



Informed Consent for Cataract Surgery and/or Implantation of an Intraocular Lens

INTRODUCTION

This information is given to you so that you can make an informed decision about having eye surgery. Take as much time as you wish to make your decision about signing this informed consent. You have the right to ask any questions you might have about the operation before agreeing to have it.

Except for unusual situations, a cataract operation is indicated only when you cannot function satisfactorily due to decreased vision caused by the cataract. After your doctor has told you that you have a cataract, you and your doctor are the only ones who can determine if or when you should have a cataract operation, based upon your own visual needs and medical considerations. You may decide not to have a cataract operation at this time. If you decide to have an operation, the surgeon will replace your natural lens with an intraocular lens implant (IOL) in order to restore your vision. This is an artificial lens, usually made of plastic, silicone, or acrylic material, surgically and permanently placed inside the eye. Eyeglasses may be required in addition to the IOL for best vision.

EXAMINATIONS PRIOR TO SURGERY

If you agree to have the surgery, you will undergo a complete eye examination by your surgeon. This will include an examination to determine your glasses prescription (refraction) both with and without dilating drops, measurement of your vision with and without glasses (visual acuity), measurement of the pressures inside your eye (tonometry), measurement of the curvature of your cornea (keratometry), ultrasonic measurement of the length of your eye (axial length), intraocular lens calculation (biometry) to determine the best estimate of the proper power of the implanted lens, microscopic examination of the front part of your eye (slit-lamp examination), and examination of the retina of your eye with your pupils dilated (indirect ophthalmoscopy).

MORE INFORMATION ABOUT INTRAOCULAR LENS BIOMETRY

While biometry, the method used to calculate the power of the IOL, is very accurate in the majority of patients, the final result may be different from what was planned. As the eye heals, the IOL can shift very slightly toward the front or the back of the eye. The amount of this shift is not the same in everyone, and it may cause different vision than predicted. Patients who are highly nearsighted or highly farsighted have the greatest risk of differences between planned and actual outcomes. Patients who have had LASIK or other refractive surgeries are especially difficult to measure precisely.

If the eye's visual power after surgery is considerably different than what was planned, surgical replacement of the IOL might be considered. It is usually possible to replace the IOL and improve the situation.

PRESBYOPIA AND ALTERNATIVES FOR NEAR VISION AFTER SURGERY

Patients who have cataracts may have, or will eventually develop, an age-related condition known as presbyopia. Presbyopia is the reason that reading glasses become necessary, typically after age 40, even for people who have excellent distance and near vision without glasses. Presbyopic individuals require bifocals or separate (different prescription) reading glasses in order to see clearly at close range. There are several options available to you to achieve distance and near vision after cataract surgery.

- **GLASSES** You can choose to have a Standard monofocal (single focus) IOL implanted for distance vision and wear separate reading glasses.
- **MONOVISION** The ophthalmologist could implant IOLs with two different powers, one for near vision, and other for distance vision. This combination of a distance eye and a reading eye is called monovision, and would allow you to read without glasses. It has been employed quite successfully in many contact lens and refractive surgery patients. Your surgeon will discuss and demonstrate this option.
- **PREMIUM LIFESTYLE LENS** (multifocal lens) The ophthalmologist could implant a “Premium LifeStyle” IOL. These IOLs, more recently approved by the Food and Drug Administration (FDA), provide distance vision AND restore some or all of the focusing (accommodating) ability of the eye. Depending upon the technological features of the IOLs, they may be described as “accommodating,” “apodized diffractive,” or “presbyopia-correcting.” All of these lenses are “multifocal,” meaning they correct for both distance vision and other ranges, such as near or intermediate and minimizing dependence on glasses.

SURGICAL MINIMIZATION /CORRECTION OF ASTIGMATISM

Personalized Vision Package (PVP): may include one or more of the following procedures determined by my surgeon to correct astigmatism:

1. Toric intraocular lens implant
2. Limbal Relaxing Incision (LRI) with LenSx Laser (the laser can reduce or eliminate astigmatism by creating one or two precise laser incisions on the cornea called limbal relaxing incisions)
3. Laser vision correction (LASIK/PRK)

ANESTHESIA, PROCEDURE, AND POSTOPERATIVE CARE

Either the ophthalmologist or the anesthesiologist/nurse anesthetist will make your eye numb with either drops or an injection (local anesthesia). You may also undergo light sedation administered by an anesthesiologist or nurse anesthetist or elect to have the surgery with only local anesthesia. 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 natural lens in your eye will then be removed by a type of surgery called phacoemulsification, which uses a vibrating needle to break the lens up into small pieces. These pieces are gently suctioned out of your eye through a small, hollow tube inserted through a small incision into your eye. After your natural lens is removed, the IOL is placed inside your eye. In rare cases, it may not be possible to implant the IOL you have chosen or any IOL at all.

