

FLORIDA BOARD OF MEDICINE AND FLORIDA BOARD OF OSTEOPATHIC MEDICINE
APPROVED INFORMED CONSENT FORM FOR CATARACT OPERATION WITH OR
WITHOUT IMPLANTATION OF INTRAOCULAR LENS

DOES THE PATIENT NEED OR WANT A TRANSLATOR, INTERPRETOR OR READER?

YES _____ NO _____

TO THE PATIENT: You have the right, as a patient, to be informed about your cataract condition and the recommended surgical procedure to be used, so that you may make the decision whether or not to undergo the cataract surgery, after knowing the risks, possible complications, and alternatives involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so that you may give or withhold your consent to cataract surgery and should reflect the information provided by your eye surgeon. If you have any questions or do not understand the information, please discuss the procedure with your eye surgeon prior to signing.

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, various medical conditions or if you have taken certain medications such 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 to try to improve your vision. Surgery is the only way to remove a cataract. You can decide to postpone surgery or not to have the cataract removed.

ALTERNATIVE TREATMENTS:

I understand that I may decide not to have a cataract operation, at all. However, if I do not have the cataract surgery, I understand my vision loss from the cataract usually will continue to get worse. Corrective lenses, eyeglasses, or contact lenses will not improve my vision or reverse the worsening of the cataract.

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 may place in a new artificial lens called an intraocular lens or IOL. Cataract surgery will **not** correct other causes of decreased vision, such as glaucoma, optic nerve or retinal problems, diabetes, age-related macular degeneration, or dry eye. In order to obtain the best possible vision, many

Patient initials _____

Page 1 of 6

Eye Surgeon's initials _____

Date _____

people still need to wear glasses or contact lenses after cataract surgery for either near and/or distance vision, for some activities, or in low light.

WHAT ARE THE TYPES OF INTRA-OCULAR-LENSES (IOL) THAT ARE AVAILABLE FOR ME?

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 more recently developed IOLs may provide for near, intermediate, and distance vision-- these multiple focus lenses are called **multifocal IOLs**. Lenses that have some focusing power are called **accommodative 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**. With monovision the implanted IOLs have two different powers, one for near vision in one eye, and one for distance vision in the other eye. Monovision allows for near and distance vision but can decrease depth perception. Although many patients adjust well to monovision, some may find it uncomfortable, which may require compensating glasses, contact lenses or another operation to change the IOL.

No IOL is perfect, and often glasses or contact lenses are needed for certain activities even if you have chosen a special IOL lens.

DO I HAVE ASTIGMATISM IN ADDITION TO MY CATARACT? ARE THERE TREATMENTS FOR IT?

Patients with nearsightedness and farsightedness may also have astigmatism. Astigmatism is caused by an irregularly shaped cornea; instead of being round like a basketball, the cornea is shaped like an American style football. This can make your vision blurry. In addition to toric IOLs, astigmatism can be reduced by glasses, contact lenses, and refractive surgery (Laser assisted in situ keratomileusis [LASIK] or Photorefractive keratectomy [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 LRI is a small cut or incision the ophthalmologist makes into your cornea to make its shape more round. Astigmatic Keratotomy (AK) is a similar procedure that involves a smaller, more central incision in the cornea than the LRI.

Patient initials _____

Eye Surgeon's initials _____

Date _____

Any attempt at astigmatism reduction could result in over- or under-correction, in which case glasses, contact lenses, or another procedure may be needed. None of the methods of reducing astigmatism are perfect or completely predictable, but all are designed to help reduce the amount of astigmatism present.

WHAT ARE THE RECOGNIZED RISKS OF CATARACT SURGERY?

All operations and surgical procedures have risks and can have unsuccessful results or associated complications that can injure the patient, or even cause death in some instances. The recognized, specific risks of cataract surgery include problems that can lead to loss of vision, blindness or loss of your eye. Those risks include: bleeding; infection; high eye pressure; a swollen or detached retina; a droopy eyelid; double vision; displacement of the lens or portion (fragments) of the lens; injury to the cornea, iris, sclera, conjunctivae, pupil function, or other parts of the eye and nearby structures, from the operation or the anesthesia. Sometimes pieces of the lens cannot be completely removed and the vitreous can become displaced.

The specific, recognized, risks of a Limbal Relaxing Incision (LRI) or Astigmatic Keratectomy (AK), if performed in conjunction with cataract surgery are similar to those for cataract surgery, but also include perforation to the cornea, damage to the iris, increased astigmatism, and scarring, which could cause loss of vision. Furthermore, the LRI or AK may not fully correct the astigmatism and an under- or over-correction could occur, and glasses, contacts, or another surgical procedure may be needed to correct the vision.

Depending upon your eye and the type of IOL that is used, the most serious, recognized side effects include: increased night glare or halos, double vision, ghost images, impaired depth perception, decreased contrast, blurry vision, and decreased night vision.

At the time of surgery, your ophthalmologist may decide not to implant an IOL even though you may have given prior permission to do so, or your ophthalmologist may decide to implant an IOL different from the one that you initially preferred, or agreed to on pages four and five. In addition, the IOL may later need to be repositioned, replaced, or removed by way of a subsequent surgical procedure.

