

TECHNICAL CONSTRUCTION FILE (FOPL/TCF/01)	Issue No.: 03 Dated :02-05-2022 Rev.No.:03 Rev Dt – 24-09-2026	 Freedom Ophthalmic Pvt. Ltd. Plot No. 31, Phase -I, Sipcot Industrial Complex, Hosur – 635 126, Tamilnadu, INDIA
INSTRUCTIONS FOR USE (Doc No FOPL/IFU/01)	Section No.: 2.1 Page 1 of 7	

PMMA IRIS CLAW IOLS:

ENGLISH

INSTRUCTIONS FOR USE APPLICABLE FOR THE FOLLOWING MODELS:

Trade / Brand Name	Generic Name	Models	Variants
FREEDOM IRIS	Iris Claw Intraocular Lens	FIC 4272H, FIC 5085H, FIC 5585H, FIC 6085H	IOLs, PHAKIC, MONOFOC AL, SPHERICAL , PMMA
CLAR IOL		JMP 4272H, JMP 5085H, JMP 5585H, JMP 6085H	

INTENDED USE:

The Phakic intraocular lenses (IOLs) are one-piece lenses made of UV absorbing polymethylmethacrylate (PMMA). The lens is designed for implantation into the phakic human eye for the correction of a refractive error. The lens is fixated to the relatively immobile anterior midperiphery of the iris stroma by two iridoplastic bridges with enclavation mechanisms (“claws”).

INDICATIONS:

The Phakic IOL is indicated for the correction of myopia or hyperopia, in patients to all age groups, when there are no compromising ocular pathology(ies).

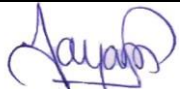
NOTES:

- This device should only be used by or under supervision of physicians trained for this process.
- This device is designed for single use only. Re-processing, re-sterilization and/or re-use may lead to failure of this device, and/or transmission of disease contracted from previous usage.
- Do not use this device:
 - For any purpose other than stated intended use.
 - If package is opened or damaged when received.
 - If date of use has expired.

CONTRAINDICATIONS/ RESIDUAL RISK:

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 Phakic correction and consider lens implantations only if alternative are deemed unsatisfactory to meet the needs of the patient.

- | | |
|----------------------------------|---------------------------|
| • Chronic severe Uveitis | • Epithelial Dystrophy |
| • Rubella Cataract | • Massive vitreous loss |
| • Concomitant severe Eye Disease | • Glaucoma problem |
| • Choroidal Hemorrhage | • Microphthalmos, Anirida |

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- IOL Dislocation
- Pseudoexfoliation Syndrome
- Retinal Pigment change
- In Cataract present in all age groups
- Posterior Capsule Opacification (PCO)
- Uveitis
- Myopia
- Eye trauma and connective tissue diseases
- Congenital cataract

POTENTIAL COMPLICATIONS:

The known complication may occur at the time of surgery or be the result of an on going post operative process, mechanical and inflammatory may produce corneal de-compensation, Cystoid Macular Edema & Hyphema , Uveitis and Glaucoma may cause reduced vision and, in some cases, chronic pain in eye.

PRECAUTIONS:

- Do not store the lens indirect sunlight & Keep away from freezing.
- Do not use if sterile pouch is opened & damaged.
- Only skilled Surgeons with experience in either viewing and or assisting numerous surgical implantations and successfully completed at least a course on IOL implantation should attempt implantation of these lenses.
- Pouch should be opened only under sterile conditions.
- Do not soak or rinse lens in solutions other than sterile balanced salt solution, sterile normal saline solute or equivalent of such.
- Do not attempt to re-sterilize this lens. Re-sterilization on this product has not been validated.
- Do not autoclave this lens.
- Handle the lens carefully, Locking forceps or needle holders should never be used to pick up lenses.
- Do not reshape the supporting structures. (Haptics).
- The device must be used by medical professional only.

ADVERSE EVENT:

The improper use / mis-use of lens may occur adverse event to patient eg Cystoid Macular Edema & Hyphema, endophthalmitis, anterior lens tissue on growth, lens dislocation, hypopyon, corneal edema, iritis, secondary glaucoma, secondary surgical intervention and glare\halos.

WARNINGS AND RESIDUAL RISKS:

- 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.

