

# PATIENT CONSENT FORM

## LASER VISION CORRECTION – GENERAL

### I. Introduction

This Patient Consent Form is provided to help you to make an informed decision about the following types of laser vision correction (collectively, “**Laser Vision Correction**”): LASIK (Laser Assisted In Situ Keratomileusis) and PRK (Photo-refractive Keratectomy). This Patient Consent Form describes each procedure and outlines the possible risks and benefits associated with Laser Vision Correction.

Take as much time as you wish to make your decision to sign this Patient Consent Form. Be sure that all of your questions have been first answered to your full understanding and satisfaction. Please ask your doctor to explain any words or information contained in this Patient Consent Form that you do not understand.

### II. How the Eye Functions

To better help you understand Laser Vision Correction and how the excimer laser can be used in an effort to correct vision problems resulting from refractive error, we have prepared a short overview of how the eye functions. When light enters the eye it is bent, or **refracted**, by a clear, strong tissue at the front of the eye called the cornea. The cornea, in effect, acts like a lens to focus incoming light onto the retina at the back of the eye. Refractive errors such as myopia (nearsightedness), hyperopia (farsightedness) and astigmatism generally result from an abnormally or irregularly shaped eye.

**Myopia, or nearsightedness**, is caused by either an eye shape that is abnormally long or by an excessively steep curvature of the cornea. In nearsightedness, light entering the eye does not focus on the retina as it should, but instead focuses on images at a point in front of the retina. The result of nearsightedness is that distant objects appear blurry, while objects near to the viewer can be seen in focus.

**Hyperopia, or farsightedness**, is caused by an eye shape, which is abnormally short, or by an excessively flat cornea. In farsightedness, light entering the eye focuses on images at a point behind the retina. The result of farsightedness is that objects near to the viewer appear blurry, while objects in the distance may be seen in focus.

**Astigmatism** causes refractive errors because the cornea is not spherical or basketball-shaped as in a normal eye, but is typically shaped more like a football. The result of astigmatism is that objects are not focused into a single image and vision is distorted or blurry. Both nearsighted and farsighted patients often also suffer from astigmatism.

**Presbyopia**, or the inability to see close-up objects, occurs normally with age and usually becomes apparent to people in their early forties. Presbyopia results from a change within the eye in which the internal lens loses its ability to focus on close-up objects. Laser vision correction can correct your distance vision, but you may still need glasses for close-up activities.

Vision problems resulting from refractive error (nearsightedness, farsightedness and astigmatism) are routinely corrected either with eyeglasses or contact lenses. The excimer laser can reshape the outer surface of the eye (the cornea) to treat the refractive error and allow the eye to focus properly, thereby reducing or eliminating the need for glasses or contact lenses.

### III. About the Procedure

Laser Vision Correction is a form of outpatient surgery performed with local anesthetic eye drops, making the procedure virtually painless. You may be given a sedative, such as Valium, to help you to relax prior to the procedure. You will be brought into the operating room, where you will lie down in a comfortable reclining chair for the duration of the procedure. Your eyelids will be held open with a lid speculum to prevent you from blinking. You will be asked to focus your eye on a special flashing light under the microscope. The entire procedure generally takes less than twenty minutes and the laser only seconds, although actual time may vary due to prescription.

Patients undergoing **LASIK**: The surgeon will use a special instrument called a microkeratome to create a flap (about the thickness of three strands of hair) in the cornea. The flap will be lifted up to expose tissue just below the cornea’s surface. The surgeon will then use the excimer laser to reshape your cornea. The flap is then replaced in its original position.

Patients undergoing **PRK**: The surgeon will either (a) remove the outer layer of corneal skin (either with the laser, by wiping with a special instrument or using a small rotating brush) or (b) create a very thin flap of corneal skin with an alcohol solution (**often referred to as LASEK**). The surgeon will use the method he or she feels is appropriate for you. With the top layer of cornea skin removed, the surgeon will then use the excimer laser to reshape the surface of your eye. A soft contact lens that acts as a bandage will be placed on your eye(s) to aid in healing and comfort. The contact lens is usually removed 3-4 days after the procedure.

Once finished, you will receive eye drops and be discharged home with your eye kit and instructions. Following LASIK, you will wear protective eye shields at night for approximately one week to prevent accidentally rubbing of your eyes. You will be required to use eye drops as directed by your doctor. Some patients experience mild discomfort for 24-72 hours after the procedure. Some sensitivity to light may also exist. You will need a companion to drive you home after the procedure and possibly to bring you back for your next day follow-up visit.

