THE FRED HOLLOWS

INTRAOCULAR LENS LABORATORY

Tecsharp

STERILE HYDROPHOBIC FOLDABLE INTRAOCULAR LENS

INSTRUCTION FOR USE

DESCRIPTION:

The Sterile Hydrophobic Foldable Intraocular Lens is posterior chamber implantable optical device for the replacement of human lens to achieve the visual correction of aphakia in patient following a cataract surgery in patient 5 years of age or older.

The Sterile Hydrophobic Foldable Intraocular Lens is made up of biocompatible material P-HEMA/MMA (2-hydroxyethylmethacrylate and Methyl methacrylate) & EOEMA (2- Ethoxyethyl methacrylate) with ultraviolet absorber and is capable of adequate folding during implantation and unfolding to a full size body following implantation.

PHYSICAL CHARACTERSTICS:

Physical Characteristics	Description
IOL Model Number	HQ12A, HQ12B, HQ56C, HQ56D
Optic Type	Aspheric Biconvex
Optic Powers	+10.0D to +30.0D with power increment of +0.5D
Body Diameter (mm)	6.0mm
Overall Diameter (mm)	13.0mm
Angulation (Degree)	0°

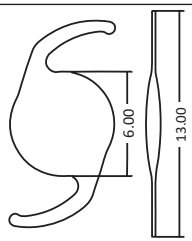


Fig 1: HQ12A, HQ56C

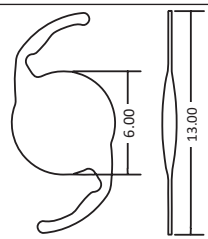


Fig 2: HQ12B, HQ56D

Figure: Drawing of Sterile Hydrophobic Foldable Intraocular Lens

CONDITIONING:

The Sterile Hydrophobic Foldable Intraocular Lens is supplied in holster with pouch sealing which is terminally sterilized with ethylene oxide. The pouch is packed in the single unit carton. The expiry date of the product is indicated on the blister label and single unit carton. Store the Intraocular Lens at temperature between 5°c to 45°c. The inner package is terminally sterilized and should be opened only under sterile conditions.

CHARACTERISTICS:

Please refer to the **Table No 1** of this leaflet named "Specifications of Sterile Hydrophobic Foldable Intraocular Lens ".

INDICATIONS:

The Sterile Hydrophobic Foldable Intraocular Lens is intended to be positioned in the posterior chamber of the eye by replacing the cloudy human crystalline lens to achieve visual correction of aphakia in adult and pediatric patients following cataract surgery. This lens is intended for placement in the capsular bag by a trained ophthalmic surgeon.

CONTRAINDICATION:

Patient with any of the following conditions may not be suitable candidates for an Intraocular Lens because the lens may intensify an existing condition or may interfere with diagnosis or treatment of a condition or may pose an unreasonable risk to the patient's eyesight.

A. **Relative Contraindication**

i. **Preexisting Conditions**

- Progressive diseases of the anterior segment of the eye (e.g. rubeosisiridis, essential iris atrophy)
- Microphthalmia
- Choroidal hemorrhage
- Proliferative diabetic retinopathy
- Severe optic nerve atrophy
- Severe corneal dystrophy
- Cataract associated with congenital rubella syndrome
- Chronic inflammation such as iritis or uveitis
- Uncontrolled glaucoma
- Macular degeneration
- Irregular corneal astigmatism with unstable refraction
- Previous corneal transplant
- Amblyopia
- Aniridia
- Microphthalmos or macrophthalmos
- Hyphema
- Patients in whom the Intraocular Lens may affect the ability to observe, diagnose, or treat posterior segment diseases.
- A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
- Circumstances that would result in damage to the endothelium during implantation.
- Suspected microbial infection
- Active ocular disease (e.g. chronic severe uveitis, proliferative diabetic retinopathy, chronic
- Glaucoma not responsive to medication)
- Corneal decompensation or corneal endothelial cell insufficiency
- Persons who are pregnant or nursing

ii. **Intra-operative condition:**

Physicians performing difficult cataract surgery and observing any of the following contraindications should weigh the potential risk / benefit ratio before implanting the IOL:

