THE FRED HOLLOWS INTRAOCULAR LENS LABORATORY

Tecsoft

ASPHERIC FOLDABLE ACRYLIC INTRAOCULAR LENS

INSTRUCTION FOR USE

DESCRIPTION:

The Aspheric Foldable Acrylic Intraocular lens is an implantable optical device for the replacement of human crystalline lens to achieve the visual correction of aphakia in patient following a cataract surgery. The Aspheric Foldable Acrylic Intraocular lens is made up of biocompatible hydrophilic acrylic polymer Poly (2-Hydroxyethyl methacrylate) with ultraviolet blocker and is capable of adequate folding during implantation and unfolding to a full size body following implantation. There are two different models available; FLEX Q and FLEX QY. These all models are monofocal biconvex lenses. The physical properties of the lenses are as follows:

1. FLEX Q is Clear Aspheric Foldable Acrylic Intraocular lenses with 360° Square edge have one biconvex Optic with Aspherical surfaces in anterior part and two supporting C loop haptics capable of providing the centration in the posterior chamber after implantation.

2. FLEX QY is Yellow Aspheric Foldable Acrylic Intraocular lenses with 360° Square edge have one biconvex Optic with Aspherical surfaces in anterior part and two supporting C loop haptics capable of providing the centration in the posterior chamber after implantation. FLEX QY has yellow chromophore that blocks blue light transmission.

CONDITIONING:

The Aspheric Foldable Acrylic Intraocular lenses are supplied in hydrated condition in holster with blister pack which is terminally sterilized with moist heat. The blister 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 sterile TEC-JET injection system is packed in the separate blister for IOLs delivery purpose.

CHARACTERISTICS:

Please refer to the Table No 1 of this leaflet named "Specifications of TECSOFT Aspheric Foldable Acrylic Intraocular lens."

INDICATIONS/INTENDED USE:

The Aspheric Foldable Acrylic Intraocular lenses for posterior chamber are indicated for the replacement of 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.

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. 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:

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

In the condition mentioned below,it is advisable no 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, etc)
- Endophthalmitis
- Hyphema
- Wound leakage
- Corneal edema
- Pupillary block
- Cystoid macular edema
- Vitreous prolapse in to 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 Aspheric Foldable Acrylic 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

Surgeons 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. Surgeons 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 Aspheric Foldable Acrylic 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 sterility blister is damaged or opened.
- Opening the sterile blister 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 blister 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 lenses in direct sun light, keep away from freezing.
- Do not soak the intraocular lenses in other solutions.
- Do not uses the intraocular lens if it is accidently dropped.
- Do not use the storage liquid from the blister pack for intraocular irrigation

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.

- 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 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 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 surgeons 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 mm	Haigis (a0,a1,a2 optimized) [2] Holladay (SF Optimized) [2],

[1] HILL, W.E. Choosing the right formula .http://www.doctor-hill.com/iol-main /formulas.htm.
[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.

CONTAINS OF PACKAGING:
- One Aspheric Foldable Acrylic Intraocular lens
- Additional Labels
- Patient Identification Card
- Patient Identification Label
- Instruction for Use (IFU)

RETURN LENS POLICY:
Please contact the manufacturer or your local distributor of TECSOFT Aspheric Foldable Acrylic 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 TECSOFT Aspheric Foldable Acrylic Intraocular lens implantation.

Surgeons are encouraged to report these events in order to aid in identifying emerging or potential problems with Poly-HEMA material with UV absorbing posterior chamber intraocular lens. Surgeons are also encouraged to inform their patients implanted with a Poly-HEMA 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 surgeons 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 TECSOFT Aspheric Foldable Acrylic 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 blister 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.

4. FOR IMPLATATION WITH INSERTION FORCEPS –
i) Gently grab the lens with non-toothed polished forceps at the center of the loaded optic.
ii) The lens must not be allowed to dehydrate. It is recommended that the lens be inserted into the eye immediately after loading it into cartridge with injector.
iii) Hydrate the lens using sterile intraocular irrigation solution before implantation into the patient's eye.

5. 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.

Table No.: 1 (Specifications of TECSOFT Aspheric Foldable Acrylic Intraocular lens)

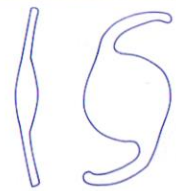
Specification \ Model	FLEX Q	FLEX QY
Body Diameter (mm)	6.0	6.0
Overall Diameter (mm)	13.0	13.0
Dioptric Power (D)	+11.0D to +32.0D	+11.0D to +32.0D
Available Dioptric Power (D)	+11.0D to +30.0D(Power increments by 0.5 D) +31.0D to +32.0D(Power increments by 1.0 D)	+11.0D to +30.0D(Power increments by 0.5 D) +31.0D to +32.0D(Power increments by 1.0 D)
Angulation (Degree)	4°	4°
Estimated A Constant	118.6	118.6
Drawing		

Fig: Tecsoft " FLEX Q" Clear Aspheric Foldable Acrylic Intraocular lens

Fig: Tecsoft " Flex QY" Yellow Aspheric Foldable Acrylic Intraocular lens

Symbols used on packaging	
MD	Medical device
LOT	Batch code
	Use-by date
SN	Serial number
	Date of manufacture
STERILE	Sterilized using steam
	Do not reuse
STERILIZE	Do not resterilize
	Double sterile barrier system
5°C 45°C	Above 5°C and below 45°C
Overall ∅ / Body ∅	Overall diameter/ Body diameter
	Consult instruction for use
	Do not use if package is damaged
	Keep away from sunlight
	Keep dry
	Manufacturer
	FLEX Q (Device drawing)
	FLEX QY (Device drawing)

Manufactured by
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