INFORMED CONSENT

IMPLANTABLE COLLAMER LENS (EVO ICL)

INTRODUCTION

This document is provided to obtain your informed consent for refractive surgery with an Implantable Collamer Lens (EVO ICL). It contains important information detailing the risks and benefits as well as alternative treatments available. Refractive surgery is an elective procedure and you are choosing it because you want to, not because you must.

It is important that you thoroughly read and understand everything, and only sign once you have read, understood, and have had all questions answered to your satisfaction enabling you to make an informed decision.

INSTRUCTIONS

- You must review this entire document prior to treatment.
- Take as much time as needed to read and understand this document prior to signing.
- Your doctor is available to answer any questions or concerns you have regarding this consent.
- This document must be signed prior to any treatment.
- You will sign this document in-person at Laser Eye Institute.
- You may request a copy of this document at any time.

INFORMED CONSENT FOR PHAKIC IMPLANT SURGERY: EVO VISIAN ICL

INDICATIONS AND PROCEDURE

The EVO Visian ICL (Implantable Collamer Lens) or Toric EVO Visian ICL are lenses that are 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 and although the lens is permanent, it is removable.. The EVO ICL has been approved by the Food and Drug Administration (FDA) for the treatment of patients with moderate to severe nearsightedness (myopia) with or without astigmatism. Myopia is a clinical term for nearsightedness or the inability to see distant objects. Myopia is measured in "diopters," a technical term used to describe the power of a lens. The EVO ICL is approved for treatment of myopia between the ranges of -3 to -20 diopters, with up to 4 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, carries 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.

Before surgery begins your pupils will be dilated and you will be given an anesthetic (topical and/or oral) to minimize any discomfort during surgery. You may undergo light sedation administered by an anesthesiologist or nurse anesthetist while your eye is numbed with either drops or an injection.

During the surgical procedure the surgeon will make a small incision in the peripheral cornea (the clear part of the eye) through which the EVO ICL will be inserted. Once inserted, the ICL slowly unfolds and is initially placed on the iris. Next, the four corners (haptics) of the implant are tucked under the iris. The ICL is designed to vault over your natural crystalline lens. Although the incision is constructed to be self-sealing, it may require closure with very fine sutures that gradually dissolve over time. Afterwards a temporary shield may be placed over the eye to protect it during the immediate post-operative period.

Post-operatively you will be examined by your surgeon and should plan to rest the remainder of the day. Your surgeon will schedule additional post-operative visits to continue to monitor the eye during healing. Although you will likely see some improvement in your vision immediately after surgery, the visual effects of surgery may take sever weeks to stabilize. Patients are generally able to return to normal activities within two or three days following surgery.

ALTERNATIVES

You are under no obligation to have surgery and alternatives exist to phakic implant surgery. Non-surgical alternatives include glasses and contact lenses. Surgical alternatives include laser vision correction (LASIK, SMILE, or PRK); as well as Refractive Lens Exchange. Additionally, refractive surgery is continually evolving, and other refractive procedures may become available as an alternative. Each method of correcting nearsightedness carries its own set of risks which you may discuss with your surgeon. You should also be aware that having any refractive procedure could potentially disqualify you from Some professions, including the military and certain law enforcement agencies.

LIMITATIONS

This procedure does not treat presbyopia, a condition common in patients over the age of 40 in which the eye loses its ability to change power to allow focusing of both near and distant objects. Even with a successful surgery, near (reading) vision will usually remain blurred for presbyopic patients. Patients over the age of 40 will likely require reading glasses to improve their near vision.

This procedure will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, retinal degeneration or detachment.

RISKS AND COMPLICATIONS

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 surgeon, 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. In giving my permission for treatment, I have received no guarantee as to the success of my case and understand the following known risks:

Irregular healing could result in a distorted cornea. This means that glasses or contact lenses may not correct your vision to the level possible before undergoing treatment, with vision being worse than before treatment. If this distortion in vision is severe, a partial or complete corneal transplant might be necessary to repair the cornea.

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 successfully treated with antibiotics, could lead to permanent scaring and loss of vision that may require surgery or, if very severe, corneal transplantation or even loss of the eye.

Pain, irritation, foreign body sensation, light sensitivity, or glare, particularly during the first 48 hours after treatment, may occur. Increased risk of eye irritation related to drying of the corneal (eye) surface following treatment. These symptoms may be temporary or, on rare occasions, chronic, and may require application of artificial tears and/or closure of the tear duct openings in the eyelid.

Macular edema (swelling in the central part of the retina which usually improves with time); corneal edema (clouding of the cornea); glaucoma (increase in eye pressure); damage to the iris (the colored portion of the eye) may occur. These conditions while rare may require additional medical and / or surgical treatment.

Loss of endothelial cells may occur. These cells play a role in keeping the cornea clear. Corneal edema and loss of endothelial cells may result in a hazy cornea, which may reduce revision. It is not yet known how much endothelial cell loss may occur and what effect the cell loss may have on the long-term health of the cornea.

Retinal detachment (separation of the retina from the inside wall of the eye). Patients with high amounts of myopia have a higher risk or retinal detachment and this risk level may be increased with surgery.

