

# **INFORMED CONSENT FOR LASIK SURGERY**

**Please read the following consent form very carefully. Please initial each page where indicated. Do not sign this form unless you read and understand each page.**

Patient's Name: \_\_\_\_\_

Surgeon's Name: Mark I Golden, MD, FACS, FICS

Date of Procedure: \_\_\_\_\_

Operative eye:           Right           Left           Both

**Introduction:**

The following information is intended to help you make an informed decision about having Laser Assisted In Situ Keratomileusis (LASIK) surgery to correct your vision. It is our hope to fully inform you concerning the side effects, limitations, and complications of laser surgery. It is impossible to list all of the possible risks and complications associated with this proposed surgery or any other treatment. The first important message to understand is that it is impossible to perform any form of surgery without the patient accepting a certain degree of risk and responsibility. Risks considered unforeseeable or remote are not discussed but that does not mean they do not exist. In addition, there may be long-term effects not yet known or anticipated at the present time.

Many of our patients are surprised and some are upset by the extent to which we attempt to inform them of the potential for complications. It is not our intention to frighten or dissuade someone from pursuing laser surgery, as the vast majority of patients will never encounter any serious complications and are very pleased with the improvement they achieve. It is our intention, however, to accurately outline the associated risks to all candidates so that they either may elect not to accept the associated risks or be prepared to deal with any unexpected complications or side effects. The only way in which a patient can avoid all surgical risks is by not proceeding with surgery.

**Background:**

The Excimer Laser reshapes the cornea to possibly reduce or eliminate the need for glasses or contact lenses in cases of myopia (nearsightedness) and hyperopia (farsightedness). The curvature of the eye must be reshaped. There are two ways it can be accomplished with the laser, on the surface with PRK (Photorefractive Keratectomy) or beneath the surface with LASIK. The surface cells of the eye (epithelium) are more reactive; they may produce more pain, infection, and scarring. In severe cases of myopia and astigmatism where more healing complications are encountered, LASIK may be the treatment of choice. By going underneath a flap of tissue with the LASIK procedure, the risks associated with healing are significantly reduced. The intra-operative risks (risks related to the surgery itself), however, are greater with LASIK than with PRK alone. This is due to the use of the microkeratome (a surgical instrument much like a carpenter's plane) in LASIK, which is not used in PRK. The disadvantages of this procedure are those associated with the microkeratome.

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Photorefractive Keratectomy (PRK) is a procedure approved by the FDA to treat nearsightedness, farsightedness and astigmatism. Laser Assisted In situ Keratomileusis (LASIK) is an FDA approved procedure using the Excimer laser and the microkeratome which also treats nearsightedness, farsightedness and astigmatism.

**Overview of the LASIK Procedure:**

Diagnosis: You have been diagnosed with myopia (nearsightedness), with or without astigmatism, or hyperopia, (farsightedness), with or without astigmatism.

LASIK Surgery Described: LASIK permanently changes the shape of the cornea. The surgery is performed using a topical anesthetic (drops in the eye). A suction ring is applied securing it for the microkeratome cut. When the suction is applied, the vision will appear gray or black until the flap is made and the suction is released. The patient cannot see or feel the incision. The procedure involves folding back a thin layer of corneal tissue (corneal flap) with a microkeratome. The thickness of this flap is about one and a half hairs thick. The cornea itself is roughly four to five hairs thick. Once the flap has been made, the cornea is reshaped with the extraordinary precision of the cool light of the Excimer laser. You will hear a clicking noise during the ablation (the removal of corneal tissue with the Excimer laser). After the ablation, the flap is replaced and bonds back into place, usually without the need for stitches. The removal of tissue (ablation) causes the center of the cornea to flatten in the case of nearsightedness, steeper in the case of farsightedness or to become more rounded in the case of astigmatism, which changes the focusing power of the cornea.

**Limits of LASIK:**

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 (weaker) glasses, this result is cannot be guaranteed. Additional procedures, spectacles, or contact lenses may be required to achieve adequate vision.

