

INFORMED CONSENT

CATARACT PROCEDURE

INTRODUCTION

This document is provided to obtain your informed consent for cataract surgery and/or the implantation of an intraocular lens. It contains important information detailing the risks and benefits as well as alternative treatments available. This document will also inform you about the various intra ocular lens options that are currently available. It is important to understand that *eyeglasses are usually required for best vision after cataract surgery.*

This is a unified consent for cataract surgery, implantation of intraocular lens, and astigmatic correction, some, or all of which may apply to your procedure. It is important that you thoroughly read and understand everything, and only sign once you have read, understood, and have had all questions answered to your satisfaction enabling you to make an informed decision and provide consent.

INSTRUCTIONS

- Your vision correction coordinator will review this document with you.
- Take as much time as needed to read, understand, and have all questions answered prior to signing.
- You must make a decision as to the type of lens implant you desire prior to signing.
- This document must be completed prior to any treatment.
- You may request a copy of this document at any time.

Name	MRN	Date

Email Address	Witness

Procedure Eye	Toric IOL	LRI	Multifocal IOL	Monovision	Near Eye

CATARACT SURGERY WITH INTRAOCULAR LENS

A cataract happens when the lens in your eye becomes cloudy and hard. The lens is the clear part of your eye that helps focus images. Cataracts can cause problems such as blurry or dulled vision, sensitivity to light and glare, and seeing shadows or ghost-like images.

A cataract will get worse if not removed. Surgery is the only way to do so. It is your choice when to have cataract surgery. Most people wait until their vision problems interfere with daily life. You can instead decide not to have your cataract removed.

During cataract surgery, an eye surgeon will remove the cloudy lens. He or she will replace it with an "IOL" (intraocular lens, a clear plastic artificial lens). The most common is a "monofocal" (one focus) IOL. This helps improve vision at mostly just one distance, either near or far. You will probably need glasses to see clearly at other distances.

Cataract surgery only corrects vision problems caused by cataracts. This surgery cannot correct vision problems caused by glaucoma, diabetes, age-related macular degeneration, or other eye illnesses or injuries.

Many patients with cataracts also have astigmatism or presbyopia (additional eye problems that make it hard to see).

Astigmatism causes blurry vision. Normally, eyes are round (like a baseball). With astigmatism, the eye is long (like a football).

Presbyopia makes it hard for the eye to focus on near vision. Most people get this as they age. People at any age who have cataract surgery with a monofocal IOL focused for distance vision will have some presbyopia. People with presbyopia might hold a book or menu at arm's length to try to see it more clearly.

Glasses help astigmatism and presbyopia. If you want to wear glasses less often, the eye surgeon can put in a special IOL or do an extra procedure during cataract surgery to treat these eye problems.

You have to pay extra for special IOLs or extra surgical procedures. Medicare and private insurance do not pay for these. Your eye surgeon will let you know if you have astigmatism or presbyopia. Your eye surgeon will give you more information if you are interested in these treatments. You will be asked to sign additional consents for them.

Cataract surgery is usually safe and successful. As with all surgery, there are risks (problems that can happen) with cataract surgery.

While the eye surgeon cannot tell you about every risk, here are some of the common or serious risks:

Risks from cataract surgery include vision loss, blindness, or not getting the result you want. You could also have bleeding, infection, a droopy eyelid, or glaucoma (high eye pressure). You could get a detached retina. This is when the retina, at the back of the eye, pulls away from where it is attached. You may need surgery to fix the detached retina). Your eye may be injured by surgery or anesthesia. You may need another surgery later to take out pieces of the cataract that were not removed during the cataract surgery.

Risks from an IOL. The IOL may be too weak or too strong. The eye surgeon might not be able to insert the IOL of your choice. The eye surgeon may need to replace or reposition your IOL months or years after surgery.

Problems during surgery that need immediate treatment. Your surgeon may need to do more surgery right away or change your surgery to treat this new problem.

Anesthesia can cause heart and breathing problems. Very rarely, it can cause death. Anesthesia can also injure your eye and cause vision loss or double vision.

Other risks. There is no guarantee that cataract surgery will improve your vision. It is possible that cataract surgery or anesthesia may make your vision worse, cause blindness, or even the loss of an eye. These problems can appear weeks, months, or even years after surgery.

You may need to wear glasses after cataract surgery.

INFORMED CONSENT CATARACT SURGERY

FOR THE REMOVAL OF NATURAL LENS AND IMPLANTATION OF ARTIFICIAL INTRAOCULAR LENS INDICATIONS AND PROCEDURE

Except for unusual situations, a cataract operation is indicated only when you cannot function satisfactorily due to poor sight produced by the cataract. You must remember that the natural lens within your own eye, even with a slight cataract, has some distinct advantages over any manufactured lens. After your doctor has told you that you have a cataract, you and your doctor are the only ones who can determine if and when you should have a cataract operation based on your own visual needs and medical considerations.

