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INFORMED CONSENT LASER IN SITU KERATOMILEUSIS (LASIK)

Do not sign this form until you have read it fully and understand what it says. You may take as much time as you wish and are encouraged to ask any questions you may have at any time about LASIK and alternative forms of treatment. This document shall utilize the term "LASIK" to provide information concerning LASIK, CUSTOM LASIK, PRK, CUSTOM PRK or INTRALASE.

INTRODUCTION

Laser IntraStromal Keratomileusis or LASIK is a surgical procedure which involves two major steps. The first step of this procedure is performed with either a surgical instrument known as an automated Microkeratome or an INTRALASE laser. The second step is performed with the excimer laser. In the first step of the procedure, the microkeratome is placed on the front surface of your eye and a hinged corneal flap is created. This flap of tissue is then folded back and the excimer laser is focused on the underlying layers of corneal tissue. The excimer laser is a medical device that produces an intense computer guided beam that reshapes the surface of the cornea (front window of the eye) by removing a thin layer of tissue from the outer surface. The result is a flattening of the corneal curvature which reduces or corrects your myopia (nearsightedness) hyperopia (farsightedness) and/or astigmatism.

The VISX STAR S4 LASER is approved for Photorefractive Keratectomy (PRK) and PRK with astigmatism (PRKa) and LASIK for the correction of myopia, myopia with astigmatism, hyperopia and hyperopia with astigmatism by the FDA. This LASIK procedure uses either a microkeratome or an INTRALASE laser to create a hinged corneal flap so that the excimer laser can reshape the corneal tissue and thereby reduce myopia, astigmatism and hyperopia. The creation of a hinged corneal flap in the LASIK procedure allows the excimer laser treatment to be performed without removing corneal epithelium and Bowman's layer. This results in a post-operative course with a more rapid visual rehabilitation and less potential for pain than PRK and PRKa. However, the use of the microkeratome introduces some additional risks not encountered with the PRK/PRKa technique. These risks are outlined in the following paragraphs. Please make certain that you understand these risks and address any concerns or questions to your doctor.

The LASIK procedure has been adopted by many surgeons as their refractive procedure of choice because it offers patients more rapid visual rehabilitation than PRK/ PRKa, and unlike radial keratotomy, can correct low and high levels of nearsightedness as well as astigmatism and hyperopia. However, the procedure is

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not without risk. The following paragraphs attempt to outline the risks of LASIK surgery. If you have any questions regarding any of these risks, please discuss them fully with your doctor.

PATIENT STATEMENT

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

1. The present goal of LASIK is to reduce or eliminate myopia, astigmatism or hyperopia, thereby reducing or eliminating my dependence on contact lenses and/or eyeglasses.
2. As with all forms of treatment, the results in my case cannot be guaranteed. The risks associated with LASIK can be divided into two categories:

➤ Vision Threatening Complications

- * It is possible there could be loss of some or all useful vision.
- * This could be caused by an ocular infection that could not be controlled by antibiotics or other means.
- * Irregular healing, swelling, or scarring of the flap created by the microkeratome could result in a distorted corneal surface which would not allow spectacles or contact lenses to correct vision to what was possible before the LASIK surgery, i.e., loss of best corrected vision.
- * It is possible that an unintended perforation of the cornea could require suturing to close the perforation, or could possibly require a full-thickness corneal transplant, or could even cause a cataract to form.
- * The flap of corneal tissue could come off in the form of a cap and could be irreversibly damaged in which case it would require donor corneal tissue to be used to restore useful vision.
- * If a cap is created instead of a flap during the surgery, this cap could be decentered or lost after surgery, resulting in distorted vision and/or astigmatism. This may require additional surgery to either reposition or replace the cap. Replacing the cap could require donor tissue from an eye bank. It is possible that even with this further surgery your best corrected vision may not be restored to what it was before surgery.
- * The Microkeratome could malfunction and the procedure would need to be aborted. This procedure may be able to be repeated at a later date or additional surgery may be needed.
- * Other possible complications and risks include, but are not limited to corneal swelling, corneal failure, retinal detachment, hemorrhage, venous and/or arterial blockage, glaucoma, cataract formation, total blindness and even loss of the eye.
- * Although the size of the pupils will be measured, it is impossible to accurately predict the absence, presence or degree of glare, halos and/or reduced vision due to pupil size. Glare, halos and/or reduced vision, both temporary or permanent, may occur regardless of the size of your pupils. Although glare, halos and/or reduced vision may diminish over time, you may experience some degree of these problems after LASIK, CUSTOM LASIK, Epi-LASIK, CUSTOM Epi-LASIK, PRK, CUSTOM PRK or INTRALASE LASIK.

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◆ **Non-Vision Threatening Complications**

Everybody experiences at least some of these for at least a short period of time.

