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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REF SOFTEC HP1
Instructions For Use

STERILE EO | Rx only

CE 2797

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Softec HP1: 08443690SOFTECHP1NM

PKI30 Rev 6
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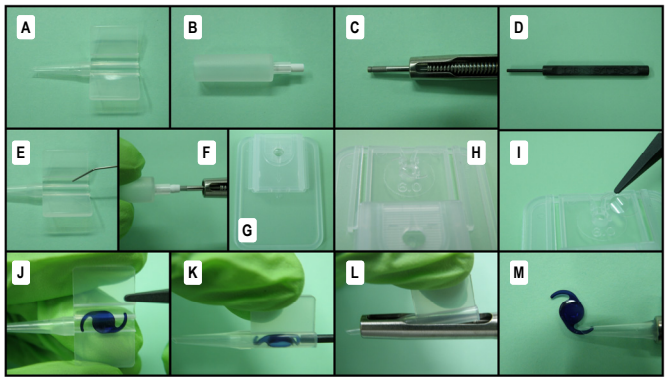

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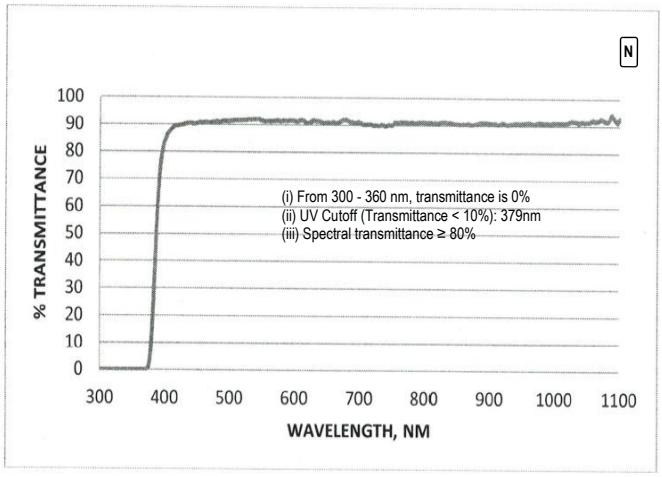

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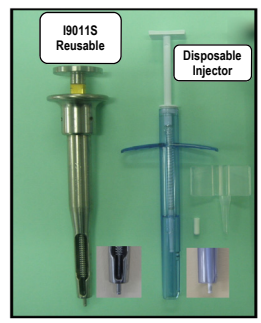
Powers (D)	Tolerances (D)	Increments (D)	Accessories
+10.0 to +14.5	±0.25	0.5	
+15.0 to +25.0	±0.11	0.25	
+25.5 to +30.0	±0.25	0.5	

LC16 Cart45S +10.0 to +30.0D	LC16I +10.0 to +30.0D

INSTRUCTIONS FOR USE - SOFTEC HP1
(NOTE GRAPHICS SHOW A BLUE SINGLE-PIECE LENS FOR DEMONSTRATION PURPOSES ONLY)

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

INTRODUCTION
The Lenstec Hydrophobic Lens (Model: Softec HP1) is an optical implant used in the visual correction of cataracts. It is a single-piece, biconvex, ultraviolet absorbing intraocular lens with step-vaulted, modified C loop haptics. The SOFTEC HP1 consists of a high refractive index soft acrylic material capable of being folded prior to insertion. The material is treated with a UV absorber which absorbs UV rays and protects against light that could lead to ocular damage.

INTENDED USE
The Softec HP1 posterior chamber intraocular lens (IOL) is indicated for treatment of aphakia with or without presbyopia. The lens is indicated for primary implantation when a cataractous lens has been removed by phacoemulsification with circular tear capsulotomy and the posterior capsule intact. Patients meeting all of the following criteria can be considered suitable for implantation:

- Male or Female
- Any race
- Patient's age at the time of surgery to be 18 years or older
- Able to provide written informed consent

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, potentially foreseeable post-operative 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 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 HP1 IOL are as follows:
Endophthalmitis, Toxic anterior segment syndrome (TASS), Anterior capsule fibrosis, Uveitis glaucoma hyphaema syndrome, Iritis, Iris capture, Cystoid macular edema, Corneal stromal edema, Posterior capsular contraction & lens deformation, Capsular damage, Decentration/tilt (small optic), Elevated IOP, Concomitant surgery

