

## ICL PHAKIC IOL - INFORMED CONSENT

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

The Visian™ phakic implantable collamer lens (IOL) has been approved by the Food and Drug Administration (FDA) for the treatment of patients with moderate to high myopia between the ranges of -3 diopters to -20 diopters, with up to 2.5 diopters of astigmatism. Surgical implantation of a phakic intraocular lens (phakic implant surgery) is one of a number of alternatives for correcting nearsightedness.

In phakic implant surgery, an artificial lens (such as the Visian™ phakic implantable collamer lens (ICL)) is surgically placed inside your eye. The lens is made from material similar to the type used for intraocular lenses currently being implanted in the eye to correct vision after cataract surgery. The difference between phakic implant surgery and other intraocular lens implants is that your natural lens is not removed during phakic implant surgery. The phakic lens is inserted in addition to your natural lens.

### PROCEDURE

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. This is done because the contact lens rests on the cornea, distorting its shape, and this distortion will have an effect on the accuracy of the doctor’s measurements of the power of surgical correction needed. Discontinuing contact lens use allows the corneas to return to their natural shape. Soft contact lens wearers should leave lenses out of the eyes for at least one week. Rigid (including gas permeable and standard hard lenses) contact lens wearers should leave lenses out of the eyes for at least three weeks. Rigid contact lens wearers usually experience fluctuating vision once their lenses have been discontinued due to changes in the shape of the cornea. Although the cornea usually returns to its natural state within three weeks, this process may take longer, and you will need to remain contact lens free until stabilization is complete.

The surgeon will make two small holes in the colored portion of your eye (the iris) to help ensure that intraocular fluid does not build up behind the phakic lens; this procedure is called an iridotomy. It will take place before the placement of the phakic implant by using a laser (YAG-laser iridotomy). Before phakic implant surgery begins, you will be given an anesthetic to minimize your pain during surgery. You may undergo light sedation administered by an anesthesiologist or nurse anesthetist while your eye is made numb by your surgeon with either drops or an injection (local anesthesia).

After your pupil has been dilated, and your eye has been anesthetized, the surgeon will make a small incision in your cornea to allow insertion of the lens. The Visian™ phakic ICL is inserted behind your iris and in front of the natural (crystalline) lens. The incision required to perform this operation is at times self-sealing but it may require closure with very fine stitches (sutures) which will gradually dissolve over time or may require removal later in the office. A temporary shield may be placed over the eye to protect it during the immediate postoperative period.

You will return to your eye doctor the next day for an examination. The shield will be removed and your eye will be observed under a slit lamp biomicroscope to make sure the lens is positioned correctly and that there are no

complications. You will return for additional postoperative exams as instructed by your ophthalmologist. Although you may see some improvement in your vision as early as the first postoperative day, the visual effects of phakic implant surgery may take several weeks to stabilize. Patients are generally able to return to their normal activities within 2 or 3 days following phakic implant surgery.

## **ALTERNATIVES**

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, the result might be affected even to the extent of making your vision worse.

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 include wearing glasses or contact lenses. Although there are essentially no risks to wearing glasses, the quality of vision with strong nearsighted glasses is not normal because of the smaller appearance of images (“minification”) and slight decrease in peripheral vision caused by the thickness of the lenses. While contact lenses provide higher quality and more normal vision, they have a slight risk of complications, especially if they are worn overnight. The risks of contact lenses include infection, allergies, irritation, and discomfort.

There are several other procedures for the correction of moderate to high myopia. PRK and LASIK do not require an incision into the inside of the eye as does phakic implant surgery. Photorefractive Keratectomy (PRK) uses an excimer laser to reshape the cornea to refocus light rays on the cornea. PRK may be used to correct low to higher amounts of myopia (generally -1 D to -12 D). Alternatively, LASIK is an operation which combines the creation of a flap using a device called a microkeratome and the removal of tissue with the excimer laser. During LASIK, a thin layer of cornea is surgically cut with the microkeratome, the exposed surface of the cornea is reshaped with the laser, and the flap is returned to its original position. LASIK has been found to be quite successful and relatively safe for the correction of moderate and high myopia up to -12 D. Above 12 diopters, LASIK is known to have a high incidence of complications involving the quality of vision, especially at night, and has proven to be less accurate than it is with the treatment of lower levels of nearsightedness. For these reasons, many surgeons have stopped performing LASIK for extremely nearsighted eyes.

