



## **INFORMED CONSENT TO HAVE LASIK**

This information is to help you make an informed decision about having Laser Assisted IntraStromal Keratomileusis (LASIK), an elective laser vision correction procedure to treat your nearsightedness, farsightedness, and/or astigmatism. Take as much time as you wish to make a decision. You are encouraged to ask any questions and have them answered to your complete satisfaction before giving your permission to have surgery. Every procedure has risks as well as benefits and each person must evaluate this risk/benefit ratio for himself/herself in light of the information that follows. The only way to avoid all of the risks of LASIK is to not have the surgery. Spectacles and contact lenses are the most common methods of correcting nearsightedness (myopia), farsightedness (hyperopia), and astigmatism. When tolerated well, they are good alternatives to LASIK.

LASIK permanently changes the shape of the cornea. The procedure is performed under a topical anesthetic (drops in the eye). The procedure involves folding back a thin layer of corneal tissue (corneal flap) and then removing a thin layer of corneal tissue with the light from an excimer laser. After removal, the flap is repositioned and bonds back into place without the need for stitches. The result of removing thin layers of tissue causes the center of the cornea to flatten in the case of nearsightedness, steepen in the case of farsightedness or become more rounded in the case of astigmatism, which changes the focusing power of the cornea. Although the goal of LASIK is to improve vision to the point of not being dependent on glasses or contact lenses or to the point of wearing thinner (or weaker) glasses, this result is not guaranteed. Refractive surgery is continually evolving and other procedures may be available as an alternative to LASIK.

You must understand that LASIK 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 after LASIK 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 nor prevent the condition known as presbyopia (aging of the eye), which occurs to most people around age 40 and may require reading glasses for close-up work. Nearsighted people over 40 may need reading glasses for clear, close vision after having corrective surgery. You

Patient Initials \_\_\_\_\_ Date: \_\_\_\_\_

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should also be aware that having any refractive procedure could potentially disqualify you from some professions, including the military and certain law enforcement agencies.

During pregnancy your refractive error can fluctuate which could influence 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. Also, be sure that you have fully disclosed to your doctor your medical history, current conditions and any medications that you are taking prior to your surgical procedure, even conditions that may seem unrelated to your eyes. Certain conditions may increase the risk of complications from the procedure.

**POTENTIAL MATERIAL RISKS AND OTHER CONSIDERATIONS OF LASIK INCLUDE:**

**1. OVER-RESPOND AND UNDER-RESPOND.** It may be that laser vision correction will not give you the result you desire. Everyone's eye heals differently and even our best efforts and calculations do not always predict your precise treatment. Occasionally it may be possible or necessary to have additional surgery to fine tune or enhance the initial result. Results from any surgery cannot be guaranteed. It is possible that your initial results could regress over time. In some, but not all cases, re-treatment could be considered.

**2. VISUAL SIDE EFFECTS.** Other complications and conditions that can occur with LASIK include: anisometropia (difference in power between the two eyes), aniseikonia (difference in image size between the two eyes), double vision, hazy vision, fluctuating vision during the day and from day to day, increased sensitivity to light which may be incapacitating for some time and may not completely go away, reduced contrast sensitivity (reduced vision in dim light conditions), dry eyes, glare, halos or starbursts around lights which may not completely go away. 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.

**3. LOSS OF VISION.** There is a possibility that LASIK can cause loss of vision or loss of best-corrected vision. This can be due to infection, inflammation or irregular scarring or other causes, and unless successfully controlled by antibiotics, steroids or other necessary treatment, could result in the loss of functional vision in one or both eyes. This can also be due to corneal perforation, which can result in the loss or damage of the natural lens, infection, and/or the need for an intraocular lens implant, corneal transplant or, rarely, blindness. Vision loss can be due to the cornea healing irregularly which could result in irregular astigmatism, making it necessary for you to wear glasses or contact lenses that still may not fully correct your vision. It is also possible that you may not be able to successfully wear contacts after LASIK.

4. **OTHER RISKS:** Additional reported complications include: corneal ulcer formation, 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 flap, damage to the corneal flap, flap 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, which may involve other parts of your body. It is also possible that the microkeratome or the excimer laser could malfunction and the procedure would need to be stopped. **Since it is impossible to state all potential risks of any surgery, this form is incomplete.**

5. **FUTURE COMPLICATIONS:** You should also be aware that there are other complications which could occur that have not been reported before the creation of this consent form, as LASIK has been performed only since the early 1990's and longer-term results may reveal additional risks and complications.

