HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES

(With or Without Injector and Cartridge)

Brand	Models	Generic Name
FREEDOM FOLD	HFR 603, HFC 603, HFM 606, HFR 573, HFR 574	Hydrophilic Acrylic Posterior Chamber Single Piece Foldable Intraocular Lens
FREEDOM FOCUS	AFR 603SQ, AFC 603SQ, AFM 606SQ, AFC 602SQ	Hydrophilic Acrylic Posterior Chamber Single Piece 360° Square Edge Aspheric Foldable Intraocular Lens
FREEDOM ELITE	AFR 603SQY, AFC 603SQY, AFM 606SQY	Yellow Hydrophilic Acrylic Posterior Chamber Single Piece 360° Square Edge Aspheric Foldable Intraocular Lens
FREEDOM ICL	ICL120, ICL225, ICL130, ICLT 120, ICLT 225, ICLT 130	Hydrophilic Implantable Intraocular Lens

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CE 2460
ISO 13485:2016 Certified

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Material used

Copolymer of methyl Methacrylate and poly hydroxyl ethyl Methacrylate

Indications

The IOLs are intended for primary or secondary implantation in the posterior chamber/anterior chamber in patients where a cataractous lens has been removed by extracapsular cataract extraction. It is recommended that the use of the intraocular lens be initially limited to one eye unless the needs of the patient dictate otherwise. Use of the lenses is especially appropriate in patients who cannot accommodate contact lenses, those who are not the candidates for cataract spectacles or for patients requiring an intraocular lens for occupational or other reasons.

Contraindications

The following are relative circumstances where the physician should consider whether implanting an intraocular lens does not create undue risk. Surgeons should explore the use of alternative methods of Aphakic correction and consider lens implantation only if alternative are deemed unsatisfactory to meet the needs of the patient.

- Chronic severe Uvelitis,
- Epithelial Dystrophy,
- Rubella Cataract,
- Massive vitreous loss,
- In cataracts present in children.
- Concomitant severe Eye Disease,
- Glaucoma problem,
- Choroidal Hemorrhage,
- Microphthalmos, Anirida,

How Supplied

IOLs are supplied STERILE in a hydrated state, in a vial with holder folder or polypropylene tray sealed by aluminum foil enclosed in a sterile autoclaved pouch and terminally sterilized using steam. The contents of the pouch are sterile unless the package is opened or damaged.
Note: To avoid dehydration, leave lens immersed in water until ready to fold and implant the lens should be folded and implanted with in 3 minutes after removal from the water.

Sterilization

The device is sterilized by Steam Sterilization (STEAM).

DIRECTIONS FOR USE

- Open the outer package to remove the peel-pouch or and verify that the information is consistent with the outer package labelling (e.g. model, LOT number,etc.,).
- Open the protective peel-pouch or blister and remove the lens container from the packaging in a sterile environment
- Open the protective peel-pouch or blister and remove the injector and cartridge from the packaging in a sterile environment
- Open the cartridge and Holding the cartridge in 180° open position and fill up the nozzle with sterile viscoelastic material. Cover both halves of the loading chamber with the viscoelastic material as well.
- Carefully remove the lens from the lens holder using parallel tipped, non-serratedforceps.
- Position the lens with 2 loop haptics position the lenses in the cartridge in a 'Z' or 'reverse-S' orientation in the cartridge.
- Cover the upper surface of the lens with the viscoelastic solution. While keeping the lens in position with open forceps, gently close the cartridge until the click sound without pinching any part of the optic or haptics. Visually observe that the lens is symmetrically folded within the loading chamber.
- Load the cartridge in to the injector. Ensure that there is no gap between the shuttersbefore loading the cartridge in to the injector.
- Push the plunger forward in a slow, controlled manner until the lens will completely come out of the cartridge tip.
- When the lens exits the cartridge nozzle,stop pressing the plunger and carefully take out the cartridge nozzle tip from the eye.

