

SightLine Laser Eye Center, LLC
INFORMED CONSENT FOR LASER IN-SITU KERATOMILEUSIS (LASIK)

I. INTRODUCTION

This information is being provided to you so that you can make an informed decision about the use of a device known as a microkeratome, combined with the use of a device known as an excimer laser, to perform LASIK. LASIK is one of a number of alternatives for correcting nearsightedness, farsightedness, and astigmatism (refractive error). In LASIK, the microkeratome is used to create a flap in the cornea. The flap then is opened like the page of a book to expose tissue just below the cornea's surface. Next, the excimer laser's cold beam is used to remove ultra-thin layers from the cornea to reshape it in order to reduce the refractive error. Finally, the flap is returned to its original position, without sutures.

LASIK is an elective procedure: There is no emergency condition or other reason that requires or demands that you have it performed. You could continue wearing contact lenses or glasses and have adequate visual acuity. While most patients will never have a serious complication and most patients are excited about their results, this procedure, like all surgery, presents some risks. It is not our intention to alarm you or dissuade you from having this procedure, but we must attempt to inform you to the best of our ability of the possible complications so you can make an informed decision about proceeding with LASIK. It is impossible to inform you of every conceivable complication. You should also understand that there might be other risks not known to your doctor, which may become known later. Despite the best of care, complications and side effects may occur. Should this happen in your case, the result might be affected even to the extent of making your vision worse. The only way to completely eliminate the possibility of complications is by not having this procedure.

ALTERNATIVES TO LASIK

There are methods, other than LASIK, of correcting your vision. Alternatives for nearsightedness, farsightedness and astigmatism include, among others, eyeglasses, contact lenses, Radial Keratotomy (RK), Astigmatic Keratotomy, clear lens extraction with the implantation of an intra ocular lens (IOL), Photorefractive Keratectomy (PRK), Epi-LASIK (LASEK).

II. PATIENT CONSENT

In giving my permission for LASIK, I will declare that I understand the following: The long-term risks and effects of LASIK are unknown. I have received no guarantee as to the success of my particular case. I understand that the following risks are associated with the procedure:

VISION RISKS

1. There may be increased sensitivity to light, glare, and fluctuations in the sharpness of vision. These conditions usually occur during the normal stabilization period of from one to three months, but they may also be permanent.
2. **Glare:** At night there may be a "star-burst" or halo effect around lights. This condition usually diminishes with time. However, **this glare could be permanent and may be serious enough to prevent you from driving or performing other activities at night.** You should not drive until your vision is adequate both during the day and at night.

Over/Under Correction & Enhancement

3. Over or under correction could occur, requiring future enhancement procedures, such as more laser treatment, Astigmatic Keratotomy, or the use of glasses or contact lenses. .

