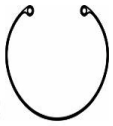
INSTRUCTIONS FOR USE

EXCELENS®
Excellence . . . in sight

CTR
Capsular Tension Ring



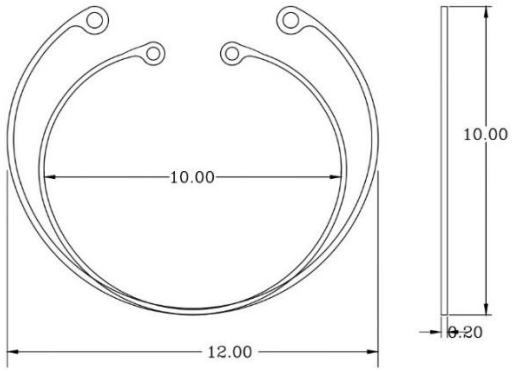
DEVICE DESCRIPTION:

EXCELENS - Capsular Tension Rings (CTR) are manufactured from Poly Methyl Methacrylate (PMMA) with an ultraviolet light filtering biologically compatible material by lathe cut, tumble polished and EO sterilized. Capsular Tension Ring (CTR) / Modified Capsular Tension Ring has one manipulation eyelet at each end of the ring.

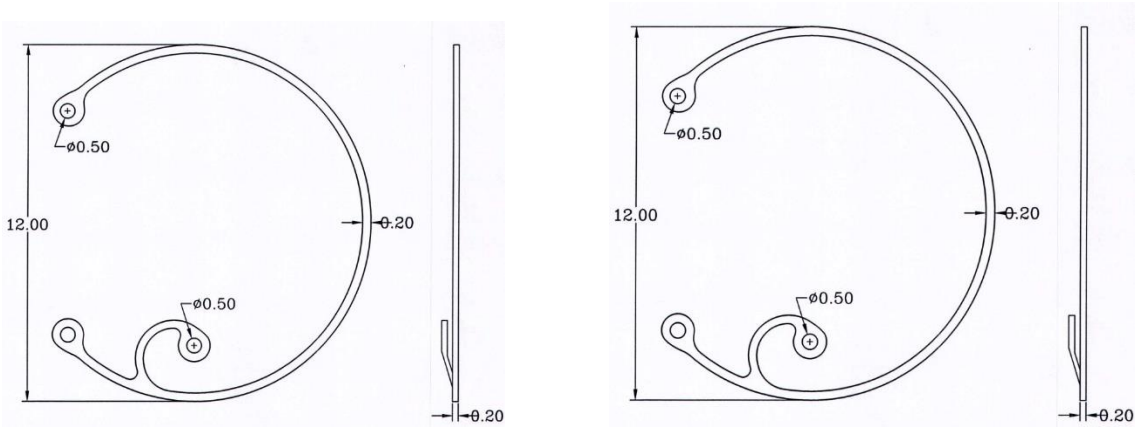
Optic Material: PMMA Clear

Refractive Index: 1.49

PRODUCT TECHNICAL SPECIFICATION:



Capsular Tension Ring



Modified Capsular Tension Ring

INTENDED PURPOSE:

- **EXCELENS** – Capsular Tension Ring (CTR) is a 270-degree open PMMA Ring placed in capsular bag during cataract surgery in the eyes with zonular instability and weakness. It is an accessory used to support the capsular bag, following the surgical implantation of any posterior chamber, Foldable IOL.

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- Modified Capsular Tension Rings: When the standard capsular tension ring is unable to center or stabilize the capsular bag in cases of more profound zonular weakness, these Modified CTR can be permanently sutured to the sclera, they are indicated for advanced zonular weakness, more than four clock hours of weak zonules, and progressive zonulopathy.

INDICATIONS:

- Weak or partially absent zonules
- Potentially complicated surgical conditions
- Luxation of IOLs
- Zonulysis
- Pseudo exfoliation
- Primary zonular weakness including Marfan Syndrome
- Secondary zonular weakness including trauma or vitrectomy.
- Stabilize the capsule in case of severe myopia.

