CE 0068

THE FRED HOLLOWS INTRAOCULAR LENS LABORATORY

INSTRUCTION FOR USE STERILE ONE PIECE RIGID PMMA INTRAOCULAR LENS

DESCRIPTION:

The Sterile One Piece Rigid PMMA Intraocular Lenses are manufactured from unfoldable poly methyl methacrylate (PMMA) material with UV-absorbent and are polyacrylic derivative with excellent optical and biocompatibility properties established it as the standard material for the manufacture of Intraocular lenses.

The Sterile One Piece Rigid PMMA Intraocular Lens is available in different models for the implantation in the Posterior chamber and in the anterior chamber so as to accommodate both extracapsular and intracapsular methods.

PRODUCT MODELS:

The Sterile One Piece Rigid PMMA Intraocular Lens Series

1. **Modified 'C' Loop Posterior Chambers Intraocular lens (FH105 and FH106):** Sterile One Piece Rigid PMMA Intraocular Lens have one biconvex Optic with spherical surfaces in anterior and posterior part and two supporting C loop haptics capable of providing the centration in the posterior chamber after implantation.
2. **Kelmann Type Anterior Chambers Intraocular lens (FA60B):** Sterile One Piece Rigid PMMA Intraocular Lens have one biconvex Optic with spherical surfaces in anterior and posterior part and kelman type haptics capable of providing the centration in the anterior chamber after implantation.

CONDITIONING:

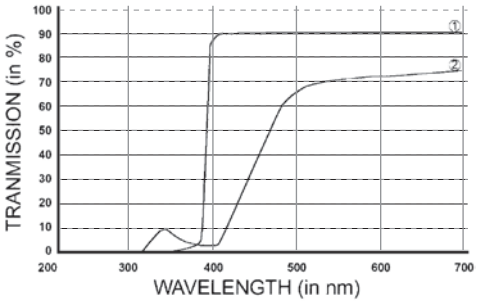
The Sterile One Piece Rigid PMMA intraocular lenses are supplied in lens case covered by lens case lid which is packed in the tyvek pouch and EO sterilized. The pouch is packed in single unit carton. The expiry date of the product is indicated on the Pouch Label &, Single unit carton End Label. Store the intraocular lens at temperature between 5°c to 45°c.

CHARACTERISTICS:

The Sterile One Piece Rigid PMMA Intraocular Lens, having a resolution efficiency of 60% or greater, are available in a dioptre range from +5.0 to +32.0 dioptres, by +0.5 dioptre increment from +5.0D to +30.0D and the increment of +1.0 dioptre for the other powers except FH105 and FH106 models. The FH105 and FH106 are available in a dioptre range of +8.0 to +30.0 dioptre by +0.5 dioptre increment. The Sterile One Piece Rigid PMMA intraocular lens is ultraviolet absorbing intraocular lenses have a light transmittance of 10% at 378 nm for a +10.0 dioptre lens and 10% at 390 nm for a +25.0 dioptre lens.

ULTRAVOILET TRANSMITTANCE:

1. One- piece Fred Hollows Intraocular Lens of 20.0D.
2. 53 years old human eye- Boettener E.A and Wolter J.R.: " Transmission of the Ocular Media" Invest.Ophthal.1:776-783:1982



INDICATION/ INTENDED USE:

Sterile One Piece Rigid PMMA Intraocualr lenses for posterior and anterior chamber are indicated for the replacement of human 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 in cases of posterior chamber and in front of Iris in cases of anterior chamber.

The Sterile One Piece Rigid PMMA intraocular lenses anterior chamber intraocular lens implantation is indicated in the case where a posterior chamber intraocular lens implantation is impossible to achieve.

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:

Contraindications mentioned below is not directly for the use of the device however, in such situation the device can have detrimental effect, either it will be difficult to implant due to preexisting conditions or it will cause more harm following implantation

i. Preexisting Conditions:

- Progressive diseases of the anterior segment of the eye (e.g. rubeosi siridis, 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:

In the conditioned mentioned below, it is advisable not to use the device either due to the structural difficulties of the eye in which the implantation of the device will lead to the permanent damage to the visual recovery

- 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 post-operative complications after cataract surgery. The following complications may be observed following implantation of any intraocular lenses. Some of them may require secondary surgical intervention.

- Inflammatory reaction (such as vitritis, iridocyclistis for example)
- Endophthalmitis
- Hyphema
- Wound leakage
- Corneal edema
- Pupillary block
- Cystoid macular edema
- Vitreous prolapse into the anterior segment
- Suspected microbial infection
- Precipitation of the lens
- Decentration of the lens
- Luxation or subluxation of the lens
- Deviation from the target refraction
- Corneal decompensation or corneal endothelial cell insufficiency
- Chronic inflammation such as iritis or uveitis
- Secondary glaucoma
- Retinal detachment

WARNINGS:

The safety of Sterile One Piece Rigid PMMA intraocular Lens implant has not been substantiated in patients with pre-existing ocular conditions such as:

- Chronic drug myosis
- Glaucoma
- Amblyopia
- Diabetic retinopathy
- Previous corneal transplant
- Previous retinal detachment
- Iritis

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.

