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| <b>TECHNICAL CONSTRUCTION FILE</b><br><b>(FOPL/TCF/02)</b> | Issue No.: 03<br>Dated :02-05-2022<br>Rev.No.:04<br>Rev Dt :23-09-2026 |  <b>Freedom Ophthalmic Pvt. Ltd.</b><br>Plot No. 31, Phase -I, Sipcot Industrial Complex,<br>Hosur – 635 126, Tamilnadu, INDIA |
| <b>INSTRUCTIONS FOR USE</b><br><b>(Doc No FOPL/IFU/02)</b> | Section No.: 2.1<br>Page 1 of 21                                       |                                                                                                                                                                                                                 |

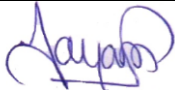
**HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES - WITH OR WITHOUT INJECTOR & CARTRIDGE .**

**ENGLISH**

**INSTRUCTIONS FOR USE APPLICABLE FOR THE FOLLOWING MODELS:**

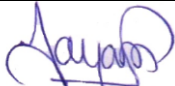
**Configuration A & B**

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

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| G.H.Syed Fayaz            |                                                                                     | G. Kannayiram   |                                                                                       |

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| <b>INSTRUCTIONS FOR USE</b><br><b>(Doc No FOPL/IFU/02)</b> | Section No.: 2.1<br>Page 2 of 21                                       |                                                                                                                                                                                                                 |

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|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|---------------------------------------------------------------------|
| FREEDOM<br>MULTIFOCAL          | Hydrophobic Acrylic<br>Posterior Chamber Multifocal<br>Diffractive-Refractive<br>Aspheric Square Edge Single<br>Piece Foldable Intraocular<br>Lens           | MPC 603SQ, MPC 602SQ          | IOLs APHAKIC,<br>MULTIFOCAL,<br>ASPHERIC,<br>HYDROPHOBIC<br>ACRYLIC |
| CLAR IOL                       |                                                                                                                                                              | JMHM 6025SQ, JMHM 6030SQ      |                                                                     |
| FREEDOM<br>MULTYFOCAL          | Yellow Hydrophobic Acrylic<br>Posterior Chamber Multifocal<br>Diffractive-Refractive<br>Aspheric Square Edge Single<br>Piece Foldable Intraocular<br>Lens    | MPC 603SQY, MPC 602SQY        |                                                                     |
| CLAR IOL                       |                                                                                                                                                              | JMHM 6025SQY, JMHM<br>6030SQY |                                                                     |
| FREEDOM<br>TRIFLEX             | Hydrophobic Acrylic<br>Posterior Chamber Trifocal<br>Diffractive-Refractive<br>Aspheric 360° Square Edge<br>Single Piece Foldable<br>Intraocular Lens        | TRPC 603SQ, TRPC 602SQ        |                                                                     |
| CLAR IOL                       |                                                                                                                                                              | JMHTF 6025, JMHTF 6030        |                                                                     |
| FREEDOM<br>TRYFLEX             | Yellow Hydrophobic Acrylic<br>Posterior Chamber Trifocal<br>Diffractive-Refractive<br>Aspheric 360° Square Edge<br>Single Piece Foldable<br>Intraocular Lens | TRPC 603SQY, TRPC 602SQY      |                                                                     |
| CLAR IOL                       |                                                                                                                                                              | JMHTF 6025Y, JMHTF 6030Y      |                                                                     |
| FREEDOM<br>EDOF                | Edof Hydrophobic Acrylic<br>Posterior Chamber Aspheric<br>Square 360° Edge Single<br>Piece Foldable Intraocular<br>Lens                                      | EDOF 603SQ, EDOF 602SQ        |                                                                     |
| CLAR IOL                       |                                                                                                                                                              | JMED 6025, JMED 6030          |                                                                     |
| FREEDOM<br>YEDOF               | Edof Yellow Hydrophobic<br>Acrylic Posterior Chamber<br>Aspheric Square Edge single<br>Piece Foldable Intraocular<br>Lens                                    | EDOF 603SQY, EDOF 602SQY      |                                                                     |
| CLAR IOL                       |                                                                                                                                                              | JMED 6025Y, JMED 6030Y        |                                                                     |
| FREEDOM<br>TORIC<br>MULTIFOCAL | Hydrophobic Acrylic<br>Posterior Chamber Multifocal<br>Toric Aspheric Square Edge<br>Single Piece Foldable<br>Intraocular Lens                               | MTPC 603SQ, MTPC 602SQ        | IOLs APHAKIC,<br>MULTIFOCAL,<br>TORIC,<br>HYDROPHOBIC<br>ACRYLIC    |
| CLAR IOL                       |                                                                                                                                                              | JMHMT 6025, JMHMT 6030        |                                                                     |
| FREEDOM<br>TORYC<br>MULTIFOCAL | Yellow Hydrophobic Acrylic<br>Posterior Chamber Multifocal<br>Toric Aspheric Square Edge<br>Single Piece Foldable<br>Intraocular Lens                        | MTPC 603SQY, MTPC 602SQY      |                                                                     |
| CLAR IOL                       |                                                                                                                                                              | JMHMT 6025Y, JMHMT 6030Y      |                                                                     |
| FREEDOM TRI<br>TORIC           | Hydrophobic Acrylic<br>Posterior Chamber Trifocal                                                                                                            | TRTPC 603SQ, TRTPC 602SQ      |                                                                     |

