

## **HOLZMAN LASER VISION INFORMED CONSENT**

### **LASER ASSISTED IN-SITU KERATOMILEUSIS (LASIK) FOR THE CORRECTION OF NEAR-SIGHTEDNESS, FAR-SIGHTEDNESS, OR ASTIGMATISM**

*You are entitled to be informed about the use of the excimer laser for performing laser assisted in-situ keratomileusis (LASIK) including the risks of the procedure and alternatives to it. Please read this document thoroughly and discuss the content with your doctor so that all of your questions are answered to your satisfaction.*

*This information is provided so that you can make an informed decision regarding the use of the excimer laser for performing LASIK to treat your myopia (near-sightedness), astigmatism or hyperopia (far-sightedness).*

In the LASIK procedure there are two steps. In the first step the surgeon uses a femtosecond laser to create a flap in the top half of the cornea. It does this by creating tiny bubbles inside the cornea that are linked together under computer control to create the appropriate shape and depth of the flap desired by the surgeon. Following this, the second step is performed. The surgeon lifts the flap that was created and then uses an excimer laser to remove a small amount of tissue from beneath the corneal flap. The excimer laser uses a mixture of gases to produce a narrow beam of invisible ultraviolet light energy, which when focused through a lens system, results in the removal of tissue, causing a change in the shape of the cornea to correct the refractive error. The LASIK procedure concludes when the corneal flap is replaced on the eye. When the corneal flap is replaced, it lies in the bed of excimer laser removed tissue, causing the surface to flatten with the effect of decreasing near-sightedness, far-sightedness and/or astigmatism. The LASIK procedure is performed under topical anesthesia (eyedrops).

The excimer laser is an approved device by the U.S. Food and Drug Administration. It is available for the correction of myopia from -1.0 to -14 diopters with astigmatism of up to -5.0 diopters or less and hyperopia of +1.0 diopters to +6.0 diopters. The femtosecond laser is an independently FDA approved device.

The alternatives to LASIK include eyeglasses, contact lenses or refractive surgery procedures such as ICL. ICL's are like implantable contact lenses that improve eyesight after being inserted surgically into the eye. The other alternative refractive surgical procedures are radial keratotomy (an operation in which a number of spoke-like incisions are made with a surgical knife in the cornea) and PRK (photorefractive keratectomy which is flattening of the cornea using the excimer laser).

**(Please initial after reading \_\_\_\_\_)**

Any questions that you have regarding LASIK or other alternative therapies for your case should be directed to your doctor.

## **PATIENT STATEMENT**

I have myopia, hyperopia and/or astigmatism, which requires me to wear corrective lenses in order to see clearly for my daily activities. I have been clearly informed of the alternatives including eyeglasses, contact lens and refractive surgery. I have decided to undergo Laser-Assisted In-Situ Keratomileusis (LASIK) with the excimer laser.

In giving my permission for the LASIK procedure, I declare that I understand the following information:

1. The goal of the LASIK procedure with the excimer laser is to reduce or eliminate myopia, hyperopia and/or astigmatism, thereby reducing my dependence or need for contact lenses and/or eyeglasses.
2. I understand that as with all forms of treatment, the results in my case cannot be guaranteed; there is no guarantee that I will completely eliminate my reliance on eyeglasses and/or contact lenses. It is possible that the treatment could result in under correction or overcorrection, requiring the use of glasses or contact lenses. It is possible that dependence on reading glasses may increase or reading glasses may be required at an earlier age. The treatment may also result in a change in my astigmatism that could require the use of glasses and/or contact lenses. I understand further treatment may be necessary, including a variety of eye drops, the wearing of eyeglasses or contact lenses (hard or soft), or additional surgery.
3. If I currently need bifocals, reading glasses over my contacts or I have to remove my glasses to read, I will likely need reading glasses immediately after this treatment. These are typically simple over the counter readers. If I am under 40 and have no trouble reading through my distance vision glasses or contact lenses currently, I understand that at some point I will need near vision glasses typically after the age of 40 when Presbyopia begins. It is possible that dependence on reading glasses may increase or that reading glasses may be required at an earlier age if I have LASIK surgery.
4. FEMALES ONLY: I am not pregnant. If it is possible that I am pregnant, then I will take a home pregnancy test to ascertain that I am not pregnant, since pregnancy could adversely affect my treatment result. If the results of the test are positive, I will not undergo treatment until the results are proven incorrect. I will notify my eye doctor immediately.
5. I understand the treatment may have greater risks when performed on persons with uncontrolled collagen vascular disease or autoimmune disease or on patients who are immunocompromised or on drugs or therapy, which suppresses the immune system. I will tell the doctor if I have any of these or other medical conditions.
6. I understand the treatment should not be performed on persons with signs of keratoconus and may be riskier in patients with history of keloid formation. I should tell my doctor if I am aware that I have either of these conditions.

