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INFORMED CONSENT FOR CATARACT AND LENS IMPLANT SURGERY

1. GENERAL INFORMATION

This information is given to you to help you make an informed decision about having cataract and/or lens implant surgery. Once you have read this **Informed Consent**, you are encouraged to ask any questions you may still have about the procedure. It is impossible to list all of the possible risks and complications associated with surgery. Risks and complications that are considered to be unforeseeable, remote, or commonly known may not be specifically discussed in this Consent.

2. AN OVERVIEW OF CATARACT AND LENS IMPLANT SURGERY

Diagnosis: A cataract occurs when the natural lens of the eye becomes cloudy. The normal natural lens is clear, and helps focus light on the retina in the back of the eye. As a cataract develops, it blocks and scatters light, reducing the quality of vision.

Cataracts are part of the normal aging process. Most people over age 50 will have some degree of cataract, although some patients develop cataract at an earlier age or even at birth. Certain diseases (such as diabetes) or medications (such as steroids) can speed the development of cataracts. Smoking, poor nutrition, and excessive exposure to ultraviolet light or radiation can also increase the risk of cataracts.

Cataract Surgery: In cataract surgery, the cloudy natural lens of the eye is removed. In almost all cases, the cataract is replaced with a clear artificial lens, called an **intraocular lens implant (IOL)**, which is placed permanently inside the eye at the same time the cataract is removed. IOLs are available in different sizes, powers, materials, and designs, and must be selected by the surgeon depending on the needs of the eye.

An IOL can be inserted later as a separate procedure after a cataract is removed. This may require a different type of IOL than is used if one is placed at the time the cataract is removed.

3. INDICATIONS FOR CATARACT SURGERY

The need for cataract surgery depends on your degree of vision impairment. If your vision is satisfactory and the symptoms caused by the cataract are not too bothersome, there is usually no need to undergo surgery right away. However, if the cataract is interfering with your work, lifestyle, or desired activities, keeping you from doing the things you want or need to do, then cataract surgery is indicated. In most cases, cataract surgery is considered an elective procedure, and the decision to have surgery is up to you, after evaluation and discussion with your surgeon.

In some patients, a cataract can hinder the doctor's ability to see inside the eye and diagnose or treat problems behind the cataract, such as diabetes. Or, a cataract can become so large that it causes inflammation or uncontrollable glaucoma. In these unusual situations, cataract surgery may be advisable even if you are not bothered by the decrease in vision.

4. RISKS AND CONTRAINDICATIONS

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

- **Loss of Vision**: Cataract surgery can possibly cause loss of vision or loss of best-corrected vision. This can be due to problems such as infection, scarring, inflammation, or hemorrhage, and if severe can even cause partial or complete loss of vision or loss of the eye. Such severe complications are extremely rare, but can and do occur.

- **Visual Side-Effects**: Visual difficulties and conditions that can occur after cataract surgery include: differences in power between the two eyes, differences in image size between the two eyes, double vision or ghost images, shadows in peripheral vision, floaters or flashes of light, and halos or reflections from lights. These problems occur commonly after only one eye has cataract surgery, and may be relieved after both eyes are done.

- **Glasses or Contact Lenses**: Cataract surgery, even with an intraocular lens implant (IOL), does not eliminate the need for glasses. Most patients will have some residual nearsightedness, farsightedness, or astigmatism, and will need glasses for optimal distance and close vision after surgery. Often the glasses strength is fairly low, and some patients feel less dependent on glasses after surgery. However, other patients may find that they need glasses more afterwards. Typically, glasses will not be changed until several weeks after surgery.

  The glasses power needed after surgery depends on a number of factors and cannot be predicted with absolute accuracy. Some patients end up with more or less nearsightedness or farsightedness than expected, and may require stronger glasses or contact lenses. If there is a large unexpected difference in the glasses prescription, then a contact lens, exchange of the IOL, placement of an additional IOL, or additional surgery to correct the vision may be required.

