



First Quality  
in Ophthalmology

## **1stQ Intraocular Lenses (IOLs)**

### **Patient Information Leaflet**

To Accompany Patient Lens Implant Card



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## What is an Intraocular Lens (IOL)?

An intraocular lens (IOL) is an artificial lens designed to replace the crystalline lens of the eye after cataract surgery. With a diameter of only 13 mm, an IOL is around half the size of a regular paper clip.



*The real size of your IOL: Compared to a standard paper clip (28 mm)*

The history of IOLs began during the Second World War when Royal Air Force pilots suffered eye injuries from shattered Perspex aircraft canopies, but their body's immune system did not react to the PMMA splinters.

Modern soft, foldable acrylic IOLs are made from a material chemically similar to PMMA lenses, which are proven to be safe in the eye.

## IOL types and performance

**Monofocal intraocular lenses** can provide sharp vision at only one distance. Clear vision is usually set for far distance and glasses are needed for intermediate and near vision tasks. If you have astigmatism, a **monofocal toric** lens can be implanted.



**Trifocal intraocular lenses** are an advanced solution that can provide sharp vision at all distances without the need for glasses after cataract surgery. If you have astigmatism, a **trifocal toric** lens can be implanted to simultaneously correct astigmatism, with the same lens.



**AddOn supplementary lenses** are implanted in to the ciliary sulcus in addition to the IOL in the capsular bag. They may be used for correction of refractive errors, presbyopia and astigmatism. They can either be implanted in a single planned procedure together with the primary lens, or at any time later in the pseudophakic eye.

## What is cataract?

### How does cataract develop?

As people age, the natural crystalline lens of the eye becomes cloudy. The most common cause of cataract is age-related, however, cataract can also develop due to trauma, the use of certain medications, or the presence of certain disease. Cataract can be present in one or both eyes.

### How does it affect your vision?

Cataract can cause blurred vision, problems with glare and faded colours. Difficulties with night vision can also occur. The severity of your cataract depends on multiple factors, including your age and individual health conditions.



Healthy eye



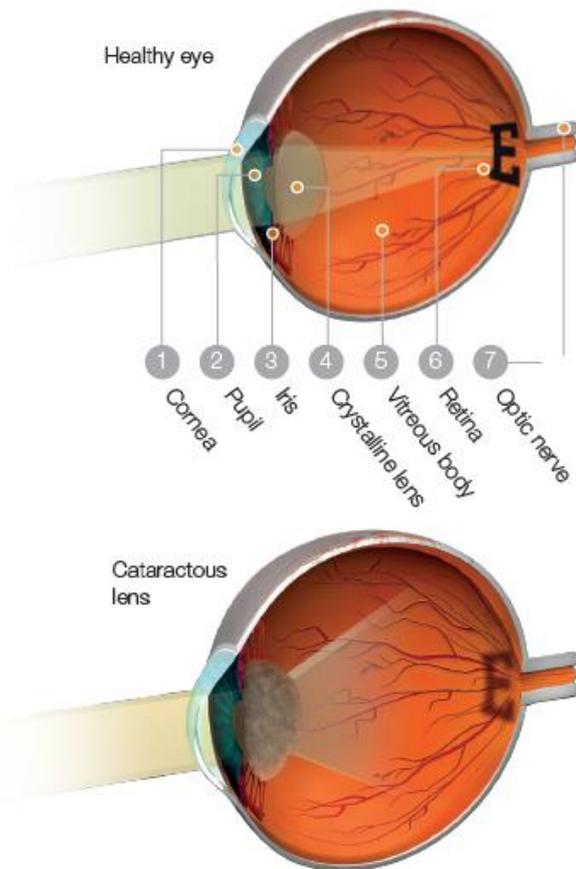
Cataract

Currently, no medications are available to treat cataract and restore your vision. The only effective solution is the surgical removal of the cataractous lens along with its replacement with an artificial lens (IOL).

### Symptoms of cataract

- Blurred or cloudy vision
- Faded colours
- Light sources can be disturbing (for example dazzling car lights at night, halos around lights, other dazzling lights, distracting light around lamps)
- Limited night vision
- Double or multiple vision
- Frequent changes needed in the diopter of glasses or contact lenses

Consult your ophthalmologist for detailed information or possible solutions.



