INFORMED CONSENT
FOR
EXCIMER LASER IN SITU KERATOMILEUSIS (LASIK)

INTRODUCTION

You have been diagnosed with myopia (nearsightedness) or hyperopia (farsightedness), with or without astigmatism, and your doctor, _____, has informed you that your vision might benefit from laser in situ keratomileusis (LASIK), a surgical procedure having the goal of correcting myopia, hyperopia, and astigmatism. It is your doctor's intent to provide you with all of the information necessary to allow you to make an informed decision about whether to undergo LASIK, including the potential risks and complications. Many patients are surprised and some are upset by the extent to which they are informed of these potential risks and complications. It is not your doctor's intention to frighten or dissuade you from pursuing LASIK surgery. Most patients will not experience any serious complications from LASIK surgery, and the great majority are pleased with the improvement they achieve. However, it is important to understand that as with all surgery, despite the best care there are risks of side effects and complications. Only by having the risks explained to you accurately and realistically and by having all of your questions answered can you be assured that you can make an informed decision whether to undergo this surgery.

THE PROCEDURE

LASIK is a form of surgery in which the part of the eye known as the cornea is reshaped in order to reduce or eliminate the need for glasses or corrective lenses in cases of myopia (nearsightedness), hyperopia (farsightedness), and astigmatism. With the aid of eye drops to numb the eye, a thin layer of corneal tissue (the outermost layer of the eye), similar in size to a soft contact lens, is formed using a mechanical device called a microkeratome and lifted to one side. The excimer laser then produces a beam of ultraviolet light energy, which, when focused through a lens system, is able to remove tissue and to change the shape or curvature of the exposed cornea. After reshaping the cornea, the surface flap of tissue is folded back into place and re-attaches without sutures.

The U.S. Food & Drug Administration (FDA) has approved LASIK with the VISX laser to treat patients with myopia between 0 and -14.00 diopters with or without -0.5 to -5.0 diopters of astigmatism.

The U.S. Food and Drug Administration (FDA) has approved LASIK to treat patients with hyperopia between +0.5 and +5.0 diopters with or without up to +3.0 diopters of astigmatism.

The goal of refractive surgery is to decrease your dependence on corrective lenses. This goal may be termed "functional vision." Functional vision allows a person to do most of their day-to-day activities without correction. You could still need correction with eyeglasses or contact lenses for your best vision. In addition, your eye may change over time, increasing the need for eyeglasses or contact lenses. Your doctor is unable to guarantee what your vision will be after surgery.

LASIK surgery does not change the eventual need for reading glasses. In fact, it could increase the need for them. Presbyopia (the need for reading glasses) is caused by an aging change to the lens inside the eye and becomes noticeable sometime after the approximate age of 35 to 45. The lens loses the ability to change focus from distance to near. By losing your nearsightedness from the LASIK surgery, you may need reading glasses to compensate.

REASONS NOT TO HAVE THIS SURGERY

LASIK surgery should not be performed on persons:

- with collagen vascular, auto-immune or immunodeficiency diseases;
- with uncontrolled vascular disease;
- with autoimmune disease (e.g., AIDS);
- who are immune-compromised or on drugs or therapy which suppress the immune system;
- with signs of keratoconus (steeping of the cornea);
- who are pregnant, nursing, or expecting to become pregnant within the six months following the LASIK procedure;
- with residual, recurrent, or active ocular disease(s) or abnormality except for myopia or hyperopia in either eye;
- with active or residual disease(s) likely to affect wound healing capability;
- with severe nearsightedness, farsightedness, or astigmatism that is outside the limits approved by the Food and Drug Administration;
- with unstable or uncontrolled diabetes;
- with progressive myopia or hyperopia;
- with amblyopia (lazy eye);
- with significant glaucoma;
- with ophthalmic Herpes Simplex or Herpes Zoster; or
- who are taking Isotretinoin (Accutane) or Amiodarone hydrochloride (Cordarone).

If you know that you have any of these conditions, you should inform your physician. 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 your physician.

POSSIBLE SIDE EFFECTS AND COMPLICATIONS

- **Pain** may be experienced during the first 24-48 hours after surgery. Patients may be light sensitive. Pain is not always a sign of complication, but more frequent examinations may be required if pain is persistent.

- **Night Vision Difficulty or Night Glare or Halos** are very common early in the healing process, and although these problems typically diminish with time, they can continue to cause unwanted symptoms. These symptoms are more common when only one eye has been treated. Glare is a sensation produced by bright lights causing discomfort and annoyance. Halos are hazy rings surrounding bright lights at night. A patient's vision may not seem as sharp at night as during the day, and the patient may need to wear glasses at night.

- **Blurriness/Loss of Best Corrected Visual Acuity.** Blurriness is very common during the healing process. It generally requires 1 - 7 days until vision is clear enough to drive; however, it may take longer. Also, patients may develop permanent corneal irregularities reducing sharpness, crispness, and clarity. Loss of best corrected visual acuity means that the best vision you can achieve with glasses or contacts after LASIK surgery may not be as good as the best vision you achieved with glasses or contacts before LASIK surgery.