7. I have been informed, and I understand that as a result of the LASIK surgery which uses the excimer laser, it is possible that my vision could be made worse. There are certain complications and risks, which include the following:

- Corneal Scarring/ Anterior Stromal Reticular Haze: Haze or scar dense enough to affect vision may occur after the procedure.
- Decrease in Best Corrected Vision: A decrease in best corrected visual acuity (vision with eyeglasses or contact lenses) may occur.
- Difficulty Wearing Contact Lens Postoperatively: May occur after refractive surgery.
- Diffuse Nebulae: A scattered cloudiness of the cornea.
- Double Vision: Perception of two images from a single object; may be horizontal, vertical, or diagonal.
- Dry Eye, which is generally treatable with artificial tears and resolves in 1-3 months, but may be permanent.
- Foreign Body Sensation: Patients may experience foreign body sensations or a feeling that something is in the eye. Over a period of a few weeks these foreign body sensations usually diminish.
- Ghost Images: Double or blurry images.
- Glare, especially from bright lights at night, may be experienced, and can cause discomfort or annoyance.
- Growth Beneath the Flap: Epithelial cells may grow beneath the corneal flap, causing clouding and necessitating repeat surgeries to try to control cell growth.
- Guttata: Small whitish deposits on the inner layer of the cornea.
- Halo: Halos or hazy rings surrounding bright lights may be seen particularly at night after the procedure.
- Hyphema: Hemorrhage in the anterior (front) chamber of the eye.
- Hypopyon: Accumulation of white blood cells in the anterior (or front) chamber of the eye.
- Over correction or Under correction: It is possible that the procedure could result in under correction or over correction and it may be necessary for the patient to continue to wear glasses or contact lenses. Over correction may also result in the eye becoming farsighted or hyperopic which may or may not require the continuing wear of corrective lenses. It is possible that overcorrection may increase dependence on reading glasses or require the use of reading glasses at an earlier age.
- Induced Regular/Irregular Astigmatism: A change in the astigmatism of the eye which may then distort vision and may or may not require the patient to continue to wear corrective lenses.
- Infection: An eye infection may result as with any type of ocular (or eye) surgery. In rare cases this could lead to ulceration, scarring, and loss of vision.
- Intraocular Pressure Elevation: An increase in the inner eye pressure due to post treatment medications which is usually resolved by drug therapy or discontinuation of post treatment medications.
- Malposition: During surgery, the corneal flap may become mispositioned. This may lead to decreased vision.
- Pain: Ocular pain may occur immediately or in the long-term postoperative period.
- Lid Droop: Some patients may experience temporary or permanent slight drooping of the

eyelid.

- Additional immediate/early postoperative symptoms may include postoperative pain, contrast sensitivity loss, tearing and pupil enlargement. There is also the rare possibility of the need for a homograft (transplant of tissue from another individual) procedure due to the problems with the flap during or after the treatment.

**(Please initial after reading \_\_\_\_\_)**

8. I understand that the doctor will prescribe certain medications as part of the treatment. The doctor is prepared to answer any questions I may have regarding the prescribed drugs and any side effects.

9. I understand the doctor may elect to use a bandage contact lens over the treated area. The benefit of the lens is to reduce discomfort after treatment. There is a small risk of inflammation known as keratitis and infection which may need antibiotic treatment.

10. I understand that this is an elective treatment and that I do not have to have this treatment. I understand that the LASIK procedure is not reversible.

11. I understand that Laser In-Situ Keratomileusis will require follow-up care for up to one year after treatment and I agree to return for required examinations.

12. I have been told that a small percentage of patients may require an additional LASIK procedure known as an enhancement, in order to correct mild to moderate levels of myopia, hyperopia and/or astigmatism.

**(Please initial after reading \_\_\_\_\_)**

Since it is impossible to state every complication that may occur as a result of surgery, I have been told that the list of complications stated in this form is not complete. There also may be risks and discomforts that are not yet known. I have also been told that the long-term effects of the procedure are unknown.

If I choose to have LASIK on one eye at a time and if my un-operated eye is significantly different in correction, this may result in a condition called anisometropia, where my two eyes do not naturally focus in the same place. As a result of this some people experience headache, double vision and/or asthenopia (eye strain). I may have to wear a contact lens in my unoperated eye to correct this condition, or I may still need to wear spectacles because of the difference in correction in my unoperated eye.

If I choose to have LASIK treatment on both eyes at the same time, I understand that greater risk is potentially involved. This includes but is not limited to risks related to the rare possibility of infection and how the laser energy affects both eyes.

**VARIANT TOPOGRAPHY.** Corneal Topography is a diagnostic testing technique that can be used to find irregularities in the shape of the cornea prior to surgery. If the testing shows that your corneal shape is atypical, you may be in a higher risk category for development of keratectasia in the future if you undergo laser vision correction surgery. Keratectasia is a condition characterized by irregular thinning and weakening of the cornea that can lead to progressive changes in the refractive error. It may result in loss of uncorrected and best corrected vision. The progressive change which occurs is similar to that in a disease called Keratoconus. This progressive weakening occurs naturally in those with Keratoconus, but in keratectasia, individuals who are susceptible develop it after laser vision correction surgery. Mild topographic changes are very common in the normal population, and there may or may not be an increased risk of developing keratectasia. The risk of keratectasia in an eye with variant topography is higher with certain surgeries where laser treatment is applied deeper in the cornea under a flap, as compared to surface ablation treatment (which is used in PRK). While severe ectasia may need to be treated with a corneal transplant or corneal collagen cross-linking, mild keratectasia can frequently be corrected with the use of glasses or contact lenses.