- Flat anterior chamber following extraction of crystalline lens
- Hyphema
- Vitreous loss (contraindication for posterior chamber lens)
- Traumatic cataract (potentially resulting in an unstable capsular bag due to irregular shrinkage)
- Zonular damage
- Presence of or predisposition to retinal detachment
- Mechanical or surgical manipulation required to enlarge the pupil
- Significant anterior chamber bleeding
- Uncontrollable positive intraocular pressure

COMPLICATIONS:

The complications that may arise following Intraocular Lens implantation are essentially the same as for surgical removal of cataracts. The risk of complication may be higher with following conditions:

Preexisting Conditions:

- Microphthalmos or macrophthalmos
- Suspected microbial infection
- Severe corneal dystrophy
- Corneal decompensation or corneal endothelial cell insufficiency
- Progressive diseases of the anterior segment of the eye (e.g. rubeosisiridis, essential iris atrophy)
- Chronic inflammation such as iritis or uveitis
- Cataract associated with congenital rubella syndrome
- Uncontrolled glaucoma
- Advanced macular degeneration
- Patients in whom the Intraocular Lens may affect the ability to observe, diagnose, or treat posterior segment diseases.
- A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible
- Persons who are pregnant or nursing

A. **Surgical conditions:**

Physicians performing difficult cataract surgery and observing any of the following contraindications should weigh the potential risk / benefit ratio before implanting the IOL:

- Flat anterior chamber following extraction of crystalline lens
- Significant anterior chamber bleeding
- Uncontrollable positive intraocular pressure
- Vitreous loss (contraindication for posterior chamber lens)
- Traumatic cataract (potentially resulting in an unstable capsular bag due to irregular shrinkage)
- Zonular damage
- Presence of or predisposition to retinal detachment
- Mechanical or surgical manipulation required to enlarge the pupil

WARNINGS

As with any surgical procedure, there are risks involved. Potential complications accompanying cataract or implantation surgery may include, but not limited to, the following:

- Lens dislocation, manifestations of inflammation, corneal endothelial damage, infection (endophthalmitis), retinal detachment, vitritis, cystoid macular oedema, papillary or cyclitic membrane, iris prolapse, and transient or persistent glaucoma.
- The safety of Sterile Hydrophobic Foldable Intraocular Lens implant has not been substantiated in patients with pre-existing ocular conditions: Chronic drug myosis, glaucoma, amblyopia, diabetic retinopathy, previous corneal transplant, previous retinal detachment or iritis etc. Physician considering lens implants in such patients should explore the use of alternative methods of aphakia correction and should consider lens implants only if alternatives are deemed unsatisfactory. Physicians considering a secondary intervention after an Intraocular Lens implantation with YAG laser, for posterior capsular cataract, must check the YAG laser focusing and the laser calibration.

PRECAUTIONS:

A. **Precautions for handling and storage:**

- The Sterile Hydrophobic Foldable Intraocular Lens must not be reused and or resterilized by any method, which could cause serious harm to the patients' health and safety.
- Sterility is guaranteed unless the pouch is damaged or opened.
- Opening the sterile pouch requires an immediate use of the Intraocular Lens .
- Check the shelf-pack integrity prior to use.
- Do not use the product if the package is wet.
- The pouch should be opened in the sterile areas only.
- Do not use the Intraocular Lens if the holster, which maintains sterility, has been damaged or opened.
- Do not store the Intraocular Lens in direct sun light, keep away from freezing.
- Do not uses the Intraocular Lens if it is accidently dropped.

