INFORMED CONSENT

LASEK RETREATMENT

INTRODUCTION

This document is provided to obtain your informed consent for laser vision correction. It contains important information detailing the risks and benefits as well as alternative treatments available. Laser vision correction is an elective procedure and you are choosing it because you want to, not because you must.

It is important that you thoroughly read and understand everything, and only sign once you have read, understood, and have had all questions answered to your satisfaction enabling you to make an informed decision.

INSTRUCTIONS

- Your vision correction coordinator will review this document with you.
- Take as much time as needed to read, understand, and have all questions answered prior to signing.
- This document must be completed prior to any treatment.
- You may request a copy of this document at any time.

Name	MRN	Date

Email Address	Witness

Procedure	Eye
LASEK Retreatment	

ID: AL REV: 20181220

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INFORMED CONSENT FOR EPITHELIAL LASIK (LASEK) RETREATMENT OF ORIGINAL PROCEDURE

FOR THE CORRECTION OF MYOPIA (NEARSIGHTEDNESS), HYPEROPIA (FARSIGHTEDNESS), AND ASTIGMATISM

INDICATIONS AND PROCEDURE

This information is being provided to you so that you can make an informed decision regarding Laser Epithelial Keratomileusis or LASEK surgery to reduce or eliminate your nearsightedness, farsightedness or astigmatism. LASEK is one of a number of alternatives for correcting farsightedness. In LASEK, the epithelium layer is removed using 18% alcohol solution. Next, an excimer laser is used to remove ultra-thin layers of tissue from the cornea to reshape it to reduce farsightedness. Last, a bandage contact lens is placed over the eye, without sutures.

It is important to realize that even if you did not experience any difficulties with your original LASEK procedure, that does not mean that you will not have any complications with the retreatment. The only way in which a patient can avoid all surgical risks is by not proceeding with surgery. Each patient must balance the risks and benefits to determine whether to proceed with further surgery.

ALTERNATIVES

LASEK is an elective procedure: there is no emergency condition or other reason that requires or demands that you have it performed. There are alternatives to this surgery: you could continue wearing contact lenses or glasses and have adequate visual acuity. As you were informed before your first LASEK procedure, retreatments are at times indicated to correct remaining or induced myopia (nearsightedness), hyperopia (farsightedness), and astigmatism. There is no guarantee that repeat LASEK will correct these problems. Alternative forms of vision correction exist, including eyeglasses, contact lenses, orthokeratology (ortho-K), radial keratotomy (RK), intracorneal ring segments (ICRS), holmium laser thermokeratoplasty (LTK), or photorefractive keratectomy (PRK).

ELIGIBILITY FOR RETREATMENTS

The ophthalmologist alone can determine whether or not you are a candidate for retreatment. Several factors determine eligibility. LASEK retreatment procedures are performed by applying additional laser to the corneal bed. An enhancement can be performed once the vision and prescription (refraction) stabilize after the original LASEK procedure, which takes between one to four months for most patients. Typically, the higher the attempted correction for the original procedure, the longer it takes for the cornea to heal.

Many surgeons wait three months before retreating any patient, others treat those with low prescriptions after one to two months. The ideal time for a retreatment is when the refraction is stable. There must be adequate corneal tissue to safely perform the reoperation and this can be measured at the time of the surgery. The remaining corneal thickness is an important factor the surgeon considers when deciding whether a retreatment can be safely performed.

RISKS AND COMPLICATIONS

The risks associated with the original LASEK procedure apply to retreatment as well.

This procedure, like all surgery, presents some risks, many of which are listed below. As with all types of surgery, there is a possibility of complications due to anesthesia, drug reactions, or other factors that may involve other parts of my body. Since it is impossible to state every complication that may occur as a result of any surgery, the list of complications in this form may not be complete.

I understand that the following risks are associated with the procedure:

POSTOPERATIVE SIDE EFFECTS AND COMPLICATIONS

Early in the postoperative period, you may experience a foreign body sensation, pain or discomfort, sensitivity to bright lights, blurred vision, dry eyes, tearing, or fluctuations in vision. Discomfort is more common during the first few hours after surgery with retreatment than with the original LASEK procedure. Persistent pain is uncommon and may indicate a disturbance of the epithelial protective layer, displacement of the corneal flap, or a possible infection. You should immediately notify the surgeon if you have persistent pain.