Cataract formation may occur. A cataract is a clouding of the natural crystalline lens, and may require removal of the natural lens, phakic implant and insertion of an artificial lens.

The cornea may scar or become damaged resulting in further loss of vision. It may not fully correct (under-correction), it could correct it too much (overcorrection), or change the type of astigmatism you have. If this occurs, you may continue to have blurry vision. You may need to wear glasses or have another procedure to make your vision clearer.

The ICL lens may need to be repositioned, removed, or exchanged for another lens. The lens may change position, or I may require a different size or powered lens than the implanted lens. Potential complications from any additional surgery include all of the complication risks from the original procedure.

The eye may be more fragile to trauma. Evidence shows, as with any scar, a corneal incision will not be as strong as the cornea originally was at that site.

If I elect to treat each eye separately there may be an imbalance between my treated and un-treated eye. This imbalance, called anisometropia, may make it difficult to judge distance or depth. This may be relieved with temporary glasses or contact lenses.

There is a natural tendency of the eyelids to droop with age and surgery may increase this tendency.

I understand that my visual outcome may not be perfect. I understand that it is not realistic to expect that this procedure will result in perfect vision at all times. I may need glasses, now or in the future, to refine my vision for some purposes.

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 after surgery.

I have been advised not to drive or operate equipment immediately after receiving sedation and for a period of eight hours afterward.

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, known or unknown, that may occur as a result of any surgery; the list of complications in this form may not be complete.

ADDENDUM: OFF-LABEL TREATMENT

When a drug, device, or procedure is approved for medical use by the Food and Drug Administration (FDA), the manufacturer produces a label to explain its use. Once approved by the FDA, physicians may use it "off-label" for other purposes if they are well-informed about the product, base its use on firm scientific method and sound medical evidence, and maintain records of its use and effects. This type of use is known as off-label use. The short- and long-term risks either now, or in the future, have not been studied by the FDA. The following sections describe off-label treatment. I understand that having an off-label treatment poses additional short and long-term risks, now, or in the future that have not been studied by the FDA, nevertheless, I consent to treatment considered FDA off-label.

MYOPIA, HYPEROPIA, OR ASTIGMATISM GREATER THAN FDA INDICATION

Treatment amount may exceed the parameters indicated by the FDA. FDA approval was based upon specific treatment constraints related to the amount of correction clinical trial participants. Treatment levels outside this range are considered off label and the short- and long-term risks, either now, or in the future have not been studied by the FDA.

ADDENDUM: BILATERAL SIMULTANEOUS TREATMENT

During ICL vision correction many patients chose to have both eyes treated at the same time. The benefits to having both eyes treated at the same time include: lower cost, increased convenience, faster overall recovery, less post-operative visits. There are risks associated with simultaneous treatment that are not present when eyes are treated on different days. If you chose to have treatment on both eyes at the same time you should understand the additional risks outlined below:

The risk of infection, severe inflammation, clouding of the cornea, corneal scarring, or internal bleeding, are very rare but potentially devastating. If these complications occur in one eye, they may also occur in the other. Should these complications occur you could experience significant loss of vision or blindness. By choosing to have both eyes treated at the same time, the risk of having any of these complications, in both eyes, is increased.

The risk of an under-correction or over-correction in both eyes, requiring additional treatment or the use of glasses or contact lenses is increased. Having each eye treated on different days allows your surgeon to monitor the healing process in one eye and make the appropriate modifications to the treatment plan for the other eye. By correcting both eyes simultaneously there is no opportunity to learn from the healing patterns of the first eye before treating the second eye.

Most patients experience rapid visual recovery, but some may experience symptoms such as blurred vision, night glare, or ghost images that can result in prolonged recovery of normal vision. This may continue for several weeks, which could make daily tasks difficult or dangerous. There is no way of predicting how long your eyes will take to heal. If the eyes are operated separately, you can generally function with the other eye while the first eye fully recovers.

Both eyes tend to experience similar side effects. If you experience undesirable side effects in one eye, you will likely experience them in both eyes. These side effects may cause a decrease in vision or other negative effects, and some patients have elected to not have their second eye treated. By having each eye treated on separate dates, you will have the opportunity to determine whether the procedure has produced satisfactory visual results without loss of vision or other undesirable side effects. If you have presbyopia (use reading glasses), you will also have an opportunity to experience the change in your close vision that results from the correction of your nearsightedness or farsightedness. This could influence your decision to fully correct your other eye to maintain some amount of close vision without the need for glasses (known as a monovision treatment).

There may be additional risks, benefits, or complications that can result from a bilateral simultaneous (both eyes) treatment. I understand these risks and wish to have both of my eyes treated at the same time if my surgeon determines that treatment in the first eye appeared to be technically satisfactory.