After the surgery, your eye will be examined the next day, then at one week, 3 to 4 weeks, and at 3 months. During the immediate recovery period, you will place drops in your eyes for 2 to 4 weeks, depending on your individual rate of healing. If you have chosen monovision or a Premium LifeStyle lens 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 OF CATARACT SURGERY

The goal of cataract surgery is to correct the decreased vision that was caused by the cataract. Cataract surgery will not correct other causes of decreased vision, such as glaucoma, diabetes, or age-related macular degeneration. Cataract surgery is usually quite comfortable. Mild discomfort for the first 24 hours is typical, but severe pain would be extremely unusual and should be reported immediately to the surgeon.

As a result of the surgery and associated 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. Depending upon the type of anesthesia, other risks are possible, including cardiac and respiratory problems, and, in rare cases, death. Although all of these complications can occur, their incidence following cataract surgery is exceptionally low.

Risks of cataract surgery include, but are not limited to:

1. Complications of removing the natural lens may include hemorrhage (bleeding); rupture of the capsule that supports the IOL; perforation of the eye; clouding of the outer lens of the eye (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 IOL 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.**
2. Complications associated with the IOL may include increased night glare and/or halo, double or ghost images, and dislocation of the IOL. Premium LifeStyle lenses may cause glare and halos. In some instances, corrective lenses or surgical replacement of the IOL may be necessary for adequate visual function following cataract surgery.
3. Complications associated with local anesthesia injections around the eye include perforation of the eye, destruction of the optic nerve, interference with the circulation of the retina, droopy eyelid, respiratory depression, hypotension, cardiac problems, and in rare situations, brain damage or death.
4. If a standard monofocal IOL is implanted, reading glasses or contacts will be needed after cataract surgery for near vision.
5. Complications associated with monovision. 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 is done, or to reverse the distance and near eye without some loss of visual quality.
6. Complications associated with Premium LifeStyle lenses. While a Premium LifeStyle lens can reduce dependency on glasses, it might result in less sharp vision, which may become worse in dim light or fog. It 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 considerable amount 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. At the time of surgery, a standard monofocal IOL may need to be implanted instead of a Premium lifeStyle lens.
7. If an IOL is implanted, it is done by surgical method. It is intended that the small plastic, silicone, or acrylic IOL will be left in the eye permanently.
8. At the time of surgery, the doctor may decide not to implant an IOL in your eye even though you may have given prior permission to do so.
9. Other factors affect the visual outcome of cataract surgery, including other eye diseases such as glaucoma, diabetic retinopathy, age-related macular degeneration; the power of the IOL; your individual healing ability; and, if certain IOLs are implanted, the function of the ciliary muscles in your eyes.

10. 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. 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.
11. The results of surgery cannot be guaranteed. If you chose a Premium LifeStyle lens, 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. Regardless of the IOL chosen, you may need laser surgery to correct clouding of vision. At some future time, the IOL implanted in your eye may have to be repositioned, removed surgically, or exchanged for another IOL.
12. If your ophthalmologist has informed you that you have a high degree of hyperopia (farsightedness) and/or that the axial length of your eye is short, 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.
13. If your ophthalmologist has informed you that you have a high degree of myopia (nearsightedness) and/or that the axial length of your eye is long, your risk for a complication called a retinal detachment is increased. Retinal detachments can lead to vision loss or blindness.
14. Since only one eye will undergo surgery at a time, you may experience a period of imbalance between the two eyes (anisometropia). This usually cannot be corrected with spectacle glasses because of the marked difference in the prescriptions, so you will either temporarily have to wear a contact lens in the non-operated eye or will function with only one clear eye for distance vision. In the absence of complications, surgery in the second eye can usually be accomplished within 1 to 2 weeks, once the first eye has stabilized.

PATIENT ACKNOWLEDGEMENT OF FINANCIAL OBLIGATIONS

My ophthalmologist's staff has informed me that if I have Medicare or other insurance coverage for this cataract surgery, the "presbyopia-correcting" Premium LifeStyle lens and associated services for fitting the lens are only considered **partially covered**. I acknowledge that I am responsible for payment of that portion of the charge for the "presbyopia-correcting" Premium LifeStyle lens and associated services that exceed the charge for insertion of a conventional, monofocal, IOL or monovision following cataract surgery. The staff has informed me about the coverage, deductible, and copayment amounts if a private insurance company is paying for this procedure.

In the event of a complication, I understand that I may require additional surgery, eye drops, or even hospitalization. Although some or even all of these costs may be covered by my health insurance policy, if they are not, I understand that I am responsible for any additional costs not covered by my insurance.

If we are unable to implant a Premium LifeStyle lens you need to understand your near vision will **NOT** be clear without the use of reading glasses. If we are unable to implant the Premium LifeStyle lens, we will refund the cost of the upgrade package to you.

By signing this consent, I understand and agree that Eye Surgery Center of Arizona's policy requires me to suspend my Advanced Directive while I am in surgery and under Post Anesthesia care. I also understand and agree that in the event of any medical emergency, I will be transferred to Banner Baywood Medical Center and my Advanced Directive will be transferred with me.

Cataract Surgery Using the LenSX Cataract Laser System

In traditional cataract surgery, a metal blade is used to create an incision on the eye to gain access to the cataract. A capsulotomy is a step during the procedure where an opening in the lens capsule is created to allow access to the cataract within the capsule. The capsulotomy is created using a sharp needle called a cystotome. Once the cataract is exposed, it is broken into small pieces and removed using a mechanical ultrasonic probe. Each of these steps are performed by your surgeon by hand.

