

INFORMED CONSENT FOR LASIK RETREATMENT FOLLOWING OTHER REFRACTIVE AND SURGICAL PROCEDURES

In addition to the complete LASIK Consent Form, you have been provided with this addendum to outline some specific risks to further enhance your understanding. Please read the following pages carefully and initial and sign the sections which apply to you where indicated. Please do not sign any section that you have not read or do not understand.

PLEASE SIGN THE APPLICABLE SECTION(S) AND SECTION 8

SECTION 1: General Information on Informed Consent

LASIK surgery following other refractive procedures such as LASIK, Photorefractive Keratectomy (PRK), Radial Keratotomy (RK), Automated Lamellar Keratoplasty (ALK), Myopic Keratomileusis, and non-refractive procedures including corneal transplant surgery, cataract surgery and retinal surgery will be reviewed.

We have tried to balance the benefits of further laser surgery with the known and unknown risks. It is important to understand that it is possible to perform any form of surgery without the patient accepting a certain degree of risk and responsibility. This consent form addendum to our full LASIK consent form and in combination with the consultation process is designed to enhance your understanding of the potential for difficulties that may be encountered during both LASIK enhancement procedure and the associated healing process. It is important to appreciate that even if you did not experience any difficulties with your original procedure, that this does not mean that you will not have any complications with your LASIK enhancement procedure. The risk of LASIK after previous ocular surgery may be higher than the risks of LASIK for an unoperated eye. The only way to avoid all additional risks associated with further LASIK surgery is to avoid additional surgery altogether. Each patient must balance the risks and benefits to determine whether to proceed.

INITIALS:

SECTION 2: LASIK Surgery following Photorefractive Keratectomy (PRK) Surgery

There are many reasons to perform LASIK rather than PRK, after PRK, the most common of which are to reduce or avoid the associated healing risks of discomfort, corneal haze, infection, prolonged visual recovery time, topical steroid or other medication reactions. Alternatively, LASIK may be preferred to treat a more complex prescription pattern, which is possibly, more amenable to LASIK techniques, such as hyperopia (farsightedness) and mixed astigmatism.

While LASIK carries additional benefit with respect to comfort and visual recovery time, it also carries additional risk with respect to the creation of the protective corneal flap as outlined in the accompanying LASIK consent form. Specifically, there may be additional

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problems encountered when treating eyes that have been previously treated with PRK. For example, since PRK involves removal of the epithelial protective layer, the epithelium may not be as strongly adherent and may occasionally become disrupted when the corneal flap is created resulting in a prolonged and more uncomfortable recovery period. Furthermore, the creation of a corneal flap may trigger PRK haze to reactivate in a small percentage of cases.

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SECTION 3: LASIK Surgery Following Radial Keratotomy (RK)

LASIK may be used to treat residual prescriptions following RK however there are specific additional risks not outlined in our accompanying LASIK consent form. It is important to recognize that the creation of the corneal flap in an eye with RK incisions increases the possibility of corneal flap complications. Specifically, the RK incisions may split, resulting in corneal flap fragmentation and possibly producing significant corneal irregularity and blurred vision. While this problem can often be managed successfully by repositioning the flap segments, the risk is real. Less significant problems may also be encountered, including but not limited to, reduced refractive predictability with over-and-under corrections, induced astigmatism, irregular healing reducing qualitative vision, which are all related to the RK incisions altering the expected corneal healing pattern in an unpredictable manner. Further, LASIK retreatment is also problematic in that the corneal flap cannot be as readily lifted or recut and re-lasered, therefore it is possible that only one attempt can be made at treating the residual RK prescription. No guarantees can be made that the residual prescription will be eliminated or even significantly reduced, although an improvement is typically achieved. LASIK epithelial ingrowth along the RK incisions may also be observed and require further management during the healing period. Problems associated with RK such as fluctuating vision and night glare, are occasionally improved however this is not typical. Lastly, the amount of farsightedness or nearsightedness may be progressive, increasing over time. LASIK does not prevent further progression or restore corneal stability. Fluctuations in your vision will most likely persist.

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SECTION 4: LASIK Following Automated Lamellar Keratoplasty (ALK) or Myopic Keratomileusis (MKM)

LASIK following other lamellar procedures such as ALK and MKM carries additional risk, in addition to those outlined in the accompanying LASIK consent form. The specific risks involved are both surgical and healing related. The overall surgical risk is elevated in that the cornea has had previous lamellar incisions that may intersect with any new LASIK incision, resulting in a free wedge of corneal tissue being produced, or disruption of the cornea at the site of the original procedure. The interaction of the two procedures may also increase the incidence of healing irregularities and reduce the predictability of achieving an ideal refractive result. Lastly, corneal stability may be adversely affected when multiple procedures are performed on an eye and there can be no guarantees made that a significant loss of stability will not occur requiring a corneal transplant. Patients at highest risk for this adverse result are those who had been previously treated with Hyperopic ALK.

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SECTION 5: LASIK Following Corneal Transplantation

LASIK following corneal transplantation carries specific risks not outlined in the accompanying LASIK consent form. LASIK carries a small but real risk of inducing corneal graft failure or rejection. Furthermore, LASIK may produce corneal graft wound dehiscence or splitting, with an increased risk of severe infection, requiring additional suturing or further surgery and possibly inducing significant astigmatism. LASIK following corneal transplantation is less predictable, and retreatment may be required. Full correction may also not be possible depending upon the severity of the prescription and the healing pattern of your eye. Irregular or prolonged healing may also be encountered in a small percentage of patients. In general, the goal is to reduce the severity of the astigmatism, farsightedness, and/or myopia.

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SECTION 6: LASIK Following Cataract Surgery

LASIK following cataract surgery carries specific risks not outlined in the accompanying LASIK consent form. LASIK following cataract surgery is associated with a slightly increased risk of corneal flap, including but not limited to, poor or irregular corneal flap quality. Visual recovery may be slower. Refractive predictability may also be reduced and a full correction may not be achieved. There is also the rare possibility that the cornea may swell uncontrollably following LASIK or the cataract implant may be dislodged if not adequately healed.

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SECTION 7: LASIK Following Previous Retinal Surgery

LASIK following retinal surgery may be associated with specific risks not outlined in the accompanying LASIK consent form. While all forms of retinal surgery, including laser, indicate that there is a problem or weakness with the retinal nerve tissue, they do not necessarily increase the risks associated with LASIK. Specifically, retinal detachment surgeries with placement of a scleral buckle and retinal tear laser surgery, both indicate that the retina is thinner and more vulnerable. While there have been anecdotal reports of retinal tears and detachments following LASIK, most reports do not appear to be the result of the procedure and the relationship is unclear. Patients that have had scleral buckle surgery however are at a somewhat higher risk of experiencing a poor or irregular flap. Furthermore, the LASIK suction ring applies increased which may possibly affect the visual outcome. All patients should appreciate that any increased vulnerability of the eye that exists prior to LASIK may result in problems in the future, which may or may not be related to the LASIK procedure.

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SECTION 8: VOLUNTARY CONSENT

Please sign below that you have carefully reviewed this consent addendum outlining further specific LASIK risks associated with your prior surgery and that you have had an opportunity to have any questions that you may have had answered. By signing below you also indicate that you are aware that LASIK is an elective procedure, that you do not need to have this procedure and that you understand your other surgical and non-surgical alternatives for vision correction.

Patient Full Name: (Print) _____

Patient Signature: _____ **Date** _____

Witness Full Name: (Print) _____

Witness Signature: _____ **Date** _____

Surgeon Name: (Print) _____

Surgeon Signature: _____ **Date** _____