Corneal infection following LASEK enhancement is rare but if serious can cause corneal scarring and require a corneal transplant. In very severe cases, blindness can result.

Corneal inflammation can be caused by medications or healing reactions which can be allergic, toxic, or immune in nature. Diffuse interface keratitis (also known as the Sands of the Sahara) may occur with both primary and repeat LASEK. This inflammatory reaction

can cause corneal haze, blurred vision, farsightedness, astigmatism, or permanent corneal irregularities. Treatment may involve topical steroids or further surgery, and treatment may or may not fully restore vision.

I understand that there is an increased risk of eye irritation related to drying of the corneal surface following the LASEK procedure. These symptoms may be temporary or, on rare occasions, permanent, and may require frequent application of artificial tears and/or closure of the tear duct openings in the eyelid.

After refractive surgery, a certain number of patients experience glare, a "starbursting" or halo effect around lights, or other low-light vision problems that may interfere with the ability to drive at night or see well in dim light. The exact cause of these visual problems is not currently known; some ophthalmologists theorize that the risk may be increased in patients with large pupils or high degrees of correction. For most patients, this is a temporary condition that diminishes with time or is correctable by wearing glasses at night or taking eye drops. For some patients, however, these visual problems are permanent. Retreatment often improves night glare by reducing the residual refractive problems, but it is limited by the remaining corneal thickness, treatment area, individual patient sensitivity to night glare, and corneal healing pattern. I understand that my vision may not seem as sharp at night as during the day and that I may need to wear glasses at night or take eye drops. I understand that it is not possible to predict whether I will experience these night vision or low light problems, and that I may permanently lose the ability to drive at night or function in dim light because of them. I understand that I should not drive unless my vision is adequate.

Some patients develop keratoconus, a degenerative corneal disease affecting vision that occurs in approximately 1/2000 in the general population. While there are several tests that suggest which patients might be at risk, this condition can develop in patients who have normal preoperative topography (a map of the cornea obtained before surgery) and pachymetry (corneal thickness measurement) . Since keratoconus may occur on its own, there is no absolute test that will ensure a patient will not develop keratoconus following laser vision correction. Severe keratoconus may need to be treated with a corneal transplant while mild keratoconus can be corrected by glasses or contact lenses.

REFRACTIVE COMPLICATIONS

Repeat LASEK may result in overcorrection and undercorrection due to the variability in patient healing patterns and other surgical variables, leaving patients nearsighted, farsighted, or with astigmatism. This may or may not require patients to wear glasses or contact lenses or undergo additional surgery. Further surgery entails additional risk and is not guaranteed to provide an ideal visual outcome, although improvement is often obtained.

Patients may heal differently between eyes based upon differences in preoperative prescriptions, corneal curvature, variation in healing, or other factors. Differences in refraction between eyes is called anisometropia. This is most severe when only one eye is treated, and may result in loss of depth perception, eyestrain, headache, double vision, and the need for contact lenses. Both farsightedness and anisometropia may result in worsening of muscle balance problems, causing the eye to wander more or producing eye fatigue.

Depending upon the severity of the original prescription, the healing pattern of the patient, and other factors, regression may occur, causing the eyes to return to their original prescription, either partially or completely. Further retreatment surgery may be performed when the eye is stable and if adequate corneal tissue is available and no medical contraindications exist.

CORNEAL HEALING COMPLICATIONS

Significant healing is still required, which can affect visual quality and ability. Corneal healing problems are more common in patients corrected for higher prescriptions for over- and undercorrection.

Corneal healing may affect not only the speed of healing but the smoothness of the cornea, leading to blurry vision or rarely corneal scarring. Corneal irregularities may develop that affect the quality, crispness, and sharpness of the final result. Corneal irregularity or corneal astigmatism is produced when the cornea heals in an irregular pattern. It may also be produced by abnormalities and complications of the laser treatment, including central islands and decentrations. These are expected during the first few weeks following an uncomplicated repeat LASEK, but if they persist beyond 3-6 months, they are considered abnormal and permanent. Further surgical intervention does not guarantee better healing and may result in a further reduction of visual quality.

