INFORMED CONSENT
LASIK 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	Change Addendum
LASIK Retreatment - New Flap		

ID: AK REV: 20181220

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INFORMED CONSENT FOR LASER IN-SITU KERATOMILEUSIS (LASIK) RETREATMENT OF ORIGINAL PROCEDURE

FOR THE CORRECTION OF MYOPIA (NEARSIGHTEDNESS), HYPEROPIA (FARSIGHTEDNESS), AND ASTIGMATISM USING FEMTOSECOND LASER TECHNOLOGY

INDICATIONS AND PROCEDURE

This information is being provided to you so that you can make an informed decision about repeat femtosecond LASIK, also known as "IntraLASIK", or "all-laser" LASIK. Traditional LASIK surgery involves two procedures: first, a microkeratome blade is used to create a flap on the cornea to expose the underlying tissue. After the flap is created, an excimer laser is used to reshape the eye by removing ultra-thin layers from the cornea in order to reduce farsightedness, nearsightedness, or astigmatism. Finally, the flap is returned to its original position, without sutures.

The femtosecond LASIK surgery also involves two procedures. First, instead of a microkeratome blade, it uses the FDA-approved VisuMax laser to create a flap with laser energy. The VisuMax laser is capable of creating extremely precise flaps by producing tiny bubbles inside the cornea that are 1/10,000 of an inch in diameter. The laser beam cannot penetrate into the eye beyond the cornea. After the flap is created, an excimer laser is used to reshape the eye by removing ultra-thin layers from the cornea in order to reduce farsightedness, nearsightedness, or astigmatism. The flap is returned to its original position, without sutures.

It is important to realize that even if you did not experience any difficulties with your original LASIK 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

Femtosecond LASIK 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 LASIK procedure, retreatments are at times indicated to correct remaining or induced myopia (nearsightedness), hyperopia (farsightedness), and astigmatism. There is no guarantee that repeat LASIK 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. LASIK retreatment procedures are performed by lifting the corneal flap and applying additional laser to the corneal bed, or by repeating the original LASIK procedure and creating a new corneal flap. Eligibility and the choice of technique are determined primarily by the amount of time that has passed since the original corneal flap was created, the amount of corneal flap healing that has taken place, and the corneal thickness. An enhancement can be performed once the vision and prescription (refraction) stabilize after the original LASIK 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 corneal flap can usually be easily lifted during the first two years, and in many cases, it can even be lifted after several years. Sometimes, however, even after a few months, the corneal flap is sealed and cannot be lifted again. If the flap cannot be lifted, the surgeon and patient must decide either to abandon the surgery, apply the laser correction to the surface (PRK), or create a new flap. Creating a new flap in an eye with an existing flap is considered by many surgeons to be a more risky option and should be approached with caution. The ideal time for a retreatment is when the refraction is stable. There must be adequate corneal tissue under the flap 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.

ADVANTAGES AND DISADVANTAGES OF ORIGINAL VERSUS NEW FLAP

Surgeon experience, patient preference, and corneal measurements determine the type of technique. The advantages of lifting the original corneal flap are related to safety, because no additional incision is required and the surgical risks associated with the creation of the corneal flap are avoided. The disadvantages are that the procedure is often more uncomfortable postoperatively for the first several hours, and the corneal flap edges must re-heal. The risk of epithelial ingrowth may be increased when the flap is lifted. If this occurs,

additional surgery may be required to remedy the problem. As stated above, depending upon the healing of the original flap, it may or may not be possible to lift the flap. Occasionally, the flap can only be partially lifted; if this happens, the retreatment must be cancelled for several months while the flap re-heals before making another incision.

The advantage of creating a new flap is that the procedure is much the same as the original procedure and many patients find it easier as they know what to expect. The most serious concern with creating a new corneal flap is that inadequate healing of the original flap may result in a free or loose piece of corneal tissue being formed. That is, while creating the new flap, a separate, small wedge of the original corneal flap tissue is produced either in the center or on the side of the flap. This wedge of tissue can make the center of the cornea irregular or cause scarring on the side that could lead to epithelial ingrowth, both of which can compromise vision.

