

INFORMED CONSENT FOR LASER ASSISTED STROMAL IN-SITU KERATOMILEUSIS (LASIK)

you are entitled to be informed about the proposed LASIK, including the risks of the treatment and alternatives to it. please read this document thoroughly and discuss the content with your doctor so that all of your questions are answered to your satisfaction.

This information is provided to allow you to make an informed decision about the use of a device known as an excimer laser, combined with the use of a device known as a microkeratome, to perform a refractive surgical procedure called "laser assisted stromal in-situ keratomileusis" (LASIK). LASIK is a procedure designed to attempt to correct your nearsightedness (myopia), farsightedness (hyperopia) and/or astigmatism.

PATIENT STATEMENT

I have nearsightedness (myopia) or farsightedness (hyperopia), resulting in (+) 4.00 to (-) 15.00 diopters of refractive error, with astigmatism of 0.0 to 4.00 diopters, which requires me to wear corrective lenses in order to see clearly for my daily activities. I have been clearly informed of the alternatives including eyeglasses, contact lenses and other refractive surgery techniques. I have decided to undergo LASIK with the excimer laser and microkeratome.

In giving my permission for the LASIK surgery, I declare that I understand the following information.

The goal of the LASIK treatment, with the excimer laser and microkeratome, is to reduce or eliminate myopia and/or hyperopia within the refractive error of between (+) 4.00 and (-) 15.00 diopters and 0.0 to 4.00 diopters of astigmatism, thereby reducing my dependence or need for (distance) contact lenses and/or eyeglasses.

I understand that as with all forms of treatment, the results in my case cannot be guaranteed; there is no guarantee that I will completely eliminate my reliance on eyeglasses and/or contact lenses. It is possible that the treatment could result in under correction or over correction, where some degree of myopia or hyperopia may remain requiring the use of glasses or contact lenses. It is possible that dependence on reading glasses may increase or reading glasses may be required at an earlier age. The treatment may also result in an under or over correction or other change in astigmatism that could require the use of glasses and/or contact lenses. I understand further treatment may be necessary including a variety of eye drops, the wearing of eyeglasses or contact lenses (hard or soft), or additional treatments. Most patients can be fitted with a contact lens following LASIK surgery if necessary, however, the fitting may be more difficult than usual. It is possible that there may be a more than normal difficulty wearing contact lenses following LASIK and, for some, contact lenses following LASIK are not tolerable. This could occur even if you were a successful contact lens wearer prior to surgery.

I understand that if I currently need reading glasses I will likely still need reading glasses after this treatment. I also understand that if I do not currently need reading glasses, I may need them at an earlier age.

(FEMALE ONLY) I am not pregnant or nursing. If it is possible that I am pregnant, then I will take a home pregnancy test to ascertain that I am not pregnant, since pregnancy could adversely affect my treatment result. If the result of the test is positive, I will not undergo treatment until the result is proven incorrect or I will reschedule the treatment for after the pregnancy. If I become pregnant in the 6 months following treatment, I will notify my eye doctor immediately.

I understand the treatment should not be performed on persons with uncontrolled vascular disease or auto immune disease, or on patients who are immuno-compromised or on drugs or therapy which suppress the immune system, so I will tell the doctor if I have any of these or other medical conditions.

I understand the treatment should not be performed on persons with signs of keratoconus since eyes with this condition may have unstable corneas.

I have been informed, and I understand, that certain side effects or complications have been reported in the long term post treatment period by patients who have had LASIK including:

SIDE EFFECTS

Starburst/Halo/Glare/Shadows

Many people, who have never had eye surgery and are careful observers, may notice some starburst, halo, glare, or shadows in their vision under some light conditions, especially if they need to wear glasses or contact lenses. It is common to notice one or more of these after refractive surgery, especially during the early post-operative period. As a generality, these side effects tend to be less the closer you get to the ideal correction of your refractive error. But, some patients will notice one or more of these even with excellent correction, sometimes for a long time or even indefinitely. Of those who do notice these side effects, most patients will find them not very bothersome, but rather just something they can notice or be aware of if they think about it. A few patients, however, will find them annoying and it is possible that some patients may feel they are mild to serious visual impediments.

Night Vision

Except for lens replacement, all of the present corneal refractive procedures create a change in curvature in the central part of the cornea. This area of change or optical zone can range from about 3 to 7 millimeters, but does not involve the entire cornea. When patients are in dim light the pupils dilate or open to let in more light, some of this light will come in around the outside of the optical zone and be focused differently than that going through the optical zone. This can result in seeing a halo type effect or perhaps just a decreased contrast or sharpness of vision. Regardless of how it is described, there are some patients who feel that their night or reduced light vision is poor even when their uncorrected vision is good or excellent in normal lighting. This may be a significant issue for some patients for night driving, playing tennis or baseball at night or other similar activities. If activities of this sort are very important in your lifestyle, be sure to discuss it with the doctor.

