INFORMED CONSENT

LASEK VISION CORRECTION

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	Off-Label	Bilateral
LASEK			

LASER EYE INSTITUTE
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INFORMED CONSENT FOR EPITHELIAL LASIK (LASEK)

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.

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.

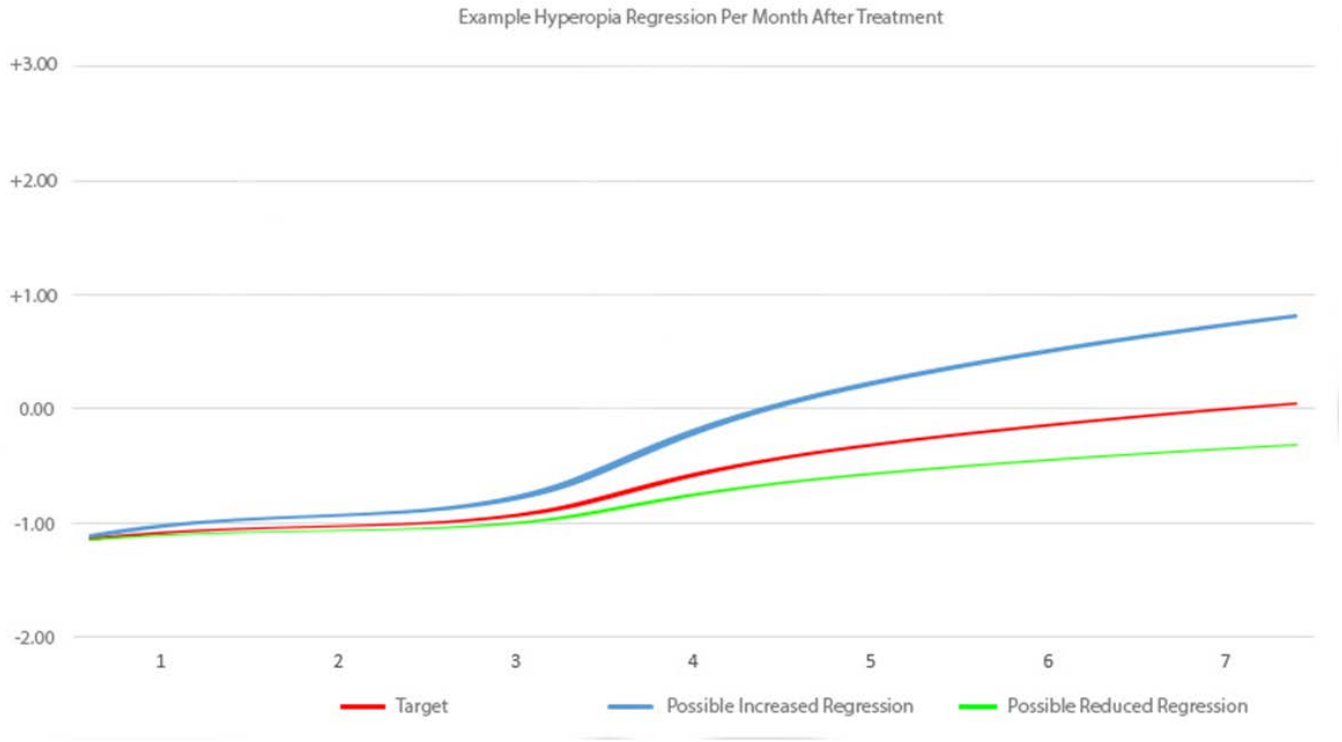
I understand that, since it is impossible to state every complication that may occur as a result of any surgery, the list of complications in this form may not be complete.

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.



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.

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

BILATERAL SIMULTANEOUS PROCEDURE ADDENDUM

LASIK, LASEK, and SMILE have become common procedures for refractive surgery. While many choose to have both eyes treated at the same surgical setting, there may be risks associated with simultaneous treatment that are not present when the eyes are treated on different days. If you elect to have surgery performed on both eyes at the same time, you should understand both the possible risks and benefits.

SAFTEY

The risks of infection, severe inflammation, delayed clouding of the cornea, corneal scarring and internal bleeding or retinal damage are very rare but potentially devastating. If these complications occur in one eye, they may also occur in the other. Should any of these complications happen, you could experience significant loss of vision or even temporary or permanent legal blindness. By choosing to have LVC performed on separate days, you avoid the risk of having one or more of these complications in both eyes at the same time.