During the re-treatment procedure, after the original flap is lifted, or after the microkeratome or IntraLase laser cuts a new flap, the flap is flipped over out of the way, and the laser application is performed within the corneal bed instead of on the corneal surface as with PRK. The flap is replaced immediately following the laser application. The flap is held in position through an almost immediate suction-type action within the cornea and by the protective layer of the cornea called the epithelial layer, which rapidly envelopes the surface within days. In most cases no stitch is required. If a stitch is required, it is below the surface and usually removed within several days. A soft contact lens may be applied as a bandage to protect the surface for the first day or so. Often, the surgeon may choose to perform the retreatment on the surface of the cornea without lifting the flap. This option is usually chosen to enhance the safety of the retreatment and to provide the best quality of vision.

RISKS AND COMPLICATIONS

The risks associated with the original LASIK 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.

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. In giving my permission for Femtosecond LASIK, I understand the following: The surgeon will use a FDA-approved VisuMax laser to create a flap, and then an FDA-approved excimer laser to reshape the eye. The long-term risks and effects of Femtosecond LASIK are unknown. I have received no guarantee as to the success of my particular case.

I understand that the creation of a flap may be susceptible to trauma. It is important to follow instructions carefully to avoid wrinkling of the flap. Correcting a flap issue caused by failure to follow instructions is subject to a surgical and facility fee.

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 LASIK 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 LASIK 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 LASIK. 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 LASIK 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 LASIK 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 FLAP COMPLICATIONS

The most severe flap complication is a corneal perforation, which requires corneal stitches or sutures, and usually the need for an intraocular lens implant as the natural lens is usually lost or damaged. Corneal perforation could also lead to infection, the need for a corneal transplant, or even blindness.

When repeat LASIK is performed by lifting the original flap, the risk associated with the flap creation are avoided, although other risks remain. Corneal flap complications that occur after the LASIK procedure during the recovery period, such as displacement and wrinkling of the flap and epithelial ingrowth, may occur whether lifting the original flap or creating a new one.

The most serious concern with creating a new corneal flap is that inadequate healing of the original flap may result in a free or separate piece of corneal tissue being formed. This wedge of tissue can make the center of the cornea irregular or cause scarring on the side that could lead to epithelial ingrowth, both of which can compromise vision.

Partial or complete corneal flap displacement may occur either during the early postoperative period or days to weeks later after trauma. Care should be taken to protect the eye from trauma, and you should not rub your eyes or forcefully close them during the first week after repeat LASIK. Partial displacement of the corneal flap may result in corneal striae or wrinkles, which blur vision. Most striae are treatable, but some patients, such as those who are highly nearsighted, may be resistant to treatment. Complete displacement of the corneal flap is often painful and requires urgent replacement. There is a higher risk of epithelial ingrowth and infection with complete flap displacement.

Epithelial ingrowth occurs during the first month after LASIK and is more likely to occur in patients with an abnormal or weakly adherent protective layer, for which age is a risk factor. Epithelial ingrowth is produced when epithelial surface cells grow underneath the corneal flap during the healing of the corneal flap incision. Epithelial ingrowth is more common with any trauma or breakdown of the epithelium, so it is more common in LASIK retreatment procedures that lift the original corneal flap. Treatment of this condition involves lifting the flap and clearing away the cells. Although most small areas of epithelial ingrowth only need to be monitored and do not cause visual problems, untreated larger areas may distort vision and may actually damage the flap integrity if severe and progressive.

CORNEAL HEALING COMPLICATIONS

The protective corneal flap of LASIK reduces the healing component of LASIK compared to PRK, but 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, which may or may not follow a surgical flap complication. 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 LASIK, 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. LASIK 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 LASIK is usually more rapid, but may follow the same course as the original LASIK 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

