

EN (English)



**Capsular Tension Ring with Scleral Fixation Arm**

**MODELS & VARIANTS**

CTR Type-6(L) (12mm-10mm), CTR Type-7(R) (12mm-10mm), CTR Type-8(LR) (12mm-10mm)

**DEVICE DESCRIPTION**

A capsular tension ring with scleral fixation arm is a highly Flexible clear PMMA ring of haptic thickness 0.18mm. The ring comes in primarily three sizes i.e., 12mm-10mm, for left, right and both arms. A capsular tension ring with scleral fixation arm is individually packed & sealed in a pouch before sterilization.

**INTENDED USE/ INDICATION FOR USE**

A Capsular tension ring with scleral fixation arm is used for circular expansion and stabilization of the capsular bag in an ophthalmic surgical procedure when the zonules are weak/ damaged or missing. This ring is specially designed for scleral fixation with sutures.

**MATERIALS USED**

Polymethyl methacrylate (PMMA)

**TARGET AGE GROUP**

Can be used for all age groups.

**INTENDED USER**

Any of the registered medical doctor/medical professionals.

**DURATION OF USE**

Long term use (more than 30 days).

**STORAGE CONDITIONS**

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

**CONTRAINDICATIONS**

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

**HOW SUPPLIED**

Capsular tension ring with scleral fixation arm is supplied sterile, packed in container and then in a peel open pouch. Such a pouch is enclosed in an outer printed box. The overall packing contains Capsular Tension Ring with scleral fixation arm and medical literature insert, in an outer enclosing box, with external identification stickers.

**CAUTION/WARNING**

- Read instructions before use.
- Do not use if package is damaged and consult Instructions for use.



- Do not use if the Capsular tension ring with scleral fixation arm is broken or damaged.
- Do not use the device if the sterilized package is open or damaged.
- The product is designed for single use only.
- The Capsular tension ring with scleral fixation arm might not have proper spring action.
- The use of this product is restricted to a qualified doctor or medical practitioners.
- Store at specified temperature and humidity.
- Keep out of reach of children.
- Do not re-sterilize the device by any method. Madhu Instruments assumes no liability for the devices that have been re-sterilized.
- Do not use the device after sterility expiry date.

**PRECAUTIONS**

- Ensure before use that product/packaging is not tampered or damaged.
- 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.

**DIRECTION FOR USE**

- Check the package sealing integrity to ensure sterility.
- Open the container cap and take out the capsular tension ring with scleral fixation arm and wash it with saline water.
- Feed one eyelet of the ring into the capsular bag using a McPherson forcep.
- Then slowly insert the ring in capsular bag till only the second eyelet remains outside the eye.
- Insert the second eyelet of the ring in the bag using a McPherson forcep and check the capsular bag integrity.
- Proceed further to complete the remaining Phaco or IOL inserting procedure.

**EXPIRATION DATE**

The expiration date of the product is the sterility expiration date. The product should not be used after the indicated sterility expiration date, the shelf life for sterile products is recommended to 5 years from the date of sterilization.

**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 report to Madhu Instruments Pvt. Ltd.

**DISPOSAL OF THE USED DEVICE**

The used device should be disposed off in compliance with applicable local, state and country's laws and regulations.

**EXPLICATION OF SYMBOLS:**

Symbol	Meaning
	Caution
	Manufacturer
	Date and Country of Manufacture
	Consult instructions for use
	Keep away from sunlight
	Medical Device
	Do not use hook
	This side up
	Temperature Limit
	Humidity Limitation
	Keep Out of reach of children

Symbol	Meaning
	Handle with care
	Maximum stacking
	Batch Code
	Use by date
	Do not use if package is damaged and consult Instructions for use
	Do not re-use
	Single Sterile Barrier System, with inside protective packaging sterilized using Ethylene Oxide
	Single Sterile Barrier System with inside and outside protective packaging, sterilized using Ethylene Oxide
	Do not re-sterilize
	Catalogue Number
	Unique device identifier

**MADHU INSTRUMENTS PVT. LTD.**  
 Mfg. Facility: A-260, Okhla Industrial Area Phase-I, New Delhi-110020 India.  
 Regd. Add.: F-90/3D, Okhla Industrial Area Phase-I, New Delhi-110020 India  
 Customer Care No.: +91-11-42701030, 42701031  
 Email: customercare@madhuinstruments.com  
 Website: www.madhuinstruments.com