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- **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 diseases, 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)

MODE OF ACTION:

An IOL implant is an acrylic lens and take over the image focusing function of the eye. The IOLs are like a natural lens focus lights inside the eye. The devices can correct a wider range of vision problem than any other vision correction surgery. The IOLs create a single elongated focal point rather than several foci to enhance the depth of focus.

PREPARATION FOR DECONTAMINATION:

No particular requirement

APPLICATION OF THE BODY:

The device is implanted in eye primarily in capsular bag for visual correction. Thus, ocular tissue is coming in contact with device.

CLEANING AUTOMATED:

No cleaning is required before used of the device.

CLEANING MANUAL:

No cleaning is required before used of device.

DISINFECTION:

No disinfection required

MAINTENANCE:

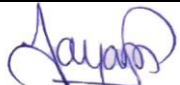
No particular requirement

INSPECTION & FUNCTION TESTING:

Check for smooth functioning of medical device. Visually inspect for damage.

ADDITIONAL INFORMATION:

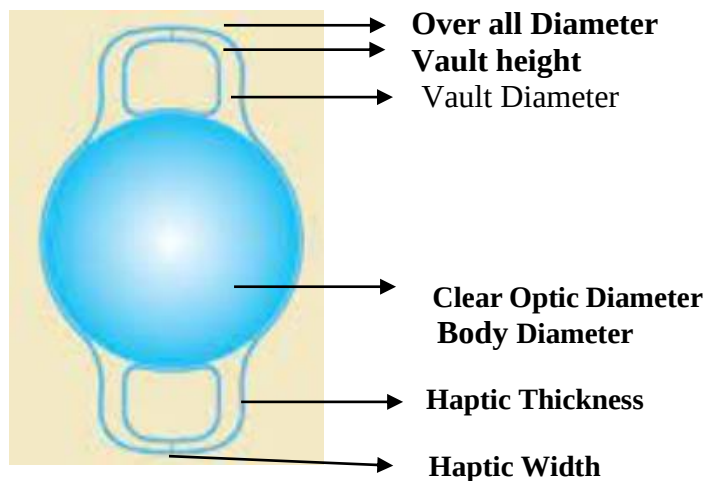
Read instructions carefully before use.

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DESCRIPTION OF COMPONENT PARTS:

The device consists of the following parts:



SYSTEM PREPARATION:

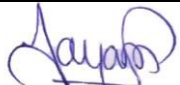
1. Check the label for manufactory and expiry dates (do not use the medical device after expiry)
2. Check for UDI number
3. Make sure the package is not damaged.
4. Visually examine the IOL to see if there are any damages on the loops.

INSTRUCTIONS FOR USE:

1. In a sterile environment, peel apart to open the pouch and remove the lens case.
2. Unscrew the lens case with care and grasp the lens optic using smooth edged forceps and lift.
3. Soak or rinse the lens in sterile balanced salt solution or their equivalent solution.
4. Ensure that the lens is in good conditions for optic and haptics surfaces for adherences of any particles.
5. Prior to implantation examine the lens for power, model, proper configuration, and optical surfaces.
6. During insertion carefully handle lenses by haptics portion only. To avoid breakage do not attempt to expand the haptics, flex the haptics out of the plane of the lens or twist or torque the lens.
7. Packing box contains extra labels. These are for convenience in maintaining and reporting records of implantable lenses during clinical investigation. One of the labels could be affixed in patients case sheet for future reference.

PATIENT INFORMATION:

The Surgeon performing the intervention must inform the patient about the complete procedure and all known complications and risks. The patient should be instructed to properly inform the doctor in charge about any side-effects after implantation.

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STORAGE:

Store in a cool, dry place, away from extreme temperatures. Expiry date showed on the pack indicates the period within which the device must be used. Store between 5°C to 40°C temperature & 35% to 65%RH away from moisture and direct heat.

RETURN OF DAMAGED PRODUCT:

Return the products in its original box identified by the LOT number, your purchase reference and reason for the return. The action shall be initiated to handle the product record as per the law of the land (IMDR 2017 under Drug and Cosmetic act 1945) and in compliance of the regulatory requirement of the destination of the product. The product recall procedure will be followed for the handling of this situation.

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 comply with institutional guidelines for bio-hazardous medical waste prevailing in the country of use.

