MEDICONTUR E-IFU

MEDICONTUR JETRING 11ACB RIGHT, 12ACB RIGHT PRELOADED CAPSULAR TENSION RING INJECTION KIT
INSTRUCTIONS FOR USE EN

DESCRIPTION

Capsular tension rings (CTR) are non-optical implants to expand and stabilize the capsular bag. The CTR is implanted into the eye by either an opthalmic surgeon or an opthalmologist during a state-of-art operation,
e.g. a small incision cataract surgery.
The CTR is intended to remain in the eye for the whole life-span of the patient.

The body and the cartridge of the preloaded injector is manufactured of medical grade polycarbonate and polypropylene respectively.

MODELS

Code	Material	Expanded diameter [mm]	Compressed diameter [mm]	Thickness [mm]
Jetring 11ACB right	PMMA	13.0	11.0	0.17
Jetring 12ACB right	PMMA	14.5	12.0	0.17

PACKAGING

The CTR is preloaded into a single-use injector system. The injector delivers the CTR clockwise to the right. The preloaded capsular tension ring injection kit is sterile and supplied in double blister packaging.
The product is sterilized by gamma irradiation.
Sterility of both type of products are guaranteed only when the packaging is neither opened nor damaged. The applied sterilisation procedure is marked on the folding box.

STORAGE

Store between 0 and 45 °C.

Do not expose to direct sunlight.
Keep dry, protect from moisture/water. Handle with care.

EXPIRATION DATE

Do not use this medical device after the expiry indicated on the carton/pouch/blister and the primary container.

INDICATION

For the stabilization of the crystalline lens capsule with 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)
- zonulolysis
- pseudoexfoliation (PEX) syndrome with zonular weakness
- Marchesani's syndrome

Further utilities:

- prevention of possible IOL luxation
- prevention of one-sided capsular bag shrinkage
- circular expansion of the capsular bag
- ease of complicated surgical conditions
- capsule stabilization in case of severe myopia.

PRECAUTIONS

High level of surgical skill is required for proper use.

Before implanting this device the surgeon must read all the material provided by Medicontur for the correct handling and insertion of this implant.

Careful preoperative evaluation and clinical judgment should be made by the surgeon to decide the benefit/risk ratio of the implantation in a patient with one or more of the following conditions/progressive diseases of the anterior segment of the eye:

- microphthalmus
- macrophthalmus
- shallow anterior chamber
- patients with a shallow anterior segment, for example with microphthalmia or certain forms of chronic angle closure glaucoma
- plate haptic IOL, since the capsular adhesion required for the fixation of the IOL is prevented by the CTR (danger of rotation and tilting out of position, as well as luxation after possible YAG laser capsulotomy)
- rupture of the posterior lens capsule, with or without vitreous prolapse
- persistent bleeding or other factors obstructing visibility
- children above 1 year of age

CONTRAINDICATION

The CTRs should not be used in:

- zonular damage larger than 4 clock hours
- children under the age of 1 year
- chronic uveitis
- progressive eye disease (e.g. diabetic retinopathy, uncontrolled glaucoma)
- in case of preoperative complications prior to cataract surgery (e.g. vitrous body prolapse, haemorrhage)
- patients with perforated or damaged capsules

COMPLICATIONS

As with any surgical procedure, there is risk involved. The risk can be reduced significantly with adherence to the instructions provided by the manufacturer.

WARNINGS

- The product must only be used by opthalmic surgeons**.**

- Use immediately after opening.
- Do not use if the sterilized package is open or damaged.
- Any occasional reuse must be avoided as it may pose serious health risk either by non-sterility or by any mechanical defect caused by the previous use.
- An implant damaged during implantation must not remain in the eye.
- The product or its waste material should be discarded of in accordance with local/national regulations and requirements.

INTERACTIONS

No direct interactions with drugs are known.

The use of antiplatelet and anticoagulant medications may increase the risk of haemorrhagic, anaesthetic or preoperative complications.

In reasonably foreseeable environmental conditions, no significant interactions or possible damage caused by exposition to magnetic fields, external electrical influences, electrostatic discharge, pressure or variation in pressure, thermal ignition sources, and acceleration is known.

PATIENT INFORMATION

The surgeon performing the intervention must inform the patient about the complete procedure and all known complications and risks.

The patient should be instructed to properly inform the doctor in charge about any side-effects after implantation.

