



PATIENT INFORMATION AND INFORMED CONSENT FOR REFRACTIVE SURGERY

I. General Information

The following information is intended to help you make an informed decision about having Laser Assisted In Situ Keratomileusis (LASIK), Laser Sub Epithelial Keratomileusis (LASEK) or Photorefractive Keratectomy (PRK) to correct your vision.

It is impossible to list all of the possible risks and complications associated with these procedures. Risks or complications that are considered to be unforeseeable or remote are not discussed. In addition, because LASIK/LASEK/PRK are relatively recent procedures, there may be long-term effects not known or anticipated at the present time.

II. Background Information on Refractive Surgery

The term "refractive surgery" refers to a group of operations on the cornea (front layer of the eye), designed to decrease a person's "refractive error," thereby improving unaided vision. Refractive errors include myopia (nearsightedness), hyperopia (farsightedness) and astigmatism (asphericity of the cornea). The primary refractive surgical procedures available today are done with the excimer laser. These procedures include LASIK, LASEK and PRK.

III. An Overview of the Procedure

LASIK Surgery Procedure:

LASIK permanently changes the shape of the cornea. The surgery is performed using topical anesthetic drops. The procedure involves creating a thin layer of corneal tissue (corneal flap) with an instrument called a microkeratome (automated blade). Once the flap has been made, it is folded back and the shape of the underlying cornea is altered with the energy of the excimer laser. The flap is then replaced and adheres to the underlying cornea. The removal of corneal tissue causes the center of the cornea to flatten in cases of myopia, steepen in cases of hyperopia or become more rounded in the case of astigmatism. This changes the focusing power of the cornea.

LASEK Surgery Procedure:

LASEK permanently changes the shape of the cornea. The surgery is performed using topical anesthetic drops. The procedure involves using an alcohol solution to loosen the superficial epithelial cells (outermost layer) of the cornea. The cells can then be folded away from the underlying tissue creating a flap without using a microkeratome (automated blade). The shape of the cornea is then altered with the energy of the excimer laser. The superficial cells are then replaced and adhere to the underlying cornea. The removal of corneal tissue causes the center of the cornea to flatten in cases of myopia, steepen in cases of hyperopia or to become more rounded in the case of astigmatism. This changes the focusing power of the cornea.

PRK Surgery Procedure:

PRK permanently changes the shape of the cornea. The surgery is performed using topical anesthetic drops. The procedure involves removing the superficial epithelial cells (outermost layer) of the cornea. The shape of the underlying cornea is then altered with the energy of the excimer laser. The removal of corneal tissue causes the center of the cornea to flatten in cases of myopia, steepen in cases of hyperopia or to become more rounded in the case of astigmatism. This changes the focusing power of the cornea.

Limits of LASIK/LASEK/PRK:

Although the goal of LASIK/LASEK/PRK is to improve vision to the point of not being dependent on glasses or contact lenses, or to the point of wearing thinner (weaker) glasses, this result is not guaranteed. Additional procedures, eyeglasses or contact lenses may be required to achieve best vision. Also, LASIK/LASEK/PRK does not correct the condition called *presbyopia* (aging of the eye), which occurs in most people around age 40 and may require them to wear reading glasses for close-up work. If you presently wear reading glasses, you will likely still need them after the procedure. If you do not wear reading glasses currently, you may need them immediately after the procedure or in the future. LASIK/LASEK/PRK surgery will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts or retinal degeneration or detachments. **Please Note:** LASEK or PRK using *wavefront* technology (custom) is considered an off-label use by the Food and Drug Administration (FDA).

IV. Risks

The risks of LASIK/LASEK/PRK include:

Loss of Vision: LASIK/LASEK/PRK surgery can possibly cause loss of vision or loss of best-corrected vision. This can be due to infection, inflammation, scarring, corneal haze (PRK), induced irregular astigmatism, destruction or loss of the corneal flap, damage to the corneal flap (LASIK), decentration of the corneal flap (LASIK) or laser treatment, corneal ectasia (progressive thinning of the cornea), epithelial ingrowth (abnormal growth of surface cells underneath the corneal flap)(LASIK) or other causes. These conditions may cause permanent decreased vision and may or may not be correctable with spectacles or contact lenses.

