

**HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES
(Preloaded System)**

Brand	Model	PRODUCT NAME
FREEDOM ACE +	FPL602SQP, FPM606SQP, FPL621P	Hydrophobic Acrylic Aspheric 360° Square edge Foldable Intraocular Lens(Preloaded)
FREEDOM ZEN+	FPL602SQYP	Yellow Hydrophobic Acrylic Aspheric 360° Square edge Foldable Intraocular Lens(preloaded)
FREEDOM ARC +	FPLS602SQP	Hydrophobic Acrylic Spheric Foldable 360° Square Edge Intraocular Lens(Preloaded)
FREEDOM TORIC +	TPC602SQP	Hydrophobic Acrylic Posterior Chamber Toric Aspheric Square Edge Single Piece Foldable Intraocular Lens (Preloaded)
FREEDOM TORIC +	TPC602SQYP	Yellow Hydrophobic Acrylic Posterior Chamber Toric Aspheric Square Edge Single Piece Foldable Intraocular Lens (Preloaded)
FREEDOM MULTIFOCAL +	MPC602SQP	Hydrophobic Acrylic Posterior Chamber Multifocal Diffractive-Refractive Aspheric Square Edge Single Piece Foldable Intraocular Lens (Preloaded)
FREEDOM MULTYFOCAL +	MPC602SQYP	Yellow Hydrophobic Acrylic Posterior Chamber Multifocal Diffractive-Refractive Aspheric Square Edge Single Piece Foldable Intraocular Lens (Preloaded)
FREEDOM TRIFLEX +	TRPC602SQP	Hydrophobic Acrylic Posterior Chamber Trifocal Diffractive-Refractive Aspheric 360° Square Edge Single Piece Foldable Intraocular Lens (Preloaded)
FREEDOM TRYFLEX +	TRPC602SQYP	Yellow Hydrophobic Acrylic Posterior Chamber Trifocal Diffractive-Refractive Aspheric 360° Square Edge Single Piece Foldable Intraocular Lens (Preloaded)
FREEDOM TORIC MULTIFOCAL +	MTPC602SQP	Hydrophobic Acrylic Posterior Chamber Multifocal Toric Aspheric Square Edge Single Piece Foldable Intraocular Lens (Preloaded)
FREEDOM TRITORIC +	TRTPC602SQP	Hydrophobic Acrylic Posterior Chamber Trifocal Toric Aspheric 360° Square Edge Single Piece Foldable Intraocular Lens (Preloaded)
FREEDOM TRITORYC +	TRTPC602SQYP	Yellow Hydrophobic Acrylic Posterior Chamber Trifocal Toric Aspheric 360° Square Edge Single Piece Foldable Intraocular Lens (Preloaded)
FREEDOM EDof +	EDOF602SQP	EDOF Hydrophobic Acrylic Posterior Chamber Aspheric Square 360 Edge Single Piece Foldable Intraocular Lens (Preloaded)



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INSTRUCTIONS FOR USE

Indications

IOL functions as a refracting medium to replace the natural lens in visual correction of Aphakia. The IOL can be placed in posterior chamber. The following indications and contra indications are based on research of medical literature and are to be used only as guides. The list is indicative and not be viewed as complete or comprehensive.

- Monocular cataract
- Mature cataract
- Congenital cataract
- Occupational Needs
- Traumatic cataract

Contraindications

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

- Chronic severe Uveitis
- Epithelial Dystrophy
- Choroidal Hemorrhage Microphthalmias
- Anirida
- Concomitant severe Eye Disease
- Glaucoma problem
- Rubella Cataract
- Massive vitreous loss
- In cataracts present in children

Warnings

1. The effectiveness of UV-absorbing intraocular lenses in reducing the incidence of retinal disorders has not been established.
2. The safety of the use of the Neodymium-YAG laser on IOLs with UV absorbing materials has not been established, the physicians is urged to use extreme caution in such cases where a patient with UV absorbing IOLs is treated with a Neodymium- YAG laser.
3. The compression force exerted on the eye tissue by the lens is not established. The physician should have knowledge in selecting type of the lens depending on the eye dimensions.
4. In the bag lenses should be used only when the posterior capsule is in good condition.
5. Care should be taken to avoid breakage of haptic while injecting and inserting lens through the Scleral tunnel or small incision.

