MEDICONTUR

MEDICONTUR INTRAOCULAR LENSES (IOLS)

Patient Information Leaflet

Content

1. Introduction

This Patient Information Leaflet aims to inform patients diagnosed with certain visual disturbances of basic facts about cataract, presbyopia, refractive errors, different treatment options, and what to expect from the surgery and after the procedure.

Cataract is a common eye condition mainly affecting the elderly. No medications, eye drops, glasses, or eye exercises can stop or reverse already-developed cataract. An advanced medical solution, the implantation of intraocular lenses (IOLs), can successfully treat cataract, presbyopia, and other refractive errors, such as myopia, hyperopia, and astigmatism. With this simple and painless procedure, dependence on spectacles can be reduced.

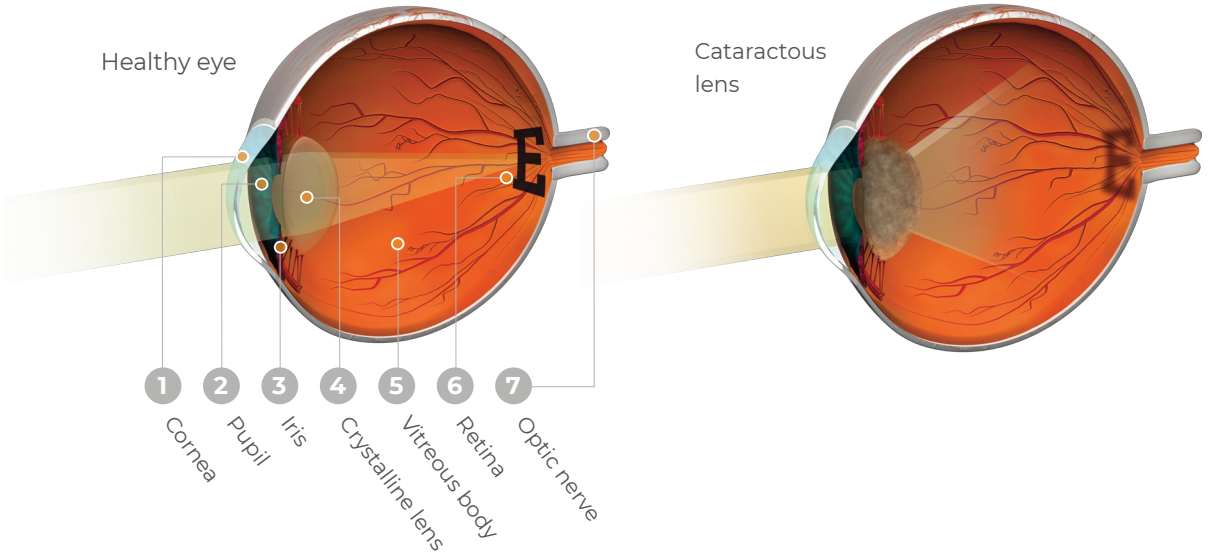
This Patient Information Leaflet describes modern treatment technologies and introduces the different types of intraocular lenses offered by Medicontur Ltd.

2. What is cataract? How does it affect vision?

Vision is an essential part of our life as it contributes significantly to the interpretation of the surrounding environment. Eye conditions (such as nearsightedness, farsightedness, astigmatism, presbyopia, or cataract) that negatively affect the quality of vision indirectly impact the overall quality of life.

The light entering the eye passes through several optical elements until it reaches the retina and creates a sharp image. The function of the natural crystalline lens is to collect the light rays passing through the pupil and bend them so they meet in one sharp focal point on the retina. Light rays coming from objects at different distances need different level of bending by the natural crystalline lens to form a sharp image. The accommodating crystalline lens, by default, has a flat shape to ensure a clear image of far objects. In case of near objects, the lens becomes compressed by the surrounding muscles of the eye, and its shape becomes curvier, resulting in a higher refractive power, enabling a clear image. With age, the crystalline lens loses the ability to accommodate, increasing difficulty in seeing near objects clearly. Presbyopia, the progressively worsening ability to focus clearly on close objects, affects many people over the age of 40.