Irregular astigmatism from both healing and surgical complications may result in a loss of best corrected vision, which means that you may be unable to read the bottom few lines of an eye chart even with glasses or contact lenses. The best vision you may experience after surgery, even with lens correction, may not be as good as before refractive surgery.

In some cases, vision may be severely impaired and affect your ability to drive legally, especially if you already have reduced vision from other causes. LASEK is not intended to improve visual potential, and many patients with high prescriptions often are unable to read 20/20 before surgery and should not expect to read 20/20 after surgery. A patient who is best corrected before surgery to 20/40 is

already borderline for driving legally and any loss of best corrected vision from healing or surgical complications may prevent legal driving.

In general, healing after repeat LASEK is usually more rapid, but may follow the same course as the original LASEK healing pattern. The speed of the original healing pattern is usually based upon the severity of the original prescription and is typically slowest for patients treated for high degrees of farsightedness.

EXPECTATIONS

The goal of repeat LASEK is to achieve the best visual result with the safest method while dramatically reducing dependency on glasses or contacts. As examples, night driving glasses and reading glasses may still be needed. The degree of correction required determines both the rate of recovery and the initial accuracy of the procedure. Severe degrees of nearsightedness may require two procedures. Patient differences in healing can also greatly affect visual recovery and final visual outcome and are impossible to predict. After the initial procedure and even if further procedures are performed, you may have some remaining nearsightedness, farsightedness, or astigmatism, If so, glasses and/or contact lenses may still be needed some or all of the time.

EPITHELIAL LASIK (LASEK) WITH THE USE OF MITOMYCIN-C (MMC) ADDENDUM

INDICATIONS AND ALTERNATIVES

Treatment with an excimer laser is associated with a chance of developing corneal scarring or "haze." This corneal haze may develop years after the original procedure and can result in decreased vision. Refractive surgeries such as Photorefractive Keratectomy (PRK), Laser-Assisted Subepithelial Keratomileusis (LASEK), and Advanced Surface Ablation (ASA) have been associated with corneal haze in some individuals.

Since 1997, a medication called Mitomycin-C (MMC) has been used to treat corneal haze. Several studies have shown that the use of MMC decreases the likelihood of developing haze after PRK, LASEK, and ASA. For this reason, ophthalmologists are also using MMC prophylactically, as a preventive measure.

MMC is an antitumor antibiotic that has been used in the medical field for a number of decades. It is used as an anti-cancer drug because it can stop the proliferation or growth of certain types of cells, such as those seen in tumors. It also stops cells in the eye which produce scarring or haze. MMC has been used in the eye since the 1980's to prevent scarring after many types of surgical procedures, such as glaucoma filtration and pterygium surgery. The use of MMC for the treatment and prevention of corneal haze is a newer use of this medication.

RISKS AND COMPLICATIONS

MMC is very potent and, under certain circumstances, potentially toxic. Eye-related and vision-threatening complications that have been reported when using MMC for other conditions include, but are not limited to: secondary glaucoma, corneal edema, corneal or scleral thinning or perforation requiring corneal transplants, permanent stem cell deficiency, sudden onset mature cataract, corneal decompensation, corectopia (displacement of the pupil from its normal position), iritis, scleral calcification, scleral melt, retinal vascular occlusion, conjunctival irritation (redness of the eye), and incapacitating photophobia and pain.

Although the complications listed above have been seen in various types of eye surgeries, no significant complications have been reported using the low-dose technique described below for corneal haze removal and prevention in refractive surgery. This techniques uses a low dose (0.02%) of MMC delivered by placing a small, circular shaped sponge on the central cornea for 20 to 40 seconds. This technique minimizes, but may not eliminate, the chance of developing MMC-related complications.

