FRONT

BACK

PMMA Capsular Tension Ring (Sterile)

DESCRIPTION
The Capsular Tension Ring (CTR) is an accessory used to support the capsular bag following the surgical implantation of any posterior chamber intraocular lens.

Model	Length
CTRB12010	12.0
CTRB125115	12.5
CTRB13011	13.0
CTRB14012	14.0

INDICATIONS
- 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.

Target Patient group : 18 year or older

CLINICAL BENEFIT
The summary of safety and clinical performance will be added in IFU, Once the SSCP is reviewed by notified body and uploaded in EUDAMED.

CONTRAINDICATIONS
There are no specific contraindications for CTR as it is an accessory for intraocular lens. Surgeons should carefully read and follow the contraindications for the IOL being implanted. Do not use the CTR if the capsular bag is torn, damaged or destabilized.

The device does not contain ED/CMR substances

COMPLICATIONS/ POTENTIAL SIDE-EFFECTS
There are no known complications for a correctly fitted CTR.

PRECAUTIONS
- 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 CTR is supplied sterile, provided that the package is not tampered with or damaged.

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 device related, need to be reported to the manufacture or local distributor

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.

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

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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

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250 mm

90 mm