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| <b>INSTRUCTIONS FOR USE</b><br><b>(Doc No FOPL/IFU/02)</b> | Section No.: 2.1<br>Page 3 of 21                                       |                                                                                                                                                                                                                     |

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|---------------------|------------------------------------------------------------------------------------------------------------------------------|----------------------------|--|
| CLAR IOL            | Toric Aspheric 360° Square Edge Single Piece Foldable Intraocular Lens                                                       | JMHTT 6025, JMHTT 6030     |  |
| FREEDOM TRI TROYC   | Yellow Hydrophobic Acrylic Posterior Chamber Trifocal Toric Aspheric 360° Square Edge Single Piece Foldable Intraocular Lens | TRTPC 603SQY, TRTPC 602SQY |  |
| CLAR IOL            | Edof Hydrophobic Acrylic Posterior Chamber Toric Aspheric Square Edge Single Piece Foldable Intraocular Lens                 | JMHTT 6025Y, JMHTT 6030Y   |  |
| FREEDOM TORIC EDOF  | Yellow Edof Hydrophobic Acrylic Posterior Chamber Toric Aspheric Square Edge Single Piece Foldable Intraocular Lens          | TEDOF 603SQ, TEDOF 602SQ   |  |
| CLAR IOL            | Yellow Edof Hydrophobic Acrylic Posterior Chamber Toric Aspheric Square Edge Single Piece Foldable Intraocular Lens          | JMEDT 6025, JMEDT 6030     |  |
| FREEDOM TORYC YEDOF | Yellow Edof Hydrophobic Acrylic Posterior Chamber Toric Aspheric Square Edge Single Piece Foldable Intraocular Lens          | TEDOF 603SQY, TEDOF 602SQY |  |
| CLAR IOL            | Yellow Edof Hydrophobic Acrylic Posterior Chamber Toric Aspheric Square Edge Single Piece Foldable Intraocular Lens          | JMEDT 6025Y, JMEDT 6030Y   |  |

## 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

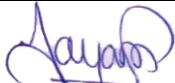
Use Status: Single-use implantable device

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 two validated commercial configurations. Configuration A comprises the Hydrophobic Acrylic Foldable Intraocular Lens supplied without an injector or cartridge and is terminally sterilized by validated

|                           |                                                                                     |                 |                                                                                       |
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Ethylene Oxide sterilization in accordance with ISO 11135. Configuration B comprises the Hydrophobic Acrylic Foldable Intraocular Lens supplied together with a sterile disposable injector and sterile disposable cartridge., whereas the sterile disposable injector and sterile disposable cartridge are terminally sterilized by validated ethylene oxide sterilization in accordance with ISO 11135. 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.

