

TECHNICAL CONSTRUCTION FILE (FOPL/TCF/04)	Issue No.: 03 Dated :02-05-2022 Rev. No.: 04 Rev Dt -24.09.2026	 Freedom Ophthalmic Pvt. Ltd. Plot No. 31, Phase -I, Sipcot Industrial Complex, Hosur – 635 126, Tamilnadu, INDIA
INSTRUCTIONS FOR USE (Doc No FOPL/IFU/04)	Section No.: 2.1 Page 1 of 8	

ENGLISH

INSTRUCTIONS FOR USE APPLICABLE FOR THE FOLLOWING MODELS:

Trade / Brand Name	Generic Name	Models	Variants
FREEDOM RING	PMMA Capsular Tension Ring	FCR1109, FCR1210, FCR1311, FCR1412	Ophthalmic Devices- Capsular Tension Rings
	PMMA Modified Capsular Tension Ring	FCC1008L, FCC1008R, FCC1008LR, FCC 1210L, FCC1210R, FCC1210LR, FCC1311L, FCC1311R, FCC1311LR	
	PMMA Capsular Segment Ring	FCS10	

INTENDED USE:

A) PMMA Capsular Tension Ring:

It is an implant designed to stabilize the capsular bag of the crystalline lens during cataract surgery in eyes with zonular weakness and replaced with Intraocular lenses where the crystalline lens is removed during surgery.

B) PMMA Modified Capsular Tension Ring:

The standard capsular tension ring is frequently unable to center or stabilize the capsular bag in cases of more profound zonular weakness.

C) PMMA Capsular Segment Ring:

A capsular tension segment or CTS is a partial PMMA segment that provides 90 degrees of capsular support. It has a central eyelet that extends anterior to the plane of the ring for suture fixation to the sclera.

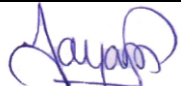
INDICATIONS:

PMMA Capsular Tension Ring

- For the stabilization of the crystalline lens capsule with weak or partially absent zonules in adult patients undergoing cataract extraction with intraocular lens implantation.
- Conditions associated with weak or partially absent zonules may include:
 - Primary zonular weakness
 - Secondary zonular weakness
 - Zonulolysis
 - Pseudoexfoliation (PEX) syndrome with zonular weakness
 - Marchesani's syndrome

Further utilities:

- Prevention of possible IOL luxation

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G.H.Syed Fayaz		G. Kannayiram	

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- Prevention of one-sided capsular bag shrinkage
- Circular expansion of the capsular bag
- Ease of complicated surgical conditions
- Capsule stabilization in case of severe myopia.

PMMA Modified Capsular Tension Ring:

They are indicated for advanced zonular weakness, more than four clock hours of weak zonules, and progressive zonulopathy. Like a standard ring, the modified ring is a C-shaped PMMA device that needs to be dialed into the bag.

PMMA Capsular Segment Ring:

It is indicated when there is advanced zonular weakness and has several distinct advantages over a Cionni modified ring. The segment does not require dialing, can be used in the presence of an anterior or posterior capsular tear, and can be used for both intraoperative stabilization and postoperative fixation. It is less likely than a capsular tension ring to trap cortical material against the capsular wall.

Product (Device) Description and Uses:

PMMA Capsular Tension Ring:

It is an implant designed to stabilize the capsular bag of the crystalline lens during cataract surgery in eyes with zonular weakness and replaced with Intraocular lenses where the crystalline lens is removed during surgery.

PMMA Modified Capsular Tension Ring:

The standard capsular tension ring is frequently unable to center or stabilize the capsular bag in cases of more profound zonular weakness.

PMMA Capsular Segment Ring:

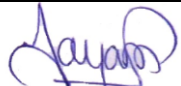
A capsular tension segment or CTS is a partial PMMA segment that provides 90 degrees of capsular support. It has a central eyelet that extends anterior to the plane of the ring for suture fixation to the sclera.

- Rings are non-optical implants to expand and stabilize the capsular bag. The Rings are implanted into the eye by either an ophthalmic surgeon or an ophthalmologist during a state-of-art operation, e. g. a small incision cataract surgery.
- The Rings are intended to remain in the eye for the whole life-span of the patient.

CONTRAINDICATIONS/ RESIDUAL RISK:

The Rings should not be used in:

- Zonular damage larger than four hours
- Chronic uveitis
- Progressive eye disease (e. g. diabetic retinopathy, uncontrolled glaucoma)
- In case of preoperative complications prior to cataract surgery

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- Patients with perforated or damaged capsules

POTENTIAL COMPLICATIONS:

As with any surgical procedure, there is risk involved. The risk can be reduced significantly with adherence to the instructions provided by the manufacturer.