Precautions

1. Do not store the lens in direct sunlight or at a temperature greater than 40°C. Keep away from freezing.
2. Do not use if sterile pouch is opened or damaged.
3. Only skilled Surgeons with experience in either viewing and/or assisting numerous surgical implantations and successfully completed at least a course on IOL implantation should attempt implantation of these lenses.
4. Pouch should be opened only under sterile conditions.
5. Do not soak or rinse lens is solutions other than sterile balanced salt solution or equivalent.
6. Use injectors supplied by Freedom ophthalmic for implanting foldable IOL's to minimize surgical trauma and immediate postoperative inflammations.
7. Do not attempt to re-sterilize this lens. Re-sterilization of this product has not been validated.
8. Handle the lens carefully, locking forceps or needle holders should never be used to pick up lenses.
9. Do not reshape the supporting structures (haptics).
10. The patient must be advised that the doctor or the medical centre should be informed of any side effects not referred in this information

Package

The lens is supplied in a sterile package, validity of sterilization applies as long as the seated inner peel-pouch is not disturbed or damaged. Any damage to the peel pouch or any accidental opening of peel-pouch is to be declared as " NOT STERILE".

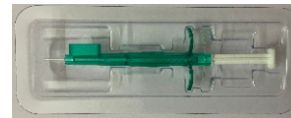
'A' Constant

'A' Constant value is estimate only. It is recommended that the Surgeon derives his own value based on his clinical experience.

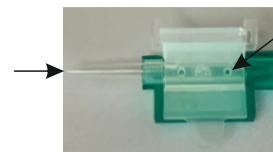
	Ultrasound	IOL Master
A Constant	118.4	SRK/T : 119.20 SRK/II : 119.50
Hoffer Q		5.65
Holladay		1 : 1.87 2 : 5.199
Haigis		a0=1.441 a1=0.400 a2=0.100

Direction of Use

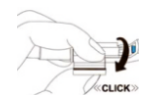
1. Open the outer package to remove the peel-pouch and verify that the information is consistent with the outer package labelling (e.g. model, Lot number, etc...). Make sure the injector is as displayed below.



2. Make sur the lens is properly loaded and the haptic and optic are inside the groove. If not, it might have been moved during transport. Remove the lens and load manually.
3. Apply first BSS in the top of the cartridge. Then fill viscoelastic solution from the distal end to the complete tip, and to the top and bottom of the lens.



4. Push the injector plunger forwards until the lateral marking notch of the plunger is flush with the end of the injector housing and the plunger engages with a light "click" in the injector housing.
5. Close the cartridge by pressing the wings together. As soon as the "click lock" mechanism clicks in place, the lens is safely loaded and ready for injection.



- IMPORTANT:** Pressing the wings together prematurely (even just slightly) before sliding the lens in can cause damage to the system and affect the functioning of the injector.
6. Press the injector plunger forward until the silicone tip of the plunger has reached the end of the injector housing.
 7. Guide the point of the cartridge through the incision and push it over the iris to the near edge of the pupil.
 8. Slowly push the injector plunger forward to push the lens forward.
 9. Slowly inject the lens into the eye and simultaneously withdraw the instrument from the eye. To avoid swelling of the silicone tip during ejection from the cartridge, only push the plunger until the lens has emerged completely, even if the plunger is not yet at the limit.
 10. If the rear haptic is jammed between the silicone tip and the cartridge tip after the plunger has been completely pushed in, retract the plunger together with the silicone tip a few millimetres until the rear haptic is exposed; then inject the rear haptic in a second thrust.

Reporting

Adverse reactions and potentially sight threatening complication that may reasonably be regarded as lens related and that were not previously expected in nature severity or degree of incidence should be reported to FREEDOM OPHTHALMIC PVT.LTD. This information is requested from the all implanting surgeons in order to document potentially long term effects of IOL implants.

Patient Identity Card

The packing contains product identification sticker for maintaining a record of the IOL implantation. Surgeons are requested to give the « patient ID card » to the patients after implantation and advise them to carry the card at all times.

Return Goods Policy

Freedom Ophthalmic Pvt. Ltd. accepts returned lenses for exchanges only. No cash refunds will be issued. To return lenses, you must obtain a return authorization number from customer services department. No returned goods will be accepted without proper authorization number. Returned lenses should be shipped by traceable method. No credit will be given to lost or damaged lenses in shipment. Lenses will be replaced as long as they are returned within 6 (six) months of their original invoice date.

Disposing of Non Sterile or Contaminated Medical Devices

There are no specific guidelines for disposing of non sterile or contaminated medical devices. Follow standard procedures for discarding outdated or contaminated products as per respective regulatory requirements.

Symbols and Meaning:

- Sterilization by ethylene oxide
- Disposable Injector & Cartridge
- Warning see instructions
- Keep away from Sunlight
- Dont use when packing damaged
- Lot Number / Batch Number
- Manufactured Date
- Temperature Limit 40°C
- Humidity limitation 65%RH
- Use until (YYYY-MM)
- Keep dry 35%RH
- Do not re-sterilize
- Do not re-use
- Manufacturer