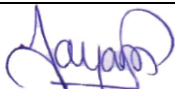
## 2.Product Configuration Identification

The Freedom Hydrophobic Acrylic Foldable Intraocular Lens product family is commercially supplied in three 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 A** consists of one sterile Hydrophobic Acrylic Foldable Intraocular Lens supplied without a sterile disposable injector or sterile disposable cartridge. This configuration includes the FREEDOM ACE, FREEDOM MULTIFOCAL, FREEDOM TORIC, FREEDOM TORIC MULTIFOCAL, FREEDOM TRIFLEX, FREEDOM SULCO, FREEDOM EDOF, FREEDOM TORIC EDOF, FREEDOM ZEN, FREEDOM MUTYFOCAL, FREEDOM TORYC, FREEDOM TORIC MULTYFOCAL, FREEDOM TRYFLEX, FREEDOM TRI TORYC, FREEDOM YEDOF, FREEDOM TORYC YEDOF, FREEDOM ICL, FREEDOM ARC, FREEDOM ARCY, FREEDOM SULCO-Y, CLAR IOL product families represented by the FPLS, FPMS, JMHS, FPL, FPM, JMH, 3HPC, JM3HP, TPC, JMHT, MPC, JHMH, TRPC, JMHTF, EDOF, JMED, MTPC, JMHMT, TRTPC, JMHTT, TEDOF and JMEDT model series. Configuration A is assigned Basic UDI-DI **8903491HB002RS**, is terminally sterilized by validated ethylene oxide sterilization in accordance with ISO 11135, and has a validated shelf life of the sixty (60) months from the date of manufacture.

**Configuration B** 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 the FREEDOM ACE, FREEDOM MULTIFOCAL, FREEDOM TORIC, FREEDOM TORIC MULTIFOCAL, FREEDOM TRIFLEX, FREEDOM SULCO, FREEDOM EDOF, FREEDOM TORIC EDOF, FREEDOM ZEN, FREEDOM MUTYFOCAL, FREEDOM TORYC, FREEDOM TORIC MULTYFOCAL, FREEDOM TRYFLEX, FREEDOM TRI TORYC, FREEDOM YEDOF, FREEDOM TORYC YEDOF, FREEDOM ICL, FREEDOM ARC, FREEDOM ARCY, FREEDOM SULCO-Y, CLAR IOL product family represented by the FPLS, FPMS, JMHS, FPL, FPM, JMH, 3HPC, JM3HP, TPC, JMHT, MPC, JHMH, TRPC, JMHTF, EDOF, JMED, MTPC, JMHMT, TRTPC, JMHTT, TEDOF and JMEDT model series. Configuration B is assigned Basic UDI-DI **8903491HB001RQ**. 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 sterile disposable injector and cartridge supplied within Configuration B have been specifically designed, verified and validated for use only with the compatible intraocular lens supplied within the

|                           |                                                                                     |                 |                                                                                       |
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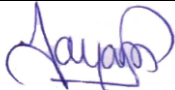
same packaged configuration. Components from different packaged systems, commercial configurations or validated product combinations shall not be interchanged or substituted.

### Product Configuration matrix:

The manufacturer has established a controlled product configuration identification system to ensure complete regulatory traceability throughout the device lifecycle. Configuration A comprises the FPLS, FPMS, JMHS, FPL, FPM, JMH, 3HPC, JM3HP, TPC, JMHT, MPC, JHMH, TRPC, JMHTF, EDOF, JMED, MTPC, JMHMT, TRTPC, JMHTT, TEDOF and JMEDT model series supplied as stand-alone intraocular lenses without an injector or cartridge and is identified by Basic UDI-DI **8903491HB002RS**. Configuration B comprises the FPLS, FPMS, JMHS, FPL, FPM, JMH, 3HPC, JM3HP, TPC, JMHT, MPC, JHMH, TRPC, JMHTF, EDOF, JMED, MTPC, JMHMT, TRTPC, JMHTT, TEDOF and JMEDT model series supplied together with the validated sterile disposable injector and sterile disposable cartridge delivery system and is identified by Basic UDI-DI **8903491HB001RQ**.