B. **Precaution for cataract surgery:**

- It is recommended to use injector and cartridge supplied by The Fred Hollows Intraocular Lens Laboratory only.
- Do not implant IOLs which are not complaint with patient's specific biometric parameters.
- Only experienced surgeons should implant an Intraocular Lens .
- In cases of patients with chronic illnesses such as diabetes mellitus, chronic renal failure, heart diseases, chronic respiratory lung diseases and any other chronic condition, refer to physician and perform surgery after fitness clearance.
- Patients are routinely screened for HIV 1 and II, HBsAg, HCV (Categorized as High Risk) and in positive cases, the safety precaution is practiced during the surgery.
- Surgery is deferred if there is ocular infection and rescheduled once it is under control.
- Pediatric cataract surgery is performed under general anaesthesia, therefore the patient will have pre anesthetic check up by anaesthetic team.
- WHO guideline of surgical safety checks is implemented during surgery.

CALCULATION OF LENS POWER

The recommended A-constant listed on the lens carton label is intended for use with axial length measurements obtained by optical biometry. Use of axial length measurements by other techniques (e.g. Applanation A-scan) will normally require a different lens constant. The physician should determine preoperatively the power of the lens to be implanted. Lens power calculation methods are described in the following references:

- Hoffer K J. The Hoffer Q formula: a comparison of theoretic and regression formulas, Journal of Cataract and Refractive Surgery Vol. 19, pp. 700-712, 1993; ERRATA, Vol. 20, pp. 677, 1994.
- Holladay JT, Musgrove KH, Prager TC, Lewis JW, Chandler TY, Ruiz RS. A three-part system for refining intraocular lens power calculations. Journal of Cataract and Refractive Surgery, Vol. 14, pp. 17-24, 1988.
- Norrby NES. Unfortunate Discrepancies, Letter to the Editor and Reply by Holladay JT. Journal of Cataract and Refractive Surgery, Vol. 24, pp. 433-434, 1998.
- Olsen T, Olesen H, Thim K, and Corydon L. Prediction of pseudophakic anterior chamber depth with the newer IOL calculation formulas.Journal of Cataract and Refractive Surgery, Vol. 18, pp. 280-285, 1992.
- Retzlaff JA, Sanders DR, Kraff MC. Development of the SRK/T Intraocular Lens implant power calculation formula. Journal of Cataract and Refractive Surgery, Vol. 16, pp. 333-340, 1990; ERRATA, Vol. 16, pp. 528, 1990.
- Haigis W: The Haigis Formula. In: Intraocular Lens power calculations. H. John Shammas(eds), Slack Incorporated, Thorofare, NJ, USA, pp. 39-57, 2004

PATIENT INFORMATION

The patient identification card included in the package is to be completed and given to the patient, together with instruction to keep this card as a permanent record of the implant and to show the card to any eye care professional seen in future.

RETURN LENS POLICY

Please contact the manufacturer or your local distributor of TECSHARP Sterile Hydrophobic Foldable Intraocular Lens to do so.

ADVERSE REACTION REPORTING

Adverse reactions (hypopyon, intraocular infection, acute corneal decompensation, and/or secondary surgical intervention) and/or potentially sight-threatening complications that may reasonably be regarded as lens related and that were not previously expected in nature, severity or degree of incidence should be promptly reported to The Fred Hollows Intraocular Lens Laboratory. This information is being requested from all surgeons in order to document potential long-term effects of TECSHARP Sterile Hydrophobic Foldable Intraocular Lens implantation.

Patients are to be advised that their physician or medical centre should be informed of any side effects that they might experience that were not referred to in the information given to the patients prior to surgery.

Any serious incident that may reasonably be regarded as device related should be reported to The Fred Hollows Intraocular Lens Laboratory:

By phone: +977-1-5970048

Website: https://fhiol.com/contact-us

DIRECTIONS FOR USE

There are various surgical procedures that can be used for the TECSHARP Sterile Hydrophobic Foldable Intraocular Lens implantation. The surgeon should select a procedure that is appropriate to the patient.

