LAUDERDALE EYE SPECIALISTS

Informed Consent For Cataract Surgery And/Or Implantation of an Intraocular Lens And/Or use of a Femtosecond Laser

INTRODUCTION

This information is given to you so that you can make an informed decision about having eye surgery. Take as much time as you wish to make your decision about signing this informed consent document. You have the right to ask any questions you might have about the operation before agreeing to have it.

Except for unusual situations, a cataract operation is indicated only when you cannot function satisfactorily due to decreased vision caused by the cataract. After your doctor has told you that you have a cataract, you and your doctor are the only ones who can determine if or when you should have a cataract operation, based upon your own visual needs and medical considerations. You may decide not to have a cataract operation at this time. If you decide to have an operation, the surgeon will replace your natural lens with an intraocular lens implant (IOL) in order to restore your vision. This is an artificial lens, usually made of plastic, silicone, or acrylic material, surgically and permanently placed inside the eye. Eyeglasses or contact lenses may be required in addition to the IOL for best vision.

EXAMINATIONS PRIOR TO SURGERY

If you agree to have surgery, you will undergo a complete eye examination by your surgeon. This will include an examination to determine your glasses prescription (refraction), measurement of your vision with glasses (visual acuity), measurement of the pressures inside your eye (tonometry), measurement of the curvature of your cornea (keratometry), ultrasonic measurement of the length of your eye (axial length), intraocular lens calculation (biometry) to determine the best estimate of the proper power of the implanted IOL, microscopic examination of the front part of your eye (slit-lamp examination), and examination of the retina of your eye (funduscopic exam).

MORE INFORMATION ABOUT INTRAOCULAR LENS BIOMETRY

While biometry, the method used to calculate the power of the IOL, is very accurate in the majority of patients, the final result may be different from what was planned. 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. 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 any other refractive surgeries are especially difficult to measure precisely, which may lead to refractive surprise after cataract surgery. If the eye's visual power after the surgery is considerably different than what was planned, surgical replacement of the IOL might be considered. It is usually possible to replace the IOL and improve the situation. Your IOL may need to be exchanged after the cataract surgery.

PRESBYOPIA AND ALTERNATIVES FOR NEAR VISION SURGERY

Patients who have cataracts may have, or will eventually develop, an age-related condition known as presbyopia. 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 (different prescription) 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.

- GLASSES: You can choose to have a monofocal (single focus) IOL implanted for distance vision and wear separate reading glasses, or have the IOL implanted for near vision and wear separate glasses for distance.
- TORIC IOL: Astigmatism is caused by an irregularly shaped cornea; instead of being round like a basketball, the cornea is shaped like a football. After cataract surgery if you have uncorrected astigmatism, your vision will still be somewhat blurry at all distances. Toric IOLs are available which can correct regular astigmatism. This can reduce, but not eliminate, the need for glasses. For example, if a Toric IOL is chosen for you to see well at distance, glasses will still be needed to read. Further correction of astigmatism can be performed with glasses, contact lenses, limbal relaxing incisions, or a corneal refractive procedure such as LASIK or PRK.

- BLENDED VISION: Your ophthalmologist could implant IOLs with two different powers, one for near vision, and other for distance vision. This combination of a distance eye and a reading eye is called blended vision, and would allow you to reduce your need for glasses. It has been employed quite successfully in many contact lens and refractive surgery patients. Your surgeon will discuss and demonstrate this option.
- MULTIFOCAL IOL : Your ophthalmologist could implant a "multifocal" IOL. These IOLs provide distance vision AND restore some near vision. Depending upon the technological features of the IOLs, they may be described as "apodized diffractive," or "presbyopia-correcting." All of these lenses are "multifocal," meaning they correct for a range of vision with some limitations.
- ACCOMMODATING IOL (Crystalens): This lens flexes in the eye and provides distance and intermediate vision.

I choose to have near/reading vision after cataract surgery provided by:
(glasses/blended/Multifocal/Crystalens) _____

Patient Initials _____

MORE INFORMATION ABOUT BLENDED VISION

For most people, depth perception is best when viewing with both eyes optimally corrected and "balanced" for distance. Eye care professionals refer to this as binocular vision. Blended vision can impair depth perception to some extent, because the eyes are not focused together at the same distance. Blended vision can reduce optimum depth perception.

Ocular dominance, and choosing the distance eye correctly: Ocular dominance is analogous to right or left-handedness. Typically, eye care professionals believe that for most individuals, one eye is the dominant or preferred eye for viewing. Several tests can be performed to determine which eye, right or left, is dominant in a particular person. Conventional wisdom holds that if contemplating blended vision, 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 small percentage of individuals may be co-dominant (rather analogous to being ambidextrous), and in some 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: 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 through the use of blended vision with a contact lens trial. Under no circumstance should you consider undertaking cataract surgery with blended vision 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 without some loss of visual quality.