- **Infection** is possible after LASIK surgery. Makeup, swimming, and other possible contamination should be avoided during this time. A serious corneal infection can result in scarring, a permanent reduction in vision, and even complete loss of vision.

- **Over-Correction and Under-Correction.** It may be that LASIK surgery will not give you the result that you desired. Some procedures result in the eye being undercorrected. If this occurs, it may be possible or necessary to have additional surgery to fine-tune or enhance the initial result. It is also possible that your eye may be overcorrected to the point of becoming farsighted (by overtreating myopia) or nearsighted (by overtreating hyperopia). It is also possible that your initial results could regress over time. In some, but not all cases, retreatment, glasses, or contact lenses might not be effective in correcting vision.

- **Increases Risk of Trauma Injury.** After LASIK surgery, the eye may become more fragile to trauma from impact for the first several weeks or even months. As with any scar, the cornea will not be as strong after healing as the original cornea was at the site of the incision with the microkeratome. It will be advisable to wear protective eyewear when engaging in sports or other activities in which the possibility of a ball, projectile, elbow, fist, or other object hitting the eye exists.

- **Epithelial Ingrowth.** During the first 24 hours after surgery, the epithelial protective layer grows over the corneal flap. There is a small risk that epithelial cells also grow underneath the flap, a risk that increases with age and in re-treatment LASIK procedures. Treatment of this condition involves lifting the flap and clearing the cells, which is typically, but not always successful.

- **Anisometropia.** When only one eye is treated and the untreated eye is nearsighted, the two eyes may not focus in the same place (anisometropia) or may have a difference in image size (aniseikonia). These conditions can cause eyestrain, headache, and/or double vision or difficulty with distance or depth perception. A patient may have to wear a contact lens or possibly glasses for the untreated eye to correct this condition.

- **Decentered Ablation** occurs when the laser's ablation or "zone" of correction is not aligned with the patient's visual center or axis. If this condition occurs, it can result in multiple images, halos, or glare, especially at night. An additional laser procedure may be needed to try to correct this condition; however, in rare cases it may not be treatable.

- **Scar Tissue or Healing Haze.** Healing haze consists of collagen proteins which develop on the surface of the eye during the normal LASIK healing process. Mild haze may not be noticeable and heals over time. However, more severe haze causes clouded vision, which may develop over weeks or months. Even if scar tissue develops, it usually can be treated with another laser procedure. Nevertheless, scarring may be persistent or recurrent, requiring multiple surgeries and potentially can cause loss of visual sharpness or over-correction.

- **Other Complications.** 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, and hemorrhage. One healing reaction may be an immune or toxic reaction known as Diffuse Interface Keratitis or "Sands of Sahara." This reaction may reduce vision and could require further treatment including steroids or

other topical medications as well as surgical intervention. Complications could also arise requiring further corrective procedures, including either a partial (lamellar) or full thickness corneal transplant using a donor cornea. These complications include: loss of the corneal disk, damage to the corneal disk, disk decentration, and progressive corneal thinning (ectasia). Sutures may also be required which could induce astigmatism. There are also potential complications due to anesthesia and medications which may involve other parts of your body. It is also possible that the microkeratome or the excimer laser could malfunction and the procedure stopped. Depending on the type of malfunction, visual loss may result. Since it is impossible to state all potential risks of any surgery or procedure, this form does not provide a comprehensive listing of every conceivable problem.

- **Partial or Total Blindness.** Loss of some or all vision, including loss of the eye, could be caused by perforation of the cornea, internal or external infection that is not controlled with antibiotics or other means, retinal detachment, hemorrhage, venous and arterial blockage, and cataract formation.

- **Later-Discovered Complications.** LASIK is a recently developed technique. You should be aware that other complications may occur that have not yet been reported, especially complications that may arise years after surgery.

ALTERNATIVES

LASIK is purely an elective procedure, and you may decide not to have this surgery at all. My doctor has discussed the following alternatives with me:

- No intervention.
- Eyeglasses/spectacles.
- Contact lenses.
- Photorefractive keratectomy (PRK).
- Radial keratotomy (RK).
- Corneal relaxing incision.
- Intracorneal ring segments.

PREPARATION

- Must be at least 18 years of age.
- Complete eye exam to access the health and refractive status of your eyes.
- Contact lens patients must stop using their lenses prior to surgery. The length of time patients should be out of contact lenses prior to surgery will be determined by their doctor.

FOLLOW-UP

Patients are requested to return for follow-up examinations several times during the first year following LASIK in order to monitor healing following surgery. If an enhancement is needed or a complication occurs, a patient may be required to return or stay longer. Your cooperation in following your doctor's instructions for post-operative care is an important factor in the success of the procedure.

Avoid exposing the eye to tap water in the bath or shower, since non-sterile water may expose the eye to increased risks of infection. The eye shield should not be removed, except for putting eye drops in

the operated eye for the first 24 hours. It is advisable to wear protective eyewear when engaging in sports or other activities in which the possibility of a ball, projectile, elbow, fist, or other object hitting the eye exists.

