

TECHNICAL CONSTRUCTION FILE (FOPL/TCF/02)	Issue No.: 03 Dated :02-05-2022 Rev.No.:05 Rev Dt -23-09-2026	 Freedom Ophthalmic Pvt. Ltd. Plot No. 31, Phase -I, Sipcot Industrial Complex, Hosur – 635 126, Tamilnadu, INDIA
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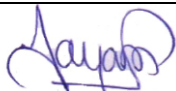
HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES - (PRELOADED SYSTEM).

ENGLISH

INSTRUCTIONS FOR USE APPLICABLE FOR THE FOLLOWING MODELS:

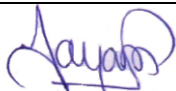
Configuration C

Trade / Brand Name	Generic Name	Models	Variants
FREEDOM ARC +	Hydrophobic Acrylic Spheric Foldable 360° Square Edge Intraocular Lens - Preloaded	FPLS 603SQP, FPLS 602SQP, FPMS 606SQP	IOLs APHAKIC, MONOFOCAL, SPHERICAL, HYDROPHOBIC ACRYLIC
CLAR IOL		JMHS 6025SQP, JMHS 6030SQP, JMHS 6010SQP	
FREEDOM ARCY +	Yellow Hydrophobic Acrylic Spheric Foldable 360° Square Edge Intraocular Lens - Preloaded	FPLS 603SQYP, FPLS 602SQYP, FPMS 606SQYP	
CLAR IOL		JMHS 6025SQYP, JMHS 6030SQYP, JMHS 6010SQYP	
FREEDOM ACE +	Hydrophobic Acrylic Aspheric Foldable 360° Square Edge Intraocular Lens – Preloaded	FPL 621SQP, FPL 603SQP, FPL 602SQP, FPM 606SQP	IOLs APHAKIC, MONOFOCAL, ASPHERIC, HYDROPHOBIC ACRYLIC
CLAR IOL		JMH 6251SQP, JMH 6025SQP, JMH 6030SQP, JMH 6010SQP	
FREEDOM ACE +	Hydrophobic Acrylic Aspheric Foldable Intraocular Lens – Preloaded	FPL 621P	
CLAR IOL		JMH 6251P	
FREEDOM ZEN +	Yellow Hydrophobic Acrylic Aspheric Foldable 360° Square Edge Intraocular Lens - Preloaded	FPL 603SQYP, FPL 602SQYP, FPM 606SQYP	
CLAR IOL		JMH 6025SQYP, JMH 6030SQYP, JMH 6010SQYP	
FREEDOM SULCO	3 – Piece Hydrophobic Acrylic Foldable Aspheric Intraocular Lens - Preloaded	3HPC 630P, 3HPC 640P	
CLAR IOL		JM3HP 6030P, JM3HP 6040P	
FREEDOM SULCO -Y	3 – Piece Yellow Hydrophobic Acrylic Foldable Aspheric Intraocular Lens - Preloaded	3HPC 630YP, 3HPC 640YP	
CLAR IOL		JM3HP 6030YP, JM3HP 6040YP	
FREEDOM TORIC +	Hydrophobic Acrylic Posterior Chamber Toric	TPC 603SQP, TPC 602SQP	IOLs APHAKIC,

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CLAR IOL	Aspheric Square Edge Single Piece Foldable Intraocular Lens -Preloaded	JMHT 6025P, JMHT 6030P	MONOFOCAL, TORIC, HYDROPHOBIC ACRYLIC
FREEDOM TORYC +	Yellow Hydrophobic Acrylic Posterior Chamber Toric Aspheric Square Edge Single Piece Foldable Intraocular Lens -Preloaded	TPC 603SQYP, TPC 602SQYP	
CLAR IOL	Aspheric Square Edge Single Piece Foldable Intraocular Lens -Preloaded	JMHT 6025YP, JMHT 6030YP	
FREEDOM MULTIFOCAL +	Hydrophobic Acrylic Posterior Chamber Multifocal Diffractive-Refractive Aspheric Square Edge Single Piece Foldable Intraocular Lens - Preloaded	MPC 603SQP, MPC 602SQP	IOLs APHAKIC, MULTIFOCAL, ASPHERIC, HYDROPHOBIC ACRYLIC
CLAR IOL	Aspheric Square Edge Single Piece Foldable Intraocular Lens - Preloaded	JMHM 6025SQP, JMHM 6030SQP	
FREEDOM MULTYFOCAL +	Yellow Hydrophobic Acrylic Posterior Chamber Multifocal Diffractive-Refractive Aspheric Square Edge Single Piece Foldable Intraocular Lens - Preloaded	MPC 603SQYP, MPC 602SQYP	
CLAR IOL	Aspheric Square Edge Single Piece Foldable Intraocular Lens - Preloaded	JMHM 6025SQYP, JMHM 6030SQYP	
FREEDOM TRIFLEX +	Hydrophobic Acrylic Posterior Chamber Trifocal Diffractive-Refractive Aspheric 360° Square Edge Single Piece Foldable Intraocular Lens - Preloaded	TRPC 603SQP, TRPC 602SQP	
CLAR IOL	Aspheric 360° Square Edge Single Piece Foldable Intraocular Lens - Preloaded	JMHTF 6025P, JMHTF 6030P	
FREEDOM TRYFLEX +	Yellow Hydrophobic Acrylic Posterior Chamber Trifocal Diffractive-Refractive Aspheric 360° Square Edge Single Piece Foldable Intraocular Lens -Preloaded	TRPC 603SQYP, TRPC 602SQYP	
CLAR IOL	Aspheric 360° Square Edge Single Piece Foldable Intraocular Lens -Preloaded	JMHTF 6025YP, JMHTF 6030YP	
FREEDOM EDOF +	Edof Hydrophobic Acrylic Posterior Chamber Aspheric Square 360° Edge Single Piece Foldable Intraocular Lens - Preloaded	EDOF 603SQP, EDOF 602SQP	
CLAR IOL	Aspheric Square Edge Single Piece Foldable Intraocular Lens - Preloaded	JMED 6025P, JMED 6030P	
FREEDOM YEDOF +	Edof Yellow Hydrophobic Acrylic Posterior Chamber Aspheric Square Edge single Piece Foldable Intraocular Lens - Preloaded	EDOF 603SQYP, EDOF 602SQYP	
CLAR IOL	Aspheric Square Edge single Piece Foldable Intraocular Lens - Preloaded	JMED 6025YP, JMED 6030YP	
FREEDOM TORIC MULTIFOCAL +	Hydrophobic Acrylic Posterior Chamber Multifocal Toric Aspheric Square Edge Single Piece Foldable	MTPC 603SQP, MTPC 602SQP	IOLs APHAKIC, MULTIFOCAL, TORIC,