When a zonular defect is present, a CTR can be inserted at any stage of the procedure to reestablish the capsular contour and to prevent capsular aspiration, vitreous herniation into the anterior chamber, IOL decentration, and closure of the capsular opening. The CTR is helpful for stabilizing a loose lens, supporting the contour of the capsule, and stretching the posterior capsule. CTRs maintain the configuration and stability of the capsular equator by improving zonular integrity. Therefore, it helps to avoid postoperative shrinkage of the anterior capsular opening and prevent IOL decentration.

INTENDED USER:

Ophthalmic surgeons only.

PATIENT TARGET GROUP:

Aphakic adult patients of age 18 years and above.

MODE OF ACTION:

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.

CONTRAINDICATIONS:

- Excelens CTR should not be used in children 12 years of age or younger since the device is contraindicated for eyes still growing.
- For adults, while there is no specific contraindication for CTR, since this CTR is an accessory to foldable IOL, physician should carefully read the contraindication for the IOL being implanted and follow the instruction completely.

WARNINGS, UNDESIRABLE SIDE EFFECTS AND RESIDUAL RISK:

- The complications listed below may occur following implantation of any IOL / CTR and may require treatment, or in severe cases can lead to secondary surgery for which the surgeon should carefully evaluate the risk/benefit ratio.
- Possible complications linked to surgery for crystalline lens removal and IOL implantation include, but are not limited to, those listed below. The risks of accidents and side effects are practically same as found during the extraction of cataract in particular: lens dislocation, non-pigment precipitates, corneal endothelial damage, high intraocular pressure, infection (endophthalmitis),corneal edema, pupillary membranes, flat anterior chamber, iris prolapse, hypopyon, and secondary glaucoma, Temporary Collapse of the anterior Chamber, Retinal detachment, Pupillary block, Iridocyclitis, Vitritis, Temporary Fistula, Cystoid macular edema, Formation of a posterior membrane, Hyphema, Vascular occlusion , Dystrophy of corneal endothelium, Striated Keratitis, Hernia of vitreous in anterior chamber, Subluxation or luxation of lens, Secondary reopacification, Evisceration or enucleation, Presence of Intra-ocular debris, Ophthalmitis, Malposition of the lens, Ablation of the lens.

INSTRUCTIONS FOR USE

PRECAUTIONS:

- Do not store the CTR in direct sunlight, temperature range for storage condition 5° C - 40° C. Keep away from freezing.
- Do not use if sterile packaging has been opened or damaged.
- Only skilled surgeons with experience in either viewing and /or assisting numerous surgical implantations and successfully completed at least one course on IOL implantation should attempt implantation of these CTR.
- Pouch should be opened only under sterile conditions.
- Do not soak or rinse CTR in solutions other than sterile balanced salt solution or equivalent of such.
- Do not attempt to re-sterilize this CTR.
- Do not autoclave this CTR.
- Handle the CTR carefully. Looking forceps or needle holders should never be used to pick up CTR.
- The patient must be advised that the doctor or the medical centre should be informed of any side effects not referred in this information.

Note: Because the CTR and the packaging materials are plastic, the CTR may pick up an electrostatic charge upon opening the package. The CTR should be carefully examined to ensure that particles have not been attracted to it.

Implantation of CTR should not be performed in patients under the age of 12.

DIRECTIONS FOR USE:

Preparatory Steps:

- Prior to implantation examine the CTR for the correct Size.
- During insertion handle CTR by the circular body.
- Carton box contains extra labels. These are for convenience in maintaining and reporting records of implantable lenses / CTR during clinical procedure. One the labels could be affixed in patients case sheet, for future reference.
- "Rinse the CTR in sterile B.S. Solution before implantation to minimize the static discharge which enhance the microbial contamination".

Implanting Steps:

- In a sterile environment, peel apart to open the pouch and remove the CTR case.
- Soak or rinse CTR in sterile balanced salt solution or sterile normal saline solution.
- The CTR due to some static charge produced while opening the CTR case, may stick to the cap in rare instances.
- Ensure that the CTR is in good condition for the shape and surfaces for adherence of any particles.
- Do not attempt to re sterilize this CTR.
- Do not autoclave this CTR.
- Handle the CTR carefully. Locking forceps or needle holders should never be used to pick up CTR.
- The CTR ring can be implanted by dialling manually into the capsular bag using forceps and a Sinskey hook.
- Modified CTR needs scleral fixating by surgeon with 9-0 polypropylene or CV-8 Gore-Tex suture.