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

Witness Initials \_\_\_\_\_

#### IV. Alternatives to Laser Vision Correction

Laser Vision Correction is an elective procedure done to reduce or eliminate the need for glasses or contacts. There is no emergency condition or other reason that requires or demands you have the procedure performed. You could continue wearing contact lenses or glasses and have adequate visual acuity. Laser Vision Correction, like all surgery, presents some risks, many of which are listed below. 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.

If you decide not to have Laser Vision Correction, there are other methods of correcting your vision. These alternatives include, among others, eyeglasses, contact lenses, Radial Keratotomy(RK), Astigmatic Keratotomy (AK), Automated Lamellar Keratoplasty (ALK), Intacs and Intraocular lens implants (IOLs).

#### V. Eligibility and Contraindications

Patients must be at least 18 years of age, must not be pregnant or nursing in the previous 3 months, and must not have had a significant eyeglass/contact lens prescription change within the last twelve months. The conditions listed below may limit your ability to undergo Laser Vision Correction as they present additional risks or complications and should be discussed with the optometrist and the surgeon prior to the procedure. All are reviewed on a case-by-case basis.

Keratitis sicca (advanced dry eyes)	Severe or poorly controlled glaucoma
Diabetes	Ocular herpes simplex or shingles
Cataracts	Active ocular inflammatory disease
Vascular disease	Heart condition requiring pacemaker regulation
Amblyopia (lazy eye)	History of keloid formation
Keratoconus	Immunosuppression (HIV, organ transplant, etc.)
Autoimmune disease	On drugs/therapy which suppresses the immune system
Immune compromised	Expect to become pregnant within 6 months
Correction outside the limits approved by the FDA	Depressed cornea scars
Progressive myopia or hyperopia	Patients who demand 20/20 unaided vision

I acknowledge that I have informed my surgeon of any medications which I am taking and any allergies that I have.

#### VI. Risks and Possible Side Effects

No surgical procedure is 100% safe or 100% effective. Complications can and do occur from Laser Vision Correction. Fortunately, serious complications are rare and minor complications are not common. This informed consent is not exhaustive and complications, risks or side effects may exist that have not yet been determined. There may be other long term complications which are not yet known.

a. I understand that Laser Vision Correction may create an increased sensitivity to light, glare, and fluctuations in the sharpness of vision. I understand that these conditions usually occur during the normal stabilization period of from one to three months, but they may also be permanent. These conditions may affect my ability to drive and I understand that I should not drive unless my vision is adequate.

b. I understand that after Laser Vision Correction there is an increased risk of eye irritation related to drying of the corneal surface, also known as "dry eye syndrome." These symptoms may be temporary or, on rare occasions, permanent. Dry eye syndrome may require frequent application of artificial tears, punctal plugs and/ or closure of the tear duct openings in the eyelids.

c. I understand that with Laser Vision Correction an overcorrection or undercorrection may occur resulting in farsightedness or nearsightedness with or without astigmatism as well as an increase in my astigmatism. I understand that this "left over prescription" may be permanent, requiring the use of glasses or contact lenses for reading or distance vision some or all of the time along with a decrease in my best spectacle corrected visual acuity with glasses.

d. Many patients over 40 years of age have a condition causing a reduced ability to see or read up close also known as presbyopia. I understand Laser Vision Correction does not correct presbyopia and may increase my dependence on reading glasses. I understand that if I currently need reading glasses, I may still need reading glasses after Laser Vision Correction.

e. I understand that after Laser Vision Correction, during the day and at night, there may be a "halo", "starburst", or "glare" effect around lights and I may experience double or triple vision, and while these effects are generally temporary and usually diminish with time, they could be 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. I understand that I should not drive for at least twenty-four hours after the procedure and I should not drive until my vision is adequate during both the day and night. Additionally, I understand that in rare instances I may lose my ability to drive at night.

