

# OcuSight Eye Care Center

## Laser Vision Correction Surgery Consent Form

The following information is intended to help you make an informed decision about having Laser Vision Correction (LVC) surgery to correct your vision.

It is impossible to list all of the possible risks and complications associated with this proposed surgery or any other treatment. Risks and complications that are considered to be unforeseeable, remote, or commonly known are not discussed. In addition, because LVC is a relatively recent surgery, there may be long-term effects not yet known or anticipated at the present time.

The excimer laser has been approved by the US Food & Drug Administration (FDA) for use in LVC. LVC combines two FDA approved procedures including Automated Lamellar Keratoplasty (ALK) and Photorefractive Keratectomy (PRK), and treats myopia (nearsightedness), hyperopia (farsightedness), and astigmatism. These LVC procedures are practiced in various other countries such as Canada, Germany and Australia and are approved for use in all branches of the US Military and NASA.

There are many types of LVC possible, including LASIK (Laser Assisted Keratomileusis In Situ) and PRK (Photorefractive Keratectomy). The type of procedure used is determined by your doctor using a variety of factors including the thickness of the cornea available for reshaping.

### ***An Overview of the LVC Procedure***

**Diagnosis:** You have been diagnosed with myopia (nearsightedness) or hyperopia (farsightedness) with or without astigmatism.

**LVC Surgery Described:** LVC permanently changes the shape of the cornea. The surgery is performed using a topical anesthetic (drops in the eye). PRK uses an invisible excimer laser light beam to remove a layer from the clear outer covering of your eye (the cornea). The LASIK procedure involves folding back a thin layer of corneal tissue (corneal flap) with a microkeratome (a surgical instrument much like a carpenter's plane). Once the flap has been made, a thin layer of corneal tissue is removed with the light from an excimer laser. After removal, the flap is replaced and bonds back into place usually without the need for stitches. The removal of thin layers of tissue causes the center of the cornea to flatten in the case of nearsightedness, or to steepen in the case of farsightedness, or become more rounded in the case of astigmatism, which changes the focusing power of the cornea.

The long-term outcomes of PRK and LASIK are shown to be essentially identical.

**Limits of LVC:** Although the goal of LVC is to improve vision to the point of not being dependent on glasses or contact lenses, or to the point of wearing thinner (weaker) glasses, this result is not guaranteed. Additional procedures, spectacles, or contact lenses may be required to achieve adequate vision. LVC does not correct the condition known as presbyopia (aging of the eye) which occurs in most people around age 40 and may require them to wear reading glasses for close-up work. If you presently need reading glasses, you will likely still need reading glasses after this treatment. If you do not need reading glasses, you may need them at a later age. LCV surgery will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, retinal degeneration or detachment.