Patients who received preventive MMC treatments have shown improvement in visual acuity and a decrease in corneal haze. No corneal haze developed during an average follow-up period of one year. However, there is no guarantee that you will obtain a similar result. Over long periods of time, corneal haze or unforeseen toxicity may develop, which may require additional treatment.

PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

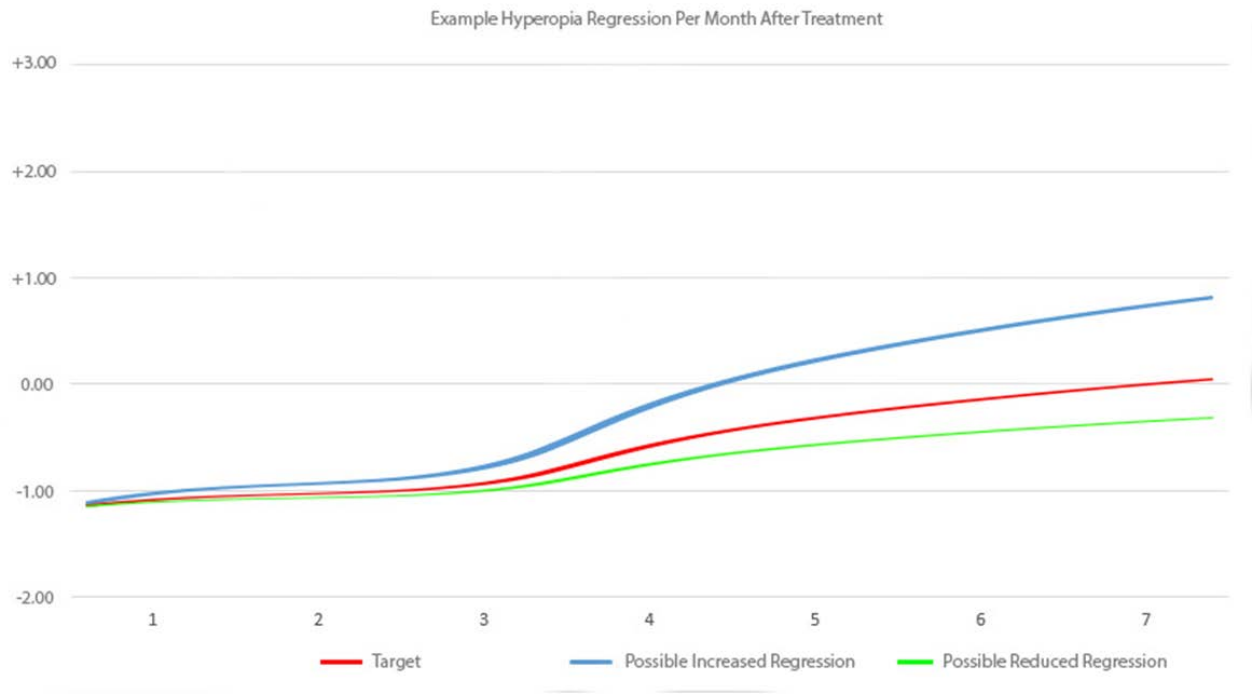
I understand that administering MMC for treatment and prevention of corneal haze is considered an off-label use of an FDA-approved medication. When a drug or device is approved for medical use by the Food and Drug Administration (FDA), the manufacturer produces a label to explain its use. Once a medication is approved by the FDA, physicians may use it off-label for other purposes if they are well-informed about the product, base its use on firm scientific method and sound medical evidence, and maintain records of its use and effects. I have read and understood the information presented above about the risks, benefits, and alternatives to using MMC for both treatment and prevention of corneal haze. I understand that there are no guarantees as to the success of the procedure for removing or preventing haze and that toxic side effects may develop.

HYPEROPIC TREATMENT ADDENDUM

Hyperopic (farsighted) treatments are complex in nature. Unlike myopic treatments (nearsighted) the amount of regression has a greater variance of treatment regression. Target treatment parameters are selected based on historical clinical data with similar treatment profiles. Hyperopic patients will experience some regression and fluctuation during, approximately, the first six months following correction. This is normal and expected. The amount of fluctuation or the degree of fluctuation will vary for each individual in part due to an individual's biology. Patients with larger amounts of astigmatism will experience greater variances immediately after treatment. This is normal and expected.

