

# TAILORED EYES

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## **INFORMED CONSENT FOR PHAKIC IMPLANT SURGERY WITH VISIAN ICL**

### **INTRODUCTION**

This information is provided to help you make an informed decision about having eye surgery to reduce or eliminate your nearsightedness. Only you and your ophthalmologist can determine if you should have phakic implant surgery based upon your own visual needs and medical considerations. Take as much time as you wish to make your decision before signing this consent form. You have the right and are encouraged to ask your doctor questions about this procedure before agreeing to have it.

The Visian ICL (Implantable Collamer Lens) is a lens that is permanently implanted in the eye behind the iris and in front of the natural lens. It is called a phakic intraocular lens (IOL) because the eye still has its natural lens. The Visian ICL has been approved by the Food and Drug Administration (FDA) for the treatment of patients with moderate to severe nearsightedness (myopia). Myopia, the clinical term for nearsightedness, is a condition that causes light rays to focus in front of the retina, causing distant objects to look blurry or distorted. It can be caused by an eyeball that is too long for its optical power or by curvature of the cornea or lens that is too high for the actual length of the eyeball. The amount of myopia is measured in “diopters,” a technical term used to describe the power of a lens. The Visian ICL is approved for treatment of myopia between the ranges of -3 diopters to -20 diopters, with up to 2.5 diopters of astigmatism. There is also a Toric version of the ICL lens approved for -3 to -20 diopters with astigmatism correction ranging from 1 to 4 diopters.

Phakic implant surgery is an elective procedure: there is no emergency condition or other reason that requires or demands that you have it performed. You could continue wearing contact lenses or glasses and have adequate visual acuity. This procedure, like all surgery, presents some risks, many of which are listed below. 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, your vision could be affected, and might even be worse than before surgery.

### **ALTERNATIVES TO PHAKIC IMPLANT SURGERY**

You are under no obligation to have phakic implant surgery. If you decide not to have phakic implant surgery, there are other methods of correcting your nearsightedness:

#### **Non-Surgical Alternatives**

Contact lenses or glasses are non-surgical, extremely accurate, permit easy changes in prescription, and also allow the eye to retain focusing power for near vision. Although there are essentially no risks to wearing glasses, the quality of vision produced by high powered glasses is poor because the thick lenses can make images appear very small (minification) and they decrease peripheral vision. While contact lenses provide higher quality vision than glasses, they have an increased risk of complications, especially if they are worn overnight. The risks of contact lenses include infection, allergies, irritation, limbal stem cell failure, discomfort, and eye pain.

### **Surgical Alternatives, Including Laser**

There are several other procedures for the correction of moderate to high myopia. Unlike phakic implant surgery, PRK and LASIK reshape the cornea and do not require an incision into the inside of the eye. Generally, the higher the amount of treatment needed for PRK and LASIK, the lower the quality of vision after surgery. Photorefractive Keratectomy (PRK) uses an excimer laser to reshape the cornea to focus light rays on the retina. PRK may be used to correct myopia generally from -1 D to -12 D. LASIK is a two-phase operation. First, a thin flap of cornea is cut with a microkeratome or a laser. The flap is lifted back and the exposed surface of the cornea is reshaped with an excimer laser. The flap is then returned to its original position. PRK and LASIK have been very successful and safe for the correction of myopia up to -12 D. Above 12 diopters, LASIK and PRK produce lower quality of vision, especially at night, and have proven to be less accurate than when treating lower levels of nearsightedness. Refractive Lens Exchange (RLE) is an intraocular procedure in which the natural lens is removed and replaced with a lens implant of a more optimal power. Patients may request an advanced technology or multifocal lens that corrects for a range of vision including near and distance vision. Highly nearsighted patients may have an increased risk of retinal detachment at some point after RLE, so this procedure is most appropriate for patients who are not extremely nearsighted.

### **Contact Lenses**

If you wear contact lenses, you will be required to leave them out of the eyes for a period of time prior to having your preoperative eye examination and before your surgery. Contact lenses can distort the cornea which can impact the accuracy the measurements of the power of surgical correction needed. To help the corneal return to its natural state, soft contact lens wearers should leave lenses out of the eyes for 1 week. Toric soft lenses should be out for 2 weeks. Rigid (including gas permeable, hybrid, and scleral hard lenses) contact lens wearers should leave lenses out of the eyes for at least 4 weeks. Rigid contact lens wearers usually experience fluctuating vision once their lenses have been discontinued due to changes in the shape of the cornea.