The surgeon will numb your eye with either drops or an injection (local anesthesia). You may also undergo light sedation administered by an anesthesiologist, or elect to have the surgery with only local anesthesia. An incision, or opening, is then made in the eye. This is at times self-sealing but it may require closure with very fine stitches which will gradually dissolve over time. 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 a vibrating probe 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 implant is placed inside your eye. In rare cases, it may not be possible to implant the implant you have chosen, or any implant at all.

Your eye will be examined later that day or 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 about 2 to 4 weeks, depending on your individual rate of healing. 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.

ALTERNATIVES

You can decide not to have the cataract removed. If you elect to not have your cataract treated at this time it will not get better on its own and your vision will continue to diminish which may lead to additional health complications including but not limited to, a complete loss of vision in the affected eye(s). This decrease in vision can influence your ability to drive and even lead to failed vision exams when renewing your license. The more advanced a cataract becomes, the harder it will be to remove in the future.

RISKS AND COMPLICATIONS

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 intraocular lens include, but are not limited to:

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.

Complications of removing the natural lens may include bleeding (hemorrhage); rupture of the capsule that supports the implant; 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 implant is placed 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.

Complications associated with the implant may include increased night glare and/or halos, double or ghost images, and dislocation of the implant. Multifocal implants 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 implant may be necessary for adequate visual function following cataract surgery.

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.

If a monofocal (single focus) implant is implanted, either distance or reading glasses or contacts will be needed after cataract surgery for adequate vision.

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.

Multifocal (multiple focus) implants 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 implant may need to be implanted instead of a multifocal implant. If you chose a multifocal implant, 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.

If complications occur at the time of surgery, the doctor may decide not to implant an implant in your eye even though you may have given prior permission to do so.

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 implant; your individual healing ability; and, if certain implants are implanted, the function of the ciliary (focusing) muscles in your eyes.

Your doctor will use special equipment and computer formulas to select the best implant 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 implant exchange, placement of an additional implant, or refractive laser surgery may be needed if you are not satisfied with your vision after cataract surgery.

Regardless of the implant chosen, you may need laser surgery (a YAG capsulotomy) to correct clouding of vision. At some future time, the implant implanted in your eye may have to be repositioned, removed surgically, or exchanged for another implant.

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 (< 18.0mm), 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.

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.

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 2 to 4 weeks, once the first eye has stabilized.

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.

INFORMED CONSENT FOR ASTIGMATIC CORRECTION **ADDENDUM**

FOR THE CORRECTION OF ASTIGMATISM WITH TORIC INTRAOCULAR LENS OR RELAXING INCISION INDICATIONS AND PROCEDURE

Astigmatism causes blurry vision. Normally, eyes are round (like a baseball). With astigmatism, the eye is long (like a football). Many people with cataracts have astigmatism. If you have astigmatism, wearing glasses or contact lenses can help you see more clearly. Or you could have surgery (called LASIK or PRK) to change the shape of your eye to correct astigmatism.

There are two options to correct astigmatism during cataract surgery:

Toric IOL: Your eye surgeon can put a special type of IOL called a toric IOL in the eye that has astigmatism.

Limbal Relaxing Incision: Your eye surgeon can make a cut called a relaxing incision in the cornea (clear covering over the eye) to change its shape. The goal of a relaxing incision is to make your cornea rounder so your vision is clearer.

YOU HAVE TO PAY EXTRA FOR TORIC IOL AND RELAXING INCISIONS. MEDICARE AND PRIVATE INSURANCE DO NOT PAY FOR THESE.

ALTERNATIVES

You could elect to not have your astigmatism treated surgically at this time. There are alternate procedures you could undergo to correct your astigmatism, including, but not limited to laser vision correction such as LASIK or PRK.

IF YOUR ASTIGMATISM IS NOT TREATED YOU WILL REQUIRE THE USE OF GLASSES OR CONTACT LENSES TO SEE CLEARLY.

RISKS AND COMPLICATIONS

As with all surgery and medical procedures, problems can happen. In addition to all the risks for cataract surgery, here are some common or serious risks for astigmatism correction:

The toric IOL may be placed in the wrong position or may shift position after surgery is over. The toric IOL may not correct all of the astigmatism (under-correction). Or it could correct it too much (overcorrection) or change the type of astigmatism you have. If you are under-corrected or over-corrected, you may continue to have blurry vision. You may need to wear glasses or have another procedure to make your vision clearer.

Relaxing incisions may cause vision loss. They can damage or scar your cornea. They may not correct all of the astigmatism (under-correction). Or they could correct it too much (overcorrection) and change the type of astigmatism you have. If you are under-corrected or over-corrected, you may continue to have blurry vision. You may need to wear glasses or have another procedure to make your vision clearer.