Common complications with Rings insertion are intraoperative posterior capsular rent (PCR), increase in the size of existing posterior capsular rent, its posterior dislocation or rarely anterior dislocation.

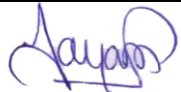
PRECAUTIONS:

- Before implanting this device, the surgeon must read all the material provided by Freedom ophthalmic for the correct handling and insertion of this implant.
- Careful preoperative evaluation and clinical judgment should be made by the surgeon to decide the benefit/risk ratio of the implantation in a patient with one or more of the following conditions/progressive diseases of the Posterior segment of the eye:
 - Microphthalmus
 - Macrophthalmus
 - Patients with a shallow posterior segment, for example with microphthalmia or certain forms of chronic angle closure glaucoma
 - Plate haptic IOL, since the capsular adhesion required for the fixation of the IOL is prevented by the CTR (danger of rotation and tilting out of position, as well as luxation after possible YAG laser capsulotomy)
 - Rupture of the posterior lens capsule, with or without vitreous prolapse
 - Persistent bleeding or other factors obstructing visibility



WARNINGS AND RESIDUAL RISKS:

- Device damaged during implantation must not remain in the eye.
- The device should be handled only by ophthalmic surgeons.
- The product if in case to be discarded or its waste material should be discarded of in accordance with local/national regulations and requirements.
- Do not use the device if the sterilized package is open or damaged.
- Device should be used immediately after opening.
- Reuse of device should be avoided as it may cause serious health risk either due to non-sterility or by any mechanical defect caused by the previous use.

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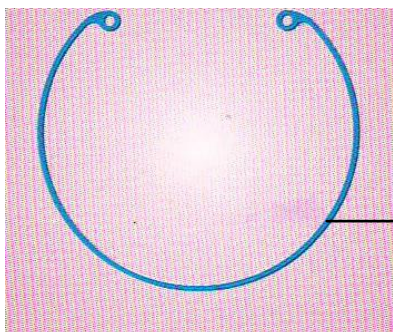
MODE OF ACTION:

The device is highly flexible 'C' shaped clear PMMA rings. Each end has a blunt tipped eyelet to aid in insertion of the rings. When positioned in the capsular bag, the rings exerts an outward force that redistributes tension from areas of intact zonules to strengthen areas of weak or missing zonules and support the capsule bag during an ophthalmic surgical procedure.

INSPECTION & FUNCTION TESTING:

Check for smooth functioning of medical device. Visually inspect for damage.

DESCRIPTION OF THE PRODUCT:



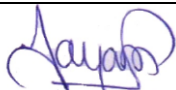
Normal Size

SYSTEM PREPARATION:

1. Check the label for manufactory and expiry dates (do not use the medical device after expiry)
2. Check for UDI number
3. Make sure the package is not damaged.
4. Visually examine the Rings to see if there are any damages on the loops.

INSTRUCTIONS FOR USE:

1. 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.
2. Unscrew the ring case with care and grasp the ring with smooth edged forceps and lift.
3. Open the container cap and take out the capsular tension ring and rinse with normal saline.
4. Feed one eyelet of the ring into the capsular bag using a McPherson forceps or using a capsular tension ring injector.
5. Then slowly insert the ring in capsular bag using the tension ring injector or using forceps and proceed further to complete the remaining surgery as per surgical Procedure.

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PATIENT INFORMATION:

The Surgeon performing the intervention must inform the patient about the complete procedure and all known complications and risks. The patient should be instructed to properly inform the doctor in charge about any side-effects after implantation.

STORAGE:

- Store between 5 to 40 °C.
- Do not expose to direct sunlight.
- Keep dry, protect from moisture/water. Handle with care.

RETURN OF DAMAGED PRODUCT:

Return the products in its original box identified by the LOT number, your purchase reference and reason for the return. The action shall be initiated to handle the product record as per the law of the land (IMDR 2017 under Drug and Cosmetic act 1945) and in compliance of the regulatory requirement of the destination of the product. The product recall procedure will be followed for the handling of this situation

DISPOSAL OF DISCARDED PRODUCT AND PACKAGING:

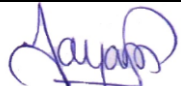
Ensure safe and proper disposal of used/discarded product and packaging to avoid adverse effect to environment, children, and stray animals. The Disposal should be in compliance to local laws related to disposal of biomedical waste, in the country of use.

