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**INFORMED CONSENT FOR LASIK (LASER IN SITU KERATOMILEUSIS) and  
PRK (PHOTOREFRACTIVE KERATECTOMY)**

Please read the following consent form very carefully. Please initial or sign each page where indicated. Do not sign this form unless you have read and understood each section. If you have any questions, please discuss them with Dr. Goodman.

Patient Name: \_\_\_\_\_

Surgeon Name: \_\_\_\_\_

Date: \_\_\_\_\_ Date of surgery: \_\_\_\_\_

Treatment: Right Eye \_\_\_\_\_ Left Eye \_\_\_\_\_ Both Eyes \_\_\_\_\_

Monovision: Yes \_\_\_\_\_ No \_\_\_\_\_

**PATIENT SIGNATURE:** \_\_\_\_\_

My signature below indicates that I have read and agree to follow the pre-operative and post-operative instructions included with my packet.

**PATIENT SIGNATURE:** \_\_\_\_\_

Success rate for 20/ \_\_\_\_\_ or better is \_\_\_\_\_%; 20/ \_\_\_\_\_ or better is \_\_\_\_\_%.

Retreatment Rate is \_\_\_\_\_%

Surgeon Comments:

\_\_\_\_\_  
\_\_\_\_\_

**SURGEON SIGNATURE:** \_\_\_\_\_

## **INTRODUCTION:**

It is our intent to completely inform you concerning the benefits, alternatives, side effects, limitations, and complications of laser surgery. The first important message to understand is that it is impossible to perform any form of surgery without the patient accepting a certain degree of risk and responsibility.

This consent form in combination with the extensive educational material provided and the entire consultation process is designed to enhance your understanding of the procedure. Laser Vision Correction procedure is an elective procedure. Any patient who does not wish to accept these risks can simply elect not to have surgery.

**Patient Initials \_\_\_\_\_**

## **BACKGROUND:**

The cornea is the “window” to the eye -- a colorless, clear dome-shaped tissue -- much like the crystal on your wristwatch. The excimer laser reshapes the cornea in an attempt to reduce or eliminate the need for glasses or contact lenses. In cases of myopia (nearsightedness), hyperopia (farsightedness), and astigmatism (ovalness or uneven curvature of the cornea) the excimer laser is used to perform PRK (photorefractive keratectomy) on the surface of the eye or LASIK beneath the surface.

Photorefractive Keratectomy (PRK) and Laser in situ Keratomileusis (LASIK) are procedures utilizing an excimer laser. Refractive techniques that involve making a flap have been in existence for over 20 years. Shortly after the FDA approval of the excimer laser in 1995, surgeons began combining these flap-making techniques with excimer laser PRK. In the LASIK technique, an instrument known as a microkeratome is used to create a flap from the surface of the cornea. This instrument is extremely precise with delicate gears that run on the tracks of a suction ring. A strong suction force holds the suction ring on the white part of the eye. When the suction is applied, the vision may temporarily fade out. This attachment of the suction ring allows the flap-making portion of the microkeratome to maintain a precise relationship to the surface of the cornea. The corneal flap is approximately 3 hairs thick, with the entire cornea typically 11 hairs thick; patients cannot see or feel the incision. The flap remains attached to the surface of the eye with a “hinge”. The laser application is performed within the corneal bed instead of on the corneal surface, as with PRK. Most people state that they do not feel any pain, but rather experience a slight pressure around the eye. During the laser treatment, the patient will hear a clicking sound and may smell transient odor. Following the application of the laser, the surgeon replaces the flap, which initially adheres because of a natural suction force generated by the cornea. No stitches are required. Within a day the epithelium grows over the edge of the flap, adding to the firmness of its attachment. Over the following months, the flap becomes more and more firmly attached, as the body generates new connective tissue between the flap and the main body of the cornea.

Alternative Treatments: Patients must have rejected alternatives to LASIK (Laser in situ Keratomileusis), which include not having the surgery, glasses, contact lenses, and pursuing other refractive procedures such as PRK, Intacs (intra-corneal rings), CK (conductive keratoplasty), or phakic IOL's (implantable contact lenses).

Contraindications: Patients with any residual, recurrent or active ocular disease or abnormality except for myopia, hyperopia or astigmatism in either eye are not candidates. Also excluded are patients with residual, recurrent or active systemic disease that may affect corneal wound healing. Such diseases include poorly controlled rheumatic arthritis, lupus, or other autoimmune disorders.