Visual Side Effects: Other complications and conditions that can occur with LASIK/LASEK/PRK surgery include: dry eye, anisometropia (difference in power between the two eyes), epithelial ingrowth (abnormal growth of surface cells underneath the corneal flap)(LASIK), aniseikonia (difference in imaging size between the two eyes), double vision, hazy vision, fluctuating vision during the day and from day to day, increased or decreased sensitivity to light that may be incapacitating and may not go away completely, glare and halos around lights that may be incapacitating and, which may not go away completely. Some of these conditions may affect your ability to drive and judge distances and driving should only be done when you are certain your vision is adequate.

Overcorrection or Undercorrection: LASIK/LASEK/PRK surgery may not give you the result you desired. The procedure may result in under or overcorrection. It is also possible that your initial results may regress over time. If these conditions occur, it may be possible or recommended to have an enhancement surgery (re-treatment) to improve

the initial result. In some cases, glasses or contact lenses may effectively correct vision and may be recommended.

Other Risks: Other reported complications include: dry eye syndrome, corneal ulcer formation, endothelial cell loss (loss of cell density on the inner layer of the cornea, possibly resulting in corneal swelling), epithelial healing defects, ptosis (eyelid drooping), corneal swelling, contact lens intolerance, retinal detachment and hemorrhage. Complications could also arise which require further corrective procedures including a partial (lamellar) or full-thickness corneal transplant using donor cornea. These complications include: loss of the corneal flap, damage to the corneal flap, flap decentration, cornea perforation and progressive corneal ectasia (thinning). Sutures could also be required, which may induce astigmatism. It is possible that the microkeratome or the excimer laser could malfunction and the procedure stopped. There are also potential complications due to anesthesia and medications that may involve other parts of your body. Since it is impossible to state all potential risks of any surgery or procedure, this form does not provide a comprehensive listing of every conceivable problem.

Long-term Complications: LASIK/LASEK/PRK are relatively new techniques. You should be aware that other complications might occur that have not been reported yet. Long-term results may reveal additional risks and complications. After the procedure, you should continue to have routine check ups to assess the condition of your eyes.

Cost of Post-Procedure Care: Cost of post-procedure care, including follow up care for one (1) year, is included in the fee for the LASIK/LASEK/PRK procedure. There will be additional charges for medications, punctal plugs (a device for severe dry eye treatment), contact lenses and spectacles if required after surgery.

Risks of Not Undergoing LASIK/LASEK/PRK: The risks of not having the surgery are limited to those associated with your current visual condition. These include the dangers that may be associated with wearing glasses or contact lenses, and the risk of trauma to the eye caused by breakage of spectacles or contact lenses.

V. Contraindications

You should inform your doctor of any past or current medical conditions that you have. Certain medical conditions make patients poor candidates for refractive surgery or may make refractive surgery contraindicated. The procedure is contraindicated in patients who are pregnant, lactating or anticipating pregnancy within the next year.

VI. Alternatives to LASIK

Refractive surgery is entirely elective, and patients may continue to use their existing type of eyewear for vision correction, including glasses and/or contact lenses. THERE IS NO HURRY, URGENCY, OR PRESSURE TO DECIDE TO HAVE REFRACTIVE SURGERY, AND IT MAY BE PERFORMED NOW, LATER, OR NOT AT ALL.

You should discuss these options with your physician.

VII. Pre- and Post- Treatment Care

Before the LASIK/LASEK/PRK Surgery

Pregnancy: Pregnancy or nursing could adversely affect your treatment because refractive errors can fluctuate during these conditions. In addition, pregnancy may affect your ability to heal properly, and some medications may pose a risk to an unborn or nursing child. If you are pregnant, or expecting to become pregnant, you should not undergo LASIK/LASEK/PRK until after the pregnancy. You should not plan on getting pregnant for 12 months following the procedure. If you are currently nursing, you should wait at least three (3) months after cessation of nursing. If it is possible that you are pregnant, you should be tested to determine if you are pregnant. If you become pregnant in the six (6) months following treatment, you should notify your eye doctor immediately.

