Informed Consent

Cataract Surgery with Intraocular Lens Implant

Please initial below indicating that you have read and understand each section

Introduction

Initials _

The internal lens of the eye can become cloudy and/or hard, a condition known as a cataract. Cataracts can develop from normal aging, from an eye injury, 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 to the extent 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 and live with your current vision. If you don't have the surgery, your vision loss from the cataract will continue to get worse.

Explanation of the Procedure

Your cataract will be removed and the cloudy lens replaces with an intraocular lens (IOL.)

After you arrive, you will be given eye drops or gel containing antibiotics, dilating drops and topical anesthetics. An IV line will be used to give you sedation. Your skin and eye will be cleansed with an antiseptic and drapes applied to reduce bacterial exposure. Small incisions are made and the cataract is removed with ultrasound. Additional procedures may be performed as indicated to reduce the astigmatism, stabilize the lens or enlarge the pupil. An intraocular lens is selected to replace the optical functioning of the natural lens. This lens may reduce but will not eliminate the need for glasses.

You will be expected to follow post-operative instructions, use your drops and return as scheduled for follow-up appointments. It is your responsibility to notify us if you cannot comply with any aspect of the procedure or follow-up.

Intraocular Lens Options

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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 <u>or</u> distance vision: these single focus lenses are called monofocal IOLs. Some IOLs can provide for near, intermediate, and distance vision: these multiple focus lenses are called multifocal or accommodating 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. At the time of surgery a different IOL than was originally planned may be needed.



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Alternatives to Cataract Surgery

There is no other way to improve vision reduced by cataract. You may choose to live with your present vision.

Patient Consent

I understand that cataract surgery is an elective procedure. I have received no guarantee as to the success of my particular case. The long-term risks and side effects of some current techniques and IOL's are unknown. This procedure, like all surgery, presents some risks, many of which are listed below. There may be other risks not known to your doctor, which may become known later. Despite the best of care, complications and side effects may occur which could result in an untreatable, permanent loss of vision or, rarely, loss of the eye.

Vision Threatening Complications

All theses complications may require further medical and/or surgical treatment and result in a permanent reduction or loss of vision.

- Anesthetic injections around the eye may be given. Complications with these injections are possible including drug reactions, droopy eyelid, medical side effects and/or inadvertent penetration of the eye or optic nerve with the injection.
- Medication drops are used before and after surgery. Side effects of these medications include: drug reactions, pain, glaucoma, cataract, infection.
- Specific examples of complications of cataract surgery include: malfunction of surgical equipment, surgical trauma to various parts of the eye, retinal detachment, especially in patients with nearsightedness, double vision, swelling of the corneal and/or retina, bleeding, inflammation, scarring, pain, irregular and/or enlarged pupils, glare/halos/starbursting around bright lights at night, poor night vision which may impair the ability to drive, glaucoma, dry eye and eyelid drooping.
- Specific examples of complications associated with the IOL include: IOL dislocation, nighttime vision problems, double or ghost images.
- Certain medications, especially those used to treat an enlarged prostate (such as Flomax) increase surgical risk by weakening the iris (floppy iris syndrome) and causing a small pupil. Additional procedures may be needed to stabilize the iris and/or enlarge the pupil and may result in irregular and/or enlarged pupils after surgery.
- Ocular conditions including glaucoma, macular degeneration, diabetic retinopathy, history of herpes simplex or zoster, iritis, keratoconus, pellucid marginal degeneration, previous eye surgery or injury, lazy eye (amblyopia), large pupils and high corrections may increase risks and limit the effectiveness of cataract surgery. High amounts of nearsightedness increases the risk for retinal detachment. Please notify us on your history form if you have any of these conditions.
- I understand that surgery may interfere with my ability to drive and work and could result in mental anguish, a loss of wages, lifestyle or personal relationships.
- I understand that I may be at increased risk for some complications compared to the general population. I understand that I may not be informed about every complication for which I may be at increased risk.

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Initials

- I understand that during surgery that unforeseen conditions may occur that may result in stopping the procedure or doing a different procedure. I am authorizing my ophthalmologist to perform whatever procedure(s) he determines are advisable.

