

# LENS IMPLANT – INFORMED CONSENT

(WITH OR WITHOUT A CATARACT)

## PROCEDURE OVERVIEW

At birth, your natural lens is clear. However, as you age, the lens may begin to gradually become cloudy. This condition is called a cataract, and is usually a result of the natural aging process. As the lens becomes cloudier, your vision becomes slowly more blurred, sometimes so slowly that you are unaware how much it is affecting your vision. A cataract can progress until eventually there is a complete loss of vision in your eye. Surgery is the only way a cataract can be removed. You should consider surgery when cataracts cause enough loss of vision to interfere with your daily activities. If you wait until the cataract has reached a very advanced stage, the risk of complications with surgery increases and may reduce the success of restoring vision.

In addition, the lens in your eye hardens as you age, reducing your ability to focus clearly on objects up close. This condition is called presbyopia, and is the result of the natural aging process. Presbyopia can be corrected through spectacle wear, contact lens wear or lens replacement.

## THE PURPOSE OF YOUR OPERATION IS:

- to remove the cataract (cloudy lens) from your eye and replace it with an intraocular lens implant to improve your vision.
- to remove the crystalline lens (clear lens) from your eye and replace it with an intraocular lens implant to improve your vision.

This procedure, like all surgery, presents some risks, many of which are listed on the following page. You should also understand that 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; should this happen in your case, the result might be affected even to the extent of making your vision worse.

## 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 with glasses. Presbyopic individuals require bifocals or separate 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) IOL implanted for distance vision and wear separate reading glasses. There is no guarantee that a single focus IOL will allow you to be spectacle-free for distance vision as other factors such as astigmatism may require you to wear glasses at all times.

**MONOVISION:** You can choose to have your surgeon implant monofocal (single focus) IOLs of different powers so that one eye functions primarily for distance and one eye functions primarily for near vision.

**MULTIFOCAL or ACCOMMODATING IOL:** You can choose to have your surgeon implant multifocal (multiple focus) or accommodating IOLs, to provide distance vision and some or all of the near vision focusing ability of the eye. The PanOptix®, TECNIS®, Symphony®, ReSTOR®, Crystalens® and Trulign™ IOLs have been approved by the FDA for adult patients in whom a cataractous lens has been removed and are intended to provide near, intermediate and distance vision with reduced spectacle dependence. If you do not yet have a visually significant cataract, the implantation of any of these lenses in your eye may be off-label from current FDA approvals and will be discussed with you by your doctor.

## ALTERNATIVES TO CATARACT REMOVAL AND LENS IMPLANTATION

Cataract surgery, by itself, means the removal of the natural lens of the eye by a surgical technique. There is no known alternative treatment, other than no surgery at all. In order for an intraocular lens to be implanted in your eye, you must have the crystalline lens removed first.

After lens removal, there are three methods of restoring useful vision after the operation.

1. **Spectacles (glasses):** Cataract spectacles are usually thicker and heavier than regular eyeglasses. Cataract spectacles increase the size of objects by about 25%.
2. **Contact Lenses:** A hard or soft contact lens increases the size of objects about 8%. Handling of a contact lens can be difficult for some individuals. Most lenses must be inserted and removed daily and not everyone can tolerate them.
3. **Intraocular Lenses (IOL):** A small plastic, silicone, hydrogel or acrylate artificial lens with supports is surgically and permanently placed inside your eye. The intraocular lens appears to show no change in the size of objects you see. Greater than 99% of all lens replacement patients choose this method of visual rehabilitation following lens extraction.

Dr. Harvey, in consultation with you, will choose the best IOL for you. It is intended that the implant remain in your eye permanently. The result of the surgery cannot be guaranteed. At the time of the surgery, Dr. Harvey may decide not to implant an intraocular lens in your eye due to surgical findings, even though you may have given prior permission to do so, or may need to implant a different type of IOL than was originally planned.

## ANESTHESIA, THE LENS PROCEDURE AND POST-OPERATIVE CARE

A nurse will make your eye numb with drops. You will undergo light sedation. This will make you very comfortable for your procedure. A small incision is then made in the eye, which generally is self-sealing but may occasionally require a very fine suture. The lens is then gently dissolved into small pieces with a small ultrasound instrument. These pieces are gently aspirated out of the eye and the new IOL (intraocular lens) you have chosen is placed in the eye.

After your surgery, your eye will be examined within the next 48 hours, and approximately a few weeks after, then at three to six months post-surgery. It is necessary that you have an eye health exam performed each year following your surgery. Sight-threatening eye conditions, not related to your lens surgery, may appear at a point later in life. It is your responsibility, and vital to your overall eye health, to have this exam annually.

## RISKS AND SIDE EFFECTS

Lens replacement surgery, with or without a cataract, will not correct other causes of decreased vision such as glaucoma, diabetes or age-related macular degeneration. Lens surgery is usually quite comfortable. Mild discomfort for the first 24-hours is typical, but severe pain is extremely unusual and should be reported immediately to your surgeon.

Complications of cataract surgery may include but are not limited to: hemorrhage (bleeding), rupture of the capsule that supports the intraocular lens, eye infection, swelling in the central area of the retina, swelling and clouding of the cornea, detachment of the retina, increased astigmatism, inaccuracy of the intraocular lens power, decentration of the intraocular lens, which may provide unwanted images and increased glare, and development of increased pressure in the eye (glaucoma). Some or all of these complications can occur, however, their incidence following cataract surgery is exceptionally low. Additional surgery may be required to treat these complications.

