



**SUBJECT INFORMED CONSENT FORM**  
Excimer Laser in situ Keratomileusis (LASIK)

1. Patient Name: \_\_\_\_\_

**2. Introduction:** This form contains information regarding Excimer Laser in situ Keratomileusis (LASIK). This surgery is used to treat nearsightedness, farsightedness and astigmatism. Please read this information carefully! Also we encourage you ask any questions you may have regarding this procedure since it is important that you understand the nature of this surgery before making your decision. Every surgical procedure has risks associated with the benefits received, and each person has the right to decide based on their understanding of the risks/rewards associated with LASIK. This form and the associated video are critical components in that process.

**3. Description of Procedure:** LASIK effects the outermost portion of the eye, the cornea. A topical anesthetic (eye drops) are used to numb the eye. A thin layer of corneal tissue (a corneal flap) is created and folded back and then a cool, Excimer laser is used to remove a precise portion of the resulting corneal bed. Since this reshapes the cornea, light is now focused more correctly on the back of the eye, generally resulting in improved vision. The flap is replaced and it adheres to the corneal bed with no stitches required. After LASIK, the ideal would be no need for glasses but individual results vary and in some cases thin glasses or reading glasses may be required.

You should understand that LASIK surgery will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, retinal degeneration or detachment. After the procedure you should avoid rubbing the eye. Your eyes may be more susceptible to traumatic injury and protective eyewear is recommended for all contact and racquet sports where a direct blow to the eye could occur. Also, LASIK does not correct the condition known as presbyopia (or aging of the eye) which occurs to most people around age 40 and may require them to wear reading glasses for close-up work. People over 40 that have their nearsightedness corrected may find that they need reading glasses for clear, close vision.

During pregnancy your refractive error can fluctuate which could influence your results. If you know you are pregnant or attempting to become pregnant within the next three months, it is important that you advise your doctor immediately. You should also tell your doctor about any medications that you are taking such as hormone replacement therapy or antihistamines as they may influence healing.

**4. Traditional Correction of Refractive Errors:** Eyeglasses remain the most common method of correcting refractive errors. Glasses are safe, relatively inexpensive and when tolerated well, they are likely to be a good alternative to LASIK surgery.

Contact lenses are much like glasses. Contacts rest directly on the cornea and, when fitted and used properly, are effective and relatively safe.

Radial Keratomileusis (RK) was brought to the U.S. in 1979. It involves making deep cuts (90% of the corneal thickness) in a radial or spoke-like fashion. The amount of nearsightedness that can be corrected with RK is relatively limited.

Keratomileusis refers to removing the surface of the cornea, exposing the underlying bed. This was first done by Dr. Barraquer in South America. Currently, a microkeratome is used to create a hinged flap or cap. In Automated Lamellar Keratoplasty (ALK), the microkeratome makes a second pass and the tissue is removed and discarded. In LASIK, the laser sculpts a new shape on the corneal bed.

Refractive surgery is continually evolving and in the future other refractive procedures may be available as an alternative to LASIK. New LASIK technology such as "Wavefront" also bring potentially better results to a broader range of patients.

**5. Potential Risks: Vision Loss.** LASIK surgery can possibly cause a reduction in overall vision. This can result from infection, scarring or other causes. The use of antibiotics, steroids or other treatment can control these but in extremely rare cases, the affected eye may be lost. The cornea may heal irregularly and the added astigmatism could make wearing glasses or contact lenses necessary. Improper healing may also make it impossible to wear contact lenses after LASIK.

**Improper Correction.** Although every precaution is taken to insure quality there is always an element of uncertainty in any surgical procedure. It is possible that your vision may be over or under corrected. If you are undercorrected, additional fine-tuning called an enhancement surgery may be required. During an enhancement the corneal flap is re-lifted and the corneal bed is reshaped slightly to improve results. Sometimes overcorrections will diminish with time but each case must be evaluated on an individual basis. It is also possible for an initially good result to decrease over time.

**Visual Imperfections.** There are several other complications that can occur after LASIK surgery. These may include: amisometropia (power differences between the two eyes): anisikonia (different image size between the two eyes), double vision, hazy vision, fluctuating vision, increasing sensitivity to light, which may never go away and glare and halos around lights. Driving and judgement of distances can be effected so driving should only be resumed when your vision is acceptable.