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CLAR IOL	Intraocular Lens - Preloaded	JMHT 6025P, JMHT 6030P	HYDROPHOBIC ACRYLIC
FREEDOM TORYC MULTIFOCAL +	Yellow Hydrophobic Acrylic Posterior Chamber Multifocal Toric Aspheric Square Edge Single Piece Foldable	MTPC 603SQYP, MTPC 602SQYP	
CLAR IOL	Intraocular Lens -Preloaded	JMHT 6025YP, JMHT 6030YP	
FREEDOM TORIC TRIFLEX +	Hydrophobic Acrylic Posterior Chamber Trifocal Toric Aspheric 360° Square Edge Single Piece Foldable	TRTPC 603SQP, TRTPC 602SQP	
CLAR IOL	Intraocular Lens - Preloaded	JMHTT 6025P, JMHTT 6030P	
FREEDOM TRI TROYC+	Yellow Hydrophobic Acrylic Posterior Chamber Trifocal Toric Aspheric 360° Square Edge Single Piece Foldable	TRTPC 603SQYP, TRTPC 602SQYP	
CLAR IOL	Intraocular Lens - Preloaded	JMHTT 6025YP, JMHTT 6030YP	
FREEDOM TORIC EDOF +	Edof Hydrophobic Acrylic Posterior Chamber Toric Aspheric Square Edge Single Piece Foldable Intraocular	TEDOF 603SQP, TEDOF 602SQP	
CLAR IOL	Lens - Preloaded	JMEDT 6025P, JMEDT 6030P	
FREEDOM TORYC EDOF +	Edof Yellow Hydrophobic Acrylic Posterior Chamber Toric Aspheric Square Edge Single Piece Foldable	TEDOF 603SQYP, TEDOF 602SQYP	
CLAR IOL	Intraocular Lens - Preloaded	JMEDT 6025YP, JMEDT 6030YP	

1. Device Identification

Trade Name: FREEDOM ACE, FREEDOM MULTIFOCAL, FREEDOM TORIC, FREEDOM TORIC MULTIFOCAL, FREEDOM TRIFLEX, FREEDOM TORIC TRIFLEX, FREEDOM SULCO, FREEDOM EDOF, FREEDOM TORIC EDOF, FREEDOM ACE+, FREEDOM MULTIFOCAL+, FREEDOM TORIC+, FREEDOM TORIC MULTIFOCAL+, FREEDOM TRIFLEX+, FREEDOM TORIC TRIFLEX+, FREEDOM EDOF+, FREEDOM TORIC EDOF+, FREEDOM ZEN, FREEDOM MUTYFOCAL, FREEDOM TORYC, FREEDOM TORYC MULTIFOCAL, FREEDOM TRYFLEX, FREEDOM TRY TORYC, FREEDOM YEDOF, FREEDOM TORYC YEDOF, FREEDOM ZEN+, FREEDOM MUTYFOCAL+, FREEDOM TORYC+, FREEDOM TORYC MULTIFOCAL+, FREEDOM TRYFLEX+, FREEDOM TRY TORYC+, FREEDOM ICL, FREEDOM ARC, FREEDOM ARC+, FREEDOM ARCY, FREEDOM ARCY+, CLAR IOL

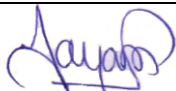
Generic Device Description: Hydrophobic Acrylic Foldable Posterior Chamber Intraocular Lens

Device Type: Implantable ophthalmic medical device

Use Category: Long-term surgically invasive implantable medical device

Sterility Status: Sterile, Ethylene oxide sterilized

Use Status: Single-use implantable device

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Expected Implant Lifetime: Permanent implantation unless clinical circumstances require repositioning, exchange, or explanation.

