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LENSTEC™
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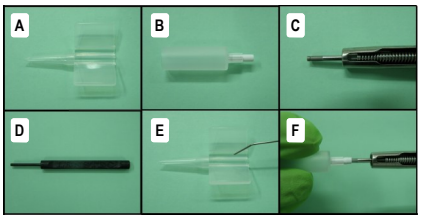

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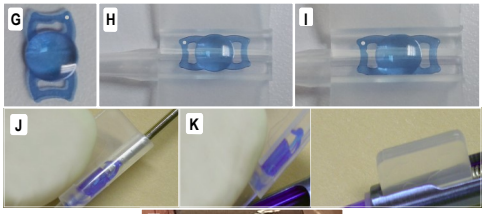
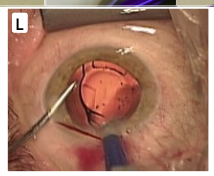
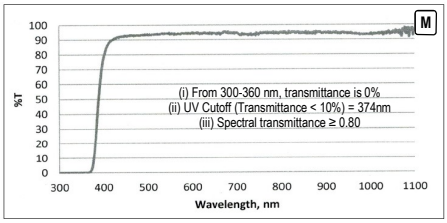
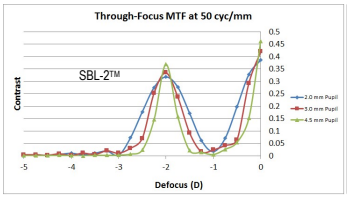
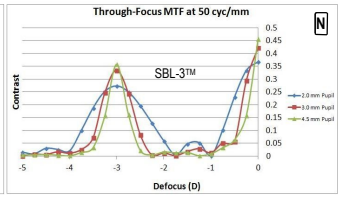
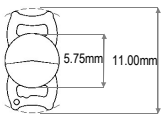
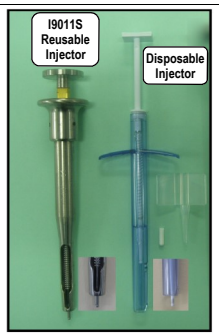










MODEL	POWERS (D)	TOLERANCES (D)	INCREMENT (D)	ACCESSORIES O
 **SBL-2™ / SBL-3™**	+10.0 to +14.5 +15.0 to +25.0 +25.5 to +36.0	±0.25 ±0.11 ±0.25	0.5 0.25 0.5	 **I9011S Reusable Injector** LC16, Cart45S +10.0D to 26.0D LC24 +10.0D to 36.0D **Disposable Injector** LC16I, Cart45SI +10.0D to 26.0D LC24I +10.0D to 36.0D

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 SBL IOL Series are single piece, bi-aspheric[1] intraocular lenses (IOLs) with 'Closed' loop haptics. The Lenstec SBL-2™ and SBL-3™ are manufactured from a medical grade co-polymer of hydrophilic acrylic, with a polymerisable UV blocker. The hydrophilic nature of the Lenstec IOL material reduces problems associated with silicone oil adhesion and silicone oil induced opacification[2-4]. The Lenstec SBL-2™ and SBL-3™ are designed with square optic edges[5].

INTENDED USE

The Lenstec Segmented Bifocal Lens (SBL) series are ultraviolet absorbing optical implant intended for the replacement of the human crystalline lens following phacoemulsification cataract removal (Aphakia) in adults 18 years or older. The lenses are indicated for those persons who require independence from spectacles for near, intermediate and distance vision. The SBL IOLs are single-use only and intended for capsular bag placement only.

CONTRAINDICATIONS

Outside of general contraindications for ocular surgery, the following specific contraindications apply:
Uncontrolled glaucoma, microphthalmia, chronic severe uveitis, retinal 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
- Presbyopia

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

PERFORMANCE CHARACTERISTICS

The intended benefit of the SBL-2™ and SBL-3™ Posterior Chamber IOLs is to provide enhanced distance, intermediate and near vision with increased independence from corrective lens wear.