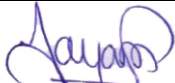
Each commercial configuration possesses a unique Basic UDI-DI corresponding to its validated packaging configuration, supplied components, labeling, sterilization method and regulatory documentation. The applicable Basic UDI-DI, UDI-DI, product model, labeling and packaging information provide complete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

| Si No | Configuration type | Product code / Model                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Dioptic Power        | Injector | Cartridge | Basic UDI      | Sterilization            | Shelf life |
|-------|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------|-----------|----------------|--------------------------|------------|
| 1     | Configuration A    | FPLS603SQ,FPLS 602SQ,FPMS 606SQ,JMHS 6025SQ,JMHS 6030SQ,JMHS 6010SQ,FPLS 603SQY,FPLS 602SQY,FPMS 606SQY,JMHS 6025SQY,JMHS 6030SQY,JMHS 6010SQY,FPL 603SQ,FPL 602SQ,FPM 606SQ,JMH 6025SQ,JMH 6030SQ,JMH 6010SQ,FPL 603SQY,FPL 602SQY,FPM 606SQY,JMH 6025SQY, JMH 6030SQY,JMH 6010SQY,3HPC 630,3HPC 640,JM3HP 6030,JM3HP 6040,3HPC 630Y,3HPC 640Y,JM3HP 6030Y,JM3HP 6040Y,TPC 603SQ,TPC 602SQ,JMHT 6025,JMHT 6030,TPC 603SQY,TPC 602SQY,JMHT 6025Y, JMHT 6030Y,MPC 603SQ,MPC 602SQ,JMHM 6025SQ,JMHM 6030SQ,MPC 603SQY,MPC 602SQY,JMHM 6025SQY,JMHM 6030SQY,TRPC 603SQ,TRPC 602SQ,JMHTF 6025,JMHTF 6030,TRPC 603SQY,TRPC 602SQY,JMHTF 6025Y,JMHTF 6030Y,EDOF 603SQ,EDOF 602SQ,JMED 6025,JMED 6030,EDOF 603SQY,EDOF 602SQY,JMED 6025Y,JMED 6030Y,MTPC | -15.00 D to +40.00 D | Nil      | Nil       | 8903491HB002RS | EO sterilization for IOL | 5 Year     |

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|---|---------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|------------|----------------------------|--------------------|---------------------------------------------------------------------------|------------|
|   |                     | 603SQ,MTPC 602SQ,JMHMT 6025,<br>JMHMT 6030,MTPC 603SQY,MTPC<br>602SQY,JMHMT 6025Y,JMHMT<br>6030Y,TRTPC 603SQ,TRTPC 602SQ,<br>JMHTT 6025,JMHTT 6030,TRTPC<br>603SQY,TRTPC 602SQY,JMHTT<br>6025Y,JMHTT 6030Y,TEDOF 603SQ,<br>TEDOF 602SQ,JMEDT 6025,JMEDT<br>6030,TEDOF 603SQY,TEDOF<br>602SQY,JMEDT 6025Y,JMEDT 6030Y                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                              |            |                            |                    |                                                                           |            |
| 2 | Configur<br>ation B | FPLS 603SQ,FPLS 602SQ,FPMS<br>606SQ,JMHS 6025SQ,JMHS<br>6030SQ,JMHS 6010SQ,FPLS<br>603SQY,FPLS 602SQY,FPMS<br>606SQY,JMHS 6025SQY,JMHS<br>6030SQY,JMHS 6010SQY,FPL<br>603SQ,FPL 602SQ,FPM 606SQ,JMH<br>6025SQ,JMH 6030SQ,JMH<br>6010SQ,FPL 603SQY,FPL<br>602SQY,FPM 606SQY,JMH 6025SQY,<br>JMH 6030SQY,JMH 6010SQY,3HPC<br>630,3HPC 640,JM3HP 6030,JM3HP<br>6040,3HPC 630Y,3HPC 640Y,JM3HP<br>6030Y,JM3HP 6040Y,TPC 603SQ,TPC<br>602SQ,JMHT 6025,JMHT 6030,TPC<br>603SQY,TPC 602SQY,JMHT 6025Y,<br>JMHT 6030Y,MPC 603SQ,MPC<br>602SQ,JMHM 6025SQ,JMHM<br>6030SQ,MPC 603SQY,MPC<br>602SQY,JMHM 6025SQY,JMHM<br>6030SQY,TRPC 603SQ,TRPC<br>602SQ,JMHTF 6025,JMHTF<br>6030,TRPC 603SQY,TRPC<br>602SQY,JMHTF 6025Y,JMHTF<br>6030Y,EDOF 603SQ,EDOF<br>602SQ,JMED 6025,JMED 6030,EDOF<br>603SQY,EDOF 602SQY,JMED<br>6025Y,JMED 6030Y,MTPC<br>603SQ,MTPC 602SQ,JMHMT 6025,<br>JMHMT 6030,MTPC 603SQY,MTPC<br>602SQY,JMHMT 6025Y,JMHMT<br>6030Y,TRTPC 603SQ,TRTPC 602SQ,<br>JMHTT 6025,JMHTT 6030,TRTPC<br>603SQY,TRTPC 602SQY,JMHTT<br>6025Y,JMHTT 6030Y,TEDOF 603SQ,<br>TEDOF 602SQ,JMEDT 6025,JMEDT<br>6030,TEDOF 603SQY,TEDOF<br>602SQY,JMEDT 6025Y,JMEDT 6030Y | - 15.00 D<br>to + 15.00<br>D | FHI00<br>1 | FDC<br>240 /<br>FDC<br>250 | 8903491H<br>B001RQ | EO<br>sterili<br>zation<br>for<br>IOL,<br>Inject<br>or &<br>cartri<br>dge | 5<br>Years |
|   |                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | +15.50 D<br>to + 23.50<br>D  | FHI00<br>1 | FDC<br>260                 |                    |                                                                           |            |
|   |                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | +23.50 D<br>to +32.00<br>D   | FHI00<br>1 | FDC<br>280                 |                    |                                                                           |            |
|   |                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | +32.50 D<br>to +40.00<br>D   | FHI00<br>1 | FDC<br>300                 |                    |                                                                           |            |