Initials \_\_\_\_\_

## 2. **Risks and Contraindications**

**Risks:** The risks of LVC surgery include, but are not limited to:

- **Loss of Vision:** LVC surgery can possibly cause loss of vision or loss of best corrected vision. This can be due to infection (internal or external) or irregular scarring or other causes, and unless successfully controlled by antibiotics, steroids, or other necessary treatment, could even cause loss of the infected eye. Vision loss can be due to the cornea healing irregularly, which could add astigmatism and making wearing glasses or contact lenses necessary or lead to loss of useful vision. Irregular cornea healing could result in a distorted corneal surface so that distorted vision or “ghosting” occurs. This may or may not be correctable by spectacles or contact lenses.
- **Visual Side Effects:** Other complications and conditions that can occur after having LCV surgery include: anisometropia (difference in power between the two eyes), epithelial ingrowth (epithelial cells growing underneath the corneal flap of LASIK), aniseikonia (difference in imaging size between the two eyes), double vision, hazy vision, fluctuating vision during the day and from day to day, increased or decreased sensitivity to light that may be incapacitating for some time and may not completely go away, glare and halos around lights which may not completely go away.
- **Overcorrection or Undercorrection:** It may be that LVC surgery will not give you the result you desired. Many procedures result in the eye being undercorrected. If this occurs, it may be possible or necessary to have additional surgery to fine-tune or enhance the initial result. It is also possible that your eye may be overcorrected to the point of becoming farsighted (by overtreating myopia) or nearsighted (by overtreating hyperopia). It is possible that your initial results could regress overtime. In some but not all cases, re-treatment, glasses or contact lenses could be effective in correcting vision.
- **Other Risks:** Other reported complications include: corneal ulcer formation, endothelial cell loss (loss of cell density in the inner layer of the cornea possibly resulting in corneal swelling), ptosis (droopy eyelid), corneal swelling, contact lens intolerance, retinal detachment, hemorrhage. Complications could also arise requiring further corrective procedures including either a partial (lamellar) or full-thickness corneal transplant using donor cornea. These complications include: loss of corneal disc, damage to the corneal disc, disc decentration, progressive corneal thinning (ectasia). Sutures may also be required which could induce astigmatism. There are also potential complications due to anesthesia and medications that may involve other parts of your body. It is also possible that the microkeratome or the excimer laser could malfunction and the procedure stopped. Since it is impossible to state all potential risks of any surgery or procedure, this form does not provide a comprehensive listing of every conceivable problem.
- **Later Discovered Complications:** LVC is a relatively recent procedure. You should be aware that other complications may occur that have not yet been reported. Longer-term results may reveal additional risks and complications. After the procedure, you should continue to have routine check ups to assess the condition of your eyes.
- **Cost of Post-Procedure Care:** Costs for post-procedure care and corrective procedures are included in the cost of the LVC procedure for one year. Costs of any post-procedure medications or enhancements (in order to treat undercorrection or overcorrection) are not included in the cost of the LVC procedure.
- **Enhancements:** Occasionally, patients treated by LVC require additional LVC treatment to enhance the effect of the initial treatment. The risks of re-treatment are essentially the same as the original treatment as discussed in this document. Cost for an enhancement within the first year of the original procedure is \$250 per eye. Any enhancements done after one year from the original procedure will be at full price.
- **Risks of Not Undergoing LVC:** The risks of not having the surgery are limited to those associated with your current visual condition. These include, but are not limited to, the dangers that may be associated with losing glasses or contact lenses, the risks of corneal distortion and/or infection from wearing contact lenses, and the risks of trauma to the eye caused by breakage of plastic spectacles or contact lenses in the eye.

Initials \_\_\_\_\_

**Contraindications:** The treatment should not be performed on persons:

- With uncontrolled vascular disease
- With autoimmune disease
- Who are immune-compromised or on drugs or therapy that suppress the immune system
- With signs of keratoconus (steepening of the cornea)
- Who are pregnant, nursing or expecting to become pregnant within 6 months following the LVC procedure
- With residual, recurrent, or active ocular disease(s) or abnormality except for myopia or hyperopia in either eye
- With active or residual disease(s) likely to affect wound-healing capability
- With unstable or uncontrolled diabetes
- With progressive myopia or hyperopia
- With glaucoma

If you know that you have any of these conditions, you should inform your physician. In addition, if you have any other concerns or possible conditions that might affect your decision to undergo LVC surgery, you should discuss them with your physician.

### **3. *Alternatives to LVC***

LVC is purely an elective procedure and you may decide not to have this operation at all. Among the alternatives are:

- Eyeglasses/spectacles
- Contact lenses
- Radial keratotomy (RK)
- Orthokeratology to temporarily mold the cornea
- Corneal limbal relaxing incisions for astigmatism correction

You should discuss these options with your physician.

### **4. *Pre- and Post-Treatment Care***

#### **Before The LVC Surgery**

- **Pregnancy:** Pregnancy could adversely affect your treatment result since your refractive error can fluctuate during pregnancy. In addition, pregnancy may affect your healing process and some medications may pose a risk to an unborn or nursing child. If you are pregnant or expecting to become pregnant, you should not undertake the LVC procedure until after the pregnancy. If it is possible that you are pregnant, you should be tested so as to determine whether you are pregnant. If you become pregnant in the six months following treatment, you should notify your eye doctor immediately.
- **Taking medication and allergies:** You should inform your physician of any medications you may be taking so as to account for the risk of allergic reactions, drug reactions, and other potential complications during the LVC surgery and subsequent treatment.
- **Contact lens wearers:** Patients who wear gas-permeable, hard, or toric contact lenses must completely stop wearing such lenses at least two weeks prior to the initial eligibility examination. This period may be longer for some patients. Patients who wear soft contact lenses must completely stop wearing their soft contact lenses at least one week prior to the eligibility examination. Following the examination, if both you and your doctor agree that LVC is the appropriate treatment, you must leave the contact lens out of the eye to be treated.

