SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

The SSCP is available in the European database on medical devices (EUDAMED) where it is linked to the BASIC UDI. The EUDAMED website can be accessed at https://ec.europa.eu/tools/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.

BIBLIOGRAPHY (O)

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.

http://www.lenstec.com
ISO 13485 Registered Company

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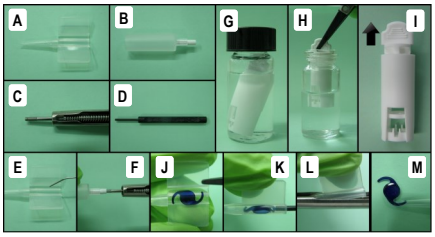
Softec HEMA



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BASIC UDI

Softec I: 08443690SOFTECIWL
Softec HD: 08443690SOFTECHD8G

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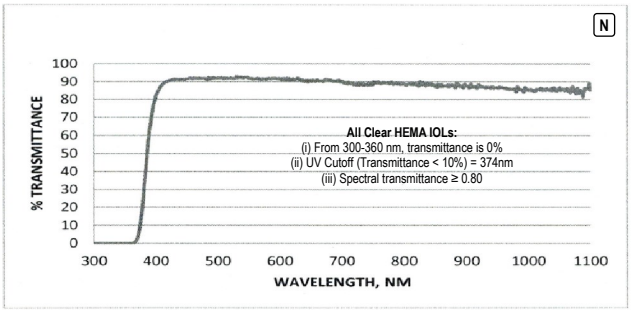

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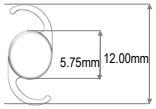
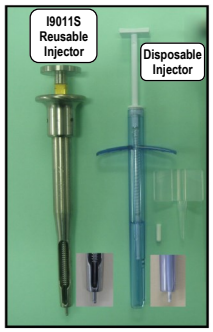
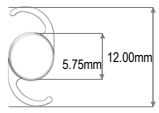
1 Holladay, J. Quality of Vision: essential optics for the cataract and refractive surgeon. Pgs 27-35
2 Pandey SK, Apple DJ, et al. Posterior Capsule Opacification: A Review of the Aetiopathogenesis, Experimental and Clinical Studies and Factors for Prevention. Indian J Ophthalmol 2004;52:99-112
3 Apple DJ, Kleinmann G, et al. A new classification of calcification of intraocular lenses. Ophthalmology. Jan 2008, Volume 115, Issue 1, Pages 73-79

MODEL	POWERS (D)	TOLERANCES (D)	INCREMENT (D)	ACCESSORIES
 SOFTEC I™	-5.0 to +10.0 +10.5 to +30.0 +31.0 to +36.0	±0.25 ±0.25 ±0.5	1.0 0.5 1.0	**I9011S Reusable Injector** LC16, Cart45S -5.0D to +26.0D LC24 -5.0D to +36.0D **Disposable Injector** LC16I -5.0D to +26.0D 
 SOFTEC HD™	+5.0 to +10.0 +10.5 to +14.5 +15.0 to +25.0 +25.5 to +30.0 +31.0 to +36.0	±0.25 ±0.25 ±0.11 ±0.25 ±0.5	1.0 0.5 0.25 0.5 1.0	**I9011S Reusable Injector** LC16, Cart45S +5.0D to +26.0D LC24 +5.0D to +36.0D **Disposable Injector** LC16I +5.0D to +26.0D

INSTRUCTIONS FOR USE - HEMA MODELS

(NOTE GRAPHICS SHOW A BLUE SINGLE-PIECE LENS FOR DEMONSTRATION PURPOSES ONLY)

IMPORTANT NOTICE

This product is intended for use by a qualified ophthalmic surgeon in a sterile medical setting. It is highly recommended that the surgeon adheres to the contraindications and warnings outlined in these instructions.

DEVICE DESCRIPTION

The HEMA intraocular lenses manufactured by Lenstec are optical implants for the replacement of the human lens in the visual correction of aphakia. Lenstec HEMA lenses are manufactured from a medical grade co-polymer of hydrophilic acrylic, with a polymerisable UV blocker. Softec I™ intraocular lenses are manufactured with spherical optics. Softec HD™ intraocular lenses are manufactured with bi-aspheric optics[1]. The Lenstec HEMA series of IOLs are designed with square edges[2].

INTENDED USE

The Lenstec HEMA series of posterior chamber intraocular lenses are ultraviolet absorbing optical implants intended for the replacement of the human crystalline lens following phacoemulsification cataract removal (Aphakia). The lenses are single-use only and indicated for capsular bag placement only.

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.

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 anticipated effects on patient quality of life are prevention of loss of sight and improved visual acuity.

RISKS

The potential risks of implanting the Lenstec Softec Series IOLs are as follows:

Posterior capsule opacification, Cystoid macular edema, Elevated IOP, Iritis, Dysphotopsia (includes glare, halos, ghosting, temporal shadows), IOL decentration/tilt/dislocation, Endophthalmitis, Capsular bag damage, Toxic anterior segment syndrome (TASS), Crystalline lens dislocation, Implant material clouding, Anterior capsule fibrosis, Concomitant surgery, Iris capture

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

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.

