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 -3.0 diopters to -20.0 diopters, with up to 2.5 diopters of astigmatism. Visian Toric ICL was approved in September of 2018. It is approved for treatment of myopia between the ranges of -3.0 diopters to -20.0 diopters and with astigmatism from 1.0 to 4.0 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 ICL SURGERY**

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

**Non-Surgical Alternatives**

Contact lenses or glasses are non-surgical, extremely accurate, permit easy changes in prescription, and 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 nearsightedness glasses is not normal because of the smaller appearance of images (“minification”) and the sight decrease in peripheral vision caused by the thickness of the lenses.
2. Contact 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.

**Surgical Alternatives, Including Laser**

There are several other procedures for the correction of moderate to high myopia. Unlike ICL 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 -1.0D to -12.0D).
2. LASIK is a two-phase operation. First, a thin layer of cornea is either surgically cut with a microkeratome or a flap is created using a 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 to high myopia up to -12.0D. Above 12 diopters, LASIK is known to have high incidence of complications involving 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 pver 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 (-10D and above).

**GENERAL DESCRIPTION OF TREATMENT WITH PHAKIC IMPLANT SURGERY**

If you wear contact lenses, you will be required to leave the 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 the 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 eyes (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 either at the time of surgery by using an instrument (a surgical iridotomy) or within two weeks before the placement of the phakic implant by using a laser (YAG-laser iridotomy).

**COMPLICATIONS OF IRIDOTOMY**

Potential complications of a Yag-laser iridotomy are very rare but include damage to the natural lens; inflammation inside the eye; temporary increase in 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 the lens of the eye (synechia) that prevents the pupil from moving correctly; corneal damage and vision disturbances such as double vision (diplopia), glare and halos.

Before phakic implant surgery begins, your pupils will be dilated, and 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); you may elect to have the surgery with local anesthesia only, without sedation; or, if your surgeon determines that it is in your best interest, you may undergo general anesthesia, in which case you will not be awake during the operation. All methods of anesthesia have risks, and although not common, may include the risk of serious bodily injury or death.  Your ophthalmologist or other qualified health care professional will explain the method of anesthesia that has been selected for you as well as the associated risks. You have the right and are encouraged to ask your doctor or health care professional any questions you have related to 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 ICL is inserted into the posterior chamber of the eye, behind the iris and in front of the natural lens. The incision required to perform this operation is usually 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.

You will return to your ophthalmologist the same afternoon as your surgery for an examination. Your eye will be examined with a microscope 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 as early as the first postoperative day, the visual effects of ICL surgery may take several weeks to stabilize. Patients are generally able to return to their normal activities within 2 or 3 days following ICL surgery.

**BENEFITS OF ICL SURGERY**

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

**LIMITATIONS OF ICL 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 on 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 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 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. 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.
2. I understand that I could experience damage to the iris (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.
3. 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 increase with implantation of the ICL.
4. I understand that I may develop a cataract, or 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. Patients with high levels of nearsightedness are at higher risk of cataract development, and that risk may be increased with implantation of the ICL.
5. 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.
6. I understand that I may develop glaucoma, which is an increase in the pressure of the eye caused by slow 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 ICL. The effect of the Visian ICL on the future risk of glaucoma is not known.
7. I understand that other complications could threaten my vision, including, but not limited to, iritis or inflammation of the iris (immediate or 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. 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 id 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 there may be increased sensitivity to light or night glare. I also understand that at night there may be a “star-bursting” 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 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.
4. I understand that the ICL 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, after ICL 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 my eyes are somewhat more vulnerable to all varieties of injuries, at least for the first year following phakic implant surgery.
6. 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 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 ICL 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 ICL surgery may not be perfect.
11. I understand that it is not realistic to expect that this procedure will result in perfect vision.
12. I understand I may need glasses to refine my vision for some purposes requiring fine detailed vision.
13. 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.
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. 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 RESPONSIBILITY FOR COSTS**

Health insurance generally does not pay for elective ICL 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.

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**PATIENT CONSENT**

I give **Dr. Kopstein** \_permission to perform either a YAG-laser iridotomy or a surgical iridotomy AND ICL 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. 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.

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

The details of ICL surgery have been presented to me in details 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 for YAG-laser iridotomy or surgical iridotomy, AND ICL surgery, I am stating that I have read this informed consent and 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

\_\_\_\_\_\_\_\_\_\_\_\_(initials) ICL Surgery on Both my Right Left (circle one) eyes.

\_\_\_\_\_\_\_\_\_\_\_\_(initials) Toric ICL Surgery on Both my Right Left (circle one) eyes.

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

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Patient Signature

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