### Is it possible for me to see clearly again?

After a visual acuity test and a thorough examination, your doctor will make the right diagnosis for you. If your doctor determines that you have cataract, further examination will be required to find the most appropriate surgical procedure, according to your individual needs.

### What is presbyopia?

Presbyopia is a condition of the eye where the natural crystalline lens has lost its elasticity and adaptability, making it increasingly difficult for the eye to focus on nearby objects.

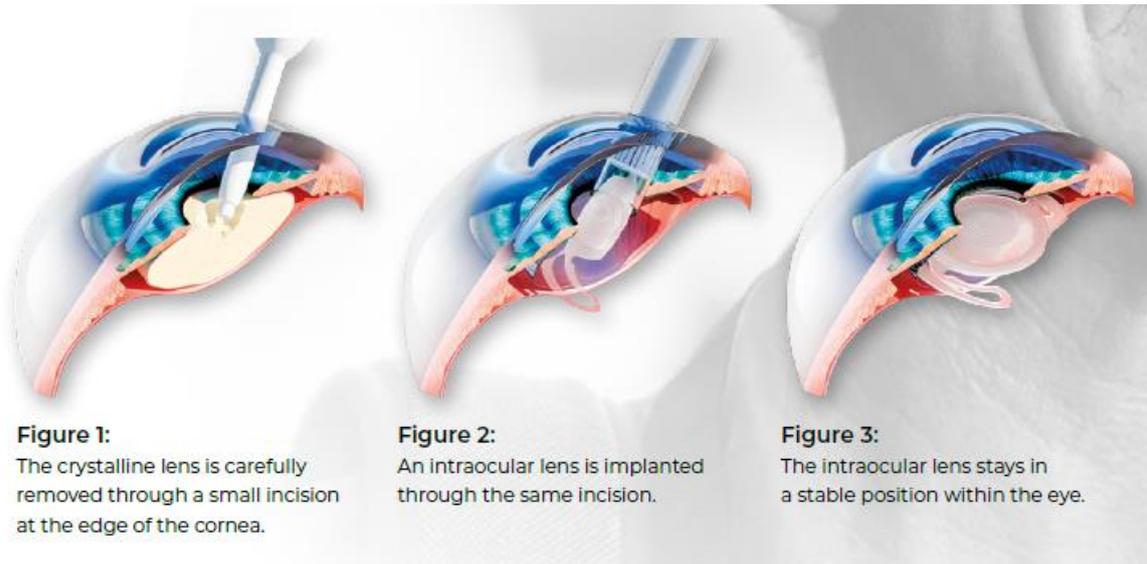
### What is astigmatism?

Astigmatism is the condition when the cornea doesn't have a regular, evenly curved shape but an ovoid shape, similar to a rugby ball. In the astigmatic eye, the light rays passing through the cornea do not meet at a single focal point, which causes blurred images, often resulting in poor vision. Special toric IOLs can correct this kind of refractive error in the eye.

### Cataract surgery

During cataract surgery, the blurred lens is removed and an artificial lens is implanted into your eye. The doctor makes a small cut (1.8-2.2 mm) on the cornea. Using an ultrasonic or laser instrument, the doctor slices the cataractous lens into tiny pieces

and sucks it out from the capsular bag. The IOL is then implanted through the same small incision.



### Is the surgery painful?

Cataract surgery is usually not painful due to the use of anesthesia.

### Can I see anything during the surgery?

It is possible that you will see light and movement.

### How much time does the surgery take?

The average duration of the surgical procedure is usually not more than 20-30 minutes.

### Will my vision improve immediately after surgery?

You are likely to experience an immediate improvement in your vision, however, it might take a few weeks to achieve optimal visual outcomes.

### Can the IOL be seen in my eye?

Usually the IOL cannot be seen in your eye.

### How successful is cataract surgery and what about the risks?

Cataract surgery is considered to be one of the safest operations with a success rate over 98%. It is also one of the most common operations performed in the world. While the surgery is considered a safe procedure, the occurrence of complications and adverse events cannot be completely ruled out. However, these adverse events are relatively rare and can be treated successfully.

### Will my health insurance cover the cost of surgery?

Your health insurance provider may cover most of the costs associated with cataract surgery including the intraocular lens. Please contact your health insurance provider to find out what you are covered for and if there are any out of pocket costs.

