FRONT

BACK

250 mm

90 mm

i Medical®

PMMA Capsular Tension Ring (Sterile)

INTENDED PURPOSE

The Capsular Tension Ring (CTR) is intended to support the capsular bag prior to surgical implantation of any posterior chamber intraocular lens.

Model	Length
CTRB12010	12.0
CTRB125115	12.5
CTRB13011	13.0
CTRB14012	14.0

INDICATION

For the stabilization of the crystalline lens capsule in the presence of weak or partially absent zonules in adult patients undergoing cataract extraction with intraocular lens implantation. Conditions associated with weak or partially absent zonules may include primary zonular weakness (e.g., Marfan's Syndrome), secondary zonular weakness (e.g., trauma or vitrectomy), cases of zonulysis, cases of pseudoexfoliation and cases of Marchesani's Syndrome.

CLINICAL BENEFIT

- CTR stabilize the capsule in a patient with high myopia.
- CTR is used to expand and create a smooth circular shape to the capsular bag.
- CTR reduces the risk of subluxation.
- CTR provides better centration for the IOL.

PATIENT POPULATION

Cataract patients 18 years of age or above

CONTRAINDICATIONS

The Capsular Tension Ring should not be used in children 18 years of age or younger since this device is contraindicated in eyes still growing. Capsular Tension Ring is contraindicated for patients with perforated or damaged capsules.

The device does not contain ED/CMR substances

COMPLICATIONS/ POTENTIAL SIDE-EFFECTS

Complications related to the surgeries, CTR and IOL implantation are :

- Transient IOP spike
- Anterior Capsule Contraction (Phimosis)
- Anterior (AC) Chamber Collapse
- Capsular bag contraction/tear/folds
- Corneal edema
- Cystoid Macular Edema
- IOL decentration/ IOL subluxation postoperatively
- Suture fixation of IOL
- Posterior capule disintegration
- Posterior capsule rupture
- Vitreous loss/ Vitreous strands requiring anterior vitrectomy
- Zonular dehiscence
- Zonular dialysis
- Posterior Chamner Opacification (PCO)

PRECAUTIONS

- CTR Should be implanted by an experienced surgeon. The CTR is intended to be used by qualified ophthalmic surgeon only.
- Do not resterilize. Product integrity may compromised.
- Do not reuse, if reuse, it will lead to toxic effect to eye.
- Do not use if the package has been opened or damaged.
- Do not implant after expiry date.
- CTR is made from a biocompatible PMMA material that could carry a static electrical charge which may attract dust particles. Carefully rinse any particulate matter with sterile BSS or its equivalent before surgical implantation.
- The implanted device does not contain any metallic components and are safe with no potential for interaction with the Magnetic Resonance (MR) Field.

DIRECTIONS FOR USE

- Ensure the correct size is selected.
- Open the package in sterile area.
- Carefully remove the CTR from the tray taking care not to scratch or damage the product.
- Insert the ring using a proper inserter or according to customary surgical procedure.
- The procedure involves slowly "dialing in" the ring through the capsulorhexis into the capsular bag.
- Smooth blade forceps may be used to gently insert the ring, which due to its shape will tend to follow the natural curve of the capsular bag. A hook (Sinskey type) may be helpful in the trailing eyelet of the ring to achieve the final insertion and placement in the capsule.
- The CTR is supplied sterile, provided that the package is not tampered with or damaged.

Note: 1. Improper handling can result in the perforation of the capsule.
2.The physician should discuss the indications, contraindications, warnings, precautions, treatment responses, adverse events and procedure with the patient prior to the implant of a Capsular Tension Ring

HOW SUPPLIED

CTR is supplied dry, in a package terminally sterilized with ethylene oxide, and must be opened only under aseptic conditions.

DISCLAIMER OF LIABILITY

I MEDICAL OPHTHALMIC INTERNATIONAL HEIDELBERG GMBH will not be liable for any injury suffered to patient as a result of:

- Any implantation method or technique used by a physician to implant the CTR.
- Any prescription selection and use of the CTR for any individual patient or patient's condition.

I MEDICAL OPHTHALMIC INTERNATIONAL HEIDELBERG GMBH makes no expressed or implied warranties in connection with the sale of this CTR and specifically disclaims warranty liability of the marketability or fitness for use.

REPORTING

Adverse reactions and potentially sight threatening complications that may reasonably be regarded as CTR related need to be reported to I MEDICAL OPHTHALMIC INTERNATIONAL HEIDELBERG GMBH or Authorized Representative and competent authority of the member state where patient and/or user is located.

RETURN OF DAMAGE GOODS

Return the CTR in its original container identified with the Lot Number, Style and reason for return. Do not attempt to resterilize the CTR.

PROVISION FOR SSCP

Summary of Safety and Clinical Performance (SSCP) of this device is available on the
EUDAMED website https://ec.europa.eu/tools/eudamed
Note : Once the SSCP is reviewed by notified body and uploaded in EUDAMED.

See instruction for use
Do not resterilise
Do not reuse
Do not store below 0°C & above 45°C
Store away from sunlight
Do not use if package damaged
Store in dry place

STERILE EO

CE 2460

MFG/MD/2020/000163
i-Medical® Ophthalmic International Heidelberg GmbH
Markircher Straße 7 · D-68229 Mannheim · Germany
Fax: +49 (0) 621-48 44 90-20 · www.imedical.de

Rev. 06 | Artwork No. IMO-013-I-R6 | 10-2024