Astigmatism may change or come back as you get older and cause blurry vision again.

You may need to wear glasses after getting a toric IOL or having a relaxing incision.

Limbal Relaxing Incision During cataract surgery I consent to a relaxing incision to correct my astigmatism

Patient Signature

Toric IOL During cataract surgery I consent to implantation of a Toric IOL to correct my astigmatism

Patient Signature

INFORMED CONSENT FOR PRESBYOPIA CORRECTION ADDENDUM

FOR THE CORRECTION OF PRESBYOPIA USING PREMIUM INTRAOCULAR LENS OR MONOVISION INDICATIONS AND PROCEDURE

Presbyopia makes it hard for the eye to focus on near vision. This happens to most people as they age. It can also happen after cataract surgery to people of any age if they have a monofocal IOL for distance vision. People with presbyopia might hold a book or menu at arm's length to see it more clearly. Reading glasses can improve vision problems caused by presbyopia.

Your eye surgeon can correct presbyopia during cataract surgery. The goal is to reduce your need to wear eyeglasses. There are two options for correcting presbyopia during cataract surgery:

Monovision using two different monofocal (single focus) IOLs. The eye surgeon can correct presbyopia by placing a monofocal IOL for near vision in one of the eyes having surgery. The eye surgeon will put in a monofocal IOL for distance vision in the other eye. The goal is to improve both near and distance vision by having these two IOLs work together. But some patients do not like having two different monofocal IOLs. To see if you will, your eye surgeon might have you try two different monofocal contact lenses before your surgery.

Premium IOL. Another option to correct presbyopia is for your eye surgeon to put in a premium IOL. Premium IOLs allow your eye to focus at more than one distance so that you do not have to wear glasses as much. Premium IOLs work best if put into both eyes. There are different types of premium IOLs. Your eye surgeon told you about them and helped you decide which is best for you.

YOU HAVE TO PAY EXTRA FOR A PREMIUM IOL AND MONOVISION. MEDICARE AND PRIVATE INSURANCE DO NOT PAY FOR THESE.

ALTERNATIVES

You could elect to not have your presbyopia treated surgically at this time. There are alternate procedures you could undergo to correct your presbyopia with monovision, including, but not limited to laser vision correction such as LASIK or PRK.

IF YOUR PRESBYOPIA IS NOT TREATED YOU WILL REQUIRE THE USE OF GLASSES OR CONTACT LENSES TO READ.

MONOVISION OCULAR DOMINANCE, AND CHOOSING THE DISTANCE EYE CORRECTLY

Ocular dominance is similar to right- or left-handedness. Typically, eye care professionals believe that for most individuals, one eye is the dominant eye for viewing. Several tests can be performed to determine which eye, right or left, is dominant in a person. Conventional wisdom holds that if contemplating monovision, the dominant eye should be corrected for distance, and the non-dominant eye corrected for near. While this is a good guideline, it should not be construed as an absolute rule. A very small percentage of persons may be co-dominant, and in rare circumstances a person may actually prefer using the dominant eye for near viewing. The methods for testing and determining ocular dominance are not always 100% accurate; and there is some subjective component in the measurement process. Be sure you understand this and have discussed with your surgeon which eye should be corrected for distance, and which for near. If you have any doubts or uncertainty whatsoever, surgery should be delayed until a very solid comfort level is attained. Under no circumstances should you consider undertaking monovision surgical correction before you are convinced it will be right for you. Once surgery is performed, it is not always possible to undo what is done, or to reverse the distance and near eye.

RISKS AND COMPLICATIONS

As with all surgery and medical procedures, problems can happen. In addition to all the risks for cataract surgery, here are some common or serious risks for presbyopia correction:

You may see halos and ghost images. Or you could have night glare, double vision, or blurry vision.

You might have trouble with depth perception (seeing which of two objects is closer) or problems driving at night.

Premium IOLs may not work well if you have certain eye problems or large pupils.

You may need to wear glasses at all times or just for some activities, even after getting premium IOLs.

Monovision can reduce depth perception to some extent, because the eyes are not focused together at the same distance. Because monovision can reduce optimum depth perception, it is recommended that this option be tried with trial lenses or contact lenses (which are removable) prior to contemplating a surgical correction (which is permanent).

I understand the importance of selecting the correct power and near eye. I have been encouraged to take as much time as needed and try as many different powers of correction until I am satisfied with monovision. I have been given the opportunity to try monovision for an extended period of time through the use of contact lenses or temporary corrective lenses.

