



electronic INSTRUCTIONS FOR USE (eIFU)EU Representative:

BEMEDIS e.k., Breitewiesen 4, 75210 Keltern, Germany, Email: bemedis@t-online.de

Brand Name	FREEDOM RING	
Generic Name	PMMACAPSULARTENSION RINGS	PMMA MODIFIED CAPSULAR TENSION RING
MODELS	FCR1109, FCR1210, FCR1311, FCR1412,	FCC1008L, FCC1210L, FCC1311L, FCC1008R, FCC1210R, FCC1311R, FCC1008LR, RCC1210LR, FCC1311LR

DESCRIPTION:

Freedom Ophthalmic Pvt., Ltd., manufactures the capsular tension rings & the modified capsular tension rings, crafted to be placed in the capsular bag. Rings were made from clinical grade Poly Methy Metha Acrylate (PMMA), aphakia eyes after extracapsular cataract extraction by means of surgical correction& are indicated for use with the intraocular lens.

Sterilization method: Ethylene oxide

INDICATIONS:

1. Capsular bag to extend the circular.
2. IOL to prevent Luxation.
3. Defective or partly missing zonules
4. Zonulolysis
5. To stabilize the capsule in case of severe myopia.

CONTRAINDICATIONS:

For cataract surgery and lens implantation include the usual kontraendiksiyonlar.

1. Chronic uveitis.
2. Rubella cataract
3. In diabetic retinopathy.
4. Acute inflammation.
5. Chronic iritis.
6. Severe atrophy of the iris.



7. Uncontrolled chronic glaucoma.
8. Patients with perforated or damaged capsules
9. Retina and optic nerve defects Loss of vitreous or choroidal hemorrhage during the operation.

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.

Precautions

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

NOTE:

Do not neglect to review before using the capsular tension rings & the modified capsular tension rings.

WARNINGS:

1. Do not Re-sterilize.
2. Store between 0° C to 40°C.
3. Do not use after expiry date.
4. In the bag Rings should be used only when the posterior capsule is in good condition.



Symbols Used On Labeling

	Sterilized by Ethylene oxide		Store in Dry place
	Do not reuse		Lot Number / Batch number
	Do not re-sterilize the IOLs		Date of Manufacturing
	Do not use if the pouch is opened		CE mark, Notified Body identify number
	Attention, see instruction for use		European Representative
	Keep away from sunlight		Manufacturer
	Temperature limitation 0°- 40° C.		Use by (YYYY-MM: Year-month)