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
As with any surgical procedure, there is potential risk involved. Potential complications accompanying intraocular lens implantation may include, but are not limited to the following:
Lens Dislocation, Vitreous Loss, Corneal Endothelial Damage, Pupillary Block, Non-pigment Precipitates, Secondary Glaucoma, Cystoid Macular Edema, Iris Prolapse, Infection, Vitreous Wick Syndrome, Retinal Detachment, Papillary Membrane.
Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/ benefit ratio:

- Recurrent severe anterior or posterior segment inflammation or uveitis.
- Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment diseases.
- Surgical difficulties at the time of cataract extraction which might increase the potential for complications (e.g. persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss).
- A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
- Circumstances that would result in damage to the endothelium during implantation.
- Suspected microbial infection.
- Children under the age of 2 years are not suitable candidates for intraocular lenses.
- 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.
- The effectiveness of this ultraviolet absorbing lens in reducing the incidence of retinal disorders has not been established.
- Patients with ocular pathology may not achieve the visual acuity and/or have increased complications compared to patients without such pathology. Physicians should explore the use of alternative methods of aphakia correction in these patients and should consider lens implantation only if alternative treatments are deemed unsatisfactory to meet the needs of the patient.
- Secondary glaucoma has been reported occasionally in patients with preexisting glaucoma who received lens implants. The intraocular pressure of implant patients with glaucoma should be carefully monitored postoperatively.
- Hyphema, secondary glaucoma, pupillary block, cyclitic membrane formation and vitritis have been reported at increased rates in patients who have surgical complications associated with cataract extraction procedure.
- Patients who have operative complications should be monitored postoperatively for the occurrence of these complications.

PRECAUTIONS

- Do not autoclave or attempt to resterilize the lens. Lenses requiring resterilization should be returned to LENSTEC.
- Do not implant this lens in the anterior chamber.
- Do not use the device if sterile packaging has been opened or damaged.
- Do not reuse the lens.
- 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 will remain 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.
- 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.

HOW SUPPLIED/DIRECTIONS FOR USE
The SOFTEC HP1 is ethylene oxide sterilized in a lens tray contained within two (2) sealed Tyvek sterilizable peel pouches. The contents of the pouch are sterile unless the pouch has been opened or damaged.
The lens box contains peelable labels that display the lens serial number, model name and number. These labels are designed to be affixed to the patient's hospital chart, physician's chart and the patient identification card. This card should be given to the patient as a permanent record of their implant.

DIRECTIONS FOR FOLDING AND INSERTING 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 injector cartridge 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, making sure that the plunger tip is exposed, and use the applicator to fix the silicone tip onto the plunger tip and then retract the plunger as far as it will go (F).
3. The lens is held in a plastic lens case (G). Remove the lens case from the peelable Tyvek pouch. Firmly hold the case in one hand and slide downward to expose the lens (H). Inspect the lens for debris and damage. Using a pair of "toothless" forceps, carefully remove the lens from its case, being careful to grasp the lens by the haptics not the optic (I). Place the lens on the cartridge and ensure that it is orientated correctly (J).
4. Use the pair of "toothless" forceps to 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 optics 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 II into the back of the closed cartridge chamber (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).
6. Place the cartridge into the housing of the injector and push it in as far as it will go (L). 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 (M).
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 into the anterior chamber. Rotate the injector counterclockwise if necessary to ensure the IOL remains orientated correctly as it emerges from the cartridge. 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 it is 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.

QUALITATIVE & QUANTITATIVE DATA FOR THE SOFTEC HP1 IOL
Hydrophobic: Copolymer of phenyl ethyl acrylate (PEA) and phenyl ethyl methacrylate (PEMA) which is cross-linked with butanediol diacrylate (BDDA). The devices have been tested and proven safe in accordance with ISO 10993-3, ISO 10993-5, ISO 10993-7, ISO 10993-10 and ISO 11979-5. Contact Lenstec for further details.

DETAILED DEVICE DESCRIPTION

Construction:	Single Piece
Material:	Hydrophobic Acrylic
Light transmittance:	Refer to diagram (N)
Index of refraction:	1.555
Diopter power range:	Refer to diagram (O)
Optic design:	Bi-convex
Overall length (diameter):	13.0 mm

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.

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.

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, BB17092, Barbados: Tel: +1 246-420-6795 • Fax: +1 246-420-6797; Email: feedback@lenstec.com or contact your Lenstec representative.

BIBLIOGRAPHY (P)