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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.

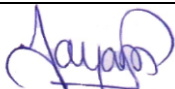
### 7. Intended Patient Population

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.

### 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.

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## 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

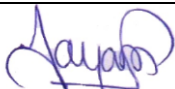
The device is contraindicated where implantation would create an unacceptable clinical risk, including active ocular infection, severe uncontrolled ocular inflammation, uncontrolled glaucoma, severe corneal endothelial compromise, insufficient capsular support, severe zonular instability, retinal disorders 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.

## 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.

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- 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, dioptic 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

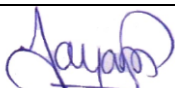
Potential adverse events and surgical complications include corneal endothelial damage, corneal edema, hyphema, raised intraocular pressure, cystoid macular edema, uveitis, iris trauma, endophthalmitis, retinal detachment, vitreous loss, capsular rupture, wound leakage, lens decentration or dislocation, 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.

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

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## 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 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 lens container, and sterile barrier integrity. Do not use if the package is opened, damaged, wet, punctured, or otherwise compromised.

## 18. Sterility Information

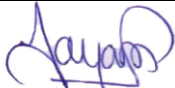
The applicable sterilization method depends upon the validated commercial configuration supplied to the user. Configuration A consists solely of the Hydrophobic Acrylic Foldable Intraocular Lens, which is terminally sterilized by validated ethylene oxide sterilization in accordance with ISO 11135. Configuration B comprises the Hydrophobic Acrylic Foldable Intraocular Lens together with a sterile disposable injector and sterile disposable cartridge. Within this configuration, the intraocular lens is terminally sterilized by validated ethylene oxide sterilization in accordance with ISO 11135, whereas the injector and cartridge are 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 A comprises a Hydrophobic Acrylic Foldable Intraocular Lens terminally sterilized by validated ethylene oxide sterilization in accordance with ISO 11135 and has a validated shelf life of the sixty (60) months from the date of manufacture.

Configuration B comprises a Hydrophobic Acrylic Foldable Intraocular Lens terminally sterilized by validated ethylene oxide sterilization in accordance with ISO 11135 together with a sterile disposable

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injector and sterile disposable cartridge terminally sterilized by validated ethylene oxide sterilization 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.