Follow-up Examinations: Patients are requested to return for follow-up care several times during the first six months following LASIK, then yearly after the surgery in order to monitor healing of the eye and patient progress following surgery.

All patients are to understand and accept the fact that if an enhancement is needed or a complication occurs, they may require more frequent visits over a longer follow-up period, and additional costs may be incurred. Typically, regular office visit charges are incurred one year after the LASIK procedure. Enhancement surgery, when indicated, is not always possible.

**Patient Initials \_\_\_\_\_**

**RECOVERY/RISKS:**

- 1) The risk of INFECTION is approximately 1/2000 with PRK and 1/10,000 with LASIK.

**Patient Initials \_\_\_\_\_**

- 2) The risk of PAIN is approximately 1/10 with PRK and 1/50 with LASIK. It is common to feel a "scratchy", tearing, light sensitivity, redness and swelling, especially for the first 4-6 hours after the procedure. Some patients may experience symptoms of "dry eye" up to 6 months following surgery or, rarely, permanently.

**Patient Initials \_\_\_\_\_**

- 3) The risk of developing SCAR TISSUE or CORNEAL HAZE with LASIK is less than 0.01% (one per 10,000). The risk of scar tissue formation with PRK is approximately 0.5% (5/1000), increasing in incidence with the degree of attempted correction. Scar tissue is composed of collagen proteins that develop on the surface of the eye with PRK and beneath the corneal flap with LASIK. The development of haze may require retreatment with additional laser and application of an antimetabolite drop (mitomycin C).

**Patient Initials \_\_\_\_\_**

The two side effects that are similar for both the LASIK and PRK procedures are NIGHT GLARE and BLURRINESS. They are very common early in the healing process, and are observed by most patients. Both night glare and blurriness typically, but not always, improve over several months once both eyes have been treated.

- 4) NIGHT GLARE is common in nearsighted individuals even before any refractive procedure is performed but increases almost immediately in the healing process and is more common when only one eye has been treated. Typically, 6 months after both eyes have been treated, less than 0.1% (1/1000) of patients still experience significant night glare which seriously interferes with their night driving. Severe night glare can reduce vision in all reduced-lighting conditions producing blurriness, ghosting or halos. Patients with large pupils and severe myopia and/or astigmatism are at greater risk for night glare.

**Patient Initials \_\_\_\_\_**

- 5) Almost all patients describe BLURRINESS immediately following surgery. Blurriness to one degree or another is common. With the LASIK procedure there is considerable improvement in vision within the first 24-48 hours. Approximately 80% of the visual recovery occurs within the first several days, with the last 20% of vision improving over 3-6 months. Patients typically experience significant improvement of vision within days. The qualitative "fine tuning" may take much longer, on the order of several weeks to months. Some patients do experience a profound and dramatic visual improvement and become able to read half or more of the eye chart the next day, but most state it is still not clear and crisp, and has been described as "Vaseline vision".

Approximately 0.1% (1/1000) of patients, independent of the procedure performed, will develop corneal irregularities reducing the sharpness, crispness and/or clarity of their vision. This may prevent them from reading the bottom 2 or more lines on an eye chart. It may not be possible to correct this with glasses, contacts, or other surgery. There is no way of predicting or predetermining who will be in this 0.1%. A patient that loses sharpness may have vision that is permanently worse. Some patients in this group may require full-time contact lens wear (soft and/or rigid gas permeable contact lenses). All forms of eye surgery alter human tissue and possess some risk.

**Patient Initials \_\_\_\_\_**

- 6) CORNEAL FLAP COMPLICATIONS: The entire incision time is approximately 15 seconds, but during this brief interval a lot of things need to go right. There is an approximate 0.1% (1/1000) risk that the eye will experience a corneal flap complication. Corneal flap complications may necessitate postponing surgery for three months.

**Patient Initials \_\_\_\_\_**

- 7) EPITHELIAL INGROWTH: During the first 24 hours the epithelial protective layer grows over the corneal flap. There is a 0.5% (5/1000) risk that epithelial cells may grow underneath the flap. This is more common in people with weak protective layers which bond poorly to the eye surface. Any intra-operative breakdown of the protective layer may increase the incidence of epithelial ingrowth. Treatment involves lifting the flap and clearing the cells. Untreated epithelial ingrowth may distort vision and may actually damage the flap if severe and progressive. Small ingrowths do not usually present any visual problems and need only be monitored. This complication cannot occur with PRK, because it is flap-related.

