Informed Consent for LASIK

Patient name (printed):_____

Date of birth:_____

Please review this information so you can make an informed decision about whether to have LASIK or not . Because this surgery is elective, and because alternatives to the surgery exist, we want you to make an informed decision about whether this surgery is appropriate for you.

By signing below, you agree that you understand the risks, potential benefits, and alternatives of the surgery, that all of your questions have been satisfactorily answered, and that you want your surgeon to perform the surgery.

LASIK has been performed since about 1999. Millions of patients have had LASIK safely and with excellent results. Most of these patients have reduced or eliminated their need for glasses or contact lenses and are glad they had the surgery. However, because this is a medical procedure, there are risks associated with it that can not be eliminated. You must understand and accept these risks prior to deciding to have LASIK.

NATURE OF THE PROCEDURE

LASIK ("Laser In-Situ Keratomileusis") uses a sophisticated ultraviolet laser to reshape the clear dome covering the front of the eye (the "cornea") to improve the eye's optical properties. Prior to the laser being used, the eye is anesthetized with powerful eye drops, so that you do not feel pain during the procedure. An eyelid holder keeps your eye open so you do not blink during application of the laser. Your surgeon raises a thin flap on the surface of the eye to expose the structural part of the cornea (the "stroma"). The laser then reshapes the stroma according to a computer algorithm programmed into it by the laser's manufacturer, and data given to it by your surgeon. At the conclusion of the procedure, the flap is replaced, and drops are applied to the eye.

Following the procedure, you can expect your eyes to be red and to feel irritated. In most cases your eyes will not be painful, although this can occur. After several hours, most patients are comfortable. Visual recovery is rapid, with most patients seeing well the next day, or even sooner. There may be some fluctuation in vision in the weeks or months after LASIK, but generally the long term effects of the surgery are stable, with most patients retaining their post-operative focus indefinitely.

This is the typical course following LASIK, but your recovery may differ significantly from this.

Please initial:_____

POTENTIAL BENEFITS OF THE PROCEDURE

Although the results of LASIK can not be guaranteed, the procedure has the potential benefit of reducing or eliminating your dependence on glasses or contact lenses. Many patients who have had the procedure can drive without glasses or contacts, and wake up in the morning with clear vision. They may also save money in the long term, because they no longer need to purchase glasses and contact lenses. The vast majority of patients are happy with their result, and glad they had the procedure.

WILL I BE 20/20?

The goal of LASIK is to reduce or eliminate your dependence on glasses and contact lenses and to make you happy with your unaided vision afterwards. You may be 20/20, better than 20/20, or worse than 20/20. Because of variations in healing, and the natural unpredictability inherent in any surgical procedure, there is no guarantee of 20/20 vision.

NEED FOR READING GLASSES AFTER LASIK IN PATIENTS OVER FORTY

The eye works much like a camera. If a camera is focused at distance, images up close will appear to be blurry through the viewfinder, unless the camera lens is turned to change its focal power. Similarly, if the eye is focused at distance (with contact lenses, laser surgery, or glasses), it will need to change its focal power to see clearly at near. It does this by changing the shape and position of the natural lens (the one that you're born with) inside the eye. When the eye is under about forty years old, it does this automatically, so that if the eye is focused at distance, it will be able to focus on near objects too.

Over time, the natural lens inside the eye becomes less able to change the focal power of the eye. After about the age of forty, the eye becomes more like a fixed focus camera, so that if it is focused at distance, it will have trouble seeing clearly up close. Patients over the age of forty will therefore need reading glasses to see at near if their LASIK surgery corrects their distance vision in both eyes.

MONOVISION OPTION

Some patients elect to have one eye corrected with LASIK to see at distance, and the other eye corrected to see at near. This allows them to be more independent of glasses when they are over forty years of age. With this "monovision" option, one eye sees distant objects clearly, and near objects are blurry. The other eye sees near objects clearly, and distant objects are blurry. Used together, clear vision is possible at all distances.

Many patients feel that monovision would make them feel unbalanced, and that they would have trouble adapting. These patients choose to have both eyes corrected for distance, and to wear reading glasses for near when they are over forty years old. Adaptation to monovision depends heavily on the patient's personality and goals. Some patients love it, and others have great difficulty adapting. If monovision is something you wish to consider, you must discuss this option with your surgeon prior to the surgery.

Please initial:_____

ALTERNATIVES TO LASIK

The alternatives to this procedure include, among others, eyeglasses, contact lenses, and other refractive surgical procedures. Excimer laser surface ablation is an alternative laser vision correction procedure. LASIK has a generally shorter recovery time than surface ablation. Excimer laser surface ablation procedures (PRK, LASEK, and epi-LASIK) are performed directly on the surface of the eye, without the creation of a LASIK flap, and have the advantage of avoiding possible flap complications. Other procedures exist, including implantation of intraocular lenses. You should discuss these options with your surgeon prior to undertaking LASIK to ensure you choose the best one for you.

RISKS OF THE SURGERY

Although the vast majority of laser vision correction patients do very well, it is important to realize that like all medical and surgical activities, there are risks. Just as with driving an automobile, most people have no problems. In rare cases, however, disasters can occur. While the risk of major morbidity is worse with driving than with this procedure, it is important that you understand the risks of LASIK prior to surgery:

1) Under and over correction of optical errors. Although the laser is usually quite precise and predictable, under and over correction of optical errors in the eye are possible. This could result in blurred vision, and require the use of glasses or contact lenses to see well after the surgery. These errors are usually treatable with a second laser surgery, but not always.