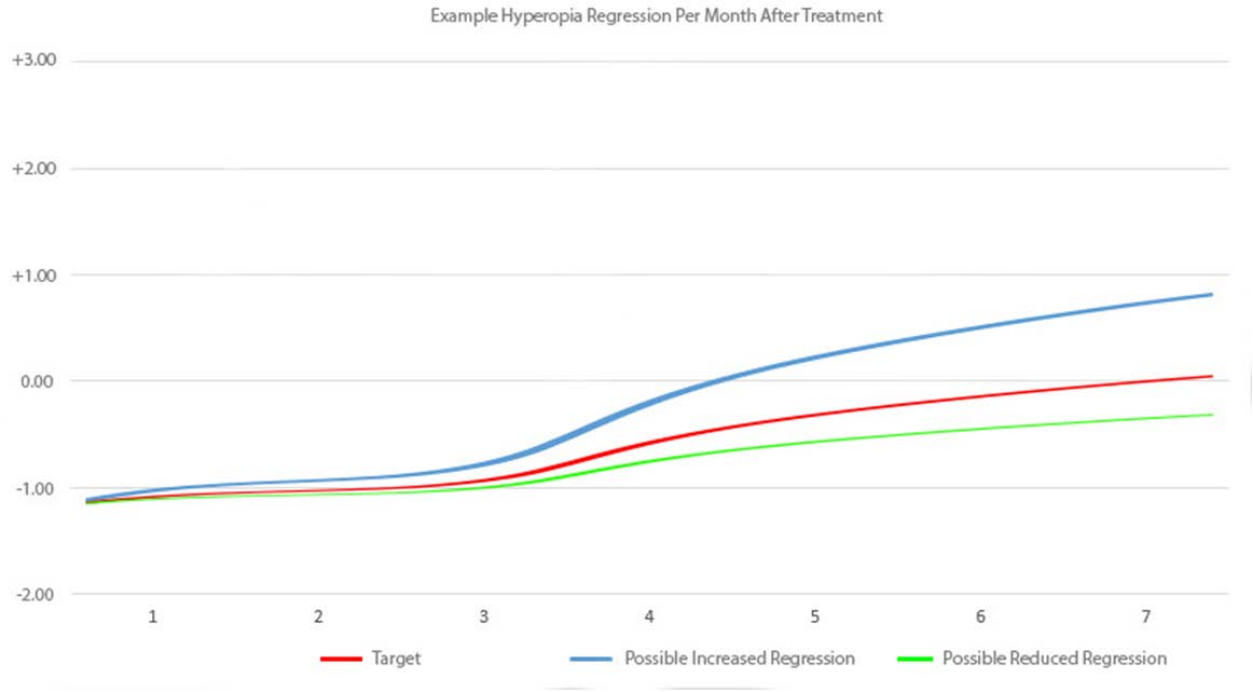
The goal of repeat LASIK is to achieve the best visual result with the safest method while dramatically reducing dependency on glasses or contacts. As examples, night driving glasses and reading glasses may still be needed. The degree of correction required determines both the rate of recovery and the 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.

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 LASIK 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 LASIK 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.

PROCEDURE CHANGE ADDENDUM

During your laser vision correction routine situations may occur during which the surgeon may need to change either the procedure being performed, or the excimer laser being utilized. Because you will be given a sedative prior to treatment you will be unable to make an informed decision and must make that decision in advance to allow the surgeon to continue treatment, or to stop and reschedule treatment for a later date. The most common condition that may occur during LASIK is an ability or loss of the flap-making laser to apply adequate suction on your eye. Should this occur you will have the option to abort treatment and reschedule for a later date and time, or change your procedure to LASEK.

A. STOP TREATMENT ONLY (THIS ADDENDUM WILL NOT APPLY TO YOU)

Should a condition occur that requires a change in either procedure or laser platform become warranted I prefer to stop treatment and have my treatment rescheduled at a later date and time.

Stop Treatment: I prefer to stop treatment if LASIK is unable to be successfully performed. The remainder of *Procedure Change Addendum* does not apply to me. You may continue to the *Informed Consent* (Page 14)

Patient Signature

B. SWITCH TO LASEK (THIS ADDENDUM WILL APPLY TO YOU)

Certain conditions may occur that would require a change in either procedure or laser platform and in the surgeons' professional opinion should a switch from LASIK to LASEK be warranted I consent to a change in procedure(s) covered in this informed consent as warranted by my surgeons' professional opinion. If you elect this option, the following LASEK consent will apply to your procedure.

I understand that by selecting this option I will still be given the opportunity to stop and reschedule my treatment for a later date.

INFORMED CONSENT FOR EPITHELIAL LASIK (LASEK)

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. 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.

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. There are also other types of refractive surgery, including LASIK and SMILE.

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. In giving my permission for LASEK, I understand the following: The surgeon will use a FDA-approved excimer laser to reshape the eye. The long-term risks and effects LASEK 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:

VISION-THREATENING COMPLICATIONS

I understand that the excimer laser could malfunction, requiring the procedure to be stopped before completion. Depending on the type of malfunction, this may or may not be accompanied by visual loss.

I understand that mild or severe infection is possible. Mild infection can usually be treated with antibiotics and usually does not lead to permanent visual loss. Severe infection, even if successfully treated with antibiotics, could lead to permanent scarring and loss of vision that may require corrective laser surgery or, if very severe, corneal transplantation or even loss of the eye.

