

**INFORMED CONSENT FOR:  
Excimer Laser in situ Keratomileusis (LASIK)**

Patient name: \_\_\_\_\_

**1. 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 to 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.

**2. Description of the procedure:** LASIK affects 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 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, cataract, 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-up 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 you advise your doctor immediately. You should tell your doctor about any medications that you are taking, such as hormone replacement therapy, or antihistamines as they may influence healing.

**3. 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. Refractive surgery is continually evolving, and in the future, other refractive procedures may be available as an alternative to LASIK.

**4. 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 ensure 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 under-corrected, a touch-up enhancement surgery may be required. During an enhancement, the cornea is reshaped slightly to improve results. Sometimes over-corrections will diminish with time, but each case must be evaluated on an individual basis. It is also possible for a good result to decrease over time.

**Visual Imperfections:** There are several other complications that can occur after LASIK surgery. These may include: anisometropia (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 affected, so driving should only be resumed when your vision is acceptable.

**Keratoconus:** I understand that I could develop Keratoconus. Keratoconus is a degenerative corneal disease affecting vision that occurs in approximately 1/2000 in the general population. While there are several tests that suggest which patients might be at risk, this condition can develop in patients who have normal pre-operative topography (a map of the cornea obtained before surgery) and pachymetry (corneal thickness measurement). Since keratoconus may occur on its own, there is no absolute test that will ensure a patient will not develop keratoconus following laser vision correction. Severe keratoconus may need to be treated with corneal transplant, while mild keratoconus can usually be corrected by glasses or contact lenses.

**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 possible 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 patients, especially in those who have a lot of screen time (phone, computer, TV), those not tolerating contact lenses, and those whose contacts or glasses screen wind. Also, dry eye increases with age, regardless of whether or not you have had LASIK. 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, resulting in the placement of punctal plugs and/or the permanent use of artificial tears.

5. **Health of the Rest of the Eye:** LASIK does not affect the health of the rest of the eye, As you age, you will likely need reading glasses once you get into the 40s, get cataracts once you approach the 60s, and may develop glaucoma, diabetes, macular degeneration, dry eye, or other eye problems just with the natural course of life.
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 videotaped 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, please print the following statement on the lines provided below: "I have read/watched and understand the information in this form and 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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My physician has explained to me in a way that I understand:

- a. The above treatment or procedure to be undertaken.
- b. There may be other procedures or methods of treatment.
- c. There are risks to the procedure or treatment proposed.
- d. I consent to the treatment or procedure and the above listed items (1-7). My physician has also asked if I want a more detailed explanation, but I am satisfied with the informed consent, and do not want more information.

I wish to have the LASIK procedure performed on (please circle) Left    Right    Both    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 corrections.
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 surgery.
6. T    F    It is important to follow all the doctor's 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 either in this form, or in 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 patients.
6. True: Following the doctor's directions 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 to 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.