**Patient Initials** \_\_\_\_\_

### **COMPLICATIONS:**

Less than 1% of patients develop significant complications. NO ONE ever believes they will be in this group. LASIK performed for severe myopia and astigmatism is associated with a higher risk of complications, approximately 1%.

**Patient Initials** \_\_\_\_\_

None of our patients have ever gone blind from excimer laser surgery BUT you can always be the first. Theoretical risks are potential problems that have not happened yet. The risk of blindness is estimated to be one per million procedures. There are no guarantees of perfect vision. There are no guarantees that you will not need glasses or contacts. There are no guarantees that you will not be in the small fraction of patients that have significant complications.

**Patient Initials** \_\_\_\_\_

LASIK carries a higher risk of flap complication than PRK, but a lower risk of pain, infection, scarring with faster recovery and less need for eye drops. LASIK carries a higher risk of intra-operative complications and lower risk of post-operative complications.

**Patient Initials** \_\_\_\_\_

**EXPECTATIONS:**

The goal is to achieve the best visual results in the safest way. The goal is NOT to eliminate glasses and contacts completely but to dramatically reduce your dependence upon them. Night driving glasses and readers may always be needed even with a successful procedure.

**Patient Initials** \_\_\_\_\_

The degree of correction required determines both the rate of recovery and the accuracy of the procedure. Severe prescriptions often require at least two procedures. Patient differences in healing will also greatly affect visual recovery and final visual outcome, and are impossible to predict.

**Patient Initials** \_\_\_\_\_

**ENHANCEMENTS:**

Enhancement surgeries are generally performed no sooner than 3 months after the first surgery. Generally, at this point, there is no need to make another cut with the microkeratome for LASIK enhancements. The original flap can usually be lifted with specialized techniques. After 2 years, the use of the microkeratome may be required to form a new flap, incurring additional risk. In PRK enhancements, the outer layers or the cornea are removed prior to laser treatment as in the original procedure.

In order to perform any enhancement surgery, there must be adequate corneal tissue remaining. If the cornea is too thin, it may not be possible to perform an enhancement. An assessment and consultation will be held with the surgeon at which time the benefits and risks of an enhancement surgery will be discussed.

**Patient Initials** \_\_\_\_\_

**FDA APPROVAL**

The FDA has approved the excimer laser for up to -12.00 diopters of correction for nearsightedness, 4.00 diopters of correction for astigmatism, and +6.00 diopters of correction for farsightedness in the United States. For nearsightedness or astigmatism greater than the approved range, Dr. Goodman may provide treatment to the patient if he/she is a suitable candidate and specifically requests correction beyond the FDA recommendations. This is also an accepted "standard of care" application of excimer laser surgery.

LASIK has been approved for treatment of Nearsightedness with or with out -0.50 to -5.00 diopters of Astigmatism

I request that Dr. Goodman treat my nearsightedness beyond -12.00 diopters and/or my astigmatism beyond 4.00 diopters of correction.

**Patient Initials** \_\_\_\_\_

I request that Dr. Goodman treat my farsightedness beyond +6.00 diopters of correction.

**Patient Initials** \_\_\_\_\_

**IMPROVEMENT OF VISUAL POTENTIAL:**

Patients who do not see 20/20 or 100% before surgery, even with the strongest prescription, cannot expect or anticipate 20/20 or 100% after surgery. That is, after surgery the best vision a patient can attain is the vision they experienced before their procedure with their best correction. Rigid gas permeable lenses may actually provide certain patients with better vision than glasses, soft lenses or refractive surgery. This surgery does not improve visual potential. Each patient will continue to require routine annual eye examinations to rule out several conditions, including glaucoma, cataracts or retinal disease, which typically requires a yearly dilated comprehensive examination.

Legal driving vision is approximately 20/40. If you cannot achieve corrected vision of 20/40 or better you may not qualify to renew your driver's license.

Patients with borderline visual function must understand that a loss of sharpness may prevent them from driving legally, or performing other equally demanding visual tasks (occupational and/or recreational).