The intraocular lens is intended as a permanent implant designed to remain in the eye for the lifetime of the patient unless clinical circumstances require repositioning, exchange, or explanation.

Sterility Status

The Freedom Hydrophobic Acrylic Foldable Intraocular Lens product family is marketed in one validated commercial configurations. Configuration C comprises the Hydrophobic Acrylic Foldable Intraocular Lens preloaded directly into a sterile disposable injector system. Within this configuration, the intraocular lens is terminally sterilized by validated ethylene oxide sterilization in accordance with ISO 11135. The applicable sterilization method for each supplied component is clearly identified on the product labeling and packaging to ensure correct identification and safe clinical use.

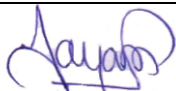
2.Product Configuration Identification

The Freedom Hydrophobic Acrylic Foldable Intraocular Lens product family is commercially supplied in distinct validated configurations to accommodate different clinical preferences and methods of implantation while maintaining the same intended medical purpose and clinical performance of the implanted intraocular lens.

Configuration C

Configuration C consists of one sterile Hydrophobic Acrylic Foldable Intraocular Lens supplied together with one sterile disposable injector and one sterile disposable cartridge as a complete validated delivery system. This configuration includes FREEDOM SULCO, FREEDOM ACE+, FREEDOM TORIC+, FREEDOM TORIC MULTIFOCAL+, FREEDOM TRIFLEX+, FREEDOM TORIC TRIFLEX+, FREEDOM EDOF+, FREEDOM TORIC EDOF+, FREEDOM YEDOF, FREEDOM ZEN+, FREEDOM TORYC+, FREEDOM TORYC MULTIFOCAL+, FREEDOM TRYFLEX+, FREEDOM TRI TORYC+, FREEDOM ARC+, FREEDOM ARCY+, Freedom SULCO-Y, FREEDOM TORYC EDOF+, CLAR IOL product family represented by the FPLS, FPMS, JMHS, FPL, FPM, JMH, 3HPC, JM3HP, TPC, JMHT, MPC, JMHM, TRPC, JMHTF, EDOF, JMED, MPC, JMHM, TRPC, JMHTF, EDOF, JMED, MTPC, JMHT, TRTPC, JMHTT, TEDOF, JMEDT model series. Configuration C is assigned Basic UDI-DI **8903491HB003RU**. The intraocular lens is terminally sterilized by validated ethylene oxide sterilization in accordance with ISO 11135, while the sterile disposable injector and sterile disposable cartridge are terminally sterilized by validated ethylene oxide sterilization in accordance with ISO 11135. The complete packaged configuration has a validated shelf life of sixty (60) months from the date of manufacture.

The preloaded disposable injector and cartridge supplied with configuration C have been specifically designed, verified and validated for use only with the compatible intraocular lens supplied within the same packaged configuration. Components from different packaged systems, commercial configurations or validated product combinations shall not be interchanged or substituted.

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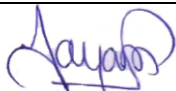
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Product Configuration matrix:

The manufacturer has established a controlled product configuration identification system to ensure complete regulatory traceability throughout the device lifecycle. Configuration C comprises the model series supplied with preloaded injector system and is identified by basic UDI-DI **8903491HB003RU**.

Each commercial configuration possesses a unique Basic UDI-DI corresponding to its validated packaging configuration, supplied components, labeling, sterilization method and regulatory documentation. The applicable Basic UDI-DI, UDI-DI, product model, labeling and packaging information provide complete traceability throughout manufacturing, distribution, implantation and post-market surveillance activities.