Cataract is a progressive change within the protein structure of the natural crystalline lens that causes the originally transparent lens to become increasingly cloudy, blocking the light from forming a clear image. The most common cause of cataract is age-related, mainly affecting the population over 50. However, cataract can also develop due to trauma, the use of certain medications, or the presence of certain diseases. Cataract can be present in one or both eyes.



Common symptoms of cataract:

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

Healthy eye

Cataract

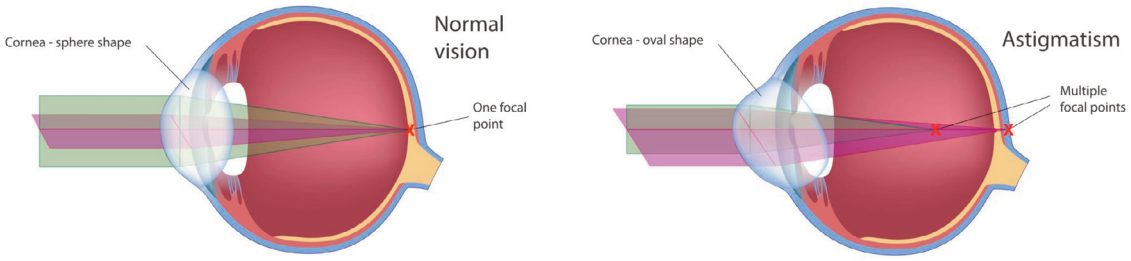
Effective cataract treatment is only possible with the surgical removal of the cataractous lens and its replacement with an artificial lens. Currently, no other treatment methods or medications are available to treat cataract and restore vision.

3. 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.

4. What is a refractive error?

Refractive error means that the shape of the eye does not bend the light correctly, resulting in a focusing issue with a visual effect of a blurred image. The main types of refractive errors are myopia (nearsightedness), hyperopia (farsightedness), and astigmatism. In a normal eye, the cornea has a round shape (like a basketball); therefore, the light rays entering the eye focus at a single point on the back (retina) to form a clear image. In an eye with corneal astigmatism, the cornea has an oblong shape (like an American football). As a result, the light rays passing through the cornea do not meet at a single focal point, which causes blurred images, often resulting in poor vision.



5. What is an Intraocular Lens (IOL)?

Intraocular lenses are artificial lenses used in cataract surgery. They replace the cloudy crystalline lens of the eye to restore vision. IOLs are implanted in the capsular bag that originally wraps around the natural crystalline lens. Medicontur intraocular lenses are intended for adult patients (18 years old and older) diagnosed with a cataract and/or ametropia (hyperopia, myopia, astigmatism) and/or presbyopia.

The history of IOLs began during the Second World War when British Royal Air Force pilots suffered eye injuries from shattered Perspex aircraft canopies, but the immune system of their bodies 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 safe in the eye.

Medicontur offers different types of intraocular lenses to best suit the patient's needs. The soft and foldable intraocular lenses are made from a transparent biocompatible material that is either a 100% hydrophobic acrylic random copolymer (based on ethyl acrylate and ethyl methacrylate with a covalently bound UV blocker) or a 100% hydrophilic acrylic random copolymer (based on hydroxyethyl methacrylate and ethoxyethyl methacrylate, with covalently bound UV blocker), with a water content of

25%. Yellow IOLs have a blue-light filtering chromophore covalently bound to the material. The lifetime of the IOLs is defined as 20 years – at least – from the implantation. During this period of time, the characteristics and performance of the device do not adversely affect the health or safety of the patient when the device is subjected to the stresses which can occur during normal conditions of use. These intraocular lenses are neither visible nor perceivable in the eye.

The actual size of the IOL: compared to a standard paper clip (28 mm):

6. IOL types and performance

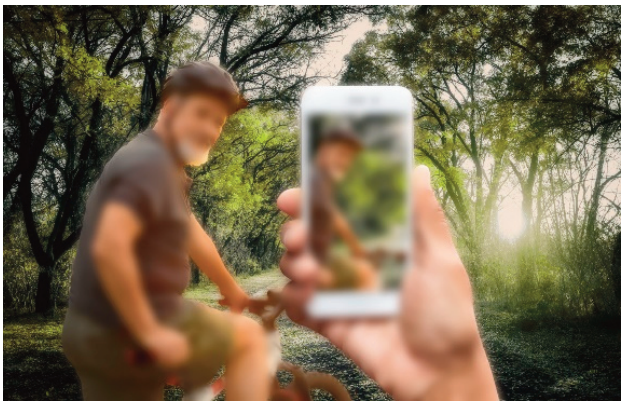
A variety of intraocular lenses available on the market have different optical design and performance.