Non-Vision Threatening Complications

Initials _____

- Cataract surgery may increase your need for glasses. If you were nearsighted before cataract surgery and have as a goal good distance vision, you will lose you natural ability to see at near without glasses.
- Calculations are done to select the power of the IOL for your eye. However, the measurements used in the calculations and the calculations themselves are not completely predictable. This is particularly true if you have higher amounts of nearsightedness, farsightedness, astigmatism or if you have had previous vision correction surgery (RK, LASIK, PRK).
- It is possible that the IOL may be mislabeled by the manufacturer or that the incorrect IOL power may be use. You may have residual or induced nearsightedness, farsightedness and/or astigmatism that may require additional surgery with laser, lens removal and exchange, a second IOL or continued use of glasses and/or contact lenses.
- I understand that, as with all types of surgery, there is a possibility of complications due to anesthesia, drug reactions, or other factors that may involve other parts of my body including cardiac and respiratory problems and, very rarely, death. I understand that, since it is impossible to state every complication that may occur as a result of any surgery, the list of complications in this form may not be complete.
- During the procedure, your surgeon may decide not to implant an IOL even though you have planned on it and given permission to do so.
- YAG capsulotomy: A thin membrane supports the IOL. Months to years after surgery that membrane may become cloudy and cause decreased vision. This problem can be treated with a procedure called a YAG capsulotomy. This procedure is relatively easy, safe and effective. However, complications are possible such as retinal detachment.
- Until your second eye can be done, you may experience an imbalance between the eyes. This may not be correctable with glasses. You may need to wear a contact lens in the unoperated eye or function with only one eye.
- I understand that there is a natural tendency of the eyelids to droop with age and that eye surgery may speed this process.
- I understand that temporary glasses either for distance or reading may be necessary while healing occurs and that more than one pair of glasses may be needed. I understand that I am financially responsible for any glasses needed after surgery and for the measurement of the refractive error needed to prescribe such glasses.
- I understand that the correction that I can expect to gain from cataract surgery may not be perfect at all times, under all circumstances, for the rest of my life. I understand I will still likely need glasses to refine my vision for distance and near, especially for visually demanding tasks.
- I understand that staff members and other doctors besides my surgeon may be performing parts of my pre- and post-operative testing, examinations and care.

Patient Responsibility for Costs

In the event of a complication, additional expenses are possible including other surgery, eye drops, glasses, contact lenses, medical consultations, travel, time off work, etc. It may be possible that other surgery, eye drops or even hospitalization may be required. The patient is responsible for the costs of surgery and any additional expenses.

Monovision

Monovision may be an option to reduce dependency on glasses for near. One eye is corrected for distance and the other for near. Monovision does not eliminate glasses. Patients with monovision typically still need glasses for visually demanding activities such as driving and reading finer detail, especially in low light conditions. Monovision can decrease depth perception. If you would like to pursue monovision or low nearsightedness with surgery, it is your responsibility to have trialed the option with glasses or contact lenses for at least one week in a variety of visual situations. Your result from surgery may not be exactly like the vision you experienced during your trial.

Off Label Use

When a drug or device is approved for medical use by the Food and Drug Administration (FDA), the manufacturer is required to produce a "label" to explain its use. Physicians, using their best medical judgment, may not follow FDA protocols exactly and/or may use a drug or device for things not on the label. This is called "off-label." We cannot guarantee to document every off-label use in every patient. Devices, including the IOL, used in your surgery may be "off-label" for your situation.

Video and Photographic Recording

I give permission for my ophthalmologist to record on video or photographic equipment my procedure, for purposes of education, research, or training of other health care professionals. I also give my permission for my ophthalmologist to use data about my procedure and subsequent treatment to further understand cataract surgery. I understand that my name will remain confidential, unless I give subsequent written permission for it to be disclosed.

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PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

The details of the procedure known as cataract surgery have been presented to me in detail. I understand that it is impossible for the doctor to inform me of every possible complication that may occur. My ophthalmologist has answered all my questions and provided further explanations to my satisfaction. I have read this informed consent (or it has been read to me), fully understand the possible risks, complications, alternatives and benefits, and give my consent to have the procedure on:

CIRCLE Right Eye Left Eye Both Eyes

I have checked my choice for type of IOL.

- Monofocal IOL/Glasses Option (will need glasses)
 I wish to have a cataract operation with a monofocal IOL on my) with a goal to optimize [circle: Near Distance] vision without glasses.
- 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 this eye corrected to optimize [circle: Near Distance] vision without glasses
- Toric monofocal IOL/Glasses Option for Astigmatism Reduction (will need glasses)

 I wish to have a cataract operation with a toric monofocal IOL to optimize my [circle: Near Distance] vision.
- Crystalens IOL Option (may still need glasses for some tasks) I wish to have a cataract operation with a Crystalens IOL.
- □ **ReStor IOL Option (may still need glasses for some tasks)** I wish to have a cataract operation with a ReStor IOL.

Patient's Signature	Date
Witness' Signature	Date