

INFORMED CONSENT

INTRAOCULAR LENS EXCHANGE

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 IOL exchange. It will also help you decide the type of replacement lens you want. *Eyeglasses or contact lenses are usually required for best vision after an IOL exchange.*

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

- You must review this entire document prior to treatment.
- Take as much time as needed to read and understand this document prior to signing.
- Your doctor is available to answer any questions or concerns you have regarding this consent.
- This document must be signed prior to any treatment.
- You will sign this document in-person at Laser Eye Institute.
- You may request a copy of this document at any time.

INFORMED CONSENT FOR EXCHANGE OF INTRAOCULAR LENS

INDICATIONS AND PROCEDURE

Intraocular lens implants (IOLs) are usually inserted in patient's eyes, as a part of cataract surgery. IOL Exchange involves removing the previously placed IOL, and replacing it with another one. The indications for IOL Exchange 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 of improper or inaccurate power, an IOL causing undesirable visual symptoms, or as part of other operations such as corneal transplant surgery.

During the procedure your eye will be numbed 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 remove and replace the IOL.

Your eye will be examined after surgery and 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.

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. Risks of Intraocular Lens (IOL) Exchange 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.

Mild discomfort for the first 24 hours is typical, but severe pain is extremely unusual and should be reported immediately to the surgeon.

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. In addition, the IOL may later need to be repositioned or replaced.

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

IOL Exchange 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.

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.

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:

Complications of exchanging 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 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 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.

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 exchange 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.

INFORMED CONSENT FOR IOL EXCHANGE

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 Exchange Consent: I consent to an IOL exchange.

Patient Signature