



Leaders in Eye Care

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## Informed Consent Enhancement Photorefractive Keratectomy (PRK)

**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 Enhancement PRK and alternative forms of treatment.

### INTRODUCTION

Enhancement Photorefractive Keratectomy or PRK is a surgical procedure, which involves the use of an Excimer laser. 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 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.

### PATIENT STATEMENT

**In giving my permission for *Enhancement PRK*, I declare that I understand the following:**

1. The present goal of Enhancement PRK 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. There is no guarantee that your reliance on spectacles and/or contact lenses will be completely eliminated. The risks associated with Enhancement PRK 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 could result in a distorted corneal surface which would not allow spectacles or contact lenses to correct vision to what was possible before the Enhancement PRK 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.
- ❖ 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.

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

➤ **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 Enhancement PRK procedure and this may, in the sole opinion of my surgeon, require further surgical enhancement - a second repeat PRK procedure (ENHANCEMENT PRK) or other refractive surgery procedure. I understand that the appropriateness of an additional ENHANCEMENT PRK or other refractive surgery procedure 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 Enhancement PRK procedure, the surgeon may determine that the condition of the cornea or the inability to properly align the laser on the cornea may result in the decision to not perform Enhancement PRK. Enhancement PRK also involves the possible complications discussed in this document. I also understand that at any time prior to my Enhancement PRK or during the Enhancement PRK surgery my surgeon may determine that he/she believes the Enhancement PRK surgery is not appropriate or recommended and the Enhancement PRK surgery may be cancelled immediately.

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

Informed Consent For Enhancement Photorefractive Keratectomy (PRK). Con't –

3. **(FEMALE ONLY)** I am not a candidate for Enhancement PRK if I am pregnant or nursing, as this may adversely affect 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 Enhancement PRK, I will notify my eye doctor of my pregnancy prior to any consideration of an additional enhancement procedure.
4. I must tell my doctor of any systemic diseases I have, since certain uncontrolled vascular disease, autoimmune diseases, or diseases or drugs (Amiodarone) that suppress the immune system are contraindications to Enhancement PRK.
5. I am not a candidate for Enhancement PRK 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 Enhancement PRK is not a reversible procedure.
9. Following your Enhancement PRK 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, monitor this care on an on-going basis and believe this to be very convenient for most patients. Post- Enhancement PRK exams are recommended for one day, 3-4 days, six weeks, four months and once a year every year following your Enhancement PRK. Any unacceptable risks or complications during or after 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.
10. Dry eye syndrome (DES) is a common eye condition that is occasionally experienced after Enhancement PRK. 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 PRK 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, prescription eye drops 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.
11. I understand that certain complications have been reported in the long-term post-treatment period by patients who have had PRK including:
  - Anterior Stromal Reticular Haze: the loss of perfect clarity of the cornea, usually not affecting vision, which usually resolves over time.
  - Glare: Sensation produced by bright lights that is greater than normal and can cause discomfort and annoyance. Glare may produce temporary reduction in night vision.
  - Halos: Hazy rings surrounding bright lights may be seen particularly at night.
  - Loss of best spectacle or contact lens corrected visual acuity: a decrease in the best-corrected visual acuity with spectacles and/or contact lenses.

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

Informed Consent For Enhancement Photorefractive Keratectomy (PRK). Con't –

- IOP elevation: An increase in the inner eye pressure due to post-treatment medications that is usually resolved by drug therapy or discontinuation of post-treatment medications.

- 12.** Presbyopia, the loss of reading / focusing ability brought on by aging, may coincide (require an initial reading prescription) with Enhancement PRK and will continue following Enhancement PRK. 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.
- 13.** 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 Enhancement PRK.
- 14.** I understand that the following complications have been reported and may occur in the short term post-treatment of Enhancement PRK and are part of the normal post-treatment healing process: These include: pain (first 24 to 48 hours), corneal swelling, double vision, feeling something is in the eye, shadow images, light sensitivity, tearing, itching, reading difficulty and pupil enlargement.
- 15.** Since it is impossible to state every long and short-term complication that may occur as a result of Enhancement PRK, I understand that the above lists of complications are not complete or exhaustive.
- 16.** 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 PRK, yearly examinations are necessary to assess my eye health.

**ALTERNATIVES TO ENHANCEMENT PRK INCLUDE:**

- Spectacles. These are the traditional means of correction myopia.
- Contact Lenses. These often provide better vision than spectacles.

**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. Enhancement PRK does not cause, delay or accelerate the onset of Presbyopia. I can possibly minimize the use of reading glasses if I elect to undergo 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 Enhancement PRK fee, for which you or your insurance company will be responsible.

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

**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 Enhancement PRK 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 Enhancement PRK, may not be perfect. It is not realistic to expect that Enhancement PRK 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 for performing the Enhancement PRK 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 Enhancement PRK is an elective treatment and that I do not have to have this treatment. I understand that the Enhancement PRK treatment is not reversible.

I agree to allow the viewing of my Enhancement PRK procedure by others via a television located in the Eye Center of Texas office or through a window in the surgical suite. If I do not wish others to view my Enhancement PRK 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 regarding this treatment I can call a doctor at (713) 797-1010.

**My decision to undergo the Enhancement PRK procedure has been made on my own and has been made without duress of any kind.**

**I wish to have:**

\_\_\_\_\_ Enhancement PRK surgery on my **right** eye on \_\_\_\_\_ (date)

\_\_\_\_\_ Enhancement PRK surgery on my **left** eye on \_\_\_\_\_(date)

by Dr. \_\_\_\_\_.

\_\_\_\_\_  
PATIENT'S NAME (Type or Print)

\_\_\_\_\_  
DATE OF BIRTH

\_\_\_\_\_  
PATIENT'S SIGNATURE

\_\_\_\_\_  
DATE

\_\_\_\_\_  
WITNESS SIGNATURE

\_\_\_\_\_  
DATE