



Date:

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**Laser Surgery Information and Informed Consent Package
("LASIK")**

Prepared for: _____

**This packet is being provided to you by Siems Advanced Lasik and Eye Center to assist you in making an informed decision about whether to undergo the surgical procedure: Laser Assisted In-Situ Keratomileusis. This surgical procedure will be referred to as "Lasik" in this package.

Please read this material carefully

You are encouraged to discuss and ask questions regarding the information in this packet with your surgeon, optometrist and or counselor.

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I. Risks

All surgical procedures, including Lasik, involve risks. These risks may be from known, yet unforeseen causes. This includes but is not limited to an unsuccessful surgical outcome and or complications. During your pre-operative examination, the expected (or likely) outcome of your procedure will be discussed with you.

Patient's Initials

_____ **A. Reading Glasses:** Lasik will not prevent a need for reading glasses. Presbyopia is a condition that causes the regression of near vision. Patients over 40 years of age are particularly susceptible to this condition. Presbyopia may cause a patient to need reading glasses or other corrective visual devices after lasik surgery. This may be temporary, but can be permanent.

Currently the only lasik solution to Presbyopia is a technique known as monovision. Monovision may reduce the need for reading glasses.

_____ **B. Halos and Starbursts:** After a lasik procedure, some patients do not see clearly at night or in low lighting. They may even notice an optical effect called a “halo” or a “starburst” around lights and illuminated objects. These effects are generally temporary but may become permanent.

These conditions are more likely to occur in patients with higher levels of nearsightedness (Myopia), farsightedness (Hyperopia) and or larger than average pupil size. Today's newer technologies have greatly diminished this problem but have not been fully eliminated.

_____ **C. Under-Correction or Over Correction:** While the procedure is designed to completely neutralize your refractive error (unless otherwise discussed with your eye surgeon), the accuracy may vary due to the unique healing response of your eye/s. If your eye's healing response is atypical (irregular), your treatment may result in an under or over correction. A patient's tolerance to under or over-correction varies. In the majority of instances the under or over-correction can be corrected with glasses, contact lenses, or an additional surgery (enhancement).

_____ **D. Increased light sensitivity –** patients may experience light sensitivity following the procedure. This symptom is generally temporary and subsides within approximately one (1) to three months (3).

_____ **E. Regression –** Long term studies from the American Society of Cataract and Refractive Surgery have shown Lasik to be a stable and extremely effective procedure. However each individual's healing response time may vary. One consequence of this variable is that the initial refractive effect may regress with time. Regression is more likely to occur with higher degrees of refractive errors. In most cases, the patient can have a subsequent procedure (an enhancement) to improve the decrease in vision caused by the regression.

**Continued:**

In rare cases the remaining corneal tissue may not be sufficient for enhancement. In this situation glasses or contact lenses may be the only corrective option available.

_____ **F. Corneal Ectasia** – A certain amount of tissue must remain under the flap following a laser procedure. This is believed to relate to the long-term structural stability of the cornea. In rare instances, pre-operative inaccuracies in the measurement of the corneal thickness combined with an imprecise microkeratome cut can result in less than the desired amount of tissue remaining under the flap. The consequences of this would be:

- < A bulging of the cornea which reverses the intended flattening effect of the treatment
- < A progressive deformity of the cornea involving thinning and increasing curvature changes.

In very severe instances, this progressive deformation (Corneal Ectasia) may require corneal transplant in order to restore vision. The probability of occurrence is 1 in 50,000 or 0.00002% of patients (less than one-one thousandth of a percent).

_____ **G. Flap abnormalities** – When using a **bladed Keratome**, the corneal flap is subject to irregularities. These irregularities include:

- | | |
|----------------------------|---------------------|
| < Button holes | < Surface abrasions |
| < Free flap (not hinged) | < Flap wrinkling |
| < Partially completed flap | |

These conditions may be temporary, but may create a need to postpone the surgery until Dr. Siems is able to create a new flap. In some instances the cornea may suffer permanent damage. If an abnormal flap is created, Dr. Siems will generally recommend a one year postponement before attempting to create a new one. Flap abnormalities of this nature occur in less than 1 in 50,000 or 0.00002% of patients.