Medications and Allergies: You should inform your physician of any allergies or medications you are taking including vitamins, herbal supplements or medications used on an occasional basis (such as drugs for headaches). Certain medications are contraindicated in patients undergoing refractive surgery.

Contact lens wearers: Patients who wear gas-permeable or hard contact lenses must stop wearing lenses at least one (1) month prior to the initial eligibility examination (this period may be longer for some patients). Patients who wear soft contact lenses must stop wearing lenses for two (2) weeks, and patients who wear soft toric contact lenses must stop wearing lenses for three (3) weeks prior to the eligibility examination. Following the examination, if both you and your doctor agree that LASIK/LASEK/PRK is an appropriate treatment, you must leave the contact lenses out of the eye(s) to be treated.

Post treatment Precautions

Eye Protection: Avoid exposing the eye to tap water in the bath or shower; nonsterile water may expose the eye to infection. The eye shield should be removed only as directed by your doctor. Use only eye drops prescribed by your doctor after surgery. **Do not rub the eye(s)**. The eye is vulnerable to trauma from impact. Evidence has shown that, even after healing, the corneal incision will not be as strong as the unoperated cornea prior to surgery. Therefore, the eye is vulnerable to all varieties of injury after LASIK/LASEK/PRK, especially for the first year after surgery. It is advisable to wear protective eye wear when engaging in contact or racquet sports or other activities in which the possibility of a ball, projectile, elbow, fist, or other traumatizing object contacting the eye may be high.

Operating Motor Vehicles: After surgery, you may experience star burst-like images or “halos” around lights, your depth perception may be slightly altered, and image sizes may appear slightly different. Some of these conditions may affect your ability to drive and judge distance. Driving should only be done when you are certain that your vision is adequate. On the day of the LASIK/LASEK/PRK procedure, you should arrange to be driven home after the procedure.

Pain and Discomfort: The amount of pain and discomfort that can be expected soon after the LASIK/LASEK/PRK procedure varies with the individual. You should expect that the eye would be painful and sore to some extent after the surgery. Patients who have LASEK or PRK may experience more discomfort. Vision may be blurry, and you may experience some redness and/or corneal edema (swelling of the cornea). Some patients report the sensations of a foreign object in the eye.

VII. Patient Statement

I have read this Informed Consent Form (or it has been read to me). The LASIK/LASEK/PRK procedure has been explained to me in terms that I understand.

I have been informed about the possible benefits and possible complications, risks, consequences, and contraindications associated with LASIK/LASEK/PRK. I Understand that it is impossible for my doctor to inform me of every conceivable complication that may occur, and that because LASIK/LASEK/PRK are relatively new procedures, there may be unforeseen risks. I have been given the opportunity to ask questions and have received satisfactory answers to any questions I have asked. I understand that no guarantee of a particular outcome was given and that my vision could become better or worse following treatment.

My decision to undertake the LASIK/LASEK/PRK procedure was made without duress of any kind. I understand that LASIK/LASEK/PRK is an elective procedure, and my myopia or hyperopia and/or astigmatism may be treated by alternative means, such as spectacles, contact lenses, or other forms of refractive surgery. It is hoped that LASIK/LASEK/PRK will reduce or possibly eliminate my dependency on glasses or contact lenses. I understand that the correction obtained may not be completely adequate and that additional correction with glasses or contact lenses may be needed. I have had an opportunity to ask any questions related to this form and have received a satisfactory answer.

I authorize the physicians and other health care personnel involved in performing my LASIK/LASEK/PRK procedure and in providing my pre- and post-procedure care to share with one another any information relating to my health, my vision, or my LASIK/LASEK/PRK procedure that they deem relevant to providing me with care.

I consent to have **LASIK / LASEK / PRK** performed on my **Right / Left / Both** eyes.

Patient Name

Patient Signature

Date

Witness Signature

Date

Physicians Name

Physician Signature

Date