Visual Acuity

Table 2 summarizes the postoperative visual acuity outcomes at the 1 year visit (330-420 days) for the Softec HD™ PCIOL Study Group who did *not* have a preoperative ocular pathology or postoperative macular degeneration ("Best Case" Cohort).

Table 3 for "All Eyes" Cohort in the Softec HD™ PCIOL Study Group.

Note: 30 study subjects had YAG capsulotomies 12 months or earlier; 17 six months or less, YAG capsulotomy is anticipated to produce an improved BCVA outcome versus a pre-YAG outcome.

Table 2 - BEST CORRECTED DISTANCE VISUAL ACUITY at 1 Year (Form 5)
Best Case Analysis - Stratified by Age (Years)

	< 60	60 to < 70	70 to < 80	≥ 80
20/10 or better	0 / 32 (0%)	0 / 118 (0%)	0 / 135 (0%)	0 / 42 (0%)
20/16 or better	5 / 32 (15.6%)	12 / 118 (10.2%)	4 / 135 (3%)	2 / 42 (4.8%)
20/20 or better	24 / 32 (75%)	79 / 118 (66.9%)	68 / 135 (50.4%)	21 / 42 (50%)
20/25 or better	30 / 32 (93.8%)	100 / 118 (84.7%)	108 / 135 (80%)	31 / 42 (73.8%)
20/30 or better	32 / 32 (100%)	115 / 118 (97.5%)	127 / 135 (94.1%)	39 / 42 (92.9%)
20/40 or better	32 / 32 (100%)	117 / 118 (99.2%)	132 / 135 (97.8%)	42 / 42 (100%)
20/50 or better	32 / 32 (100%)	117 / 118 (99.2%)	133 / 135 (98.5%)	42 / 42 (100%)
20/60 or better	32 / 32 (100%)	117 / 118 (99.2%)	134 / 135 (99.3%)	42 / 42 (100%)
20/80 or better	32 / 32 (100%)	117 / 118 (99.2%)	134 / 135 (99.3%)	42 / 42 (100%)
20/100 or better	32 / 32 (100%)	117 / 118 (99.2%)	135 / 135 (100%)	42 / 42 (100%)
20/200 or better	32 / 32 (100%)	117 / 118 (99.2%)	135 / 135 (100%)	42 / 42 (100%)
Worse than 20/200	0 / 32 (0%)	1 / 118 (0.8%)	0 / 135 (0%)	0 / 42 (0%)
Not Reported	0	0	0	0
Total	32	118	135	42

Table 3 - BEST CORRECTED DISTANCE VISUAL ACUITY at 1 Year (Form 5)
Stratified by Age (Years)

	< 60	60 to < 70	70 to < 80	≥ 80
20/10 or better	0 / 36 (0%)	0 / 128 (0%)	0 / 155 (0%)	0 / 47 (0%)
20/16 or better	6 / 36 (16.7%)	12 / 128 (9.4%)	4 / 155 (2.6%)	2 / 47 (4.3%)
20/20 or better	26 / 36 (72.2%)	85 / 128 (66.4%)	78 / 155 (50.3%)	22 / 47 (46.8%)
20/25 or better	33 / 36 (91.7%)	110 / 128 (85.9%)	121 / 155 (78.1%)	33 / 47 (70.2%)
20/30 or better	36 / 36 (100%)	125 / 128 (97.7%)	143 / 155 (92.3%)	41 / 47 (87.2%)
20/40 or better	36 / 36 (100%)	127 / 128 (99.2%)	152 / 155 (98.1%)	45 / 47 (95.7%)
20/50 or better	36 / 36 (100%)	127 / 128 (99.2%)	153 / 155 (98.7%)	47 / 47 (100%)
20/60 or better	36 / 36 (100%)	127 / 128 (99.2%)	154 / 155 (99.4%)	47 / 47 (100%)
20/80 or better	36 / 36 (100%)	127 / 128 (99.2%)	154 / 155 (99.4%)	47 / 47 (100%)
20/100 or better	36 / 36 (100%)	127 / 128 (99.2%)	155 / 155 (100%)	47 / 47 (100%)
20/200 or better	36 / 36 (100%)	127 / 128 (99.2%)	155 / 155 (100%)	47 / 47 (100%)
Worse than 20/200	0 / 36 (0%)	1 / 128 (0.8%)	0 / 155 (0%)	0 / 47 (0%)
Not Reported	0	0	0	0
Total	36	128	155	47

ADVERSE EVENTS

Cumulative adverse events consist of all adverse events (AEs) that occurred at any point in postoperative follow-up during the first year after Softec HD™ PCIOL surgery.

