UCLA Health

MRN:
Patient Name:

(Patient Label)

LASER REFRACTIVE CENTER
INFORMED CONSENT DOCUMENT
IMPLANTABLE COLLAMER LENS (ICL)

GENERAL INFORMATION

The purpose of this document is to provide written information regarding the risks, benefits, and alternatives of Implantable Collamer Lens (ICL) implantation. This material serves as a supplement to the discussion you had with your physician. It is important that you fully understand this information, so please read this document thoroughly. If you have any questions regarding the procedure, ask your physician before signing this consent form. We appreciate your selecting the UCLA Health System to meet your needs.

This procedure, like all surgery, presents some risks, many of which are listed below. It is impossible to list all the possible risks and complications associated with this proposed surgery or any other treatment. Risks and complications that are unforeseeable, remote, or commonly unknown are not discussed.

AN OVERVIEW OF THE ICL PROCEDURE

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 out of focus. Myopia can be the result of an eyeball that is too long for its optical power or by a curvature of the cornea or lens that is too steep to match the length of the eyeball. The amount of myopia is measured in "diopters (D)," a technical term used to describe the power of a lens. The STAAR Surgical EVO Visian ICL is approved by the Food and Drug Administration (FDA) for the treatment of patients with moderate to high myopia between -3 and -20 D, with up to 4 D of astigmatism.

Surgical implantation of a phakic intraocular lens (phakic implant surgery) is one of several alternatives for correcting nearsightedness. In phakic implant surgery, an artificial lens (such as the ICL) is surgically implanted inside the eye. The lens is made from a material that is like the type used in intraocular lenses 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 front of your natural lens.

Phakic implant surgery is an elective procedure. There is no emergency condition or other reason that requires you have it performed. You could continue wearing glasses or contact lenses and have adequate visual acuity. This procedure, like all surgery, presents some risks, many of which are listed below. You should 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 that your corrected vision is worse than it is right now.

BENEFITS OF ICL IMPLANTATION

If you have moderate to high myopia, ICL implantation may improve your natural distance vision without the need for glasses or contact lenses.

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LIMITATIONS OF ICL IMPLANTATION

Although the goal of ICL implantation is to improve your vision to the point of being independent of glasses or contact lenses, or to the point of wearing thinner (weaker) glasses, this result cannot be guaranteed. Additional procedures, spectacles, or contact lenses may be required to achieve adequate vision. ICL surgery will not prevent you from developing naturally occurring eye conditions such as glaucoma, cataract, retinal degeneration, or retinal detachment. Patients with moderate to high myopia are naturally at some risk of retinal detachment based on eye anatomy.

ICL implantation does not correct the condition known as presbyopia (aging of the eye), which becomes symptomatic in most people around age 40, and which requires them to wear reading glasses for close-up work, sometimes including computer distance. The key question to ask yourself is, can you read up close while looking through the top part of your distance glasses? If you must take off your distance glasses or use bifocals or progressive lenses to read up close, you have presbyopia. Patients with presbyopia who have both eyes fully corrected for distance will subsequently need reading glasses to see up close. This sometimes includes computer distance. Therefore, if you presently need reading glasses, you will still need reading glasses after this treatment. If you do not need reading glasses because you take off your distance glasses to read, you will likely need reading glasses after this treatment if you have both eyes corrected fully for distance. If you do not need reading glasses right away, you will need them at a later age. You may consider having one eye weighted for mid-range near vision. Many patients over the age 40 make this decision and are pleased with both their distance and mid-range near vision (example: computer screen, shopping tags, grocery shelves) and then use simple reading glasses for close-range and for smaller printed materials (example: newspapers, some magazines, mobile phone).

With increasing age, patients also 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 extraction with or without implantation of a replacement intraocular lens.

ALTERNATIVES TO ICL IMPLANTATION

You are under no obligation to undergo phakic implant surgery. If you decide not to have phakic implant surgery, there are other methods to correct your nearsightedness. They include non-surgical and surgical alternatives.