RISKS

The potential risks of implanting the Lenstec SBL-2™ and SBL-3™ Posterior Chamber IOLs 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, Implant material clouding

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 SBL-2™ and SBL-3™ 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 the SBL-2™ or SBL-3™: 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 the SBL-2™ or SBL-3™. This may include, but is not limited to: persistent bleeding, significant iris damage, uncontrolled positive pressure or significant vitreous prolapse or loss.
9. Whether intraocular lens implantation would deleteriously affect the surgeon's ability to otherwise observe, diagnose or treat posterior segment diseases in the patient.
10. Whether patients who have a distorted eye due to previous trauma or developmental defects in which appropriate support of the IOL is not possible should have the SBL-2™ or SBL-3™ implanted.
11. Whether patients who have recurrent severe anterior or posterior segment inflammation or uveitis should have the Lenstec SBL-2™ or SBL-3™ implanted.
12. Any circumstances which could lead to damage to the corneal endothelium during implantation should be avoided.
13. Children under the age of 2 are not suitable candidates for intraocular lenses.
14. 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

- The IOL must be stored in dry conditions.
- 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.
- 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[6]. 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.

DIRECTIONS FOR USE

Each Lenstec SBL-2™ and SBL-3™ are autoclave sterilized in a lens bottle contained within a sealed Tyvek sterilizable peel pouch. The lens is held in a glass vial containing sterile 0.9% saline solution. The contents of the pouch/vial are sterile unless the package is damaged or opened. Perform standard phacoemulsification technique. Ensure capsulorhexis is between 5.0 and 5.5 mm in diameter. Prior to implanting, examine the lens package for IOL, power, and expiration date. The lens can be introduced either by insertion after folding or by injection, using the instructions detailed below.

NOTE: Only folders/injectors validated for use with the Lenstec SBL-2™ and SBL-3™ should be used.

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 (A) by opening the cartridge flaps and injecting saline or 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 affix the silicone tip onto the plunger tip and then retract the plunger as far as it will go (F).
3. Remove the lens bottle from the peelable Tyvek pouch. Firmly hold the vial in one hand and unscrew the cap. Remove the stopper and then carefully remove the lens holder from the vial. Inspect the lens for debris and damage. Retract the plunger to release the holding pins from the lens. Using a toothless forceps, grasp the lens by the optic and place the lens on the cartridge as shown in figure (H). The SBL-2™ and SBL-3™ have an indentation and hole into one of the haptics, which signifies the side closest to the 'add' portion (anterior surface). When this indentation and hole are on the top right (G), the 'add' portion is being implanted as intended.
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 (I).
5. Slowly close the cartridge, keeping gentle pressure on the optic with the forceps, and ensure that 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 (J), 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 II 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, open the cartridge and repeat steps 4 and 5. 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 of the injector and push it in as far as it will go (K). 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, assisting with delivery into the capsular bag, until the tip of the cartridge is near the mid-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. Ensure the leading haptic is in the bag. Gently withdraw the cartridge from the eye as the trailing haptic emerges from the cartridge (L). Reconfirm that the anterior chamber is deep, and if not, introduce additional saline or 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 footplates by manipulating the lens once it is fully inside the capsule. Irrigate the saline or 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.
10. 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.
    NOTE: The haptics of the SBL lenses are flexible. It is very important to perform a visual inspection during the surgery to verify their position. If the haptics are not completely flat and extended in the expected position, reposition them by manipulating carefully following the method described above, until they are fully open.

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 (M)
Index of refraction:	1.460
MTF:	Refer to diagram (N)
Diopter power range:	Refer to diagram (O)
Optic design:	Bi-aspheric surfaces: Equal conic bi-aspheric with posterior/anterior ratio 1:1
Optic size:	5.75 mm
Overall length (diameter):	11.00 mm

EXPIRATION DATE

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

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.

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.

Persistent Adverse Events including, but not limited to:

Corneal stromal oedema, iritis, cystoid macular oedema, raised intraocular pressure requiring treatment