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.

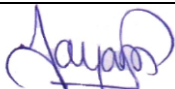
Do not implant a lens that appears damaged or contaminated.

## 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.

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## 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.

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.

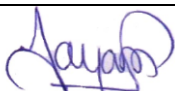
The healthcare institution or surgeon shall complete the implant card with patient identification, device name, model, lot number, UDI, manufacturer details, implantation date, and healthcare institution details.

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 : YYYY   |
| UDI-DI: _____                                                            | Mfg Date :YYYY / MM |
| Lot Number: _____                                                        | Exp Date :YYYY / MM |
| Diopter Power: _____                                                     |                     |
| Implantation Date: _____                                                 |                     |
| Patient Name: _____                                                      |                     |
| Eye Implanted:                                                           |                     |
| <input type="radio"/> Right Eye (OD) <input type="radio"/> Left Eye (OS) |                     |
| Healthcare Institution: _____                                            |                     |
| Implanting Surgeon: _____ FO/IC/001-R01 Date : 18.09.2026                |                     |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>This card identifies your implanted intraocular lens</p> <p>Always keep this card and present it to any ophthalmologist or healthcare professional involved in your eye care.</p> <p>Contact your ophthalmologist immediately if you experience</p> <ul style="list-style-type: none"> <li>Sudden Loss of vision</li> <li>Severe eye pain</li> <li>Persistent redness</li> <li>Flashes of light</li> <li>New floaters</li> <li>Significant visual disturbance</li> <li>Any unexpected ocular symptoms</li> </ul> <p><b>Freedom Ophthalmic Pvt Ltd.</b><br/>           Plot No.31,Phase-1,SIPCOT Industrial Complex,<br/>           Tamil Nadu, 635 126, India.<br/>           e-mail: <a href="mailto:fre@freedomophthalmic.com">fre@freedomophthalmic.com</a><br/>           Website: <a href="http://www.freedomophthalmic.com">www.freedomophthalmic.com</a><br/>           Tel: +91 95855 99301</p> <p><b>EU REP</b><br/>           CMC Medical Devices &amp; Drugs S.L.<br/>           C/Horacio Lengo N° 18, CP 29006, Malaga, Spain<br/>           Email: <a href="mailto:info@CMCmedicaldevices.com">info@CMCmedicaldevices.com</a><br/>           Phone: +34951214054</p> <p>Keep this implant card permanently and present it to healthcare professionals whenever relevant medical treatment is received</p> |
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## PART B: STERILE DISPOSABLE INJECTOR AND CARTRIDGE SYSTEM

| Trade /<br>Brand Name | Generic Name           | Models                                              | Variants                            |
|-----------------------|------------------------|-----------------------------------------------------|-------------------------------------|
| FREEDOM<br>I-JET      | Intraocular Lens Guide | FHI001, FDC240, FDC250, FDC260,<br>FDC 280, FDC 300 | Disposal<br>Injector &<br>Cartridge |

### 26. Accessory Device Identification

Accessory Device: Sterile Disposable Injector and Cartridge System

Trade Name: FREEDOM I-JET

Generic Description: Intraocular Lens Injector and Cartridge System

Use Status: Single-use disposable accessory

Sterility Status: Ethylene oxide sterilized

Reusable Status: Not reusable

Re-sterilization Status: Not permitted

The injector and cartridge are single-use disposable accessories and shall not be reused.

### 27. Accessory Intended Purpose

The sterile disposable injector and cartridge are intended to assist qualified ophthalmic surgeons in the loading, folding, and controlled implantation of compatible Freedom Ophthalmic foldable hydrophobic acrylic intraocular lenses during cataract surgery.

The injector and cartridge provide a validated sterile delivery pathway for compatible IOLs when used in the specified configuration.

### 28. Accessory Intended User and Environment

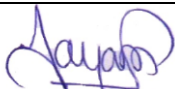
The injector and cartridge are intended for use only by qualified ophthalmic surgeons or trained sterile theatre personnel under the supervision of the operating surgeon.

The accessory shall be used only in a sterile ophthalmic surgical environment.