RISKS/COMPLICATIONS

Possible need to abort procedure

The microkeratome has proved to be a very elegant, very dependable device for cutting the cornea to make the flap. Nevertheless, we are working on a tissue that is about 0.6 mm thick and as with any mechanical device the microkeratome is not perfect. In spite of best efforts, there are times that it produces a less than perfect flap. Although we have not seen it occur, it is conceivable that it could either damage the flap in an irreparable way or penetrate inside the eye and result in damage to any of the eye's internal structures. A fundamental part of the LASIK procedure involves placing a small suction ring on the surface of the eye. This is crucial to creating a good corneal "flap". An occasional patient (perhaps 2 in 1,000) has an

anatomical structure of the bony area around the eye that simply prevents us from safely getting this ring in place. We have found no reliable way to predict this with certainty until we begin the procedure. If this occurs, we have to abandon the LASIK procedure. For most patients who are not in the very high range of nearsightedness, PRK (photorefractive keratectomy) may be a possible alternative. We cannot ask you to consider or give your permission for an alternative once you have had sedation for you procedure so if you wish us to be in a position to proceed with PRK, we need to obtain your informed consent ahead of time.

CORRECTION OF ASTIGMATISM

Because of technicalities in how the corneal tissue beneath the flap is removed, it is possible to correct astigmatism as well as myopia and hyperopia using the excimer laser. It is possible for astigmatism to be either under corrected or over corrected just as with nearsightedness and farsightedness. It is also possible for the axis of the astigmatism to change which, although difficult to explain, might best be thought of as the direction of astigmatism. In the absence of other problems, changes in the axis and under or over corrections of astigmatism do not affect best-corrected visual acuity, which means that, vision could be corrected simply by wearing glasses or possibly contact lenses. Also, it is usually possible to consider correcting these problems with additional surgery, but the remaining astigmatism must be looked at in relation to the entire refractive error to determine what type of additional surgery might be needed.

Risk of Enhancement or Attempt to Treat Major or Minor Complications

To a greater or lesser degree, any additional procedure can involve some or all of the risks and side effects as have been already discussed for the primary procedure. As always, this risk should be weighed against the expected or hoped for benefit. As an example, if you can already see 20/40 without correction after your primary procedure to undergo these risks again in order to try to go from 20/40 to 20/20 might or might not seem like a good idea. This depends at least in part upon your perception of the quality of your vision and how well you function without correction with vision of 20/40. On the other hand, if you have had a large under correction or especially if you have some serious complication requiring treatment to try to preserve the health of your eye the decision to proceed may seem fairly obvious.

It is important to clearly understand that there are inherent risks involved in having refractive surgery. Generally these risks are expressed as probabilities. For most people undergoing eye surgery, the fear of blindness is perhaps uppermost in their minds. We have never had an eye become totally blind and have never encountered even a major, permanent loss of vision after refractive surgery. Nevertheless, these are possibilities and this risk, however small, must be accepted. Some possible causes of profound vision loss are infection, hemorrhage, vascular blockage, retinal detachment, perforation of the eye, damage to the cornea, and damage to the optic nerve. Some of these are treatable if they occur, but sometimes even the best known treatment does not or cannot help.

Retinal Detachment

Although retinal detachment is not usually considered a specific complication of LASIK it is at least a possibility. It seems conceivable that manipulation and pressure changes in the eye related to the use of the keratome could contribute to a retinal detachment in a high-risk eye.

Infection

Infection of the cornea or of parts of the eye behind the cornea is a rare, but serious possible complication of any type of refractive surgery. Although most infections respond well to antibiotic treatment, there are occasional exceptions and it is possible to have a very serious loss of vision or even blindness as a result of infection.

I understand that the doctor will prescribe certain medications as part of the treatment. The doctor is prepared to answer any questions I may have regarding the prescribed drugs and any side effects.

I understand that this is an elective treatment and that I do not have to have this treatment. I understand that the LASIK treatment is not reversible.

I understand that LASIK will require follow-up care at frequent intervals for one year after treatment and I agree to return for required examinations.

12) I understand, that since 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.

STATEMENT OF VOLUNTARY PARTICIPATION

IN SIGNING THIS INFORMED CONSENT FORM FOR THE USE OF THE EXCIMER LASER FOR PERFORMING LASIK, I AM STATING THAT I HAVE READ THIS INFORMED CONSENT AND I FULLY UNDERSTAND IT AND THE POSSIBLE RISKS, COMPLICATIONS AND BENEFITS THAT CAN RESULT FROM THE TREATMENT. ALTHOUGH IT IS IMPOSSIBLE FOR THE DOCTOR TO INFORM ME OF EVERY CONCEIVABLE COMPLICATION THAT MAY OCCUR, THE DOCTOR HAS ANSWERED ALL MY QUESTIONS TO MY SATISFACTION.

By signing below, I agree that:

LASIK treatment has been explained to me in terms that I understand.

I have had the opportunity to have my questions answered.

I fully understand the possible risks, complications and benefits that can result from treatment.

My decision to undergo the LASIK treatment has been my own and has been made without duress of any kind.

PATIENT NAME

DATE

PATIENT'S SIGNATURE

DATE

PHYSICIAN'S SIGNATURE

DATE

WITNESS'S SIGNATURE

DATE