AT THIS TIME THERE IS NO PERFECT TREATMENT OR CURE FOR PRESBYOPIA, IT IS A COMPROMISE

Premium IOL During cataract surgery I consent to implantation of a multifocal IOL to correct my presbyopia

Patient Signature

Monovision Consent During cataract surgery I consent to monovision to correct my presbyopia

Patient Signature	Monovision Near Eye (Write in RIGHT or LEFT)

CATARACT PROCEDURE FINANCIAL POLICY

FOLLOW UP CARE NON-COVERED SERVICES

Cataract surgery includes a post-operative period of 90 days. During this time any visits directly related to the surgery are included with the original surgical fee. These are most typically your post-operative check-ups. Any additional tests, procedures, or treatments ordered by your physician are not included as part of this post-operative period. Sometimes additional procedures are warranted (the most common is a YAG laser procedure), and these are not covered by the post-operative period and are billable to your insurance, or to you, the patient.

PREMIUM LENS FEES

The surgical fees we collect for premium-class lenses include the cost of the lens, additional pre-operative testing, and physician time. The premium lens fee is an additional fee which also includes two years of post-operative care.

SELF-INSURED PATIENTS

Patients with no insurance understand that the procedure fee covers the pre-testing, the procedure, and 90 days of follow-up care related to the original procedure. The surgical fee does not include any pre-operative office visits. No other treatment, YAG laser treatment or testing, related, or unrelated to the cataract procedure is included in this fee.

INFORMATION REGARDING REFERRALS

Under some circumstances it may be necessary to refer you to an additional specialist that may be either related, or un-related to your cataract procedure. There are many different parts of the eye and our facility specializes in only one. Referrals to other specialists are made at the discretion of your physician and you are under no obligation to see the particular specialist we recommend. In all cases any referral to an outside physician is not included with any of our fees, and Laser Eye Institute has no financial interest with any parties we may refer you to for additional care. Depending on your insurance carrier this may or may not be covered and you may incur additional out of pocket expenses.

MEDICATIONS

Medications are required for use both before and after your procedure. These medications reduce the chance of infection as well as promote fast healing. You are responsible for any costs associated with these medications. If you are unable to afford your medications please inform us, as many of the pharmaceutical companies have patient assistance programs to ensure medication is being taken.

INSURANCE BILLING

Cataract surgery is an extremely routine procedure and as such is covered by most insurance providers. Under most circumstances you will be responsible for your co-pays and deductibles from Laser Eye Institute, the outpatient surgery center, and possibly the anesthesia provider. We will estimate your deductible amount in advance and collect that portion prior to your procedure. If the deductible amount changes you will either receive a refund, or a bill for the difference. Every insurance carrier and plan is different. If you would like to know the exact out-of-pocket cost you must contact your insurance carrier, it is your responsibility to know your plan limits, co-pays, and deductibles.

FACILITY BILLING

In addition to the billing from the surgeon, the surgery center fees are billed separately. If you are using insurance, you will receive an additional bill for the facility fee, which covers the use of the OR, supplies, as well as a fee from the anesthesiologist. If you are a cash patient, this will be bundled together in your total surgery price.

INFORMED CONSENT

By signing the below, I certify the following to the best of my knowledge:

All 9 pages of this document have been given to me in its entirety.

All of my questions regarding any procedure have been answered to my satisfaction allowing me to give my informed consent.

I understand that during the course of the proposed procedure(s) unforeseen conditions may be revealed requiring the performance of additional procedures, and I authorize such procedures to be performed at my physician's discretion.

I have read, understand, and agree to *Cataract Procedure Financial Policy* (page 9).

I understand that no warranty or guarantee has been made to me regarding the result, cure or safety.

I understand that all or part of my procedure may not be covered by my insurer and accept responsibility for all out-of-pocket expenses.

I give my permission for Laser Eye Institute to videotape or photograph my procedure, for purposes of documentation, education, research or training of other health care professionals. I also give my permission for Laser Eye Institute its employees and agents to use data about my procedure and subsequent treatment to further understand refractive vision correction. I understand that my name will remain confidential, unless I give subsequent written permission for my identity to be disclosed outside of Laser Eye Institute.

MY SIGNATURE BELOW CERTIFIES THAT I AM NOT UNDER THE INFLUENCE OF ANY NARCOTIC, ALCOHOL OR ANY OTHER DRUG, OR SUBSTANCE THAT MAY IMPAIR MY JUDGEMENT, OR MY ABILITY TO UNDERSTAND THIS CONSENT. I FURTHER CERTIFY THAT I WAS ABLE TO READ AND UNDERSTAND THIS INFORMED CONSENT AND ANY QUESTIONS I HAD REGARDING THE ABOVE PROCEDURE(S), RISKS, BENEFITS, AND ALTERNATE PROCEDURES HAVE BEEN EXPLAINED TO MY SATISFACTION ALLOWING ME TO GIVE MY INFORMED CONSENT FOR THE ABOVE PROCEDURE(S)

Name	MRN	Date

I consent to have Cataract Surgery with an Intraocular Lens (IOL)

Patient Signature	Eye