LASIK does not correct the condition known as presbyopia (aging of the eye), which occurs in people around the age of 40 and usually requires them to wear reading glasses for close-up work. If you presently need reading glasses, you will likely still need reading glasses after this treatment. If you do not need reading glasses, you will probably need them at a later age (40-45). Some patients over 40 who have a low degree of myopia are able to read but only by removing their distance glasses, something they did not have to do before the age of forty. This is because presbyopia has set in and they are relying on their natural nearsightedness to read, but they must remove their corrective lenses to do this. If you elect to have surgery to correct your myopia, this “second mechanism” to read up close will be lost and you may need reading glasses, perhaps right after the surgery.

LASIK surgery will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, macular degeneration or retinal detachment. Decreasing or eliminating your need for corrective eyewear does not eliminate your risk for developing eye problems in the future. Therefore, it is highly recommended that you continue to see your eye care professional at regular intervals as you did prior to surgery.

**Risks of Not Undergoing LASIK:** The risks of not having the surgery are limited to those associated with your current visual condition. These include, but are not limited to the dangers that may be associated with losing glasses or contact lenses, the risks of corneal distortion and/or infection from wearing contact lenses, and the risks or trauma to the eye caused by breakage of spectacles or contact lenses in the eye.

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### **Contraindications:**

The treatment should not be performed on persons:

- with uncontrolled vascular disease
- with active autoimmune or collagen vascular diseases (e.g.: lupus, scleroderma, Rheumatoid Arthritis, etc.)
- who are immunocompromised or on drugs or therapy that suppress the immune system
- with signs of keratoconus (progressive steepening of the cornea)
- who are pregnant or nursing
- with residual, recurrent, or active eye disease(s) or abnormality
- with active or residual disease(s) likely to affect wound healing capability.
- with unstable or uncontrolled diabetes
- with progressive myopia or hyperopia
- with uncontrolled glaucoma
- with previous herpes infection of the eye

If you know that you have any of these conditions, you should inform us. In addition, if you have any other concerns or possible conditions that might affect your decision to undertake LASIK surgery, you should discuss them with the doctors.

### **Alternatives to LASIK:**

LASIK is purely an elective procedure. Among the alternatives to having the surgery are the following:

- Eye glasses or spectacles
- Contact lenses
- Photorefractive Keratectomy (PRK)
- Radial Keratotomy (RK)
- Orthokeratology
- Corneal relaxing incision
- Intracorneal ring
- Intraocular lens implant
- Lens extraction with Intraocular lens implantation

If you have any questions about these options, please ask us.

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**Recovery/Risks:**

1) The risk of serious INFECTION is reduced five-fold from approximately 1/1000 with PRK to 1/5000 with LASIK.

2) The risk of DISCOMFORT is reduced substantially in comparison with PRK. With LASIK, it is common to feel a scratchy sore feeling for the day of the procedure. Patients may also be light sensitive, with tearing, but this is usually short-lived. The eye may be red and the lids may be swollen following the procedure but this quickly resolves.

3) The two side effects that are similar for both the LASIK and PRK procedures are NIGHT GLARE and BLURRINESS. They are very common early in the healing process, and are observed by most patients. The risk of night glare is higher with astigmatic corrections. Both night glare and blurriness typically, but not always, improve over several months.

4) NIGHT GLARE is common in nearsighted individuals even before any refractive procedure is performed, but increases almost immediately in the healing process and is more common when only one eye is treated. With modern WaveFront technology, most people state that they have less glare postoperatively than preoperatively once the eye is fully healed. It is still possible to have severe night glare that could reduce vision in all reduced lighting conditions producing blurriness, ghosting, or halos. Patients with large pupils and severe myopia and/or significant astigmatism are at greatest risk for night glare.

5) Almost all patients describe BLURRINESS immediately following surgery. Blurriness to one degree or another is common. With LASIK procedures, there is considerable improvement in vision within the first 24 to 48 hours. Approximately 90% of the visual recovery occurs within the first several days, with the last 10% of vision improving over 3 to 6 months. Patients experience a large quantitative jump in vision within days, with the qualitative fine-tuning or sharpness of vision taking much longer, on the order of several weeks. Many patients experience a profound and dramatic visual improvement and become able to read half or more of the eye chart the next day, but most state it is still not clear and crisp, but rather has been described as "Vaseline vision". Some patients will develop corneal irregularities reducing the sharpness, crispness, and clarity to their vision preventing them from reading the bottom two or more lines on an eye chart that glasses, contact lenses, or another surgery cannot restore. That is, the initial blurriness resolves in 98% to 99% of patients over 6 to 12 months, however, it may be permanent in 1% to 2% of treated patients. There is no way of predicting or predetermining who will be in this 1% to 2%. A patient who loses sharpness will have vision that is permanently worse than the vision the patient enjoyed with glasses or contact lenses prior to the surgery. Each patient heals differently and this may cause differential results in seemingly similar patients. The recovery from blurriness after PRK is typically much slower than with LASIK.

