



INFORMED CONSENT FOR PHAKIC IMPLANT SURGERY: VISIAN ICL™

This information is being provided to you so that you can 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.

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 which may include:

- Eyeglasses/Spectacles
- Contact Lenses
- Astigmatic Keratectomy (AK)
- Corneal Relaxing Incisions
- Intracorneal Ring Segments (Intacs)
- Clear Lens Extraction

BENEFITS OF PHAKIC IMPLANT SURGERY

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

LIMITATIONS OF PHAKIC IMPLANT SURGERY

1. This procedure does not treat presbyopia, a natural condition that usually begins 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 that results in good distance vision, close vision will usually remain blurred for presbyopic patients. Therefore, 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.

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.

Complications of Iridotomy

The surgeon will make one small opening 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 at the time of surgery. Potential complications of 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 phakic IOL (synechia) that prevents the pupil from moving correctly; corneal damage; and vision disturbances such as double vision (diplopia), glare, or halos.

Important Items to Note

You should be aware that some agencies or organizations that have physical or visual requirements for participation, governmental or otherwise, including the military, FAA, airlines, fire departments, police and possibly others, may at the present or in the future, decide to impose limitations on various physical conditions including having LASIK/PRK/ICL or other refractive surgery. We cannot be responsible for keeping current on the legislation of every conceivable organization, either locally or nationally, and if there is a particular group that you are either a member of or anticipate the possibility of joining as a member, you should verify the requirements in writing before having such surgery.

Vision-Threatening Complications

- Infection
- Damage to the iris
- Retinal detachment
- Cataract
- Corneal swelling (edema)
- Loss of cells lining the inner surface of my cornea (endothelial cells)
- Glaucoma

Other Rare Risks

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 Complications

- Sedation
- Increased sensitivity to light or night glare
- “Starbursting,” halo, or “heat wave” effect in my vision
- Over-correction or under-correction
- Lens may change position (decentration)

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

Refractive surgery for vision correction is a choice. You should be aware that the practice of medicine and surgery is not an exact science and no guarantees can be made as to the results of the operation. There are other methods of obtaining useful vision without surgery. These alternatives which include spectacles and/or contact lenses have been explained to me.

The details of phakic implant surgery have been presented to me in detail in this document 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, I am stating that I have read this informed consent fully and understand the possible risks, complications, and benefits that can result from the surgery and the alternatives available to me. I understand the medical necessity to follow the post-operative instructions as directed by my surgeon, and hereby give my consent to have phakic implant surgery performed on my:

- Left Eye
- Right Eye
- Both Eyes

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.

Patient Signature	Date
-------------------	------

Witness Signature	Date
-------------------	------

Pre- and Post- Operative Care (Co-management)

Co-management: In ophthalmology, often pre-operative examination data is gathered by the patient’s referring eye doctor. He/she then recommends the patient to an eye surgeon for evaluation for the procedure. In most cases, patients are referred back to their primary eye doctors for care after the procedure of laser vision correction. This system of shared care between two eye care providers is termed co-management. It is important for you to understand that the decision whether or not to be co-managed is yours alone. The most common reasons patients choose co-management are (a) a relationship and trust in their doctor, (b) travel distances and (c) convenience.

Your pre-operative examination and post-operative care may be managed by an Optometrist, a person licensed by the state in the diagnosis and treatment of eye diseases and conditions. Your laser vision correction will be performed by an Ophthalmologist, a person licensed by the state of Utah in the diagnosis, treatment, and surgery of the eye.

- Accept co-management with Dr. _____.
- Decline co-management.

Patient Signature