HANDLING

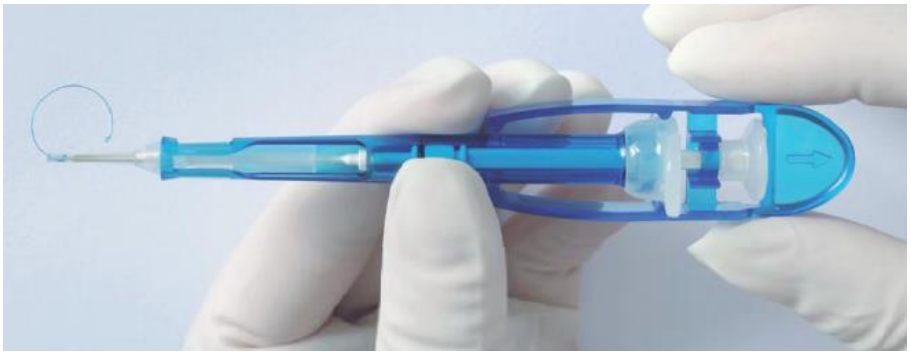
Before opening the peel-pouch or the sterile blister, check the details on all labels concerning the type, specific data and the expiration.

Remove the CTR/injector from the package under aseptic conditions.

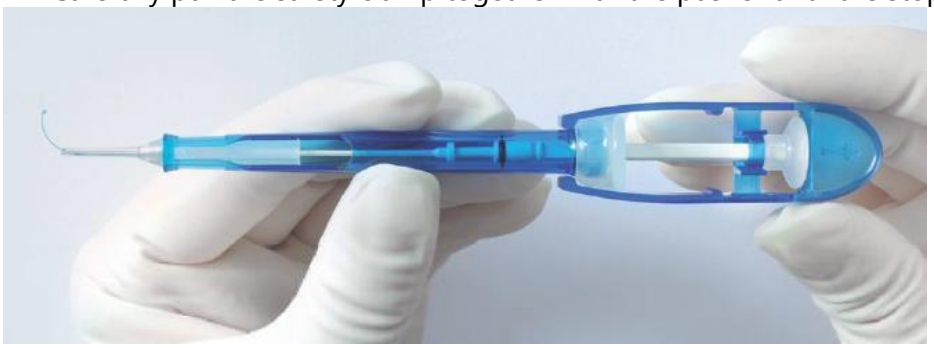
Rinse the non-preloaded CTR with sterile intraocular irrigating solution (BSS) before the implantation/loading into the injector.