6) CORNEAL FLAP COMPLICATIONS: The entire incision times for making the flap is approximately 2-3 seconds, but during this brief interval a variety of things are important for an optimal result. Primarily, there must be adequate internal suction pressure within the eye. Suction pressure and microkeratome assembly

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and function determine the thickness of the corneal flap tissue. There is a 1% risk that the eye will experience a corneal flap complication. The primary result of inadequate suction pressure is a corneal flap that is too thin which may result in (1) postponing the procedure for 3 months, or (2) temporary or permanent blurred vision. Other potential flap complications include a corneal flap incision that is too long resulting in a free flap; this may increase the potential for a prolonged visual recovery, blurred vision, and epithelial ingrowths (discussed

below). Corneal flap incisions that are too short necessitate postponing surgery for 3 months. Occasionally, (approximately 5%), the microkeratome may cause an abrasion on the corneal flap. This is unlikely to cause a change in the visual result, but may cause discomfort for a longer time than usual (on the order of days rather than hours) and may necessitate the use of a bandage contact lens. The overwhelming majority of LASIK complications are related to the creation of the corneal flap.

7) EPITHELIAL INGROWTH: During the first 24 hours, the epithelial protective layer grows over the edge of the corneal flap. There is an approximately 1% risk that epithelial cells may grow underneath the flap. This is more common in people with protective layers that bond poorly to the eye surface. Any intra-operative breakdown of the protective layer may increase the incidence of epithelial ingrowths. Treatment involves lifting the flap and clearing out the cells. Untreated, epithelial ingrowths may distort vision and may actually damage the flap if severe and progressive. Small ingrowths do not usually present any visual problems and need only to be monitored. The risk of epithelial ingrowth is increased for enhancement procedures.

8) FLAP STRIAE: Within the flap is a layer of cornea called Bowman's layer, which has the consistency of cellophane paper. In a small number of cases, micro folds or striae can occur after the flap has been properly positioned. These microstriae can cause distortions in vision, blurred vision, and double vision. If they are treated early (within one-two weeks), they are usually of no consequence. They are treated by lifting the flap and repositioning it with pressure on the cornea to relieve them. This technique is most successful if done early on as microstriae can become permanent with time. By lifting the flap and repositioning it, it is often necessary to break through the healed epithelium and this increases the risk of epithelial ingrowths. Flap striae are far and away the most likely flap complication. This risk is within the patient's ability to avoid by carefully ensuring that nothing touches the eye or around the eye for the first week after the procedure.

9) LOSS OF VISION: LASIK surgery can possibly cause loss of vision or loss of best-corrected vision. This can be due to infection (internal or external) or irregular scarring or other causes, and unless successfully controlled by antibiotics, steroids, or other necessary treatment, could even cause loss of the infected eye. Vision loss can be due to the cornea healing irregularly, which could add astigmatism, and make wearing glasses or contact lenses necessary or lead to loss of useful vision. Irregular corneal healing could result in a distorted corneal surface so that distorted vision or "ghosting" occurs. This may or may not be correctable by spectacles, contact lenses or further surgery. As with any eye procedure, there is always a risk of blindness. That risk is generally considered to be about one in a million.

10) VISUAL SIDE EFFECTS: Other complications and conditions that can occur with LASIK surgery include: anisometropia (difference in power between the two eyes); aniseikonia (difference in imaging size between the two eyes); double vision; hazy vision; fluctuating vision during the day and from day to day; increased sensitivity to light; glare and halos around lights which usually diminish with time but may not.

11) OVERCORRECTION OR UNDERCORRECTION: It may be that LASIK surgery will not give you the result you desired. It could be that the eye is under corrected. If this occurs, it may be possible or necessary to have additional surgery to fine-tune or enhance the initial result. It will be up to our surgeon to determine the appropriate time to pursue such options. It is also possible that your eye will be overcorrected to the point of being farsighted. At this point, this can also be corrected with the VISX laser. Significant over corrections are treated with glasses or contact lenses. It is also possible that your initial results will regress over time. The regression is usually not severe but may be treated with an enhancement, glasses or contact lenses.

