PATIENT INFORMATION BROCHURE

IC-8™ IOL
Small Aperture Intraocular Lens

Introduction

This brochure has been written to help you and your eye doctor make an informed decision about the best intraocular lens (IOL) for your cataract surgery. Your doctor will advise you about the potential risks and benefits of the surgical procedure to remove the cataract and implant an IOL. This brochure will help you decide if the **IC-8** small aperture IOL from AcuFocus, Inc. is an appropriate choice for you. Please see the section "What types of IOLs are available for this procedure" to learn about other options you may have. This brochure also provides postoperative care information.

What is a Cataract?

To understand what a cataract is, it is helpful to understand how the human eye works[1]. As shown in **Figure 1** below, the front of the eye is made of the cornea, iris, pupil and a natural lens which is contained in the lens capsule. The back of the eye is the retina, where images are focused. When you look at an object, light reflected from the object enters the eyes through the cornea. The cornea focuses the light before it passes through the pupil. The amount of light that can reach the retina is controlled by the iris which automatically adjusts the size of the pupil to allow light through. Located directly behind the pupil, the natural lens further focuses light onto the retina, the light-sensitive inner lining of the back of the eye. When light reaches the retina, the retina converts optical images into signals, then the optic nerve transmits these signals to the part of brain that controls our sense of sight.

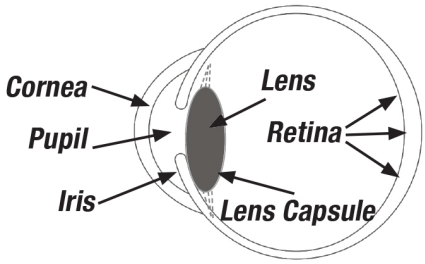

Figure 1 – Drawing of the Human Eye

When the natural lens of your eye is clear, it helps focus images onto the back of your eye so you can see objects and text clearly. Over time, the natural lens of your eye may start to become "cloudy." When this happens, it is called a cataract. Most cataracts are related to the natural aging process. Cataracts can also be caused by certain medical conditions, medications or eye injuries. While cataracts may start out small at first and have little effect on vision, as they grow larger, they may cloud more of the lens and distort the light passing through. If left untreated, cataracts can result in complete loss of vision. Early noticeable symptoms of cataracts include:

- Cloudy, blurry, foggy, or filmy vision
- Glare from lamps, the sun, or headlights
- Frequent changes in eyeglass prescription
- Double vision

Cataracts can only be removed with cataract surgery. You should consider cataract surgery when vision loss is interfering with your daily activities. It is typically performed as an outpatient procedure under local or topical anesthesia. The natural lens of the eye is removed and replaced with a permanent IOL implant.

Please see "*What to Expect During Cataract Surgery*" for more detailed information about this surgical procedure, and "*Types of IOLs*" for more details about the various IOL options available today. There are also other options for restoring your functional vision, such as glasses and contact lenses, which don't involve surgery. You should discuss these options fully with your eye doctor to select the option that best meets your expectations and lifestyle.

What is Corneal Astigmatism?

Astigmatism is a common eye condition that causes blurry far and/or near vision. In a normal eye, the cornea (the clear front part of the eye) has a round shape. It allows the light rays coming into the eye to focus at a single point on the back of the eye (retina) to form a clear image. In an eye with corneal astigmatism, the cornea has an oval shape and as a result, the light rays do not focus at the same point on the retina. This may cause some parts of an object to be unclear. This may also lead to eye discomfort and headaches. During a comprehensive eye exam, your eye doctor will be able to tell you if you have corneal astigmatism.

[1] https://www.allaboutvision.com/resources/anatomy.htm

What is an Intraocular Lens (IOL)?

During cataract surgery, the cloudy natural lens of the eye is removed and replaced with a clear artificial lens known as an intraocular lens or IOL.

Figure 2 shows the basic parts of the human eye with an implanted IOL.

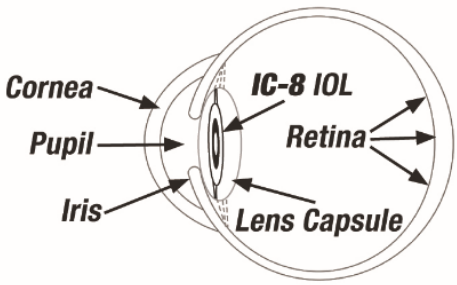

Figure 2 – Drawing of the Human Eye with an Implanted IOL

What to Expect Before Cataract Surgery

After completing a comprehensive eye exam and determining you have a cataract, you and your eye doctor will discuss cataract surgery. Before surgery, your doctor will measure your eye. This will help determine which IOL will be suitable for you.