### 29. Compatibility and Validated Configuration

The Freedom I-JET Sterile Disposable Injector and Cartridge System has been specifically designed, verified and validated for use only with compatible Freedom Ophthalmic Hydrophobic Acrylic Foldable Intraocular Lens models supplied within Configuration B.

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.

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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 any injector, cartridge or delivery system combination other than those validated by the manufacturer has not been demonstrated to be safe or effective and may adversely affect lens loading, lens delivery performance, device integrity, surgical incision characteristics, implantation safety and clinical outcome.

### 30. Accessory Contraindications

The injector and cartridge shall not be used if the package is opened, damaged, wet, punctured, expired, or otherwise compromised.

The injector and cartridge shall not be used with incompatible IOLs.

The injector and cartridge shall not be reused or re-sterilized.

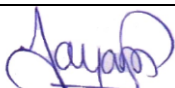
The injector and cartridge shall not be used if there is visible deformation, cracking, blockage, contamination, roughness, malfunction, incomplete assembly, or plunger movement abnormality.

The injector and cartridge shall not be used outside a sterile ophthalmic surgical environment.

### 31. Accessory Warnings

- Do not reuse.
- Do not re-sterilize.
- Reuse or re-sterilization may result in loss of sterility assurance, material degradation, altered mechanical performance, endotoxin contamination, cross-contamination, device malfunction, ocular tissue injury, or patient infection.
- Use only the validated IOL, cartridge, injector, and OVD combination.
- Excessive injection force may damage the IOL or ocular tissues.
- Do not continue injection if abnormal resistance, blockage, or lens misfolding is observed.
- 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

|                           |                                                                                     |                 |                                                                                       |
|---------------------------|-------------------------------------------------------------------------------------|-----------------|---------------------------------------------------------------------------------------|
| Issued By: QA Manager /MR |  | Approved By: MD |  |
| G.H.Syed Fayaz            |                                                                                     | G. Kannayiram   |                                                                                       |

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The following residual risks have been identified and evaluated within the Risk Management File and remain acceptable when weighed against the clinical benefits of cataract surgery 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.
- Incorrect lens orientation.
- Device malfunction.
- Ethylene oxide residual exposure.
- Surgical delay resulting from accessory failure.

Risk control measures include:

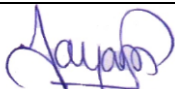
- Compatibility matrix verification.
- Validated injector/cartridge combinations.
- Surgeon training.
- Label warnings.
- UDI traceability.
- Sterility assurance validation.
- Packaging integrity verification.
- Shelf-life validation.

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

- Inspect the injector and cartridge before use.

|                           |                                                                                     |                 |                                                                                       |
|---------------------------|-------------------------------------------------------------------------------------|-----------------|---------------------------------------------------------------------------------------|
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- Apply adequate sterile ophthalmic viscosurgical device to the cartridge lumen and loading chamber.
- Load the lens only in the validated orientation.
- Confirm that the optic and haptics are not trapped, pinched, folded incorrectly, or damaged before advancing the plunger.
- Advance the plunger slowly and continuously.
- Do not force the plunger.
- Do not allow the cartridge tip to contact intraocular tissues unnecessarily.

#### 34. Accessory Packaging and Sterility

- The injector and cartridge are supplied sterile in a validated sterile barrier packaging system.
- The injector and cartridge are terminally sterilized using ethylene oxide sterilization in accordance with ISO 11135.
- The sterile barrier system is designed to maintain sterility until the labeled expiry date if the packaging remains intact and storage conditions are maintained.
- 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 in accordance with ISO 11135.

##### Shelf Life:

60 months from date of manufacture.

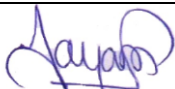
##### Combined IOL System Configurations

- Store between 5°C and 40°C.
- Keep dry.
- Protect from direct sunlight.