Patient Initials _____

4. Under some circumstances only one eye may be treated even if the pre-operative plan is to treat both eyes. The surgeon may elect not to proceed with the second eye because of unanticipated problems with the first eye. There may be a "balance" problem between the two eyes if LASIK is performed on one eye, but not the other. This phenomenon is called anisometropia. This could cause eyestrain and make judging distance or depth perception more difficult. If that eye takes longer to heal than usual, this would prolong the time the imbalance symptoms could persist.
5. Following surgery, if the uncorrected refractive error is significant and causing vision distress, enhancement surgery may be performed when vision is stable UNLESS it is unwise or unsafe. If you are not seeing adequately, an assessment of the need for an enhancement will be made by your doctor, and then the risks and possible benefits of an enhancement will be discussed.
6. If the enhancement is performed within the first six months following the procedure, there generally is no need to make another incision with the microkeratome. The original flap can usually be lifted with specialized techniques. After 6 months of healing, a new LASIK incision may be required. In order to perform an enhancement surgery, there must be adequate tissue remaining. If there is inadequate tissue, it may not be possible to perform an enhancement.
7. Following LASIK, the eye may be more fragile to trauma from impact. Evidence has shown that, as with any scar, the corneal incision will not be as strong as the cornea originally was at that site. A treated eye, therefore, is somewhat more vulnerable to all varieties of injuries, at least for the first year following LASIK. It would be advisable to wear protective eyewear when engaging in sports or other activities in which the possibility of a ball, projectile, elbow, fist, or other traumatizing object contacting the eye may be high.
8. There may be pain or a foreign body sensation, particularly during the first 48 hours after this procedure.
9. Infrequently, the outer layer of the cornea (epithelium) is disturbed during the procedure. This can result in extreme discomfort requiring the short-term use of a contact lens and other drops. This discomfort could last for longer than a week, interfere with vision and increase the risk of epithelial ingrowth.
10. This procedure may cause or exacerbate eye dryness that can result in significant discomfort. This dryness could be severe enough to cause vision decrease. This condition could require therapy that could be expensive and yet ineffective.
11. Temporary glasses either for distance or reading may be necessary while healing occurs and more than one pair of glasses may be needed.
12. The effects of LASIK beyond seven years presently are unknown. Unforeseen complications or side effects could occur in the future.
13. The visual acuity initially gained from LASIK could regress, and vision could drift away from the original result over time requiring the use of glasses, contacts, or additional surgery in the future.
14. You may be given medication in conjunction with the procedure and your eye may be patched afterward. You must not drive for at least one day following the procedure and not until your doctor determines that your vision is adequate for driving.
15. If you currently need reading glasses or bifocals, you will still likely need reading glasses after this treatment if both eyes are corrected for distance. It is possible that dependence on reading glasses may increase or that reading glasses may be required at an earlier age if you have LASIK. By correcting one eye for distance and the other eye for near vision (monovision) you likely will reduce your dependence on reading glasses. If you do not need reading glasses now, and have both eyes treated for distance, you will need reading glasses in the future.

My doctor has discussed mono vision with me and I have elected:

to have mono vision treatment

not to have mono vision treatment.

Patient Initials _____

16. The correction that you can expect to gain from LASIK may not be perfect. It is not realistic to expect that this procedure will result in perfect vision, at all times, under all circumstances, for the rest of your life. You may need glasses to refine your vision for some purposes. In the future your vision might change, increasing the need for glasses. Vision after surgery might not reach pre-surgery corrected levels.
17. As with all types of surgery, there is a possibility of complications due to anesthesia, drug reactions, or other factors that may involve other parts of the body. Because it is impossible to state every complication that may occur as a result of any surgery, the list of complications in this form may not be complete.
18. You must make your doctor aware of electronic implants such as a cardiac pacemaker, insulin pump etc.
19. You must make your doctor aware if you are pregnant or nursing. If you are pregnant or nursing, it is best to delay LASIK.

EYE THREATENING COMPLICATIONS

1. The microkeratome or the excimer laser could malfunction, requiring the procedure to be stopped before completion. Depending on the type of malfunction, this may or may not be accompanied by visual loss.
2. In using the microkeratome, instead of making a flap, an entire portion of the central cornea could be cut off, and very rarely could be lost. If preserved, the surgeon would put this tissue back on the eye after the laser treatment. This usually causes no vision reduction, but if the corneal tissue is lost or damaged the visual loss can be significant. It is also possible that the flap incision could result in an incomplete flap, or a flap that is too thin. If this happens, it is likely that the laser part of the procedure will have to be postponed until the cornea has a chance to heal sufficiently to create the flap again.
3. In the LASIK procedure irregular healing may still occur. Irregular healing of the flap could result in a distorted cornea. This would mean that glasses or contact lenses might not correct vision to the level possible before undergoing LASIK. Lasik surgery also weakens the underlying cornea. Calculations are made to minimize this weakening, however, if distortion in vision or weakening of the cornea is severe, a partial or complete corneal transplant might be necessary.
4. It is possible that a perforation of the cornea could occur causing devastating complications, including the loss of some or all of your vision.
5. Mild or severe infection is possible. Mild infection can usually be treated with antibiotics and usually does not lead to permanent visual loss. Severe infection, even if successfully treated with antibiotics, could lead to permanent scarring and loss of vision that may require a corrective laser procedure or, if very severe, corneal transplantation. Other very rare complications threatening vision include, but are not limited to, retinal detachment, hemorrhage, venous and arterial blockage, cataract formation, total blindness and even loss of your eye.
6. Corneal inflammation (interface keratitis) may occur which can lead to corneal hazing, corneal irregularity, farsightedness and blurred vision. This is usually successfully treated with steroid drops or subsequent laser treatment but may result in reduced vision.
7. Epithelial cells (the outer layer of the cornea) can lodge and grow underneath the flap. Rarely, these must be removed by lifting the flap and clearing the cells away. If this ingrowth is severe enough it can result in melting of the flap and severe visual loss.