Table 4 presents all cumulative adverse events through the 1 year visit (330-420 days).; **Table 5**, all persistent adverse events at 6 months (120-180 days) and 1 year visits. The overall incidence of cumulative and persistent IOL Grid adverse events in the Softec HD™ PCIOL Study Group (n = 366) was 2.2% (CME 0.8%, secondary surgical interventions 0.8%, iritis 0.3% and raised IOP requiring treatment 0.3%).

Table 4 - Patient Population
Softec HD™ PCIOL
n = 366 eyes in 366 study subjects with 1 year follow-up

Cumulative Adverse Event through 1 year	Softec HD™ PCIOL Incidence	FDA PCIOL Grid n = 300
Cystoid Macular Edema	0.8%*	6.0%
Hypopyon	0%	1.8%
Endophthalmitis	0%	1.0%
Dislocated Lens (from Posterior Chamber)	0%	1.0%
Pupillary Block	0%	1.0%
Retinal Detachment	0%	1.8%
Secondary Surgical Intervention**	0.8%	2.6%

Table 5

Persistent Adverse Event at 6 mths and/or 1 year	Softec HD™ PCIOL Incidence	FDA PCIOL Grid n = 300
Corneal Stromal Edema	0%	1.8%
Cystoid Macular Edema	0.8%*	2.2%
Iritis	0.3%	1.8%
Raised IOP Requiring Treatment	0.3%	1.8%

**Identical cases reported in persistent & cumulative CME rows*
***All unrelated to Softec HD™ PCIOL*

Non-IOL Grid AEs included 9 haptic break AEs at the time of the initial surgery and 1 sub-retinal hemorrhage.

EXPIRATION DATE

The expiration date on the lens package is the sterility expiration date. Do not use the IOL after the expiration date. The expiration date on the PLI Tips packaging is the sterility expiration date. Do not use the PLI Tip after the expiration date.

RETURNS POLICY

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

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 patent 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 Lenstec (Barbados) Inc., Airport Commercial, 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

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3 Hayashi H, Hayashi K., et al. Quantitative comparison of posterior capsule opacification after polymethylmethacrylate, silicone and soft acrylic intraocular lens implantation. Arch. Ophthalmol. 1998; 116: 1579-82.
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6 Apple DJ, Kleinmann G, et al. A new classification of calcification of intraocular lenses. Ophthalmology Jan 2008, Volume 115, Issue 1, Pages 73-79.
7 ISO 11979-7 Ophthalmic Implants – Intraocular lenses – Part 7: Clinical Investigations; 2006.

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.

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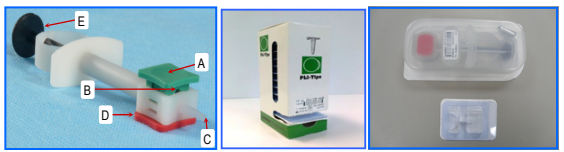
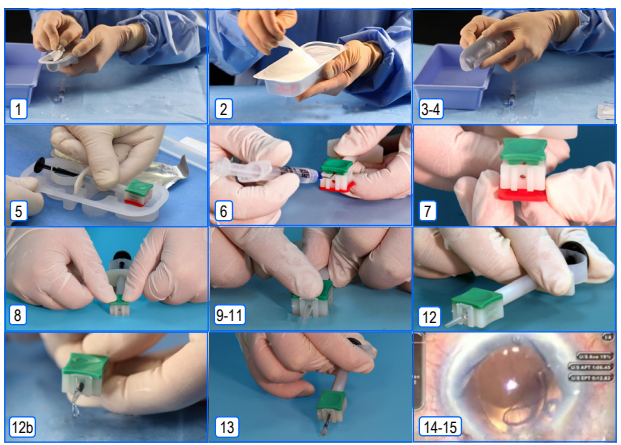
ISO 13485 Registered Company

