.
- Other studies have shown that YAG-laser posterior capsulotomies should be delayed until at least 12 weeks after implant surgery. Any posterior capsulotomy opening should be limited to no more than 4 mm. Consistent with other IOLs; there is an increased risk of lens dislocation and/or secondary surgical reintervention with early or large YAG capsulotomies.
- The Tetraflex™ HD intraocular lens should not be implanted if the capsular bag is not intact or if there is any zonular rupture/dehiscence.
- Mechanical fatigue testing has been evaluated in a laboratory setting and the Tetraflex™ HD intraocular lens showed no degradation or damage after 1 million compression cycles. However, long-term stability in the human eye has not been established. Therefore, surgeons should continue to monitor implant patients postoperatively on a regular basis.
- The effectiveness of ultraviolet light absorbing lenses in reducing the incidence of retinal disorders has not been established. As a precaution, patients should be informed that they should wear sunglasses with UV protection when in sunlight.
- The rate of cystoid macular edema may increase with extracapsular bag placement of the haptics.
- The haptics of the Tetraflex™ HD intraocular lens are very pliable. Even when asymmetrical forces are applied to the lens, such as might occur when a haptic is twisted or misplaced, the optic may appear well centered, masking a potential problem. A need to reposition the Tetraflex™ HD intraocular lens haptics post-operatively may be a result of improper placement of the haptics within the capsular bag at the time of surgery. Signs of misplaced haptics include posterior displacement of the optic or lens tilt.
- Re-use of the IOL is strictly prohibited, as it raises serious safety and efficacy concerns.
  - Lenstec does not provide cleaning/sterilization instructions. An improperly cleaned and/or sterilized IOL can cause significant damage to a patient's vision, due in part to cross contamination induced infection.
  - Once removed from its original packaging, the IOL can lose traceability. In the event an IOL is re-used, it is unlikely the user will know the correct expiry date, serial number or dioptric power.
  - Lenstec cannot guarantee stability or proper function of either haptic or optic portions in the event that an IOL is re-used. Failure of either of these components can render the IOL ineffective.

PRECAUTIONS

- Do not autoclave or attempt to re-sterilize the lens. Lenses requiring re-sterilization should be returned to Lenstec Inc.
- Do not implant this lens in the anterior chamber.
- Do not use the device if sterile packaging has been damaged or if there are traces of leakage on the bottle or pouch.
- Do not soak the intraocular lens with any solution other than a sterile balanced salt solution or balanced sterile saline solution.
- Once packaging has been opened the intraocular lens must be used immediately. The hydrophilic nature of the lens can cause the lens to absorb substances with which it comes into contact, such as disinfectants, medicines, blood cells, etc. This may cause a "Toxic Lens Syndrome". Rinse the lens carefully once removed from the glass vial.
- The lens must be implanted in the capsular bag.
- Do not use the intraocular lens after the expiration date shown on the outside package label. After this date, Lenstec cannot guarantee that the performance of the IOL remains unchanged.
- Handle the intraocular lens carefully. Rough handling or excessive handling may damage the lens.
- A high level of surgical skill is required for intraocular lens implantation. A surgeon should have observed and/or assisted in numerous surgical implantations and successfully completed one or more courses on intraocular lenses prior to attempting to implant lenses.
- Prior to implant, the surgeon should examine the intraocular lens to assure the correct haptic angle orientation.
- The lens must be implanted within two (2) minutes of removal from the saline solution to prevent dehydration and possible damage to the haptics.
- The surgeon must be aware of the risk of opacification of the intraocular lens, which may necessitate lens removal. NOTE: Although the Lenstec hydrophilic intraocular lens has no history of material-related opacification, there is a history of lens opacification with lenses from other manufacturers. The material used by Lenstec, unlike the materials used by other manufacturers has not had any reported 'Adverse Events' due to material discoloration, opacification and/or other material related deficiencies, which have caused post-operative patient problems. Ophthalmic surgeons should keep in mind that there have been cases of reported opacification of hydrophilic IOLs. Most, if not all, of these type of cases required explantation.
- Medical facilities utilizing this IOL, and its accessories (if any), must ensure proper disposal as medical waste.

DIRECTIONS FOR USE
The Lenstec Inc. Tetraflex™ HD intraocular lens is autoclave sterilized in a lens bottle contained within a sealed Tyvek sterilizable peel pouch. The contents of the pouch/bottle are sterile unless the package is damaged or opened. Perform standard phacoemulsification technique. Ensure capsulorhexis is up to 5.5 mm in diameter. Prior to implanting, examine the lens package for IOL, power, and expiration date. The lens box contains peelable labels, which display the lens diopter, serial number, model name and model number. These labels are designed to be affixed to the patient's hospital chart and the physician's chart. One of these labels should be affixed to the patient's identification card contained in the lens box and given to the patient as a permanent record of their implant.
NOTE: Only folders/injectors validated for use with the Tetraflex™ HD intraocular lens should be used.

