

Capsular Tension Ring with Scleral Fixation Arm

MODELS & VARIANTS

12-10mm, 13-11mm, 14-12mm

DEVICE DESCRIPTION

A capsular tension ring with scleral fixation arm is a highly Flexible clear PMMA ring of haptic thickness 0.10mm. The ring comes in primarily three sizes i.e. 12-10mm, 13-11mm, 14-12mm 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 FORUSE

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.

TARGET AGE GROUP

Use All Age Groups

STORAGE CONDITIONS

Store at specified temperature and humidity (Temperature in between 5°C to 55°C and Humidity in between 55RH to 75RH).

CONTRAINDICATIONS

The device is contraindicated for patients with known silicon and plastic sensitivity.

NATURE OF BODY CONTACT

Eyeball (Supporting devices for Ophthalmic Surgery)

MODE OF ACTION

The device 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 during an ophthalmic surgical procedure. An additional eyelet is used to suture the ring to scleral tissue for better stability of the capsular bag.

HOW SUPPLIED

Capsular Tension Ring with scleral fixation arm is supplied sterile, in a peel open pouch. Such pouch is enclosed with 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.

CAUTIONS

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

DEVICE LIFE

The expiration date of the product is the sterility expiration date. The product should not be use 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.

EXPLICATION OF SYMBOL:

Symbol	Meaning
	Caution
	Manufacturer
	Date of Manufacture
	Do not re-sterilize
	Consult instructions for use
	Keep away from sunlight
	Don't re-use
	Authorized Representative in European Community
	This side up
	Do not use hook



WARNING

- Madhu Instruments Pvt. Ltd does not hold any responsibility if the device is reused. Reusing the device may cause serious problems to patients as under: -
- Do not use if the Capsular Tension Ring with scleral fixation arm is broken or damaged.
- The used Capsular Tension Ring with fixation arm might not have proper spring action.
- Contagious and communicable disease such as HIV, Hepatitis, contagious diseases/ communicable diseases/ undue diseases etc.
- Only qualified medical practitioner should use the device.
- Do not use the device if the sterilized package is open or damaged.
- Sterility is guaranteed only when the packing is neither opened nor damaged.
- Do not re-sterilize the device by any method. Madhu Instruments assumes no liability for devices that have been re-sterilized.
- Do not reuse the device.
- Read instruction before use.
- Store at specified temperature and humidity.
- Do not use the device after sterility expiry date.
- Keep out of reach of children

PRECAUTIONS

- While 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

- Open the pouch of sterile capsular tension ring with scleral fixation arm (BY AN UNSTERILE PERSON) and drop the inner container with capsular tension ring with scleral fixation arm on a sterile surface without touching it.
- 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.

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 and packaging should be disposed off in compliance with the local regulatory requirements.

Symbol	Meaning
	Conformity of European Norm with Notified Body Number
	Batch Code
	Use by date
	Temperature Limit
	Do not use if package is damaged
	Humidity Limitation
	Sterilized using Ethylene Oxide
	Handle with care
	Maximum stacking

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