- **Surgical Complications**: Surgical complications can arise from anesthesia, the intraocular lens implant, or from surgery itself. In some cases, complications can occur weeks, months or even years later. Such complications may include bleeding, clouding of the cornea, retained pieces of cataract in the eye, infection, retinal detachment, droopy eyelid, glaucoma, dislocation of the IOL, or an uncomfortable or painful eye. Reactions to anesthesia can also occur. If there is a complication at the time of surgery, the surgeon may decide not to implant an IOL in your eye, even though you may have given permission to do so.

- **Other Risks:** Cataract surgery may cause changes in the appearance of the eye, such as distortion of the pupil, or a reflection or shiny appearance in the pupil from the lens implant. Other eye conditions, such as macular degeneration, glaucoma, or diabetic retinopathy, may worsen following cataract surgery.

- **Risks of Not Undergoing Cataract Surgery**: If you do not undergo cataract surgery, your cataract will worsen with time. Although this does not generally cause other damage to the eye, your risk of falling and sustaining a hip fracture or other injury, or of being involved in a car accident if you drive, may be higher because of the cataract. The cataract may also become more difficult to remove, and the surgery more risky, if the cataract grows too dense. In rare instances, the cataract can grow so much that it causes sudden severe glaucoma or inflammation, leading to permanent damage to the eye and loss of vision.

Cautions: Extra caution may be required if cataract surgery is needed on patients with active inflammation in the eye, uncontrolled diabetes, severe glaucoma, who have taken certain medications such as Flomax®, or who have only one useful eye. If you know that you have any of these conditions, you should discuss them with your surgeon.

5. ALTERNATIVES TO CATARACT SURGERY

In the early stages, a change in glasses and attention to better lighting can sometimes improve the vision enough to delay surgery. Except in unusual circumstances, there is little danger to the eye from delaying cataract surgery, except that the vision will remain impaired until the cataract is removed. If delayed, surgery can usually be done later with a good chance of success. However, cataracts do not go away without surgery, and will get worse with time.

It is possible to remove the cataract and not insert an IOL. In this situation, strong glasses or a contact lens are usually required to focus. If glasses are used, the lenses may be very thick, and can cause distorted or double vision or visual imbalance. Contact lenses may not be tolerated by some individuals, and may be difficult to handle, insert, and remove. Because of these problems, an IOL is recommended for almost all cataract surgery patients today.

6. CORRECTION OF PRESBYOPIA

Most people develop a condition called **presbyopia** around age 40. Presbyopia is the loss of the eye's ability to change focus from distance to near, resulting in the need for reading glasses or bifocals. The standard lens implants used to replace the cataract in surgery have just one focus, so even if glasses are not needed for distance after surgery, correction will still be necessary for close vision. After cataract surgery, close vision can be corrected by:

- **Reading Glasses or Bifocals:** This is the standard approach chosen by most patients in the past.

- **Leave Both Eyes Nearsighted:** This is a good option for patients who are used to being nearsighted and for whom close vision is most important. A prescription will be needed for distance vision, and a weaker or minimal prescription needed for close vision. If you are accustomed to reading without glasses and using them for distance and wish to do so after surgery, be sure to discuss this with your surgeon.

- **Leave One Eye Nearsighted ("Monovision" or "Blended Vision"):** Some patients prefer to have one eye focused for close and one for distance. This allows them to do many things without glasses. Depth perception at distance may be compromised, but for patients who go back and forth from distance to close and don't want to wear glasses, this is a popular option. This works especially well for patients who have successfully used Monovision with contact lenses in the past. Patients with Monovision often still need glasses for nighttime driving or prolonged reading.

- **Contact Lenses:** Contact lenses are available with bifocals, or can be fitted to produce Monovision with one eye focused for close. Contacts usually provide good vision, but may be difficult to handle for some patients.

