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Informed Consent for Cataract Surgery

INTRODUCTION

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

Except for unusual situations, a cataract operation is indicated only when your vision interferes with your lifestyle 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 and 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 in the eye. Eyeglasses may be required in addition to the IOL for optimal distance or reading vision.

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 desired 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 vision and optical power after surgery is considerably different than what was planned, it is usually possible to correct this with excimer laser refractive surgery, an IOL exchange, or placement of an additional "piggy back" IOL.

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 cannot change the focus of their lens and may see distance or near but not both. They may 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.

I have read and understood this page. Patient's initials _____ Page 1 of 5

- **GLASSES** You can choose to have a monofocal (single focus) IOL implanted for distance vision and wear separate reading glasses, or have the IOL implanted for near vision and wear separate glasses for distance.
- **MONOVISION** The ophthalmologist could implant IOLs with two different powers, one for near vision, and the other for distance vision. This combination of a distance eye and a reading eye is called monovision, and could allow you to read without glasses. It has been employed quite successfully in many contact lens and refractive surgery patients. This option will be discussed with you. This option is generally reserved for patients who have already experienced success with monovision contact lenses.
- **MULTIFOCAL IOL** The ophthalmologist could implant a “multifocal” 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 IOL, they may be described as “accommodating”, “apodized diffractive”, or “presbyopia-correcting”. All of these lenses are “multifocal”, meaning they correct for both distance and other ranges, such as near or intermediate. FDA studies show that 80% of patients rarely need glasses with these lenses implanted in both eyes.

CATARACT SURGERY: PROCEDURE, AND POSTOPERATIVE CARE

The ophthalmologist or the anesthesiologist will numb your eye with either drops or an injection (local anesthesia). You may also undergo light sedation administered by an anesthesiologist, or have the surgery with local anesthesia only.

An incision, or opening, is then made in the eye. This is, at times, self-sealing but may require closure with very fine stitches (sutures) that will gradually dissolve over time or need to be removed. The natural lens in your eye will then be removed by a type of surgery called phacoemulsification, which uses a vibrating ultrasound probe to break the lens up into small pieces. These pieces are gently suctioned out of your eye through a small, hollow tube inserted through the small incision in 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, 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 monovision or a multifocal IOL 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 to 3 days, and your eye will usually be stable within 3 to 6 weeks, at which time glasses or contact lenses could be prescribed by your own eye care professional, Dr. Snyder, or Dr. Murphy. Medicare and most private insurance companies do not cover refractions, therefore, if you wish to have a refraction performed at our office the charge will be \$40.00.

I have read and understood this page. Patient's initials _____ Page 2 of 5

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 Dr. Snyder or his staff.

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 on 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 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; perforations 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 the lens in the eye, which may need to be removed surgically; infection; detachment of the retina, which is 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 the loss of the eye in rare situations. **Additional surgery may be required to treat these conditions.**
2. Complications associated with the IOL may include increased night glare and/or halo, double or ghost images, and dislocation of the IOL. Multifocal IOLs may increase the likelihood of these problems. 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 monofocal IOL is implanted, either distance or reading glasses or contact lenses will be needed after cataract surgery for adequate vision.
Complications associated with multifocal IOLs. While a multifocal IOL 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. If complications occur at the time of surgery, a monofocal IOL may need to be implanted instead of a multifocal IOL.

I have read and understood this page. Patient's initials _____ Page 3 of 5

5. If an IOL is implanted, it is done by a surgical method. It is intended that a small plastic, silicone, or acrylic IOL will be left in the eye permanently.
6. If complications occur 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.
7. Other factors may 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 (focusing) muscles in your eyes.
8. The selection of the proper IOL, while based upon sophisticated equipment and computer formulas, is not a perfect 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 at an additional cost to you if you are not satisfied with your vision after cataract surgery.
9. The results of the surgery cannot be guaranteed. If you choose a multifocal IOL, 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 the posterior capsule. At some future time, the IOL implanted in your eye may have to be repositioned, removed surgically, or exchanged for another IOL.
10. 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, (less than 20mm), 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.
11. 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 retinal detachment is increased. Retinal detachments can usually be repaired but may lead to vision loss or blindness.
12. 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 one clear eye for distance vision. In the absence of complications, surgery in the second eye can usually be accomplished within 2 to 4 weeks, once the first eye has stabilized.