- I may develop irregular or regular astigmatism. This could decrease my best corrected vision where glasses would not improve my vision.
 - I may become farsighted or overcorrected. This farsightedness may be permanent.
 - I understand that I may not get full correction from the LASIK procedure and this may, in the sole opinion of my surgeon, require further surgical enhancement - a repeat LASIK procedure (ENHANCEMENT LASIK) or other refractive surgery procedure, such as Photorefractive Keratectomy (PRK). I understand that the appropriateness of an ENHANCEMENT LASIK
 - is a decision to be made by my surgeon based solely on his/her appraisal of the risks and/or complications inherent in my individual procedure(s).
 - There may be increased sensitivity to light, glare and a fluctuation in the sharpness of vision. These conditions usually persist only during the normal stabilization period of one to four weeks, but they may also be permanent.
 - At night there may be a "starburst" or "halo" affect around lights. This usually diminishes with time, but could be permanent.
 - There could be a "balance" problem between the two eyes called anisometropia. This could cause an alteration in the apparent size or position of objects and accompanying "shadow" or "ghost images" is possible which could make judging distances and depth perception more difficult, especially in comparison between the two eyes.
 - There may be a difference in spectacle correction between eyes, making the wearing of glasses difficult or impossible. Contact lens fitting and wearing may also be more difficult or impossible.
 - There may be an over-response or under-response in healing resulting in the need for spectacles and/or contact lenses prior to an enhancement procedure. I understand that the expense associated with spectacles and/or contact lenses is my responsibility.
 - The eye may be more fragile to trauma from impact. I understand that protective eye wear is strongly recommended for activities that could result in eye trauma, such as racquetball, tennis, softball, and karate. A severe blow to the eye could result in the loss of the eye.
 - There may be a natural tendency of the eyelids to droop with age and eye surgery can hasten this process. There may be pain, particularly during the first 24 hours following surgery.
 - At the time of the LASIK procedure, the surgeon may determine that the condition of the cornea or the inability to properly align the microkeratome on the cornea may result in the decision to perform PRK (photo-refractive keratectomy) instead of LASIK. PRK also involves the possible complications discussed in this document. I also understand that at any time prior to my LASIK or during the LASIK surgery my surgeon may determine that he/she believes the LASIK surgery is not appropriate or recommended and the LASIK surgery may be cancelled immediately.
3. (FEMALE ONLY) I am not a candidate for LASIK if I am pregnant or nursing, as this may adversely effect my results. I have not been pregnant for the past four months and have not been nursing for the past six weeks. After my initial LASIK, I will notify my eye doctor of my pregnancy prior to any consideration of an enhancement procedure.

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4. I must tell my doctor of any systemic diseases I have, since certain uncontrolled vascular disease, autoimmune diseases, or diseases or drugs (Accutane, Amiodarone) that suppress the immune system are contraindications to LASIK.
5. I am not a candidate for LASIK if I have keratoconus since my cornea may be unstable.
6. I should make my doctor aware of any history of Herpes infection of the eye, because the Infection could recur after surgery, permanently reducing my vision.
7. The doctor will prescribe certain medications as part of my treatment. These may include but are not necessarily limited to the following: antibiotic drops to prevent infection, steroid drops to prevent inflammation, and non-steroidal anti-inflammatory drops for comfort.
8. This is an elective treatment and is not a treatment I have to have. I also understand that LASIK is not a reversible procedure
9. Some prescriptions combine nearsightedness, farsightedness and astigmatism in a manner that is not correctable following the present FDA guidelines. Should my prescription require a laser treatment modality using two or more “key cards” or other procedures outside present FDA guidelines, these procedures and the associated additional fees will be fully discussed with me prior to my procedure. It is my decision to elect this procedure(s). The risks and complications associated with this procedure(s) mimic those for LASIK and PRK discussed in this document.
10. The rate at which each individual heals plays a critical role in the recovery from LASIK surgery. Slowly healing individuals may experience a prolonged period of blurred and/or distorted vision. It is impossible to predict the healing rate of any individual or the exact amount of time it may take for complete healing and vision recovery.
11. Following your LASIK procedure, several examinations will be necessary to monitor the health of your eyes and the healing process. We may suggest to patients that they return to their optometrist or to an optometrist affiliated with our clinic at some point during this process for appropriate post-operative examinations. We have full confidence in the clinical competence of optometrists affiliated with our office and monitor this competence on an on-going basis. Post-LASIK exams are recommended for one day, 3-4 days, six weeks and four months and once a year every year following your LASIK procedure. Any unacceptable risks or complications during your surgery may result in modifications to our recommended post-operative care. Although we recommended the care provided by our affiliated doctors, should you wish to receive your post-operative care at our office we will be happy to accommodate your request.
12. Dry eye syndrome (DES) is a common eye condition that is occasionally experienced after LASIK. This condition results in the use of artificial tears and occasionally, collagen / silicon implants for the relief of dry eye symptoms. **DES is not caused or created by the LASIK procedure** and may be the result of a prior eye condition and/or the eye’s normal healing process. I understand that, should they be necessary, I will be responsible for the purchase of artificial tears and collagen / silicon implants. I will be responsible for the doctor fees for the insertion of collagen / silicon implants as well as the fees for the collagen / silicon implant materials.