ANESTHESIA, PROCEDURE, AND POSTOPERATIVE CARE

The ophthalmologist or the anesthesiologist/nurse anesthetist will make your eye numb with either drops or an injection (local anesthesia). You may also undergo light sedation administered by an anesthesiologist or nurse anesthetist, or elect to have the surgery with only local anesthesia. Cataract surgery is usually quite comfortable. Mild discomfort for the first 24 hours is typical, but severe pain would be extremely unusual and should be reported immediately to the surgeon.

An incision, or opening, is made in the eye. This is at times self-sealing but it may require closure with fine stitches (sutures). The natural lens in your eye will then be removed by a process called phacoemulsification, which uses a vibrating probe that uses ultrasound energy to break the lens up into small pieces which are gently suctioned out of 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. It is also possible that the IOL may later need to be repositioned or replaced in some rare circumstances.

After the surgery, your eye will be examined the next day, and then at intervals determined by your surgeon. During the immediate recovery period, you will place drops in your eye for about four weeks, depending on your individual rate of

healing. If you have chosen blended vision, multifocal IOL, or accommodating IOL to reduce your dependency on glasses or contacts, glasses or contact lenses 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 a week, 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

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. It is possible that certain preexisting eye conditions such as dry eyes, diabetic retinopathy, or epiretinal membrane could worsen after cataract surgery.

As a result of the surgery and associated 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. Depending upon the type of anesthesia, other risks are possible, including cardiac and respiratory problems, and in rare cases, death. Although all these complications can occur, their incidence following cataract surgery is low.

RISKS OF CATARACT SURGERY INCLUDE, BUT ARE NOT LIMITED TO:

1. Complications of removing the natural lens may include hemorrhage; rupture of the capsule that supports the lens; perforation of the eye; clouding of the cornea; swelling of the central area of the retina (cystoid macular edema); retained pieces of lens in the eye which may require surgical removal; infection; retinal tear or detachment, particularly for nearsighted patients; uncomfortable or painful eye; droopy eyelid; iris damage causing pupil irregularity; glaucoma; double vision; increased astigmatism. 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.**
2. Complications associated with the IOL may include increased night glare and/or halos, double or ghost images, light sensitivity, and dislocation or malfunction of the IOL. Multifocal IOLs may increase the likelihood of some of these problems. In some instances, corrective lenses or surgical replacement of the IOL may be necessary for adequate visual function following cataract surgery.
3. Complications associated with local anesthesia around the eye include perforation of the eye, optic nerve damage, interference with the circulation of the retina, droopy eyelid, eye muscle damage, respiratory depression, hypotension, cardiac problems, and in rare situations, brain damage or death.
4. If a monofocal lens is implanted, distance glasses, reading glasses and/or contacts will be needed after cataract surgery for adequate vision.
5. Complications associated with blended vision may include impaired depth perception. Choosing the nondominant eye for distance correction may result in prolonged or lack of adjustment to blended vision.
6. Complications associated with multifocal IOLs include reduced contrast sensitivity and may result in less sharp vision, which may be worse in dim light or fog. It may cause some visual side effects such as halos around lights, especially at night. Driving at night may be affected. It may be difficult to distinguish an object from a dark background, which will be more noticeable in areas with less light. Multifocal IOLs can reduce contrast sensitivity for patients with glaucoma or macular degeneration. Although you may not have these conditions now, if you develop them later in life, you might have more difficulty with contrast than if you had chosen a monofocal lens. If you drive a considerable amount 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 lens may need to be implanted instead of a multifocal IOL.
7. Complications associated with toric IOLs. Improper alignment or rotation of the IOL after surgery may result in more residual astigmatism than predicted. Any attempt at astigmatism reduction could result in under or over correction, in which case glasses, contact lenses, or another procedure may be needed. In addition, surgical

realignment of the toric IOL may be required. You may also develop astigmatism later in life after implantation of the toric IOL which would not be corrected by the lens implant.