PATIENT ACKNOWLEDGEMENT OF FINANCIAL OBLIGATIONS

I acknowledge that I have been informed that if I have Medicare or private insurance coverage for this cataract surgery, the “presbyopic-correcting” multifocal IOL and associated services for fitting the lens are only considered **partially covered**. I also acknowledge that I am responsible for payment of that portion of the charge for the “presbyopic-correcting” multifocal IOL and associated services that exceed the charge for insertion of a traditional monofocal IOL for cataract surgery and that it is my responsibility to verify the coverage, deductible, and co-payment amounts if a private insurance company is paying for this procedure.

I have read and understood this page. Patient’s initials _____ Page 4 of 5

PATIENT CONSENT

Cataract surgery, by itself, means the removal of the natural lens of the eye by a surgical technique. In order for an IOL to be implanted in my eye, I understand that I must have cataract surgery performed either at the time of the IOL implantation or before IOL implantation. If my cataract was previously removed, I have been informed that my eye is medically acceptable for IOL implantation.

I acknowledge that the basic procedures of cataract surgery, the reasons for the type of IOL chosen for me, and the advantages and disadvantages, risks, and possible complications of alternative treatments have been explained to me. Although it is impossible to inform me of every possible complication that may occur, all my questions have been answered to my satisfaction.

In signing this informed consent for cataract surgery and/or implantation of an IOL for my **Right Eye** **Left Eye**, I am stating that I have been offered a copy of these forms, my lens options have been discussed with me, and I am aware that some of my postoperative visits may be performed by Dr. John Murphy. I fully understand the possible risks, benefits, and complications of cataract surgery and have read this informed consent.

Patient Signature 1st eye

Date

Patient Signature 2nd eye

Date

Witness Signature

Date

Physician Signature

Date

Implant Lens Option Selection 1st eye

Traditional (Monofocal IOL) Distance only with Glasses Option

I wish to have a cataract operation with a distance only implant and understand it will not correct astigmatism and I will most likely need glasses for near (reading) and intermediate (computer) work.

Right eye **Left eye and wear glasses for near vision.**

Traditional (Monofocal IOL) Near only with Glasses Option

I wish to have a cataract operation with near only implant and understand it will not correct astigmatism and I will most likely need glasses for distance.

Right eye **Left eye and wear glasses for distance vision.**

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 my _____ (state "right" or "left") eye corrected for **distance** vision. I wish to have my _____ (state "right" or "left") eye corrected for **near** vision. I understand the lens will not correct astigmatism.

Premium IOL Option (may still need glasses) **Crystalens/** **ReStor**

This option offers patients the possibility to see well at a variety of ranges. I wish to have a cataract operation with a multifocal IOL or accommodating IOL implant on my _____ (state "right" or "left") eye. While we are able to minimize the patient's postoperative prescription, I understand that the choice of the premium IOL lens does not necessarily equate with the elimination of the need for glasses as there may be amounts of residual nearsightedness, farsightedness, or astigmatism. In such cases, additional surgery may be able to reduce this refractive error, however, there may be additional expenses incurred by the patient. I understand that this option is not considered medically necessary and, therefore, not covered by my insurance.

I have been informed that if I have medical coverage for this cataract surgery, the multifocal/ accommodating IOL 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 procedure that is not covered. I have been informed that an additional professional fee of \$1200 per eye will be charged. I am also aware that the surgery center will charge between \$800 and \$1000 per eye for the lens. I further understand that I am responsible for all deductible and copayment amounts if a private insurance company is paying for this procedure.

