



www.eyecenteroftexas.com

6565 West Loop South  
Suite 650  
Bellaire, Texas 77401  
Ph. 713.797.1010  
Fax.713.357.7276

4415 Crenshaw  
Pasadena, Texas 77504  
Ph. 281.977.8800  
Fax.281.977.8877

15400 Southwest Frwy  
Suite 301  
Sugar Land, Texas 77478  
Ph. 281.277.1010  
Fax.281.277.4504

21700 Kingsland Blvd.  
Suite 102  
Katy Medical Complex  
Professional Building 1  
Katy, TX 77450  
Ph. 713.797.1010  
Fax.713.357.7276

450 Medical Center Blvd.  
Suite 305  
Webster, Texas 77598  
Ph. 281.332.1397  
Fax 281.338.1215

11914 Astoria Blvd.  
Suite 325  
Memorial SE Prof. Bldg.  
Houston, Texas 77089  
Ph. 281.484.2030  
Fax 281.484.6549

Edward C. Wade, M. D.  
Ting Fang-Suarez, M. D.  
Mark L. Mayo, M. D.  
Gurpreet D. Singh, M. D.

Christopher D. Allee, O. D.  
Jill Autry, O. D.  
Randall N. Reichle, O. D.  
Amanda Bachman, O. D.

## **Informed Consent** **Enhancement 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**

The Enhancement Laser Intrastromal Keratomileusis or ENHANCEMENT LASIK is a surgical procedure which involves two major steps. The first step of this procedure lifts the corneal flap that was created during your previous LASIK procedure. The second step is performed with the excimer laser. In the first step of the procedure, 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 that reduces or corrects your myopia (nearsightedness) hyperopia (farsightedness) and/or astigmatism.

The VISX STAR S4 20/20 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 ENHANCEMENT LASIK procedure uses the hinged corneal flap created in your previous LASIK procedure so that the excimer laser can reshape the corneal tissue and thereby reduce myopia, astigmatism and hyperopia. The ENHANCEMENT LASIK procedure involves some additional risks in addition to those encountered in your LASIK procedure. 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.

### **PATIENT STATEMENT**

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

1. The present goal of an ENHANCEMENT LASIK is to reduce or eliminate myopia, astigmatism or hyperopia, thereby reducing or eliminating my dependence on contact lenses and/or eyeglasses.

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

## Lasik Enhancement Informed Consent Con't.-

2. As with all forms of treatment, the results in my case cannot be guaranteed. The risks associated with an ENHANCEMENT 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 lifting and replacement of the flap 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 or after 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.
- \* Complications such as the growth of tissue under the flap (epithelial ingrowth), irregular astigmatism, a healing over-response or under-response, stria (wrinkles) in the flap and irregular wound healing may result in the loss of corrected visual acuity (best vision with glasses and/or contact lenses).
- \* 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.

❖ *As these Vision Threatening Complications (noted above) are beyond the control of the surgeon, additional charges will be incurred with subsequent treatment / surgery. These charges shall be the responsibility of the patient and/or the patient's health insurance.*

### ➤ Non-Vision Threatening Complications

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

- \* I may develop regular astigmatism or corneal irregularities. This could decrease my vision resulting in the requirement of glasses and/or contact lenses to 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 ENHANCEMENT LASIK procedure and this may require further surgical enhancement, a repeat LASIK procedure or other refractive surgery procedure, such as radial keratotomy or astigmatic keratotomy.

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

**Non-Vision Threatening Complications con't.-**

- \* 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. This anisometropia could be permanent.
  - \* 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 additional enhancement procedures. 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 ENHANCEMENT LASIK procedure, the surgeon may determine that the condition of the cornea or the inability to properly align the excimer laser on the cornea may result in the decision to perform PRK (photo-refractive keratectomy) instead of an ENHANCEMENT LASIK. PRK also involves the possible complications discussed in this document.
3. (*FEMALE ONLY*) I am **not** a candidate for an ENHANCEMENT 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 LASIK.
  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 an ENHANCEMENT LASIK.
  5. I am not a candidate for an ENHANCEMENT 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.

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

Patient Statement con't.-

8. This is an elective treatment and is not a treatment I have to have. I also understand that an ENHANCEMENT LASIK is not a reversible procedure.
9. I understand that a three (3) or four (4) month "healing period" between my ENHANCEMENT LASIK and an additional ENHANCEMENT LASIK is necessary should my doctor decide an additional ENHANCEMENT LASIK is required.
10. The rate at which each individual heals plays a critical role in the recovery from Enhancement 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 Enhancement 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 are fully confident in the post-operative care delivered by optometrists affiliated with our office and believe this to be very convenient for most patients. We have full confidence in the clinical competence of your optometrist and monitor this competence on an on-going basis. 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 an ENHANCEMENT 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 ENHANCEMENT 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.
13. Presbyopia, the loss of reading / focusing ability brought on by aging, will continue following Enhancement. This natural, progressive blurring of reading materials, usually after the age of forty (40), will continue due to the normal aging process.
14. 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 ENHANCEMENT 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.

Patient's Initials \_\_\_\_\_

**Alternatives To An Enhancement Lasik Include:**

- \* **Spectacles.** These are the traditional means of correction myopia.
- \* **Contact Lenses.** These often provide better vision than spectacles.
- \* **Radial Keratotomy.** This is an established procedure for low to moderate degrees of nearsightedness and astigmatism.
- \* **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.

**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 an ENHANCEMENT 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 the correction that I expect to obtain from an ENHANCEMENT LASIK may not be perfect. It is not realistic to expect that an ENHANCEMENT 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.

Patient's Initials \_\_\_\_\_

***Statement of Voluntary Participation***

In signing this Informed Consent Form for the lifting of my corneal flap(s) and the use of the excimer laser for performing the ENHANCEMENT 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 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 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 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 ENHANCEMENT LASIK procedure has been made on my own and has been made without duress of any kind. I wish to have:**

ENHANCEMENT LASIK surgery on my **right** eye on \_\_\_\_\_ date

ENHANCEMENT LASIK surgery on my **left** eye on \_\_\_\_\_ date

**By: (circle one)**

**Dr. Edward C. Wade**

**Dr. Gurpreet Singh**

**Dr. Mark Mayo**

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**PATIENT'S NAME (Type or Print)**

**Patient's Date of Birth**

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**PATIENT'S SIGNATURE**

**DATE**

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**WITNESS SIGNATURE**

**DATE**