



Patient Name: \_\_\_\_\_ DOB: \_\_\_\_\_ MRN: \_\_\_\_\_

## INFORMED CONSENT FOR CATARACT AND/OR LENS IMPLANT SURGERY

This information is given to you to help you make an informed decision about having cataract and/or lens implant surgery. **You will live with the vision resulting from your decisions for the rest of your life, so please read the following explanations carefully.** Once you have read this Informed Consent, you are encouraged to ask any questions you may still have about the procedure. This document will help you understand the risks of cataract surgery. It will also help you decide the type of replacement lens you want. Eyeglasses or contact lenses are usually required for best vision after cataract surgery.

### WHAT IS A CATARACT?

The natural lens in the eye can become cloudy and hard, a condition known as a cataract. Cataracts can develop from normal aging, from an eye injury, or if you have taken medications known as steroids. As a cataract develops, it blocks and scatters light, reducing the quality of vision. Cataracts may cause blurred vision, dulled vision, sensitivity to light and glare, and/or ghost images. If the cataract changes vision so much that it interferes with your daily life, the cataract may need to be removed. Surgery is the only way to remove a cataract. You can decide not to have the cataract removed. If you don't have the surgery, your vision loss from the cataract will continue to get worse.

### HOW WILL REMOVING THE CATARACT AFFECT MY VISION?

The goal of cataract surgery is to correct the decreased vision that was caused by the cataract. Cataract surgery will not correct other causes of decreased vision, such as glaucoma, diabetes, or age-related macular degeneration. During the surgery, the ophthalmologist (eye surgeon) removes the cataract and typically puts in a new artificial lens called an Intra-Ocular Lens (IOL).

It is possible to remove the cataract and not insert an IOL. In this situation, strong glasses or a contact lens are usually required to focus. If glasses are used, the lenses may be very thick and can cause distorted or double vision or visual imbalance. Contact lenses may not be tolerated by some and can be difficult to handle, insert, and remove. Because of these problems, an IOL is recommended for almost all cataract patients today. IOLs are available in different sizes, powers, materials, and designs, and must be selected by you and your surgeon depending on the needs of your eye and your activities. The IOL will be left in the eye permanently. An IOL can be inserted later as a separate procedure after a cataract is removed, but this may require a different type of IOL than would be used if one is placed at the time the cataract is removed.

**Most people still need to wear glasses or contact lens after cataract surgery for either near and/or distance vision and astigmatism.**

### PRESBYOPIA AND ALTERNATIVES FOR NEAR VISION AFTER SURGERY

Patients who have cataracts have, or will eventually develop, presbyopia, which is a condition caused by the aging eye losing its ability to shift from distance to near vision. Presbyopia is the reason that reading glasses become necessary, typically after age 40, even for people who have excellent distance and near vision without glasses. Presbyopic individuals require bifocals or separate reading glasses in order to see clearly at close range. There are several options available to you to achieve distance and

near vision after cataract surgery. This is probably the most important decision you need to make about your cataract surgery, so please take the time to review the following options and ask questions.

**Plan to wear Glasses.** You can choose to have a monofocal (single focus) IOL implanted for distance vision in both eyes and wear reading glasses, or have an IOL implanted for near vision in both eyes and wear glasses for distance.

**Leave Both Eyes Nearsighted.** This is an option for patients who are used to being nearsighted and for whom close vision is most important. A prescription lens will be needed for distance vision, and a weaker or minimal prescription needed for close vision. If you are accustomed to reading without glasses and wish to do so after surgery, be sure to discuss this with your surgeon.

**Leave one eye Nearsighted and one Farsighted (“Monovision” or “Blended Vision”).** Some patients prefer to have one eye focused for close and one for distance, in which case the ophthalmologist would implant IOLs with two different powers. This combination of a distance eye and a reading eye is called monovision. This works especially well for patients who have successfully used monovision with contact lenses in the past; in fact, we recommend this primarily for such patients. This can allow you to do many things without glasses, but depth perception at distance will be compromised, so we suggest you wear glasses at night when driving and patients with monovision often still need glasses for prolonged reading.

