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

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 document. 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 (IOL) implant 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 or contact lenses 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), 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 IOL, microscopic examination of the front part of your eye (slit-lamp examination), and examination of the retina of your eye with your pupils dilated.

INFORMATION ABOUT INTRAOCULAR LENS (IOL) 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 predicated. 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.

If a replacement IOL is necessary Dr. Brumm will charge for his physician service on the replacement IOL (accepting the insurance payment as full payment). The facility and anesthesia group will also charge for their services. There will not be a refund for the original IOL or the original physician service(s).

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INFORMATION ABOUT INTRAOCULAR LENS (IOL) IMPLANTS

Through advanced IOL implant technology, you are now offered many choices that can improve your vision and quality of life. These advanced IOLs [aka: Premium IOLs] are available in many different materials and designs. One design may be great for one person but not another and it is up to you and your ophthalmologist to decide which IOL and technique is best for your lifestyle needs.

Medicare and most insurance plans consider the monofocal IOL and associated physician service(s) to be a covered benefit subject to your plan provisions (i.e. deductible, copay and/or coinsurance).

Medicare and most insurance plans consider the premium IOL and associated physician service(s) to be a **partially or non-covered** item &/or service(s). Medicare will only consider the coverage portion of the monofocal IOL and associated physician service(s), any balance remaining is your responsibility and payment is due at least 10 days prior to your procedure. Insurance plans may or may not consider the coverage portion of the monofocal IOL and associated physician service(s), the balance is your responsibility and payment is due at least 10 days prior to your procedure.

If you are considering having a premium intraocular lens [toric or multifocal IOL] implanted when you have your cataract operation, this is an elective IOL implant designed to increase the range of focus compared to a monofocal lens implant. This will reduce your dependency on eyeglasses or contact lenses.

A monofocal [single focus; aka: conventional] IOL implant has a limited range of focus. The overwhelming majority of patients receiving this IOL implant still have to wear eyeglasses after the operation. About 90% still wear eyeglasses, at least part time; about 10% do not.

A toric [astigmatism correcting] IOL implant has a unique design which makes it possible to reduce or eliminate corneal astigmatism and significantly improve uncorrected distance vision. The majority of patients receiving this IOL achieve quality distance vision, independent of eyeglasses and contact lenses. You may still need eyeglasses or contact lenses for either distance or near vision.

A multifocal [multi focus; aka: lifestyle] IOL implant has an extended range of focus. The overwhelming majority of patients receiving this IOL implant do not have to wear eyeglasses after the operation, but some still do. About 15% still wear eyeglasses, at least part time; about 85% do not.

A multifocal IOL implant has complex optics and many patients find it takes a while to adjust to their new optical system. Usually a patient will fully adjust within a few weeks, but some patients do take longer. An occasional patient, perhaps one in a hundred, will not be able to adjust to the multifocal IOL. In these cases the multifocal IOL can be removed and replaced with a monofocal IOL, after which eyeglasses will be needed.

If you cannot adjust to your multifocal IOL and an exchange is necessary Dr. Brumm will charge for his physician service on the exchange (accepting the insurance payment as full payment). The facility and anesthesia group will also charge for their services. There will not be a refund for the original multifocal IOL or the original physician service(s).

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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 monofocal [single focus] intraocular lens (IOL) implanted for distance vision and wear separate reading glasses, or have the IOL implanted for near vision and wear separate glasses for distance.
- **MULTIFOCAL** [multi focus; aka: lifestyle] IOL—your ophthalmologist could implant a multifocal intraocular lens (IOL). These IOLs, 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.

INFORMATION ABOUT TREATING ASTIGMATISM

Patients with nearsightedness and farsightedness often also have astigmatism. An astigmatism is caused by an irregularly shaped cornea; instead of being round like a basketball, the cornea is shaped like a football. This change in shape can make your vision blurry. There are several treatment options for astigmatism:

- You can have a TORIC intraocular lens (IOL) for distance vision with astigmatism correction; you may still need eyeglasses or contact lenses for near vision. Insurance plans may cover a portion of the toric IOL however the balance is your responsibility and payment is due at least 10 days prior to your procedure date.
- You can have a monofocal [single focus] intraocular lens (IOL) for near or distance vision and continue to wear eyeglasses or contact lenses for the astigmatism.
- You can have refractive surgery called LASIK. Insurance plans do not cover LASIK therefore the fee is your responsibility.
- Your surgeon can perform a procedure before, during or after cataract surgery called a limbal relaxing incision (LRI). A limbal relaxing incision is a small incision your ophthalmologist makes into your cornea to make its shape rounder. More than one incision may be required. Insurance plans do not cover a LRI incision(s) therefore the fee is your responsibility and payment is due at least 10 days prior to your procedure date.