What to Expect During Cataract Surgery

Cataract surgery is typically an outpatient procedure performed under local anesthesia. Local anesthesia is typically applied in the form of eyedrops. Sometimes patients may also receive additional medicine intravenously to ensure the best possible experience. Typically, you will be awake during the surgery and lying down. You should feel little or no discomfort. Your eye doctor will use a microscope to look at your eye close up. To access your eye's natural lens, which sits in a bag-like structure inside your eye called the lens capsule, your eye doctor will need to make a small incision in the outer surface of the eye. The lens capsule is located just behind the colored part of your eye known as the iris. Through this opening, the eye doctor will create a small opening in the front of the lens capsule and then insert a tiny instrument to break up and remove the cataract. Your doctor will then place an IOL into the empty capsule replacing your natural lens. The IOL will help focus light inside the eye to allow you to see more clearly. Please see "What types of IOLs are available for this procedure" for information about IOL options.

What to Expect After Cataract Surgery

Your surgeon will usually place a shield over your eye after surgery. You will be ready to go home after a short stay in the outpatient recovery area. It is possible that after the medicine wears off you might feel some itching or minor eye discomfort. Most people report that they can easily manage minor eye discomfort with short-term use of over-the-counter pain medication. Plan to have someone else drive you home.

Your eye doctor should give you a patient implant identification card to keep in your wallet. This card shows the type of implant in your eye and some other general information. Present this card to any eye doctor who examines your eyes after surgery.

Potential Risks Associated with Cataract Surgery

As with any surgery, there are risks and potential complications associated with routine cataract surgery and IOL implantation. This is unrelated to the lens you choose. Cataract surgery complications are rare, but may include inflammation, infection, bleeding, swelling, visual effects (e.g., glare, halos, possible decreased vision in dim light conditions), dislocation of the artificial lens, retinal detachment, increased eye pressure (glaucoma), secondary cataract, and injury to the eye. The problems could be minor, temporary, or they could become permanent. Additional procedures may be needed to address outcomes related to the lens. There is a small chance that your vision could be made worse by the operation. Please discuss these general risks associated with cataract surgery with your eye doctor.

Types of IOLs

There are many different IOLs to choose from. Your eye doctor will discuss your options with you based on your specific needs. These include the **IC-8** IOL. Other IOL types are also available such as monofocal IOLs, multifocal IOLs, extended depth of focus IOLs, accommodating IOLs, and toric IOLs. Each option has its own advantages and disadvantages. Discuss all your IOL options with your eye doctor so you may choose the IOL that best meets your expectations and lifestyle.

Monofocal IOLs

Monofocal IOLs are single-focus lenses designed to provide far vision. This means you will usually be able to see objects far away, but you will most likely need glasses for near vision activities such as reading, sewing, and writing, as well as intermediate vision activities such as working on a computer, putting on make-up, or shaving.

Multifocal IOLs
Multifocal IOLs provide vision at two or more distances to treat presbyopia, the loss of near vision. There are two types of multifocal IOLs, bifocal IOLs and trifocal IOLs. Bifocals offer far and intermediate or near vision at specific distances, at the same time. Trifocals offer vision at three distinct distances: near, intermediate and far. The goal of these lenses is to reduce the need for glasses or contact lenses. However, multifocal IOLs also can create problems with night vision, such as glare and/or halos around lights. They may also decrease the sharpness of your vision compared to a monofocal lens.

Extended Depth of Focus IOLs
Extended depth of focus (EDF) IOLs are the newest type of IOL for the treatment of presbyopia. Unlike multifocal IOLs, EDF IOLs provide a continuous range of vision from far to intermediate, with some lens designs also providing functional near vision. Reading glasses may still be needed to see fine details and small print. The **IC-8** IOL is an extended depth of focus IOL – see "*The **IC-8** Small Aperture IOL*" section for more details.

Accommodating IOLs
Accommodating IOLs are designed to mimic the natural focusing process of the eye. These lenses provide far vision and may change focus, enabling you to see up close (near). You may still need reading glasses to see fine details and small print.

Toric IOLs
Toric IOLs are designed for people with astigmatism. There are three types of toric IOLs – monofocal toric IOLs, multifocal toric IOLs, and EDF toric IOLs. Toric IOLs can correct the refractive error caused by a cornea with an oval shape due to astigmatism. Like the other types of IOLs, there is a chance you may still need glasses for far, intermediate, and/or near vision.