DIRECTIONS FOR FOLDING THE LENS
INJECTION SYSTEM COMPONENTS (Note colours may vary. Refer to diagrams):
Cartridge (A), Applicator (B), Injector (C), Lens Loader II (D)

SURGICAL INSTRUCTIONS (Refer to diagrams):

1. Prepare an injector cartridge (A) with viscoelastic by opening the cartridge flaps and injecting viscoelastic down each side of the chamber and across the ridge between the channels (E).
2. Take the injector (C), making sure that the plunger tip is exposed, and use the applicator (B) to fix the silicone tip onto the plunger tip (F) and then retract the plunger as far as it will go.
3. Remove the lens bottle (G) from the peelable Tyvek pouch. Firmly hold the bottle in one hand and unscrew the cap. Remove the stopper and then remove the delivery system with forceps (H). Exercise caution when removing the delivery system, as the lens can be easily damaged. Inspect lens for debris and damage. Hold the delivery system firmly in one hand and grasp the plunger with the other hand to position the device for folding the lens. Retract the plunger to release the holding pins from the lens (I). Using forceps, carefully remove the lens from the delivery system, being careful to grasp the lens by the optic (not the haptics). Place the lens on the cartridge and ensure that the lens is orientated correctly as shown in diagram (J).
4. Using a partially open pair of sterile, angled forceps, gently compress the lens (including both haptics and the full optic) into the chamber of the cartridge below the level of the flaps.
5. Slowly close the cartridge, keeping gentle pressure on the optic with the forceps, and making sure the optic and haptics are not pinched in the flaps of the cartridge as it closes. Visually inspect the closed cartridge to ensure that the lens is not trapped between the flaps. Introduce the plunger end of the Lens Loader into the back of the closed cartridge chamber (D, K), and slowly advance the lens from the chamber to the barrel (feel for any resistance which could indicate the lens is trapped between the flaps). Ensure that the Lens Loader is advanced to its farthest depth, so that the lens is in the tip (nosecone). The lens should move freely. If it does not, one (or both) of the haptics or optic is pinched by the wings of the cartridge. If the lens does not move freely, please open the cartridge and repeat this step. If the lens moves freely, the cartridge is ready to load in the injector. NOTE: FAILURE TO ENSURE THE LENS HAPTIC OR OPTIC IS PROPERLY PLACED IN THE CARTRIDGE CAN LEAD TO DAMAGE DURING INJECTION/IMPLANTATION.
6. Place the cartridge into the housing (L) of the injector and push it in as far as it will go. Depress the injector plunger so that the silicone tip fits into the back of the cartridge chamber and advance it forward until you can just see the tip in the barrel.
7. Carefully introduce the loaded injector tip into the anterior chamber with the bevel facing down to avoid touching the endothelium, until the opening of the cartridge is beyond the distal pupil margin. Gently inject the lens (M) into the anterior chamber. Rotate the injector counterclockwise if necessary to ensure the IOL remains orientated correctly as it emerges from the cartridge. Ensure the leading haptic is in the bag. Gently withdraw the cartridge from the eye as the trailing haptic emerges from the cartridge. Reconfirm that the anterior chamber is deep, and if not introduce additional viscoelastic. Using a tapered "pusher" insert the trailing haptic if protruding from the section and let it drop into the bag.
8. Immediately after lens insertion, visually confirm correct placement of the four lens footplates (N) by manipulating the lens once the lens is fully inside the capsule. Irrigate the viscoelastic from the anterior chamber and from behind the lens.
9. Confirm the lens is in the bag and with a positioning hook placed in the distal optic/haptic interface, gently move the optic proximally in order to view the distal haptic positioning. Then after placing the positioning hook in the proximal optic/haptic interface, gently move the optic distally to view the proximal haptic. If haptic is not positioned in the intended plane, adjust the haptic into proper position. The surgeon should visualize that both haptics are fully extended in the fornix of the capsule and that they are completely open with correctly orientated angulation and no snags. Note: the optic must be vaulted anteriorly.
10. Reconfirm that the anterior chamber is deep. NOTE: The haptics on the Tetraflex™ HD are flexible. It is very important to make an intraoperative visual inspection to verify proper placement of the haptics. If the haptics are not fully flat and extended in their intended position as shown (N), reposition by gently manipulating the haptics until fully open using the method described above.

EXPLANTATION
Explantation procedures may vary depending on patient condition and circumstances. The surgeon is therefore advised to use an explantation method which he/she determines will provide the most favourable patient outcomes.

QUALTITATIVE & QUANTITATIVE DATA FOR THE HEMA IOL MODELS
HEMA (clear): Hydroxyethyl methacrylate, 26% water content. The devices have been tested and proven safe in accordance with ISO 10993-3, ISO 10993-5, ISO 10993-6, ISO 10993-7, ISO 10993-10, ISO 10993-11 and ISO 11979-5. Contact Lenstec for further details.