LASER VISION CORRECTION FINANCIAL AGREEMENT

FOLLOW UP CARE, TRAUMA, AND NON-COVERED SERVICES

Vision correction includes a follow-up period, that begins on treatment date. During this time, any visits directly related to treatment (typically post-operative check-ups) are included. Any other problems, conditions, or treatments involving your eyes are not covered or included in post-operative care. As much as you try to avoid eye injury, it may occur. If you experience eye trauma, during, or after your post-op period, it is important to schedule an exam immediately to ensure your eyes are healthy. Exams related to eye trauma are not included in your treatment fee. During your post-operative care, we may encounter pathology (eye disease) unrelated to your vision correction. Examples of this include but are not limited to eye trauma, redness, irritation, accidental injury, or allergies. It is our obligation to inform and offer treatment or refer you to an appropriate specialist. Under most circumstances this treatment is billable to your medical insurance.

ANNUAL EYE EXAMS

After your included post-operative care period ends it is important to maintain annual eye exams (once per year) to ensure your treatment is stable and check the overall health of your eyes. Annual exams are billable and may be covered by insurance. If it is not practical to follow up at Laser Eye Institute, please inform us of your local ophthalmologist so we may transfer relevant medical records and properly coordinate your care with your local ophthalmologist.

SPECIALIST REFERRALS

Under some circumstances it may be necessary to refer you to a specialist that may be either related or un-related to your treatment. There are many different parts of the eye, and our facility specializes only in vision correction. Referrals are made at the discretion of your surgeon, and you are under no obligation to see the specialist we recommend. Any treatment by an outside physician is not included in your vision correction fee, and we have no financial interest with any parties we may refer you to for additional care.

MEDICATIONS

Medications are required both before and after treatment. These medications reduce the chance of infection as well as promote rapid healing. It is important to follow medication instructions provided. You are responsible for any costs associated with these medications. Typically, these medications are covered by insurance.

RETREATMENTS AND ENHANCEMENTS

After initial treatment you may be under- or over-corrected which depending on the severity may require additional treatment to correct. While rare, this typically appears within the first three to six months. This condition differs from a change in your vision due to aging, pregnancy, or other biological factors. Eligibility for re-treatment (often called an enhancement) will be determined by your surgeon. Generally, you must wait at least three months between treatment to allow adequate healing, have stable vision, and your uncorrected vision should be 20/40 or worse when measured. Retreatment involves the same risks as the original procedure. During your two-year post-operative period surgeon fees are waived for retreatments, however a facility fee applies. Changes in vision due to aging or other biological factors are not covered by this retreatment policy.

FINANCIAL POLICY

Laser Vision Correction is surgery, and no warranty or guarantee is made or implied regarding the result, cure, or safety. Payment is due on or before surgical treatment and is considered final after surgical treatment is completed, regardless of surgical outcome.

PATIENT'S RESPONSIBILITIES

Your surgeon expects you to cooperate in the care being provided. This includes being honest with your surgeon, keeping all scheduled appointments, following your surgeons' instructions before and after treatment, adhering to prescribed medications, as well as being cooperative and pleasant with your care team. Failure to cooperate with the care being provided may result in your care being withdrawn.

INFORMED CONSENT

By signing the below, I certify the following to the best of my knowledge:

All 6 pages of this document have been given to me in its entirety. I have been given this document in advance of being asked to sign it.

All of my questions regarding treatment have been answered to my satisfaction allowing me to give my informed consent.

I have read, understand, and hereby consent to: *Phakic Implant Surgery with EVO ICL*

I have read, understand, and hereby consent to addendums: *Off-Label Treatment Addendum, Bilateral Simultaneous Treatment*

I have read, understand, and hereby consent to *Vision Correction Financial Agreement*. I understand that all or part of my procedure may not be covered by insurance and accept responsibility for all out-of-pocket expenses.

I understand that during the proposed procedure(s) unforeseen conditions may be revealed requiring the performance of additional procedures, and I authorize such procedures to be performed at my physician's discretion. These additional procedures may carry additional risks in addition to the risks outlined above.

I understand that no warranty or guarantee has been made to me regarding the result, cure, or safety.

I give my permission for Laser Eye Institute to videotape or photograph my procedure for purposes of documentation, education, research, or training. Additionally, I give my permission for Laser Eye Institute to use data about my treatment to advance the field of laser vision correction. I understand that my name, or any other personally identifiable information will remain confidential unless I give subsequent written permission for my identity to be disclosed.

MY SIGNATURE BELOW FURTHER CERTIFIES:

TO THE BEST OF MY KNOWLEDGE I AM NOT CURRENTLY PREGNANT.

I AM NOT UNDER THE INFLUENCE OF ANY NARCOTIC, ALCOHOL OR ANY OTHER DRUG, OR SUBSTANCE THAT MAY IMPAIR MY JUDGEMENT OR MY ABILITY TO UNDERSTAND THIS CONSENT.

I WAS ABLE TO READ AND UNDERSTAND THIS INFORMED CONSENT. ANY QUESTIONS I HAD REGARDING THE ABOVE PROCEDURE(S), RISKS, BENEFITS, AND ALTERNATE PROCEDURES HAVE BEEN EXPLAINED TO MY SATISFACTION ALLOWING ME TO GIVE MY INFORMED CONSENT FOR THE ABOVE PROCEDURE(S).

Patient Name	Patient MRN	Date

Patient Email Address	Surgical Coordinator

Patient Signature