The **IC-8** Small Aperture IOL
The **IC-8** IOL is a first-of-its-kind small aperture lens designed for adult patients with cataracts. The **IC-8** IOL is intended for implantation in the eye after the natural lens is removed in cataract surgery. It is designed to provide near, intermediate, and far vision with less dependence on glasses.

The **IC-8** lens is designed to focus light that enters your eye using small aperture technology. When light passes through the small aperture (created by the **FilterRing™** component inside the lens), only focused light reaches the retina. Unfocused light that can cause blurry vision is filtered out. This seamlessly expands your range of vision by bringing objects and text into focus from far to near.

The **IC-8** IOL provides many key benefits, including:

- Delivering reliable, continuous range of vision from near (such as reading) to intermediate (such as computer work) to far (such as looking at a street sign), without any blurry zones
- Using small aperture technology, unfocused light is filtered out Providing high-quality optics[2]

Please discuss with your eye doctor whether this IOL is the right option for you.

Contraindications
Apart from non-specific contraindications related to any form of ocular surgery, the following non-exhaustive list of specific contraindications must be respected. Before surgery, your eye doctor will take your medical history and perform a complete eye exam to determine if you are a candidate for the **IC-8** IOL.

- Chronic uveitis (eye inflammation longer than 6 weeks)
- Younger than 18 years of age
- Microphthalmia (a birth defect in which one or both eyes did not develop fully, so they are small)
- Corneal dystrophy (a group of rare, genetic diseases that affect the cornea, the front part of your eye) or endothelial insufficiency (the inner lining of the small arteries of your eye is insufficient)
- Active ocular diseases, for example, active disease of the retina caused by diabetes and uncontrolled glaucoma

[2] Through focus image quality bench test data, measured from +1.00 diopter to -2.50 diopters in 0.50 diopter increments to establish depth of focus

Postoperative Care Instructions

You will return home after surgery. Your vision should improve within four (4) to six (6) weeks after cataract surgery. Many patients may see better within one (1) to two (2) weeks. Recovery time varies, but full healing can take up to three (3) months. During the healing process, your vision may fluctuate. You will need to take eye drops as prescribed by your doctor to help control inflammation and prevent the risk of infection. Avoid activities that could harm your eye while you are recovering from surgery, such as playing sports, bending down, or any activities where objects can put pressure on the eye or come in contact with the eye. Typically, your eye doctor will examine you the following day.

Contact your eye doctor immediately if you have any of the following symptoms after surgery: a significant decrease in vision; double vision persisting more than a few days; a significant increase in pain in the implanted eye; significant itching, redness, and/or watering of your eye; significant eye discharge; or increased sensitivity to light. These symptoms could indicate postoperative complications including a potentially serious eye infection.

Be sure to talk with your eye doctor so you can fully understand the recovery process after your cataract surgery. It may take you some time to get used to your new IOL(s). Always talk with your eye doctor if you have any questions or concerns.

After your cataract surgery, maintaining regular eye exams is important.

Patient Implant Card and Patient Information

The information about the **IC-8** IOL implanted in your eye can be found on the Patient Implant Card provided by your eye doctor. Bring your Patient Implant Card with you to any eye appointments. If you have any questions about the information in this Patient Information Brochure, please consult your eye doctor.

Device Material of Patient Exposure

The material of the **IC-8** IOL to which you will be exposed is hydrophobic acrylic.

Expected Device Lifetime and Any Necessary Follow-up

The **IC-8** IOL is designed for permanent implantation. The expected device lifetime is 20 years minimum. You should follow all postoperative care instructions from your doctor, including any follow-up visits and maintaining regular eye exams.

Serious Incident Reporting

Any serious incident that occurs in relation to the device should be reported to AcuFocus via the phone number and contact email on your Patient Implant Card, and to the Therapeutic Goods Administration (TGA) via its website: https://www.tga.gov.au.

Key Points to Remember About Your Choice

- It is important to discuss your lifestyle and/or visual needs with your eye doctor to help select the best IOL for you.
- If being able to see a continuous range of vision (far, intermediate, and near) is important for your lifestyle, the **IC-8** IOL may be a good option for you.
- Review the advantages and disadvantages with your doctor before deciding which IOL is right for you.

Symbols

Symbol	Symbol Title/ Explanation
	Patient name
	Surgeon name
	Date of surgery

	Eye implanted
LOT	Batch code
SN	Serial number
	Manufacturer

Thank you for considering the **IC-8** IOL.

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