### **Procedure**

The surgeon will make two small holes inside the eye in the colored portion of your eye (the iris) to help ensure that eye pressure does not build up behind the phakic lens; this procedure is called a laser iridotomy. The iridotomy is usually done a few days to weeks before your phakic implant surgery by using a YAG laser in the office.

ICL surgery is done under sterile technique in the operating room similar to other intraocular eye surgeries. The eye will be numbed with topical anesthetic drops and you may elect to receive

light sedation to help relax you. You will need to lie on your back for a few minutes during the procedure. ICL surgery is generally not painful (expect to feel cold water and pressure at times) and you should expect to be awake during the surgery.

The surgical steps include making incisions in your cornea and inserting the Visian ICL behind the iris and in front of your natural lens. The incision required to perform ICL surgery is usually self-sealing though rarely it can require sutures to close. A temporary shield may be placed over the eye to protect it during the immediate postoperative period.

### **BENEFITS OF PHAKIC IMPLANT SURGERY**

If you have moderate to high myopia, phakic implant surgery may improve your natural distance vision without the use of glasses or contacts.

### **LIMITATIONS OF PHAKIC IMPLANT SURGERY**

This procedure does not treat presbyopia, a condition in which the eye loses its ability to focus on both near and distance objects. Even with a successful surgery (corrected distance vision) you may require glasses for near vision. Patients age 40 and older are more likely at risk for presbyopia (difficulty reading/seeing up close) after ICL surgery. The results of this surgery cannot be guaranteed, and glasses may still be required for sharpest vision for distance, for night driving or other activities performed in low light, for reading, or for all of these activities. With increasing age, patients are likely to develop cataracts. If the cataracts are significant enough to cause visual problems, the phakic implant may need to be removed so that the eye can undergo cataract removal with likely intraocular lens implant.

### **PATIENT RESPONSIBILITY FOR COSTS**

Health insurance generally does not pay for elective phakic implant surgery for the purpose of correcting natural vision. Therefore, the patient is responsible for the cost of the surgery, including the surgeon's fee, anesthesiologist's fee, (if any), and the surgical center's or hospital's fee. In the event of a complication, it may be possible that other surgery, eye drops, or even hospitalization may be required. Some or even all of these costs may be covered by health insurance. The patient is responsible for the costs of any uncovered surgery-related injuries.

### **RISKS OF PHAKIC IMPLANT WITH ICL SURGERY**

The goal of ICL surgery is to correct or improve your blurry vision caused by myopia (nearsightedness) and reduce your dependency upon glasses or contact lenses. ICL surgery is usually quite comfortable. Mild discomfort for the first 24 hours is typical, but severe pain would be unusual and should be reported immediately to your surgeon.

#### **Other risks of ICL surgery include, but are not limited to:**

Hemorrhage (bleeding), infection, damage to the structures in or around the eye, perforation of the eye; cataract formation, corneal edema (corneal swelling or haze), cystoid macular edema (retinal swelling), retinal tear or detachment, eye irritation or pain, droopy eyelid, increased astigmatism, glaucoma or high eye pressure, visual distortions such as glare or halos, double vision. Additional surgery may be required.

There are additional risks for ICL surgery including the risks of the YAG laser iridotomy. A YAG laser iridotomy can cause double vision, glare, halos, other visual disturbances, inflammation inside the eye, bleeding or scarring inside the eye, and temporary rise in eye pressure. These risks are reviewed in more detail in the YAG laser iridotomy consent form.

