Womack Army Medical Center
Refractive Surgery Center
Phone: (910) 907-6033/6001

INFORMED CONSENT FOR LASER REFRACTIVE SURGERY

Your doctor has determined that you are a good candidate for laser refractive surgery for the correction of your refractive error (nearsightedness, farsightedness, and/or astigmatism). There are three forms of laser refractive surgery currently available: laser-assisted in situ keratomileusis (LASIK), photorefractive keratectomy (PRK), and laser epithelial keratomileusis (LASEK). All procedures use the excimer laser to reshape the front surface of the eye (the cornea) and these procedures are permanent and irreversible.

The excimer laser is an FDA-approved medical device that uses ultraviolet light energy to reshape the cornea so that visible light entering the eye is focused properly, resulting in a possible reduction or correction of my nearsightedness, farsightedness, or astigmatism.

Laser Assisted in Situ Keratomileusis (LASIK). The Intralase iFS laser creates a flap of corneal tissue. This flap is then folded back in such a way that the excimer laser can be used to remove microscopic layers of tissue from the underlying cornea. Once the laser treatment is completed, the flap is then returned to its original position.

Photorefractive Keratectomy (PRK). After removing the outermost layer of the cornea (the epithelium) PRK uses the excimer laser to reshape the underlying cornea. Your surgeon may recommend mitomycin C, a topical medication that helps to prevent postoperative scarring, which is applied during the procedure and then rinsed off. A soft contact lens is then usually placed over the treated cornea while the corneal epithelium is healing.

Laser Epithelial Keratomileusis (LASEK). This procedure is similar to PRK. The outermost layer of the cornea (the epithelium) is loosened and folded to the edge of the cornea. The excimer laser is then used to reshape the underlying cornea. The folded epithelial tissue is then unfolded into its original position.

LASIK, PRK, and LASEK surgery are performed under a topical anesthetic to numb the eye and make it so there is minimal discomfort during the procedure.

You are entitled to be informed about the proposed LASIK/PRK/LASEK treatment for MYOPIA (NEARSIGHTEDNESS), with or without astigmatism, or HYPEROPIA (FARSIGHTEDNESS), with or without astigmatism, including the risks of the treatment and the alternatives. This information is provided so that you can make an informed decision regarding laser refractive surgery. Please read this document thoroughly and discuss the content with your doctor, so that all of your questions are answered to your satisfaction.

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PATIENT STATEMENT

I have **MYOPIA** with or without astigmatism or **HYPEROPIA** with or without astigmatism.

MYOPIA with or without astigmatism requires me to wear corrective lenses in order to see clearly for my daily activities. I have been informed of the alternatives including eyeglasses, contact lenses and other types of refractive surgery.

HYPEROPIA with or without astigmatism requires me to wear corrective lenses in order to see clearly for my daily activities. I have been informed of the alternatives including eyeglasses, contact lenses and other types of refractive surgery.

- **POTENTIAL BENEFITS**: The goal of LASIK, PRK or LASEK is to reduce or eliminate myopia with or without astigmatism, or hyperopia with or without astigmatism. The potential benefit of the procedure is to reduce my need for corrective lenses and improve my vision without glasses or contact lenses.

- **ALTERNATIVES**: The alternate procedure(s) or course of treatment has been explained to me as follows: I can continue to wear either glasses or contact lenses to correct my refractive error. Surgical alternatives include LASIK, PRK and LASEK.

- **RISKS**: I understand that as with all forms of treatment, the results of my surgery cannot be guaranteed. There is also **NO GUARANTEE** that I will eliminate my reliance on glasses or contact lenses. It is possible that the treatment could result in under correction or over correction, where I may have some residual myopia or hyperopia. This may require the need for glasses or contact lenses to sharpen vision.

- It is possible that this treatment may increase my dependence on reading glasses, or that I may require reading glasses at an earlier age. The treatment could also result in a change in my astigmatism that could cause the need for the use of glasses or contact lenses. I understand that further treatment may be necessary, including the use of eye drops, the wearing of glasses or contact lenses, or an additional treatment with the laser.

- I have been informed that complications can occur after the procedure including:

  - Decrease in best-corrected visual acuity. A decrease in my best possible vision even with eyeglasses or contact lenses may occur, usually transiently. This may improve with additional treatment.

  - I may experience glare from bright lights or halos around lights, especially at night. The glare may be severe enough to cause difficulty driving at night (up to 3%). This may occur immediately after the procedure and usually resolves gradually.

However, I understand that highly myopic patients are at a greater risk of experiencing haze, and patients with large pupils may be at increased risk report night glare.

- Decrease in contrast sensitivity. A decrease in the quality of vision may occur even with excellent visual acuity. This may occur immediately after the procedure and usually resolves gradually.
- Corneal scarring. A scar dense enough to affect vision may occur after the procedure (up to 2%). The scar may respond to treatment.

- Elevated intraocular pressure. High pressure in my eye may reduce vision. This may occur while taking eye drops after the procedure and usually responds to treatment.