Payment arrangements for the elective portion must be made prior to your surgery date. _____

Initial

Toric monofocal IOL/Glasses Option for Astigmatism Reduction

This option offers the possibility of correcting the astigmatism at one focal point, generally distance.

I wish to have a cataract operation with a toric monofocal IOL on my _____ (state "right" or "left") eye and wear glasses for _____ (state "near" or "distance") vision.

I have been informed that if I have medical coverage for this cataract surgery, the toric implant 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 procedure that is not covered. I have been informed that an additional professional fee of \$500 per eye will be charged. I am also aware that the surgery center will charge approximately \$500 per eye for the lens. I further understand that I am responsible for all deductible and copayment amounts if a private insurance company is paying for this procedure.

Payment arrangements for the elective portion must be made prior to your surgery date. _____

Initial

Sign below indicating that you have read, understand, and chosen from the above options.

Patient

Date

Witness

Date

Surgeon

Date

Implant Lens Option Selection 2nd eye

Traditional (Monofocal IOL) Distance only with Glasses Option

I wish to have a cataract operation with a distance only implant and understand it will not correct astigmatism and I will most likely need glasses for near (reading) and intermediate (computer) work.

Right eye **Left eye and wear glasses for near vision.**

Traditional (Monofocal IOL) Near only with Glasses Option

I wish to have a cataract operation with near only implant and understand it will not correct astigmatism and I will most likely need glasses for distance.

Right eye **Left eye and wear glasses for distance vision.**

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 my _____ (state "right" or "left") eye corrected for **distance** vision. I wish to have my _____ (state "right" or "left") eye corrected for **near** vision. I understand the lens will not correct astigmatism.

Premium IOL Option (may still need glasses) Crystalens

This option offers patients the possibility to see well at a variety of ranges. I wish to have a cataract operation with a multifocal IOL or accommodating IOL implant on my _____ (state "right" or "left") eye. While we are able to minimize the patient's postoperative prescription, I understand that the choice of the premium IOL lens does not necessarily equate with the elimination of the need for glasses as there may be amounts of residual nearsightedness, farsightedness, or astigmatism. In such cases, additional surgery may be able to reduce this refractive error, however, there may be additional expenses incurred by the patient. I understand that this option is not considered medically necessary and, therefore, not covered by my insurance.

I have been informed that if I have medical coverage for this cataract surgery, the multifocal/ accommodating IOL 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 procedure that is not covered. I have been informed that an additional professional fee of \$1200 per eye will be charged. I am also aware that the surgery center will charge between \$800 and \$1000 per eye for the lens. I further understand that I am responsible for all deductible and copayment amounts if a private insurance company is paying for this procedure.

Payment arrangements for the elective portion must be made prior to your surgery date. _____

Initial

Toric monofocal IOL/Glasses Option for Astigmatism Reduction

This option offers the possibility of correcting the astigmatism at one focal point, generally distance.

I wish to have a cataract operation with a toric monofocal IOL on my _____ (state "right" or "left") eye and wear glasses for _____ (state "near" or "distance") vision.

I have been informed that if I have medical coverage for this cataract surgery, the toric implant 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 procedure that is not covered. I have been informed that an additional professional fee of \$500 per eye will be charged. I am also aware that the surgery center will charge approximately \$400 per eye for the lens. I further understand that I am responsible for all deductible and copayment amounts if a private insurance company is paying for this procedure.

Payment arrangements for the elective portion must be made prior to your surgery date. _____

Initial

Sign below indicating that you have read, understand, and chosen from the above options.

Patient

Date

Witness

Date

Surgeon

Date

Pre-Operative Health Questionnaire

1. Do you now, or have you ever, had any heart problems, heart procedures, or heart surgeries? Please list in detail. _____

If yes, please contact your primary care provider and request that they provide clearance for cataract surgery.