CLINICAL BENEFITS:

- The clinical benefit of the implantation of an CTR along with IOL for cataract patients is the prevention of blindness.
- EXCELENS CTR strengthens zonular instability Improves capsular bag stability & centration and improves patient's quality of life.

HOW SUPPLIED:

Each carton box contains one Capsular Tension Ring (CTR), an implant card (instructions for completion of implant card is given below) and product traceability labels.

INSTRUCTIONS FOR USE

Excelens CTR are supplied in a CTR case contained within a heat-sealed Tyvek peel pouch and terminally sterilized using Ethylene Oxide (EO). The contents of the pouch are sterile unless the package is opened or damaged. The outer box should be opened in sterile condition only.

IMPLANT CARD

The implant card supplied with this device is to be completed by the healthcare provider. A product traceability label also supplied with this device must be affixed to the implant card after completion of the surgery. The additional labels can be used for the patient file or clinical follow up. Completed implant cards must be provided to the patient post-procedure. Patients should be instructed to keep the card as a permanent record of their implant. The patient should also be instructed to show the card to any eye practitioner he or she may see in the future.

WARNINGS:

- The safety of the use of the Neodymium-YAG laser and CTR with UV absorbing materials has not been established. The physician is urged to use extreme caution in such cases where a patient with UV absorbing CTR is treated with a Neodymium – YAG laser.
- The compression force exerted on the eye tissue by the CTR is not established. The physician should have knowledge in the selection of the type of CTR depending on the eye dimensions.
- Unscrew the CTR case with care and grasp the CTR body using smooth edged forceps and lift.

REPORTING OF SERIOUS INCIDIENTS:

Users should report the serious incident with medical device information to the manufacturer and/or to the national competent authority depending on the national practice. Once corrective (or other) action is identified from the manufacturer, hospital administrators, medical practitioners, and other health- care professionals, and USER representatives responsible for the maintenance and the safety of MEDICAL DEVICEs, can take the necessary steps. Such steps should, where practicable, be taken in co-operation with the MANUFACTURER. For the purposes of Medical Devices Vigilance System in member states are represented by appointed National Competent Authorities, their vigilance contact points being listed on the European Commission web site:http://ec.europa.eu/growth/sectors/medicaldevices/contacts/index_en.html

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE:

Summary of Safety and Clinical Performance (SSCP) of this device will be available on the EUDAMED website https://ec.europa.eu/tools/eudamed after notified body acceptance of SSCP.

CAUTION:

GOVERNMENT LAWS RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

DISPOSAL

Discarded CTRs (used or unused) are classified as medical (clinical) waste that harbours a potential infection or microbial hazard and must be disposed of accordingly.

STORAGE CONDITIONS:

Store between 0°C to 40°C temperature.

EXPIRATION DATE:

- The expiration date on the CTR package is the sterility expiration date.
- Do not use the CTR after the expiration date.

LIMITATION OF WARRANTY AND LIABILITY

EXCEL OPTICS (P) LIMITED accepts no liability for any injury suffered to patients as a result of:

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

Excel Optics (P) Limited, makes no expressed or implied warranties in connection with the sale of the CTR.

INSTRUCTIONS FOR USE

Symbols and their explanations

EC REP	Authorized Representative in the European community		Caution
STERILE EO	Sterilized using Ethylene Oxide		Do not re-sterilize
40°C 5°C	Storage Condition between 5°C to 40°C		Keep away from sunlight
	Manufacturer		Consult Instructions for Use
LOT	Sterile Batch No		Keep Dry
UDI	Unique device identifier	MD	Medical Device
SN	Serial Number		Single sterile barrier system with protective packaging inside
#	Model Number		Use by Date
	Do not Use If package is Damaged		Date of Manufacturer
IN	Country of Manufacture	PC	Posterior Chamber
UV	Ultraviolet		Do Not re-use

EC REP

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CE 1434

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