***More information about monovision:***

In order to have good depth perception, your eyes need to be corrected for any refractive problems such as nearsightedness or farsightedness and "balanced" for distance. Eye care professionals refer to this as binocular vision. Monovision or "blended" vision can impair depth perception, because the eyes are not focused together at the same distance. It is important to choose which eye you will use for distance vision. Eye surgeons generally believe that one eye is the dominant one (the one you prefer for viewing). This is similar to people being right- or left-handed. Several tests can be performed to determine which eye is dominant in a particular person. With monovision, the dominant eye is usually corrected for distance, and the non-dominant eye corrected for near. However, a very small percentage of persons may be co-dominant (this is similar to being ambidextrous). In rare circumstances, a person may actually prefer using the dominant eye for near viewing. Your doctor will discuss and try to demonstrate monovision with glasses or even contact lenses to simulate the type of vision you will have after cataract surgery. Because your vision is decreased by the cataract, it is not possible to show you exactly what your postoperative vision will be like. If you would prefer not to have to wear glasses for quick tasks like looking at your cell phone, a menu, a computer, or an invoice, then you might be interested in monovision. Most monovision patients will often be more comfortable wearing glasses to balance their vision for prolonged reading tasks or for driving (especially at night), or for sports like tennis or golf, so you will most likely still need to wear glasses even with monovision. If you have been wearing contacts lens for monovision, you will most likely be happy with this option after cataract surgery. Although many patients will adjust well to monovision, some may find it uncomfortable. For those patients, the monovision can usually be reversed by elective laser vision correction, but this surgery will not be covered by your medical insurance.

***Blended vision*** is when one eye is set for distance and one intermediate such as computers but not particularly for reading. With blended vision depth perception is not always compromised but reading glasses may be needed.

**Multifocal and Extended depth of focus IOLs.** Advanced-technology IOLs can correct presbyopia by providing multiple distinct focal points at various distances (“Multifocal”) or within a continuous range of focus (“Extended Depth of Focus”). For the purposes of this discussion, we will use “Multifocal” to refer to this category of IOL. Multifocal IOLs can provide both distance and close vision. This is a good option for those who are strongly motivated to minimize their dependence on glasses after cataract surgery. These IOLs typically need to be implanted in both eyes to work optimally. Many Multifocal IOL patients do not use glasses at all but this cannot be guaranteed. Extra professional services are required to plan for the use of a Multifocal IOL.

## **MORE INFORMATION ABOUT MEASURING YOUR IOL**

While the method used to estimate the power of the IOL is very accurate in most patients, the final result may be different from what you and your surgeon expected. As the eye heals, the IOL can shift very slightly toward the front or the back of the eye. The amount of this shift is not the same in everyone, and it may cause different vision than predicted. If the eye’s visual power after surgery is considerably different than what was planned, surgical replacement of the IOL or fine tuning the focus with LASIK might also be considered. Patients who are highly nearsighted or highly farsighted have the greatest risk of differences between planned and actual outcomes. Patients who have had LASIK or other refractive surgeries are especially difficult to measure precisely and are not candidates for fine-tuning with another LASIK procedure.

## **INFORMATION ABOUT TREATING ASTIGMATISM**

Patients with nearsightedness and farsightedness often also have astigmatism. An astigmatism is caused by an irregularly-shaped cornea; instead of being round like a basketball, the cornea is shaped like a football. This change in shape can make your vision blurry.

### **There are several treatment options for astigmatism:**

- You can select an IOL for near or distance vision and **continue to wear glasses or contact lens for the astigmatism;**
- You can select a monofocal or multifocal **Toric IOL** that is especially designed to either reduce or eliminate the astigmatism,
- You can have **refractive surgery such as LASIK or PRK,** or
- Your surgeon can perform a procedure before, during, or after cataract surgery called a **limbal relaxing incision (LRI)**. An LRI is a small cut the ophthalmologist makes into your cornea to make its shape rounder. More than one incision may be required.

## **ANESTHESIA, PROCEDURE, AND POSTOPERATIVE CARE**

The ophthalmologist or the nurse anesthetist will make your eye numb with either drops or an injection (local anesthesia). You may also undergo light sedation administered by a nurse anesthetist, or elect to have the surgery with only eye drops or local anesthesia. There are risks associated with anesthesia and sedation. These include injury to the eye, heart and breathing problems, and in very rare cases, death.