Si No	Configuration type	Product code / Model	Dioptric Power	Injector	Cartridge	Basic UDI	Sterilization	Shelf life
1	Configuration C	FPLS 603SQP,FPLS 602SQP,FPMS 606SQP,JMHS 6025SQP,JMHS 6030SQP,JMHS 6010SQP,FPLS 603SQYP, FPLS 602SQYP,FPMS 606SQYP,JMHS 6025SQYP,JMHS 6030SQYP,JMHS 6010SQYP,FPL 621SQP,FPL 603SQP,FPL 602SQP,FPM 606SQP,JMH 6251SQP,JMH 6025SQP,JMH 6030SQP,JMH 6010SQP,FPL 621P,JMH 6251P,FPL 603SQYP,FPL 602SQYP,FPM 606SQYP,JMH 6025SQYP,JMH 6030SQYP,JMH 6010SQYP,3HPC 630P,3HPC 640P,JM3HP 6030P,JM3HP 6040P,3HPC 630YP, 3HPC 640YP,JM3HP 6030YP,JM3HP 6040YP,TPC 603SQP,TPC 602SQP,JMHT 6025P,JMHT 6030P,TPC 603SQYP,TPC 602SQYP,JMHT 6025YP,JMHT 6030YP,MPC 603SQP,MPC 602SQP,JMHM 6025SQP,JMHM 6030SQP,MPC 603SQYP,MPC 602SQYP,JMHM 6025SQYP,JMHM 6030SQYP,TRPC 603SQP,TRPC 602SQP,JMHTF 6025P,JMHTF 6030P,TRPC 603SQYP,TRPC 602SQYP,JMHTF 6025YP,JMHTF 6030YP,EDOF 603SQP,EDOF 602SQP,JMED 6025P,JMED 6030P,EDOF 603SQYP,EDOF 602SQYP,JMED 6025YP, JMED 6030YP,MTPC 603SQP,MTPC 602SQP,JMHMT 6025P,JMHMT 6030P,MTPC 603SQYP,MTPC 602SQYP,JMHMT 6025YP,JMHMT 6030YP,TRTPC 603SQP,TRTPC 602SQP,JMHTT 6025P,JMHTT 6030P,TRTPC 603SQYP,TRTPC	- 15.00 D to + 15.00 D +15.50 D to + 23.50 D +24.00 D to +32.00 D +32.50 D to +40.00 D	FHI001 FHI001 FHI001 FHI001	FDC 240 / FDC 250 FDC 260 FDC 280 FDC 300	8903491HB003RU	EO sterilization for Intraocular Lens System - Preloaded	5 Years

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		602SQYP,JMHTT 6025YP,JMHTT 6030YP,TEDOF 603SQP,TEDOF 602SQP,JMEDT 6025P,JMEDT 6030P,TEDOF 603SQYP,TEDOF 602SQYP,JMEDT 6025YP,JMEDT 6030YP						
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3.Device Description and Material Composition

The device is a sterile, foldable, posterior chamber intraocular lens manufactured from hydrophobic acrylic biomaterial. The lens incorporates ultraviolet absorbing properties. Selected yellow models additionally include blue-light filtering chromophore technology.

The device is designed for implantation in the capsular bag following cataract extraction or phacoemulsification surgery for visual correction of aphakia.

The essential device characteristics include optic diameter, overall diameter, dioptric power, haptic design, optical performance, material composition, UV absorption characteristics, and sterile barrier configuration as defined in the approved device specifications and technical documentation.

The hydrophobic acrylic material, water content, UV absorber, blue-light chromophore applicability, and other material characteristics shall be consistent with the approved device master specification, biological evaluation, and clinical evaluation documentation.

4. Intended Purpose

A hydrophobic intraocular lens is intended used for implantation in the capsular bag in the posterior chamber of the eye to replace the natural crystalline lens for the correction of aphakia following cataract extraction.

5. Intended Users

The intraocular lens is intended for use only by qualified ophthalmic surgeons trained and experienced in cataract surgery and intraocular lens implantation.

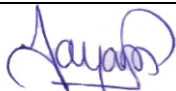
6. Intended Clinical Environment

The device is intended for use in sterile ophthalmic operating theatres, hospitals, ambulatory surgical centres, and ophthalmic surgical environments.

7. Intended Patient Population

The device is intended for adult patients requiring cataract surgery with posterior chamber intraocular lens implantation.

Safety and effectiveness in pediatric patients have not been established. Pediatric implantation should only be performed where the surgeon determines that the expected clinical benefit outweighs the potential risk based on individual clinical assessment.

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8. Expected Clinical Benefits

Expected clinical benefits include restoration of visual function following cataract removal, correction of aphakia, improvement in postoperative visual acuity, reduced dependence on aphakic spectacles or contact lenses, and improvement in functional vision and quality of life.

9. Indications

The device is indicated for implantation in adult patients undergoing cataract extraction where placement of an intraocular lens in the capsular bag is clinically appropriate.

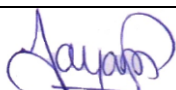
Suitability for implantation shall be determined by the surgeon based on ocular anatomy, capsular support, corneal endothelial status, retinal health, visual prognosis, systemic and ocular risk factors, and patient-specific benefit-risk assessment.

10. Contraindications

The device is contraindicated where implantation would create an unacceptable clinical risk, including active ocular infection, severe uncontrolled ocular inflammation, uncontrolled glaucoma, severe corneal endothelial compromise, insufficient capsular support, severe zonular instability, retinal disorders severely limiting visual prognosis, known hypersensitivity to device materials, severe chronic uveitis, clinically unsuitable microphthalmos, and inability to comply with postoperative follow-up.

11. Warnings

- The device is supplied sterile and is intended for single use only.
- Do not reuse or re-sterilize the lens.
- Reuse or re-sterilization may result in sterility compromise, endotoxin contamination, material degradation, altered optical or mechanical performance, cross-contamination, infection, inflammation, or patient injury.
- Do not use if the sterile barrier system is opened, damaged, wet, or compromised.
- Do not use after the expiry date.
- Posterior capsule integrity should be confirmed before implantation.
- Excessive manipulation may damage the optic or haptics.
- The surgeon should verify correct lens orientation and centration before completing implantation.
- Hydrophobic acrylic intraocular lenses may rarely demonstrate postoperative calcification, opacification, glistenings, subsurface optical changes, or other long-term material changes.
- Nd:YAG capsulotomy may increase the risk of IOL displacement, optic damage, retinal complications, or secondary intervention.
- Visual performance may be affected by postoperative lens decentration, tilt, or rotational instability.