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13. Presbyopia, the loss of reading / focusing ability brought on by aging, may coincide (require an initial reading prescription) with LASIK and will continue following LASIK. This natural, progressive blurring of reading materials, usually experienced beyond the age of forty (40), although it may occur earlier, will continue due to the normal aging process.
14. Monovision, the intentional correction of one eye for distance vision and one eye for near vision, may result in acceptable vision for a period of time. With the natural aging process, your near vision will progressively deteriorate until your middle to late 50's. Patients in their late 40's, 50's and 60's experience a reduction of their near vision depth of focus (the range of clear near vision from close to your nose to "arm's reach"). At this age, monovision will allow clear near vision at either "reading distance" (15 to 17 inches) or "computer distance" (18 to 24 inches) but not both. You must choose which area of clear near vision you require and wear glasses for the other area. Should you have any questions concerning this issue, ask your doctor prior to your monovision LASIK.
15. Follow up care is important and may be necessary for up to one year. I agree to return for the required examinations. I understand that after my LASIK, yearly examinations are necessary to assess my eye health. *My LASIK fee does not cover yearly examinations. I understand there will be a fee for my exam one year after my initial LASIK procedure.*
16. Since it is impossible to state every long and short-term complication that may occur as a result of PRK, I understand that the above lists of complications are not complete or exhaustive.

ALTERNATIVES TO LASIK INCLUDE:

- * **Spectacles**. These are the traditional means of correction myopia.
- * **Contact Lenses**. These often provide better vision than spectacles.
- * **PRK or Photorefractive Keratectomy**. This has currently been FDA approved in the United States using the Summit or VISX laser, but the visual rehabilitation time is generally much longer than the LASIK procedures.

PRESBYOPIA (PATIENTS USING READING GLASSES)

I understand that if I presently wear bifocals, reading glasses or remove my glasses to read, I will still need a reading prescription after this surgical procedure. Dependence on my reading glasses may increase or reading glasses may be required at an earlier age. LASIK does not cause, delay or accelerate the onset of presbyopia. I can possibly minimize the use of reading glasses if I elect to undergo a partial correction of one of my eyes in what is called monovision, but there is never any guarantee that I will be completely free of reading glasses. Glasses and/or contact lenses will involve a separate fee, not included in your LASIK fee, for which you or your insurance company will be responsible.

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CONCLUSION

As with any surgery, I receive no guarantee as to the success of my particular case. I further understand that there is always a possibility of one or more late complications that are not known or anticipated at this time. I understand that LASIK surgery does not necessarily mean total freedom from spectacles and/or contact lenses and there is a good chance I will have to wear at least some sort of spectacle and/or contact lens correction in the future. I understand that the correction which I expect to obtain from LASIK may not be perfect. It is not realistic to expect that LASIK will result in perfect vision at all times, under all circumstances for the rest of my life. At best, I can expect that I will still require using reading glasses at times to refine my vision for some purposes at some point in my life.

I understand that I may be given a sedative at the time of my surgery. I agree to arrange for someone to drive me home after my procedure and to refrain from driving myself until I am comfortable with my vision of day and night. As with all surgery, there is a possibility of other complications due to anesthesia, drug reactions and other factors which involve other parts of the body, which cannot be fully described in this document.

STATEMENT OF VOLUNTARY PARTICIPATION

In signing this Informed Consent Form for the use of the excimer laser and the microkeratome or the INTRALASE laser for performing the LASIK procedure, 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, benefits and alternative treatments as explained to me in full detail by my doctor and his/her staff. Although it is impossible for the doctor to inform me of every conceivable complication that may occur, the doctor has answered all of my questions to my satisfaction. I understand that LASIK is an elective procedure and I do not have to consent to this treatment. I understand that the LASIK procedure is not reversible.

I agree to allow the viewing of my LASIK procedure by others via a television located in the Eye Center of Texas office or through a window in the LASIK suite. If I do not wish others to view my LASIK procedure I will provide a note at the bottom of this page so advising Eye Center of Texas.

I authorize the release of my medical records to my referring physician, primary care physician or a physician involved in my care and any managed care program possibly involved in the payment of my procedure(s).

*I understand that if I have any questions with respect to this treatment,
I can call a doctor at (713) 797-1010.*

**My decision to undergo the LASIK procedure has been made on my own
and has been made without duress of any kind. I wish to have:**

____ LASIK surgery on my right eye on _____ date

____ LASIK surgery on my left eye on _____ date

by Dr. _____.

PATIENT'S NAME (Type Or Print)

PATIENT'S SIGNATURE

DATE

WITNESS SIGNATURE

DATE