

**MEDICAL CENTER OPHTHALMOLOGY  
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**LASEK/PRK Consent Form**

**1.     *General Information***

The following information is intended to help you make an informed decision about having Laser Assisted Subepithelial Keratomileusis (LASEK) or Photorefractive Keratectomy (PRK) surgery to correct your vision.

On this consent form, we discuss the risks, benefits, and alternatives of these procedures. It is impossible to list all of the possible risks and complications, whether common or remote, associated with these proposed surgeries or any other treatment. In addition, because LASEK and PRK are relatively recent surgeries, there may be unforeseen or long-term effects not yet known or anticipated at the present time.

**2.     *An Overview of the LASEK/PRK Procedure***

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

**LASEK/PRK Surgery Described:** LASEK/PRK permanently changes the shape of the cornea. The surgery is performed under a topical anesthetic (drops on the eye). The procedure begins with the removal of the surface of the cornea (epithelium). With LASEK, the epithelium is loosened with diluted alcohol solution and pushed aside. With PRK, the surface can be removed either with the alcohol or with the excimer laser itself. Next, a thin layer of corneal tissue is removed with the light from the excimer laser. The removal of a thin layer of tissue causes the center of the cornea to flatten in the case of nearsightedness, steepen in the case of farsightedness, or become more rounded in the case of astigmatism, thus changing the focusing power of the cornea. In LASEK, the epithelium is then pushed back into place at the end of the procedure. A soft contact lens will be placed on the cornea during the healing process, which the doctor will remove after healing is completed. During this time, you will sleep with the contact lens. You will be prescribed certain medications as part of the treatment.

**Limits of LASEK/PRK:** Although the goal of LASEK/PRK 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. LASEK/PRK does not correct the condition known as presbyopia (aging of the eye), which occurs to 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 after the surgery or at a later age. LASEK/PRK surgery will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, retinal degeneration, or retinal detachment.

**3.     *Risks and Contraindications***

**Risks:** The risks of LASEK/PRK surgery include, but are not limited to:

- Loss of Vision:** LASEK/PRK 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 or to the development of haze, which could add astigmatism and make 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 with LASEK/PRK surgery include: anisometropia (difference in power between the two eyes); 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 LASEK/PRK 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 over time. In some, but not all cases, retreatment, glasses, or contact lenses could be effective in correcting vision.
- Other Risks:** Other reported complications include: dry eye; corneal ulcer formation; endothelial cell loss (loss of cell density in the inner layer of the cornea, possibly resulting in corneal swelling); corneal swelling; inflammation of the iris; ptosis (droopy eyelid); contact lens intolerance; retinal detachment and hemorrhage. An increase in the inner eye pressure due to post-treatment medications may occur—this usually resolves after discontinuation of the medications. Complications could also arise requiring further corrective procedures including either a partial (lamellar) or full thickness corneal transplant using donor cornea. 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, causing the procedure to be 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:** LASEK/PRK is a relatively recent technique. You should be aware that other complications may occur that have not yet been reported. Long-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, including follow-up care for one year, are included in the costs of the LASEK/PRK procedure. If enhancement laser surgery is required, its cost is not included, but offered at a reduced price.
- Risks of NOT Undergoing LASEK/PRK:** 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 spectacle lenses or contact lenses in the eye.

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

- with uncontrolled collagen-vascular disease;
- with autoimmune disease;
- who are immune-compromised or on drugs or therapy which suppress the immune system;
- with signs of keratoconus (steepening of the cornea);
- with a previous history of keloid formation;
- who are pregnant, nursing, or expecting to become pregnant within the six months following the LASEK/PRK procedure;
- with residual, recurrent, or active ocular disease(s) or abnormality;
- with active or residual disease(s) likely to affect wound healing capability;
- with severe nearsightedness, farsightedness or astigmatism that is outside the treatment limits approved by the Food and Drug Administration;
- with unstable or uncontrolled diabetes;
- with progressive myopia or hyperopia;
- with moderate to severe amblyopia (lazy eye);
- with uncontrolled or severe glaucoma; or
- who have severe dry eye or are at risk for this by taking Accutane or other high-risk medications.

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 undertake LASEK/PRK surgery, you should discuss them with your physician.

#### **4. *Alternatives to LASEK/PRK***

LASEK/PRK is purely an elective procedure. It is not a necessary procedure, and you may decide not to have this operation at all. Among the alternatives are:

- **Eyeglasses/spectacles:** spectacles have been, and still are, the most common method of correcting vision when nearsightedness (myopia), farsightedness (hyperopia), and astigmatism exist. Spectacles adequately correct vision for many people, but for others they are a hindrance or an obstacle in their work, recreation, or other pursuits. In high degrees of myopia or hyperopia, glasses may be thick and tend to minimize peripheral vision and change image size.
- **Contact lenses:** a hard or soft contact lens could be fitted to your eye if you have no corneal diseases or other problems that would prevent you from wearing such a lens. Wearing of such types of lenses restores the vision as long as the lenses are worn, and might offer advantages over spectacles for you. These advantages might include improved peripheral or side vision and seeing a more normal image size. Handling of a contact lens can be difficult for some individuals. Though contact lenses are fairly safe, they do carry a higher risk of infection to the eye. In some contact lens wearers, the visual acuity may not be as good as with glasses, and near vision may become worse.
- **Orthokeratology:** this is the use of rigid reverse-geometry contact lenses, worn while sleeping, to change the shape of the cornea such that glasses or contact lenses are not required during the day. This method of vision correction has only recently regained some interest. Its utility is limited, and still requires the placement of contact lenses on the eye.