Medicontur offers the following intraocular lens types:

- Monofocal IOLs
- Monofocal toric IOLs
- Trifocal IOLs
- Trifocal toric IOLs
- EDoF IOLs
- EDoF toric IOLs

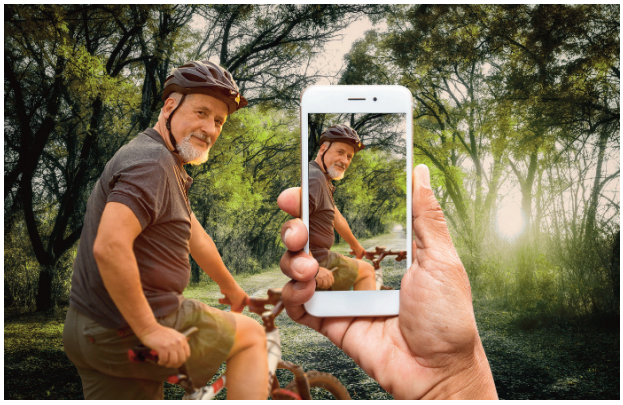
6.1 Monofocal intraocular lenses

Monofocal intraocular lenses are the most widely used IOLs. They provide sharp vision at only one distance, as the light entering the eye implanted with a monofocal IOL can be focused to a single focal point on the retina. Clear vision is typically set for far distance, and glasses are needed for intermediate and near vision tasks. Patients with corneal astigmatism can be implanted with a **monofocal toric IOL** to reduce or eliminate the level of astigmatism at the same time.



6.2 Trifocal intraocular lenses

Trifocal intraocular lenses are an advanced solution for presbyopia and provide independence from glasses after cataract surgery. The special optic of the trifocal IOL bends the light entering the eye from far, intermediate, and near distances. It focuses this light into a single focal point on the retina. This enables patients to focus on objects at different distances simultaneously, providing near, intermediate, and distance vision without gaps. Patients with corneal astigmatism can be implanted with a **trifocal toric IOL** to reduce or eliminate the level of astigmatism.



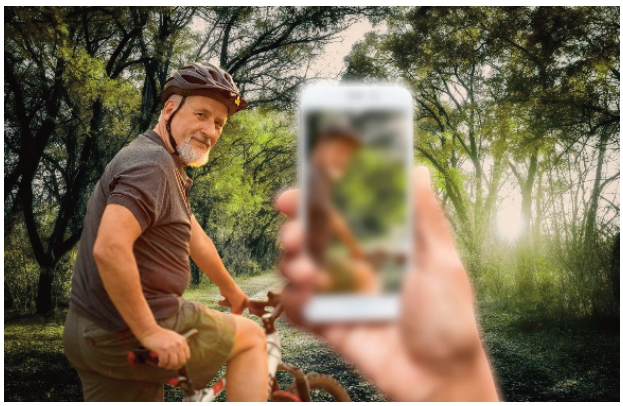
Trifocal intraocular lenses offer a high level of spectacle independence; however, compared to monofocal IOLs, some side effects might appear due to the trifocal technology that splits the entering light. Besides reduced contrast sensitivity, patients might ex-

perience light phenomena (dysphotopsia), halos, and glares, when looking into a bright light source in a dark environment.

Trifocal intraocular lenses might not be suitable for patients suffering from eye diseases, such as glaucoma, diabetic retinopathy, diabetic macular oedema, or macular degeneration. Patients suffering from any of these diseases should consult with their ophthalmologist about alternative solutions.

6.3 Extended Depth of Focus (EDoF) intraocular lenses

Extended Depth of Focus (EDoF) intraocular lenses provide sharp vision from far to intermediate distances (such as a computer screen or a car dashboard). EDoF intraocular lenses ensure more spectacle independence than monofocal IOLs, patients are usually spectacle independent for far and intermediate distances, but they might need reading glasses for close-up activities such as reading and doing precision work. The main advantage of EDoF lenses is that compared to trifocal IOLs, they are usually less associated with disturbing light phenomena (dysphotopsia) that are typically perceived while looking into bright light sources in a dark environment. Patients with corneal astigmatism can be implanted with an **EDOF toric IOL** to reduce or eliminate the level of astigmatism at the same time.