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f. I understand that I may not get a full correction from Laser Vision Correction. I understand that I may require future enhancement procedures, such as more laser treatment, RK or Astigmatic Keratotomy (a technique similar to RK for correcting astigmatism) or the use of glasses or contact lenses to achieve better vision.

g. I understand that Laser Vision Correction may result in a "balance" problem called anisometropia. I understand this may cause eyestrain and make judging distance or depth perception more difficult and that I should not drive until my vision is stable. I understand that one eye may take longer to heal than is usual, prolonging the time that I could experience anisometropia or an imbalance. I understand that if Laser Vision Correction is only performed on one eye, the anisometropia I experience may be worse. I also understand that I may experience aniseikonia (difference in imaging size between the two eyes).

h. After Laser Vision Correction, I understand that my eye may be more fragile to trauma from impact. Evidence has shown that the corneal incision will not be as strong as the cornea originally was prior to surgery. After Laser Vision Correction, I understand that my eye is somewhat more vulnerable to all varieties of injuries. I understand it would be advisable for me to wear protective eyewear when engaging in sports or other activities in which the possibility is high of a ball, projectile object, elbow, fist, or other traumatizing object contacting the eye. I understand that it would be advisable for me to avoid wearing eye makeup the week following my Laser Vision Correction and swimming during two weeks following my Laser Vision Correction.

i. I understand that there is a natural tendency of the eyelids to droop with age and Laser Vision Correction may hasten this process.

j. I understand that after Laser Vision Correction there may be pain or a foreign body sensation, particularly during the first 48 hours after surgery, and that discomfort could continue for the first week. I understand that I should contact my doctor if pain persists for more than 48 hours.

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

l. I understand that the long term effects of Laser Vision Correction are unknown and unforeseen complications, risks or side effects can and do occur.

m. I understand that the visual acuity I initially gain from Laser Vision Correction could regress, and my vision may go partially or completely back to the level it was immediately prior to having the procedure.

n. I understand the correction that I can expect to gain from Laser Vision Correction may not be perfect. I understand it is not realistic to expect Laser Vision Correction will result in perfect vision, at all times, under all circumstances, for the rest of my life. I also understand that Laser Vision Correction will not prevent me from developing naturally occurring eye problems.

o. I understand that I may be given medication in conjunction with Laser Vision Correction, my eye may be patched afterward or a contact lens may be placed on my eye. I understand that I must immediately contact my doctor if I have an allergic reaction to any medication that I'm given.

p. I understand that even 90% clarity of vision is still slightly blurry. Enhancement surgeries can be performed when vision is stable unless it is unwise or unsafe. In order to perform an enhancement surgery, there must be adequate tissue remaining. I understand, if there is inadequate tissue, it may not be possible to perform an enhancement. An assessment and consultation will be held with the surgeon at which time the benefits and risks of an enhancement surgery will be discussed.

q. I understand the excimer laser could malfunction, requiring Laser Vision Correction to be stopped before completion. Depending on the type of malfunction, this may or may not be accompanied by visual loss that could be temporary or permanent. I understand the surgeon may be forced to reschedule Laser Vision Correction should a malfunction occur.

r. I understand that with LASIK, the microkeratome could malfunction, requiring the procedure to be stopped before completion. I understand with LASIK, when using the microkeratome, instead of making a flap, an entire portion of the central cornea could be cut off and possibly lost. If preserved, I understand my doctor would put this tissue back on the eye after the laser treatment, possibly with sutures/stitches, according to the ALK procedure method. It is also possible the flap incision could result in an incomplete flap, buttonhole, bottom hole or a flap that is too thin. If this happens, it is likely the laser part of Laser Vision Correction will have to be postponed until the cornea has a chance to heal sufficiently to try to create the flap again. I understand with LASIK possible perforation of the cornea may occur, causing devastating complications including loss of my vision or eye.

s. I understand that with LASIK, irregular healing of the flap could result in a distorted cornea, flap dislocation, corneal ectasia, loss of corneal cap or free cap. This would mean that glasses or contact lenses may not correct my vision to the level possible before undergoing LASIK. I understand that if this distortion in vision is severe, a partial or complete corneal transplant might be necessary to repair the cornea.

t. I understand that during the postoperative period after Laser Vision Correction, my eye(s) may develop glaucoma, haze or scarring which may require additional types of eye treatments. I understand Laser Vision Correction may result in infection or inflammation of my eye(s). Infections of the eye can be caused by an internal or external eye bacteria or fungus that may not be able to be controlled by antibiotics or other means. Should an infection occur following my Lasik Vision Correction, a potentially lengthy course of treatment may be necessary that may include invasive laboratory tests, special medication, multiple doctor visits and hospitalization. I understand that other rare complications including, but are not limited to, corneal swelling, retinal detachment, hemorrhage, venous and arterial blockage, cataract formation, total blindness, damage to the optic nerve and even loss of my eye may occur from the procedure. I understand the important of taking my postoperative medicine as recommended and using artificial tears as recommended.

