

**ADDENDUM****PRK (PHOTOREFRACTIVE KERATECTOMY) INFORMED CONSENT**

**Informed Consent.** This PRK Informed Consent is intended to supplement the Vision Correction Surgery Patient Information Form to provide you with additional information concerning PRK surgery so that you can make an informed decision whether to undergo PRK surgery. You should carefully read both the Vision Correction Surgery Patient Information Form and this PRK Informed Consent and discuss all your questions and concerns with your surgeon or personal eye care provider.

**Alternatives to PRK.** The safest alternative to PRK is to continue to wear your eyeglasses or contact lenses and not have PRK. Other surgical alternatives to PRK include LASIK, INTACS, CK and LASEK. To learn more about these procedures, be sure to ask your surgeon or personal eye care provider.

**You May Not Be a Candidate for PRK If You:**

- Have eye inflammation or infection, severely dry eyes, excessive corneal scarring, certain degenerations or dystrophies of the cornea, amblyopia (lazy eye), strabismus (muscle imbalance) or previous strabismus surgery, keratoconus or any recurrent, residual or active eye condition which may affect healing.
- Have a history of Herpes Simplex eye infections, uncontrolled vascular disease, uncontrolled diabetes, an autoimmune disease or rheumatologic conditions, such as lupus or rheumatoid arthritis.
- Are immunocompromised or take medications that may suppress your immune system.
- Have an implanted electronic device such as a pacemaker or defibrillator.
- Have progressive nearsightedness or farsightedness.
- Have previously undergone corneal surgery.
- Have corneal blood vessel growth within 1 mm of the ablation zone.
- Have a history of keloid formation.
- Take certain medications, such as Accutane, Cordarone or Imitrex.

**Risks and Complications of PRK.** This PRK Informed Consent summarizes possible risks and complications associated with PRK; however, it is impossible to list all the potential risks and complications of PRK. Because PRK is a relatively new procedure, certain risks and complications associated with it may be unforeseeable at this time. As a result, it is important to be aware that the long-term studies and results of PRK may reveal additional risks and complications not described in this PRK Informed Consent.

**Vision Threatening Complications.** Certain complications of PRK may seriously affect your vision and may not be correctable with eyeglasses or contact lenses. The most serious complications can result in loss of vision or require a corneal transplant. These complications include:

- Excimer laser malfunction, causing permanent irregularity of the cornea and leading to loss of vision not correctable with eyeglasses or contact lenses.
- Irregular corneal healing, causing distortion, ghost images or scarring.
- Corneal surface defect, swelling or infection, which could lead to permanent scarring or perforation of the cornea.
- Potential for loss of cells lining the inner layer of the cornea, which may cause corneal swelling.
- Decentered treatment causing permanent irregularity of the cornea and leading to loss of vision not correctable with eyeglasses or contact lenses.
- Epithelial healing defects, which could result in delayed healing or infection
- Retinal detachment, venous or arterial blockage of the retina, hemorrhage of the retina, cataract formation, total blindness or loss of the eye.

**Other Complications.** PRK may result in additional complications, including:

- Astigmatism, creating a need for eyeglasses.
- Haze or scar formation dense enough to affect post operative vision, this risk may be higher in patients that have had previous surgery on their cornea.
- Under correction or over correction, causing farsightedness or nearsightedness.
- Worsening of your near vision while improving your distance vision if you are over 40 years of age.
- Complications due to anesthetic drops and other medications used in conjunction with PRK surgery.
- Dry eyes, which is treatable with artificial tears and which usually resolves in 1-3 months, but may be permanent.
- Alteration in your night vision, which for some patients means poorer quality night vision.
- The following common side effects which are usually temporary but which may be permanent: pain and discomfort, foreign body sensation, increased sensitivity to light, glare and halos around lights, fluctuating vision and itching.
- Diminished contrast sensitivity.
- Difference in the image size perceived by each eye, double vision or difference in refractive error between each eye, which can affect your depth perception and may cause eye strain.
- Ptosis (droopy eyelids).

- Permanent change in the shape of the cornea resulting in inability to wear contact lenses if vision changes occur later in your life or if your vision is under corrected or over corrected.
- Regression (loss of your initial favorable result over time) which may not be treatable.
- Difficulty identifying necessary intraocular lens power for cataract surgery lens calculations and predicting refractive outcome.
- Increased intraocular pressure due to post-treatment medications, which is usually resolved by drug therapy or discontinuation of post-treatment medications.
- Death.

**Additional Risks.** Because of the potential risks associated with PRK, it is very important to provide complete and accurate medical information to your surgeon. If you fail to provide complete and accurate information, you may be subject to additional risks and complications or the risk of complications may increase.

**Patient Agreement**

**By signing this PRK Informed Consent, you understand and agree as follows (check all that apply):**

- The information contained in this PRK Informed Consent has been explained to me using terms I could understand, and all my questions and concerns have been addressed.
- I have received and reviewed the Vision Correction Surgery Patient Information Form and the information contained therein has been explained to me using terms I could understand, and all my questions and concerns have been addressed. (For more information regarding PRK, please consult the Vision Correction Surgery Patient Information Form, page 2)
- My clinical findings in relation to the risks of keratectasia have been thoroughly explained to me and I am fully aware of the possible risks and complications associated with vision correction surgery. I understand that there is no absolute test to ensure that I will not develop keratectasia following vision correction surgery, and that while severe keratectasia may need to be treated with a corneal transplant, mild keratectasia can be corrected with the use of glasses or contact lenses. (For more information regarding keratectasia, please consult the Vision Correction Surgery Patient Information Form, page 6)
- I understand that PRK is an elective procedure and hereby freely accept all possible risks, complications and side effects that may result from PRK.
- I understand that no guarantees have been made to me regarding the outcome of PRK, and that I remain financially responsible for all costs associated with the surgery.

**Patient's Signature** \_\_\_\_\_

**Patient's Name (print)** \_\_\_\_\_

**Date** \_\_\_\_\_

**Witness's Signature** \_\_\_\_\_

**Witness's Name (print)** \_\_\_\_\_

**Date** \_\_\_\_\_

**Surgeon's Signature** \_\_\_\_\_

**Surgeon's Name (print)** \_\_\_\_\_

**Date** \_\_\_\_\_