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

RIGHT EYE

LEFT EYE

BOTH EYES

The intent of this document is to inform you as to the nature, risks, and complications of laser assisted in-situ keratomileusis (LASIK). It is a lengthy and detailed explanation. It is not intended to frighten or dissuade you or to imply that this surgery is dangerous. LASIK has been approved by the United States Food and Drug Administration. Although rare, serious complications can occur. It is important to read this document thoroughly so that you have an understanding of unexpected complications that may arise. LASIK is an elective procedure. If you do not wish to accept any of these risks, you may elect not to have the surgery.

Laser assisted in-situ keratomileusis (LASIK) is a surgical procedure that may permanently restore vision compromised by myopia (nearsightedness), with or without astigmatism, and hyperopia (farsightedness), with or without astigmatism. The information contained herein is provided to you so that you can make an informed decision about whether to undergo surgery for nearsightedness, farsightedness, or astigmatism.

Focusing Problems

Myopia, or nearsightedness, is a condition in which the individual can see clearly to read but cannot see clearly in the distance without glasses or contact lenses. The cause is a combination of the curvature (power) of the cornea being too strong and/or the power of the crystalline lens being strong and/or the eyeball being too long. These conditions focus the image in front of the retina. Glasses and contact lenses push the poorly focused image back towards the retina.

Myopia can be minimal, creating only slight blurring of distance vision. Patients with minimal myopia may be able to read most of the vision chart in the doctor’s office without glasses. When myopia is moderate, patients are barely able to see the big ‘E’ on the chart without glasses or contact lenses. (Such eyes have myopia between 2 and 6 diopters.

Hyperopic, or farsightedness, is the reverse. The curvature of the cornea is too weak, causing images to focus behind the retina. As a result, in youth, distance vision is clear but objects close to the eye are blurry. Glasses pull the poorly focused images forward toward the retina. For hyperopic individuals over 40 years of age, the focusing mechanism of the eye weakens. The focusing change (called accommodation) helps the farsighted person see well in the distance, but as one ages and this accommodative process deteriorates, distance vision becomes blurred. This aging process is called presbyopia.

Two thirds of the focusing power of the eye is determined by the curvature of the cornea and the remainder is controlled by the lens. The greater the curvature of the cornea, the greater the focusing power.

In astigmatism, the curvature of the cornea, and therefore its focusing power, varies from one point of the cornea to another. In the normal eye, the corneal curvature is spherical – like the inside of a mixing bowl. With astigmatism, the cornea more closely resembles the bowl of a teaspoon – still curved, but unevenly so.

When individuals can no longer tolerate contact lenses or when vocational or avocational goals demand good vision without optical devices, the surgical correction of myopia, astigmatism, or hyperopia can be considered.

Wavefront technology

The advent of wavefront technology enables ophthalmologist to measure and treat the defects of the eye's visual system that extend beyond what can be corrected by the basic prescription for eye glasses or contact lenses.

The most commonly used wavefront technology passes light into the eye, reflects it off the inside of the back of the eye, and then measures how this light is distorted as it exits. All of the light rays that exit the eye form the wavefront, which is representative of the eye's focusing characteristics. The reflected light or wavefront is analyzed by computer software for distortions caused by the eye's optical imperfections. The laser-based vision correction procedures, that information is then used to generate a customized treatment plan that guides the laser as it treats the individual eye in question.

The LASIK Procedure

LASIK was first performed in 1989 in Greece and was introduced to U.S. surgeons in 1990. LASIK is a combination of ALK (Automated Lamellar Keratoplasty and PRK). ALK, a procedure that was performed from 1988 to 1995, involved creating a flap of corneal tissue using a microkeratome. This corneal flap is gently folded aside while still attached to the cornea, and a second section of tissue is removed completely from the center of the cornea with the microkeratome. The corneal flap is then repositioned into its pre-surgical position. Since 1995, when the Excimer laser was approved by the USFDA, the laser has been used in place of the microkeratome in the second step of the ALK procedure.

The Excimer laser produces a unique beam of ultraviolet light. When it comes into contact with a substance, it does not produce heat or cause the substance to burn as other types of lasers may do. Instead, the Excimer light energy breaks molecular bonds and vaporizes tissue a few molecular layers at a time without any heat damage. This special ability makes the Excimer laser ideal for changing the shape of the cornea to correct focusing problems.