- Contact lenses and glasses are non-surgical, extremely accurate, permit easy changes in prescription, and allow the eye to retain focusing power for near vision if you are below 40. Although there are essentially no risks to wearing glasses, the quality of vision with strong glasses is suboptimal because of the smaller appearance of images (“minification”) and the slight decrease in peripheral vision caused by the edge thickness of the lenses. Contact lenses provide higher quality and more normal vision, but they have a small risk of complications, especially if worn overnight. The risks of contact lenses include corneal abrasion, recurrent erosion, infection, allergy, irritation, and discomfort.

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- Several surgical procedures are available for correcting moderate to high myopia. Photorefractive keratectomy (PRK) and laser assisted in situ keratomileusis (LASIK) do not require an incision into the eye as does phakic implant surgery. PRK uses an excimer laser to reshape the cornea to refocus light rays. PRK may be used to correct low to higher amounts of myopia (generally -1 D to -12 D). LASIK is a two-part operation that achieves the same effect as PRK, but with a quicker recovery. First, a thin layer of cornea is either surgically cut with a mechanical microkeratome or a flap is created using a femtosecond laser. The exposed deeper layer of the cornea is then 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 D, LASIK is known to have a high incidence of complications involving quality of vision, especially at night, and a risk for inducing corneal ectasia. It has also proven to be less accurate for the correction of high myopia than it is for lower levels of nearsightedness. For these reasons, many surgeons stopped performing LASIK for extremely nearsighted eyes.

- Clear Lens Exchange (CLE) is an intraocular procedure that involves making an incision into an eye and replacing the natural lens with a synthetic lens of sufficient power to correct the refractive error of the eye. Patients aged 40 or over may request a multifocal lens that simultaneously improves their near vision for reading. Because of the increased risk of retinal detachment, clear lens exchange is most appropriate for patients who are hyperopic (farsighted) or extremely nearsighted (-10 D and above).

- Other refractive surgical procedures for correcting myopia include keratomileusis, corneal inlays, and radial keratotomy (RK). These procedures are rarely performed, and RK is generally effective only for patients with low degrees of myopia.

DESCRIPTION OF THE PROCEDURE

If you wear contact lenses, you will be required to keep them out of your eyes for some time prior to your preoperative eye examination and before surgery. This is done because a contact lens rests on the cornea, distorting its shape, and this distortion can influence the accuracy of the doctor's measurements of the power of the surgical correction needed. Discontinuing contact lens wear allows the corneas to return to their natural shape. Soft contact lens wearers should keep lenses out of their eyes for at least three days. Rigid (including gas permeable and standard hard lenses) contact lens wearers should keep lenses out for at least three weeks. Rigid contact lens wearers usually experience fluctuating vision once their lenses are discontinued due to changes in the shape of the cornea. Although the cornea usually returns to its natural state within three weeks, the process may take longer, and you will need to remain contact lens free until stabilization is complete.

Previous versions of the ICL required a surgeon to make two small holes in the periphery of the colored portion of the eye (the iris), in a procedure known as an iridotomy, to help ensure that intraocular fluid does not build up behind the ICL and cause both pupillary block and angle closure. The design of the EVO Vision ICL obviates the need for the iridotomies. The EVO

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Vision ICL has a center hole that prevents pupillary block by exchanging fluid between the posterior chamber and the anterior chamber.

Before ICL surgery begins, you will be given an anesthetic to minimize pain during the procedure. You may also be given light sedation by an anesthesiologist or nurse anesthetist through an intravenous line. You may elect to have the surgery with topical anesthesia only, or with an orbital injection, and without or without intravenous 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 involve 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 the anesthesia.

After your pupil has been dilated, and your eye has been anesthetized, the surgeon will make a small incision in your peripheral cornea to allow insertion of the phakic lens. The ICL is initially inserted into the front part of your eye (anterior chamber) between your cornea and iris. It is then manipulated into the posterior chamber behind the iris. The incision required to perform this operation is usually self-sealing, but it may require closure with fine sutures that will 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 ophthalmologist the next day for an examination. Your eye will be observed at 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 of phakic implant surgery.

One or both eyes may be treated on the same day. This is a decision you will make with your doctor.