The following graph illustrates three possible scenarios for a patient being treated with a preoperative correction of +3.00, and a target treatment of -1.00. This is just one possible example and there are currently no clinical methods to determine the amount of regression that may occur. The time period in this example is 6 months, however it could be sooner, or possible longer.

I understand when undergoing a hyperopic treatment my vision will regress or change over an unknown period of time. I understand that this is expected and that it is possible I may result with a residual amount of overcorrection or undercorrection.



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WAVEFRONT GUIDED (CUSTOMVUE) TREATMENT ADDENDUM

INDICATIONS AND PROCEDURE

Standard or conventional laser vision correction surgery refers to correction of spherical (near or far sightedness) and cylindrical (astigmatic) refractive errors. Such treatment is based upon measurements of the refraction, using lenses combined within an instrument called a phoropter. Wavefront-guided treatment is based upon an imaging system using a wavefront aberrometer to take additional measurements for treatment. In 2003, VISX received approval for wavefront guided LASIK under the brand name CustomVue using their WaveScan aberrometer and S4 laser.

Wavefront measurement is relatively new to the eye care profession, having evolved around imaging and manufacturing applications in the fields of astronomy and engineering. A wavefront aberrometer is able to detect subtle imperfections known as higher-order aberrations in an optical system that contribute to imperfect focus of an image.

It is recognized that a minority of patients treated with conventional laser treatment describe some visual difficulties after their treatment including, but not limited to, glare, halos around lights, diminished comfort at night, and ghosting of images. Data presented to the FDA suggests that a significant amount of these adverse visual consequences may be reduced by wavefront-guided treatment. The data also suggest that with wavefront-guided treatment a higher percentage of patients achieve better visual acuity, and a lower percentage have complaints, even in reduced illumination. The research was performed in very tightly-controlled circumstances on a relatively small number of patients (several hundred) by a small group of surgeons. These results have not yet been reproduced or confirmed in large-scale studies.

The advantages of wavefront-guided treatment may include: A higher percentage of patients are reported to achieve better visual acuity (20/20 and 20/15) after wavefront ablation treatment than with conventional therapy. There is no guarantee that you will achieve these results. A lower percentage of patients report glare, halo, or discomfort with night vision after treatment. The process eliminates some of the subjective component of the refraction measurement process.

ALTERNATIVES

At present, the range of prescriptions treatable by wavefront-guided systems is narrower than the range of treatments approved for conventional treatment, or treatment with other excimer lasers. There are other excimer laser treatment methods, including, but not limited to: conventional or broad-beam treatment, wavefront optimized treatment, and topography guided treatment.

RISKS AND COMPLICATIONS

This procedure, like all surgery, presents some risks, many of which are listed below. You should also understand that there may be other risks not known to your doctor, which may become known later. Despite the best of care, complications and side effects may occur; should this happen in your case, the result might be affected even to the extent of making your vision worse. The long-term risks and effects wavefront guided treatment are unknown. I have received no guarantee as to the success of my particular case.
I understand that the following risks are associated with the procedure:

I understand the supposed benefit of wavefront guided treatment may be intangible as it cannot always be measured accurately

I understand a wavefront guided treatment will remove more tissue when compared to a conventional treatment.

I understand that data related to the efficacy of wavefront guided treatment was conducted under tightly controlled circumstances on a relatively small number of patients and have not yet been reproduced or confirmed in large scale studies.

OFF-LABEL LASER VISION CORRECTION ADDENDUM

WAVEFRONT GUIDED LASEK RETREATMENT

When a drug or device is approved for medical use by the Food and Drug Administration (FDA), the manufacturer produces a label to explain its use. Once it is approved by the FDA, physicians may use it off-label for other purposes if they are well-informed about the product, base its use on firm scientific method and sound medical evidence, and maintain records of its use and effects.

I understand that there may be both short term and long-term risks either now, or in the future, not studied by the FDA that may be related or unrelated to an off-label treatment.

