



## Patient Information Leaflet

CAPSULAR RINGS

Manufacturer

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**The leaflet should be one of many sources of information that inform a discussion on the decision regarding the implantation of a device.**

**If you have any questions concerning a Capsular Ring manufactured by MORCHER® you should contact your doctor.**

## INTRODUCTION

This brochure has been written to assist you and your surgeon in making an informed decision regarding the best Capsular Ring for your cataract surgery. Your surgeon will advise you about the potential risks and benefits of the surgical procedure. This brochure will aid you in deciding if a MORCHER® Capsular Ring would be an appropriate choice for you. Only a doctor can determine if you are a good candidate for a Capsular Ring.

## WHAT IS A CAPSULAR RING?

Capsular Rings (CR) are intended for the stabilisation of the crystalline lens capsule in the presence of weak or partially absent zonules in patients undergoing cataract extraction with intraocular lens implantation. MORCHER® Capsular Rings are made of polymethylmethacrylate (PMMA), and are either blue in colour or colourless.

There are three different types of Capsular Rings: “Capsular Tension Rings”, “Cionni Rings For Scleral Fixation” and “Capsular Segments For Scleral Fixation”. Your doctor will determine which capsular ring is best for your procedure.

### Capsular Tension Rings

Type 14, Type 14C, Type 14A, Type 13, Type 13A, Type 13B, Type 13S, Type 10C, ACTR10, ACTR11, ACTR12, EyeJet® CTR Type 14 RIGHT/LEFT, EyeJet® CTR Type 14C RIGHT/LEFT, EyeJet® CTR Type 14A RIGHT/LEFT, EyeJet® CTR Type 13 RIGHT, EyeJet® CTR Type 13A RIGHT, EyeJet® CTR Type 13B RIGHT, EyeJet® CTR Type 10C RIGHT, EyeJet® CTR Type 19D RIGHT, Type 15 RIGHT, Type 15A RIGHT, Type 15B RIGHT

### Cionni Rings For Scleral Fixation

Type 1G, Type 1L, Type 2C, Type 1S, Type 2L, Type 2S, EyeJet® CTR Type 10L RIGHT, EyeJet® CTR Type 10G RIGHT

### Capsular Segments For Scleral Fixation

Type 6D, Type 6E

**The specification "RIGHT" and "LEFT" refers to the implantation (clockwise or counter clockwise) and is only relevant for the operating surgeon. The information is not related to the eye to be operated on.**

### Capsular Tension Rings (CTR)

The CTR is an PMMA open-ring device with blunt tipped eyelets at either end. The CTR is designed to be implanted into the capsular bag and left permanently in place. CTRs work by imparting a radial expansile force to the equator of the capsular bag. This force is equalized throughout the entire zonula-capsule apparatus, thereby transferring the tension from intact and normal zonules to those areas of zonular weakness or absence. By increasing overall bag stability, the risk of intraoperative complications is reduced. In addition, the tension imparted to the entire bag with a CTR decreases postoperative capsular contraction (phimosis) as well as posterior capsular opacification and improves intraocular lens centration.

**CTRs have no effect on the refractive results of cataract surgery.**

### Cionni Rings For Scleral Fixation

Cionni Rings For Scleral Fixation are CTRs with additional fixation eyelets to allow the entire ring to be fixated permanently to the sclera with sutures. The suturing eyelets are positioned slightly anterior to the ring, allowing the ring to be placed into the capsular bag while the eyelets remain anterior to the capsule. This configuration allows suturing of the ring to the scleral wall by means of the eyelet without compromising the integrity of the capsular bag. There are different models available to provide more versatility in placement of scleral fixation depending on the extent and area of zonular weakness.

## Capsular Segments For Scleral Fixation

Capsular Segments For Scleral Fixation are indicated for significant zonular weakness and may be used intraoperatively or as permanent support.

One or more segments may be used as necessary to support the areas of the capsule that have damaged or insufficient zonular support.

## PRECAUTIONS

- Before surgery, your eye doctor will check to see if you have any eye diseases or swelling. Be sure to tell your eye doctor if you have any health conditions (e.g., breathing difficulties, heart trouble, allergies, previous eye surgery) that may affect your surgery or vision.
- You should avoid any activity that could harm your eye while you are recovering from surgery. Your eye doctor will tell you what activities you should avoid.
- Take all prescribed medicines and apply eye drops as instructed.

## INDICATIONS

- Used only in connection with a cataract operation with intraocular lens
- Capsular Rings help to stabilize the capsular bag in the case of high myopia

Additional indications only for Capsular Tension Rings and Cionni Rings For Scleral Fixation:

- With Zonulolysis
- In Pseudoexfoliation
- Primary zonular weakness
- Defective or missing zonules

Additional indications only for Capsular Tension Rings:

- Marchesani syndrome

Additional indications only for Cionni Rings For Scleral Fixation:

- Secondary zonular weakness (e.g. Marfans's syndrome)

## CONTRAINDICATIONS

The usual contraindications for a cataract operation apply here, as well as the following ones:

- Patients, whose eyes are not fully developed, i.e. implants are contraindicated in eyes that are still in their developmental stage.
- Pre-operative complications of the cataract surgery (vitreous humour prolapse, bleeding)
- Expected post-operative problems caused by the cataract surgery
- Severe microphthalmia or macrophthalmia
- Patients with a flat front section, e.g. microphthalmia or certain types of chronic angle closure glaucoma
- Chronic uveitis
- ICCE (intra capsular cataract extraction) technology
- Flat anterior chamber
- Progressive ophthalmic diseases (proliferative diabetic retinopathy, uncontrolled glaucoma)

Certain operative complications could also lead to a contraindication against the use of the implant, e. g.:

- Rupture of the capsule of the lens with or without vitreous prolapsed.
- Damage to the capsular bag
- Prolonged bleeding or other visual impairments
- Anterior chamber inflammation (occurring in nearly half of patients)
- Cortical remnants
- Vitreous problems
- Druses
- Cortical macular edema
- Macular degeneration
- Posterior capsular opacification (at least in conventional capsular rings without sharp edge)
- Intraocular lens decentered
- Elevated intraocular pressure
- Optic atrophy
- Retinal detachment

- Deposits on intraocular lens
- Iritis
- Cystoid macular edema
- Posterior synechiae

#### COMPLICATIONS OF THE IMPLANT (SPECIFIC AND NON-SPECIFIC)

- Zonular trauma
- Impairments caused during cortical cleansing
- Possible dislocation of the intraocular lens or the capsular bag when the posterior capsular surface tears
- Angle closure

#### SIDE EFFECTS

The possible side effects of the Capsular Ring is as follows:

- Zonular trauma
- Impairments caused during cortical cleansing
- Possible dislocation of the intraocular lens or the capsular bag when the posterior capsular surface tears

#### POSTOPERATIVE CARE INSTRUCTIONS

You will return home after surgery. Typically, your eye doctor will examine you the following day. Your eye doctor will give you eye drops to speed up the healing process and to prevent infection.

**Always consult your eye doctor if you have any questions or concerns as a result of cataract surgery.**

#### PATIENT IMPLANT ID CARD

After your cataract procedure, your doctor will give you a Patient Implant ID Card. Your ID card will list the following information:

- model of the device
- batch code/lot number
- Serial number
- Manufacturers address and website
- Date of implant
- Operated eye (left / right)

#### EXAMINATION / MONITORING

Routine monitoring after cataract surgery.

#### EXPECTED DEVICE LIFETIME

Without any complications or adverse events the products may stay in the patient for his lifetime.

#### NOTIFICATION OF ADVERSE EFFECTS

If you note any serious incident that occurs in relation to the device, please report it to the manufacturer and the Therapeutic Goods Administration

Web [www.tga.gov.au](http://www.tga.gov.au)

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