LASIK is performed in a surgical suite using numbing (anesthetic) eye drops. After cleansing the skin about the eye, a sterile plastic drape is placed over the eye. The eyelids are kept open with a small instrument to prevent blinking. While the eye is numb, the surgeon places marks on the surface of the cornea with an instrument that has a dye on its surface to mark the orientation of the cornea. Based on a pre-surgical exam, the surgeon adjusts the microkeratome to partially remove a disk of corneal tissue. This disk, or corneal flap, is gently folded aside. In myopia, the laser then is used to remove a section of the cornea from the center. The hinged corneal flap is replaced into its pre-surgical position. It sinks into the space created by the laser tissue removal, thereby reducing the myopia. In hyperopia, the laser removes a donut shape of corneal tissue, causing a steepening of the central section of the cornea. When the flap is replaced over the reshaped cornea, the hyperopia is reduced. With astigmatism, an oval shape of tissue is removed along with concurrent myopia and hyperopia surgery. No sutures are used. A timer will be set for four minutes allowing additional time for the flap to settle and adhere to the underlying tissue. The entire procedure is complete in about 10 to 15 minutes per eye. A pair of dark goggles will be worn or a single shield will be applied and should be kept in place for 24 hours by the patient. In most instances, bilateral simultaneous surgery is performed.

After surgery, the patient may experience some mild burning, scratchiness, and/or grittiness in the eye or eyes. It may feel as though there is something in the eye. The patient will likely experience tearing. At this time it is important not to touch the eyes or put any drops in them. The goggles need to remain on and not taken off for any reason until seen by the doctor the next day. For many patients, the vision will be greatly improved after the shield is removed, whereas for others variable improvement will be noted at this time. Eye drops will be prescribed. The drops are vital in regulating the healing and ultimate surgical result. They must be used as instructed until the surgeon indicates otherwise. Vision may fluctuate for up to 90 days. For some patients, once the vision is stable, thin spectacles may be needed. Further surgery to enhance the results may be indicated. The timing for enhancement correction is usually after 12 weeks following the initial surgery. Enhancement surgery is recommended if the vision without glasses is worse than 20/25 AND there is a residual refractive error that can be operated upon. Because there is a small risk of losing some vision without glasses with enhancement surgery, the decision to perform enhancement surgery is made between the patient and surgeon.

ACTIVITIES AFTER SURGERY

In most cases, patients are able to return to work 24 hours after the procedure. As instructed by the surgeon, eye medications should be continued during working hours. Most activities may be resumed almost immediately. The face, however, should not be placed under water for the first week following surgery, but showering with the eyes closed is acceptable.

Care should be taken to avoid rubbing and/or causing trauma to the eyes. An eye shield should be placed over the eyes at night for 7 days following the surgical procedure. No eye make up is to be worn for the first 7 days as well. Jogging, biking, and aerobics are permitted.

Risks and Complications

All eye surgery carries risk, but LASIK has fewer risks compared to cataract or corneal transplantation. It is not possible to list all risks here. Some of the most important are stated below.

Undercorrection – The patient may need to undergo additional LASIK surgery if the myopia, astigmatism, or hyperopia are not completely corrected with the first LASIK procedure.

Overcorrection – The procedure could create a farsighted condition in myopic patients or a nearsighted condition in hyperopic patients. In a nearsighted patient, this could create a farsighted condition where both distance and near vision are blurry. In this condition only glasses, contact lenses or hyperopic LASIK could be used to correct the condition.

Presbyopia – Whether or not one has refractive surgery, the patient will ultimately need glasses for reading, usually after the age of 43.

Dry Eye – Following LASIK surgery the patient may experience dry eye symptoms. Use of artificial tears may help relieve this condition. Occlusion of the tear drainage system (punctal occlusion) may also be an alternative.

Infection – This is always a risk for any surgical procedure but every precaution will be used to prevent the possibility of infection. Infection could lead to permanent corneal scarring and loss of vision.

Corneal Scarring – It is possible for scar tissue to build up underneath the top layer of the cornea in the area of the laser treatment. If scar tissue develops, it could reduce best possible vision, even with the best glasses or contact lenses. If this were to occur the only possible means of improving the vision would be through additional laser surgery or possibly through cornea transplantation.