## **REVIEW AND ACCEPTANCE OF VISION THREATENING COMPLICATIONS**

1. I understand that mild or severe infection is possible. Mild infection can usually be treated with antibiotics and usually does not lead to permanent visual loss. Severe infection, even if treated with antibiotics, could lead to permanent scarring and loss of vision, corneal transplantation, blindness, or even loss of the eye.
3. I understand that I could experience damage to the iris (the colored portion of the eye) or develop a rise in the pressure in the front of my eye (secondary glaucoma). I may require another iridotomy or eye drops to control the pressure if this occurs.
4. I understand that I could develop a retinal detachment, a separation of the retina from the inside wall of the eye, which usually results from a tear in the retina and could lead to vision loss. Patients with moderate to high levels of nearsightedness have a higher risk of retinal detachment when compared to the general population. This risk level may be increased with implantation of the phakic IOL.
5. I understand that I may develop a cataract, or a clouding of the eye's natural lens, which impairs normal vision, and may require removal of the lens, the phakic implant, and insertion of a different type of lens implant. Patients with high levels of nearsightedness are at higher risk for cataract development, and that risk may be increased with ICL surgery.
6. I understand that I may develop corneal swelling (edema) and/or ongoing loss of cells lining the inner surface of my cornea (endothelial cells). These cells play a role in keeping the cornea healthy and clear. Corneal edema and loss of endothelial cells may result in a hazy and opaque appearance of the cornea, which could reduce vision. It is not yet known how much endothelial cell loss will occur and what effect the cell loss and phakic implant will have on the long-term health of the cornea. If too many cells are lost over time, I may need a corneal transplant.
7. I understand that I may develop glaucoma, which is an increase in the pressure of the eye caused by slowed fluid drainage. Glaucoma can lead to vision loss, and may require treatment with long-term medications or surgery. Patients with high levels of nearsightedness are at an increased risk for the development of glaucoma, and that risk may be increased after ICL surgery. The effect of the Visian ICL Phakic IOL on the future risk of glaucoma is not known.
8. I understand that other complications could threaten my vision, including, but not limited to, iritis or inflammation of the iris (immediate and persistent), uveitis, bleeding, swelling in the retina (macular edema), and other visual complications. Though rare, certain complications may result in total loss of vision or even loss of the eye. Complications may develop days, weeks, months, or even years later.
9. I understand this surgery takes place inside the eye so it shares similar risks to other intraocular surgery, such as cataract surgery. As a result of the surgery, it is possible that my

vision could be made worse. I also understand that 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 from ICL surgery is exceptionally low.

## **REVIEW AND ACCEPTANCE OF OTHER RISKS**

1. I understand that I may be given sedation in conjunction with the procedure and that my eye may be patched afterward. I have been advised not to drive immediately after receiving sedation and for a period of eight hours thereafter. I understand that my life and health and the life of others will be at risk if I drive during this period. This is because I may be impaired by the sedative. I also understand that driving while impaired may violate traffic laws.
2. I understand that after ICL surgery there may be increased sensitivity to light, night glare, “starbursting,” or halo effect around lights. The risk of this side effect may be related to the size of my pupil, and larger pupils may put me at increased risk.
3. I understand that an over-correction or under-correction of my vision could occur, causing me to become farsighted, remain nearsighted, or increase my astigmatism. I understand that this could be permanent and/or treatable with glasses, contact lenses, or additional surgery.
4. I understand that the phakic lens may need to be repositioned, removed surgically, or exchanged for another lens implant. The lens may change position (decentration), or I may require a different size or power of lens than that of the implanted lens. In rare instances, lens power measurements may significantly vary, resulting in the need for corrective lenses or surgical replacement of the phakic lens. Potential complications of additional surgery include all of the complications possible from the original surgery.
5. I understand that there may be a difference in vision between my two eyes after the phakic implant surgery if it has been performed on one eye but not the other. This imbalance is called anisometropia. I understand this would cause eyestrain and make judging distance or depth perception more difficult. Because of the marked difference in the prescriptions, vision correction using glasses most likely would not be comfortable or provide good vision. In order to have balanced vision in both eyes, I may need to wear a contact lens in the eye without the phakic implant or consider a phakic implant or another type of surgery for that eye.
6. I understand that, after phakic implant surgery, the eye may be more fragile to trauma from impact. Evidence has shown that, as with any scar, a corneal incision will not be as strong as the cornea originally was at that site. I understand that the treated eye, therefore, is somewhat more vulnerable to all varieties of injuries, at least for the first year following phakic implant surgery. I understand it would be advisable for me to wear protective eyewear when engaging in sports or other activities in which the possibility of a ball, projectile, elbow, fist, or other traumatizing object contacting the eye may be high.
7. I understand that there is a natural tendency of the eyelids to droop with age and that any eye surgery may hasten this process.
8. I understand that there may be pain or a foreign body sensation, particularly during the first 48 hours after surgery.
9. I understand that the long-term effects of phakic implant surgery are unknown and that unforeseen complications or side effects could possibly occur.