8. If an IOL is implanted, it is done by a surgical method. It is intended that the small silicone or acrylic IOL will be left in the eye permanently.
9. If complications occur at the time of surgery, the surgeon may decide not to implant an IOL in your eye even though you have planned on it and given 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, epiretinal membrane; the power of the IOL; your individual healing ability; and, if certain IOLs are implanted, the function of the ciliary (focusing) muscles in your eye.
11. The selection of the proper IOL, while based upon sophisticated equipment and computer formulas, is not an exact science. After your eye heals, its visual power may be different from what was predicted by preoperative testing. 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. The results of cataract surgery **cannot** be guaranteed. 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. Regardless of the IOL chosen, you may need laser surgery to correct clouding of vision that can occur after cataract surgery. At some future time, the IOL implanted in your eye may need to be repositioned, removed surgically, or exchanged for another IOL.
13. If your ophthalmologist has informed you that you have a high degree of hyperopia (farsightedness) and/or that the axial length of your eye is short, your risk for complications such as corneal edema and nanophthalmic choroidal effusion is increased. Complications could result in difficulties completing the surgery and implanting a lens, or even loss of the eye.
14. If your ophthalmologist has informed you have a high degree of myopia (nearsightedness) and/or that the axial length of your eye is long, your risk for a complication of retinal tear or detachment is increased. Retinal detachments can usually be repaired but may lead to vision loss or blindness.
15. If you have had any prior retinal surgery (vitrectomy, scleral buckle, repair of retinal detachment), your risk of having a complication during cataract surgery is slightly increased.
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 spectacle glasses 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. The accommodating IOL or Crystalens may not work well for fine print. Most patients need reading glasses for small print with the Crystalens. It may assume a tilted position that could reduce vision and require removal of the lens.

PATIENT ACKNOWLEDGEMENT OF FINANCIAL OBLIGATIONS

There are additional fees **NOT** covered by Medicare or private insurance associated with blended vision, toric IOLs, multifocal IOLS, and accommodating IOLs. I acknowledge that I am responsible for payment of that portion of the charges for blended vision, toric IOLs, multifocal IOLs, accommodating IOLs and associated services that exceed the charge for insertion of a conventional monofocal IOL following cataract surgery. I have been informed about the coverage, deductible, and copayment amounts if a private insurance company is paying for this procedure.

Patient Initials_____

I have read and understood this page. Patient's initials _____

LIMBAL RELAXING INCISION (LRI)

If you have regular astigmatism, your ophthalmologist can reduce this by making extra incisions on your cornea to make its shape rounder. The reduction of astigmatism may decrease your need for glasses. The major risks of a LRI are similar to those of cataract surgery, but also include damage to the cornea, corneal perforation, and infection. Any attempt at astigmatism reduction could result in over- or under-correction, in which case glasses, contact lenses, or another procedure may be needed. I understand and I wish to proceed with limbal relaxing incisions if recommended by my doctor.

RIGHT EYE: Yes_____ No_____ **LEFT EYE:** Yes_____ No_____ **Patient Initials_____**

PATIENT CONSENT

Cataract surgery, by itself, means the removal of the natural lens of the eye by a surgical technique. In order for an IOL to be implanted in my eye, I understand I must have cataract surgery performed either at the time of the IOL implantation or before IOL implantation. If my cataract was previously removed, I have been informed that my eye is medically acceptable for IOL implantation.

The basic procedures of cataract surgery, the reasons for the type of IOL chosen for me, and the advantages and disadvantages, risks, and possible complications as well as alternative treatments have been explained to me by my ophthalmologist. In the event of a complication, additional expenses are possible including eye drops, glasses, contact lenses, medical consultations, travel, time off work, etc. It may be possible that other surgery or even hospitalization may be required. The patient is responsible for the costs of surgery and any additional expenses.

Although it is impossible for the doctor to inform me of every possible complication that may occur, the doctor has answered all of my questions to my satisfaction. If anything is discovered during my surgery which was not anticipated, I permit my surgeon to use his/her best judgement in doing whatever is most appropriate for my care.

In signing this informed consent for cataract surgery and/or implantation of an IOL, I am stating that I have been offered a copy, I fully understand the possible risks, benefits, and complications of cataract surgery and

- I have read this informed consent _____ **(Patient Initials)**
- The consent form was read to me by _____ **(Name)**

WHAT IS THE FEMTO LASER?

The femtosecond laser is a medical device that can be used for many purposes; it is approved by the Food and Drug Administration to perform some of the steps of surgery to remove a cataract or cloudy lens (approved use). It is also being used to perform some of the steps of surgery to remove a clear lens or refractive lens exchange (RLE), and to make accurate incisions in the cornea (AK) to reduce astigmatism. There are benefits and risks associated with the use of the laser and there are additional costs. This section of the consent document will provide information to help you decide if you would like your eye surgeon (ophthalmologist) to use the laser to perform parts of the cataract/refractive lens surgery or to reduce astigmatism.

HOW DOES SURGEY WITH THE LASER DIFFER FROM TRADTIONAL SURGERY TO REMOVE THE LENS? WHAT ARE THE POSSIBLE BENEFITS?