u. 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 resulting in serious injury or death. 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 be incomplete.

v. I understand that Epithelial in-growth can occur during the first month following LASIK and is more likely to occur in patients with an abnormal or weakly adherent protective layer for which age is a factor. Epithelial in-growth is produced when epithelial surface cells grow underneath the corneal flap during the healing of the corneal flap incision. Epithelial in-growth is more common with any trauma or breakdown of the epithelium, which is more common in LASIK enhancement procedures and long-term contact lens wearers. Treatment of this condition involves lifting the flap and clearing the cells away. Although most small areas of epithelial in-growth need only be monitored, untreated large areas of epithelial in-growth may distort vision and may actually damage the flap integrity if severe and progressive.

w. I understand that, in severe cases, undetected keratoconus can be exacerbated (made worse) by my Lasik Vision Correction and that rare cases of keratoconus following LASIK have occurred.

x. In the unlikely event resuscitation should be necessary, I **DO** or **DO NOT** want to be resuscitated. I understand that my surgeon will not honor advance directives concerning the treatment of my medical health. If necessary, my surgeon or other certified staff member would perform life-sustaining services and call 911.

#### **VII. Patient's Statement of Understanding and Acceptance**

In giving my consent for Laser Vision Correction, I understand and accept:

a. Laser Vision Correction is an elective surgery. There is no health or medical reason why I need to have the surgery. Alternative treatments including eyeglasses and contact lenses are available.

b. The results of Laser Vision Correction cannot always be predicted. The long-term safety and efficacy of Laser Vision Correction cannot be guaranteed. I may still need eyeglasses or contact lenses to achieve satisfactory vision after the procedure.

c. Laser Vision Correction is not without risk. Complications from Laser Vision Correction, as described in this Patient Consent Form, can and do occur. Re-treatment may be necessary, but there is no guarantee that re-treatment will be successful. As with any procedure of this type, Laser Vision Correction has remote risks such as partial loss of best-corrected visual acuity or even blindness.

d. Adherence to the recommended eye drop regimen and periodic follow up visits with an eye doctor after Laser Vision Correction are required to reduce the risk of complications and increase the likelihood that the desired outcome will be achieved.

e. I have confirmed that I am neither pregnant nor a nursing mother now or have been anytime in the past three months and that I will notify my doctor if I become pregnant in the six month period following my Laser Vision Correction. I understand that pregnancy may affect my healing response. I also understand that some medications may pose a risk to an unborn or nursing child.

f. At any time prior to my Laser Vision Correction, I may withdraw my consent. My decision to undergo Laser Vision Correction has been my own and has been made without duress of any kind.

g. I authorize the doctors involved to collect data and to record on video or photographic equipment my procedure for purposes of education, research, or training of other health care professionals. I also give my permission for the doctors to use data about my Laser Vision Correction and subsequent treatment to further understand Laser Vision Correction. I also authorize the doctors involved in my pre-operative, intra-operative and post-operative care to share medical information relating to my health, my vision and/or my Laser Vision Correction with other health care professionals my doctors deem as prudent. I understand that my name will remain confidential, unless I give subsequent written permission for it to be disclosed outside my doctor's office or the center where my Laser Vision Correction will be performed.

h. The information gathered about my Laser Vision Correction may be used to study these procedures.

i. I agree to accept personal financial responsibility for the payment of all charges and fees related to my Laser Vision Correction. This includes charges for the procedure itself, for medications I may need, for pre and post-procedure care, for punctal plugs,

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for any eyeglasses or contact lenses required after Laser Vision Correction, and for the expenses connected with my travel to the center where my Laser Vision Correction will be performed. I understand that my Laser Vision Correction may not be covered by insurance and this it is my responsibility to deal with my insurance carrier and to determine whether or not my Laser Vision Correction procedure is covered.

j. I verify that I will not wear/have not worn contact lenses at any time during the period recommended by my doctors prior to undergoing Laser Vision Correction.

