

NORTH ATLANTA EYE SURGERY CENTER

INFORMED CONSENT FOR CATARACT SURGERY WITH FEMTO LASER—READ ONLY

WHAT IS A CATARACT AND HOW IS IT TREATED?

The 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. 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. During the surgery, the ophthalmologist (eye surgeon) removes the cataract and puts in a new artificial lens called an intraocular lens or IOL. Cataract surgery will not correct other causes of decreased vision, such as glaucoma, diabetes, or age-related macular degeneration. Most people still need to wear glasses or contact lens after cataract surgery for either near and/or distance vision and astigmatism.

WHAT TYPES OF IOL's (Intraocular Lenses) ARE AVAILABLE?

Your ophthalmologist will help you decide on the type of IOL that will replace your cloudy lens. There are IOLs available to treat nearsightedness (myopia), farsightedness (hyperopia), and astigmatism. IOLs usually provide either near or distance vision: these single focus lenses are called monofocal IOLs. Some newer IOLs can provide for near, intermediate, and distance vision: these multiple focus lenses are called multifocal IOLs. IOLs that treat astigmatism are called toric IOLs. You can also have one eye corrected for near vision, and the other for distance vision, a choice called monovision, but this choice does not guarantee that you will not need to wear glasses or contact lenses after cataract surgery.

WHAT IS ASTIGMATISM? ARE THERE OTHER TREATMENTS FOR IT?

Patients with nearsightedness and farsightedness often also have astigmatism. Astigmatism is caused by an irregularly shaped cornea; instead of being round like a basketball, the cornea is shaped like a football. This can make your vision blurry. In addition to toric IOLs, astigmatism can be reduced by glasses, contact lenses, and refractive surgery (LASIK or PRK). There is also a procedure called a limbal relaxing incision (LRI), which can be done at the same time as the cataract operation, or as a separate procedure. A limbal relaxing incision (LRI) is a small cut or incision the ophthalmologist makes into your cornea to make its shape rounder. Any attempt at astigmatism reduction could result in over- or under-correction, in which case glasses, contact lenses, or another procedure may be needed.

WHAT ARE THE MAJOR 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 include, but are not limited to bleeding; infection; injury to parts of the eye and nearby structures from the anesthesia, the operation itself, or pieces of the lens that cannot be removed; high eye pressure; a detached retina, and a droopy eyelid. The major risks of a limbal relaxing incision are similar to those for cataract surgery, but also include loss of vision, damage to the cornea, and scarring; under- or over-correction could occur.

Depending upon your eye and the type of IOL, you may have increased night glare or halos, double vision, ghost images, impaired depth perception, blurry vision, and trouble driving at night. The ophthalmologist might not be able to put in the IOL you choose. In addition, the IOL may later need to be repositioned or replaced.

Depending upon the type of anesthesia, other risks are possible, including cardiac and respiratory problems, and, in rare cases, death.

There is no guarantee that cataract surgery or astigmatism reduction 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.

WHAT IS THE FEMTOSECOND LASER?

The femtosecond laser is a medical device that can be used for many purposes; it was recently 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 may be 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 SURGERY WITH THE LASER DIFFER FROM TRADITIONAL 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 of these steps. The possible benefits of the laser include the ability to make more precise and consistent incisions in the cornea, a more circular and centered capsulotomy.

HOW IS THE LASER USED TO TREAT ASTIGMATISM?

Patients with astigmatism have several choices for the reduction of astigmatism. Nonsurgical 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 accurate 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.

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: decentration of the corneal or capsulotomy incisions; incomplete or interrupted capsulotomy, fragmentation, or corneal incision procedure; 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 interrupted or incomplete corneal incision, the laser can be recentered and the incisions repeated at a different location, or the incisions can be completed using hand-held blades. In the case of an incomplete or interrupted capsulotomy, the procedure may be immediately repeated with a slightly larger diameter to complete the capsulotomy or the surgeon may elect to complete the procedure using traditional manual capsulotomy methods. In the case of an incomplete or interrupted fragmentation, the procedure can be repeated after recenteration or the surgeon may elect to complete 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.