An incision is then made in the eye. This is at times self-sealing but it may require closure with very fine stitches (sutures). The natural lens in your eye will then be removed. There are several ways to remove the lens; the most common technique is called phacoemulsification, which uses an ultrasound to break the lens up into small pieces. These pieces are gently suctioned out of your eye through a small, hollow tube inserted through a small incision into your eye. After your natural lens is removed, the IOL is placed inside your eye. In rare cases, it may not be possible to implant the IOL you have chosen, or any IOL at all. Lasers may also be used to help break up the lens, but typically ultrasound (phacoemulsification) is still needed when lasers are used.

Your eye will be examined the day after surgery by your surgeon or an eye doctor chosen by your surgeon, and then at intervals determined by your surgeon. During the immediate recovery period, you will place drops in your eyes for approximately 4 weeks. Diabetics may require longer use of drops and, in some cases, even injections into the eye *prior* to surgery.

Dry eye disease is common in those having cataract surgery, even when the patient does not realize prior to surgery his eyes are dry. Using drops or other related medications and treatments may be required both before and after cataract surgery to provide you with the clearest vision.

If you have chosen monovision or a multifocal IOL to reduce your dependency on glasses or contacts, dry eye treatments may still be required either for further improvement in your distance vision, reading vision, or both. You should be able to resume your normal activities within 2 or 3 days, and your eye will usually be stable within 3 to 6 weeks, at which time glasses or contact lenses could be prescribed.

## **RISKS OF CATARACT SURGERY**

All operations and procedures are risky and can result in unsuccessful results, complications, injury, or even death, from both known and unknown causes. The major risks of cataract surgery with implantation of an IOL include, but are not limited to:

1. **Mild discomfort.** Cataract surgery is usually quite comfortable. Mild discomfort for the first 24 hours is typical, but severe pain is extremely unusual and should be reported immediately to the surgeon.
2. **Complications of removing the natural lens** may include bleeding (hemorrhage); rupture of the capsule that supports the IOL; perforation of the eye; clouding of the normally clear outer layer of the eye called the cornea (a condition known as corneal edema), which can be corrected with a corneal transplant; swelling in the central area of the retina (called cystoid macular edema), which usually improves with time; retained pieces of lens in the eye, which may need to be removed surgically; infection; detachment of the retina, which is definitely an increased risk for highly nearsighted patients, but which can usually be repaired; uncomfortable or painful eye; droopy eyelid; increased astigmatism; glaucoma; and double vision. These and other complications may occur whether or not an IOL is implanted and may result in poor vision, total loss of vision, or even loss of the eye in rare situations. Additional surgery may be required to treat these complications. The cost for this additional surgery is not included in the price you pay for the cataract surgery.
3. **Complications associated with limbal relaxing incisions** include damage to the cornea, infection, and fluctuating vision while the incision heals. They can also lead to under- and over-correction; if this occurs, another procedure and/or glasses or contact lenses may be required.
4. **Complications associated with local anesthesia injections around the eye** include a hole (perforation) of the eye, injury to the optic nerve, interference with the circulation of the retina, droopy eyelid, breathing problems, low blood pressure (hypotension), heart (cardiac) problems, and in rare situations, brain damage or death.
5. **Complications associated with the IOL** may include increased night glare and/or halos, double or ghost images, and dislocation of the IOL. Multifocal IOLs may increase the likelihood of these problems, so you should think carefully about how these problems might affect your job, your hobbies, and your daily life. In some instances, corrective lenses or surgical replacement of the IOL may be necessary for adequate visual function following cataract surgery.
6. If a monofocal (single focus) IOL is implanted, either distance or reading glasses or contacts will be needed after cataract surgery for adequate vision.

