

# **BLOOMBERG EYE CENTER**

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

### **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. In LASIK, the microkeratome is used to shave the cornea to create a flap. The flap then is opened like the page of a book to expose tissue just below the cornea's surface. Next, the excimer laser is used to remove ultra-thin layers from the cornea to reshape it to reduce nearsightedness. 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. This procedure, like all surgery, presents some risks, many of which are listed below. You should also understand that there may 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.

### **ALTERNATIVES TO LASIK**

If you decide not to have LASIK, there are other methods of correcting your nearsightedness, farsightedness or astigmatism. These alternatives include, among others, eyeglasses, contact lenses and other refractive surgical procedures such as PRK and lens implants.

### **PATIENT CONSENT**

In giving my permission for LASIK, 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 THREATENING COMPLICATIONS**

1. I understand that 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. I understand that, 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, I understand that my doctor would put this tissue back on the eye after the laser treatment, using sutures, according to the ALK procedure method. 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 try to create the flap again.
3. I understand that irregular healing of the flap (e.g. wrinkling) or progressive thinning of the cornea (ectasia) could result in a distorted cornea. This would mean that glasses or contact lenses may not correct my vision to the level possible before undergoing LASIK. If this distortion in vision is severe, a partial or complete corneal transplant might be necessary to repair the cornea.

4. I understand that it is possible a perforation of the cornea could occur, causing devastating complications, including loss of some or all of my vision. This could also be caused by an internal or external eye infection that could not be controlled with antibiotics or other means.
5. I understand that mild or severe infection or inflammation is possible. Mild infection or inflammation can usually be treated with antibiotics and steroids and usually does not lead to permanent visual loss. Severe conditions, even if successfully treated, could lead to permanent scarring and loss of vision that may require corrective laser surgery or, if very severe, corneal transplantation or even loss of the eye.
6. I understand that a small percentage of patients may develop epithelial ingrowth, where surface cells grow under the flap. While most of these are harmless, if the central vision is progressively affected, additional corrective procedures may be necessary and permanent distortion of the flap and loss of vision is possible.

I understand that other very rare complications threatening vision include, but are not limited to, corneal swelling, corneal thinning(ectasia), appearance of “floaters” and retinal detachment, hemorrhage, venous and arterial blockage, cataract formation, total blindness, and even loss of my eye.