DIRECTIONS FOR USE

1. Gently remove the injector from the package.

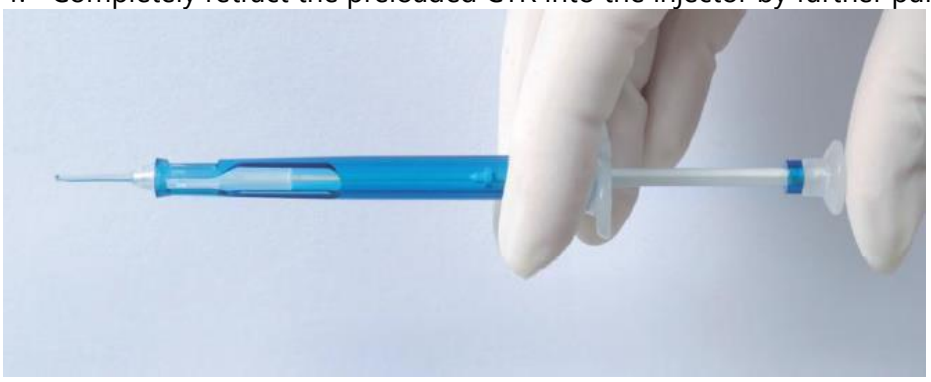


2. Carefully pull the safety clamp together with the pusher until the stop.

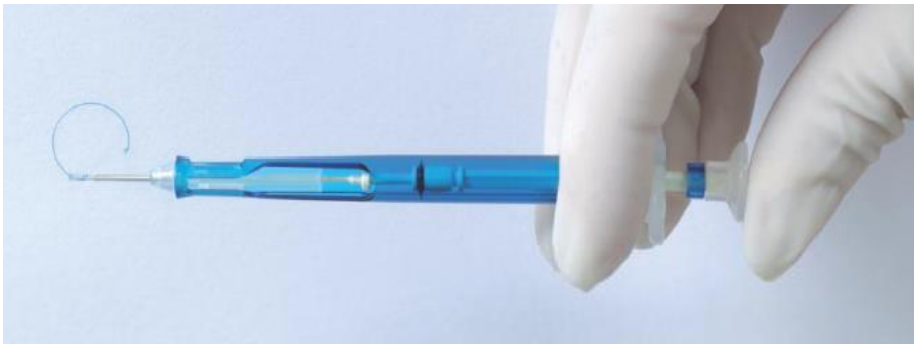


3. Remove the safety clamp from the pusher in a lateral direction.

4. Completely retract the preloaded CTR into the injector by further pulling the pusher until the end.



5. The inscription on the injector should be visible during the implantation. This way the injector is in the correct position. Insert the injector tip into the capsular bag at 6 o'clock and release the ring along the capsular equator clockwise by gently pushing the rod. Make sure the ring is sliding smoothly around. At the end, the ring will be released from the hook. Retract the empty hook into the injector and remove it from the eye.



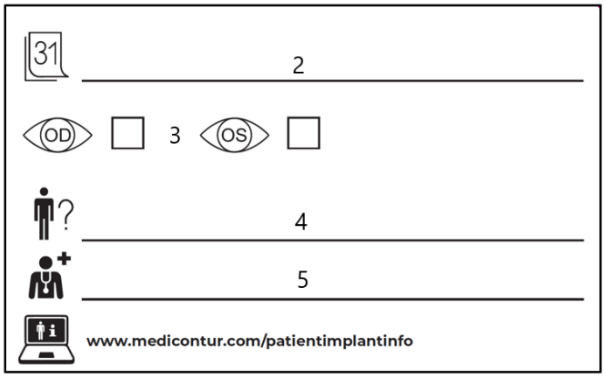
LIABILITY

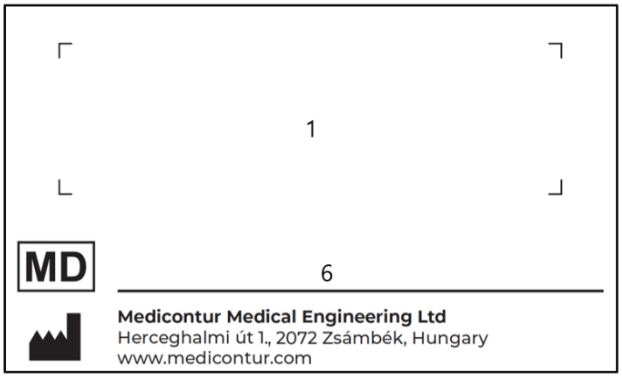
Medicontur does not bear any responsibility for improper model selection by the physician, for improper handling, use, surgical technique applied or for any other iatrogenic error caused by the implanting surgeon.

IMPLANT CARD AND PATIENT INFORMATION

All relevant details should be entered onto the implant card enclosed. One of the self-adhesive labels with the CTR's details and UDI 2D barcode printed on it is designed to be placed on the Implant Card, also enclosed in the packaging. This Patient Card should be handed over to the patient for future reference allowing the patient to identify the surgeon and the type of CTR implanted.

The implant card has to be filled in by the healthcare facility / healthcare provider as follows:





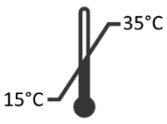
1. Place the label with UDI 2D barcode on the Implant card.
2. Fill in the date of implantation
3. Mark the implanted eye - left (OS) or right (OD).
4. Fill in the name of patient or patient ID.
5. Fill in the name and address of the healthcare institution / provider.
6. Fill in the medical device name.

The link to access the patient information is printed on the implant card.

SYMBOLS – IMPLANT CARD

 Patient Name or patient ID	 Date of implantation	 Name and Address of the implanting healthcare institution/provider
 Name and Address of the manufacturer	 Information website for patients	 Device Name
 Serial Number	 Unique Device Identifier	 Right Eye
 Left Eye		

SYMBOLS - PACKAGING

 CE certified	 Keep dry	 Do not re-use
 Keep away from sunlight	 Consult instructions for use	 Do not re-sterilize
 Serial Number	 Use by date	 Sterilized using irradiation
 Do not use if package is damaged	 Manufacturer	 Single sterile barrier system with protective packaging inside
 Temperature limit	 Date of manufacture	 Caution
 Medical device	 Unique Device Identifier	

MANUFACTURER

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Any adverse event that the lens may have caused, any serious incident should be reported to Medicontur's Quality Assurance at QA@medicontur.hu and to the competent regulatory authority.

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This document is executed in the English language. In the event of any inconsistencies, the English version shall prevail.