

**Orlando Ophthalmology Surgery Center**  
**Authorization for Surgical Procedure**  
**Insertion of Visian Implantable Collamer Lens**

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

Proposed Procedure: Insertion of Visian Implantable Collamer lens eye(s)

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**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.

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**

**Non-Surgical Alternatives:**

Contact lenses or glasses are non-surgical, extremely accurate, permit easy changes in prescription, and also allow the eye to retain its focusing power for near vision.

1. Spectacles (glasses) 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 Refractive Surgery Center images (“minification”) and the slight decrease in peripheral vision caused by the thickness of the lenses.
2. Contact Lens. 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.

**Surgical Alternatives, Including Laser:** There are several other procedures for the correction of moderate to high myopia. Unlike phakic implant surgery, PRK and LASIK do not require an incision into the inside of the eye.

1. 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).

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2. LASIK is a two-phase operation. First, a thin layer of cornea is either surgically cut with the microkeratome or a flap is created using a laser. Then the exposed surface of the cornea is reshaped with an excimer 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.
3. 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 a multifocal lens that corrects for both near and distance vision. Because of the increased risk of retinal detachment, refractive lens exchange is most appropriate for patients who are extremely nearsighted (-10 D and above).
4. Other Refractive Surgery Procedures include keratomileusis, corneal inlays, and radialkeratotomy (RK). These procedures are rarely performed, and RK is generally effective only for patients with low to moderate degrees of myopia.

### **BENEFITS OF PHAKIC IMPLANT**

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**

1. This procedure does not treat presbyopia, a condition common in patients age 40 or older in which the eye loses its ability to 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. If the amount of astigmatism remaining after ICL implantation is visually significant another procedure may be required (e.g. limbal relaxing incision, PRK/LASIK "touch-up" surgery)
3. 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.
4. 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 an artificial intraocular lens.

### **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, damage to the retina or optic nerve leading to loss of vision and hypotension.
2. 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. Damage to the iris (the colored portion of the eye) may develop causing a rise in the pressure in the front of my eye (secondary glaucoma) and may require another iridotomy or eye drops to control the pressure if this occurs. Retinal detachment, a separation of the retina from the inside wall of the eye, which usually results from a tear in the retina may develop and could lead to vision loss. You 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. Your natural lens could be injured during phakic IOL implantation, causing conversion of the surgical procedure to the removal of your natural lens and implantation of an artificial lens used in cataract patients. Corneal swelling (edema) may develop and/or ongoing loss of cells lining the inner surface of the cornea and 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. Glaucoma, which is an increase in the pressure of the eye caused by slowed fluid drainage, may also develop and can lead to vision loss, and may require treatment with long-term medications or surgery.
4. Other complications could threaten your 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 Complications:**

1. You may be given sedation in conjunction with the procedure and your eye may be patched afterward. Do not 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. You may have increased sensitivity to light or night glare. At night there may also be a “starbursting” or halo effect around lights. Overcorrection or undercorrection could occur, causing you to become farsighted, remain nearsighted, or increase astigmatism. This could be either permanent or treatable with either glasses, contact lenses, or additional surgery. The phakic lens may need to be repositioned, removed surgically, or exchanged for another lens implant. The lens may change position (decentration), or you 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.
3. There may be a difference in vision between your two eyes after the phakic implant surgery has been performed on one eye but not the other. This imbalance is called anisometropia. 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, you 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.
4. 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. The treated eye, therefore, is somewhat more vulnerable to all varieties of injuries, at least for the first

year following phakic implant surgery. It is advisable 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.

5. There is a natural tendency of the eyelids to droop with age and eye surgery may hasten this process. There may be pain or a foreign body sensation, particularly during the first 48 hours after surgery.
6. The long-term effects of phakic implant surgery are unknown and unforeseen complications or side effects could possibly occur.
7. If you currently need reading glasses, you 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 you have this surgery.