The following sections describe off-label usage that may apply to your treatment and consent is required for treatment.

WAVEFRONT GUIDED (CUSTOMVUE) ENHANCEMENT

I understand that wavefront guided treatment to retreat an original LASEK treatment is an off-label procedure. Nevertheless, I wish to have laser vision correction performed on my eye(s).

EPITHELIAL LASIK (LASEK) WITH THE USE OF MITOMYCIN-C (MMC)

I understand that the use of mitomycin-c during LASEK treatment is an off-label procedure. Nevertheless, I wish to have laser vision correction performed on my eye(s).

Off-Label Treatment Consent: (Page 8) I consent to a treatment that may be considered Off-Label.

Patient Signature

RETREATMENT POLICY

FOLLOW UP CARE & NON-COVERED SERVICES

Your original vision correction procedure includes a post-operative period of two years from the procedure date. If you are nearing the end of your two-year post-operative period as calculated from your original treatment date, your post-operative care will be extended 90 days from the date of your re-treatment at no additional cost.

AFTER INCLUDED CARE

After your included post-operative care ends, your continued care does not. It is important to visit us on a yearly basis to check your overall eye health. Yearly visits may be covered by either medical or vision insurance. If it is not practical to follow up at one of our centers please inform us of your local ophthalmologist so we may transfer relevant medical records to them.

WAVEFRONT GUIDED RETREATMENT

As outline in your original vision correction financial policy, all wavefront guided procedures must be licensed from the manufacturer of the laser. If your original treatment was not a wavefront guided treatment, and you are having a wavefront guided retreatment; a wavefront guided license fee will apply to your retreatment.

MEDICATIONS

Medications are required for use both before and after your procedure. These medications reduce the chance of infection as well as promote fast healing. You are responsible for any costs associated with these medications. If you do not have prescription benefits please inform us as some pharmaceutical companies offer discounts to non-insured patients.

INFORMED CONSENT

By signing the below, I certify the following to the best of my knowledge:

All 8 pages of this document have been given to me in its entirety.

All of my questions regarding LASEK retreatment have been answered to my satisfaction allowing me to give my informed consent.

I understand that during the course of the proposed procedure(s) unforeseen conditions may be revealed requiring the performance of additional procedures, and I authorize such procedures to be performed at my physician's discretion.

In the event that part or all of my treatment is off-label, as outlined in *Off-Label Laser Vision Correction Addendum* (page 7), I have read, understand, and hereby consent to *Off-Label Laser Vision Correction Addendum* (page 7).

I have read, understand, and agree to *Retreatment Policy* (page 7).

I understand that no warranty or guarantee has been made to me regarding the result, cure or safety.

I understand that all or part of my procedure may not be covered by my insurer and accept responsibility for all out-of-pocket expenses.

I give my permission for Laser Eye Institute to videotape or photograph my procedure, for purposes of documentation, education, research or training of other health care professionals. I also give my permission for Laser Eye Institute its employees and agents to use data about my procedure and subsequent treatment to further understand refractive vision correction. I understand that my name will remain confidential, unless I give subsequent written permission for my identity to be disclosed outside of Laser Eye Institute.

MY SIGNATURE BELOW CERTIFIES THAT I AM NOT UNDER THE INFLUENCE OF ANY NARCOTIC, ALCOHOL OR ANY OTHER DRUG, OR SUBSTANCE THAT MAY IMPAIR MY JUDGEMENT, OR MY ABILITY TO UNDERSTAND THIS CONSENT. I FURTHER CERTIFY THAT I WAS ABLE TO READ AND UNDERSTAND THIS INFORMED CONSENT AND ANY QUESTIONS I HAD REGARDING THE ABOVE PROCEDURE(S), RISKS, BENEFITS, AND ALTERNATE PROCEDURES HAVE BEEN EXPLAINED TO MY SATISFACTION ALLOWING ME TO GIVE MY INFORMED CONSENT FOR THE ABOVE PROCEDURE(S).

Name	MRN	Date

LASEK Consent: I consent to a retreatment of Epithelial LASIK (LASEK) with the use of mitomycin-c.

Patient Signature

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