BAUSCH + LOMB

Loop Guardian™

PMMA INTRAOCULAR LENS

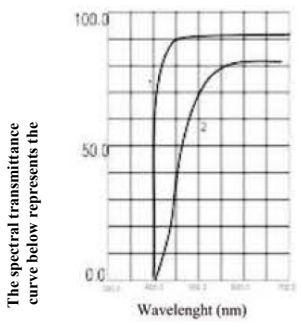
PRODUCT TO WHICH THESE INSTRUCTION FOR USE APPLY
These instructions for use apply to the following product.

Brand Name and Model	Performance Characteristics	Implantation site
Loop Guardian™ B60130S	Spherical, Monofocal, Single piece	Anterior Chamber Iris supported

DEVICE DESCRIPTION

Loop Guardian™ PMMA intraocular lens (IOL) is a monofocal PMMA single piece IOL. This IOL is designed to be surgically implanted in the human eye as a replacement for the natural crystalline lens. It is made of medical grade Poly Methyl Methacrylate (PMMA) of refractive index 1.49 at 35° C with incorporated UV filter and transmission of visible light of more than 90%.

Refer label on the outer box for lens type, lens type attributes and refractive power/diopter. The overall diameter of the lens is 13.0mm and optic diameter is 6.0mm.



1 : Spectral transmission (UV) of Intraocular Lens 20 D

2 : Spectral transmission (UV) of a blind due to a cataract of 53 years. (According to Boettner & Holt Transmission of ocular media 1962, INVEST OPTHAL1.776,783)

Figure 1: Transmittance graph of Loop Guardian™ PMMA IOL

HOW EACH IOL SUPPLIED

Each Loop Guardian™ PMMA Intraocular Lens is supplied sterile in a unique lens case for easy handling during surgery. The IOL is placed in a lens case and secured by an Acrylic cap. Finally the lens case is packaged in a medical grade Tyvek pouch and sealed using a heat sealing process. The IOL is EO (Ethylene Oxide) sterilized and should be opened in sterile conditions only.

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

INDICATION

Loop Guardian™ single piece PMMA IOL is intended to replace the human crystalline lens for surgical correction of the aphakia after intra or extra capsular extraction of the lens in patients with cataracts.
Patient target group:
Aphakic adult patient of 18 years or older

MECHANICAL CHARACTERISTICS

Compression Data

		B60130S (13.0 mm)
1.	The force required to compress the diameter of the lens 0.5 mm less than the original diameter:	0.67 mN
2.	The force required to compress the diameter of the lens the maximum amount expected in clinical usage:	2.09 mN

Vaulting Data

1.	Haptic vault height:	0.4 mm
2.	The vault observed after compressing the diameter of the lens 1.5 mm: The force required to compress the lens that amount:	0.764 mm vault 4.31 mN
3.	The vault observed after compressing the diameter 1.0 mm beyond the maximum amount expected in clinical usage: The force required to compress the lens that amount:	0.996 mm vault 9.89 mN

Sizing Guidance

White-to-white range (anterior chamber diameter):	12.0 mm – 12.4 mm

MODE OF ACTION

Loop Guardian™ PMMA IOL is intended to be implanted to replace 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 A-constants 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. 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

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 judgement 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:

- Congenital bilateral cataracts
- Patients with recurrent anterior or posterior segment inflammation of unknown etiology
- Corneal endothelial dystrophy
- Chronic severe uveitis
- Rubella cataract
- Proliferative diabetic retinopathy
- Microphthalmos
- Associated severe ocular pathology
- Surgical difficulties at the time of cataract extractions which might increase the potential of complications, e.g., persistent bleedings, significant iris damage, inability to clear the anterior chamber of vitreous, uncontrollable positive pressure, significant vitreous loss, or significant anterior chamber bleeding; Choroidal hemorrhage
- Only one eye with potentially good vision

Contraindications specific to Anterior chamber IOLs:

- Implantation in a Phakic eye
- Iridocorneal angle under 30°
- Corneal endothelial cell count (cECC) below 2300 cells/mm2, (below 2000/mm^2, if the patient is older than 40 years)
- Any anomaly of the iris or pupil function
- Mesopic pupil size ≥ 6.0 mm
- Intraocular pressure above 21 mmHg or know glaucoma disease
- Active disease in the anterior segment of the eye
- Recurrent or chronic uveitis
- "True" ACD (from corneal endothelial surface to the anterior surface of the lens) below average value (≤ 2.5 mm)
- Insufficient depth of anterior chamber
- Aniridia
- Severe atrophy of the iris
- Chronic glaucoma medically non controllable