- **Refractive Surgery:** Various surgical procedures, such as Conductive Keratoplasty, PRK, and LASIK, can be used to correct close vision by creating nearsightedness in one eye. This is a form of Monovision. These procedures can be performed on one or both eyes after the eye has healed from cataract surgery. Medical insurance generally does not cover Refractive Surgery, so the patient is financially responsible for the cost of these procedures. These costs are not included in the cost of cataract surgery.

- **Multifocal IOLs:** Special IOLs, known as presbyopia-correcting or Multifocal IOLs, can provide both distance and close vision. This is a good option for those who are strongly motivated to minimize their dependence on glasses after cataract surgery. These IOLs typically need to be implanted in both eyes

to work optimally. Multifocal IOLs may compromise the crispness of vision, especially in low light or poor contrast conditions, and some patients may notice halos or glare around lights with these implants. However, patients with Multifocal IOLs are usually less dependent on glasses for distance and close vision than patients with standard IOLs. Many Multifocal IOL patients do not use glasses at all, although this cannot be guaranteed. Extra services are required for use of a Multifocal IOL. Medical insurance generally does not cover the extra costs associated with these "premium" implants, so the patient is financially responsible for the cost difference between Multifocal IOL surgery and standard IOL surgery.

7. BENEFITS AND POSSIBLE LIMITATIONS OF MULTIFOCAL LENS IMPLANTS

- The goal of inserting a presbyopia-correcting IOL after cataract surgery is to restore some or all of the near (and intermediate, depending upon the lens) focusing ability of your eye.
- There is no guarantee that all of the near (and intermediate) focusing ability of the eye will be restored.
- Other factors affect your visual outcome of cataract surgery, including the power of the lens implant, your individual healing ability, and the function of the ciliary muscles and retina in your eyes.
- The selection of the proper lens implant, while based upon sophisticated equipment and computer formulas, is not an exact science. In addition, individual healing factors cannot be predicted with 100% accuracy, so the focus of the eye after surgery is not completely predictable.
- Any residual focusing error after the surgery may need to be corrected with eyeglasses, refractive surgery, or replacement of the lens itself, or an additional intraocular lens implant.
- At the time of surgery, your ophthalmologist may decide not to implant an intraocular lens even though you have given prior permission to do so.
- At the time of surgery, a monofocal lens may need to be placed in your eye instead of a presbyopia-correcting IOL.

Your best option for correcting presbyopia will depend on many factors, including your pre-operative vision, visual preferences, occupational and lifestyle needs, shape and size of the eye, type of cataract, other eye and medical conditions, personality, age, and your tolerance for glasses and contact lenses. Not all patients are good candidates for all options. Your surgeon can help determine the recommended options for your individual case. However, it is important to remember that regardless of the option chosen, it is impossible to guarantee a particular visual result, and your final outcome and need for glasses may differ from the desired goal.

8. WHAT IS ASTIGMATISM? ARE THERE OTHER TREATMENTS FOR IT?

- Patients with nearsightedness and farsightedness often also have astigmatism. Astigmatism is caused by an irregularly shaped cornea; instead of being round like a basketball, the cornea is shaped like a football. This can make your vision blurry. Toric lens implants can be used for correcting high degrees of astigmatism. In addition to toric lens implants, astigmatism can be reduced by glasses, contact lenses, and refractive surgery (LASIK OR PRK). There is also a procedure called a limbal relaxing incision (LRI), which can be done at the same time as the cataract operation, or as a separate procedure. A limbal relaxing incision (LRI) is a small cut or incision in the cornea to make its shape rounder. Any attempt at astigmatism reduction could result in over or under-correction, in which case glasses, contact lenses, or another procedure may be needed.

9. 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), laser and/or, 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. Other tests such as Endothelial Cell Counts and OCT evaluation of the retina help to plan the surgery. Not all tests are covered by insurance.

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 adjustment is usually possible.

10. THE PROCEDURE AND POST-OPERATIVE CARE

Surgery: Surgery is typically performed as an outpatient, using eye drops and/or ointments for anesthesia. In the majority of cases, injections or stitches are not needed, depending on how your eye responds before and during surgery.