#### **NON-VISION THREATENING SIDE EFFECTS**

1. I understand that there may be increased sensitivity to light, glare, and fluctuations in the sharpness of vision. I understand these conditions usually occur during the normal stabilization period of from one to three months, but they may also be permanent.
2. I understand that there is an increased risk of eye irritation related to drying of the corneal surface following the LASIK procedure. These symptoms may be temporary or, on rare occasions, permanent, and may require frequent application of artificial tears and/or closure of the tear duct openings in the eyelid.
3. I understand that an overcorrection or undercorrection could occur, causing me to become farsighted or nearsighted or increase my astigmatism and that this could be either permanent or treatable. I understand an overcorrection or undercorrection is more likely in people over the age of 40 years and may require the use of glasses for reading or for distance vision some or all of the time.
4. After refractive surgery, a certain number of patients experience glare, a “starbursting” or halo effect around lights, or other low-light vision problems that may interfere with the ability to drive at night or see well in dim light. Although there are several possible causes for these difficulties, the risk may be increased in patients with large pupils or high degrees of correction. For most patients, this is a temporary condition that diminishes with time or is correctable by wearing glasses at night or taking eye drops. For some patients, however, these visual problems are permanent. I understand that my vision may not seem as sharp at night as during the day and that I may need to wear glasses at night or take eye drops. I understand that it is not possible to predict whether I will experience these night vision or low light problems, and that I may permanently lose the ability to drive at night or function in dim light because of them. I understand that I should not drive unless my vision is adequate. These risks in relation to my particular pupil size and amount of correction have been discussed with me.
5. I understand that I may not get a full correction from my LASIK procedure and this may require future enhancement procedures, such as more laser treatment or the use of glasses or contact lenses.
6. I understand that there may be a “balance” problem between my two eyes after LASIK has been performed on one eye, but not the other. This phenomenon is called anisometropia. I understand this would cause eyestrain and make judging distance or depth perception more difficult. I understand that my first eye may take longer to heal than is usual, prolonging the time I could experience anisometropia.
7. I understand that, after 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. I understand that the treated eye, therefore, is somewhat more vulnerable to all varieties of injuries, at least for the first year following LASIK. I understand it would be advisable for me 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. I understand that there is a natural tendency of the eyelids to droop with age and that eye surgery may hasten this process.
9. I understand that there may be pain or a foreign body sensation, particularly during the first 48 hours after surgery.
10. I understand that temporary glasses either for distance or reading may be necessary while healing occurs and that more than one pair of glasses may be needed.
11. I understand that the long-term effects of LASIK are unknown and that unforeseen complications or side effects could possibly occur.
12. I understand that visual acuity I initially gain from LASIK could regress, and that my vision may go partially back to a level that may require glasses or contact lens use to see clearly.
13. I understand that the correction that I can expect to gain from LASIK may not be perfect. I understand that it is not realistic to expect that this procedure will result in perfect vision, at all times, under all circumstances, for the rest of my life. I understand I may need glasses to refine my vision for some purposes requiring fine detailed vision after some point in my life, and that this might occur soon after surgery or years later.
14. I understand that I may be given medication in conjunction with the procedure and that my eye may be patched afterward. I therefore, understand that I must not drive the day of surgery and not until I am certain that my vision is adequate for driving.
15. I understand that if I currently need reading glasses, I will still likely need reading glasses after this treatment. It is possible that dependence on reading glasses may increase or that reading glasses may be required at an earlier age if I have this surgery.
16. Even 90% clarity of vision is still slightly blurry. **Enhancement** surgeries can be performed when vision is stable UNLESS it is unwise or unsafe. The original flap can usually be lifted with specialized techniques and additional laser applied. If significant healing has occurred, a new LASIK incision may be required, incurring greater risk. In order to perform an enhancement surgery, there must be adequate tissue remaining. If there is inadequate tissue or corneal distortion or instability, it may not be possible to perform an enhancement. In this situation glasses or contact lenses may be recommended. Perfect vision is rarely achieved with eye surgery. Even after an enhancement, the vision may regress again, and repeat enhancements may not be advisable. The risks and side-effects of LASIK explained in this document also apply to enhancement procedures. Some, such as ingrowths, occur more frequently with enhancements.
17. I understand that, 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 my body. 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.

**PRESBYOPIC PATIENTS** (those requiring a separate prescription for reading): The option of monovision has been discussed with my ophthalmologist.

**BILATERAL PROCEDURE.** Most Patients choose to have LASIK done on both eyes simultaneously for reasons of cost, convenience, and faster recovery. Complications and side-effects described herein can occur as a result of surgery. If these complications occur in one eye, they may also occur in the other. Should any of these complications happen, one may experience significant loss of vision or even temporary or permanent legal blindness. By choosing to have LASIK performed on separate days, one may avoid the risk of having these complications in both eyes at the same time. I understand that I have this option and that I may have to pay a somewhat higher fee if I choose to have surgery on different days.

**PATIENT’S STATEMENT OF ACCEPTANCE AND UNDERSTANDING**

The risks and benefits of the procedure have been presented to me in detail in this document and explained to me by my ophthalmologist. My ophthalmologist has answered all my questions to my satisfaction. I therefore consent to:

\_\_\_\_\_ LASIK                      \_\_\_\_\_ LASIK ENHANCEMENT

surgery on my:

\_\_\_\_\_ Right eye                      \_\_\_\_\_ Left eye                      \_\_\_\_\_ Both eyes

I give permission for my ophthalmologist to record on video or photographic equipment my procedure, for purposes of education, research, or training of other health care professionals. I also give my permission for my ophthalmologist 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 ophthalmologist’s office or the center where my LASIK procedure will be performed.

Patient Name    Date    Witness Name    Date

I have been offered a copy of this consent form and I have read and understood all 4 pages (please initial) \_\_\_\_\_