

# 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

- 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 | Patient Selection Replacement IOL |
|---------------------------|-----|-----------------------------------|
| Intraocular Lens Exchange |     |                                   |

ID: AN REV: 20181220

## INFORMED CONSENT FOR EXCHANGE OF INTRAOCULAR LENS

### WHAT ARE THE INDICATIONS FOR IOL EXCHANGE SURGERY

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.

### WHAT ARE THE MAJOR RISKS OF IOL EXCHANGE 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) 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.

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.

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 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 remove and replace 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 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. 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.** Cataract surgery is usually quite comfortable. 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 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 cataract surgery 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.

If complications occur at the time of surgery, the doctor may decide not to implant an implant in your eye even though you may have given prior permission to do so.

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 (< 18.0mm), 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.

The results of surgery cannot be guaranteed.

PATIENT SELECTION

**MONOFOCAL IOL/GLASSES OPTION (WILL NEED GLASSES).** I wish to have an IOL Exchange operation with a monofocal IOL on my eye indicated below and wear glasses for near and distance vision.

| Patient Signature | Eye |
|-------------------|-----|
|                   |     |

**MONOVISION WITH 2 IOLS OPTION (MAY STILL NEED GLASSES).** I wish to have an IOL Exchange operation with two different-powered IOLs implanted to achieve monovision. I wish to have my distance eye indicated below corrected for distance vision. I wish to have my near eye indicated below corrected for near vision.

| Patient Signature | Distance Eye | Near Eye |
|-------------------|--------------|----------|
|                   |              |          |

**MULTIFOCAL IOL OPTION (MAY STILL NEED GLASSES).** I wish to have an IOL Exchange operation with a multifocal IOL implant on my eye indicated below.

| Patient Signature | Eye | Multifocal IOL |
|-------------------|-----|----------------|
|                   |     |                |

**TORIC MONOFOCAL IOL FOR ASTIGMATISM REDUCTION (MAY STILL NEED GLASSES).** I wish to have an IOL Exchange with a toric monofocal IOL on my eye indicated below and wear glasses for near and distance vision.

| Patient Signature | Eye |
|-------------------|-----|
|                   |     |

**LIMBAL RELAXING INCISION FOR ASTIGMATISM REDUCTION (MAY STILL NEED GLASSES).** I wish to have this procedure done in addition to the operation. There is no guarantee that these corneal incisions will successfully or completely reduce my Astigmatism.

| Patient Signature | Eye |
|-------------------|-----|
|                   |     |

## INFORMED CONSENT FOR IOL EXCHANGE

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

All 5 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 |
|-------------------|
|                   |