WARNINGS

The implanting ophthalmic surgeon shall consider the following warnings, and identify a risk/benefit ratio prior to surgery:

1. Failure to follow the implantation instructions supplied with this lens could lead to mishandling and subsequent IOL damage prior to or during implantation.
2. There is no clinical data to support placing this lens in the ciliary sulcus.
3. Any posterior capsulotomy opening should be limited to approximately 4 mm. Consistent with other IOLs, there is an increased risk of lens dislocation and/or secondary surgical re-intervention with early or large YAG capsulotomies.
4. The Lenstec HEMA series of intraocular lenses should not be implanted if the capsular bag is not intact or if there is significant zonular rupture/dehiscence.
5. 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.
6. The rate of cystoid macular edema may increase with extracapsular bag placement of the haptics.
7. Patients with any of the following could be at increased risk for complication(s) following implantation of any of the Lenstec HEMA series of IOLs: previous ocular surgery, those meeting any of the listed factors in the 'Contraindications' section of this document, non-age related cataract, vitreous loss, iris atrophy, severe aniseikonia, ocular hemorrhage, macular degeneration or suspected microbial infection.
8. Patients who present complications at the time of cataract extraction could be at increased risk for complication(s) following implantation of any of the Lenstec HEMA series of IOLs. This may include, but is not limited to: persistent bleeding, significant iris damage, uncontrolled positive pressure or significant vitreous prolapse or loss.
9. Intraocular lens implantation may deleteriously affect the surgeon's ability to otherwise observe, diagnose or treat posterior segment diseases in the patient.
10. Patients who have a distorted eye due to previous trauma or developmental defects in which appropriate support of the IOL is not possible could be at increased risk for complications following the implantation of the Lenstec Softec Series IOLs .
11. Patients who have recurrent severe anterior or posterior segment inflammation or uveitis could be at increased risk for complications following the implantation of the Lenstec Softec Series IOLs .
12. Any circumstances which could lead to damage to the corneal endothelium during implantation should be avoided.
13. 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 can not 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 resterilize the lens. Lenses requiring resterilization should be returned to Lenstec.
- 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.
- 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 prior to implantation.
- The lens must be implanted within 2 minutes following removal from its saline bath, as dehydration causes the lens material to become brittle.
- 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 or excessive handling may damage the lens.
- 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[3]. 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 types of cases required explantation.
- Patients with compromised blood-aqueous barriers may be more likely to experience lens deposits which may necessitate lens removal
- All cases of lens removal must be reported to Lenstec.
- Medical facilities utilizing this IOL, and its accessories (if any), must ensure proper disposal as medical waste.

CALCULATION OF LENS POWER

It is recommended that the surgeon uses a power calculation method with which they are comfortable. In general, the power of the lens for each patient can be calculated from the keratometry measurements and axial length of the eye according to formulas in published literature. Additional reference to this topic can be found at http://www.doctor-hill.com/iol-master/lens_constants.html

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.

DIRECTIONS FOR USE

Each Lenstec HEMA intraocular lens is autoclave sterilized in a lens bottle contained within a sealed Tyvek peel pouch. The lens is held in a plastic Delivery System in sterile 0.9% saline solution. 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 type, power, and expiration date. The lens can be introduced either by insertion after folding or by injection, using the instructions detailed below.

NOTE: Only use folders/injectors validated for use with the particular model of Lenstec HEMA intraocular lens.

- 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).
- 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.
- 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).
- 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.
- 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.
- 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.
- 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. Visually confirm correct placement of the haptics. Irrigate the viscoelastic from the anterior chamber and from behind the lens. Hydrate the edges of the section to seal it. Sutures are not normally required but if the section appears leaky or the chamber remains shallow a suture may be advisable.

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 10993-10, ISO 10993-11 and ISO 11979-5. Contact Lenstec for further details.

DETAILED DEVICE DESCRIPTION: (Refer to Model Specifications)

Construction:	Single Piece	
Material:	One piece: 26% Water Content HEMA (Hydroxyethyl methacrylate) Chemical Formulation of the Clear HEMA material used to manufacture the Softec Series IOLs: • 2-(4-Benzoyl-3-hydroxyphenoxy) Ethyl Acrylate • Azobisisobutyronitrile (AIBN) Initiator • Ethylene Glycol Dimethacrylate • Hydroxyethyl Methacrylate • Methyl Methacrylate	
Light Transmittance:	Refer to diagram (N)	
Index of refraction:	1.460	
Optic design:	Spherical Models:	Equi-convex with posterior/anterior ratio 1:1. Low power lenses use plano-convex or meniscus optic design as appropriate to achieve required power.
	Aspheric Models:	Equal conic bi-aspheric with posterior/anterior ratio 1:1. Lenstec does not manufacture its Softec HD™ IOLs in plano-convex or meniscus optic designs. NOTE: Each of the Softec HD™ aspheric IOLs are manufactured 'aspheric neutral' and as such impart no aberrations to the optical system.

EXPIRATION DATE

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

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.