Instructions for use

CE 2460

BAUSCH + LOMB

Loop Keeper™ Hydrophilic Acrylic Foldable Intraocular Lens (three piece)

Brand Name & Generic Name	Models	Material	Performance Characteristics
Loop Keeper™ Hydrophilic Acrylic Foldable Intraocular Lens (three-piece)	TP613	Hydrophilic Clear	Spheric, Monofocal, multipiece

DEVICE DESCRIPTION

Loop Keeper™ hydrophilic intraocular lens (IOL) is acrylic foldable three-piece posterior chamber IOL. This IOL is designed to be surgically implanted in the human eye as a replacement for the natural crystalline lens. This IOL is made from medical implantable grade hydrophilic material with 26 % water content and a refractive index of 1.46 at 35°C. The material includes a covalently bound UV blocker and ≤ 10% Cut-off at 370 nm wavelength.

Refer label on the outer box for lens type, lens type attributes, and refractive power/diopter. The optic diameter is 6 mm and overall diameter of the lens is 13 mm.

The spectral transmittance curve (figure 1) represents the transmittance of Loop Keeper™ IOL.

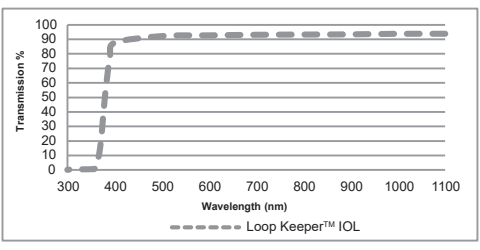

Figure 1: Transmittance graph of Loop Keeper™ IOL.

HOW EACH IOL IS SUPPLIED

Each Loop Keeper™ Hydrophilic Acrylic Intraocular Lens (Three-piece) is supplied sterile in a unique holder for easy handling during surgery. The IOL & holder are placed inside a 5 ml glass vial filled with water for injection and secured by a rubber stopper and a screw cap. The vial is packaged in a medical-grade blister pack and sealed with a tyvek Lid. The IOL is steam sterilized and should be opened only under sterile conditions.

Each carton box contains one IOL, an implant card, instructions for completion of implant card and product traceability labels.

INDICATION

Loop Keeper™ hydrophilic acrylic IOL is intended to be implanted in the posterior chamber of the eye (sulcus or capsular bag) for the visual correction of aphakia secondary to the removal of the crystalline lens in adult patients with cataracts.

Patient target group: Aphakic adult patients (18 years old or older).

MODE OF ACTION

Loop Keeper™ hydrophilic acrylic IOLs are intended to be implanted in posterior chamber of the eye, replacing the natural crystalline lens. It functions as a refractive element help to focus the light rays which are coming from cornea on the retina.

CALCULATION OF LENS POWER

Prerequisites of successful visual outcomes of cataract surgery include accurate biometry. Pre-surgery calculation of required lens power should be determined using expertise by the surgeon as per the preference. An estimated theoretical A-Constant value is mentioned on the IOL packaging outer label. These reference A -Constants anticipate the use of other parameters corneal curvature and axial length values from respective biometry equipment, required for power calculation and a spectacle distance vision at 6 meters or 20 feet. IOL power calculation methods are often included with biometry equipment, and they are also described in the references mentioned below. It is recommended to personalize the lens Aconstants to compensate differences in instrumentation, surgical techniques, and IOL power calculation formulas that may exist between clinical practice.

- Retzlaff, J.A., Sanders D.R., and Kraff, M.C., "Development of the SRK/T intraocular lens implant power calculation formula," Journal of Cataract and Refractive Surgery, Vol. pp. 222-240, 1990; ERRATA, Vol. 16 pp. 528, 1990.
- Hoffer KJ. The Hoffer Q formula: a comparison of theoretic and regression formulas. J. Cataract Refract Sur. 1993;19(6):700-12.
- Holladay JT. et al Standardizing constants for ultrasonic biometry, keratometry, and intraocular lens power calculations. J. Cataract Refract Surg. 1997;23(9):1356-70.
- Sanders, D.R., Retzlaff, J., and Kraff, M.C., "Comparison of the SRKII formula and other second generation formulas," Journal of Cataract and Refractive Surgery Vol. 14, pp. 136-141, 1988.