## Precautions

Your doctor is supposed to evaluate your condition before surgery in order to determine the risk/benefit ratio of the implantation if you have one or more of the following pre-existing conditions. These conditions do not necessarily pre-empt surgery but should definitely be considered by the surgeon:

- Choroidal hemorrhage
- Significant vitreous loss
- Extremely shallow anterior chamber
- Posterior capsule rapture
- Severe corneal dystrophy
- Severe optic nerve atrophy
- Zonular separation
- Colour vision deficiencies
- Uncontrolled glaucoma
- Chronic uveitis
- Diabetic retinopathy
- Retinal detachment
- Recurrent anterior or posterior segment inflammation of unknown etiology
- Clinically significant macular/RPE changes
- Keratoplasty, especially in case of toric IOLs

## Complications

As with any surgical procedure, there is risk involved. The following non-exhaustive list specifies the complications associated with the implantation of IOLs. All are relatively rare and treatable conditions.

**Corneal damage or edema.** Swelling of the cornea.

**Cystoid macular edema.** Painless swelling of the retina.

**Secondary glaucoma.** Raised eye pressure due to an identifiable cause.

**Pupillary block.** Occurs when the flow of fluids between the chambers of the eye is obstructed. It can lead to glaucoma.

**Uveitis.** A form of eye inflammation. It may entail eye redness, pain and blurred vision.

**Iris trauma.** Any trauma to the iris may degrade visual function.

**Hemorrhage.** Bleeding.

**Damage to the zonules or to the capsule with consequential IOL dislocation.** When the apparatus that holds the IOL in place within the eye is damaged, it may result in a dislocated IOL that would lead to impaired function.

**Posterior capsule opacification.** Occurs when a cloudy layer of scar tissue forms behind your IOL implant.

**Postoperative calcification of the IOL.** Rare cloudiness of the implant after surgery.

**Endophthalmitis.** Inflammation of the interior cavity of the eye, usually caused by infection.

**Asthenopic discomfort.** Eye strain.

**Reduced contrast sensitivity.** The ability to distinguish between finer and finer increments of light versus dark (contrast) is impaired.

**Reduced night vision or in poor visibility conditions.**

**Perception of halos or radial lines around point sources of light.**

**Dissatisfactory visual outcome due to incorrect IOL refraction.** Occurs when the power of the IOL was incorrectly calculated prior to surgery.

## Lifetime of IOLs

The lifetime of an IOL after implantation is defined as at least 20 years. During this period, the characteristics and performance of the IOL do not affect your health or safety negatively as long as the IOL is subject to stresses that may occur in normal conditions of use.

## Glossary

**Accommodation.** The adjustment of the crystalline lens to keep close objects in focus on the retina.

**Astigmatism.** A common vision condition that causes blurred vision. It usually occurs when the cornea (the clear front cover of the eye) is irregularly shaped.

**Hyperopia.** Also known as far-sightedness, it is a common vision condition which results in near objects appearing blurry, whereas far objects may appear normal.

**Intraocular Lens (IOL).** An artificial lens implanted in the eye during cataract surgery or clear lens extraction.

**Monofocal IOL.** The most common type of intraocular lens for cataract patients. Monofocal lenses are usually designed to restore far vision, while near vision usually will need further correction.

**Monofocal toric IOL.** Monofocal IOLs which also correct astigmatism.

**Myopia.** Also known as near-sightedness, it is a common vision condition which results in far objects appearing blurry, while near objects may appear normal.

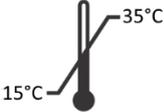
**PMMA.** Polymethyl methacrylate, plexiglass.

**Trifocal IOL.** Novel intraocular lenses with advanced technology, providing sharp vision for all distances (near, intermediate and far).

## Notice

Any serious incident that occurs in relation to the device should be reported to the manufacturer ([info@1stq.de](mailto:info@1stq.de)) and to the Therapeutic Goods Administration (<https://www.tga.gov.au>).

### Glossary for the Symbols and Abbreviations used

	Patient Name or patient ID		Date of implantation		Name and Address of the implanting healthcare institution/provider
	Serial Number		Information website for patients		Unique Device Identifier
	Left Eye		Right Eye		Do not re-use
	CE certified		Keep dry		Do not re-sterilize
	Keep away from sunlight		Consult instructions for use		Sterilized using steam or dry heat
	Do not use if package is damaged		Manufacturer		Single sterile barrier system with protective packaging inside
	Temperature limit		Date of manufacture		Caution
	Medical device		Use by date		

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