The purpose of the LenSx cataract laser is to replace the use of the traditional manual instruments with an automated laser.

The LenSx cataract laser is an FDA-approved device designed to use laser energy to break up the cataract within the eye and create an opening in the capsule that holds the cataract to allow the surgeon to remove the fragmented cataract. The laser is also designed to make a precise incision in the cornea to gain access to the cataract. Finally, the laser can reduce or eliminate astigmatism by creating one or two precise laser incisions on the cornea called relaxing incisions.

Potential Complications Associated with the LenSX Laser

Although rare, complications can exist with any procedure. The following are some of the possible complications which include, but are not limited to: Decentration of the corneal or capsulotomy incisions; Incomplete or irrupted capsulotomy, fragmentation, or corneal incision procedure; Anterior capsular tear; Posterior capsular tear with lens/lens fragment dislocation into the vitreous; Corneal abrasion or defect; Pain; Infection; Bleeding; Damage to intraocular structures; Anterior chamber fluid leakage; Anterior chamber collapse; Elevated eye pressure. These complications are uncommon and can occur with or without the LenSX laser treatment.

For Women Only: I am not pregnant or nursing. I understand that pregnancy could adversely affect my treatment.



SWAGEL WOOTTON

EYE INSTITUTE - PATIENT CONSENT FOR CATARACT SURGERY

By signing this informed consent for cataract operation and implantation of an IOL, I acknowledge that I have read the document entitled "Informed Consent for Cataract Surgery and/or Implantation of an Intraocular Lens," and have been given the opportunity to ask questions and have had all of my questions answered to my satisfaction. I have also been given a copy of the document for my review.

The procedure has been explained to me in detail and all of my questions have been answered. The risks, Benefits, and alternatives of the procedure have been explained to me, including such rare complications a loss of vision and severe infection requiring removal of the eye.

Options for intra-ocular lenses (IOLs) have been discussed, including standard mono-focal IOLs, Personalized Vision Package, Premium LifeStyle lenses and laser assisted cataract surgery to reduce astigmatism.. I understand that if I have a standard mono-focal IOL implanted, I will require glasses for distance and/or near vision. Whereas a Premium LifeStyle lens package will give me distance and near vision with less dependence on glasses. Additional surgery, such as laser vision correction, may be required to improve your vision after cataract surgery. I understand the cost of the Premium LifeStyle lens package and Personalized Vision Package procedures, which also include the use of the LenSx cataract laser, are not covered by Medicare and/or private insurance and that I am required to pay for the additional cost of the lens, laser and additional testing required. I also understand that a situation may arise during surgery that prevents the use of the laser or implantation of a Premium LifeStyle Lens.

I hereby give my consent to (Circle): Dr. Loan Ramsey | Dr. Lance Stutz | Dr. Joshua Brozek and any personnel she requires to perform cataract extraction with intra ocular lens implantation on my:

RIGHT EYE LEFT EYE (Checked box indicates which eye)

And request that he/she implant the following type of intra-ocular lens package: (please initial which option you would like)

Option 1:

Premium Lifestyle Lens Package: Multi-focal lenses allow for a extended range of vision. This package is designed to reduce your dependency on glasses most of the time for distance, intermediate and near vision. Glasses may be needed occasionally to obtain your best vision, especially at near. This package includes: Femtosecond laser assisted cataract surgery, Toric Multi-focal if needed, ORA and a LASIK/ PRK touch-up if necessary. This package is not billable to your insurance and you would be responsible for non-covered services.

Option 2:

Personalized Vision Package: (PVP) This package offers a way to correct distance vision for those patients who want to reduce their dependence on glasses for distance by correcting astigmatism with a limbal relaxing incision or a toric IOL. It is important to understand that glasses will be needed for intermediate and reading after your surgery. This package would also include options for patients seeking mono-vision correction. Typically, your surgeon will only recommend mono-vision if you have had experience with mono-vision prior to your cataract procedure. This package includes: Femtosecond laser assisted cataract surgery, Toric IOL if needed, and a LASIK/PRK touch up if necessary. This package is not billable to your insurance and you would be responsible for non-covered services.

Option 3:

Femtosecond Laser-Assisted Cataract Surgery to Reduce Astigmatic Correction: This option is for patients who want to take advantage of the newest femtosecond laser assisted cataract surgery. There will be a limbal relaxing incision to reduce astigmatism. Your surgeon will discuss whether you are a candidate for this option. Patients will typically need to update their bifocals after surgery. This option is not billable to your insurance and you would be responsible for non-covered services.

Option 4:

Standard Lens: This package includes a standard lens that does not correct astigmatism, intermediate or near distances. Bi-focals or Progressives may be needed after surgery. This option is billable to your medical insurance. Coverage depends on your plan.

Patient Signature (or person responsible)

Date

DO NOT SIGN,

Witness Signature

Date

FOR YOUR RECORDS

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Date

Witness Signature

Date

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