I understand that it is possible scarring of the cornea could occur, causing loss of some clarity of the vision.

An increase in the inner eye pressure due to post-treatment medications, which is usually resolved by drug therapy or discontinuation of post-treatment medications.

I understand that other very rare complications threatening vision include, but are not limited to, corneal swelling, corneal thinning (ectasia), appearance of "floaters" and retinal detachment, hemorrhage, venous and arterial blockage, cataract formation, total blindness, and even loss of my eye.

NON-VISION-THREATENING SIDE EFFECTS

I understand that my vision after surgery using LASEK may not be clear immediately and that I might not notice improvement for several days to several weeks. Mild discomfort or pain (first 3 to 7 days), corneal swelling, double vision, foreign body sensation (feeling something is in the eye), ghost images, light sensitivity and tearing.

Further treatment may be necessary, including a variety of eye drops, the wearing of eyeglasses or contact lenses, or additional LASEK or other refractive surgery.

I understand that there may be increased sensitivity to light, glare, and fluctuations in the sharpness of vision. These conditions usually occur during the stabilization period of from one to three months, but they may also be permanent.

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.

I understand that an overcorrection or under-correction could occur, causing me to become farsighted or nearsighted or increase my astigmatism and that this could be either permanent or treatable. I understand an overcorrection or under-correction is more likely in people over the age of 40 years and may require the use of glasses for reading or for distance vision some or all of the time.

After refractive surgery, a certain number of patients experience glare, a "starburst" 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. Although there are several possible causes for these difficulties, 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.

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. These risks in relation to my particular pupil size and amount of correction have been discussed with me.

I understand that I may not get a full correction from my LASEK procedure and this may require future retreatment procedures, such as more laser treatment or the use of glasses or contact lenses.

I understand that there may be a "balance" problem between my two eyes after LASEK has been performed on one eye, but not the other. This phenomenon is called anisometropia. I understand this would cause eyestrain and make judging distance or depth perception more difficult. I understand that my first eye may take longer to heal than is usual; prolonging the time I could experience anisometropia.

I understand that there is a natural tendency of the eyelids to droop with age and that eye surgery may hasten this process.

I understand that there may be pain, irritation, or a foreign body sensation, particularly during the first 48 hours after surgery. I also understand that pain may be associated with complications such as infection.

I understand that temporary glasses either for distance or reading may be necessary while healing occurs and that more than one pair of glasses may be needed.

I understand that long-term effects of LASEK are unknown and that unforeseen complications or side effects could occur.

I understand that visual acuity I initially gain from LASEK could regress, and that my vision may go partially back to a level that may require additional surgery or require glasses or contact lens use to see clearly.

I understand that the correction that I can expect to gain from LASEK may not be perfect. I understand that it is not realistic to expect that this procedure will result in perfect vision, at all times, under all circumstances, for the rest of my life. I understand I may need glasses to refine my vision for some purposes requiring fine detailed vision after some point in my life, and that this might occur soon after surgery or years later.

I understand that I may be given medication in conjunction with the procedure and that my eye may be patched afterward, and \ or a bandage contact lens may be applied. I, therefore, understand that I must not drive the day of surgery and should not drive until I am certain that my vision is adequate for driving.

I understand that if I currently need reading glasses, I will still likely need reading glasses after this treatment. It is possible that dependence on reading glasses may increase or reading glasses may be required at an earlier age if I have this surgery.

I understand that if I am over 40 years of age and have both eyes corrected for clear distance vision, I will need reading glasses for many close tasks. The strength of readers I will need may vary over the course of my healing. It is possible that my dependence on near correction may increase or decrease after surgery.

I understand that, 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.

I understand that, 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.

USE OF MITOMYCIN-C (MMC)

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 technique 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. I have had the opportunity to ask questions and have them answered to my satisfaction.

Switch To LASEK: I prefer to switch to LASEK treatment if LASIK is unable to be successfully performed. I have read, understand, and consent to LASEK and understand this *Procedure Change Addendum* will apply to me.

Patient Signature

INFORMED CONSENT

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

All 13 pages of this document have been given to me in its entirety.

All of my questions regarding LASIK 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 8), I have read, understand, and hereby consent to *Off-Label Laser Vision Correction Addendum* (page 8).

I have read, understand, and agree to *Retreatment Policy* (page 8).

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

LASIK Consent: I consent to a retreatment of Laser In-Situ Keratomileusis (LASIK) with the creation of a flap.

Patient Signature

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