10. I understand that the correction that I can expect to gain from phakic implant surgery may not be perfect. I understand that 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. I understand I may need glasses to refine my vision for some purposes requiring fine detailed vision after some point in my life, and that this might occur soon after surgery or years later.
11. I understand that if I currently need reading glasses, I will still likely need reading glasses after this treatment. It is possible that dependence on reading glasses may increase or that reading glasses may be required at an earlier age if I have this surgery.
12. 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. 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 is not complete.

### **PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING**

I acknowledge that I understand the following: I have received no guarantee as to the success of my particular case and I understand that I may still need glasses, contact lenses, or a laser procedure such as LASIK for further improvement of my vision. I understand that during the surgical procedure, the doctor may decide not to implant the lens even though I have given permission to do so.

The details of phakic implant surgery have been presented to me in detail and 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, my ophthalmologist has answered all my questions to my satisfaction. In signing this informed consent for phakic implant surgery, I am stating that I have read this informed consent (or it has been read to me), fully understand the possible risks, complications, and benefits that can result from the surgery and the alternatives available to me, and hereby give my consent to have phakic implant surgery performed on my:

LEFT EYE       RIGHT EYE       BOTH EYES

My personal reason(s) for choosing to have phakic implant surgery are as follows:

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I give permission for my ophthalmologist to record on video or photographic equipment my procedure, for purposes of education, research, or training of other health care professionals. I also give my permission for my ophthalmologist to use data about my procedure and subsequent treatment to further understand phakic implant surgery. I understand that my name will remain confidential, unless I give subsequent written permission for it to be disclosed outside my ophthalmologist's office or the center where my phakic implant surgery will be performed.

\_\_\_\_\_ (Initial) I have been offered a copy of this consent form.

\_\_\_\_\_  
Patient Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness Name

\_\_\_\_\_  
Date

**ADDENDUM FOR BILATERAL SAME DAY PHAKIC IMPLANT SURGERY**

*This addendum is to be used in conjunction with the consent form “Informed Consent for Phakic Implant Surgery”. Do not sign this addendum without first reading and signing “Informed Consent for Phakic Implant Surgery.”*

**Discussion:**

My doctor has determined that I am a candidate to have phakic implant surgeries in both eyes. If I choose to have bilateral same day phakic implant surgeries, my doctor has discussed certain steps he will take to reduce the risk of complications, especially infection, in each eye.

**Benefits:**

Having both phakic implant surgeries done on the same day reduces the risks for me of having anesthesia twice and the inconvenience and problems associated with anisometropia which can make it hard to see well between surgeries scheduled days or weeks apart.

**Risks:**

Having both phakic implant surgeries done on the same day may increase the consequences of having vision-threatening complications such as infection, swollen corneas, swollen retinas, retinal detachment. Instead of vision impairment or loss in one eye, it could lead to loss of vision or even blindness in both eyes. In addition, the planned visual outcome may not be as precise since my doctor won't have the advantage of knowing the final vision results from the first eye phakic implant surgery, and altering the surgical approach or IOL power accordingly.

My personal reason(s) for choosing to have bilateral same day phakic implant surgeries are as follows:

- Greater convenience
- Possible faster recovery
- Less time away from work
- Contact lens intolerance and/or difficulty wearing contacts
- Elimination of possible vision imbalance between treated and untreated eyes
- Other: \_\_\_\_\_

By signing below, I am indicating my willingness to accept the possible increased risk of eye complications of bilateral phakic implant surgery.

\_\_\_\_\_  
Patient Name

\_\_\_\_\_  
Date

By signing below, I am confirming that I have discussed with the patient the risks and benefits surrounding bilateral same day phakic implant surgery.

\_\_\_\_\_  
Physician Name

\_\_\_\_\_  
Date