PMMA Capsular Tension Ring		
Brand	**Models**	**Generic Name**
FREEDOM RING	**FCR1109, FCR1210, FCR1311, FCR1412**	**PMMA Capsular Tension Ring**
FREEDOM RING	**FCC1008L, FCC1008R, FCC1008LR FCC1210L, FCC1210R, FCC1210LR FCC1311L, FCC1311R, FCC1311LR**	**PMMA Modified Capsular Tension Ring**

Material used
- Poly Methyl Methacrylate

Indications
- Capsular bag to extend the circular.
- IOL to prevent Luxation.
- Defective or partly missing zonules
- Zonulolysis
- To stabilize the capsule in case of severe myopia.

Contraindications

For cataract surgery and lens implantation include the usual contraindication.
- Chronic uveitis.
- Rubella cataract
- n diabetic retinopathy.
- Acute inflammation.
- Chronic iritis.
- Severe atrophy of the iris.
- Uncontrolled chronic glaucoma.
- Patients with perforated or damaged capsules
- Retina and optic nerve defects Loss of vitreous or choroidal hemorrhage during the operation

How Supplied

Capsular tension rings 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).

Precautions
- Do not store the Rings 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 atleast a course on IOL implantation should attempt implantation of these Rings.
- Pouch should be opened only under sterile conditions.
- Do not soak or rinse Rings is solutions other than sterile balanced salt solution, sterile normal saline solution or equivalent of such.
- Do not attempt to re-sterilize these Rings. Re-sterilization on this product has not been validated.
- Do not autoclave this Rings.
- Handle the Rings carefully while picking up the Rings.

Instructions for Use
- Open the pouch of sterile capsular tension ring and take out the inner container with capsular tension ring on a sterile surface without touching it.
- Unscrew the ring case with care and grasp the ring with smooth edged forceps and lift.
- Open the container cap and take out the capsular tension ring and rinse with normal saline.
- Feed one eyelet of the ring into the capsular bag using a Mcpherson forceps or using a capsular tension ring injector.
- Then slowly insert the ring in capsular bag using the tension ring injector.
- Insert the second eyelet of the ring in the bag using a McPherson forceps and check the capsular bag integrity.
- Proceed further to complete the remaining Phaco or IOL inserting procedure.

Warnings
- Do not Re-sterilize.
- Do not uses after expiry date.
- In the bag Rings should be used only when the posterior capsule is in good condition.
- The device must be used by medical professional only.
- 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 devices 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 dieses, undue diseases to patient and/or user, Glaucoma problem, Rubella Cataract.
- Re-use of device 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)

Adverse Event:
- Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as product related and that were not previously expected in nature, severity or incidence must be report to Freedom Ophthalmic Pvt Ltd.

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:

STERILE EO	Sterilization by ethylene oxide	65 %RH 35 %RH	Humidity limitation		Do not re-use
	Warning see instructions		Keep away from Sunlight		Do not re-sterilize
	Use until (YYYY-MM)		Keep dry		Manufacturer
	Dont use when packing damaged	40°C 5°C	Temperature Limit		
LOT	Lot Number / Batch Number		Manufactured Date		

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ISO 13485:2016 Certified

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