The above visualizations are for demonstrative purposes only. Individual results may vary.

7. Cataract surgery

Cataract surgery is considered to be one of the safest operations, with a success rate of over 98%. It is one of the most common surgeries worldwide and usually takes between 20 to 30 minutes. The surgery is usually performed on one eye at a time. Implantation of the second eye is scheduled for a few weeks later.

7.1 Before the surgery

After a cataract diagnosis, the patient is directed to the eye clinic for further eye examinations prior to the surgery. The optimal diopter power of the required intraocular lens is determined based on precise biometric measurements. During the consultation, the surgeon explains how to prepare for the surgery.

7.2 During the surgery

To ensure a painless surgery and to numb the eye, topical anesthesia drops are applied before the surgery. Then, the surgeon places an eyelid holder to prevent the patient from blinking during the surgery and applies a disinfecting solution. During the procedure, a hydrating BSS solution is applied on top of the eye to avoid eye dryness. The whole surgery is performed through a small (2.2-2.4 mm) incision on the cornea. Once the incision is created, the surgeon injects a jelly-like substance into the eye to fill up the space and protect the corneal endothelium and other tissues from the instruments. To remove the opacified crystalline lens from the capsular bag, the surgeon creates a small opening on it. Then with a special instrument, the cataractous crystalline lens is broken into small pieces that are carefully removed. This process is called phacoemulsification.

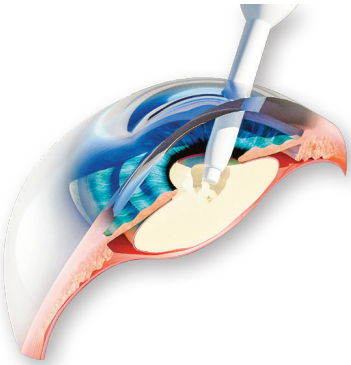


Figure 1:
The crystalline lens is carefully removed through a small incision at the edge of the cornea.

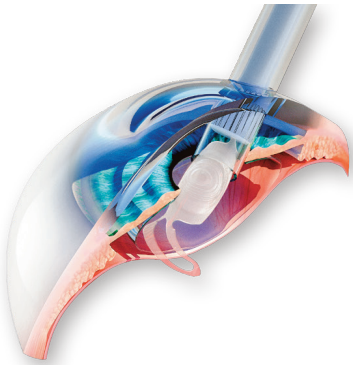


Figure 2:
An intraocular lens is implanted through the same incision.

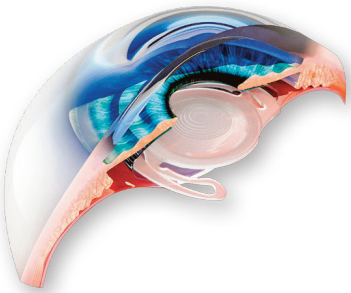


Figure 3:
The intraocular lens stays in a stable position within the eye.

Once the crystalline lens is removed, the surgeon implants the intraocular lens into the capsular bag using a thin injector. After precise positioning, the IOL will stay in the eye in a stable position. The corneal incision is typically self-sealing; there is no need for suturing at the end of the surgery. To protect the eye after the surgery and avoid direct contact and rubbing, a protective eye patch is used to cover the eye.

7.3 After the surgery

It is important to follow the doctor's instructions about what to do and what to avoid for the first few weeks while the eye is healing after the surgery. Eye drops and medications should be used as prescribed. The doctor may advise you to relax and avoid activities involving heavy loads and weights. 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. In case of experiencing any adverse event related to the surgery, the doctor has to be informed immediately.

After the surgery, the patient receives an Implant Card including essential details about the surgery, such as the unique identifier of the implanted intraocular lens, the date of the surgery, and the name and address of the implanting healthcare institution.

8. Complications, warnings, and precautions

As with any surgical procedure, there is risk involved. The following non-exhaustive list specifies the complications and warnings that have been associated with the implantation of IOLs. All are relatively rare and treatable conditions; however, unexpected outcomes may necessitate additional surgical intervention. Patients suffering from any of these conditions should consult with their ophthalmologist.