**Other risks:** Other reported conditions have included: corneal ulcers: endothelial cell loss, epithelial healing defects; ptosis (droopy eyelid); corneal swelling, retinal detachment and hemorrhage. Complications could also arise requiring further corrective procedures including either a partial (lamellar) or full thickness corneal transplant using a donor cornea. These complications include loss of corneal disc, damage to the corneal disc, disc decentration and progressive corneal thinning (ectasia). Sutures may also be required which could induce astigmatism. There are also potential complications due to anesthesia and medications that may involve other parts of your body. It is also possible that the microkeratome or the excimer laser could malfunction and the procedure stopped. It is impossible to list all potential complications so this list is incomplete. Simply put, in any surgery there are risks, even though every precaution is taken to guard against them.

**Dry Eye:** Dry eye is fairly common in those older then the middle 30's. It also is found among contact intolerant individuals. LASIK can make this condition worse temporarily. In most cases, the eye usually returns to its pre-LASIK state within several months. In some cases the increased dry eye may be permanent, requiring the placement of punctual plugs and/or the permanent use of artificial tears.

**6. Post-Operative instructions:** After your surgery you will be given medications and instructions to help prevent infection and promote healing. It is CRITICAL that you follow ALL instructions exactly as they are given to you. Follow up visits with your eye doctor are also a vital factor in producing a good outcome for your vision.

**7. Elective Clause:** This procedure is elective. There is no medical necessity that it be done.

**8. Consent:** By signing this form, you are stating that you have read it and although it contains medical terms which you may not completely understand, you have had the opportunity to ask questions and had them answered to your satisfaction. You have also viewed the video and understand and answered the questions presented at the bottom of this form.

Your surgery may be video taped for analysis. By signing this form you agree to release this recording and medical data related to your surgery to PCVI, physicians and others, if needed, for clinical research.

To assure that you understand the information presented in this form, please print the following statement on the lines provided below: "I have read/watched and understand the information in this form and the accompanying video. I understand that there are risks and I may need glasses, contact lenses or further surgery following LASIK to achieve my best possible level of vision."

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I wish to have the LASIK procedure performed on (please circle) Left Right Both eye(s) by surgeon, \_\_\_\_\_, on \_\_\_\_\_, 20\_\_\_\_.

**Patient Signature:** \_\_\_\_\_ **Date** \_\_\_\_\_

**Witness Signature:** \_\_\_\_\_ **Date** \_\_\_\_\_

**Physician Signature:** \_\_\_\_\_ **Date** \_\_\_\_\_

#### QUESTIONS ABOUT LASIK

Please answer the following questions to confirm your understanding of the LASIK procedure.

1. T F : Everyone that has LASIK will see 20/20 after the surgery.
2. T F : There are alternatives to LASIK for vision correction.
3. T F : You may become more sensitive to light after the surgery resulting in halos at night, which may be permanent.
4. T F : You don't need to see your eye doctor after the surgery.
5. T F : There is a procedure called an enhancement that you could require after the surgery.
6. T F : It is important to follow all the doctors' instructions during the surgery.
7. T F : There is no possibility that LASIK could damage your vision.
8. T F : The discomfort can be mild or moderate pain following the LASIK procedure.
9. T F : After LASIK you will never need glasses.
10. T F : All the risks for LASIK are known and covered in either this form or the consent video.

Answers:

1. False: Everyone's results will vary depending on several factors.
2. True: There are several alternatives such as PRK, glasses or contacts.
3. True: In some cases sensitivity to light may increase. Usually this will moderate over time but not always.
4. False: Follow up visits to your eye care provider are important to your recovery.
5. True: Enhancements occur in approximately 5% of LASIK patients.
6. True: Following the doctor's direction during the surgery is critical to a successful outcome.
7. False: In any surgery there are risks. With eye surgery this may include loss of vision.
8. True: Usually there is little or no pain from LASIK, but occasionally there may be a degree of discomfort.
9. False: As you age, normally your eyes will require some correction whether you have LASIK or not.
- 10: False: As time goes on we learn more and more about LASIK and the risks and benefits involved