TREATMENT OF BOTH EYES AT THE SAME TIME

I understand that I can elect to have both eyes treated at one time or one eye at a time. There are advantages and disadvantages to both. The imbalance between the two eyes while waiting to have the second eye done is the major disadvantage of doing one eye at a time. Patients usually prefer having both eyes done together for reasons of convenience. However, treating both eyes together exposes both eyes to the risk of infection at the same time. While very unlikely, infection can cause severe vision loss. It is possible that any of the above complications could occur in both eyes, if both eyes are done simultaneously. Treating one eye also allows for adjustment to the treatment level of the second eye based on the first eye's result.

Patient Initials _____

DRIVING RESTRICTION

The above conditions, if severe enough, could cause best corrected vision to drop below 20/40. If this occurs in both eyes, your license to drive a car could be limited or revoked. Glare could be severe enough to prevent you from driving at night. In some patients healing is slow and the return to good vision is delayed. Driving could be restricted during this period. If, prior to LASIK, you already have reduced vision in one eye, you must seriously consider the risk of licensure loss if LASIK is being performed on your best eye.

EXPECTATIONS

I understand that laser vision correction is intended to reduce my dependence on glasses or contact lenses. There have been no guarantees or promises made to me that this procedure will eliminate my need for glasses or contact lenses. I also understand that I could experience any of the above complications and these could cause a reduction in my best corrected vision.

Patient Initials _____

MEDICATION & HEALTH HISTORY DISCLOSURE

Certain medications, as well as certain eye and general health conditions can affect the outcome of the procedure. If you are pregnant or nursing you should not have this procedure. You must inform your eye doctor of all medications you are taking and of any history of eye or general health problems.

Patient Initials _____

MANAGEMENT OF CARE

I understand that my referring eye doctor (optometrist / ophthalmologist) will direct my care both before and after the procedure. This care arrangement has been approved by the surgeon. I understand that my eye doctor accepts the responsibility for the pre- and post-operative care and will notify SightLine Laser Eye Center of any complications and will provide periodic written reports on my post-operative progress. The SightLine Laser Eye Center staff and surgeon will manage my care during the time of my procedure at the Center. I understand that both my eye doctor and the SightLine surgical staff are available to me for care throughout the pre- and post-procedure period.

Patient Initials _____

PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

The procedure known as LASIK has been presented to me in detail in this document and explained to me by my eye doctor. My eye doctor has answered all my questions to my satisfaction. I therefore consent to having LASIK. I give my permission to use data about my procedure and subsequent treatment to further understand LASIK. I understand that my name will remain confidential, unless I give subsequent written permission for it to be disclosed outside my doctor's office or the center where my LASIK procedure will be performed.

Eyes To Be Treated: Right Eye (OD) Left Eye (OS) Both (OU)

Print Name _____

Patient Signature _____ Date _____

Witness Signature _____ Date _____

(I have reviewed this consent document with my patient, and I agree to fulfill my responsibilities as the case managing doctor.)

Eye Doctor Signature _____ Date _____

Surgeon Signature _____ Date _____

I have been offered a copy of this consent form (please initial) _____