_____ **H. Intralase** – If the Intralase laser is selected to create the corneal flap, many of the complications associated with the bladed Keratome are avoided. Thus far, over 30,000 cases have been performed and the only observed complication has been “waviness” on the corneal bed. Although this may cause blurred vision, it is temporary and resolves with time. As more cases continue to be performed, it is possible that previously unnoted complications may be observed.

_____ **I. Infection** – Infections are a rare occurrence and can be avoided by using the prescribed antibiotic eye drops. The drops must be used as instructed and for the specified duration. To further minimize the chance of infection, great care and attention to detail are taken by our medical staff when sterilizing all medical tools and equipment between patients.

In the unlikely even that a patient’s eye becomes infected, Dr. Siems may need to re-lift the corneal flap to culture and treat the infection.



Continued:

_____ **J. Diffuse Lamellar Keratitis (DLK) or “Sands of Sahara”** – In some cases patients experience a temporary complication caused by an inflammatory reaction between the flap and the corneal bed. This condition has been nicknamed “Sands of Sahara” for its appearance under the slit lamp.

The exact cause of this complication has not, as of yet, been determined. Patients with DLK may not show any symptoms at all or they may experience blurred vision and tearing. DLK can generally be successfully treated with topical or oral steroids. In rare instances corneal scarring may result.

_____ **K. Epithelial Abrasion** – The epithelium (skin) is a layer of surface cells that protect the cornea. If the epithelium is cut or removed, it grows back. In Lasik, the surgeon creates a flap consisting of epithelium and stroma (thickness and central layer of corneal cells). In some cases, the epithelium is not well attached to the underlying stroma. Such cases are at an increased risk for epithelial abrasions or epithelial sliding; especially as the flap maker is passing over the corneal surface to create the flap.

We can identify some patients whose eyes are at higher risk for this condition and advise them in advance about risks associated with the elected procedure. However there are some patients that **DO NOT** display any clues as to the existence of this condition.

If an abrasion occurs, Dr. Siems will generally place a bandage contact lens over the cornea to protect the eye during the healing process. Patients who experience an abrasion may incur a longer recovery period and may be at an increased risk for complications such as infection, inflammation, recurrent erosion, flap wrinkles or epithelial in-growth. Dr. Siems may choose **not** to treat the second eye during the same session following a severe abrasion on the first eye.

_____ **L. Epithelial In-Growth** – Epithelial in-growth is a condition in which epithelial cells from the surface of the cornea grow under the edge of the flap if the cells continue to grow, they can affect the underlying tissue resulting in an astigmatism, flap edge thinning, and reduction of vision. This condition generally requires no treatment.

If in-growth progresses; surgery may be needed to remove the epithelial cells from the surface.

_____ **M. Dry Eyes** – Dry Eyes are a potential complication arising from LASIK. This condition can usually be treated with lubricating eye drops and, if necessary, temporary inserts or “plugs” that prevent the normal eye drainage of tears into the nose. Dry eyes generally improve within a few months after surgery, but in some instances can continue for a longer period of time. Long term use of lubricant eye drops and permanent plugs may be required. Patients who have dry eyes prior to LASIK are more likely to experience dry eyes after the procedure.

_____ **N. Re-treatment** – If a candidate has residual refractive error after the procedure, he or she may be a candidate for a LASIK re-treatment (enhancement) procedure. Patients must generally wait at least three (3) to six (6) months after the initial procedure, have adequate corneal thickness and stable vision before an enhancement will be considered. Generally the original flap is simply re-lifted, followed by the Lasik treatment. Post op care is normally equal to that of the original post op treatment plan.



II. Risk of NOT Undergoing Lasik

The risks of not having Lasik surgery are limited to those associated with your current visual condition. They include but are not limited to the dangers that may be associated with losing glasses or contact lenses, the risks of corneal distortions and/or infection from wearing contact lenses and the risks of trauma to the eye caused by breakage of plastic spectacles or contact lenses in the eye.

III. Preparing for the Procedure

Contact lenses can “warp the corneal surface thus changing its curvature”. This can result in inaccuracies when measuring a person’s refractive error. It is necessary to stop contact lens usage at some stage prior to the initial examination and Lasik procedure. The timeline for this depends on the type of lenses that you use and the length of time you have used them.