12) OTHER RISKS: Other reported complications include corneal ulcer formation; endothelial cell loss (loss of cell density in the inner layer of the cornea, possibly resulting in corneal swelling); ptosis (droopy eyelid); corneal swelling; contact lens intolerance; retinal detachment; hemorrhage. Complications could also

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arise requiring further corrective procedures including either a partial (lamellar) or full-thickness corneal transplant using donor cornea. These complications include: loss of corneal flap; damage to the corneal flap; 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. Some patients experience a toxic response to the anesthetic drops that could lead to epithelial (surface protective layer) sloughing. This can lead to more irritation and discomfort than normal while healing. It could also lead to slower vision recovery. It is also possible that the microkeratome or the laser could malfunction and the procedure be stopped. This could possibly result in the procedure being postponed for up to three months.

13) LATER-DISCOVERED COMPLICATIONS: Other complications might occur in the future that have not yet been reported. Longer-term results may reveal additional risks and complications.

**PREOPERATIVE CONSIDERATIONS:**

**PREGNANCY AND BREAST FEEDING:** Pregnancy and breast-feeding could adversely affect your treatment result since your refractive error (glasses prescription) can fluctuate during this time. In addition, pregnancy and breast-feeding may affect your healing process, and some medications may pose a risk to the unborn or nursing child. Therefore, if you are pregnant or nursing, you should not undertake the LASIK procedure until after the pregnancy and breast-feeding period, usually at about four months, or with the resumption of your normal menstrual cycles.

**TAKING MEDICATIONS AND ALLERGIES:** You should inform your physician of any medications you may be taking, to avoid allergic reactions, drug reactions, and other potential complications during the LASIK surgery and subsequent treatment.

**CONTACT LENS WEARERS:** Patients who wear gas-permeable or hard lenses must completely stop wearing such lenses 4-6 weeks per decade prior to the pre-op examination (this period may be longer in some patients). Patients who wear soft lenses must completely stop wearing their soft contact lenses at least 4-7 days prior to the pre-op examination. Following the examination, you must leave the contact lenses out of the eye to be treated.

**POST-TREATMENT PRECAUTIONS:**

**EYE PROTECTION:** Avoid exposing the eye to dirty water as this may expose the eye to increased risks of infection. The eye shield should be worn at bedtime and any time while sleeping for one week after surgery. Avoid rubbing the eye. The eye may be more fragile to trauma from impact. Evidence has shown that, as with any other scar, the corneal incision will not be as strong after healing as the original cornea was at the site of the incision. Therefore, the eye is somewhat more vulnerable to all varieties of injuries after LASIK, at least for the first year after the surgery. It is advisable to wear protective eye wear when engaging in contact or racket sports or other activities in which the possibility of a ball, projectile, elbow, fist, or other traumatizing object contacting the eye may be high.

**OPERATING MOTOR VEHICLES:** After surgery, you may experience starburst-like images or “halos” around lights, your depth perception may be slightly altered, and image sizes may appear slightly different. Some of these conditions may affect your ability to drive and judge distances. Driving should only be done when you are certain that your vision is adequate. On the day of the LASIK procedure, you should arrange to be driven home after the procedure.

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**PAIN AND DISCOMFORT:** The amount of pain and discomfort that can be expected soon after the LASIK procedure varies with the individual. You should expect that the eye might burn and be irritated to some extent after the surgery. These sensations usually last only 3-4 hours after the procedure. You may have small hemorrhages on the white portion of your eye because of the suction device. Vision may be blurry and you may have the feeling of a foreign object in the eye.

**EXPECTATIONS:**

The goal of the procedure is to achieve the best visual result the safest way possible, and to dramatically reduce the dependence on glasses or contact lenses in an attempt to help improve the quality of life. Night driving glasses and/or readers may be necessary.

The degree of correction required determines both the rate of recovery and the initial accuracy of the procedure. Severe prescriptions may require more than one procedure. Patient differences in healing will also greatly affect visual recovery and final visual outcome and is impossible to predict.