COMBINATION OF THE DEVICE:

The description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with it; as our CTR is used in the combination of accessories like Injector, Ophthalmic surgical Instruments.

ORDERING INFORMATION:

Trade / Brand Name	Model	Description
FREEDOM RING	FCR1109, FCR1210, FCR1311, FCR1412	PMMA Capsular Tension Ring
	FCC1008L, FCC1008R, FCC1008LR, FCC1210L, FCC1210R, FCC1210LR, FCC1311L, FCC1311R, FCC1311LR	PMMA Modified Capsular Tension Ring
	FCS10	PMMA Capsular Segment Ring

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PACKAGING:

The device is supplied in Polypropylene case contained within a heat-sealed Tyvek sterilizable peel pouch, along with IFU, inner labels in a duplex box with external identification labels.

TARGET AGE GROUP:

Use above 18 age Group.

Implant Card and Traceability

An implant card is supplied with the device in accordance with MDR Article 18.

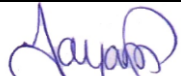
The healthcare institution or surgeon shall complete the implant card with patient identification, device name, model, lot number, UDI, manufacturer details, implantation date, and healthcare institution details.

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 : YYYYY
UDI-DI: _____	Mfg Date :YYYY / MM
Lot Number: _____	Exp Date :YYYY / MM
Diopter Power: _____	
Implantation Date: _____	
Patient Name: _____	
Eye Implanted:	
☐ Right Eye (OD) ☐ Left Eye (OS)	
Healthcare Institution: _____	
Implanting Surgeon: _____ FO/IC/001-R01 Date : 18.09.2026	

This card identifies your implanted intraocular lens Always keep this card and present it to any ophthalmologist or healthcare professional involved in your eye care. Contact your ophthalmologist immediately if you experience - Sudden Loss of vision - Severe eye pain - Persistent redness - Flashes of light - New floaters - Significant visual disturbance - Any unexpected ocular symptoms Freedom Ophthalmic Pvt Ltd. EU/REP Plot No.31,Phase-I,SIPCOT Industrial Complex, Tamil Nadu, 635126,India. e-mail:fred@freedomophthalmic.com Website:www.freedomophthalmic.com Tel:+91 95855 99301 CMC Medical Devices & Drugs S.L C/Horacio Lengo N° 18, CP 29006, Malaga, Spain Email: info@CMCmedicaldevices.com Phone:+34951214054 Keep this implant card permanently and present it to healthcare professionals whenever relevant medical treatment is received
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NOTICE FOR USER / OR PATIENT:

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the User and/or Patient is established.
 The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for safe use.

STERILIZATION & EXPIRY DATE:

The device is sterilized by Ethylene Oxide (EO) & 60 months from the date of manufacturing

WARRANTY:

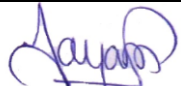
We warrant that reasonable care has been used in the design and manufacture of IOL. This warranty is limited to replacement of IOL only. We shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. We do not assume or authorize any other person to assume on our behalf, any other or additional liability or responsibility in connection with use of this device.

ELECTRONIC VERSION OF IFU:

Available on the website www.freedomophthalmic.com

EXPLANATION OF SYMBOLS:

Symbol	Meaning	Symbol	Meaning
	Lot Number/ Batch Number		Sterilization by Ethylene Oxide
	Warning see instruction		Use Until (YYYY-MM)
	Don't use when packing damaged		Humidity Limitation
	Do not reuse		Do not re-sterilize
	Keep away from sunlight		Keep dry
	Temperature limit		Manufacturer
	Country of Manufacturer		CE Mark

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	Single Sterile Barrier System		Medical Device
	Patient number		Unique Device Identifier
	Date of Manufacture		Consult instructions for use or Consult electronic instructions for use
	Catalogue number		Country Code
	Authorized representative in the European Union		

Summary of Safety and Clinical Performance
(Doc No: [FOPL/SSCPR/CTR/001](#))- Refer section 6.1.c CER



Freedom Ophthalmic Pvt Ltd

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e-mail: fred@freedomophthalmic.com

Website: 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@cmcmmedicaldevices.com

Phone: +34951214054

SRN Number: ES-AR-000000293

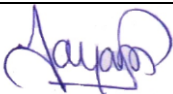


2460 Notified Body:

DNV Product Assurance AS

Veritasveien 1, 1363 Høvik, Norway

Tel +47 67 57 88 00. www.dnv.com

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