8.1 Complications

Postoperative complications of cataract surgery:

Corneal damage or edema
Swelling of the cornea

Secondary glaucoma
Raised eye pressure due to an identifiable cause.

Intraocular infection

Asthenopic discomfort, adaptational difficulties
Eye strain.

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

Cystoid macular edema
Painless swelling of the retina.

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 (PCO)
Occurs when a cloudy layer of scar tissue forms behind your IOL implant.

Macular degeneration leading to blindness in long term (years)
Abnormal blood vessels that leak fluid or blood into the macula negatively affect the central vision.

TASS, endophthalmitis
Inflammation of the interior cavity of the eye, usually caused by infection.

Retinal tear, break, or detachment

Persistent iritis
Inflammation of the coloured part of the eye (iris).

Ptosis
Drooping of the eyelid.

Light sensitivity

Diplopia
Double vision, occurs when the patient sees two of the same image.

Blindness
Lens-related visual disturbances (dysphotopsias)

8.2 Warnings and precautions

Warnings and precautions related to residual risks:

Temporary opaqueness of the lens
May occur in case of a considerable change of temperature, but reverts to transparency after some time.

Postoperative opacification/calcification/glistening of the IOL
Rare cloudiness of the implant after surgery.

Reduced contrast sensitivity
In case of trifocal models, the ability to detect contrast between an object and the background is decreased.

Reduced vision at night or in poor visibility conditions

Perception of halos or radial lines around point sources of light
In case of trifocal models, visual effects may be experienced.

Dissatisfactory visual outcome due to incorrect IOL refraction
Occurs when the power and type of the IOL was incorrectly calculated prior to surgery. Due to the diversity and complexity of an IOL product, there may be a risk of implanting an improper model. In case of trifocal models, unexpected outcomes could lead to continued spectacle dependence.

IOL replacement or extraction
Unexpected outcomes may necessitate additional surgical intervention. The intraocular lens might be replaced in case of damage or incorrect diopter power.

Eye tissue damage or inflammation

Reduced UV protection of the eye
The implantation of an artificial IOL to replace the crystalline lens might change the exposure of the eye to external factors (e.g.: UV light, blue light etc.). Wearing UV protection spectacles in the sunlight is advised to avoid damage by ultraviolet rays.

The safety and effectiveness of Medicontur IOLs have not been studied in patients with certain existing conditions and /or intraoperative complications (as these patients were excluded from clinical studies). In case of any preexisting conditions or complications, consult your ophthalmic surgeon for careful preoperative and perioperative evaluation and clinical judgment to decide the risk/benefit ratio before the implantation of Medicontur IOLs.

The artificial material of the IOL may expose the patient to unintended, material-based risks (e.g.: glistening, material fatigue, opacification, leaching etc.)

9. 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 at all distances. It usually occurs when the cornea (the clear front cover of the eye) is irregularly shaped.

Cataract
Cataract is a progressive change within the protein structure of the natural crystalline lens that causes the originally transparent lens to become increasingly cloudy, blocking the light to form a clear image.

Cylinder
A cylinder diopter is a measurement used in eyeglass prescriptions to correct astigmatism, indicating how much the lens needs to curve to correct the uneven shape of your eye

Dysphotopsia
Disturbing light phenomena, such as halos and glares, which are typically perceived while looking into bright light sources in a dark environment. Typically associated with trifocal IOLs.

EDoF IOL
Extended (elongated) depth of focus intraocular lens with an extended range of vision from far to intermediate distances.

Far vision
Vision for objects located approximately further than 2 m, for example, reading a traffic sign.

Glaucoma
Glaucoma is an eye disease due to the increased intraocular pressure that causes damage of the optic nerve connecting the eye to the brain. It has a negative effect on the visual field and the visual acuity.

Hyperopia
Also known as farsightedness, it is a common vision condition which results in near objects appearing blurry, while far objects may appear normal.

Intermediate vision
Vision for objects located approximately within the range of 50-60 cm, for example, computer work or cooking.

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

Monofocal IOL
Intraocular lens with one focal point, typically set for far vision.

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

Near vision
Vision for objects located approximately within the range of 30-45 cm, for example reading.

PMMA
Polymethyl methacrylate, plexiglass.