POTENTIAL RISKS AND COMPLICATIONS OF ICL IMPLANTATION

Most ICL surgery proceeds smoothly and without complications. However, complications are possible and not completely avoidable. They can be grouped into vision-threatening complications and non-vision-threatening complications. We will start with vision-threatening complications

- In most cases, the surgery will be performed with numbing drops for anesthesia, but in some cases the surgeon may elect to anesthetize the eye using an orbital injection. 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.

 I have read and understand this page. Patient initials: _____

- 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 inside the eye (endophthalmitis), even if treated with antibiotics, can lead to permanent scarring and loss of vision that may require corrective surgery or, if very severe, corneal transplantation, blindness, chronic pain, or even loss of the eye.

- The iris (the colored part of the eye) can be damaged, or the eye can develop a rise in pressure in the front of the eye (secondary glaucoma) from pupillary block and angle closure, despite the presence of the central hole in the ICL. Treatment may involve an iridotomy or drops to control the pressure.

- A retinal detachment, which is a separation of the retina from the inside wall of the eye, could develop days, weeks, months, or even years after surgery. A retinal detachment results from a tear in the retina and it can lead to peripheral or central vision loss or both. Patients with moderate to high levels of nearsightedness have a higher risk of retinal detachment than those in the general population. This risk may be increased with implantation of a phakic IOL.

- A cataract, a clouding of the eye's natural lens, may develop days, weeks, months, or years after surgery. Cataract is expected to develop in all eyes eventually. Cataract surgery requires removal of the ICL, the cloudy natural lens (cataract), and insertion of an artificial replacement lens. Patients with high levels of nearsightedness are naturally at higher risk of cataract development, and that risk may be increased by implantation of a phakic IOL.

- The cornea may swell (edema) after surgery and/or there may be an ongoing loss of the endothelial cells lining the inner surface of the cornea. 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, it could necessitate corneal transplantation.

- Glaucoma may develop after ICL implantation. Glaucoma is an increase in pressure inside the eye that is caused by slowed fluid drainage. Glaucoma can lead to vision loss and may require treatment with long-term medications or additional surgery. Patients with high levels of nearsightedness are at increased risk for the development of glaucoma already, and that risk may be further increased by implantation of a phakic lens. The effect of the EVO Visian ICL on the future risk of glaucoma is unknown.

- Other complications could threaten vision after ICL implantation including, but not limited to, rupture of the lens capsule and rapid cataract development, iritis (inflammation of the iris), uveitis (inflammation of the iris, ciliary body, and choroid), bleeding, swelling of the retina (macular edema), and other visual complications. Though rare,

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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.

As mentioned, non-vision-threatening complications are also possible.

- You may be given intravenous sedation in conjunction with the procedure and your eye may be patched afterward. You will be unable to drive immediately after receiving sedation and you should not drive until you are examined the next day. Your life and health and the lives of others will be at risk if you drive during this period. Driving while impaired may also violate traffic laws.

- There may be an increased sensitivity to light or glare at night. There may be "star bursting" or halos around lights. The risk of this side effect may be related to the size of the pupils, and larger pupils put patients at increased risk. The central hole in the optic of the lens may also produce some starbursts.

- Over correction or under correction can occur, causing the eyes to become farsighted, remain nearsighted, or experience more astigmatism. This residual refractive error could be permanent and treatable with glasses or contact lenses, or it could necessitate that you undergo 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 the complications possible from the original surgery.

- There may be a difference in vision between your two eyes if phakic ICL surgery has been performed on one eye but not the other. This imbalance is called anisometropia. This might cause eyestrain and make judging distances (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. To have balanced vision in both eyes, you might 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.

- Your eye may be more fragile to trauma from impact following ICL implantation, particularly during the first few months after surgery. Evidence has shown that, as with any scar, a corneal incision will not be as strong as the cornea was originally at that site. The treated eye, therefore, will be somewhat more vulnerable to all types of injuries, at least for the first year following phakic implant surgery. It would be advisable for you to wear protective eyewear when engaging in sports or other activities during which the possibility of a ball, projectile, elbow, fist, or other traumatizing object contacting the eye might be high.

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- There is a natural tendency for the eyelids to droop with age and ICL surgery might hasten this process.