2. a) Are you now, or have you ever, been followed as a Diabetic? YES / NO
b) Do you have to take insulin? YES / NO

3. Are you now, or have you ever, been on Dialysis YES / NO

4. Are you taking Travatan, Lumigan and/or Xalatan for Glaucoma? YES / NO

5. Are you taking Flomax and/or medication for Prostate problems? YES / NO

6. Are you allergic to any medication or medical device, including latex?

7. Are you experiencing any medical problems that you see a doctor for on a recurring basis, for example, high blood pressure, high cholesterol, or breathing problems. If yes, please explain in detail.

8. Have you ever had any anesthesia or bleeding problems with any type of surgery, major or minor? _____

a. Have you ever had any eye surgeries? (Refractive, Lasek, Lasik, RK, cornea transplant, retinal, or strabismus) YES / NO

b. Have you ever had cataract surgery in the past? YES / NO

9. Please list any medications you take on a regular basis, including vitamins, minerals, and supplements (**or provide a list that we can copy**).

Patient Signature 1st eye

Date

Patient Signature 2nd eye

Date

Informed Consent for Off-label use of Medication

When the Food and Drug Administration (FDA) approves a drug for medical use, the manufacturer produces a "label" to explain its use and the indication for which it has been approved. Once the FDA approves a device/ medication, physicians may use it "off label" for other purposes as long as they consider it safe and in the best interest of the patients.

The medication(s) prescribed for you to use post operatively are considered to be "off label" in their use. If you have any questions or concerns regarding your medication(s), please discuss them with your doctor.

_____ I understand that **Acular LS** was approved by the FDA for the reduction of ocular pain and burning/stinging following corneal refractive surgery.

_____ I understand that **Zymar** was approved by the FDA for the treatment of "bacterial conjunctivitis" caused by susceptible strains of (specific) organisms.

Nevertheless, I wish to have surgery performed on my eye(s) and to use the above noted medication and am willing to accept the potential risks that have been discussed with me. I acknowledge that there may be other unknown risks and that the long-term effects and risks of the above noted medication are not known.

Printed Name

Patient Signature

Date

Pre-surgical Cataract Patient Questionnaire

Patient name: _____

Chart Number: _____

Eye Being Evaluated:

RT LT

Visual Functioning

Do you have difficulty, even with glasses with the following activities?

YES

NO

- | | | |
|--|--------------------------|--------------------------|
| 1. Reading small Print, such as labels on medicine bottles, telephone books, or food labels? | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Reading a newspaper or book? | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Reading a large-print book, or large-print newspaper, on large numbers on a telephone? | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Recognizing people when they are close to you? | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Seeing steps, stairs or curbs? | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Reading traffic signs, street signs, or store signs? | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Doing fine handwork like sewing, knitting, crocheting, or carpentry? | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Writing checks or filling out forms? | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Playing games such as bingo, dominos, or card games? | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Taking part in sports like bowling, handball, tennis, or golf? | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Cooking? | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. Watching Television? | <input type="checkbox"/> | <input type="checkbox"/> |

SYMPTOMS

Have you been bothered by:

YES

NO

- | | | |
|---|--------------------------|--------------------------|
| 1. Poor night vision? | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Seeing rings or halos around lights? | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Glare caused by headlights or bright sunlight? | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Hazy and/or blurry vision? | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Seeing well in poor or dim light? | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Poor color vision? | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Double vision? | <input type="checkbox"/> | <input type="checkbox"/> |

DRIVING

1. Have you ever driven a car? **YES** (continue) **No** (stop)
2. Do you currently drive a car? **YES**(continue) **No** (stop)
3. How much difficulty do you have driving during the day because of your Vision?
 No difficulty A moderate amount of difficulty
 A little difficulty A great deal of difficulty
4. How much difficulty do you have driving at night because of your vision?
 No difficulty A moderate amount of difficulty
 A little difficulty A great deal of difficulty
5. When did you Stop driving?
 Less than 6months ago 6-12 months ago More than 1year ago

Patient signature: _____

Date: _____