**ADDITIONAL UNFORSEEN CONDITIONS OF SURGERY IN GENERAL:**

Just as there are benefits to the procedure(s), I also understand that medical and surgical procedures involve risks. These risks include, but are not limited to allergic reactions, bleeding, blood clots, infections, adverse side effects of drugs, or even loss of bodily function or life as well as the transmission of infectious disease, including hepatitis and Acquired Immune Deficiency Syndrome (AIDS).

**AUTHORIZATIONS**

1. I hereby authorize the above named surgeon and whomever he/she may designate as his/her assistants, to perform upon me (the above named patient) the above specified operation or procedure and if any unforeseen condition arises in the course of the operation, which in the judgment of the attending physician or the surgeon in charge calls for procedure(s) or operation(s) in addition to or different from those now contemplated, I further request and authorize him or her to do whatever he/she deems advisable.
2. I consent to the administration of such anesthetics as indicated in the judgment of the Surgeon in charge of me.
3. If any unforeseen medical condition should arise while I am at the Surgery Center, I hereby authorize treatment including, but not limited to evaluation, consultation and transfer to another level of care.
4. I consent to the administration of medications, and other substances and the use of other procedures deemed appropriate by the physician(s) or surgeon(s) in charge of me in the exercise of his or her judgment.
5. I consent to the examination, use or disposal by my physician or surgeon or an appointed physician or surgeon of the Orlando Ophthalmology Surgery Center, of any organs, tissues, fluids, or parts removed from the body.
6. I consent to the taking and publication of any photographs or videotaping in the course of this operation for medical, scientific or educational purposes. Photographs may include appropriate portions of the body, provided no identity by the pictures or by descriptive text accompany them. Video tapes are property of the physician. Photographs will be incorporated in the medical record.
7. I consent to the admittance of observers in the operating room for the purpose of advancing medical education if requested by my surgeon.

8. I understand that I am responsible for payment to Orlando Ophthalmology Surgery Center for services described above.

I CERTIFY THAT I HAVE READ OR HAVE HAD READ TO ME AND FULLY UNDERSTAND THE ABOVE CONSENT FOR SURGICAL AND/OR DIAGNOSTIC PROCEDURES. THE NATURE AND PURPOSE OF THE OPERATION AND ANESTHESIA, POSSIBLE ALTERNATIVE METHODS OF TREATMENT, THE RISKS INVOLVED, AND THE POSSIBILITY OF COMPLICATIONS LISTED ABOVE HAVE BEEN FULLY EXPLAINED TO ME BY MY PHYSICIAN. I ACKNOWLEDGE THAT NO GUARANTEE OR ASSURANCE HAS BEEN MADE AS TO THE RESULTS THAT MAY BE OBTAINED. ALL BLANKS OR STATEMENTS REQUIRING INSERTION OR COMPLETION WERE FILLED IN AND IN APPLICABLE PARAGRAPHS, IF ANY, WERE STRICKEN BEFORE I SIGNED.

Signature of Patient \_\_\_\_\_ Date \_\_\_\_\_ Time \_\_\_\_\_

When Patient is a minor or incompetent to give consent:

Patient is a minor \_\_\_\_\_ years of age or is unable to sign because \_\_\_\_\_

Signature of person authorized to give consent for Patient: \_\_\_\_\_

Relationship to Patient \_\_\_\_\_ Date \_\_\_\_\_ Time \_\_\_\_\_

WITNESS: \_\_\_\_\_ Date \_\_\_\_\_ Time \_\_\_\_\_

Translator/Interpreter (Print Name, Address and Phone Number) \_\_\_\_\_

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**PHYSICIAN'S AFFIRMATION OF CONSENT**

I certify that I have informed the patient or his/her representative of the nature of this procedure, alternative methods thereto, including non-treatment, and the risks associated therewith.

Physician's Signature \_\_\_\_\_ M.D./ D.O. Date \_\_\_\_\_

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