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12. Precautions

- Store the device within validated storage conditions.
- Protect from direct sunlight, moisture, and freezing.
- Open the package only under sterile conditions.
- Handle the lens using non-serrated ophthalmic forceps.
- Avoid contact with sharp instruments.
- Do not reshape or mechanically deform the haptics.
- Avoid excessive force during handling, loading, or implantation.
- Use only compatible ophthalmic viscosurgical devices.
- Verify lens model, dioptric power, UDI, lot number, expiry date, and sterile barrier integrity before use.
- Ensure complete removal of viscoelastic material after implantation to reduce the risk of postoperative intraocular pressure elevation.

13. Residual Risks and Benefit-Risk Communication

Potential residual risks include posterior capsule opacification, dysphotopsia, glare, halos, refractive surprise, IOL decentration, tilt, rotational instability, endothelial cell loss, cystoid macular edema, retinal detachment, endophthalmitis, elevated intraocular pressure, corneal edema, secondary glaucoma, calcification, glistenings, opacification, Nd:YAG-related complications, and secondary surgical intervention.

The residual risks associated with implantation are considered acceptable when weighed against the expected clinical benefits of cataract removal and visual rehabilitation.

Long-term safety and performance of the device continue to be monitored through the manufacturer's post-market surveillance and post-market clinical follow-up systems

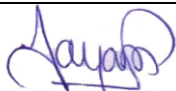
14. Potential Adverse Events and Surgical Complications

Potential adverse events and surgical complications include corneal endothelial damage, corneal edema, hyphema, raised intraocular pressure, cystoid macular edema, uveitis, iris trauma, endophthalmitis, retinal detachment, vitreous loss, capsular rupture, wound leakage, lens decentration or dislocation, incorrect refractive outcome, posterior capsule opacification, inflammation, pain, visual disturbance, and need for secondary medical or surgical intervention.

Pre-existing clinical risk factors such as pseudoexfoliation syndrome, high myopia, zonular weakness, prior ocular trauma, retinal disease, glaucoma, and corneal endothelial compromise should be considered during patient selection and surgical planning.

15. Mode of Action

The intraocular lens functions as an optical refractive implant replacing the natural crystalline lens removed during cataract surgery. The device focuses incident light onto the retina to support restoration of visual function.

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No enhanced depth-of-focus or multifocal performance claim is made unless specifically supported by validated optical and clinical evidence.

16. Optical Performance

Optical bench testing is conducted in accordance with applicable ISO 11979 requirements, including ISO 11979-2 where applicable.

MTF testing is performed under standardized laboratory optical bench conditions using a 3 mm aperture. Test conditions, wavelength, medium, model eye assumptions, and monochromatic or polychromatic conditions shall be consistent with the approved optical performance verification report.

Representative optical performance: $MTF \geq 0.43$ at 3 mm aperture.

Laboratory optical performance values represent controlled test conditions and may not directly predict individual postoperative clinical outcomes.

17. Packaging and Sterile Barrier System

The intraocular lens is supplied sterile in its validated primary sterile barrier system. The IOL may be supplied in a Polypropylene fold case lens container or blister configuration containing sterile, as applicable to the approved product configuration.

The sterile barrier system is designed to maintain sterility until the labeled expiry date when stored under specified conditions and when the packaging remains unopened and undamaged.

Before use, inspect the outer carton, pouch, Polypropylene fold case, Blister, lens container, and sterile barrier integrity. Do not use if the package is opened, damaged, wet, punctured, or otherwise compromised.

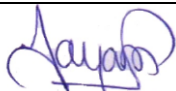
18. Sterility Information

The applicable sterilization method depends upon the validated commercial configuration supplied to the user. Configuration C consists solely of the Hydrophobic Acrylic foldable intraocular Lens with preloaded injector system, the preloaded lens is terminally sterilized by validated ethylene oxide sterilization in accordance with ISO 11135.

The sterilization method applicable to each individual component is clearly identified on the package labeling and associated product documentation. Sterility is assured only when the sterile barrier system remains intact and undamaged until the time of use. The device and all associated sterile accessories are intended for single use only and shall neither be reused nor re-sterilized.

19. Sterilization, Shelf Life and Storage

Configuration C comprises a Hydrophobic Acrylic Foldable Intraocular Lens (Preloaded) terminally sterilized by validated ethylene oxide sterilization in accordance with ISO 11135 in accordance with ISO 11135. The complete packaged system has a validated shelf life of sixty (60) months from the date of manufacture when stored under the specified storage conditions.

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The expiry date indicated on the package label applies to the complete validated packaged configuration and shall not be exceeded. Storage conditions specified on the product labeling shall be maintained throughout transportation, storage and distribution to preserve the validated sterility and performance of all supplied components.

20. Preparation Before Surgery

Before use, verify model, dioptric power, packaging integrity, expiry date, UDI, lot number, implant card labels, and compatibility with the intended injector and cartridge configuration.

