

PMMA Intraocular Lenses

Brand	Models	Generic Name
FREEDOM LENS	PCC 503, PMC 524, PMC 553, PCC 553, PCC 603H PMC 602, PMC 602H, PMC 652H, PSF 651,	PMMA Posterior Chamber Single Piece Intraocular lens
FREEDOM LENS	PMS 603, PMS 602,	PMMA Anterior Chamber Single Piece Intraocular lens
FREEDOM POWER	PMC 523SQA, PMC 553SQA, PMC 603HSQA	360° Square Edge Aspheric PMMA Posterior Chamber Single Piece Intraocular lens
FREEDOM GOLD	PMC 523SQYA, PMC 553SQYA, PMC603 HSQYA	360° Square Edge Aspheric Yellow PMMA Posterior Chamber Single Piece Intraocular lens
FREEDOM IRIS	FIC 5585H	PMMA Iris Claw Intraocular Lens

Material used : Poly Methyl Methacrylate

Indications: It is an implant designed to be placed into the posterior chamber for cataract surgery, suitable for replacing the crystalline lens in the correction of aphakia during surgical procedures in which the crystalline lens is removed.

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,	Concomitant severe Eye Disease,	uveitis
Epithelial Dystrophy,	Glaucoma problem,	Pseudoexfoliation Syndrome
Rubella Cataract,	Choroidal Hemorrhage,	Myopia
Massive vitreous loss,	Microphthalmos, Anirida,	Retinal pigment change
In cataracts present in children.	IOL dislocation,	Eye trauma and connective tissue diseases

How Supplied: IOLs are supplied in polypropylene case contained within a heat sealed Tyvek sterilizable peel pouch and terminally sterilized using ethylene oxide(EO) the contents of the pouch are sterile unless the package is opened or damaged.

Sterilization: The device is sterilized by Ethylene Oxide (EO).

Instructions for Use:

- In a sterile environment, peel apart to open the pouch and remove the lens case.
- Unscrew the lens case with care and grasp the lens optic using smooth edged forceps and lift.
- Soak or rinse lens in sterile balanced salt solution or their equivalent solution.
- The lens, due to some charge produced while opening the lens case, may stick to the cap in rare instance.
- Ensure that the lens is in good conditions for Optic and Haptics surfaces for adherences of any particles.
- Prior to implantation examine the lens for power, model, proper configuration and optical surfaces.
- During insertion carefully handle lenses by Haptics portion only. To avoid breakage do not attempt to expand the Haptics, flex the Haptics out of the plane of the lens or twist or torque the lens.
- Packing box contains extra lables. These are for convenience in maintaining and reporting records of implantable lenses during clinical investigation. One of the lables could be affixed in patient's case sheet for future reference.

Warnings :

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

- **Don't re-sterilize the device.** Re-sterilization of the device will have a detrimental effect on its known properties thereby rendering it inappropriate for the intended use .Re-sterilization of Lens can also cause to change in mechanical & chemical properties.
- **Don't reuse the device** . if reuse of device can work as carrier for communicable disease, HIV, Chronic severe uveitis, Epithelial Dystrophy, Anirida, Hepatitis, contagious diseases, undue diseases to patient and/or user, Glaucoma problem, Rubella Cataract.
- Re-use of lens may not meet the intended use as lens may be blunt, Surgical difficulties at time of cataract extraction, which may increase the potential for complications(like: persistent bleeding, significant iris damage, uncontrolled positive pressure or significant vitreous prolaps or loss)

Precautions:

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

Adverse Event :

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

Storage:

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














Return of Damaged Product:

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

Disposal of Discarded Product and Packaging

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

Symbols and Meaning:

	Sterilization by ethylene oxide		Humidity limitation		Do not re-use
	Warning see instructions		Keep away from Sunlight		Do not re-sterilize
	Use until (YYYY-MM)		Keep dry		Manufacturer
	Do not use when packing damaged		Temperature Limit		
	Lot Number / Batch Number		Manufactured Date		

CE/REP CMC Medical Devices & Drugs S.L
C/Horacio Lengo N° 18, CP 29006, Malaga, SPAIN
info@cmcmedicaldevices.es / +34951214054

NOTIFIED BODY:
DNV Product Assurance AS
Veritasveien 3, 1363 Høvik, Norway
Tel +47 67 57 88 00. www.dnv.com



freedom Mfg. Lic. No.: MFG/MD/2020/000139
Ophthalmic Pvt. Ltd. Plot # 31, Phase 1, SIPCOT, Industrial Complex
Hosur - 635 126, Tamil Nadu, INDIA

International Sales:
5113 Brockworth Drive, Mississauga,
ON L5V1S1, CANADA
sales@freedomophthalmic.com