PATIENT'S ACCEPTANCE OF RISKS

I understand that it is impossible for the doctor to inform me of every possible complication that may occur. By signing below, I agree that my doctor has answered all of my questions, that I have been offered a copy of this consent form, and that I understand and accept the risks, benefits, and alternatives of cataract surgery with a femtosecond laser.

CONSENT FOR TREATMENT

I recognize that, during the course of the operations, unforeseen conditions may necessitate additional or different procedures that were not discussed at the time of my scheduled procedure. I further authorize and request that the Physicians and staff of North Atlanta Eye Surgery Center perform such procedures as are in their professional judgment necessary and desirable. These procedures include but are not limited to, procedures involving pathology, IV access and administration of medication to facilitate the process of my surgery. The authority granted under this consent shall extend to routine and non routine procedures that are necessary to treat and correct conditions not known at the time the operation is commenced.

I consent to the administration of anesthesia to be applied by or under the direction and supervision of Atlanta Anesthesia Consultants and to the use of such anesthetics as he/she may deem advisable.

I am aware that the practice of medicine and surgery is not an exact science and I acknowledge that no guarantees have been made to me as to the results of the operation or procedure.

I have had nothing to eat or drink (no food or water) since midnight. I understand that food or liquids in my stomach will jeopardize my life while under anesthesia.

With the approval of my physician, I consent to the use of video during, or after the surgery for medical documentation and, with the approval of my surgeon, consent to authorized observers in the operating room.

I understand that physicians on the staff of the surgery center providing medical services are not agents or employees of the surgery center, but to the contrary, are independent medical practitioners exercising independent medical judgment at facilities provided by the surgery center.

EXPOSURE BLOODBORNE OR BODILY FLUIDS

I, the undersigned, do hereby consent to the withdrawal of a blood sample from my body for tests including HIV (AIDS) and HBV (Hepatitis B). This test would only be performed in the event that a health care provider or an employee of the surgery center is exposed to my blood or other bodily fluids, in such a manner as to

create a risk that he/she could become an infected person. I understand that the surgery center will keep the results confidential in accordance with Georgia law and that I will not be charged for any such test. I have been advised that I am not required to submit to a test.

PATIENT'S ACCEPTANCE OF RISKS

I understand that it is impossible for the doctor to inform me of every possible complication that may occur. By signing below, I agree that my doctor has answered all of my questions, that I have been offered a copy of this consent form, and that I understand and accept the risks, benefits, and alternatives of cataract surgery. I have checked my choice for astigmatism correction and type of IOL.

Please write in the box below: "I may still need to wear glasses after cataract surgery."

PLEASE LEAVE BLANK!

Please write in the box below: "I may not achieve the result I hope for."

PLEASE LEAVE BLANK!

Please write in the box below: "There are risks and there are no guarantees."

PLEASE LEAVE BLANK!

Please write in the box below: "All of my questions have been satisfactorily answered."

PLEASE LEAVE BLANK!

I wish to proceed with the following Option(s):

Monofocal IOL/Glasses Option

I wish to have a cataract operation with a monofocal IOL on my **READ ONLY!** (state "RIGHT" or "LEFT" eye) and wear glasses after my surgery.

Toric monofocal IOL/Glasses Option for Astigmatism Reduction

I wish to have a cataract operation with a toric monofocal IOL on my **READ ONLY!** (state "RIGHT" or "LEFT" eye) and wear glasses for **READ ONLY!** (state "near" vision or choose to achieve monovision.

Multifocal IOL Option (may still need glasses)

I wish to have a cataract operation with a **READ ONLY!** multifocal IOL implant (state name of implant) on my **READ ONLY!** (state "RIGHT" or "LEFT") eye.

Monovision with 2 IOLs Option (may still need glasses)

I wish to have a cataract operation with two different-powered IOLs implanted to achieve monovision.
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.

***** IF MONOVISION, MAKE SURE TO SIGN WHICH EYE IS TO BE OPERATED ON AND WHICH IOL IS TO BE PLACED *****

DO NOT SIGN!

Patient (or person authorized to sign for patient)

Date

Time

DO NOT SIGN!

Witness Signature

Date

Time

DO NOT SIGN!

Surgeon Signature

Date

Time