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

- Open the injector and cartridge package under aseptic conditions.
- Open the cartridge fully.
- Apply sterile ophthalmic viscosurgical device to the cartridge nozzle, lumen and loading chamber.

|                           |                                                                                     |                 |                                                                                       |
|---------------------------|-------------------------------------------------------------------------------------|-----------------|---------------------------------------------------------------------------------------|
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- Place the lens in the validated orientation as shown in the manufacturer-approved loading diagram.
- Confirm that the haptics are positioned correctly.
- Close the cartridge gently until it clicks or locks as designed.
- Visually confirm that no part of the optic or haptic is pinched.
- Insert the cartridge into the injector body until fully seated.
- Advance the plunger slowly until the lens enters the cartridge tip.
- Insert the cartridge tip through the recommended incision.
- Advance the plunger steadily and slowly until the lens is delivered into the capsular bag.
- Stop injection if abnormal resistance is encountered.
- After lens delivery, withdraw the cartridge carefully without contacting intraocular tissues.
- Confirm correct unfolding, centration, and stability of the IOL.

### 37. Visual Instruction Requirement

The final released IFU should include validated illustrations showing:

- correct cartridge opening
  - OVD application area
  - correct lens loading orientation
  - incorrect lens loading orientation
  - correct haptic position
  - cartridge closure
  - injector assembly
  - nozzle insertion position
  - correct lens delivery
  - final IOL unfolding and centration
- The illustrations should be controlled under the manufacturer's labeling and usability validation process.

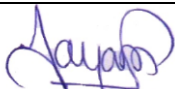
### 38. Accessory Disposal

- Used injectors and cartridges may contain biological contamination including ocular fluids and OVD residues.
- Dispose of used accessories immediately after surgery in accordance with hospital infection control procedures, biomedical waste requirements, and applicable local regulations.
- Do not attempt to clean, reuse, or reprocess the injector or cartridge.

## 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.

|                           |                                                                                     |                 |                                                                                       |
|---------------------------|-------------------------------------------------------------------------------------|-----------------|---------------------------------------------------------------------------------------|
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- 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.

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.

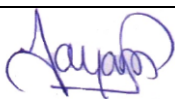
#### 42. Symbol Information

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

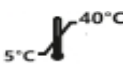
The symbol table shall include, as applicable:

##### For Intraocular Lens:

| Symbol                                                                              | Meaning                  | Symbol                                                                              | Meaning                                     |
|-------------------------------------------------------------------------------------|--------------------------|-------------------------------------------------------------------------------------|---------------------------------------------|
|  | Manufacturer             |  | Authorized representative in European Union |
|  | Medical Device           |  | Catalogue number                            |
|  | Lot Number/ Batch Number |  | Unique Device Identifier                    |

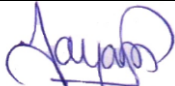
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|                                                                                     |                                                                         |                                                                                    |                                |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------|------------------------------------------------------------------------------------|--------------------------------|
|    | 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            |
|    | Country of Manufacturer                                                 |   | Country Code                   |
|  | Patient number                                                          |                                                                                    |                                |

**For Intraocular Lens with Injector & cartridge:**

| 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                                    |

|                                             |                                                                                     |                                  |                                                                                       |
|---------------------------------------------|-------------------------------------------------------------------------------------|----------------------------------|---------------------------------------------------------------------------------------|
| Issued By: QA Manager /MR<br>G.H.Syed Fayaz |  | Approved By: MD<br>G. Kannayiram |  |
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|  |                                                                         |  |                           |
|--|-------------------------------------------------------------------------|--|---------------------------|
|  | Consult instructions for use or Consult electronic instructions for use |  | Temperature limit         |
|  | Keep away from sunlight                                                 |  | CE Mark                   |
|  | Caution                                                                 |  | Humidity Limitation       |
|  | Country of Manufacturer                                                 |  | Country Code              |
|  | Patient number                                                          |  | Fragile, handle with care |

### 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](mailto:fred@freedomophthalmic.com)

Website: [www.freedomophthalmic.com](http://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](mailto: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](http://www.dnv.com)

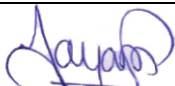
SRN, UDI-DI, Basic UDI-DI, CE marking details, implant card traceability details, and applicable regulatory identifiers shall be provided on the approved device labeling, implant card, and technical documentation.

|                           |  |                 |  |
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| G.H.Syed Fayaz            |  | G. Kannayiram   |  |

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#### 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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