ACCURACY

If there is an over-correction or under-correction in one eye, chances are it may happen in both eyes. If a retreatment is required in one eye, it is quite possible that your fellow eye may also require a retreatment. By having surgery on separate days, the doctor can monitor the healing process and visual recovery in the first eye and may be able to make appropriate modifications to the treatment plan for the second eye. In some patients, this might improve the accuracy of the result in the second eye. By correcting both eyes simultaneously, there is no opportunity to learn from the healing patterns of the first eye before treating the second eye.

VISUAL RECOVERY

Most patients experience rapid visual recovery, but some may experience symptoms such as blurred vision, night glare or ghost images that can result in prolonged recovery of normal vision. Blurred vision may rarely continue for several weeks, which could make driving difficult or dangerous and could interfere with your ability to work if it occurs in both eyes. There is no way of predicting how long your eyes will take to heal. If the eyes are operated separately, you can generally function with the fellow eye while the first eye fully recovers. However, there may be a period of imbalance in vision between your two eyes, producing a form of double vision. If you are able to wear a contact lens in your un-operated eye, the corrective lens could minimize this imbalance. The balance in vision between your two eyes will usually be restored more rapidly if they are operated on the same day. The healing corneal flap is most susceptible to trauma during the first several weeks after surgery. Should both flaps become accidentally displaced, significant visual loss in both eyes may result.

SATISFACTION

Both eyes tend to experience similar side effects. If you experience undesirable side effects such as glare, ghost images, increased light sensitivity, or corneal haze in one eye, you will likely experience them in both eyes. These side effects may cause a decrease in vision or other negative effects, and some patients have elected to not have their second eye treated. By having each eye treated on separate dates, you will have the opportunity to determine whether the procedure has produced satisfactory visual results without loss of vision or other uncommon undesirable side effects. If you are over age 40, you will also have an opportunity to experience the change in your close vision that results from the correction of your nearsightedness or farsightedness. This could influence your decision on whether or not to fully correct your other eye to maintain some degree of close vision without the need for glasses (monovision).

COST AND CONVENIENCE

Fees are greater if the eyes are operated on different days, and the additional time off work that may also be needed may be costly. Additionally, it may be inconvenient for you to have each eye treated at separate visits.

PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

I have read and understand the above risks and benefits of bilateral simultaneous LVC, and I understand that this summary does not include every possible risk, benefit and complication that can result from bilateral simultaneous LVC.

I wish to have both of my eyes treated during the same treatment session if my doctor determines that the treatment in the first eye appeared to be technically satisfactory.

Bilateral Simultaneous Procedure: (Page 7) I consent to bilateral simultaneous procedure

Patient Signature

OFF-LABEL LASER VISION CORRECTION ADDENDUM

PROCEDURE OR LASER PARAMETERS OUTSIDE OF FDA APPROVED INDICATIONS

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.

MYOPIA, HYPEROPIA, OR ASTIGMATISM GREATER THAN FDA INDICATION

Treatment amount may exceed the parameters indicated by the FDA for my required treatment. FDA approval for the excimer lasers indicated below were based upon specific treatment constraints related to the correction and age of the clinical trial participants and the amount of treatment required may be outside of these parameters.

I understand that the amount of my myopia, hyperopia, or astigmatism may be greater than the amount approved for correction by the FDA. Nevertheless, I wish to have off-label laser vision correction performed on my eye(s), and I am willing to accept a residual amount of myopia, hyperopia, or astigmatism.

Laser Name	FDA Indication
MEL80	**Myopia: -7.00 D Hyperopia: +5.00 D Astigmatism: +3.00 D**
STAR S4	**Myopia: -11.00 D Hyperopia: +3.00 D Astigmatism: +3.00 D**

EPITHELIAL LASIK (LASEK) USING WAVEFRONT GUIDED (CUSTOMVUE) TREATMENT

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

WAVEFRONT GUIDED (CUSTOMVUE) PROCEDURE, PATIENT UNDER THE AGE OF 21

I understand that wavefront guided treatment in patients under the age of twenty-one (21) but over the age of eighteen (18) 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

VISION CORRECTION FINANCIAL POLICY

FOLLOW UP CARE NON-COVERED SERVICES

Vision correction includes a post-operative period of two-years from the procedure date. During this time any visits directly related to the procedure are included at no cost. These are most typically your post-operative check-ups. As much as you try to avoid eye injury, it does happen. At any time during, or after, your included post op care if you experience eye trauma it is important to schedule an exam immediately. Exams related to eye trauma are not included as part of post-operative treatment. Additionally during the course of your post-operative care we may encounter pathology not related to your vision correction procedure. It is our obligation to inform and offer treatment or a referral to have additional pathology treated. Under most circumstances examinations for trauma or pathology are covered under your medical insurance.

