

# INFORMED CONSENT

## INTRAOCULAR LENS REPOSITIONING

### INTRODUCTION

This information is given to you so that you can prepare for the discussion with your eye surgeon. This document will help you understand the risks of an intraocular lens repositioning. *Eyeglasses or contact lenses are usually required for best vision after an IOL repositioning.* 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.

### INSTRUCTIONS

- Your procedure coordinator will review this document with you.
- Take as much time as needed to read, understand, and have all questions answered 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
Intraocular Lens Repositioning	

ID: RA REV:

## INFORMED CONSENT FOR REPOSITIONING OF INTRAOCULAR LENS

### WHAT ARE THE INDICATIONS FOR IOL REPOSITIONING SURGERY?

Intraocular lens implants (IOLs) are usually inserted in patient's eyes, as a part of cataract surgery. IOL Repositioning involves adjusting the placement of the previously placed IOL. The indications for IOL Repositioning may include: a dislocated IOL (one that has shifted out of position), an unstable IOL (one that isn't properly anchored in place), an IOL causing undesirable visual symptoms, or as part of other operations such as corneal transplant surgery.

### WHAT ARE THE MAJOR RISKS OF IOL REPOSITIONING 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 Intraocular Lens (IOL) Repositioning include, but are not limited to bleeding; infection; injury to parts of the eye and nearby structures from anesthesia, or the operation itself; retained pieces of the original IOL that cannot be removed and may require additional surgery; high eye pressure or glaucoma; a detached retina, a swollen retina, a swollen cornea, a distorted pupil, dislocation of the IOL, increased astigmatism, an uncomfortable or painful eye, a droopy eyelid, and blindness.

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 reposition the IOL requiring it to be replaced.

It is sometimes necessary to perform vitrectomy surgery as part of the IOL Repositioning procedure. Vitrectomy involves removal of some, or all, of the vitreous jelly inside the eye, so it can better accommodate the IOL.

IOL Repositioning surgery will not correct other causes of decreased vision, such as glaucoma, diabetes, macular degeneration, or macular epiretinal membranes (wrinkled retina). These ocular conditions may progress or worsen after surgery.

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.

IOL selection after previous refractive surgery, such as RK, PRK, and LASIK Patient's, is particularly difficult because of the irregular corneal shape. 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.

### ANESTHESIA, PROCEDURE, AND POSTOPERATIVE CARE

The ophthalmologist will make your eye numb 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. 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, or opening, is then made in the eye. This is at times self-sealing but it may require closure with very fine stitches (sutures) which will gradually dissolve over time. The surgeon will then reposition the IOL.

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. If you have chosen a multifocal or toric implant to reduce your dependency on glasses or contacts, they 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.

### THERE IS NO GUARANTEE THAT IOL REPOSITIONING 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.

## 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. Some risks include, but are not limited to:

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 repositioning the 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 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 fee for this procedure.

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 the 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.

Other factors may affect the visual outcome of 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.

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 ( $< 18.0$ 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.

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.

There is no guarantee that an IOL repositioning 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.

The results of surgery cannot be guaranteed.

## INFORMED CONSENT FOR IOL REPOSITIONING

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

All 4 pages of this document have been given to me in its entirety and I have been offered a copy of this consent.

All of my questions have been answered to my satisfaction allowing me to give my informed consent to have the procedure listed above.

I UNDERSTAND THAT NO MATTER WHAT IOL I SELECT, I MAY STILL REQUIRE GLASSES TO ACHIEVE THE BEST POSSIBLE VISION.

I understand that during the course of the 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 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 the Laser Eye Institute to record on video or photographic equipment 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 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

**IOL Repositioning Consent:** I consent to an IOL Repositioning Procedure.

Patient Signature