

MODEL	POWERS (D)	TOLERANCES (D)	INCREMENT (D)	ACCESSORIES
<p>SOFTEC HD™ Click</p>	+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	<p>Click Injection System</p> <p>Injector tip 2.0mm REF # 200-12-203-0020401</p>

LENSTEC (BARBADOS) INC., Airport Commercial Centre, Pilgrim Road, Christ Church BB17092, Barbados
 ☎ +1 (246) 420-6795 📧 lenstecbarbados@lenstec.com

🇸🇰 CMI spol. s.r.o. Trenčianska 47, 821 09 Bratislava, Slovakia
 ☎ +421 (2) 52631441 ☎ +421 (2) 52922882 📧 lenstec@cmi.sk

UK SALES: LENSTEC (BARBADOS) INC., Lenstec House, Unit 8, Mariner Court, Calder Park, Wakefield, WF4 3FL, UK
 ☎ +44 (0) 1924 382 678 ☎ +44 (0) 1924 850 454 📧 lenstecuk@lenstec.com

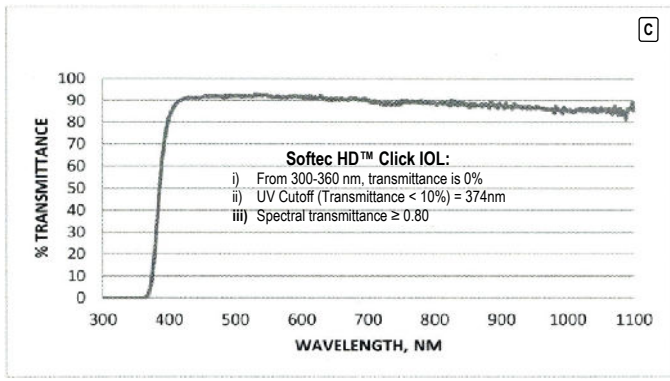
WORLD HEADQUARTERS: LENSTEC, INC., 1765 Commerce Ave N, Saint Petersburg, Florida 33716, U.S.A.
 ☎ +1 (727) 571-2272 ☎ +1 (727) 571-1792 📧 lenstec@lenstec.com

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

SoftecHD™

Click

CE 2797 BASIC UDI PKI33 Rev 5 EN
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NOTE: This package only contains the intraocular lens

STERILE

Sterilized using steam

Do not reuse

Do not re-sterilize

Do not use if damaged

Caution, Consult accompanying documents

R_x only

D

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

1 & 2

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3 & 4

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12 & 13

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1" Click: The IOLMATIC® injector is connected to the lens. The lens is inserted into the eye. The injector is removed from the eye.

2" Click: The Softec HD lens.

Remove activation lock safety feature from the plunger by pressing on the arrow mark.

INSTRUCTIONS FOR USE - SOFTEC HD™ CLICK

IMPORTANT NOTICE

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

DEVICE DESCRIPTION

The Softec HD™ Click intraocular lens manufactured by Lenstec is an optical implant for the replacement of the human lens in the visual correction of aphakia. It is manufactured from a medical grade co-polymer of hydrophilic acrylic, with a polymerisable UV blocker. The lens carries a bi-aspheric optic¹ and is designed with a square edge².

INTENDED USE

The Lenstec Softec HD™ Click 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 HD™ Click IOL are as follows:

Posterior capsule opacification, Cystoid macular edema, Elevated IOP, Iritis, Dysphotopsia (includes glare, halos, ghosting, temporal shadows), IOL concentration/tilt/dislodgement, Endophthalmitis, Capsular bag damage, Toxic anterior segment syndrome (TASS), Crystalline lens dislocation, Implant material clouding, Anterior capsule fibrosis, Concomitant surgery, Pupilary 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 Softec HD™ Click intraocular lens 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 Softec HD™ Click IOL: 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 Softec HD™ Click IOL. 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 Softec HD™ Click.
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 Softec HD™ Click IOL.
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 will remain 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:** The Lenstec hydrophilic intraocular lens has no history of primary material-related opacification, as has been seen with certain lenses from other manufacturers³. The material used by Lenstec, unlike that used by other manufacturers, has not had any reported 'Adverse Events' due to material discoloration, opacification and/or other material related deficiencies, known to have caused post-operative problems. Ophthalmic surgeons should keep in mind that there have also been cases of secondary opacification of hydrophilic IOLs. Many of these 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.

USER REQUIREMENTS

The IOL should be injected in a sterile medical setting at temperatures between 18°C and 22°C

DIRECTIONS FOR USE (A)

Each Softec HD™ Click intraocular lens is autoclave sterilized in a lens bottle contained within a sealed Tyvek peel pouch. The lens is held in a lens holder 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 using the instructions detailed below.

1. Peel open the Tyvek pouch of the lens bottle and drop the bottle in sterile field.
2. Obtain the Click injection system and peel open the lid from its sterile blister tray.
3. Using all precautions to prevent contamination, open the lens bottle and hold it opened in one hand.
4. Take the injector out of the blister tray with the other hand.
5. Insert the tip of the injector in the lens bottle to load the lens on the injector. Push the tip until a click is heard.
6. Check correct loading of the lens holder and that it is secured on the injector.
7. Ensure the lens is at rest in its holder (not tilted, squeezed or bent).
8. Move the sliders as indicated in the picture to compress the haptics.
9. Close the folding flap to fold the lens in the injector. Push the flap until a click is heard.
10. Once the click has been heard, the lens is loaded and ready for injection.
11. Remove the activation lock safety feature from the plunger by pressing on the arrow mark.
12. Depress the plunger and inject within two minutes.
13. When the IOL is loaded and ready to inject, 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 injector tip is beyond the distal pupil margin. Gently inject the lens. Rotate the injector counterclockwise if necessary, to ensure the IOL remains orientated correctly as it emerges from the injector tip. Ensure the leading haptic is in the bag. Gently withdraw the injector tip from the eye as the trailing haptic emerges from the injector tip. 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.

VIDEO

See the Lenstec website, <https://www.lenstec.com/>, for a video on lens loading and implantation.

EXPLANATION

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

QUALITATIVE & QUANTITATIVE DATA FOR THE SOFTEC HD™ CLICK IOL

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 HD™ Click IOL:

- 2-(4-Benzoyl-3-hydroxyphenoxy) Ethyl Acrylate
- Azobisisobutyronitrile (AIBN) Initiator
- Ethylene Glycol Dimethacrylate
- Hydroxyethyl Methacrylate
- Methyl Methacrylate

Light Transmittance: Refer to diagram (C)

Index of refraction: 1.460

Optic design: Aspheric Models: Equal conic bi-aspheric with posterior/anterior ratio 1:1. Lenstec does not manufacture its Softec HD™ Click IOL in plano-convex or meniscus optic designs.
NOTE: The Softec HD™ Click aspheric IOL is manufactured 'aspheric neutral' and, as such, imparts 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.

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 (D)

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.