Other factors may induce complications during cataract surgery including medications that you are taking. Medications that can have such an effect include, but are not limited to, Flomax or other prostate medicines, blood thinners such as aspirin or coumadin, and some vitamins or supplements, such as Vitamin E. In order to take the appropriate precautions during your procedure, it is important that prior to surgery you inform your surgeon

of ALL medications and supplements you are currently, or have recently, used.

It is important to understand that you may not get a full correction from the lens procedure and this may require future enhancement procedures, alternative refractive procedures, or the use of glasses or contact lenses. If necessary, these will be reviewed and discussed with you by your surgeon.

### **NON-VISION THREATENING SIDE EFFECTS**

1. I understand enhancement procedures can be performed when vision is stable UNLESS it is unwise or unsafe. An assessment will be held with my doctor, at which time the benefits and risks will be discussed.
2. I understand that the correction that I can expect to gain from lens surgery may not be perfect and it is not realistic to expect that this procedure will result in perfect vision, at all times, under all circumstances, for the rest of my life.
3. **I understand that I may need glasses to refine my vision for some purposes requiring fine detailed vision at some point in my life, and that this might occur soon after surgery or years later.**
4. **I understand that as the eye heals, the IOL can shift very slightly toward the front or back of the eye. This shift is not the same in everyone, and may cause different vision than predicted.**
5. I understand that if I am highly nearsighted, highly farsighted or have had LASIK or other forms of vision correction surgery, I have the greatest risk of difference between planned and actual outcome. It is usually possible to correct this situation, which my doctor has explained to me may involve an enhancement procedure at a future date.
6. I understand that I may experience problems with glare, halos and/or visual crescents due to the optics of the intraocular implants. These might occur soon after surgery and may resolve over time, or may be permanent.
7. I understand if I choose a monofocal implant that reading glasses or contact lenses will be necessary for near vision tasks.
8. I understand if I choose monovision with monofocal implants that I may experience problems with impaired depth perception that may or may not resolve over time without further enhancement procedures.
9. I understand if I choose a multifocal or accommodating lens implant to reduce my overall dependency on glasses, that I may experience some loss of sharpness in vision, which may become worse in dim light or fog.
10. I understand that there may be pain, scratchiness, a foreign body sensation, or slight dryness in my eye, particularly during the first 48 hours after surgery, which will be alleviated with medications provided by my doctor.
11. I understand that there is a natural tendency of the eyelids to droop with age and that eye surgery may hasten this process.
12. I understand that I may be given medication in conjunction with the procedure. I agree to arrange for a driver following my procedure and that I must not drive until I am certain that my vision is adequate for driving.
13. I understand that between the time I have surgery on my first and second eye, I may experience a period of imbalance between the two eyes (anisometropia). This can usually only be corrected with a temporary contact lens in the non-operated eye, or clear functionality in the operated eye until the second procedure is performed.

- 14. 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.
- 15. 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 be incomplete.

**PATIENT’S STATEMENT OF ACCEPTANCE AND UNDERSTANDING**

I have read and understand the information on this form. The specifics in this document have been presented to me in detail and explained to me by Dr. Harvey. My doctor has answered all of my questions to my satisfaction. By signing this Consent, I am stating that I have read this form, and I understand the risks, benefits and alternatives as explained by my physician.

I authorize and direct Dr. Harvey to perform the surgical procedure(s) described in this consent, including any additional medical or surgical procedures or services that they deem necessary or reasonable, including, but not limited to, the administration of drugs; topical, regional or general anesthesia. I understand that my surgeon, along with my referring optometrist or ophthalmologist, use a team approach to my care. I authorize any of these doctors, at the discretion of my surgeon, to participate in my pre-operative and post-operative care. I understand that the surgeon indicated above exclusively will perform my actual lens surgery.

**There is no guarantee that cataract surgery, astigmatism reduction, or presbyopia correction will improve your vision. There is no guarantee that you will be free of glasses after cataract surgery. As a result of the surgery and/or anesthesia, it is possible that your vision could be made worse. By signing this form, you agree that charges incurred for cataract surgery and lens implantation are for surgery performed, and are not to be construed as a guarantee of vision results.**

The procedure of lens extraction with intraocular lens implantation, the advantages and disadvantages, risks and possible complications of the surgery and alternative treatments have been explained to me. Although it is impossible for my doctor to inform me of every possible complication that may occur, my doctor has answered all my questions to my satisfaction. I understand that the implanting of this intraocular lens in my eye will require periodic visits by me to an eye doctor for at least one month post-operatively to evaluate the results of my operation.

I give permission for my doctor to record on video or photographically my procedure, for the purpose of education, research or training of other health care professionals. I give permission to my doctor to use data about my procedure and subsequent treatment as deemed necessary by him. I understand that my name will remain confidential, unless I give subsequent written permission for it to be disclosed outside my doctor’s office or the center where my lens procedure will be performed.

- I am making an informed decision in giving my permission to have CATARACT REMOVAL AND LENS IMPLANTATION SURGERY performed on my \_\_\_\_\_ RIGHT eye \_\_\_\_\_ LEFT eye.
- I am making an informed decision in giving my permission to have CLEAR LENS REMOVAL AND LENS IMPLANTATION SURGERY performed on my \_\_\_\_\_ RIGHT eye \_\_\_\_\_ LEFT eye. I understand that this treatment is off-label from current FDA guidelines.
- I am unable to read but this consent form has been read and explained to me by \_\_\_\_\_. I understand the information presented above and willingly sign this Consent Form.

Patient Signature \_\_\_\_\_ Date \_\_\_\_\_ Witness \_\_\_\_\_  
 Surgeon Signature \_\_\_\_\_ Date \_\_\_\_\_