No intraocular lens or power calculation is perfect and you will likely still need glasses. Calculating IOL power is difficult in patients who are highly nearsighted or farsighted, as well as in patients that have had previous eye surgeries such as cornea surgery, glaucoma surgery, refractive surgery or retina surgery. This difficulty in calculating IOL power may result in your post-operative prescription being different from what you and the doctor thought it would be. This may require you to wear glasses, contact lenses, need refractive surgery, or have an IOL exchange or piggyback lens placed. Furthermore, because only one eye is operated on at a time, you may experience a feeling of imbalance between the two eyes which may require correction.

Patient initials _____

Page 3 of 6

Eye Surgeon's initials _____

Date _____

There is no guarantee that cataract surgery or astigmatism reduction will improve your vision, even with glasses or contacts. You may need glasses or contacts for best vision. In some cases, complications may occur weeks, months or even years later.

OTHER RISKS FROM CATARACT SUGERY:

Depending upon the type of anesthesia that is used, other risks are possible. Local anesthesia may affect or damage the retina, the optic nerve and may lead to: bleeding behind the eye, double vision, and permanent vision loss, perforation of the eye, cardiopulmonary complications, and in rare cases coma or death.

If you have **OTHER KNOWN MEDICAL CONDITIONS**, such as heart disease, history of heart failure, or lung disease such as Asthma or Chronic Obstructive Pulmonary Disease, or if you are **TAKING MEDICATIONS** such as Coumadin (a blood thinner) **OR OTHER SUPPLEMENTS OR VITAMINS**, tell your ophthalmologist so that you can minimize the risk of additional complications during and after surgery.

WHAT ARE MY OUT OF POCKET COSTS?

There is usually an additional charge for multifocal, accommodating, and toric IOLs, which is not paid by insurance. Therefore you understand that you may be responsible for that additional charge.

In some cases, additional sutures to support the IOL or wound, or a vitrectomy (or other additional surgery) may be needed at the time of the procedure or at a later time. The cost for additional surgery is not included in the price paid for the cataract surgery.

I understand that I may need additional treatment with medicines or surgery after my cataract removal. One common occurrence after cataract surgery is a clouding of the capsule behind the IOL requiring a laser treatment months or years later. This additional treatment is not included in the fee for this procedure.

PATIENT’S ACCEPTANCE OF RISKS:

I have read this informed consent (or it has been read to me) and I fully understand it and the possible alternatives to cataract surgery, the risks, complications, and benefits that can result from that surgery.

By signing below, I (we) certify that this form has been fully explained to me (us) , that I (we) have filled in all the blank spaces, and that my ophthalmologist has answered all of my (our)

Patient initials _____

Eye Surgeon’s initials _____

Date _____

questions, and I (we) understand and accept the risks, benefits, and understand the alternatives of cataract surgery.

The surgery is on my _____RIGHT EYE _____LEFT EYE

_____ I am aware of the recognized specific risks related to cataract surgery that are described in this form.

_____ I am aware that no intraocular lens is perfect, and that I may still need to use glasses or contacts for at least some activities or in low light regardless of the type of lens implanted. I am aware that no intraocular lens calculation is perfect, and that it is more difficult in an eye that has had prior corneal surgery or retinal or glaucoma surgery. I am also aware that the intraocular lens may later need to be repositioned, replaced, or removed by way of a subsequent surgical procedure.

On the advice of my Ophthalmologist, he/she and I choose the following premium lenses:

_____Multifocal Intraocular Lens

_____Toric Intraocular Lens

_____Accommodative Intraocular Lens

_____Monofocal/Monovision lens (Right eye near/distance; Left eye near/distance).

_____Other _____

_____ I understand that if during surgery, my ophthalmologist is unable to use any of the premium lenses; I consent to the implantation of a Monofocal Intraocular Lens.

_____ I am aware of the recognized specific risks related to Limbal Relaxing Incision (LRI) or Astigmatic Keratectomy (AK) for Astigmatism Reduction are those that are described in this form, and I understand that any of these risks could result in loss of vision, blindness or loss of the eye, and may require me to undergo further surgery. Furthermore, the LRI or AK may not fully correct the astigmatism, and glasses, contacts, or another surgical procedure may be needed to correct the vision.

_____ On the basis of the above statements, I voluntarily consent and authorize this cataract surgery procedure.

_____ I am aware that I have the right to report adverse incidents to the Florida Board of Medicine or the Florida Board of Osteopathic Medicine.

Patient initials _____

Page 5 of 6

Eye Surgeon's initials _____

Date _____

Patient Print Name: _____

Patient Signature: _____

Date: _____ **Time:** _____

(Or person authorized to sign for patient)

Witness Print Name: _____

Witness Signature: _____

Date: _____ **Time:** _____

Surgeon Print Name: _____

Surgeon Signature: _____

Date: _____ **Time:** _____

Patient initials _____

Eye Surgeon's initials _____

Date _____