Following inspection, the lens will be ready for insertion. This may include the use of a viscoelastic or other transitional medium for implantation.

1. Before opening the shelf-pack, please check the requested model, dioptric power and expiry date. Inspect the damage to the packaging.
2. Open the sterile pouch in a sterile area and extract the holster. Verify information such as model, power, serial number and expiry date for consistency with the outer packaging labeling.
3. Peel the lid of the holster and extract the lens holder. Inspect the lens placement in the holder.

1. **FOR IMPLANTATION WITH INJECTION SYSTEM -**

i) Extract the Intraocular Lens from the lens holder and place it on a sterile IOL cartridge hydrated with visco-elastic substance.

ii) Make sure that the Intraocular Lens is centered and haptics and optic do not get caught in between the cartridge flaps while folding the flaps.

iii) Ensure that the haptic facing the cartridge barrel is pointing left (in opposite "S" position).

iv) Now the IOL cartridge loaded with the folded IOL is ready to be placed into a sterile injector for smooth delivery of the Intraocular Lens into the patient's eye.

Note:

Relevant procedures from the manufacturer of the IOL injector and IOL cartridge being used should be checked. Since the lens and packaging materials are in plastic, the lens may pick up an electrostatic charge when the package is opened. The lens should be carefully examined to ensure that particles have not been attached to it

Symbols used in primary and secondary packaging	
REF	Catalogue Number
LOT	Batch Code
#	Model Number
	Use By date
SN	Serial Number
	Date of Manufacture
STERILE EO	Sterilized using ethylene Oxide
	Do Not Reuse
	Do not resterilize
	Double Sterile Barrier System
45°C 5°C	Above 5 °C and Below 45°C
Overall ∅ / Body ∅	Overall Diameter/ Body Diameter
	Consult Instructions for use or consult electronic instructions for use
	Do not use if Package is Damage
31	Date
	Caution
MD	Medical Device

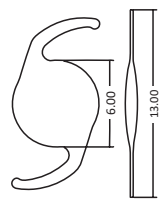
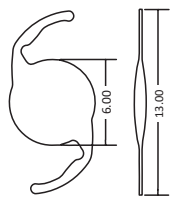
Symbols used in primary and secondary packaging	
	Patient identification
	Patient information website
UDI	Unique device identifier
	Keep away from sunlight
	Keep Dry
	Manufacturer
	Device Drawing HQ12A, HQ56C
	Device Drawing HQ12B, HQ56D
EC REP	Authorized Representative in the Europe-an Community

EC REP Authorized Representative in Europe:
OBELIS S.A
Bd. General Wahis 53,
B-1030, Brussels, Belgium
Tel: +32.2.732.59.54
Fax: +32.2.732.60.03
Email: mail@obelis.net

Manufactured by:
The Fred Hollows Intraocular Lens Laboratory
Tilganga Eye Center, P.O. Box #561,
Gaushala, Kathmandu, NEPAL
Phone: +977-1-4493775, 4493684
Email: sales@tilganga.org
www.tilganga.org / www.fhiol.com

TABLE NO : 1

Specifications of TECSHARP Sterile Hydrophobic Foldable Intraocular Lens

Specification		Model :			
		HQ12A	HQ56C	HQ12B	HQ56D
Optical Diameter (mm)		6.0	6.0	6.0	6.0
Overall Diameter (mm)		13.0	13.0	13.0	13.0
Dioptric Power (D)		+10.0D to +30.0D	+10.0D to +30.0D	+10.0D to +30.0D	+10.0D to +30.0D
Available Dioptric Power (D)		+10.0D to +30.0D with Power increment of +0.5D			
Angulation (Degree)		0°	0°	0°	0°
Estimated A -Constant Formula	SRK/T Formula	118.6	118.4	118.6	118.4
	SRK/II Formula	118.9	118.7	118.9	118.7
Device Drawing		 Fig 1: Device Drawing		 Fig 2: Device Drawing	