If there is any adverse event happened during or post-surgery, Intraoperative or Secondary surgical interventions include, but not limited to: Lens repositioning, Lens replacement, vitreous aspiration, or iridectomy for pupillary block, wound leak repair and retinal detachment repair. In case of endophthalmitis intravitreal antibiotics will be given.

PRECAUTIONS:

A. Precautions for handling and storage:

- The Sterile One Piece Rigid PMMA Intraocular lens must not be reused and or resterilized by any method, which could cause serious harm to the patient's 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 pouch, which maintains sterility, has been damaged or opened.
- Do not store the intraocular lenses in direct sunlight, keep away from freezing.
- Do not use the intraocular lens if it is accidently dropped.

B. Precaution for cataract surgery:

These are the precautions to be taken in general for the cataract surgery not directly related to the use of the Device in the eye.

- Do not implant IOLS which are not compliant with patient's specific biometric parameters.
- Only experienced surgeons should implant an intraocular lens.
- In cases of Patients with co-morbidities or 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 I 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 physician should determine the power of the lens to be implanted. Calculations should estimate from the refractive error or calculations based on the corneal radius, depth of the anterior chamber and the paraxial length of the eye according to published formulas:

Short eyes	AL ≤ 22.0mm	Haigis (a0,a1,a2 optimized) [2] Holladay (ACD Optimized) [2], Hoffer Q[2]
Normal eyes	22.0 mm < AL < 25.0 MM	SRK/T [2], Haigis [2], Holladay[2], Hoffer Q[2]
Long eyes	AL ≥ 25.0 m	Haigis (a0,a1,a2 optimized) [2] Holladay (SF Optimized) [2],

[1] HILL, W.E. Choosing the right formula. {https://doctor-hill.com/iol-power-calculations/}
[2] SHAMMAS, H.J. Intraocular Lens Power Calculations. SLACK, Inc.

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 The Sterile One Piece Rigid PMMA 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 Sterile One Piece Rigid PMMA Intraocular Lens implantation.

Physicians are encouraged to report these events in order to aid in identifying emerging or potential problems with UV absorbing posterior/anterior chamber intraocular lens. Physicians are also encouraged to inform their patients implanted with a PMMA intraocular lens of possible characteristic modification of the intraocular lens when absorbing drugs prescribed by them or others.
These problems may be related to a specific lot of lenses or may be indicative of a long-term problem associated with lenses or intraocular lenses in general.

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.

DIRECTIONS FOR USE:

There are various surgical procedures that can be used for the Sterile One Piece Rigid PMMA Intraocular lens implantation. The surgeon should select a procedure that is appropriate to the patient.

Following inspection, the lens will be ready for insertion.

1. Before opening the shelf-pack, please check the requested model, dioptric power and expiry date. Inspect the damage to the packaging. Upon opening the lens package, again confirm the lens power and the stated dioptric power. Inspect the external pouch to insure that sterility has been maintained. The clear portion of the pouch may appear wrinkled.
2. Open the sterile pouches in a sterile field and remove the lens case from the pouch.
3. To open the lens case, grasp the lens case such that the index, second & third fingers support the lens case, and the thumb is placed on the grips of the lens case lid. Press the lid slightly and steadily draw the lid back towards the centre of the lens case to expose the Sterile One Piece Rigid PMMA intraocular lens.
   Caution: Before sliding the lid, slightly tap the top of the lid to ensure the lens firmly places itself in its room (i.e. in the pins that holds the lens).
4. Again inspect to make sure the correct lens model is contained in the lens package.
5. Carefully remove the lens vertically from the case using a sterile forceps. Be careful to grasp only the distal portion of the haptic and lift it straight up from the lens case.
6. Inspect the optic and haptic for defects and scratches that may have occurred during transportation.
   Because 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.

CONTAINS OF PACKAGING:

- One Sterile One Piece Rigid PMMA Intraocular Lens
- Additional Labels
- Patient Identification Card
- Instruction for Use (IFU)

Symbols used in primary and secondary packaging	
LOT	Batch Code
	Use By Date
SN	Serial Number
	Date of Manufacture
STERILE EO	Sterilized using Ethylene Oxide
2	Do Not Reuse
2 STERILIZE	Do not Resterilize
45 °C / 5 °C	Above 5°C and Below 45°C
Overall ∅ / Body ∅	Overall Diameter/ Body Diameter
	Consult Instruction for use
	Do not use if Package is Damage
	Keep away from sunlight
	Keep Dry
	Manufacturer
	FH106 (Device Drawing)
	FH105 (Device Drawing)
	FA60B (Device Drawing)

EC REP
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