Traditionally, the eye surgeon uses blades to create the incisions in the cornea (the front window of the eye), and other special instruments to create the capsulotomy (the circular incision in the outer layer of the cataract or clear lens). The surgeon also uses a phacoemulsification device that utilizes ultrasound power to break up the lens and remove it from the eye. The femtosecond laser can be used to perform some or all of these steps. the possible benefits of the laser include the ability to make more precise, a more circular and A better centered capsulotomy, and to pre-soften the cataract so less ultrasound energy is necessary with the phacoemulsification device.

HOW IS THE LASER USED TO TREAT ASTIGMATISM?

Patients with astigmatism have several choices for the reduction of astigmatism. Nonsurgical options for astigmatism have several choices for the reduction of astigmatism. Non-surgical options for astigmatism correction include glasses

and contact lenses. Surgical correction of astigmatism can be achieved through a toric intraocular lens, a limbal relaxing incision (LRI) made manually with a blade or an arcuate incision made with the femtosecond laser (AK). Refractive surgery such as LASIK or PRK can also treat astigmatism. The shape and size of incisions made with the laser may be more precise.

THE FS LASER CAN ALSO TREAT ASTIGMATISM DUING THE CATARACT SURGERY.
Astigmatism causes blurry vision. Normally, eyes are round (like a baseball). With astigmatism, the eye is long (like a football). Glasses can treat this. Or eye surgeons can treat astigmatism during cataract surgery by making a cut in the cornea to change its shape. This cut is called a **relaxing incision.**

THERE MAY BE MORE RISK IF THE FS LASER IS USED AFTER REFRACTIVE SURGERY.
Refractive surgery is a procedure that makes you see better (improves your refraction) by changing the shape of the cornea, the clear front of the eye. The FS laser uses suction. If you have had a type of refractive surgery called LASIK, the suction could open up or move the flap. If you have had other refractive surgeries called AK or RK, the suction could open up the old wound. If the flap or the wound is opened up or moved, this could cause leaking, astigmatism, or scarring.

THE USE OF THE FS LASER ON PATIENTS WHO HAVE HAD REFRACTIVE SURGERY IS CONSIDERED "OFF-LABEL."
This means that the U.S. Food and Drug Administration (FDA) approved the laser for cataract surgery on the eyes of patients who have not already had refractive surgery. When eye surgeons use the laser during cataract surgery on patients who have had refractive eye surgery, its use is considered "off-label". Your visual outcome after surgery may not be as good if these problems happen.

WHAT ARE THE COMPLICATIONS ASSOCIATED WITH THE FEMTOSECOND LASER?
Use of the laser could increase the time needed to perform the surgery, and you may need to have the procedure performed in two different locations or two different rooms at the surgery center. It could also lead to complications, which include but are not limited to: anterior capsular tear; posterior capsular tear with lens/lens fragment dislocation into the vitreous; corneal abrasion or defect; pain; infection; bleeding; damage to intraocular structures; anterior chamber fluid leakage; anterior chamber collapse; and elevated eye pressure.
In the case of an incomplete or interrupted capsulotomy, the procedure may be immediately repeated with a slightly larger diameter to complete fragmentation, the procedure using traditional manual capsulotomy methods. In the case of an incomplete or interrupted fragmentation using conventional phacoemulsification treatment. In the case of loss of lens fragments into the vitreous, a separate procedure called a vitrectomy may be necessary to remove the vitreous and lens fragments.

I have read and understood this page. Patient's initials _____

Please indicate your choice for type of IOL below:

☐ **Femtosecond Laser Option** I wish to undergo cataract surgery using the Femtosecond Laser in my _____ (state "right" or "left" eye)

☐ **Monofocal IOL/Glasses:** I wish to have a cataract operation with a monofocal IOL in my ☐ Right eye ☐ Left eye and wear glasses for _____ (state near or distance vision).

☐ **Blended Vision with Two IOLs Option:** I wish to have a cataract operation with two different-powered IOLs implanted to achieve blended vision.

I wish to have my _____ (**state right or left**) eye corrected for **DISTANCE** vision.
I wish to have my _____ (**state right or left**) eye corrected for **NEAR** vision.

☐ **Multifocal IOL Option (may still need glasses):** I wish to have a cataract operation with a _____ multifocal implant (state name of implant) in my ☐ Right eye ☐ Left eye.

☐ **Toric IOL Option for Astigmatism Reduction:** I wish to have a cataract operation with a Toric IOL implant in my ☐ Right eye ☐ Left eye and wear glasses for _____ (state near or distance vision).

_____	_____	_____	_____
Right Eye	Patient (or person authorized to sign for patient)	Physician Signature	Date
_____	_____	_____	_____
Left Eye	Patient (or person authorized to sign for patient)	Physician Signature	Date

I have read and understood this page. Patient's initials _____