Initials \_\_\_\_\_

**Post-Treatment Precautions:**

- **Eye Protection:** Avoid exposing the eye to tap water in the bath or shower as such nonsterile water may expose the eye to increased risks of infection. The eye shield should be worn at night while you sleep, to avoid any contact with your eyes. Avoid rubbing the eye. Also, use only the medication prescribed by your doctor. The eye may be fragile to trauma from impact. Evidence has shown that, as with any other scar, the corneal incision will not be as strong after healing as the original cornea was at the site of the incision. Therefore, the eye is somewhat more vulnerable to all varieties of injuries after LVC, at least for the first year after surgery. It is advisable to wear protective eye wear when engaging in contact or racquet sports or other activities in which the possibility of a ball, projectile, elbow, fist or other traumatizing object contacting the eye may be high.
- **Operating Motor Vehicles:** After surgery, you may experience starburst-like images or “halos” around lights, your depth perception may be slightly altered, and image sizes may appear slightly different. Some of these conditions may affect your ability to drive and judge distances. Driving should only be done when you are certain that your vision is adequate. On the day of the LVC procedure, you should arrange to be driven home after the procedure.
- **Pain & Discomfort:** The amount of pain and discomfort that can be expected soon after the LVC procedure varies with the individual. You should expect that the eye would be painful and sore to some extent after the surgery. Vision may be blurry and you may experience some redness and/or corneal edema (swelling of the cornea). Some patients report the sensation of a foreign object in the eye.

## PATIENT STATEMENT

- I have read this Informed Consent Form (or it has been read to me). The Laser Vision Correction (LVC) surgery has been explained to me in terms that I understand.
- I have been informed about the possible benefits and possible complications, risks, consequences, and contraindications associated with LVC. I understand that it is impossible for my doctor to inform me of every conceivable complication that may occur and that because LVC is a relatively recent procedure, there may be unforeseen risks. I have been given the opportunity to ask questions and have received satisfactory answers to any questions I have asked. I understand that no guarantee of a particular outcome can be given and that my vision could become better or worse following treatment.
- My decision to undertake the LVC procedure was made without duress of any kind. I understand that LVC is an elective procedure and my myopia or hyperopia and/or astigmatism may be treated by alternative means such as spectacles, contact lenses or other forms of refractive surgery. It is hoped that LVC will reduce or possibly eliminate my dependency on glasses or contact lenses. I understand that the correction obtained may not be completely adequate and that additional correction with glasses or contact lenses may be needed.
- I authorize the physicians and other health care personnel involved in performing my LVC procedure and in providing my pre- and post-procedure care to share with one another any information relating to my health, my vision, or my LVC surgery that they deem relevant to providing me with care.

Initials \_\_\_\_\_

I consent to have LVC performed on my RIGHT EYE / LEFT EYE / BOTH EYES (CIRCLE ONE).

\_\_\_\_\_  
Patient's Name

\_\_\_\_\_  
Date

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

\_\_\_\_\_  
Witness' Name

\_\_\_\_\_  
Date

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

\_\_\_\_\_  
Physician's Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Physician's Signature

**For surrogate consent:**

I am the guardian, next-of-kin, or legal representative of the patient whose name appears above on the patient signature line. I have read and fully understand the foregoing information and have discussed this information and its terms with the patient to the extent of the patient's understanding. Due to the patient's inability to provide informed consent, I consent to have LVC performed on the patient's RIGHT EYE / LEFT EYE / BOTH EYES. (circle one)

\_\_\_\_\_  
Surrogate's Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Surrogate's Signature

\_\_\_\_\_  
Nature of relationship to Patient

\_\_\_\_\_  
Witness' signature