

## Preloaded Capsular Tension Ring

### DEVICE DESCRIPTION

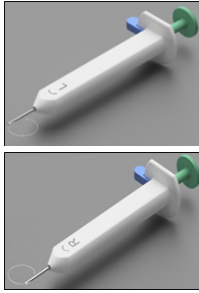
CapSafe Preloaded Capsular Tension Ring is a single-use injector with a capsular tension ring preloaded in it.

Capsular Tension Ring is hereafter referred to only as "CTR". The single-use injector is hereafter referred to only as "injector".

The injector delivers the CTR anticlockwise to the left and clockwise to the right depending upon the model being used.

A CTR is a highly flexible clear PMMA ring of haptic thickness 0.18 mm. The ring comes in primarily three sizes i.e., 12.0mm – 10.0mm, 13.0mm-11.0mm, & 14.0mm – 12.0mm.

The Preloaded CTR is packed in a blister and then in a pouch, before sterilization.



### INTENDED USE / INDICATION FOR USE

A CTR is used for expansion and stabilization of the capsular bag to facilitate a safe IOL implantation and maintain good IOL centration.

Preloaded CTR is used for inserting a CTR which is preloaded in it into the capsular bag in an ophthalmic surgical procedure.

### TARGET AGE GROUP

Not recommended for children under the age of 12.

### DURATION OF USE

Long Term Use (more than 30 days).

### STORAGE CONDITIONS

Store at specified temperature and humidity (Temperature in between 10°C to 30°C and Humidity in between 45RH to 65RH).

### CONTRAINDICATIONS

The device should not be used in patients who show hypersensitivity to any of the components of the preparation.

### INDICATION/INTENDED APPLICATION

Eyeball (Supporting devices for Ophthalmic Surgery)

### MODE OF ACTION

CTR is highly flexible 'C' shaped clear PMMA ring. Each end has a blunt tipped eyelet to aid in insertion of the ring. When positioned in the capsular bag, the ring 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 temporarily during an ophthalmic surgical procedure.

Injector is a mechanical device which comes with a CTR preloaded in it. The CTR is attached to the injector via a hook which pulls the CTR into the PTFE Incision tube when the Plunger is pulled back for loading. Injector is designed in such a way to ensure

smooth and controlled movement of the Plunger. Tapered Incision tube makes inserting the tube easy. When Plunger is pushed to implant the CTR, it comes to a halt at the end to prevent from accidental detachment of the CTR, upon applying little force CTR is released from the injector.

### HOW SUPPLIED

The Preloaded CTR is packed in a blister and then in a pouch, before sterilization. Such pouch is enclosed within an outer printed box. The overall packaging contains Preloaded CTR, medical literature insert, User Instruction leaflet, Patient card and labels in the outer printed box, with external identification stickers.

### CAUTIONS

Do not use the device if the sterilized package is open or damaged.


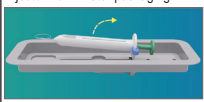
### WARNING




- Do not reuse the device. Madhu Instruments Pvt. Ltd does not hold any responsibility if the device is reused. Reusing the device may cause serious problems to patients such as:
  - The used Capsular Tension Ring might not have proper spring action.
  - Might spread contagious and communicable diseases such as HIV, Hepatitis, etc.
  - The used Incision tube might damage the eye.
- Only qualified medical practitioner should use the device.
- Do not use if the Capsular Tension Ring is broken or damaged.
- Do not re-sterilize the device by any method. Madhu Instruments Pvt. Ltd. assumes no liability for devices that have been re-sterilized.
- Read Preloaded CTR User Instructions.
- Store at specified temperature and humidity.
- Do not use the device after sterility expiry date.
- Check the CTR model and the implantation direction on the external identification stickers and engraving on the product.
- Keep out of reach of children.

### PRECAUTIONS

- When handling the product care should be taken to avoid damage from handling. Avoid crushing and crimping damage to the product due to application of surgical instruments such as forceps etc.

### DIRECTIONS FOR USE

1. Open the pouch of sterile Preloaded CTR (BY AN UNSTERILE PERSON) and drop the sealed blister packaging with Preloaded CTR on a sterile surface without touching it.	3. Remove the Plunger Lock.
2. Remove the Preloaded CTR with injector from Blister packaging.	
	

4. Pull the Plunger backwards up to the end to load the CTR.	5. Check the CTR implantation direction engraved on the injector body.
	
6. Keeping the engraved side upwards, push the Plunger forward to implant the CTR.	7. Proceed further to complete the remaining Phaco or IOL inserting procedure.
	

### DEVICE LIFE

- The expiration date of the product is the sterility expiration date. The product should not be used after the indicated sterility expiration date.

### RETURN OF DAMAGED PRODUCT

- Return the product in its original packing identified by the batch number, purchase information, your reference and reason for return. Please contact your local distributor office regarding product return/exchange.

### REPORTING

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 reported to Madhu Instruments Pvt. Ltd.

### DISPOSAL OF THE USED DEVICE

The used device should be disposed of in compliance with the local regulatory requirements.

### EXPLICATION OF SYMBOLS:

Symbol	Meaning
	Caution/Warning
	Manufacturer
	Date of Manufacturing
	Do not re-sterilize
	Consult Instructions for Use
	Keep away from sunlight
	Do not Reuse
	This side up
	Do not use hook

Symbol	Meaning
	Batch/Lot Number
	Use By Date
	Temperature Limitation
	Do not use if package is damaged
	Humidity Limitation
	Sterilized using Ethylene Oxide
	Handle with care
	Maximum stacking

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