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.

INFORMATION REGARDING REFERRALS

Under some circumstances it may be necessary to refer you to an additional specialist that may be either related, or un-related to your procedure. There are many different parts of the eye and our facility specializes in only one. Referrals are made at the discretion of your physician and you are under no obligation to see the particular specialist we recommend. In all cases any referral to an outside physician is not included with any of our fees, and has no financial interest with any parties we refer to for additional care. Your medical insurance may cover these services.

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.

RETREATMENT POLICY

Under some circumstances you may have a residual amount of refractive error, and while rare, this differs than a general shift in a patient's vision due to their biology. Residual refractive error will be evident within the first six months of treatment. Your physician will determine if you may be a candidate for a "retreatment" or "enhancement" to correct the residual error. Generally, you must wait at least three (3) months after the first procedure, have adequate corneal tissue, stable vision, and uncorrected visual acuity should be 20/30 or worse. The discretion to perform a retreatment is determined by your physician's clinical judgment. A retreatment involves the same risks of the original procedure. In some instances with a LASIK treatment it may be possible to re-lift the original flap. Surgeon fees are waived for re-treatments during your two-year's of included follow up care. Facility fees are not included as part of our two-year follow up care. If a wavefront-guided treatment was not originally performed and a wavefront-guided enhancement is required a license fee applies to the wavefront guided treatment.

INFORMED CONSENT

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

All 10 pages of this document have been given to me in its entirety.

All of my questions regarding LASEK 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 I am having bilateral simultaneous treatment (both eyes treated at the same time), as outlined in *Bilateral Simultaneous Procedure Addendum* (page 7), I have read, understand, and hereby consent to *Bilateral Simultaneous Procedure Addendum* (page 7).

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 *Bilateral Vision Correction Financial Policy* (page 9).

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 Epithelial LASIK (LASEK) with Mitomyocin C.

Patient Signature

OPIOID START TALKING

Michigan Department of Health and Human Services

Patient Name	Patient MRN

Name of Controlled Substance containing an Opioid

Norco

Dosage	Quantity Prescribed (For a minor, if signature is not the parent or guardian, the prescriber must limit the opioid to a single, 72 hour supply)
5.0 / 325	**12**

Number of refills

0

A controlled substance is a drug or other substance that the United States Drug Enforcement Administration has identified as having a potential for abuse. My provider shared the following:

a. The risks of substance use disorder and overdose associated with the controlled substance containing an opioid.

b. Individuals with mental illness and substance use disorders may have an increased risk of addiction to a controlled substance. (Required only for minors.)

c. Mixing opioids with benzodiazepines, alcohol, muscle relaxers, or any other drug that may depress the central nervous system can cause serious health risks, including death or disability. (Required only for minors.)

d. For a female who is pregnant or is of reproductive age, the heightened risk of short and long-term effects of opioids, including but not limited to neonatal abstinence syndrome.

e. Any other information necessary for patients to use the drug safely and effectively as found in the patient counseling information section of the labeling for the controlled substance.

f. Safe disposal of opioids has shown to reduce injury and death in family members. Proper disposal of expired, unused or unwanted controlled substances may be done through community take-back programs, local pharmacies, or local law enforcement agencies. Information on where to return your prescription drugs can be found at http://www.michigan.gov/deqdrugdisposal.

g. It is a felony to illegally deliver, distribute or share a controlled substance without a prescription properly issued by a licensed health care prescriber.

I acknowledge the potential benefits and risks of an opioid medication as described by my provider along with the responsibility of properly managing my medication as stated above.

Signature of Prescriber (when prescribing to a minor)	Date
Signature of Patient, if a minor, patient's parent/guardian	Date
Signature of Patient's Representative or other authorized adult	Date

Printed Name of Parent/Guardian; Patient's Representative or other authorized adult

AUTHORITY: PCA 246 of 2017, MCL 333.7303b and MCL 333.7303c
COMPLETION: Required.
PENALTY: Probation, limitation, denial, fine, suspension, revocation or permanent revocation.

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