Possible complications:

As with any surgical procedure, there is risk involved. The most common potential complications and undesirable effects accompanying cataract or implant surgery –some of them may lead to a secondary surgical intervention (e.g. IOL replacement or extraction) or medication -may include, but are not limited to the following

- Damage to cornea, Descemet membrane or endothelia
- Flat anterior chamber after lens extraction
- Corneal (stromal) oedema, bullous keratopathy
- Haemorrhage, hyphemia
- Raised intraocular pressure, secondary glaucoma
- Cystoid macular oedema
- Uveitis
- Iris trauma, pupillary block, iris prolapse, seclusiopupillae, iris capture, iritis, epithelial
- Ingrowth
- Intraocular infections, inflammation, endophthalmitis
- Dissatisfactory visual outcome (e.g. due toincorrect IOL refraction), visual impairment,
- Glares/blinding, secondary surgical or medicinal intervention
- Retinal detachment
- Hypopyon
- IOL dislocation, decentration, tilt, axial shift or, rotation of the IOL
- Unanticipated surgically induced change in thecornea, e.g. astigmatism
- Vitreous loss
- Cyclitic membrane
- Fibrotic reaction
- Synechia
- Wound gape, wound leak/dehiscence
- Thermal burns
- Incorrect positioning of the IOL during surgery
- Damage to the IOL during implantation
- Damage to anterior and posterior capsule (e.g. ruptures, tears) or to the zonules
- Capsularphymosis and capsule block syndrome
- Posterior capsule opacification (PCO)
- Postoperativeopacification/calcification of the IOL, deposits, discoloration, decolouration
- Asthenopic discomfort, adaptional dfficulties
- Pseudoexfoliation Syndrome
- Myopia
- Retinal pigment change
- Eye trauma and connective tissue diseases

Warnings

- The effectiveness of UV-absorbing intraocular lenses in reducing the incidence of retinal disorders has not been established.
- The safety of the use of the Neodymium-YAG laser on IOLs with UV absorbing materials has not been established, the physicians is urged to use extreme caution in such cases where a patient with UV absorbing IOLs is treated with a Neodymium- YAG laser
- The compression force exerted on the eye tissue by the lens is not established. The physician should have knowledge in selecting type of the lens depending on the eye dimensions.
- In the bag lenses should be used only when the posterior capsule is in good condition.
- Care should be taken to avoid breakage of haptic while injecting and inserting lens through the Scleral tunnel or small incision.
- The device must be used by medical professional only.
- Don't re-sterilize the device. Re-sterilization of the device will have a detrimental effect on its known properties thereby rendering it inappropriate for the intended use .Re-sterilization of Lens can also cause to change in mechanical & chemical properties.
- Don't reuse the device . if reuse of device can work as carrier for communicable disease, HIV, Chronic severe uveitis, Epithelial Dystrophy, Anirida, Hepatitis, contagious dieses, undue diseases to patient and/or user, Glaucoma problem, Rubella Cataract.
- Re-use of lens may not meet the intended use as lens may be blunt, Surgical difficulties at time of cataract extraction, which may increase the potential for complications(like: persistent bleeding, significant iris damage, uncontrolled positive pressure or significant vitreous prolaps or loss)

Adverse Event :

The improper use /mis-use of Lens may occur adverse event to patient eg macular edema, endophthalmitis, anterior lens tissue on growth, lens dislocation, hypopyon, corneal edema, iritis, hyphema, secondary glaucoma, secondary surgical intervention and posterior capsular opacification

Storage:

- Store at Temperature 5 to 40°C and Humidity 35 to 65% RH
- Protect from light & freezing
- Expiry date showed on the pack indicates the period within which the device has to be used.

Return of Damaged Product:

Return the device in its original box identified by the LOT number, your purchase reference and reason for the return.

Disposal of Discarded Product and Packaging:

Ensure safe and proper disposal of used/discarded product and packaging to avoid adverse effect to environment, children and stray animals. The disposal should be in compliance to local laws related to disposal of biomedical waste, in the country of use.

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Symbols and Meaning: