

## ACPi-11 Capsular Tension Ring

### Patient Information Leaflet

This leaflet will help you understand general information on cataracts, treatment with surgery and intraocular lenses with capsular tension ring implantation and is not a substitute for advice from your ophthalmologist. Please discuss any questions with your ophthalmologist.

### Intended Purpose

The ACPi-11 is a sterile single-use capsular tension ring (CTR) designed to be permanently implanted in adult patients during cataract surgery at the same time as the artificial lens.

The CTR is made of surgical quality polymethylmethacrylate (PMMA) plastic material, so it is expected to have a long lifetime. The CTR is supplied pre-loaded in an injection syringe.

### What are Cataracts?

Cataracts are a clouding of the eye's natural lens and usually develop as a normal part of ageing. Cataracts develop when protein builds up in the lens of your eye and makes it cloudy. This keeps light from passing through clearly and can interfere with your vision.

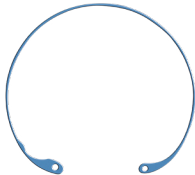
### Treatment for Cataracts

Surgery is needed to remove the cloudy lens and replace it with a permanently implanted artificial lens to restore your vision. Your ophthalmologist will determine the best lens for you based on your needs and the results of your eye examination.

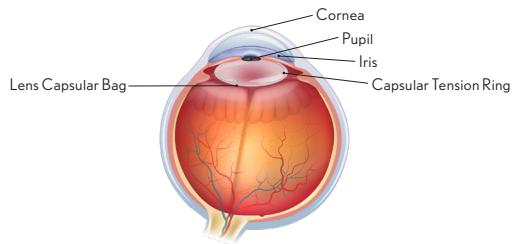
Once the cataractous lens is removed, the artificial lens is placed in the same capsular bag, which is a thin membrane that wraps and supports the natural lens. This capsular bag is itself maintained and stabilized into eye by fibers, called zonules.

The stability of the bag is important to ensure a perfect positioning of the artificial lens and good vision. In some eye conditions, this stability could be compromised: patients with damaged, broken or fragile zonules, high risk of bag retraction in high myopic patients. In such conditions, and in the absence of contra-indications, that will be evaluated by your ophthalmologist, a CTR could be implanted into the capsular bag. The ACPi-11 is designed to stabilize and prevent the retraction of the capsular bag to ensure artificial lens centration and good vision.

**PICTURE 1**  
**Capsular Tension Ring**

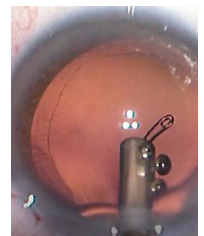


**PICTURE 2**  
**The eye anatomy showing a capsular bag with the CTR**



ACPi-11 is implanted by your eye surgeon into the capsular bag using an injection syringe through the same small incision he has performed in your cornea to remove your cataract.

**PICTURE 3**  
**Implantation procedure**



## Potential Risks

Cataract surgery is safe but does have risks of complications. Complications may occur as a result of the removal of your cataract whether an intraocular lens (IOL) is implanted. Complications of cataract surgery with artificial lens implantation range from minor, usually temporary side effects, to sight-threatening complications including, but are not limited to, inflammation, infection, bleeding, swelling, and retinal detachment. People with existing medical conditions affecting the eye might be at a higher risk of developing complications, your ophthalmologist will weigh the potential benefit/risk ratio. Specific complications with the use of a capsular tension ring such as perforation or rupture of the capsular bag may occur during the surgery. After surgery there is a risk of dislocation of the CTR and/or the artificial implant. Routine eye exams remain very important after cataract surgery to monitor the health of your eyes and the clarity of your vision. Your ophthalmologist will advise on the frequency of these examinations.

## Before Cataract Surgery

Your doctor will also explain the cataract procedure and a pre-admission assessment will be performed. Your ophthalmologist will also need to know your medical history to plan the best treatment. Tell your ophthalmologist about any health problems you have. Some may interfere with surgery, anesthesia, recovery and ongoing medical treatment following recovery. Cataract operations are usually performed in a day surgery facility, so you should be able to return home on the same day as the procedure, without any overnight stay. You may have a protective pad placed on your eye which you will need to wear up until your follow up appointment. You will also be shown how to correctly put in the eye drops.

## After Cataract Surgery:

Be sure to attend all follow-up visits so that your eye doctor can monitor healing. Expect your vision to begin improving within a few days. Your vision may be blurry at first as your eye heals and adjusts. It is normal to feel itching and mild discomfort for a couple of days after surgery. Avoid rubbing or pushing on your eye.

Avoid most exercise or heavy lifting. Your doctor will tell you when you can do those activities again.

Your doctor may ask you to wear a protective shield for a few days after surgery. This is especially important during sleep.

Your doctor may prescribe eye drops or other medication to prevent infection, reduce inflammation, and control eye pressure.

After a couple of days, most of the discomfort should disappear. Often complete healing occurs within eight (8) to twelve (12) weeks.

Contact your doctor immediately if you experience any of the following:

- Vision loss
- Persistent or severe pain
- Increased eye redness
- Light flashes or multiple new spots (floaters) in front of your eye

## Reporting a serious event

Always follow your doctor's instructions. Any serious event that you experience in relation to the device, you can report to the manufacturer or the Therapeutic Goods Administration online at:  
[www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems)

## Sponsor Information

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