Even 90% clarity of vision is 10% blurry. Enhancement surgeries can be performed when stable UNLESS unwise or unsafe. Typically, if vision is 20/40 or worse, an enhancement may be performed. Enhancement surgeries are generally performed no sooner than three months after the first surgery, however, under corrections can be enhanced earlier. Generally there is no need to make another incision in the cornea with the microkeratome. The original flap can usually be lifted with specialized techniques.

In order to perform an enhancement surgery, there must be adequate corneal tissue remaining from the original surgery. If there is inadequate tissue, it may not be possible to perform an enhancement or such enhancement may have to be performed with PRK. An assessment and consultation will be held with the surgeon at which time the benefits and risks of an enhancement surgery will be discussed.

**REASONS TO CANCEL OR POSTPONE PROCEDURES:**

At the time of the consultation for candidacy, it is not possible to rule out all possible contraindications for Laser Vision Correction. In a minority of cases, contraindications are found at the pre-operative exam that makes it necessary to cancel Laser Vision Correction.

At the time of surgery, cases can be postponed for the following reasons: 1) problems with the laser; 2) storms that may affect the laser's ability to perform; 3) problems with the proper functioning of the microkeratome; 4) irregular flaps. Irregular flaps would necessitate postponing the procedure for at least 3 months to allow for adequate healing of the cornea. In this rare circumstance, the vision in most cases returns to pre-operative levels with corrective glasses or contacts.

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**PATIENT STATEMENT:**

- I have read this Informed Consent Form. The LASIK procedure has been explained to me in terms that I understand.
- I have been informed about the possible benefits and possible complications, risks, consequences, and contraindications associated with LASIK.
- I understand that it is impossible for my doctor to inform me of every conceivable complication that may occur, and there may be unforeseen risks.
- I have been given the opportunity to ask questions and have received satisfactory answers to any questions I have asked.
- I understand that no guarantee of a particular outcome was given and that my vision could become better or worse following treatment.
- My decision to undertake in the LASIK procedure was made without duress of any kind.
- My decision to participate in the consent process was made without duress of any kind.
- I understand that LASIK is an elective procedure, and my myopia, hyperopia, and/or astigmatism may be treated by alternative means, such as spectacles, contact lenses, or other forms of refractive surgery.
- It is hoped that LASIK will reduce or possibly eliminate my dependency on glasses and contact lenses. I understand that the correction obtained may not be completely adequate and that additional correction with glasses or contact lenses may be needed.
- I authorize my physicians and other health care personnel involved in performing my LASIK procedure and in providing my pre- and post-procedure care to share with one another any information relating to my health, my vision, or my LASIK procedure that they deem relevant to providing me with care.
- I understand the great importance of keeping all of my required post-procedure visits and I agree to follow up at proper intervals as recommended by my physician. I understand, further, that by not complying with these recommended visits, I might jeopardize the ultimate outcome of my surgery.
- I understand that the decision to have surgery on both eyes at the same time versus one eye at a time is my choice and I have discussed the risks and benefits of these choices with my physician.

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**INFORMED CONSENT FOR BILATERAL LASIK PROCEDURE**

I have consented to have refractive surgery performed on my eyes at Doctors For Visual Freedom. I have discussed and considered the risks and benefits associated with bilateral simultaneous surgery (surgery performed on both eyes on the same day) versus unilateral sequential surgery (surgery performed on one eye at a time on different days). I realize that complications that may occur in one eye could possibly occur in both eyes by having the procedure done simultaneously. I understand that these risks are low statistically but there still is a small possibility that they may occur in either one eye or both eyes.

I understand that if visual recovery is delayed in both eyes, it could prevent or delay my return to work and other normal activities (e.g. driving).

I hereby consent to have bilateral simultaneous LASIK performed on my eyes.

**Please answer the following:**

- 1) I consent to have the LASIK surgery performed on my (choose one) right eye/ left eye/ both eyes.
- 2) I consent to having LASIK surgery performed on both eyes on the same day.    Yes    No
- 3) I consent to have my surgeon try for Monovision results.                            Yes                            No

Patient Name \_\_\_\_\_ Date \_\_\_\_\_

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

Patient Tech Name \_\_\_\_\_ Date \_\_\_\_\_

Patient Tech Signature \_\_\_\_\_

Physician Name \_\_\_\_\_ Mark Golden, MD \_\_\_\_\_ Date \_\_\_\_\_

Physician Signature \_\_\_\_\_

Doctor's Notes: \_\_\_\_\_  
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