Presbyopia
With age, the crystalline lens loses the ability to accommodate, resulting in an increased difficulty to see near objects clearly. Presbyopia, the progressively worsening ability to focus clearly on close objects affects many people over the age of 40.

Spherical equivalent
The spherical equivalent is a single number that represents the overall strength of your prescription by combining your nearsightedness or farsightedness and astigmatism.

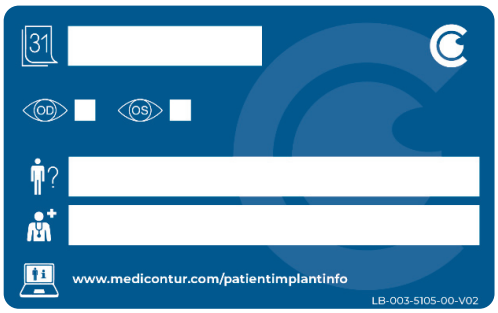
Toric IOL
IOL with a special optic design to correct corneal astigmatism.

Trifocal IOL
Intraocular lens with three focal planes: far, intermediate, and near.

Zonule
Fibrous strands that connect the ciliary body and the crystalline lens of the eye.

10. Symbols

Interpretation of symbols included on the Implant Card.



MD	Device name
	Information website for patients
PWR	IOL Power
ADD	Add Power of IOL
UDI	Unique device identifier (Note: in barcode format)
UDI-DI	Unique device identifier (Note: in number format)
IOL	Intraocular lens
SEQ	Spherical equivalent
31	Date of implantation
	Patient name or patient ID
	Name and address of the implanting healthcare institution/provider
	Name and address of the manufacturer
SN	Serial number (identification number for IOL)
OD	Right Eye
OS	Left Eye
CYL	Cylinder

11. List of Medicontur IOL models

The information provided in this Patient Information Leaflet covers the following intraocular lens models manufactured by Medicontur Ltd.

Model	Type
611HPS 613AD 677AD 640AD 690AD	Monofocal
677ADY 640ADY 690ADY	Monofocal
677P 640P	Monofocal
677PY 640PY	Monofocal
877FAB 860FAB	Monofocal
877FABY 860FABY	Monofocal
877PA 860PA	Monofocal
877PAY 860PAY	Monofocal
677TA 690TA	Monofocal Toric
677TAY 690TAY	Monofocal Toric
677CTA 690CTA	Monofocal Toric
677CTAY 690CTAY	Monofocal Toric

Model	Type
877PT 860PT	Monofocal Toric
877PTY 860PTY	Monofocal Toric
877EBY	EDof
877PEY 860PEY	EDof
877PETY 860PETY	EdoF Toric
677M	Trifocal
640PM 690CM	Trifocal
677MY 640MY 690MY	Trifocal
677CMY 640CMY	Trifocal
690CMY 677PMY	Trifocal
677MT	Trifocal Toric
677MTY 690MTY	Trifocal Toric
677CMTY 690CMTY	Trifocal Toric

MA-IOL-GENRL-PT013-FLY-EN 202212

Product availability may vary by country.
All listed intraocular lens models are manufactured by:

Medicontur Medical Engineering Ltd.
Herceghalmi út 1.
2072 Zsámbék, HUNGARY
www.medicontur.com
Email: mc@medicontur.com

12. Notice

Any serious incident that occurs in relation to the intraocular lens should be reported to the doctor.

13. References

LB-002-5101-00-V05 POSTERIOR CHAMBER HB IOL IFU
LB-006-5100-00-V12 POBMA Injector IFU
LB-003-5101-00-V07 POSTERIOR CHAMBER HL IOL IFU
LB-005-5100-00-V07 HL Preloaded Flex IFU
CER_01_B_v16 - Clinical Evaluation Report of hydrophilic IOLs
CER_01_C_v12 - Clinical Evaluation Report of hydrophobic IOLs
CER_01_D_v11 - Clinical Evaluation Report of preloaded hydrophobic IOLs

A Turner, TD. - **What are the risks of cataract surgery?**
Available from:
https://visionaware.org/your-eye-condition/cataracts/risks-ofcataract-surgery/125/

Paine, DA. - **How long does it take to remove a cataract?**
Available from:
https://www.emedicinehealth.com/ask_how_long_does_it_take_to_remove_a_cataract/article_em.htm

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