- There might be pain or a foreign body sensation, particularly during the first 48 hours following surgery.

- The long-term effects of phakic implant surgery are unknown and unforeseen complications or side effects could possibly occur.

- The correction that you can expect to gain from phakic implant surgery may not be perfect. It is not realistic to expect that this procedure will result in perfect vision, always, and under all circumstances, for the rest of your life. You may need glasses to refine your vision for some purposes requiring fine detailed vision after some point in your life, and this might occur soon after surgery or years later.

- If you currently need reading glasses, you will continue needing them after this treatment. It is possible that dependence on reading glasses will increase or that reading glasses may be required at an earlier age if you undergo this surgery.

- 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 your body. Since it is impossible to state every complication that may occur from any surgery, the list of complications in this form is incomplete.

PATIENT STATEMENT

- I have read this Informed Consent form (or it has been read to me). The details of phakic ICL surgery have been presented to me in detail in this document and in the *Patient Information Booklet* and by my ophthalmologist in terms that I understand.

- I understand the ICL procedure is approved by the FDA for the treatment of myopia (nearsightedness) with or without astigmatism.

- I have been informed about the possible benefits, risks, complications, alternatives, consequences, and contraindications associated with ICL implantation. I understand that it is impossible for my doctor to inform me of every conceivable complication that may occur, and that unforeseen risks may develop. I have been given the opportunity to ask questions and I have received satisfactory answers to any questions I have asked. I understand that no guarantee of a particular outcome was given and that my vision could become worse after treatment.

- My decision to undertake ICL implantation is made without duress of any kind. I understand that ICL implantation is an elective procedure, and that my myopia and/or astigmatism may be treated by alternative means, such as spectacles, contact lenses, or other forms of

refractive surgery. It is hoped that ICL implantation will reduce or possibly eliminate my dependence on glasses or contact lenses. I understand that the correction obtained may not be completely adequate and that additional correction with glasses or contact lenses may be needed.

- I authorize the physicians and other health care personnel involved in performing my procedure and in providing my preoperative and postoperative care to share with one another any information relating to my health, vision, and ICL procedure that they deem relevant to providing me with care.

- I understand that my surgical measurements will be entered into a database (without any personally identifiable information) for the purposes of surgical planning, research, marketing, and publication and that this non-identifiable data will be accessible to parties outside UCLA.

- I give permission for my ophthalmologist to record on video or photographic equipment my procedure for the purposes of education, research, or the training of other health care professionals.

- I have had sufficient time to review this consent form. A physician or associate has adequately addressed my questions and concerns. By signing below, I am making an informed decision to undergo ICL implantation. I have received (or been offered) a copy of this consent form for my own records.

- I authorize the release of my medical records to process medical claims or requests for further information from insurance companies.

- I understand that if I have an interpreter or legal guardian read this consent to me, they will sign in the surrogate consent area.

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I consent to have Dr. _____ perform ICL implantation on my:
(Circle one.) right eye / left eye / both eyes.

_____
Patient Printed Name

_____ _____
Patient Signature Date

_____
Witness Printed Name

_____ _____
Witness Signature Date

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FOR SURROGATE CONSENT

I am the guardian, next-of-kin, or legal representative of the patient whose name appears above on the patient signature line. I have read and fully understand the foregoing information and have discussed this information and its terms with the patient to the extent of the patient's understanding. Due to the patient's inability to provide informed consent, I consent to have ICL implantation performed on the patient's right eye / left eye / both eyes.

_____
Printed Name of Surrogate

_____ _____
Surrogate Signature Date

_____
Nature of Relationship to Patient

_____
Witness Signature

MANAGEMENT CONSENT FORM

It is my desire to have Doctor _____, perform my preoperative/postoperative follow-up care for refractive surgery. I have been assured that UCLA Laser Refractive Center will be contacted immediately if I experience any complications related to my eye surgery.

Reason for Management by this doctor, is: (please check one)

___ Maintain established eye care relationship.
___ Difficult to return to UCLA for follow-up care because of location.
___ Other (please give reason) _____

Patient Signature _____Date_____

Witness Signature _____Date_____

I have read and understand this page. Patient initials: _____