7. **Monovision may result in problems with impaired depth perception.** Choosing the wrong eye for distance correction may result in feeling that things are the “wrong way around.” Once surgery is performed, it is not always possible to undo what has done or to reverse the distance and near eye without some loss of visual quality.
8. **Multifocal (multiple focus) IOLs** may reduce dependency on glasses but might also result in less sharp vision, which may become worse in dim light or fog. They may also cause some visual side effects such as rings or circles around lights at night. It may be difficult to distinguish an object from a dark background, which will be more noticeable in areas with less light. Driving at night may be affected. If you drive a lot at night, or perform delicate, detailed, “up-close” work requiring closer focus than just reading, a monofocal lens in conjunction with eyeglasses may be a better choice for you. If complications occur at the time of surgery, a monofocal IOL may need to be implanted instead of a multifocal IOL. If you chose a multifocal IOL, it is possible that not all of the near (and intermediate) focusing ability of your eye will be restored. Additional treatment and/or surgery may be necessary.
9. If complications occur at the time of surgery, the doctor may decide not to implant an IOL in your eye even though you may have given prior permission to do so.
10. Other factors may affect the visual outcome of cataract surgery, including other eye diseases such as glaucoma, diabetic retinopathy, age-related macular degeneration; the power of the IOL; your individual healing ability; and, if certain IOLs are implanted, the function of the ciliary (focusing) muscles in your eyes.
11. Your doctor will use special equipment and computer formulas to estimate the best IOL for you, but the result may be different than what was planned. You may need to wear glasses or contact lenses after surgery to obtain your best vision. Additional surgeries such as IOL exchange, placement of an additional IOL, or refractive laser surgery may be needed if you are not satisfied with your vision after cataract surgery.
12. Regardless of the IOL chosen, you may need laser surgery (a YAG capsulotomy) to correct clouding of vision.
13. At some future time, the IOL implanted in your eye may have to be repositioned, removed surgically, or exchanged for another IOL.
14. If your ophthalmologist has informed you that you have a high degree of farsightedness (hyperopia >5.0 diopters) and/or that the axial length of your eye is short ( $\leq 18.0$  mm), your risk for a complication known as nanophthalmic choroidal effusion is increased. This complication could result in difficulties completing the surgery and implanting a lens, or even loss of the eye.
15. If your ophthalmologist has informed you that you have a high degree of nearsightedness (myopia > -7.0 diopters) and/or that the axial length of your eye is long (> 25.00 mm), your risk for a complication called a retinal detachment is increased. Retinal detachments can usually be repaired but may lead to vision loss or blindness.
16. Since only one eye will undergo surgery at a time, you may experience a period of imbalance between the two eyes (anisometropia). This usually cannot be corrected with eyeglasses because of the marked difference in the prescriptions, so you will either temporarily have to wear a contact lens in the non-operated eye or will function with only one clear eye for distance vision. In the absence of complications, surgery in the second eye can usually be accomplished within 1 to 4 weeks, once the first eye has stabilized.
17. There is no guarantee that cataract surgery will improve your vision. As a result of the surgery and/or anesthesia, it is possible that your vision could be made worse. In some cases,

complications may occur weeks, months, or even years later. These and other complications may result in poor vision, total loss of vision, or even loss of the eye in rare situations. You may need additional treatment or surgery to treat these complications. This additional treatment is not included in the fee for this procedure.

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#### ACKNOWLEDGEMENT AND CONSENT

I have reviewed all pages of this Informed Consent. The cataract and/or lens implant surgery has been explained to me in terms that I understand. I have been informed about the possible benefits, risks, and contraindications associated with the surgery. I understand that it is impossible for my doctor to inform me of every conceivable complication that may occur and that there may be unforeseen risks. I have been given the opportunity to ask questions and have received satisfactory answers to my questions. I understand that no guarantee of a particular outcome has been given and that my vision could become better or worse following surgery.

I authorize the physicians and other health care personnel involved in performing my surgery to obtain photographs and videos of my surgery and use them and my surgical results for medical education or research purposes.

By signing below, I understand and accept the risks associated with this surgical procedure, agree to follow instructions in surgery and post-operatively, and request my surgeon to perform this surgery on

my **right** eye       my **left** eye.

Initial the applicable choices below:

\_\_\_\_\_ I wish to have a **Standard Monofocal IOL** implanted and understand I will probably need glasses after surgery.

\_\_\_\_\_ I wish to have a **Toric (astigmatism-correcting) Monofocal IOL** implanted and understand I will probably need glasses after surgery, especially for near activities.

\_\_\_\_\_ I wish to have an **advanced technology Multifocal IOL** implanted and understand I will probably have less need for glasses after surgery but this cannot be guaranteed. This includes treating my astigmatism.

\_\_\_\_\_ I wish to have a **Limbal Relaxing Incision** for Astigmatism Reduction. I understand I will probably need glasses after surgery, especially for near activities.

Signature \_\_\_\_\_ Date \_\_\_\_\_  
Patient (or Parent, Legal Guardian, or Healthcare POA)

Counselor's Initials \_\_\_\_\_