INSTRUCTIONS FOR USE
SOFTEC POSTERIOR CHAMBER INTRAOCULAR LENS (PCIOL) IN A PRE-LOADED INJECTOR





STERILE

PKI08 Rev 7

INSTRUCTIONS FOR USE
SOFTEC POSTERIOR CHAMBER INTRAOCULAR LENS (PCIOL) IN A PRE-LOADED INJECTOR

IMPORTANT NOTICE

It is highly recommended that the surgeon adheres to the recommendations, precautions, contraindications and warnings outlined in these instructions. Proper procedure is the responsibility of the individual surgeon.

CAUTION: Federal (U.S.) law restricts this device to the sale by or on the order of a physician.

DEVICE DESCRIPTION

The LENSTEC Softec HD™ Posterior Chamber Intraocular Lens (PCIOL) is an ultraviolet absorbing, single-piece "C" loop intraocular lens with a balanced aspheric design (containing symmetrical aspheric anterior and posterior surfaces[1]) intended for the replacement of the human crystalline lens following phacoemulsification cataract removal. In this Pre-Loaded Injector, it is offered in the dioptric power range of +5.0 to +14.5 and +25.5 to +27.0. The Softec HD™ PS Posterior Chamber Intraocular Lens (PCIOL) is an ultraviolet absorbing, single-piece "C" loop intraocular lens with a balanced aspheric design (containing symmetrical aspheric anterior and posterior surfaces[1]) intended for the replacement of the human crystalline lens following phacoemulsification cataract removal. In this Pre-Loaded Injector, it is offered in quarter diopter increments from +15.0 to +25.0. The Softec I™ PCIOL is an ultraviolet absorbing, single-piece "C" loop intraocular lens with a balanced spherical design also intended for the replacement of the human crystalline lens following phacoemulsification cataract removal. In this Pre-Loaded Injector, it is offered in the dioptric power range of +5.0 to +27.0. Each of the Softec series of intraocular lenses are manufactured from a medical grade co-polymer of Hydrophilic Acrylic, with a polymerisable UV blocker. The hydrophilic nature of the lens material (hydrophilic acrylic) reduces the problems associated with silicone oil adhesion and silicone oil induced opacification[2-4]. Each PCIOL has a square edge design[5]. Clinical studies have not been conducted with the Softec HD™ or Softec HD™ PS to assess the effect of the aspheric surface on spherical aberration, visual acuity and contrast sensitivity. The Lenstec PLI Tips are required for placement onto the PLI body prior to surgical use. The PLI Tips are a component that can ONLY be used in conjunction with the supplied PLI Body; they are non-functional in the absence of the PLI body.

INDICATIONS FOR USE

The Preloaded Injector (PLI) is an IOL delivery system which is manufactured with an IOL pre-loaded in its housing, for use in phacoemulsification cataract surgery. In this device, the lens is provided sterile and already fitted in the injection system. The PLI will reduce the time required to prepare and perform cataract surgery, and thus expose the IOL recipient to less risk.

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, potentially 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 reintervention with early or large YAG capsulotomies.
4. The IOLs 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 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 IOLs. This may include, but is not limited to: persistent bleeding, significant iris damage, uncontrolled positive pressure or significant vitreous prolapse or loss.
9. The implanting surgeon shall consider whether patients in who intraocular lens implantation would affect the ability to observe, diagnose or treat posterior segment diseases, should have any of the IOLs implanted.
10. The implanting surgeon shall consider 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 any of the IOLs implanted.
11. The implanting surgeon shall consider whether patients who have recurrent severe anterior or posterior segment inflammation or uveitis, should have any of the IOLs 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. Reuse of the IOL is strictly prohibited, as it raises serious safety and effectiveness concerns.
15. 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.
16. 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.
17. 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.
18. The injector and PLI Tip components are designed for single-use and components of the device are not able to be re-used. Attempted re-use of the injector and the PLI Tip component will result in damage to the IOL which could cause serious harm to the patient.