Inspect the lens visually for deposits, damage, deformation, haptic defects, optic defects, discoloration, or packaging abnormalities.

Do not implant a lens that appears damaged or contaminated.

21. Implantation Instructions

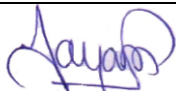
- Open the sterile package under aseptic conditions.
- Remove the lens container using sterile technique.
- Handle the lens only with appropriate non-serrated ophthalmic instruments.
- Maintain lens hydration and avoid drying of the hydrophobic acrylic lens.
- Load the lens only into the validated compatible cartridge in the correct orientation.
- Confirm correct optic and haptic orientation before injection.
- Do not pinch, twist, scrape, or excessively compress the optic or haptics.
- Implant the lens slowly and in a controlled manner into the capsular bag.
- Confirm complete unfolding, centration, and stability of the lens before completing surgery.
- Remove residual viscoelastic material according to standard surgical practice.

22. Repositioning and Explanation

- If repositioning or explanation becomes necessary, avoid excessive manipulation of ocular tissues and device components.
- Assess capsular integrity before repositioning.
- Prevent posterior dislocation into the vitreous cavity.
- Replacement, exchange, or explanation should be performed only by experienced ophthalmic surgeons.

23. Postoperative Monitoring

Postoperative follow-up should include visual acuity assessment, intraocular pressure monitoring, corneal assessment, anterior chamber inflammation assessment, capsular bag assessment, IOL position assessment, retinal evaluation, and monitoring for posterior capsule opacification, infection, inflammation, or visual symptoms.

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Patients should be advised to report pain, redness, sudden vision reduction, flashes, floaters, glare, halos, or any unexpected postoperative symptom

24. MRI Safety Information

The intraocular lens does not contain metallic or ferromagnetic components known to present MRI hazards under normal conditions of use.

25. 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.

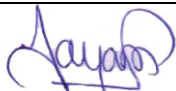
The patient should be instructed to retain the implant card and present it to healthcare professionals during future ophthalmic care or relevant medical procedures.

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. Plot No.31,Phase-I,SIPCOT Industrial Complex, Tamil Nadu, 635126,India. e-mail:freedomophthalmic.com Website:www.freedomophthalmic.com Tel:+91 95855 99301 EU REP CMC Medical Devices & Drugs S.L. C/Horacio Lengo Nº 18, CP. 29008, 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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PART B: PRELOADED INJECTOR SYSTEM

26. Accessory Device Identification

- **Accessory Device:** Preloaded Intraocular Lens Delivery System
- **Generic Description:** Integrated Preloaded IOL Injector and Delivery System
- **Use Status:** Single-use disposable system
- **Sterility Status:** Ethylene oxide sterilized
- **Reusable Status:** Not reusable
- **Re-sterilization Status:** Not permitted

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CRITICAL NOTE: The preloaded injector is a fully integrated, single-use system containing a factory-loaded intraocular lens. Do not attempt to dismantle the injector, remove the lens, or reuse the delivery system under any circumstances.

27. Accessory Intended Purpose

The Preloaded Injector System is intended to assist qualified ophthalmic surgeons in the controlled, automated folding and implantation of the integrated Freedom Ophthalmic foldable hydrophobic acrylic intraocular lens directly into the capsular bag during cataract surgery.

The preloaded system eliminates the need for manual lens handling, loading, and folding, providing a direct, validated, factory-sterile delivery pathway from packaging to the patient's eye.

28. Accessory Intended User and Environment

The preloaded injector system is intended for use exclusively by qualified ophthalmic surgeons or trained sterile theatre personnel under the direct supervision of the operating surgeon.

The accessory shall be used only within a regulated, sterile ophthalmic surgical environment (operating room).

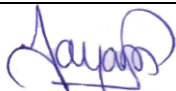
29. Compatibility and Validated Configuration

The Preloaded Injector System is a self-contained unit verified and validated for specific dioptric power ranges. The exact injector body style, internal nozzle geometry, and plunger mechanism are pre-configured by the manufacturer based upon the lens geometry, haptic configuration, and dioptric power.

Selection of the appropriate injector and cartridge is determined through validated design verification and design validation activities and is based upon the specific intraocular lens model, optic diameter, overall lens diameter, haptic configuration, lens geometry, dioptric power, validated delivery force, cartridge internal geometry, injector compatibility and intended surgical incision size.

For intraocular lenses having a dioptric power from **–15.00 D to +15.00 D**, the validated delivery system consists of injector model **FHI001** used together with cartridge model **FDC240 and FDC250**. For intraocular lenses having a dioptric power greater than **+15.00 D up to +23.50 D**, the validated combination comprises injector model **FHI001** together with cartridge model **FDC260**. For intraocular lenses having a dioptric power greater than **+24.00 D up to +32.00 D**, the validated combination comprises injector model **FHI001** together with cartridge model **FDC280**. For intraocular lenses having a dioptric power greater than **+32.00 D up to +40.00 D**, the validated combination comprises injector model **FHI001** together with cartridge model **FDC300**.