6. **OFF-LABEL:** Use of the excimer laser for LASIK to correct myopia in excess of FDA approved parameters is considered an "off-label" use of an approved medical device. Off-label usage of FDA approved devices and drugs is commonly practiced by physicians without interference from the FDA and allows physicians to practice medicine in a manner they feel most beneficial to their patients.

7. **PRE-PROCEDURE INSTRUCTIONS:** **It is imperative that you follow the physician's instructions to stare directly at the fixating light throughout the procedure due to the sophisticated computerized eye tracking feature.**

8. **POST-PROCEDURE INSTRUCTIONS:** After your procedure you will be given medications and instructions to help prevent infection and control healing. You may experience mild to moderate discomfort. **It is imperative that you follow instructions exactly as they are given to you. It is also imperative that all follow-up visits be kept as directed.** Daniel V. Zimmer, M.D. will be performing your surgery, and once surgically stable, your post-operative care will be completed by \_\_\_\_\_. To ensure the best care, both doctors will be available by appointment or by phone to address any questions or problems related to your surgery. Care relating to surgery will be provided at no additional charge to you, for one full year post-operatively.

## QUESTIONS ON LASIK INFORMED CONSENT

The following questions cover important information. **Please circle the correct answer.**

1. **TRUE OR FALSE:** LASIK and use of the excimer laser to correct myopia in excess of FDA-approved guidelines is considered an “off-label” use of approved excimer lasers by the Food and Drug Administration.
2. **TRUE OR FALSE:** There are no guarantees as to exactly how well you will see after the procedure.
3. **TRUE OR FALSE:** LASIK is the only way to correct your refractive error(s).
4. **TRUE OR FALSE:** You may experience vision irregularities such as halos and glare after your surgery and you may be more sensitive to light, which in some cases could be permanent.
5. **TRUE OR FALSE:** After the surgery, follow-up visits are not important.
6. **TRUE OR FALSE:** It is possible that another operation may be necessary after LASIK to obtain the best level of vision correction.
7. **TRUE OR FALSE:** It is very important that you look at the fixating light during the laser treatment.
8. **TRUE OR FALSE:** There is the possibility that the LASIK procedure could cause loss of vision.
9. **TRUE OR FALSE:** You may experience mild to moderate discomfort for several days after the procedure.
10. **TRUE OR FALSE:** LASIK will eliminate the need for reading glasses when you are over 40 years of age.

Please check your answers with the correct answers on the following page and mark any that you missed. If you are still unsure as to why you missed any of these questions, take the form to the doctor or staff member for an explanation.



## MONOVISION CORRECTION

After the age of 40, many people begin to notice a decrease in their ability to read or focus on close up objects. This condition, called presbyopia, is a natural consequence of the aging of the eye. Monovision correction is a way to help compensate for this condition. In monovision, one eye, usually the dominant eye is corrected fully for distance vision. The other eye is slightly undercorrected to help reading vision. The undercorrected eye then has less sharpness for distance viewing. While monovision correction is helpful for situations like reading a menu at a restaurant or looking at one's wristwatch, individuals may still require glasses for night driving or reading a phone book (fine print). People over the age of 35 may want to consider monovision correction as a way to compensate for presbyopia. People who require the best distance vision possible should avoid monovision and recognize that after surgery they will need to wear reading glasses for close up vision.

By signing below you acknowledge your doctor has discussed this matter with you and you consent to have monovision correction: I wish to have monovision correction with my  
 **Right eye**  **Left eye** corrected for **DISTANCE**.

Patient Signature \_\_\_\_\_ Date \_\_\_\_\_

In signing below, you are stating that you have read this consent form and although it contains medical terms which you may not completely understand, you have had the opportunity to ask questions and have had them answered to your complete satisfaction. To assure that you have understood the information presented, **please copy the following statement in your own handwriting: "I understand the information presented and am willing to accept the fact that I may need glasses or contact lenses or further procedures following LASIK to achieve my best possible level of vision."**

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Making an informed decision, I give my permission to have Laser Assisted Intrastromal Keratomileusis (LASIK) performed on my:  **Right eye**  **Left eye**  **Both eyes**

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

Authorized Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
(InSight Staff Member)

Optometrist Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Surgeon Signature: \_\_\_\_\_ Date: \_\_\_\_\_

*Surgeon's Notes:*

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