

**ADDENDUM****LASIK (LASER IN SITU KERATOMILEUSIS)/ PRK (PHOTOREFRACTIVE KERATECTOMY)  
INFORMED CONSENT**

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

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

**You May Not Be a Candidate for Surgery 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.
- Had previous 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 LASIK and PRK.** This Informed Consent summarizes possible risks and complications associated with LASIK and PRK; however, it is impossible to list all the potential risks and complications. Because both LASIK and PRK are relatively new procedures, certain risks and complications may be unforeseeable at this time. As a result, it is important to be aware that the long-term studies and results of LASIK and PRK may reveal additional risks and complications not described in this Informed Consent.

**Vision Threatening Complications.** Certain complications of LASIK and 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.
- Microkeratome or Pulsion-FS laser malfunction, causing an abnormal corneal flap and leading to loss of vision not correctable with eyeglasses or contact lenses.
- Decentered treatment 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.
- Epithelial (protective outer layer of the cornea) healing defects, resulting in delayed healing, pain, light sensitivity, infection or growth of epithelium under the corneal flap.
- Wrinkled, slipped, displaced or lost corneal flap.
- Corneal infection, resulting in permanent scarring or perforation of the cornea.
- Corneal inflammation, which may result in scarring, farsightedness, and irregular corneal healing.
- Intractable glare and inability to function in a dark environment.
- Retinal detachment, venous or arterial blockage of the retina, hemorrhage of the retina, cataract formation, total blindness or loss of the eye.
- Complications due to the anesthetic drops or other medications used in conjunction with LASIK.

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

- Astigmatism, creating a need for eyeglasses.

- Under-correction or over-correction, causing farsightedness, nearsightedness or the inability to wear contact lenses.
- Worsening of your near vision while improving your distance vision, if you are over 40 years of age.
- Complications due to the anesthetic drops or other medications used in conjunction with surgery.
- Dry eyes, which is generally treatable with artificial tears and resolves in 1-3 months, but may be permanent.
- The following common side effects, which are usually temporary but which may be permanent: pain or discomfort, foreign body sensation, increased sensitivity to light, glare and halos around lights, haze or fluctuating vision.
- 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).
- 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.

#### **PRK – Specific Complications**

- Corneal haze causing glare, inability to function in dark environments, distortion, halos or loss of best corrected vision.
- Potential for loss of cells lining the inner layer of the cornea, which may cause corneal swelling.
- Corneal surface defect, swelling or infection, which could lead to permanent scarring or perforation of the cornea.
- Epithelial healing defects which could result in delayed healing or infection
- 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.
- Regression (loss of your initial favorable result over time) which may not be treatable - the risk of this complication is greater for patients with greater than negative 6.00 diopters of nearsightedness.

#### **LASIK – Specific Complications.**

- Microkeratome or Pulsion-FS laser malfunction, causing an abnormal corneal flap and leading to loss of vision not correctable with eyeglasses or contact lenses.
- Wrinkled, slipped, displaced or lost corneal flap.
- Corneal inflammation, which may result in scarring, farsightedness, and irregular corneal healing.
- Retinal detachment, venous or arterial blockage of the retina, hemorrhage of the retina, cataract formation, total blindness or loss of the eye.
- Increased vulnerability of your eyes to trauma from impact for the first year or longer after LASIK; it is recommended that you wear protective eyewear when engaging in activities where the possibility of trauma to the eyes exists.

**Additional Risks.** Because of the potential risks associated with LASIK and 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 LASIK Informed Consent, you understand and agree as follows (check all that apply):**

- The information contained in this 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 the LASIK and/or PRK procedures, please consult the Vision Correction Surgery Patient Information Form, page 2)

- I wish to have the following vision correction surgery performed: \_\_\_\_\_. However, I understand that during the surgery my surgeon may, after evaluating my medical condition using his/her best medical judgment, decide to perform the following vision correction surgery instead: \_\_\_\_\_. Having been informed of the possible risks and complications associated with both procedures, I hereby consent to the provision of either procedure as determined by my surgeon based on my medical condition.
- I understand that, during the LASIK procedure, the protective flap of corneal tissue ("corneal flap") may be created using either an instrument called a microkeratome or a Pulsion-FS laser. After a thorough discussion of the benefits, risks, and complications associated with each method, I choose \_\_\_\_\_ to create the corneal flap.
- 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 both LASIK and PRK are elective procedures and I hereby freely accept all possible risks, complications and side effects that may result from the surgery I have chosen.
- I understand that no guarantees have been made to me regarding the outcome of surgery, 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** \_\_\_\_\_