

## Capsular Tension Ring Injector

### DEVICE DESCRIPTION

Capsular tension ring injector is a combination of a disposable 1cc syringe and an 18g I.V. Cannula with a 18g stainless steel needle acting as the plunger for the Capsular tension ring. An Capsular tension ring injector is individually packed & sealed in a pouch before sterilization.

### INTENDED USE / INDICATION FOR USE

Capsular tension ring injector is used for controlled injection of an Endocapsular tension ring into the capsular bag in an ophthalmic surgical procedure.

### TARGET AGE GROUP

Use All Age Groups

### DURATION OF USE

Transient Use (Less than 60 Minutes). It is recommended to withdraw the product after 60 minutes from the patient. The user is accountable for any type of problem taking place in case of use after 60 minutes of the same device.

### 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 plastic sensitivity.

### INDICATION/INTENDED APPLICATION

Eyeball (Supporting devices for Ophthalmic Surgery)

### MODE OF ACTION

A capsular tension ring injector is a combination of a disposable 1cc syringe and an 18g I.V. Cannula with a 18g stainless steel needle acting as the plunger for the capsular tension ring. The CTR is loaded into the front cavity manually with one eyelet remaining out. The tip of the injector is inserted into the anterior chamber and using the plunger, CTR is slowly injected into the capsular bag.

### HOW SUPPLIED

Capsular Tension Ring injector is supplied sterile, in a inner blister pack and an outer peel open pouch. Such 10 (Ten) pouches are enclosed within an outer printed box. The overall packing contains Capsular Tension Ring injector and medical literature insert, in an outer enclosing box, with external identification stickers.

### MATERIALS USED

Stainless Steel, PVC, PP, PTFE

### CAUTIONS

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

### WARNING

- Madhu Instruments Pvt. Ltd does not hold any responsibility if the device is reused. Reusing the device may cause serious problems to patients are as under: -

### 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.

### EXPLICATION OF SYMBOLS:

Symbol	Meaning
	Caution/Warning (Read instruction before use)
	Manufacturer Logo
	Date of Manufacturing
	Do not re-sterilize
	Consult IFU
	Keep away from sunlight
	Don't re-use
	Authorized European Representative
	This side up
	Do not use hook



- Check the plunger movement once before loading the Capsular Tension Ring.
  - Do not use any viscoelastic material to load the Capsular Tension Ring.
  - Contagious and communicable disease such as HIV, Hepatitis, contagious disease/communicable disease/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 Pvt. Ltd. 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.
  - The used Capsular Tension Ring injector and pouch should be disposed off in compliance with the local regulatory requirements.
  - Do not use the device after sterility expiry date.
  - The device is not for implant
  - 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.

### DIRECTION FOR USE

- Open the pouch of sterile Capsular Tension Ring Injector (BY AN UNSTERILE PERSON) and drop the injector on a sterile surface without touching it.
- Open the protective cap of I.V. Cannula and withdraw the plunger backwards creating space for the tension ring to be inserted in the tube cavity.
- Take out the Capsular Tension Ring Injector and feed one eyelet of the ring into the capsular tension ring injector carefully using a McPherson forcep. Slowly feed rest of the tension ring into the tube cavity. The tension ring is flexible enough to become straight and go into the tube.
- Then slowly insert the I.V. Cannula loaded with tension ring through the main port after filling the anterior chamber with viscoelastic.
- Guide the projecting end of the ring into the capsular bag and gradually push the plunger of the complete of the ring into the capsular bag.
- 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 should be disposed off in compliance with the local regulatory requirements.

Symbol	Meaning
	Conformity of European Norm with Notified Body Number
	Batch/Lot Number
	Date of Expiry
	Temperature Limitation
	Do not use if package damaged
	Moisture Limitation
	EO Sterile Product/Device
	Handle with care
	Maximum stacking

### Mfg. Facility: MADHU INSTRUMENTS PVT. LTD.

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