2) Loss of best corrected vision. Your vision after the surgery may not be as sharp as it was before the surgery, even with the best glasses or contact lenses.

3) Glare, halos, and other optical distortions. It is possible to have glare (starbursts around lights) or halos (rings around lights), or other distortions, such as ghost or double images. If present, these are usually most noticeable at night. They may affect the quality of your vision, annoy you, and even interfere with your visual function, such as making night driving difficult. They usually resolve with time, but not always.

4) Dryness or chronic irritation. Dryness after LASIK is common. It is usually temporary, and treatable with artificial tears or other methods. Severe and debilitating long-term dryness has been reported in a few patients.

5) Inflammation under the flap. Inflammation can occur under the LASIK flap, for reasons that are not completely understood. This can usually be treated, but in severe cases could cause scarring or surface irregularities that permanently interfere with vision.

6) Elevation of pressure inside the eye(s). High pressure after LASIK, if it occurs, generally results from a side effect of steroid eye drops. It is usually treatable with medications to reduce eye pressure, but if it is persistent and severe, it could permanently damage vision ("glaucoma"). In severe cases, secondary surgical procedures could be needed to control eye pressure.

Please initial:_____

7) Human errors. As with any human activity, human errors are possible. Wrong data entry into the laser, operating on the wrong eye, and other errors are reported complications of this procedure. Although we make strenuous efforts to avoid human error, they are still possible and could cause problems with your vision or ocular health.

8) Infection. Antibiotic eye drops are used after LASIK, but infection on the surface of the eye is still possible. In most cases an infection is treatable, with no permanent effect on vision. If an infection were severe, however, it could cause permanent loss of sight, or even loss of the eye.

9) Stretching of the cornea ("keratoconus" or "ectasia"). For reasons that are largely unknown, rare cases of stretching of the cornea occur after LASIK. This can cause a loss of uncorrected and best-corrected vision, and may require glasses or contact lenses to restore vision. In severe cases, corneal transplantation may be required to improve the situation.

10) Allergic reactions. Medications or surgical supplies could cause allergic reactions. Although rare, severe allergic reactions can be life-threatening.

11) Cells or debris under the flap. Sometimes debris (eyelashes, secretions, dust etc.) or cells from the surface of the eye can be deposited under the flap. This is often a benign condition, but in some cases these may have to be removed. Rarely, this can cause conditions that adversely affect vision, even permanently.

12) Flap complications. The flap is created with either a mechanical device or a secondary laser called a "femtosecond laser." Although both technologies are very reliable, neither is perfect. Occasionally the flap that is created is incomplete, poorly formed, or has holes in it. Rarely, the flap can become completely detached from the surface of the eye. These situations may prevent your surgeon from being able to perform LASIK on the day of your procedure, or in rare cases may cause problems that permanently affect your vision.

13) Irregular astigmatism. For a variety of reasons, including decentration of the laser, irregular healing, infection, or cells under the flap, the surface of the eye could become irregular. This could cause visual distortions or loss of vision, and may or may not be correctable.

14) Optical drift. The results of LASIK are usually very stable, but your eye's optics may experience a natural drift over time, or the optics may change because of disease conditions, such as cataract formation. This may cause you to need glasses or contact lenses again.

15) Eye alignment. In a few susceptible patients, usually with pre-existing conditions, LASIK could create or exacerbate problems with eye alignment. This could cause deviating eyes and double vision, and necessitate secondary procedures to re-align the eyes.

16) Other complications. The above list of risks is not exhaustive. It is not possible to state all the possible risks associated with any surgery. Other problems may occur.

Please initial:_____

Because LASIK has been performed for a limited period of time, the life-long risks are not known.

USE OF MEDICATIONS "OFF-LABEL"

As in many areas of medical care, some medications used after LASIK are used "off-label." This is a common, accepted, and legal practice in the United States. Using medications "off-label" means that your physician uses them for purposes for which they were not originally approved by the US Food and Drug Administration. Your physician does this based on medical experience and scientific evidence of the drug's safety and efficacy for this purpose.

PUBLICATION OF INFORMATION

Your physician may use data, video or photographic images, or other information related to your surgery for research, publication, presentations, or other professional medical activities. Your information would be used in accordance with professional ethical standards, and would not identify you personally.

CERTIFICATION

By signing below, you certify that you have actually read the information above and that you have discussed LASIK with your surgeon. You certify that you understand the risks, potential benefits, and alternatives of the procedure, have had your questions answered, and would like to proceed with the surgery on your **(circle one)**:

LEFT EYE BOTH EYES RIGHT EYE

MONOVISION OPTION

Some patients elect to have one eye corrected for distance, and one eye corrected for near to reduce the need for reading glasses when they are forty years or older. **Please circle your preference regarding this option:**

- I DO NOT elect monovision, and prefer to see distance clearly with both eyes. I will need reading glasses for near work when I am over the age of forty.
- I DO elect monovision. I prefer that the eye I use as my DISTANCE/FAR VISION eye is my:

LEFT EYE RIGHT EYE

Patient name and signature:_____ Date:_____

Witness name and signature:_____ Date:_____