Use of this system outside the manufacturer-specified dioptric ranges, or attempting to use parts of the system in combination with third-party components, has not been demonstrated to be safe or effective. It may result in lens damage, structural failure of the nozzle tip, or unpredictable surgical incision stress.

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30. Accessory Contraindications

The preloaded injector system shall not be used if the sterile barrier packaging is opened, damaged, wet, punctured, expired, or otherwise compromised.

The system shall not be used if the injector body or nozzle tip shows visible signs of cracking, deformation, stress whitening, structural distortion, or fluid leakage.

The system shall not be used if the internal IOL appears shifted, displaced, or structurally altered within the preloaded staging chamber prior to OVD activation.

The system shall not be used outside a sterile ophthalmic surgical environment.

The injector system shall not be reused or re-sterilized.

31. Accessory Warnings

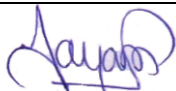
- Do not reuse.
- Do not re-sterilize.
- Reuse or re-sterilization may cause loss of sterility assurance, mechanical material degradation, toxic anterior segment syndrome (TASS), cross-contamination, material brittleness, plunger malfunction, or severe intraocular tissue injury.
- Use only the manufacturer-validated OVD
- Excessive injection force may damage the integrated IOL.
- Do not force advancement
- Wrong cartridge size selection
- Incorrect injector assembly
- Incompatibility with surgical size
- Cartridge damage during lens loading
- Cartridge tip fracture

32. Injector and Cartridge Specific Residual Risks

The following specific residual risks have been evaluated within the Risk Management File and remain acceptable when weighed against the clinical benefits of cataract extraction and visual rehabilitation:

Potential risks associated with injector and cartridge use include:

- Incorrect cartridge selection.
- Incorrect injector selection.
- Lens loading errors.
- Haptic entrapment.
- Haptic breakage.
- Optic damage.
- Cartridge tip damage.
- Excessive injection force.
- Incomplete lens delivery.

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- Incorrect lens orientation.
- Device malfunction.
- Ethylene oxide residual exposure.
- Surgical delay resulting from accessory failure.

Risk control measures include:

- Compatibility matrix verification.
- Validated injector/cartridge combinations.
- Surgeon training.
- Label warnings.
- UDI traceability.
- Sterility assurance validation.
- Packaging integrity verification.
- Shelf-life validation.

The information contained within these Instructions for Use has been developed directly from the manufacturer's approved Risk Management File established and maintained in accordance with ISO 14971. The warnings, precautions, contraindications, compatibility requirements, sterilization information, residual risks, symbols, Implant Card requirements and user instructions included within this document represent implemented risk control measures that have been identified through the manufacturer's risk management process and verified through design verification, design validation, usability engineering, biological evaluation, sterilization validation, packaging validation and post-market surveillance activities.

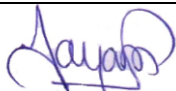
Users shall carefully read and comply with all instructions contained within this Instructions for Use in order to ensure safe implantation, maintain the validated performance of the device and its associated delivery system, and minimize the residual risks associated with implantation and clinical use.

33. Accessory Precautions

- Visually inspect the outer packaging and the transparent window of the injector to verify the IOL is properly positioned in the staging area prior to opening.
- Apply the specified volume of sterile OVD directly into the dedicated activation ports/lumen as designated by the model instructions to ensure complete lubrication of the path.
- Ensure the OVD application is performed immediately prior to injection to prevent drying or crystallization of the viscoelastic material.
- Advance the plunger smoothly, slowly, and continuously.
- Avoid jerky or erratic advancements.
- Do not allow the nozzle tip to forcefully contact or scrape intraocular tissues during insertion.

34. Accessory Packaging and Sterility

- The preloaded injector system is supplied sterile in a validated sterile barrier packaging system.
- The integrated system is terminally sterilized using validated processes in compliance with ISO 11135 (Ethylene Oxide).

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- The sterile barrier system is validated to maintain sterility until the printed expiry date, provided the packaging remains unopened, unpunctured, and stored under specified environmental parameters.
- Do not use if the sterile barrier is opened, damaged, wet, or compromised.

35. Accessory Sterilization, Shelf Life and Storage

Sterilization Method:

Validated Ethylene Oxide Sterilization (ISO 11135).

Shelf Life:

60 months from the date of manufacture for the fully integrated preloaded system.

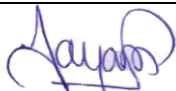
Storage Conditions:

- Store between 5°C and 40°C.
- Keep dry.
- Protect from direct sunlight and ambient ultraviolet radiation sources.

The complete product configuration, including the intraocular lens, injector and cartridge, has a validated shelf life of 60 months from the date of manufacture when stored under the specified storage conditions. The expiry date shown on the package label applies to the entire packaged system. Do not use the product after the labelled expiry date.