- < Soft contact lenses may not be worn for 4 consecutive days prior to the preoperative exam nor should they be worn for 4 consecutive days prior to surgery.
- < Soft toric lenses may not be worn for 10 consecutive days prior to the preoperative exam nor should they be worn for 10 consecutive days prior to surgery.
- < Gas permeable lenses should not be worn for a duration of 4-6 consecutive weeks prior to the preoperative exam nor should they be worn for a duration of 4-6 consecutive weeks prior to surgery.

Dr. Siems may have exceptions to the above rules based on a person’s unique individual case. You are encouraged to discuss your personal situation with the doctor.

IV. Ride Agreement

This confirms that I have been informed that I should not, under any circumstances drive following refractive surgery. More specifically I should abstain from driving until my vision has been proven to meet or exceed the minimum vision requirement as specified by Nevada State Department of Motor Vehicles (DMV).

This also confirms that I have been informed that in no event should I attempt to drive myself home immediately following surgery and that I should obtain a driver from my one day post operative visit.

I have read and agree to these terms, conditions and precautions. I fully understand and accept any risks involved by not adhering to the precautions advised within this packet. If I do not cooperate fully with these terms, conditions and precautions, I understand that I am willfully going against the medical advice given to me by Siems Advanced Lasik and Eye Center.

By signing this document I declare that I agree to the terms, conditions and precautions advised to me.

Patient’s Signature: _____ Date: _____



V. Enhancement Protocol

Less than 5% of Dr. Siems patients need enhancements. If an enhancement is deemed necessary there will be no charge from the surgeon, administration or for supplies, however, there will be a laser card fee per eye. This fee is established by the laser company and will be billed to the patient if and when an enhancement is necessary. The fee schedule is as follows:

- < Enhancements performed within 12 months of the original surgery date will be billed \$250 per eye.
- < Enhancements performed during 2-3 years after the original surgery date will be billed at \$500 per eye.

Patient's Signature: _____ Date: _____

VI. Facility Viewing Policy

Family and friends are always welcomed to be a part of your experience at our facility. A glass wall allows on lookers to view the surgery as it is being performed.

All laser suites are climate controlled and sanitized for optimum laser performance and patient safety.

By signing below this statement you are declaring that you understand that your surgery may be viewed by anyone located in or around the viewing area.

Patient's Signature: _____ Date: _____

VII. Consenting to LASIK / LASEK (PRK - Photo Refractive Keratectomy)

I give my consent to have **Jon Siems, M.D.** perform my:

- LASIK procedure
Patient Initials

- LASEK procedure
Patient Initials

I understand that I may be seen by a different physician during my post operative follow ups. I agree and fully understand the statement above.

Patient Printed Name: _____ Date: _____

Patient's Signature: _____ Date: _____

Witness Signature: _____ Date: _____



VIII. Patient – Physician Arbitration Agreement

- 1. It is understood that any dispute as to medical malpractice that is as to whether any medical services rendered under this agreement were unnecessary, improperly, negligently or incompetently rendered will be determined by submission to an arbitration as provided by Nevada Law and not by a lawsuit or resort to court process except as Nevada Law provides for judicial review of arbitration proceedings. Both parties to this contract are entering into this contract are giving up their constitutional rights to have such a dispute decided in a court of law before a jury and instead are accepting the use of arbitration.
- 2. I agree to be bound by the rules of the American Arbitration Association.
- 3. Arbitration of any dispute arising hereunder shall be subject to the provisions of the Medical Injury Compensation Reform Act of 1975 (MICRA). Furthermore, this arbitration agreement shall be binding upon the spouse, all legal heirs and minors including any unborn child or children of the patient.
- 4. **NOTICE: BY SIGNING THIS CONTRACT YOU ARE AGREEING TO HAVE ANY ISSUE OF MEDICAL MALPRACTICE DECIDED BY NEUTRAL ARBITRATION AND YOU ARE GIVING UP YOUR RIGHT TO A JURY TRIAL OR COURT TRIAL. SEE ARTICLE 1 OF THIS AGREEMENT.**

Patient Printed Name: _____ Date: _____

Patient’s Signature: _____ Date: _____

Physician’s Agreement to Arbitrate:

I likewise agree to be bound by the rules of the American Arbitration Association.

Physician or Duly-Authorized Representative Printed Name: _____

Physician or Duly-Authorized Representative Signature: _____

Date: _____

The exact wording of the first and fourth paragraphs outlined is required by the Nevada Code of Civil Procedure, Section 1295.