PRECAUTIONS

- The IOL must be stored in dry conditions between 0°C (32°F) and 45°C (113°F).
- Do not attempt to re-use the lens. Do not autoclave or attempt to re-sterilize the lens. Lenses requiring re-sterilization should be returned to LENSTEC, Inc.
- 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 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 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.
- The lens must be implanted using only injection systems validated for use with the IOLs. These include the Softec IOL Injection System (Lenstec Inc), Viscoject 1.8™ Injector Set, Model# LP604350 (Medicel AG) and the Softip injection system, Model# AS-9300 (ASICO).
- Do not use the intraocular lens after the expiration date shown on the outside package label.
- Handle the intraocular lens carefully. Rough handling 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 a satisfactory history regarding lens 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. The material used by LENSTEC has not had any confirmed reports of 'Adverse Events' due to material discoloration, opacification and/or other material related deficiencies, which have caused postoperative patient problems.
- All cases of lens removal must be reported to LENSTEC, Inc.
- Medical facilities utilizing this IOL must ensure proper disposal as medical waste if not used.

HOW SUPPLIED

The LENSTEC SOFTEC series of posterior chamber intraocular lenses are steam sterilized in a pre-loaded injector, contained within a double thermoform tray system. The contents of the outer tray are sterile unless the package is damaged or open. The injector is supplied with an ethylene oxide sterilized tip, which is separately packaged in a thermoform tray. Additionally, PLI Tips are supplied in a 12pk carton for surgical inventory. The tip is intended for single use only.

INSTRUCTIONS FOR IMPLANTATION: SOFTEC PCIOL

Calculation of Lens Power:

It is recommended that the surgeon uses a power calculation method with which they are most 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 relevant literature. An A Constant of 118.0 and an anterior chamber depth (ACD) of 5.10 should be used for the LENSTEC IOLs if an applanation A Scan unit is used. This needs to be modified for the IOL Master. Depending on the IOL power calculation formula being used by the physician, this value for use with the IOL Master will change slightly. If using the SRK/T IOL power calculation formula, this value of the A Constant should be 118.54. If using the Hoffer Q, Holladay 1, or Holladay 2 the value of the A Constant should be 118.24. Additional reference to this topic can be found at http://www.doctor-hill.com/iol-master/lens_constants.htm.

Pre-Surgical Preparation:

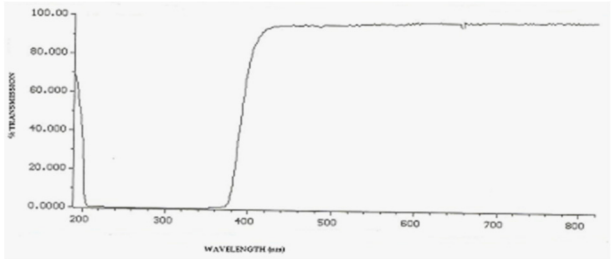
a. Determine the lens power from IOL Refractive Calculation Equation-Holladay or SRK/T.
b. Determine the Expected Post-operative Target Refraction (SE)