CONTRAINDICATIONS

Apart from non-specific contraindications related to any form of ocular surgery, the following non-exhaustive list of specific contraindications must be respected.

- Patients receiving chloroquine treatment
- Microphthalmia
- Chronic Uveitis
- Corneal dystrophy or endothelial insufficiency
- Active ocular diseases (active diabetic retinopathy, uncontrolled glaucoma)

WARNINGS, UNDESIRABLE SIDE EFFECTS AND RESIDUAL RISK

The complications listed below may occur following implantation of an IOL and may require treatment, or in severe cases can lead to secondary surgery for which the surgeon should carefully evaluate the risk/benefit ratio.

Possible complications linked to surgery for crystalline lens removal and IOL implantation include, but are not limited to, those listed below:

Intraoperative Complications

- Glaucoma
- Vitreous herniation
- Secondary membrane
- Retro lenticular membrane
- Retinal detachment
- Iridial atrophy
- Severe ametropia and aniseikonia
- IOL replacement or extraction
- Excessive intra Operative vitreous loss or Hemorrhage
- Cystoid Macular Edema
- Inflammatory reaction (e.g. vitritis, iritis, iridocyclitis, hypopyon, cyclitic membrane)
- Ocular infection (endophthalmitis, microbial keratitis)
- Toxic anterior segment syndrome
- Wound leakage
- Iris prolapse
- Elevated intraocular pressure requiring treatment
- Corneal endothelial damage

Postoperative Complications

As with any surgical procedure, there is risk involved. Potential complications accompanying cataract or implant surgery may include but are not limited to the following: corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular edema, corneal edema, pupillary block, cyclitic membrane, iris prolapse, hypopyon, transient or persistent glaucoma, and secondary surgical intervention. Secondary surgical interventions include, but are not limited to lens repositioning, lens replacement, vitreous aspirations or iridectomy for pupillary block, wound leak repair, and retinal detachment repair.

PRECAUTIONS

Precautions for use and storage:

- IOLs must be handled by health professionals and implanted by physicians/trained
- Ophthalmologists only. A high level of surgical skill is required for intraocular lens implantation. The surgeon should have observed and/or assisted in numerous implantations and successfully completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses
- Single-use only
- Do not reuse any of the parts. The used lens should be considered as biological waste. It may lead to any biological reactions including but not limited to inflammation, infection, injury, or any unknown clinical condition
- Do not resterilize the product
- Reuse and/or resterilization may compromise device performance, which could cause serious harm to the patient's health and safety
- Do not use the product if the package is damaged or there are signs of leakage from the IOL vial
- Do not use the product if the package was unintentionally opened before use
- Do not use the product beyond the expiration date
- Do not store the lens in direct sunlight or at a temperature greater than 45 °C
- Do not freeze
- Do not use the product if the package is wet
- Do not use IOL if there is no fluid in the lens container
- Do not use the storage liquid from the blister pack for intraocular irrigation. Use the only sterile intraocular irrigating solution to rinse/ soak lenses
- Do not allow the IOL to dehydrate during the procedure
- If a hydrophilic acrylic IOL has been stored below room temperature prior to implantation, a temporary opaqueness of the lens may occur. This physical reaction does not harm the lens material and clears after equilibration in each case
- Handle lenses carefully to avoid damage to the lens surfaces or haptics using smooth-edged forceps and lifting. Locking forceps or needle holders should never be used
- Do not implant IOLs that are not compliant with the patient's specific biometrical parameters
- When inserting the lens with an injector system, the lens may form fold lines. These lines are reversible and are therefore not a reason to explant the lens
- Discard cartridge & injector system used for the procedure after use

The safety and effectiveness of the IOL have not been demonstrated in patients with the following pre-existing ocular conditions and intraoperative complications listed below. Careful pre- and perioperative evaluation and sound clinical judgment should be used by the surgeon to determine the risk/benefit ratio before implanting a lens in a patient with one or more of the conditions below:

- Perioperative complications (such as posterior capsule rupture, zonular damage, vitreous loss, significant anterior chamber bleeding, or choroidal hemorrhage)
- Uncontrollable positive intraocular pressure or glaucoma
- Aniridia
- Microphthalmos or macrophthalmos