**(Please initial after reading\_\_\_\_\_)**

**MONOVISION.** This is an option for patients age 40 and older who have difficulty reading due to the natural aging process. Monovision is a technique in which one eye (typically the dominant eye) is corrected for distance and the other eye is corrected for near or intermediate vision. Monovision provides a viable option for active people who require both distance and near vision in their daily activities. Because monovision is a compromise, reading glasses may still be needed for fine print and distance vision may not be as crisp for night driving and certain sporting activities such as golf and tennis. Depth perception may also be affected. You may be asked to trial monovision prior to surgery with contact lenses if you are considering this option. Keep in mind that near vision always worsens with age, and despite having a monovision technique done, your near vision will still weaken with time.

**CO-MANAGEMENT.** You have the right to choose to have your personal eye care provider (ECP) involved in your pre and/or post-operative care. We call this collaboration between your ECP and your surgeon “co-management”. If your care is co-managed, your surgeon will perform the surgery and also be available to you and your ECP for any pre and/or post-operative issues. If you decide to have your care co-managed, a portion of the fee you pay to Holzman Laser Vision may be distributed to your ECP for providing this care.

**Please indicate your choice to treatment today:**

**Both Eyes** \_\_\_\_\_ **Patient’s Initials:** \_\_\_\_\_

**Right Eye only** \_\_\_\_\_ **Patient’s Initials:** \_\_\_\_\_

**Left Eye only** \_\_\_\_\_ **Patient’s Initials:** \_\_\_\_\_

**I choose Monovision as my treatment choice**

**Patient's Initials: \_\_\_\_\_**

**I choose to have my \_\_\_\_\_ eye targeted for near vision**

**Patient's Initials: \_\_\_\_\_**

**STATEMENT OF CONFIDENTIALITY**

All information in my patient records will be kept in confidence but my examination data may be maintained in a central database for future evaluation of the LASIK treatment. While my specific treatment data will be kept confidential, generic compilation of data possibly including (without identification) my results may be utilized in advising future patients of the safety and efficacy of the treatment. However, no specific patient data relating to my treatment will be released except as required by law.

**(Please initial after reading \_\_\_\_\_)**

**STATEMENT OF VOLUNTARY PARTICIPATION**

In signing this Informed Consent Form for the use of the excimer laser for performing Laser In-Situ Keratomileusis, I am stating that I have read this Informed Consent (or it has been read to me) and I fully understand it and the possible risks, complications and benefits that can result from the treatment. Although it is impossible for the doctor to inform me of every conceivable complication that may occur, the doctor has answered all my questions to my satisfaction.

**I understand that if I have any questions with respect to the treatment I can call:**

**# 855-995-2745**

**(Please initial after reading \_\_\_\_\_)**

**By signing below, I agree that:**

- **The Laser In-Situ Keratomileusis procedure has been explained to me in terms that I understand**
- **I have had the opportunity to have my questions answered.**
- **I fully understand the possible risks, complications and benefits that can result from the treatment**
- **I am competent in clear mind and have fully read the informed consent form**
- **I agree to return for follow up visits and follow all post-operative instructions**
- **I am responsible for the cost of any medications, contact lenses, eyeglasses or other ophthalmic devices, if required, after vision correction surgery. I am also responsible for the cost of post-op visits which occur after the time period set forth in my patient agreement.**
- **I understand that vision correction surgery will not prevent naturally occurring eye**

- **problems such as glaucoma, cataracts, retinal degeneration or retinal detachment.**  
**I understand that I am responsible for fees associated with any eye problems that may occur in the future including but not limited to, glaucoma, pink eye, allergies, dry eyes, injury to my eyes or cataract formation.**

**My decision to undergo the Laser In-Situ Keratomileusis procedure has been my own and has been made without duress of any kind.**

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**PATIENT NAME (Type or print)**

**DATE**

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**PATIENT'S SIGNATURE**

**DATE**

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**PHYSICIAN'S SIGNATURE**

**DATE**

**PATIENT CONSENT TO CO-MANAGEMENT (IF APPLICABLE)**

I desire to have my eye care provider (ECP) perform my pre and/or post-operative care associated with my vision correction procedure. I understand that my ECP and my surgeon may communicate with one another regarding my post-operative care and that my ECP will promptly contact my surgeon and plan for the transfer of care should I experience any complications related to my vision correction procedure. I also understand that I may contact or be seen by my surgeon at any time during the post-operative period should I so desire.

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**PATIENT'S SIGNATURE**

**DATE**

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**PHYSICIAN'S SIGNATURE**

**DATE**