- Other complications that have been reported in less than 1% of treated eyes include: cataract, ulceration, infection, inflammation of the iris, double vision, drooping of the eyelid, and corneal inflammation. Since it is impossible to state every complication of laser refractive surgery, it is understood that the above list of complications is not complete or exhaustive. Fortunately, most complications are rare, temporary, or mild. I understand that the long-term effects associated with LASIK, PRK or LASEK procedures are not fully known.

- There is a small risk during LASIK of experiencing a corneal flap complication. During the LASIK flap creation, a suction break can occur. This may result in having to either postpone the surgery for another day or consider a different refractive procedure, such as PRK or LASEK. Postoperatively, it may be necessary to lift a flap to remove cellular debris underneath or to try to reduce the wrinkles seen in the flap in an effort to improve vision quality. Other potential corneal flap complications include a corneal flap incision that is too long, resulting in a free flap; this may increase the potential for prolonged visual recovery, blurred vision, and epithelial ingrowth. Corneal flaps that are too short necessitate postponing the procedure. The most potentially serious risk is a corneal flap that is too deep, which results in perforation of the eye, but this is very rare.

- During the first several hours after a LASIK procedure, the epithelial protective layer grows over the corneal flap. There is potential for developing epithelial cells growth underneath the flap, which may necessitate lifting the flap and removing the ingrowth. This occurs rarely.

- There is a risk of inducing astigmatism or of astigmatism appearing in another part of the cornea.

- By having treatment on both eyes at the same time I recognize that I could have one or more of these problems in both eyes at the same time.

- Blurring is very common in the healing process. It generally takes 3 to 10 days to clear. However, I recognize it may take longer. My visual acuity will generally stabilize in

about 3 weeks, although full recovery, especially for PRK, and LASEK may take 4 to 6 months or even longer.

- I understand that if I need reading glasses prior to treatment, I will most likely need reading glasses after the treatment. I also understand that if I do not currently need reading glasses, I may need them at sometime after the procedure.

- I understand that if my eyes were dry before surgery, they will be dry after surgery. My eyes may permanently or temporarily be drier than before surgery. Artificial tear drops may be needed after surgery.

- **FEMALES**: I am not pregnant or nursing. If it is possible that I am pregnant, then I will obtain a pregnancy test to ascertain that I am not pregnant, since pregnancy could adversely affect the treatment result. Mitomycin C applied to the eye during PRK has unknown effects on a developing pregnancy. Also, I will notify my eye doctor immediately if I become pregnant within the six months following treatment. Further, I understand that I cannot be currently nursing or plan to nurse before or during the recovery period of having refractive surgery.

- I understand the treatment should not be performed on persons with uncontrolled vascular disease or autoimmune disease, or on patients who are immunocompromised or on drugs or therapy which suppress the immune system, so I will tell the doctor if I have any of these or other medical conditions.

- I understand the treatment should not be performed on persons with signs of keratoconus (a corneal condition) since eyes with this condition may have unstable corneas.

- I understand the treatment should not be performed, or performed with caution on persons known to have a previous history of keloid formation (excessive scar formation). I will notify my doctor if I have a history of keloid formation.

- I understand that the FDA has not specifically approved the use of a bandage soft contact lens immediately after PRK and LASEK procedures. The contact lens is used to reduce postoperative pain or discomfort, which can be severe without the lens. The contact lens, however, can increase the risk of corneal infection or inflammation (1-2%).

- I give permission for the medical data concerning my operation and any subsequent treatment to be submitted for outcome data analysis. I understand that my identity will be kept strictly confidential in any reports or journal articles.

- I understand that LASIK, PRK or LASEK treatment requires follow-up care at prescribed intervals for one year after treatment, and I agree to return for required examinations as requested.

- Although it is impossible for the doctor to inform me of every conceivable complication that may occur, I acknowledge that the doctor has answered all of my questions to my

satisfaction. I understand that if I have any questions with respect to the treatment, I can call my physician.

- **SPECIAL MILITARY CONSIDERATIONS:** I understand that refractive surgery procedures will require a waiver issued from USASOC Command for some USASOC sponsored schools such as HALO, SCUBA, Special Forces Qualification course, SERE, and certain ARSOF units. Waivers are generally granted for LASIK, PRK and LASEK as long as the patient is not more than -8.00 Diopters. LASIK, PRK or LASEK are allowed for Special Operations personnel.

- If my vision after the surgery should fall outside the minimum acceptable for my job, I understand that I may be required to change my rate/designation. I also understand that the surgery may disqualify me from commissioning or certain occupations such as aviation.

- If I suffer any injury directly related to my surgery, immediate medical attention is available at the nearest military medical treatment facility, if applicable. I understand that although no financial compensation is available, any injury resulting from my surgery will be evaluated and treated in keeping with the benefits of care to which I am entitled under applicable Army, other Department of Defense, and other state or Federal regulations.