36. Accessory Loading and Injection Instructions

1. Open the preloaded injector pouch under strict aseptic conditions and transfer the device to the sterile field.
2. Visually inspect the injector body and nozzle tip for any structural defects or particulate matter.
3. Locate the designated OVD injection port(s) on the injector housing.
4. Inject a sufficient amount of validated sterile OVD into the port to thoroughly coat the nozzle lumen, staging chamber, and lens optic.
5. Allow the system to sit for the manufacturer-specified wait time to ensure complete wetting of the hydrophobic acrylic lens surface.
6. Activate the system mechanical lock/latch to move the lens from the storage state to the fully staged injection position.
7. Advance the plunger slowly until the lens optic is visibly folded and positioned within the clear transition zone of the nozzle.
8. Carefully introduce the nozzle tip through the prepared surgical incision.
9. Depress or rotate the plunger mechanism steadily and slowly to deliver the intraocular lens into the capsular bag in a controlled manner.
10. Halt the procedure immediately if unexpected mechanical resistance or structural blockage is felt.
11. Gently withdraw the injector tip from the incision line without catching wound edges or intraocular tissues.

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12. Verify complete unfolding, appropriate haptic positioning, centration, and overall rotational stability of the deployed IOL.

37. Visual Instruction Requirement

The final printed Instructions for Use (IFU) must feature clear, validated graphic illustrations detailing:

- Exact location of OVD injection port(s) and directional flow arrows.
- Proper orientation of the OVD syringe tip during lubrication.
- The manual mechanism step for shifting the device from "Storage/Staging" position to "Active Injection" position.
- Visual benchmarks showing a correctly advanced/folded lens versus a bypassed/damaged lens within the nozzle tip.
- Correct angling of the nozzle tip relative to the primary clear corneal incision.
- Final expected anatomical deployment behavior inside the capsular bag.

38. Accessory Disposal

- Used preloaded injectors contain biological contaminants, including patient ocular fluids and viscoelastic chemical residues.
- Dispose of the spent injector system immediately following the surgical procedure in accordance with institutional infection control protocols, biohazard medical waste standards, and all applicable regional environmental laws.
- Do not attempt to clean, reprocess, flush, or salvage any component of the expended device.

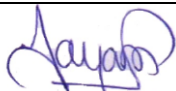
PART C: GENERAL INFORMATION APPLICABLE TO BOTH DEVICE AND ACCESSORY

39. Electronic IFU

- A paper IFU accompanies the device unless otherwise permitted by applicable regulation.
- The current approved electronic IFU is available on the manufacturer's website.
- The electronic IFU is maintained under document revision control and is available in applicable market languages.
- The website shall identify the IFU document number, revision number, date of issue, device trade name, model applicability, and language version.
- A printed copy of the IFU should be made available upon request within a reasonable time and without additional cost, where required by applicable regulatory requirements.

40. Vigilance Reporting

Any serious incident occurring in relation to the device or accessory should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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Healthcare professionals should also report device malfunctions, unexpected clinical events, packaging failures, suspected sterility issues, and recurrent usability issues to the manufacturer for PMS and PMCF evaluation.

41. PMS and PMCF Statement

The manufacturer maintains post-market surveillance and post-market clinical follow-up systems to monitor long-term safety, performance, residual risks, clinical benefits, adverse events, device deficiencies, and state-of-the-art developments.

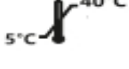
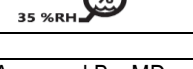
Clinical experience and post-market data are periodically reviewed to confirm continued acceptability of the benefit-risk profile.

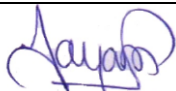
42. Symbol Information

The final printed IFU shall include actual ISO 15223-1 compliant symbols and their meanings.

The symbol table shall include, as applicable:

For Preloaded Hydrophobic Intraocular Lens:

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

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	Country of Manufacturer		Country Code
	Patient number		Disposal Injector & Cartridge

43. Manufacturer and Regulatory Information


Freedom Ophthalmic Pvt. Ltd.
Mfg.Lic.No.: MFG/MD/2020/000139
 Plot No. 31, Phase-I, Sipcot Industrial Complex,
 Hosur - 635126, Tamil Nadu, India.
 e-mail:fred@freedomophthalmic.com
 Website:www.freedomophthalmic.com
 SRN Number : IN - MF - 000013361



Authorized Representative:

CMC Medical Devices & Drugs S.L
C/Horacio Lengo N° 18, CP 29006, Malaga, Spain
 Email: info@CMCmedicaldevices.com
 Phone: +34951214054
 SRN Number: ES-AR-000000293



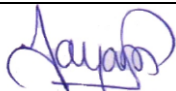
2460 Notified Body:

DNV Product Assurance AS
 Veritasveien 1, 1363 Høvik, Norway
 Tel +47 67 57 88 00. www.dnv.com

SRN, UDI-DI, Basic UDI-DI, CE marking details, implant card traceability details, and applicable regulatory identifiers shall be provided on the approved device labeling, implant card, and technical documentation.

44. Regulatory Alignment Statement

This IFU is structured to support compliance with MDR 2017/745 Annex I Section 23.4, Annex II Section 2, Article 18 implant card expectations, ISO 11979 requirements, ISO 15223-1, EN ISO 20417, ISO 11135, MDR risk communication principles, PMS/PMCF expectations, and contemporary Notified Body technical documentation review practices.

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