DIRECTIONS FOR USE

Preparatory Steps

- Prior to the implant, examine the IOL package for IOL size, Spherical Power, expiration date and other specifications
- Check the integrity of the sterile packaging before use
- Do not use if packaging integrity is found compromised
- Bring the IOL to room temperature before implanting
- The IOL must be opened in a sterile environment and used as soon as possible after opening the box
- After opening, verify primary package information (e.g., model, power, serial number) is consistent with the information on the outer package labeling
- Open the blister pack then remove the screw cap from the vial by turning in the anticlockwise direction and remove the IOL from the holder in a sterile environment.
- Pick the lens haptic gently with the help of forceps while ensuring that no optic part is in contact with the forceps
- Examine the lens optics as well as haptics part to ensure that no dust or particles have attached to it, and examine the lens optical surface for other defects
- Soak & rinse the IOL with a sterile balanced salt solution until ready for implantation

Implanting Steps

- Surgery must be performed using non-toothed, polished instruments, especially when the IOL is handled prior to loading into the injector

OPERATIVE PROTOCOL
The protocol of implantation is the responsibility of the surgeon. He must decide the procedure which is the most adequate based on the techniques which are most current and best executed on his own experience.

DISPOSAL
Discarded IOLs (used or unused) are classified as medical (clinical) waste that harbors a potential infection or microbial hazard and must be disposed of accordingly.

CLINICAL BENEFITS
- The clinical benefit of the implantation of an IOL for cataract patients is the prevention of blindness.
- Loop Keeper™ hydrophilic acrylic (three-piece) IOL provides functional far vision, improves patients' quality of life.

STORAGE CONDITIONS
Store between 0°C to 45°C temperature.

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

IMPLANT CARD
The implant card supplied with this device is to be completed by the healthcare provider. There is instruction for implant cards supplied with the product box. A product traceability label also supplied with this device must be affixed to the implant card as per the instructions for completion of the implant card provided. The additional labels can be used for the patient file or clinical follow up. Completed implant card s must be provided to the patient post-procedure.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE
Summary of Safety and Clinical Performance (SSCP) of this device is available on the EUDAMED website https://ec.europa.eu/tools/eudamed.

REPORTING OF SERIOUS INCIDENTS:
Users should report the serious incident with medical device information to the manufacturer and/or to the national competent authority depending on the national practice.

Once corrective (or other) action is identified from the manufacturer, hospital administrators, medical practitioners , and other health-care professionals, and USER representatives responsible for the maintenance and the safety of MEDICAL DEVICEs, can take the necessary steps. Such steps should, where practicable, be taken in co-operation with the MANUFACTURER.

For the purposes of Medical Devices Vigilance System in member states are represented by appointed National Competent Authorities, their vigilance contact points being listed on the European Commission web site: http://ec.europa.eu/growth/sectors/medicaldevices/contacts/index_en.htm.

RETURN AND EXCHANGE POLICY
To return or exchange a product, please contact the manufacturer or your local distributor.

LIMITATION OF WARRANTY AND LIABILITY
Biotech accepts no liability for any injury suffered to patients result of any implantation method or technique used by a physician to implant the lens, any prescription, and use of the lens for any individual patient or patient's conditions. Biotech makes no expressed or implied warranties in connection with the sale of the IOL.

ELECTRONIC IFU
Any national version has been translated from the core English text. In case of discrepancy, English text shall be considered final. For the latest version of the IFU, please refer the English version of electronic IFU. The content of this document is subject to change without prior notice.

SYMBOL/EXPLANATION:

SYMBOL	EXPLANATION
	Consult instructions for use or consult electronic instructions for use.
	Use-by date (YYYY/MM)
#	Model Number
LOT	Batch Number
SN	Serial number
STER-LOT	Sterilization batch number
	Single Sterile barrier system with protective packaging outside
MD	Medical Device
	Caution
0°C 45°C	Temperature Limit
	Do not use if package is damaged and consult instructions for use
	Do not resterilize
	Do not re-use
STERILE	Sterilized using steam
	Date of manufacture
	Manufacturer
	Keep away from sunlight
	Keep Dry
IND	Country of Manufacture
A	A-Constant
$\varnothing_B$	Body Diameter
$\varnothing_T$	Overall Diameter
EC REP	European Representative

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