DETAILED DEVICE DESCRIPTION

Construction:	Single Piece	
Material:	26% Water Content HEMA (Hydroxyethyl methacrylate)	
Light transmittance:	Refer to diagram (P)	
Index of refraction:	1.460	
Diopter power range:	Refer to diagram (O)	
Optic design:	Equi-convex with posterior/anterior ratio 1:1; the Tetraflex™ HD has an aspheric optic	
Overall length (diameter):	Tetraflex™ HD:	11.50 mm (5.0 to 27.5 D) 10.75 mm (28.0 to 36.0 D)

EXPIRATION DATE
The expiration date on the lens package is the sterility expiration date. Do not use the IOL after the expiration date.

MECHANISM OF ACTION
The Tetraflex™ HD intraocular lens was designed to move in a backward and forward motion along the axis of the eye in response to contraction of the ciliary muscle. The exact mechanism of action has not been fully elucidated.

LENS POWER CALCULATIONS
The surgeon should determine preoperatively the power of the lens to be implanted by using either immersion or IOL Master biometry and manual keratometry. Lens power calculation methods are described in the following references:

- Holladay JT et al. A Three Part System for Refining Intraocular Lens Power Calculations. J Cataract Surg 14, January 1988.
- Retzlaff JA et al. Development of the SRK/T intraocular lens implant power calculation formula. J Cataract Refract Surg 16, May 1990.
- Hoffer KJ. The Hoffer Q Formula. A comparison of theoretical and regression formulas. J Cataract Refract Surg 19, November 1993.

NOTE: The 'A' Constant and ACD values printed on the outside of the package, are estimates only. It is recommended that the surgeon determine his/her own values based on their individual clinical experience.

RETURNS POLICY
Contact your Lenstec representative regarding the return goods policy. Return the lens with full identification and the reason for the return. Label the return package as a biohazard.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE
Refer to EUDAMED.

PATIENT REGISTRATION AND REPORTING
A Patient Identification Card is included in the package. This is to be completed and given to the patient, together with instructions to keep the card as a permanent record to be shown to any eye practitioner the patient consults in future. Self-adhesive lens identification labels are provided for use on the Patient Identification Card and other clinical records.

Adverse events/complaints that may reasonably be regarded as lens-related and that were not previously expected in nature, severity, or degree of incidence should be reported to the relevant EU Competent Authority of the Member State and Lenstec at Airport Commercial Centre, Pilgrim Road, Christ Church, Barbados: Tel: +1 246-420-6795 • Fax: +1 246-420-6797; Email: feedback@lenstec.com, or contact your Lenstec representative.
The list of identified adverse events is as follows. These identified as well as possible unidentified adverse events must be documented.

Cumulative Adverse Events including, but not limited to:
Endophthalmitis, hyphema, hypopyon, intraocular infection, lens dislocation, cystoid macular oedema, pupillary block, retinal detachment, secondary surgical intervention (excluding retinal detachment and posterior capsulotomy).

Persistent Adverse Events including, but not limited to:
Corneal stromal oedema, iritis, cystoid macular oedema, raised intraocular pressure requiring treatment

BIBLIOGRAPHY (Q)

IMPLANT CARD

- All fields present on the ID card must be completed by the healthcare institution/provider.
- It is the responsibility of the healthcare institution/provider to attach the label sticker with the etched 'LENSTEC' logo to the reverse (unprinted) face of the patient ID card, and provide this to the patient as a record of their implant.

- Apple DJ, Kleinmann G, et al. A new classification of calcification of intraocular lenses. Ophthalmology. Jan 2008, Volume 115, Issue 1, Pages 73-79
- Boettner, EA, Wolter JR. Transmission of the ocular media. Invest Ophthal 1962; 1:776-783
- Busacca, A. La physiologie du muscle ciliaire etudiee par la gonioscopie. annales d'oculistique 1955:1–21
- Coleman J. On the hydraulic suspension theory of accommodation. Trans Am Ophth Soc 1986:846-868.
- Colin, J. Clinical results of implanting a silicone haptic-anchor-plate intraocular lens. J Cataract Refract Surg. 1996;2:1286–1290
- Cumming JS et al. Clinical evaluation of the Model AT-45 silicone accommodating intraocular lens. Ophthalmology 2001;108:2005-2010
- Cumming JS, Ritter J. The measurement of vitreous cavity length and its comparison pre- and postoperatively. Eur J Implant Ref Surg 1994;6:261–272
- Fisher R. The ciliary body in accommodation. Tran Ophthalmol Soc UK 1986;105:208-219
- Girard LJ et al. Complications of the simcoe flexible loop phacoprosthesis in the anterior chamber. Ophthalmic Surg 14(4) 1983;332-5
- Glasser A, Kaufman PL. The mechanism of accommodation in primates. Ophthalmol 1999:106: 863-872
- Kammann J. Vitreous-stabilizing, single-piece, mini-loop, plate haptic silicone intraocular lens. J Cataract Refract Surg 1998;24:98–106
- Thornton S. Accommodation in pseudophakia. Color Atlas of Lens Implantation. 1991;159–162