k. I understand that although my Laser Vision Correction may take place at a location that is owned or controlled by a company called The Lasik Vision Institute ("LVI), my Laser Vision Correction will not be performed by LVI, a company called Eyeglass World ("EGW"), or any employee of the foregoing companies. I further understand that LVI and EGW do not engage in the practice of medicine and that my Laser Vision Correction will instead be performed by a physician that is an independent contractor (and not an employee) of LVI. I further understand that any and all patient care decisions concerning my Laser Vision Correction will be made solely by the physician who performs the procedure and not by LVI, EGW or any of the employees of LVI or EGW. Notwithstanding the foregoing, a grievance procedure is available through LVI to address or assist you in addressing any grievance that you may have as part of your Lasik Vision Correction.

l. I understand that the physician named in any advertisement that I may have read with regard to my Laser Vision Correction may not be the person who performs my Laser Vision Correction.

m. I understand that having my Laser Vision Correction procedure could potentially disqualify me from some professions, including the military and certain law enforcement agencies. I understand that it is my responsibility to investigate any requirements and/or exclusion criteria for any profession and or sport/hobby in which I am interested.

### VIII. Pre and Post Operative Care

**Co-management:** In ophthalmology, often pre-operative examination data is gathered by the patient's referring eye doctor. He/she then recommends the patient to an eye surgeon for evaluation for the procedure. In most cases, patients are referred back to their primary eye doctors for care after the procedure or Laser Vision Correction. This system of shared care between two eye care providers is termed co-management. It is important for you to understand the decision whether or not to be co-managed is yours alone. The most common reasons patients choose co-management are (a) a relationship and trust in their doctor, (b) travel distances and (c) convenience.

Your preoperative examination and post-operative care will be managed by an Optometrist, a person licensed by the state in the diagnosis of eye conditions, who is independent from LVI and EGW. Your Laser Vision Correction will be performed by an Ophthalmologist, a person licensed by the state in the diagnosis, treatment and surgery of the eye, who is independent from LVI and EGW. I also understand that I must be assisted home by a responsible adult.

### Patient Confirmation of Co-Management:

I desire to have my optometrist, Doctor \_\_\_\_\_, perform my preoperative examination and postoperative follow-up care following my eye surgery or Laser Vision Correction. My optometrist has informed me that an optometrist may lawfully provide pre and post-operative eye care under applicable state law. I understand that my optometrist will communicate post-operative reports of my case to the operating Ophthalmologist. I understand that my optometrist will immediately contact the operating Ophthalmologist and make arrangements for transfer of care should I experience any complications related to my eye surgery or Laser Vision Correction. I also understand that I may contact and be examined by the operating Ophthalmologist at any time during the post-operative period.

### IX. Conversion of LASIK to PRK

Your surgeon may either preoperatively or intraoperatively decide to perform PRK instead of LASIK. This decision to change methods Laser Vision Correction is done in your best interest and for safety reasons. Some of these reasons may include thin corneas and irregular prescriptions. Your surgeon will discuss with you his/her reasons for the change of method.

Should my eye surgeon decide it is safer to change methods from LASIK to PRK,  
I **DO** **DO NOT** give consent to my surgeon to perform PRK.

### By signing this form, I acknowledge I understand and accept the following:

- I have had the opportunity to have my questions answered to my complete satisfaction;
- My decision to undergo my eye surgery or Laser Vision Correction has been my own and has been made without duress of any kind;
- My eye surgery has been explained to me in terms I understand; and
- I understand and accept the possible risks, side effects, benefits and alternatives that can result from my eye surgery or Laser Vision Correction.

The procedure I am consenting to undergo is (circle one):

- (a) **LASIK** (b) **PRK**

I consent to undergo for the correction of (circle one):

- (a) **Myopia** (nearsightedness) (b) **Myopic astigmatism** (nearsightedness and astigmatism) (c) **Mixed astigmatism**  
(d) **Hyperopia** (farsightedness) (e) **Hyperopic astigmatism** (farsightedness with astigmatism)

I consent to undergo treatment on my (circle one):

- (a) **both eyes** (b) **my right eye only** (c) **my left eye only**

Patient's Signature \_\_\_\_\_ Date \_\_\_\_\_

Patient's Name (Print) \_\_\_\_\_

Witness' Signature \_\_\_\_\_ Date \_\_\_\_\_

Witness's Name (Print) \_\_\_\_\_

Surgeon's Signature \_\_\_\_\_ Date \_\_\_\_\_

Surgeon's Name (Print) \_\_\_\_\_