



## THE FRED HOLLOWES INTRAOCULAR LENS LABORATORY

### INSTRUCTION FOR USE STERILE PMMA CAPSULAR TENSION RINGS



#### DESCRIPTION:

The Sterile PMMA Capsular Tension Rings is a sterile, non-optical ocular implant, manufactured from Polymethylmethacrylate of Clinical Quality and available in different models i.e. FCTR11, FCTR12, FCTR13 for the implantation in combination with Posterior chamber intraocular lens.

#### CONDITIONING:

The Sterile PMMA Capsular Tension Rings is EO sterilized and is sold as individual sterile units. Each Sterile PMMA Capsular Tension Rings is enclosed in its own case within sterilization pouch.

#### INDICATION/INTENDED USE:

The implantation of a Sterile PMMA Capsular Tension Rings is indicated:

- For circular expansion of the Capsular bag.
- To reduce the risk of luxation or decentration of an IOL.
- To stabilize the capsule in case of the zonular weakness ( e.g., Marfar's Syndrome) , Secondary Zonular Weakness (e.g., trauma or Vitrectomy) , cases of zonulysis ,cases of pseudoexfolitation and cases of Marchensani's syndrome.

#### CONTRAINDICATION :

The Sterile PMMA Capsular Tension Rings contraindications are the usual ones for cataract surgery and IOL impantation as described in the literature and in the instruction for use of the IOLs. The Sterile PMMA Capsular Tension Rings requires special consideration prior to implantation under the following conditions, therefore it is relatively contraindicated in the conditions as below:

- The capsular bag has been torn or is expected to tear in such a manner that would result in destabilisation of the Capsular Tension Rings.
- The Zonulae have been torn or is expected to tear in a greater arc than 180 degrees so that the Capsular Tension Rings would lack sufficient support from the intact zonulae to provide useful support.
- The Sterile PMMA Capsular Tension Rings should not be used in children 12 years of age or younger since this device is contraindicated in eyes still growing.

#### COMPLICATION:

As with any surgical procedures, there is risk involved. Sterile Capsular Tension Rings related complications are not known.

The Long term Effects of progressive Zonular stability following implantation of a Sterile Capsular Tension Rings are not known.

If there is any adverse event happened during or post-surgery, Capsular Tension Rings may be explanted or replaced.

#### PRECAUTIONS:

- The Sterile PMMA Capsular Tension Rings must not be resterilised by any method.
- Sterility is guaranteed unless the sterility pouch is damaged or opened.
- Opening the pouch requires an immediate use of the Sterile PMMA Capsular Tension Rings.
- Do not use the Sterile PMMA Capsular Tension Rings if the container, which maintains sterility, has been damaged or open. Surgeons should be familiar with the Sterile PMMA Capsular Tension Rings insertion technique prior to use.

Store between 5°C to 45°C.

#### DIRECTION FOR USE & OPENING INSTRUCTIONS:

There are various surgical procedures that can be used for Sterile PMMA Capsular Tension Rings implantation. The surgeon should select a procedure that is appropriate to the patient.
















Following inspection, the Sterile PMMA Capsular Tension Rings will be ready for insertion.

1. Before opening, please confirm the requested model and expiration date. Inspect the pouch to ensure the sterility has been maintained. The clear portion of the pouch may appear wrinkled.
2. Open the Sterile pouch in a sterile field and remove the CTR case.
3. To open the CTR case, grasp the case such that the index, second and third fingers support the CTR case, and the thumb is placed on the grips of the case lid. Press the lid slightly and steadily draw the lid back towards the center of the CTR case to expose the Sterile PMMA Capsular Tension Rings.  
**Caution:** Before sliding the Lid, slightly tap on the top of the lid to ensure the Sterile PMMA Capsular Tension Rings firmly places itself in its room (i.e. in the pins that holds the Sterile PMMA Capsular Tension Rings.)
4. Again inspect to make sure the correct Sterile PMMA Capsular Tension Rings model is contained in the package.
5. Carefully remove the Sterile PMMA Capsular Tension Rings vertically from the case using a sterile forceps and lift it straight up from the case.
6. Inspect for defects and scratches that may have occurred during transportation.

Because the Sterile PMMA Capsular Tension Rings and packaging materials are in plastic, the Sterile PMMA Capsular Tension Rings may pick up an electrostatic charge when the package is opened. The Sterile PMMA Capsular Tension Rings should be carefully examined to ensure that particles have not been attached to it.

#### CONTAINS OF PACKAGING :

- One Sterile PMMA Capsular Tension Rings
- Additional Labels
- Patient Identification Card
- Instruction for Use ( IFU)

Symbols used in primary and secondary packaging	
	Batch Code
	Use By Date
	Serial Number
	Date of Manufacture
	Sterilized using Ethylene Oxide
	Do Not Reuse
	Do not Resterilize
	Above 5°C and Below 45°C
	Overall Diameter/ Body Diameter
	Consult Instruction for Use
	Do not use if Package is Damaged
	Keep away from Sunlight
	Keep Dry
	Manufacturer
	FCTR11, FCTR12 FCTR13 (Device Drawing)

EC REP

Authorized Representative in Europe

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