WARNINGS, UNDESIRABLE SIDE EFFECTS AND RESIDUAL RISK

The complication listed below may occur following implantation of any 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. The risks of accidents and side effects are practically same as found during the extraction of the cataract in particular:
- Lens dislocation, non-pigment precipitates, corneal endothelial damage, high intraocular pressure, infection (endophthalmitis),corneal edema, pupillary membranes, flat anterior chamber, iris prolapse, hypopyon, and secondary glaucoma, Temporary Collapse of the anterior Chamber, Retinal detachment, Pupillary block, Iridocyclitis, Vitritis, Temporary Fistula, Cystoid macular edema, Formation of a posterior membrane, Hyphema, Vascularocclusion , Dystrophy of corneal endothelium, Striated Keratitis, Hernia of vitreous in anterior chamber, Subluxation or luxation of lens, Secondary opacification, Evisceration or enucleation, Presence of Intra-ocular debris, Ophthalmitis, Malposition of the lens, Ablation of the lens
- Special consideration should be given to the dimensions of lenses at the extreme ends of the power range in relation to the anatomical clearance in the patient's eye. The potential impact of factors such as optic central thickness, optic edge thickness and overall lens size on the patient's long-term clinical outcome must be carefully weighed against the potential benefit associated with the implantation of an intraocular lens. This is particularly true for anterior chamber lenses. The patient's clinical progress should be carefully monitored
- The patient's regular follow-up is especially important after the implantation of the anterior chamber lens which includes the monitoring of the change in the intraocular pressure and corneal endothelial cell count

PRECAUTIONS

- IOLs must be handled by health professionals and implanted by physicians/trained Ophthalmologist 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 re-sterilize
- Reuse and/or resterilization may compromise device performance, which could cause serious harm to the patient 's health and safety
- Do not use if the packaging is damaged
- Do not use the product if the packaging was unintentionally opened before use
- Do not use after the expiry date
- Handle lenses carefully to avoid damage to the lens surfaces or haptics using smooth- edge forceps and lifting. Locking forceps or needle holders should never be used
- Do not store 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
- Use only sterile intraocular irrigating solution to rinse/soak lenses
- Do not implant IOLs which are not compliant with the patient's specific biometrical parameters
- Note: Because the lens and the packaging materials are plastic, the lens may pick up an electrostatic charge upon opening the package. The lens should be carefully examined to ensure that particles have not been attracted to it

PREPARATORY STEPS

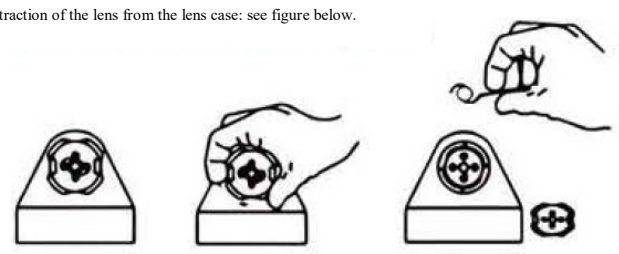
Directions for use:

- 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
- 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 Tyvek pack then remove the IOL from the lens case 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 a non-toothed, polished instruments. Irrigate / aspirate to eliminate any viscoelastic residues from the bag, especially between the IOL and posterior capsule.

Extraction of the lens from the lens case: see figure below.



CLINICAL BENEFITS

- The clinical benefits of the implantation of an IOL for cataract patients is the prevention of blindness.
- Loop Guardian™ PMMA 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 cards 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 safety of MEDICAL DEVICEs, can take the necessary steps. Such steps should, where practicable, be taken in cooperation with the MANUFACTURER.

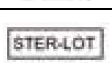
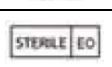
For the purpose of Medical Devices Vigilance System in member states are represented by appointed National Competent Authorities, their vigilance contact points being listed on the European Commission web site: http://ec.europa.eu/growth/sectors/medical devices/ contacts/index_en.htm

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 as a 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 to the English version of the 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)
	Batch Number
	Serial number
	Sterilization batch number
	Date of manufacture
	Medical Device
	Caution
	Temperature Limit
	Do not use if package is damaged and consult instructions for use
	Do not resterilize
	Do not re-use
	Sterilized using ethylene oxide
	Manufacturer
	Keep Dry
	Keep away from sunlight
	A-Constant
	Body Diameter
	Overall Diameter
	Model Number
	Country of manufacture
	Single Sterile barrier system with protective packaging inside

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Mfg. Lic. No.:MFG/MD/2020/000044
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