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ANESTHESIA, PROCEDURE, AND POSTOPERATIVE CARE

The ophthalmologist or an anesthesiologist or 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 self-sealing but it rarely may require closure. The natural lens in your eye will then be removed by a type of surgery called phacoemulsification, which uses a vibrating probe to break the lens up into small pieces. The 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, and then at intervals determined by your surgeon. During the immediate recovery period, you will place medicated drops in your eyes for about 4 to 8 weeks, depending on your individual rate of healing. If you have chosen a multifocal IOL to reduce your dependency on glasses or contact lenses, 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 eyeglasses 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. You may need additional treatment or surgery to treat these complications. **This additional treatment is not included in the fee for this procedure.** 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 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 (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 to 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. 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.

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3. Complications associated with limbal relaxing incisions include damage to the cornea, infection, and fluctuating vision while the incision heals. They can also lead to under- and over-correction; if this occurs, another procedure and/or glasses or contact lenses may be required.
4. If a monofocal IOL is implanted, either distance or reading glasses or contact lenses will be needed after cataract surgery for adequate vision.
5. If a toric IOL is implanted, either distance or reading glasses or contact lenses will be needed after cataract surgery for adequate vision.
6. 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 IOL 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.
7. If complications occur at the time of surgery, the surgeon may decide not to implant an IOL in your eye even though you may have given prior permission to do so.
8. 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.
9. 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 predicated by preoperative testing. You may need to wear eyeglasses 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.**
10. The results of surgery cannot be guaranteed. 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 eyeglasses or contact lenses after surgery to obtain your best vision. If you chose 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 to get your best range of focus. Regardless of the IOL chosen, you may need laser surgery (a YAG capsulotomy) 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.
11. 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.
12. 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 usually be repaired but may lead to vision loss or blindness.
13. 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 3 to 4 weeks, once the first eye has stabilized.

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PATIENT ACKNOWLEDGEMENT OF FINANCIAL OBLIGATIONS

My ophthalmologist and/or his staff have informed me that if I have Medicare &/or other insurance coverage, the multifocal IOL, toric IOL and any associated physician service(s) may only be considered **partially or non-covered**.

I acknowledge that I am responsible for payment of that portion of the charge(s) for the multifocal IOL, toric IOL and any associated physician service(s) that exceed the charge(s) for insertion of a monofocal [aka: conventional] IOL following cataract surgery.

My ophthalmologist and/or his staff have informed me about the coverage, deductible, coinsurance, and copayment amounts if a private insurance company is paying for this procedure.

Medicare and most insurance plans consider the monofocal IOL and associated physician service(s) to be a covered benefit subject to your plan provisions (i.e. deductible, copay and/or coinsurance).

Medicare and most insurance plans consider the premium IOL and associated physician service(s) to be a **partially or non-covered** item &/or service(s). Medicare will only consider the coverage portion of the monofocal IOL and associated physician service(s), any balance remaining is your responsibility and payment is due at least 10 days prior to your procedure. Insurance plans may or may not consider the coverage portion of the monofocal IOL and associated physician service(s), the balance is your responsibility and payment is due at least 10 days prior to your procedure.

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 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.

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

In signing this informed consent for cataract operation and/or implantation of an IOL, I am stating that I have been offered a copy, I fully understand the possible risks, benefits, and complications of cataract surgery and

I agree to have the type of operation listed below which I have indicated by my signature:

1. Multifocal IOL Option (may still need eyeglasses or contact lenses)

I wish to have a cataract operation with a Multifocal IOL implant on my right or left eye. _____

Patient initials

2. Toric IOL Option (may still need eyeglasses or contact lenses)

I wish to have a cataract operation with a Toric IOL implant on my right or left eye. _____

Patient initials

3. Monofocal IOL/eyeglasses Option

I wish to have a cataract operation with a Monofocal IOL implant on my right or left eye and wear eyeglasses for near or distance vision. _____

Patient initials

4. Limbal Relaxing Incision for Astigmatism Reduction (may still need eyeglasses or contact lenses)

I defer this procedure. _____
Patient initials

I wish to have this procedure done in addition to the cataract operation. _____
Patient initials

Patient signature (or person authorized to sign for patient/relationship)

Date

Patient name (printed)

Witness signature

Date

Bruce H Brumm, MD

Date

By signing this consent I acknowledge I have read and understand all pages. Page 7 of 7

revised: 2/22/2012 cmt