Irregular Astigmatism - It is possible that the top layer of the cornea may not be perfectly smooth following surgery. If this were to occur, the vision with glasses would not be as good as it possibly could be. The patient would either need to have the corneal flap re-lifted with or without additional laser surgery. A rigid gas permeable contact lens could be worn to correct the vision or undergo a replacement of the top layer of the cornea to treat this irregular astigmatism.

Glare/Light Sensitivity – A surgical procedure for vision can create the condition of glare or light sensitivity, possibly even causing the patient to see halos around lights at night, although in most circumstances these conditions are temporary. In a very small percentage of cases there could be a permanent sensitivity to light or halos around lights at night.

Double Vision – If any part of the surgical procedure is not perfectly centered on the center of the eye, there could possibly be double vision. This double vision could be caused by the natural wound healing of the eye, or the improper centering of either of the two parts of the LASIK surgical procedure. If the patient were to develop double vision, he/she could undergo a replacement of the top layer of the cornea (the flap), have additional laser surgery, wear a hard contact lens, or possibly even need to undergo a corneal transplant.

Flap Dislocation/Wrinkle – Once repositioned, the corneal flap does not form a perfect seal for up to two weeks following surgery. A severe, direct blow to the cornea could dislocate this top layer or a **simple rub** could cause a fine wrinkle in the flap. It would be necessary to return to the surgery center to relift, reposition and suture the flap back into position. There would be a time of recovery of approximately 1 week when the sutures are removed. The suturing process carries with it all the known risks of surgery, including infection and irregular astigmatism.

** If this procedure to reposition the flap has to be done there will be additional fees charged by the surgery center. To avoid this problem and risk, follow all of the preventative instruction you have been given. Do not rub the eyes the first 7 days.*

Total Flap Removal or Flap Perforation – In rare instances, the microkeratome may completely excise the corneal flap. This is not a serious complication; the flap is set aside, and once the laser portion has been completed, the flap is then replaced into its original position without suturing. The known risks of total flap removal include irregular astigmatism and flap dislocation. If the flap is perforated, it is replaced into its original position and left to heal for 2 to 4 months, after which the microkeratome procedure can be repeated.

Incomplete Flap – Rarely, the microkeratome cannot fully create the necessary dimensions of the flap. In this circumstance, the flap is replaced, and 2 to 4 months later the procedure can be safely repeated.

Inability to Complete the Surgical Procedure – If the microkeratome creates a thin corneal flap or a small perforation in the center of the cap, the procedure cannot be completed. The cap will be folded back into its original position. The eye is treated as if it had undergone surgery. Three months later, the procedure will be repeated with a different microkeratome system to obtain a thicker flap and permit completion of the LASIK procedure. It is also possible that you may need another type of procedure or may not be able to have any further procedures.

Occupational Restrictions – Vision correction surgery may disqualify a person for employment in certain professions such as the military or law enforcement or from obtaining certain licenses or certifications. It is the responsibility of the patient to learn what these restrictions may be and determine if they apply to them.

Pregnancy – It is important that the patient should not be pregnant or nursing at the time of the laser vision correction, since pregnancy could adversely affect the surgical outcome.

I understand that there are always rare and unforeseen complications that could occur and could cause permanent loss of vision.

Limitations of Surgery

It is important to understand the limits of refractive surgery. Individual corneas respond differently to surgery, and each individual has a unique healing process. These factors make exact predictions of surgical results or the promise of perfect vision without corrective lenses after refractive surgery impossible. I understand and accept these limitations.

I have read this information document about LASIK and understand the terminology about the procedure as it is used in this document. My surgeon has told me the risks and benefits of LASIK and has addressed my concerns and answered my questions to my satisfaction. I am aware of the risks of the LASIK procedure and understand everything that has been said to me and what I have read in this informed consent. I freely sign this informed consent because it is my desire to undergo vision correction with the LASIK procedure.

Please check the following:

- My doctor and his staff have answered all of my questions.
- I have viewed the Laser Vision Correction DVD.
- I have read and understand this informed consent.

Patient Signature

Date

Surgeon Signature

Date

Witness Signature

Date