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.

INFORMED CONSENT

Please read the following statements, and then indicate your understanding and acknowledgment of each by copying it in your own handwriting in the box provided.

1. I understand that as with any form of surgery, the outcome can never be guaranteed. I understand that the benefits of LASIK also cannot be guaranteed. The outcome of LASIK may be of no benefit to me and may in fact be harmful.

   Please write: "I may not achieve the result that I hoped for."

2. I understand that the correction obtained may not eliminate all of my myopia, hyperopia, or astigmatism and that additional correction with glasses, contact lenses, or additional surgery may be needed.

   Please write: "I may still need to wear glasses."

3. I understand the basic nature of the procedure as well as the possible risks and benefits of LASIK. I understand that LASIK is a relatively new procedure and that the long term effects are not known. I understand that as a result of LASIK my vision could be made worse.

   Please write: "There are risks, and my vision may be made worse."

4. I understand that LASIK is an elective procedure and is not medically necessary. I have been informed of alternative treatments, including glasses, contact lenses, and other surgical procedures such as photorefractive keratectomy, radial keratotomy, and intracorneal rings.

Please write: "All my questions have been answered."

In signing this informed consent, I certify that I have read the preceding information and understand the contents. I fully understand the possible risks, complications, and benefits that can result from the excimer laser surgery. My decision to proceed with laser in situ keratomileusis (LASIK) has been voluntarily and freely given.

Scope of Surgery (circle one): LEFT EYE or RIGHT EYE or BOTH EYES

Type of Surgery (circle one): PRIMARY or ENHANCEMENT

Patient Full Name (Print): _____

Patient Signature: _____

Date: _____

Witness Full Name (Print): _____

Witness Signature: _____

My Doctor (Print): _____

My Doctor's Signature: _____

ADDENDUM TO INFORMED CONSENT
LASER IN SITU KERATOMILEUSIS (LASIK)

BILATERAL SURGERY OR SURGERY ON SECOND EYE BEFORE 3-MONTH WAITING PERIOD

INTRODUCTION

The FDA has recommended that patients who desire to have the laser vision correction procedure performed on both eyes should have the procedure performed on one eye and then wait a minimum of three months before having the procedure performed on the second eye. However, the FDA has confirmed a patient may elect to have treatment on both eyes at the same time or to have a shorter period than three months between procedures on each eye. There are advantages and disadvantages of having bilateral surgery or surgery on the second eye prior to the end of the recommended three-month waiting period.

BENEFITS

- Convenience: **Having both eyes treated during the same visit eliminates a repetition of the entire process for the second eye. An additional period of recovery and more time off from work is required.**

- Visual Recovery: **When one eye is treated, there is a period of imbalance between the vision of your two eyes. You will need to wear a contact lens in the untreated eye or to wear glasses with a stronger corrective lens in the untreated eye, or else a strong sense of imbalance, dizziness, and a form of double vision will result. By treating both eyes at the same time or nearer in time, the balance between your eyes will be restored more quickly. Also, night glare tends to go away more quickly.**

RISKS

- Visual recovery: **It is important to realize that patients who heal abnormally have taken several weeks to heal, whether they have surgery on one eye or both eyes. There is no way of predicting who will take longer to heal. If recovery is delayed, you could function with the untreated eye while the first eye fully recovers. Even in normal healing, blurriness may continue in both eyes from 1 to 2 weeks, making driving impossible.**

- Infection: **The risk of infection or other healing complication is applicable to both eyes simultaneously; therefore, if an infection occurs in one eye, it may spread to the other eye.**

- Accuracy: **Your doctor can monitor the healing process and visual recovery in the first eye and may be able to make appropriate modifications to the treatment plan for the second eye, potentially increasing the likelihood of a**

- **Accuracy:** Your doctor can monitor the healing process and visual recovery in the first eye and may be able to make appropriate modifications to the treatment plan for the second eye, potentially increasing the likelihood of a better outcome in the second eye. This opportunity is lost when both eyes are treated at the same time or before the end of the three-month waiting period.

- **Satisfaction:** By correcting both eyes simultaneously, there is no opportunity to learn from the healing patterns of the first eye before treating the second eye. Therefore, if there is an overcorrection or undercorrection in one eye, chances are that it will occur in both eyes. If a retreatment is required in one eye, it is quite possible that your fellow eye will also require retreatment. Both eyes tend to experience similar side effects. If you experience undesirable side effects, such as glare, ghost images, increased light sensitivity, or corneal haze in one eye, you will likely experience them in both eyes. These side effects may cause a decrease in vision or other negative effects, and some patients experiencing them in the first eye have elected to not have their second eye treated.

Please choose the appropriate statement below and write the statement in the box:

"I wish to have both my eyes treated together."

-OR-

"I wish to have my second eye treated sooner than 90 days after my first surgery."

Patient Name (Print): _____