- **Radial keratotomy (RK):** this procedure done for myopia uses a hand-held blade to make a pattern of incisions on the cornea that look like the spokes of a wheel. The incisions weaken the structure of the cornea and allow the central cornea to flatten, thus decreasing its power. The predictability of this procedure and the long-term stability have been poor. It can also result in irregular astigmatism and visual problems like starbursting, glare, and decreased vision.
- **Hexagonal keratotomy:** similar to RK, but the incisions are oriented differently. Its limitations are the same as RK.
- **Astigmatic keratotomy:** again, incisions are placed in the cornea, but in this case to treat astigmatism. This procedure can be combined with cataract surgery or clear lens extraction to help achieve independence from glasses. Its main limitation is its predictability.
- **Automated lamellar keratoplasty (ALK):** this corneal shaping procedure uses a microkeratome, a medical instrument that lathes, or cuts, the cornea. For the correction of nearsightedness, the microkeratome is used a second time to lathe off a second layer of corneal tissue, which is discarded. When the primary layer is replaced upon the eye and appropriately secured, the cornea assumes a flattening effect. If the corneal disc does not adhere permanently to the cornea, an additional surgical procedure could be required to replace this disc with donor tissue. This procedure is not widely performed presently.
- **Intracorneal ring (ICR or INTACS):** this consists of two clear half rings made of a polymer material. The rings are intended to reshape the cornea without cutting or removing tissue. This procedure is reversible if the rings are removed. There are limitations to the extent of myopia that can be treated.
- **Laser assisted stromal in situ keratomileusis (LASIK):** this procedure is the most common refractive surgery procedure today. It uses a microkeratome to first cut a thin flap in the cornea. The flap is lifted, then the excimer laser is used as in LASEK/PRK to modify the shape of the cornea to decrease dependence on glasses or contact lenses. The flap is then repositioned on the cornea. LASIK leads to less post-operative pain and, in certain cases, less corneal scarring. However, there are additional risks undertaken with the use of the microkeratome to cut a flap of tissue.
- **Clear lens extraction (CLE) with intraocular lens (IOL) implantation:** this procedure is essentially the same as modern-day cataract surgery, which is one of the most common surgeries performed in the United States. In CLE, the natural lens of the eye is removed (before it develops a cataract), and replaced with an artificial lens. This procedure can have great visual results, but it involves surgery *inside* of the eye. The additional risks of intraocular surgery should be considered, and are beyond the scope of this informed consent.
- **Implantable contact lens (ICL):** this procedure was just approved in the United States at the end of 2003 by the FDA. It involves the placement of an artificial lens inside of the eye, just behind the iris (the colored part of the eye) and just in front of the natural lens of the eye. The U.S. studies of this lens suggest good results with few complications. Nevertheless, this procedure is relatively new and still involves surgery *inside* of the eye.

You should discuss these options with your physician.

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

### **Before the LASEK/PRK 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, then you should not undertake the LASEK/PRK procedure until after the pregnancy and the completion of breast-feeding. If it is possible that you are pregnant, then you should be tested so as to determine whether you are pregnant. If you become pregnant in the six (6) months following treatment, then you should notify your eye doctor immediately.
- **Taking medications 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 LASEK/PRK surgery and subsequent treatment.
- **Contact lens wearers:** Patients who wear gas permeable or hard contact lenses must completely stop wearing such lenses at least one month 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 two weeks prior to the eligibility examination. Patients who wear soft toric contact lenses (i.e., to correct for astigmatism) must completely stop wearing their lenses at least four weeks prior to the eligibility exam. Following the examination, if both you and your doctor agree that LASEK/PRK is the appropriate treatment, you must leave the contact lens out of the eye/s to be treated.

### **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. Only the eye drops given by your eye doctor should be placed in the eye. Avoid rubbing the eye.
- **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 LASEK/PRK procedure, you should arrange to be driven home after the procedure.
- **Pain and Discomfort:** The amount of pain and discomfort that can be expected soon after the LASEK/PRK procedure varies with the individual. You should expect that the eye will be painful and sore to some extent after the surgery. Vision will 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. Eye drops and pain medications will be prescribed to improve comfort.

**6. Patient Statement**

- I have read this Informed Consent Form (or it has been read to me) and the information pamphlet. The LASEK/PRK procedure 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 LASEK/PRK. I understand that it is impossible for my doctor to inform me of every conceivable complication that may occur, and that because LASEK and PRK are relatively recent procedures, 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 was given and that my vision could become better or worse following treatment.
- My decision to undertake LASEK/PRK was made without duress of any kind. I understand that LASEK and PRK are elective procedures, 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 LASEK/PRK 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 understand that this treatment will require follow-up examinations, initially at frequent intervals, for one year after treatment and I agree to return for these examinations.
- I authorize the physicians and other health care personnel involved in performing my LASEK/PRK 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 LASEK/PRK procedure that they deem relevant to providing me with care.
- I consent to have LASEK/PRK performed on my **right eye / left eye / both eyes**.

\_\_\_\_\_  
Patient Name

\_\_\_\_\_  
Patient Signature

\_\_\_\_\_  
Date

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

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

\_\_\_\_\_  
Date

\_\_\_\_\_  
Physician Name

\_\_\_\_\_  
Physician Signature

\_\_\_\_\_  
Date

**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 LASEK/PRK performed on the patient's **right eye / left eye / both eyes**.

\_\_\_\_\_  
Name of Surrogate

\_\_\_\_\_  
Surrogate Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Nature of Relationship to Patient

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

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

\_\_\_\_\_  
Date