Post-Operative Care: You will be given instructions on post-operative care. You will also be given a schedule for follow-up appointments. If you are unclear about any instructions, please ask. In most cases you will be able to resume most normal activities immediately, but should keep the eye clean and dry and avoid bumping or pushing on the eye during the initial healing. Time off work will vary, depending on your job duties and speed of visual recovery. Some blurriness during healing is normal. Glasses, if needed, can be prescribed any time after surgery, but this is usually not done for 2-3 weeks.

YAG Laser Capsulotomy: After cataract surgery, it is very common to eventually develop some haze behind the IOL. This forms a film that can make the vision worsen again, much like when the cataract was present. This can happen a few months, or many years, after cataract surgery. When this interferes with vision, it can be cleared with a YAG laser. This procedure, called a YAG Laser Capsulotomy, is usually done in the office, takes just a few minutes, is painless, and usually restores the vision to the way it was initially after cataract surgery.

11. ADDITIONAL RISK RELATED TO INDIVIDUAL EYE CHARACTERISTICS

If my ophthalmologist has informed me that if I have a high degree of hyperopic (farsightedness) and/or that the axial length of my eye is short, I am at increases risk for a rare complication known as nanophthalmic choroidal effusion. This complication could result in difficulties completing the surgery and implanting a lens, or other problems.

If my ophthalmologist has informed me that if I have a high degree of myopia (nearsightedness) and/or that the axial length of my eye is long, I am at increased risk for a retinal detachment, whether or not I have surgery. Retinal detachments can lead to vision loss or blindness. Recent studies indicate that this risk is not increased by surgery though an older study using different techniques did find an increased risk.

12. FINANCIAL IMPLICATIONS OF A PRESBYOPIA-CORRECTING IOL

My ophthalmologist has informed me that Insurance covers only the cost of a standard monofocal intraocular lens implant. For cataract surgery, if I choose the presbyopia-correcting IOL, the device and associated services for fitting the lens are **NOT** covered. I acknowledge that I am responsible for payment of

that portion of the charge for the presbyopia-correcting IOL and associated services that exceed the charge for insertion of a conventional IOL following cataract surgery. I have asked for and been informed about the coverage, deductible, and co-payment amounts.

13. PATIENT CONSENT

I have reviewed all six (6) pages of this Informed Consent. The cataract and/or lens implant surgery has been explained to me in terms that I understand. I have been informed about the possible benefits, risks, and contraindications associated with the surgery. I understand that it is impossible for my doctor to inform me of every conceivable complication that may occur, and that there may be unforeseen risks. I have been given the opportunity to ask questions and have received satisfactory answers to my questions. I understand that no guarantee of a particular outcome has been given, and that my vision could become better or worse following surgery.

I authorize the physicians and other health care personnel involved in performing my cataract surgery and pre- and post-operative care to share with one another any information relating to my health, my vision, or my surgery that they deem relevant to providing me with care. I give my permission for Dr. Jon-Marc Weston to use my photograph for display or promotion.

Initial below if you wish to proceed with surgery:

_____ I wish to have cataract extraction and / or lens implant surgery on my right eye / left eye.

_____ I wish to have cataract extraction and / or lens implant surgery and endoscopic laser for treatment of glaucoma on my right eye / left eye.

_____ Other _____.

Initial the applicable choices below:

_____ I wish to have a Standard IOL implanted. I understand I will probably need glasses after surgery.

_____ I wish to have a Premium IOL implanted. I understand that I will probably have less need for glasses after surgery, but this cannot be guaranteed.

_____ I wish to have a Toric monofocal IOL implanted. I understand I will probably need glasses after surgery, especially for near activities.

_____ I wish to have Limbal Relaxing Incision for Astigmatism Reduction. I understand I will probably need glasses after surgery, especially for near activities.

Patient Name/Legal Representative	Patient Signature/Legal Representative	Date
Witness Name	Witness Signature	Date
Jon-Marc Weston, M.D.	Physician Signature	Date