Alternatively, Refractive Lens Exchange (RLE) is an intraocular procedure in which the natural lens is removed and replaced with a synthetic lens of a more accurate power. Patients age 40 or over may request an “accommodating” lens that also helps improve near vision for reading. Because of the increased risk of retinal detachment, refractive lens exchange is most appropriate for patients who are extremely nearsighted (-10 D and above). Other Refractive Surgery Procedures include keratomileusis, corneal inlays, and radial keratotomy (RK). These procedures are rarely performed, and RK is generally effective only for patients with low to moderate degrees of myopia.

## **LIMITATIONS**

1. This procedure does not treat presbyopia, a condition common in patients age 40 or older in which the eye loses its ability to accommodate, or change power to allow focusing of both near and distant objects. Even with a successful surgery and an accurate intraocular lens calculation targeted to correct the eye’s distance vision, close vision will usually remain blurred for presbyopic patients. Patients age 40 or older are likely to require bifocals or reading glasses to improve their near vision.

2. The phakic lens does not correct astigmatism. Moreover, 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.
3. 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 or without implantation of a suitable artificial intraocular lens.

### **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, 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.

### **COMPLICATIONS OF IRIDOTOMY**

Potential complications of either a YAG-laser iridotomy are very rare but include damage to the natural lens; inflammation inside the eye; temporary increases in the pressure in the front part of the eye; cataract formation; bleeding (usually a small amount but can be a large amount); scar formation between the iris and lens of the eye (synechia) that prevents the pupil from moving correctly; corneal damage; and vision disturbances such as double vision (diplopia), glare, or halos.

### **VISION-THREATENING COMPLICATIONS**

1. In most cases, the surgery will be accomplished with numbing drops, but in some cases the eye surgeon may elect to use an injection around the eye for anesthesia. Very rare complications from injections include damage to the eye muscles, perforation of the eye, and damage to the retina or optic nerve leading to loss of vision.
2. 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 that may require corrective laser surgery or, if very severe, 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 if this occurs or eye drops to control the pressure.
4. I understand that I could develop a retinal detachment, a separation of the retina from its adhesion at the back 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 an artificial lens.
6. Patients with high levels of nearsightedness are at higher risk for cataract development, and that risk may be increased with implantation of the phakic IOL.
7. 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 long the endothelial cell loss will

continue 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.

8. 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 by implantation of the lens. The effect of the Visian™ Phakic ICL on the future risk of glaucoma is not known.
9. 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.

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

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.
2. 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.
3. I understand that there may be increased sensitivity to light or night glare. I also understand that at night there may be a “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.
4. I understand that an overcorrection or undercorrection could occur, causing me to become farsighted, remain nearsighted, or increase my astigmatism and that this could be either permanent or treatable with either glasses, contact lenses, or additional surgery.
5. 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.
6. Potential complications of additional surgery include all of the complications possible from the original surgery.
7. I understand that there may be a difference in vision between my two eyes after the phakic implant surgery 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.
8. 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 another type of surgery for that eye.
9. 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.

10. 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.
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 there may be pain or a foreign body sensation, particularly during the first 48 hours after surgery.
13. I understand that the long-term effects of phakic implant surgery are unknown and that unforeseen complications or side effects could possibly occur.
- 14. I understand that the correction that I can expect to gain from phakic implant surgery may not be perfect.**
- 15. 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.**
- 16. 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.**
17. 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 may not be complete.

#### **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 during the surgical procedure, the doctor may decide not to implant the lens even though I have given permission to do so. 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.

**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 after phakic implant surgery. 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. By signing this form, I agree that charges incurred for ICL Phakic IOL surgery are for surgery performed, and are not to be construed as a guarantee of vision results.**

The procedure of phakic implant surgery, 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 phakic implant surgery 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 ICL PHAKIC IMPLANT SURGERY performed on my**                      **RIGHT eye**                      **LEFT eye**                      **BOTH eyes.**
  
- 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 \_\_\_\_\_