ORDERING INFORMATION:

Trade / Brand Name	Generic Name	Models	Diopter range
FREEDOM IRIS	Iris Claw Intraocular Lens	FIC 4272H, FIC 5085H, FIC 5585H, FIC 6085H	-15 D to +40 D
CLAR IOL		JMP 4272H, JMP 5085H, JMP 5585H, JMP 6085H	

PACKAGING:

The device is supplied in Polypropylene case contained within a heat-sealed Tyvek sterilizable peel pouch, along with IFU, inner labels in a duplex box with external identification labels.

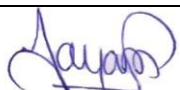
Implant Card and Traceability

An implant card is supplied with the device in accordance with MDR Article 18.

The healthcare institution or surgeon shall complete the implant card with patient identification, device name, model, lot number, UDI, manufacturer details, implantation date, and healthcare institution details.

Peel-off labels should be affixed to the patient medical record, implant card, and hospital traceability record as applicable.

The patient should be instructed to retain the implant card and present it to healthcare professionals during future ophthalmic care or relevant medical procedures.

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Implant Card	
Patient ID Card	
Model Number: _____	Optic Ø : XXXXX
Catalogue Number(REF): _____	Over all Ø : YYYYY
UDI-DI: _____	Mfg Date :YYYY / MM
Lot Number: _____	Exp Date :YYYY / MM
Diopter Power: _____	
Implantation Date: _____	
Patient Name: _____	
Eye Implanted:	
☐ Right Eye (OD) ☐ Left Eye (OS)	
Healthcare Institution: _____	
Implanting Surgeon: _____ FO/IC/001-R01 Date : 18.09.2026	

This card identifies your implanted intraocular lens Always keep this card and present it to any ophthalmologist or healthcare professional involved in your eye care. Contact your ophthalmologist immediately if you experience - Sudden Loss of vision - Severe eye pain - Persistent redness - Flashes of light - New floaters - Significant visual disturbance - Any unexpected ocular symptoms Freedom Ophthalmic Pvt Ltd. EU REP Plot No.31,Phase-I,SIPCOT Industrial Complex, Tamil Nadu, 635126,India. e-mail:fred@freedomophthalmic.com Website:www.freedomophthalmic.com Tel:+91 95855 99301 CMC Medical Devices & Drugs S.L. C/Granada Lengua N° 18, CP 29006, Malaga, Spain Email: info@CMCmedicaldevices.com Phone:+34951214054 Keep this implant card permanently and present it to healthcare professionals whenever relevant medical treatment is received
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NOTICE FOR USER / OR PATIENT:

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the User and/or Patient is established.

The instructions provided above have been validated by the manufacturer of the medical device as being Capable of preparing a medical device for safe use.

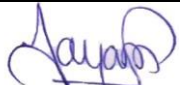
Equipment & instrument for implantation of IOLs depends on the operating procedures.

STERILIZATION & EXPIRY DATE:

The device is sterilized by Ethylene Oxide (EO) & 60 months from the date of manufacturing

WARRANTY:

We warrant that reasonable care has been used in the design and manufacture of IOL. This warranty is limited to replacement of IOL only. We shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. We do not assume or authorize any other person to assume on our behalf, any other or additional liability or responsibility in connection with use of this device.

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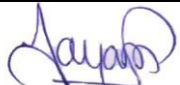
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ELECTRONIC VERSION OF IFU:

Available on the website www.freedomophthalmic.com

EXPLANATION OF SYMBOLS:

Symbol	Meaning	Symbol	Meaning
	Lot Number/ Batch Number		Sterilization by Ethylene Oxide
	Warning see instruction		Use Until (YYYY-MM)
	Don't use when packing damaged		Humidity Limitation
	Do not reuse		Do not re-sterilize
	Keep away from sunlight		Keep dry
	Temperature limit		Manufacturer
	Country of Manufacturer		CE Mark
	Single Sterile Barrier System		Medical Device
	Patient number		Unique Device Identifier
	Date of Manufacture		Consult instructions for use or Consult electronic instructions for use
	Catalogue number		Country Code
	Authorized representative in European Union		

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Freedom Ophthalmic Pvt Ltd

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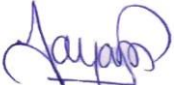


2460 Notified Body:

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