

ADDENDUM**LASEK/EPI-LASIK (LASER ASSISTED SUB-EPITHELIAL KERATECTOMY) INFORMED CONSENT**

Informed Consent. This LASEK/EPI-LASIK Informed Consent is intended to supplement the Vision Correction Surgery Patient Information Form to provide you with additional information concerning LASEK/EPI-LASIK surgery so that you can make an informed decision whether to undergo LASEK/EPI-LASIK surgery. You should carefully read both the Vision Correction Surgery Patient Information Form and this LASEK/EPI-LASIK Informed Consent and discuss all your questions and concerns with your surgeon or personal eye care provider. The United States Food and Drug Administration ("FDA") has not specifically approved the use of the excimer laser for LASEK/EPI-LASIK. However, this procedure is a modification of the technique for which FDA approval was originally granted. These modifications were designed to minimize patient discomfort and shorten the recovery period.

Alternatives to LASEK/EPI-LASIK. The safest alternative to LASEK/EPI-LASIK is to continue to wear your eyeglasses or contact lenses and not have LASEK/EPI-LASIK. Other surgical alternatives to LASEK/EPI-LASIK include PRK, LASIK, CK, INTACS 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 LASEK/EPI-LASIK if You:

- Have herpes simplex eye infection
- Have severely dry eyes
- Have excessive corneal scarring or keloid formation
- Have advanced keratoconus
- Have autoimmune disease, rheumatoid arthritis, lupus, or uncontrolled diabetes
- Take certain medications, such as Accutane or Cordarone
- Have an implanted electronic device such as a pacemaker or defibrillator

Risks and Complications of LASEK/EPI-LASIK. This LASEK/EPI-LASIK Informed Consent summarizes possible risks and complications associated with LASEK/EPI-LASIK; however, it is impossible to list all the potential risks and complications of LASEK/EPI-LASIK. Because LASEK/EPI-LASIK 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 LASEK/EPI-LASIK may reveal additional risks and complications not described in this LASEK/EPI-LASIK Informed Consent.

Vision Threatening Complications. Certain complications of Lasek/Epi-Lasik may seriously affect your vision and may not be correctable with eyeglasses or contact lenses. The most serious complications may 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.
- 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.
- Corneal surface defect, swelling or infection, which could lead to permanent scarring or perforation of the cornea.
- Decentered laser treatment.
- Epithelial healing defects, which could result in delayed healing, infection or growth of epithelium under the epithelial flap.
- Retinal detachment, venous or arterial blockage of the retina, hemorrhage of the retina, cataract formation, total blindness or loss of the eye.

Other Complications. Lasek/Epi-Lasik may result in additional complications, including:

- Astigmatism, creating the need for eyeglasses.
- Under-correction or over-correction, causing farsightedness or nearsightedness.
- If you are over 40 years of age, worsening of your near vision while improving your distance vision.
- 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.
- 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 or 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 in each eye, which may affect your depth perception and may cause eye strain.

- Ptosis (droopy eyelids).
- Permanent change in the shape of the cornea, resulting in the inability to wear contact lenses if vision changes occur later in life or if your vision is under-corrected or over-corrected.
- Regression (loss of your initial favorable result over time) which may or 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.
- Complications due to the anesthetic drops or other medications used in conjunction with surgery.
- Death.

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

- The information contained in this LASEK/EPI-LASIK 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 LASEK/EPI-LASIK procedure, 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 LASEK/EPI-LASIK is an elective procedure and hereby freely accept all possible risks, complications and side effects that may result from LASEK/EPI-LASIK.
- I understand that no guarantees have been made to me regarding the outcome of LASEK/EPI-LASIK, 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 _____