

EN (English)



### Capsular Tension Ring

#### MODELS & VARIANTS

CTR Type 3 (12-10mm), CTR Type 4 (13-11mm), CTR Type 5 (14-12mm)

#### DEVICE DESCRIPTION

A Capsular tension ring is a highly flexible clear PMMA ring of haptic thickness 0.18mm. The ring comes in primarily three sizes i.e., 12-10mm, 13-11mm, & 14-12mm. A capsular tension ring is individually packed & sealed in a pouch before sterilization.

#### INTENDED USE / INDICATION FOR USE

A capsular tension ring is used for circular expansion and stabilization of the capsular bag in an ophthalmic surgical procedure.

#### 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 of the preparation.

#### HOW SUPPLIED

Capsular Tension Rings are supplied sterile, packed in container and then in a peel open pouch. Such a pouch is enclosed within an outer printed box. The overall packing contains Capsular Tension Ring and medical literature inserted 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 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 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/package 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 and wash it with saline water.
- 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 inject or a lens dilator till only the second eyelet remains outside the eye.
- 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.

#### 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
	Maximum stacking
	Handle with care
	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

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