**Patient Initials** \_\_\_\_\_

**MONOVISION:**

Everyone over the age of 40 will eventually experience presbyopia, resulting in the need for reading glasses or bifocals. In monovision the typical aim is to have the non-dominant eye a little under-corrected to help reading vision. This involves giving up distance sharpness in the non-dominant eye, though binocular distance vision remains excellent. Night driving glasses are more common, and reading glasses may still be required for fine print or prolonged reading. BUT, overall dependence on glasses or contacts is still dramatically reduced. Monovision helps with simple near tasks such as working at the computer, opening mail, reading price tags, or looking at one’s wristwatch. Patients, who desire the best distance or night vision unaided, such as pilots or truck drivers, should avoid monovision. In our experience, people over 40 years of age should consider monovision correction.

I want my correction to include monovision (please initial):

Yes \_\_\_\_\_ No \_\_\_\_\_

**PATIENT CONSENT:**

Please initial after each paragraph, and rewrite in your own handwriting the bold faced phrases as indicated.

- 1. I understand the basic nature of the procedure and benefits as well as the possible risks and complications of PRK and LASIK. All of my questions have been answered to my satisfaction. I understand that it is impossible for my surgeon to inform me of every conceivable complication that may occur.

**Patient Initials** \_\_\_\_\_

- 2. I understand that, as with any form of surgery the outcome can never be guaranteed. I specifically understand that the benefits of the PRK and LASIK procedures cannot be guaranteed. PRK and LASIK may be of no benefit to me and may in fact be harmful.

**Patient Initials** \_\_\_\_\_

3. I understand that **“there are no guarantees”**.

Please write out: \_\_\_\_\_

4. I understand that as a result of surgery using the excimer laser that there is a small risk that my vision may be worse and not correctable to the level of my preoperative vision even with glasses or contact lenses.

**Patient Initials** \_\_\_\_\_

5. I understand that **“my vision may be made worse”** from laser surgery.

Please write out: \_\_\_\_\_

6. Complications that may occur include -- but are not limited to -- retinal tears, retinal detachments, central retinal artery occlusion (eye stroke), corneal infection, intraocular infection, corneal scarring, recurrent corneal erosions (breakdown of the protective surface layer), decrease in best corrected vision, permanent night vision problems, corneal decompensation (persistent corneal swelling), corneal ectasia (bulging of the cornea) and corneal perforation. Although vision-threatening complications are quite rare, it is possible that a significant reduction in vision may be produced. As a result of these complications, I may require a corneal transplant. Blindness resulting from LASIK may occur as a result of perforation and/or infection under very rare circumstances.

**Patient Initials** \_\_\_\_\_

7. I understand that **“I may not achieve the level or quality of vision I hope for”**

Please write out: \_\_\_\_\_

8. 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 further surgery may be needed.

**Patient Initials** \_\_\_\_\_

9. I understand **“I may still need to wear glasses or contact lenses”**

Please write out: \_\_\_\_\_

10. I understand that partially and fully sighted eyes have been treated with excimer laser since 1987 and that Lamellar Keratoplasty has been performed since the 1970s with the combined LASIK procedure being performed since 1991. The very long-term effects associated with this procedure are not known.

**Patient Initials** \_\_\_\_\_

11. I understand that no financial compensation or reimbursement is available to me from my surgeon, my ophthalmologist or optometrist, any doctor involved in my LASIK follow-up care, or the laser manufacturer in the event of any complication related to excimer laser LASIK surgery or my dissatisfaction with the results of the LASIK surgery.

**Patient Initials** \_\_\_\_\_

12. My surgery may be videotaped and/or audio taped. These tapes will be used for teaching and/or research purposes only. My identity **will not** be disclosed.

**Patient Initials** \_\_\_\_\_

13. A copy of this consent form is available to me upon request.

**Patient Initials** \_\_\_\_\_

14. I have read the patient information booklet and the pre-operative and post-operative instructions.

**Patient Initials** \_\_\_\_\_

15. FOR WOMEN ONLY: I am not pregnant or nursing. I understand that pregnancy could adversely affect my treatment result.

**Patient Initials** \_\_\_\_\_

**VOLUNTARY CONSENT:**

In signing this Informed Consent Form I certify that I have read the preceding information and understand the contents. Any questions I have concerning the consent form or concerning PRK and LASIK have been answered by my surgeon. My decision to proceed with surgery has been voluntarily and freely given.

**RIGHT EYE** \_\_\_\_\_ **LEFT EYE** \_\_\_\_\_ **BOTH EYES** \_\_\_\_\_

Patient Full Name (print): \_\_\_\_\_

Patient Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Witness Full Name (print): \_\_\_\_\_

Witness Signature: \_\_\_\_\_

Surgeon: \_\_\_\_\_

Date of Procedure: \_\_\_\_\_