SURGICAL TECHNIQUE

1. Peel the top of the smaller container (that which houses the injector tip) back and carefully drop its contents into the sterile field.
2. Open the outer tray of the larger container (that which houses the PLI Body) and carefully drop its inner sterile tray into the sterile field.
3. Carefully peel the foil lid from the sterile tray using the tab for easy opening. NOTE: Contains saline solution.
4. Pour off the saline.
5. Remove the PLI Body from the tray – the green button (A) should be on the top.
6. Inject 0.1 to 0.2 cc of ophthalmic viscosurgical device (viscoelastic) straight, not angled, into the front port of the green button.
7. While holding the PLI with the green button up, pull off the red button from the bottom, straight down.
8. Firmly press the grean button evenly, with both thumbs, until it 'clicks' into position – the lens is now folded.
9. Grasp the tip (C) with the forefinger and thumb with the pointed end of its base facing down.
10. Grasp PLI Body (with the clear button still facing up), and then gently insert the pointed end of the base of the tip into the receptacle (D) at the front of the PLI Body.
11. Press down until the flat end of the tip base prevents further downward movement. There will NOT be a 'click' signifying a final resting place.
12. Slowly push the plunger (E) to advance the folded lens into the tip. Advance the folded lens by pulsing the plunger (alternately pressing then releasing) to ensure that no part of the lens or haptics become entangled. It is imperative that the pulsing take place with the user's thumb being kept directly centered on the plunger. Do not pulse the plunger off angle, as it can cause lens displacement.
13. As the folded lens moves down the tip, slowly advance and pulse the plunger.
14. Place the injector tip inside the incision.
15. Just as the plunger nears the tip, pulse it one last time. The last pulse will ensure no haptic is caught and will provide a controlled injection into the eye. **NOTE: Pull the plunger back completely to ensure that the lens haptic is fully released.**

DETAILED DEVICE DESCRIPTION

- Construction: Single Piece
- Material: 26% Water Content HEMA (Hydroxyethyl methacrylate)
- Index of refraction: 1.460
- Light transmittance: Refer to diagram (I)



The specifications for the LENSTEC SOFTEC Series of Posterior Chamber Intraocular Lenses are as follows:

Optic Size:	5.75 mm
Optic Type:	Equiconvex
Length:	12.00 mm
Angulation:	0 degrees
Construction:	1 Piece
Position Holes:	0 Holes
Optic Material:	HEMA (26% water content)
A-Constant*:	118.0**

*Guidelines for Calculation of Implant Power
**See above section titled 'Calculation of Lens Power'.

The Softec series of Posterior Chamber Intraocular Lenses are manufactured in the following dioptric ranges:

Softec HD™ Power Ranges	Diopter Increments Offered In	Tolerances Applied***	Softec I™ Power Ranges	Diopter Increments Offered In	Tolerance Applied***	Softec HD™ PS Power Ranges	Diopter Increments Offered In	Tolerance Applied***
+5.0 D to +10.0 D	1.0 D	(± 0.25 D)	+5.0 D to +10.0 D	1.0 D	(± 0.25 D)	+15.0 D to +25.0 D	0.25 D	(± 0.11 D)
+10.5 D to +14.5 D	0.5 D	(± 0.25 D)	+10.5 D to +27.0 D	0.5 D	(± 0.25 D)			
+25.5 D to +27.0 D	0.5 D	(± 0.25 D)						

***Internal manufacturing/sorting tolerances

CLINICAL OUTCOMES

The multi-center U.S. Softec HD™ PCIOL Clinical Investigation was conducted at 8 clinical centers with Softec HD™ PCIOL implantations occurring between December 13, 2006 and June 9, 2008. One year postoperative follow-up provides documented evidence of the safety and effectiveness of the Softec HD™ PCIOL for the indications for use stated in this physician labeling.

Patient Population

Three hundred and ninety eyes of 390 study subjects were implanted with the Softec HD™ PCIOL. The Softec HD™ Study Cohort consisted of 227 females and 163 males; 334 were Caucasian, 11 Black, 6 Asian, 4 Mixed and 35 "Other". The mean age for the study cohort was 70.8 years. One year follow-up was collected for 366 eyes of 366 study subjects.

Table 1 - Patient Population - Softec HD™ PCIOL
n = 390 eyes in 390 study subjects

Patient Population		Population Description
Mean Age (years)		70.8 yrs
Patients with Pre-existing Macular Degeneration		3.1%
Other Patients with Pre-existing Conditions		30.5%
Gender	Female	58.2%
	Male	41.8%
Race	Caucasian	85.6%
	Black	2.8%
	Asian	1.5%
	Mixed	1.0%
	Other	9.0%