

<b>PT. Name:</b>	<b>DOS:</b>	<b>Informed Consent for Laser In-Situ Keratomileusis (LASIK)</b>
<b>Procedure:</b>	<b>OD / OS / OU</b>	
<b>Surgeon:</b>	<b>Co-Manage:</b>	
<b>DOB:</b>	<b>Age:</b>	

This information is being given to you so that you can make an informed decision about having Laser In-Situ Keratomileusis (LASIK) surgery to correct your nearsightedness (myopia), farsightedness (hyperopia), and astigmatism (if present). You have the right to ask questions and have them answered to your satisfaction before agreeing to have the procedure.

In **BLACK INK** please initial where indicated and sign below to authorize the LASIK procedure.

**Description of the Procedure**

LASIK is a refractive surgical procedure performed on the eye. In LASIK, specialized devices called a microkeratome/intralase and an excimer laser are used to correct the prescription of the eye. First, a microkeratome/intralase creates a thin flap of corneal tissue from the surface of the cornea. This flap of tissue is circular, resembling a soft contact lens, and is not completely free from the cornea but is left attached on one side. Next, the excimer laser removes precise amounts of corneal tissue from beneath the flap to sculpt the cornea. The corneal flap is then replaced, thus preserving the outer corneal layers. The microkeratome/intralase and excimer laser are FDA-approved devices. LASIK combines two already approved procedures: Automated Lamellar Keratoplasty (ALK) and Photorefractive Keratectomy (PRK). Depending on the desired treatment, some LASIK procedures are considered unregulated or “off label” use of an approved medical device. However, the FDA does not regulate the practice of medicine and therefore does not preclude physicians from performing LASIK with the excimer laser.

**Expected Benefit**

The purpose of the LASIK procedure is to provide much better uncorrected vision than you now have without eyeglasses or contact lenses. Often, the procedure allows patients to function most of the time without eyeglasses or contact lenses. However, excellent vision without eyeglasses cannot be guaranteed.

**Alternatives to LASIK**

You may decline to have the LASIK surgical procedure. Alternatives to LASIK for obtaining useful vision include eyeglasses or contact lenses. Any of these options can provide excellent vision. Other refractive surgery alternatives include photorefractive keratectomy (PRK), or possibly an intraocular lens implantation.

**Presbyopia and Monovision**

Presbyopia is a normal aging change to the internal, near-focusing structure of the eye that causes people to need bifocals or reading glasses around age 40. LASIK does not affect the ability of the eye to change its focus, and therefore, does not improve presbyopia. Even if you don’t need reading glasses now, as you get older, or if you are already 40 years or older in age, you will likely need eyeglasses for reading after having the procedure performed. The need for reading glasses is related to the normal aging changes of the eye, and does not result directly from the LASIK procedure. In some people, however, nearsightedness may reduce or eliminate the need for reading glasses. Consequently, the correction or reduction of nearsightedness after LASIK may

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necessitate the use of reading glasses. LASIK surgery will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, retinal degeneration or detachment.

If you now wear bifocals or reading glasses, you will probably still need to use glasses for reading after your LASIK procedure. However, to eliminate or reduce dependency on reading glasses, some patients may elect to make or leave one eye slightly nearsighted for reading and attempt to have the other eye fully corrected for distance vision. This option results in monovision, which reduces or eliminates the ability of two eyes to generate stereoscopic (or 3D) vision.

### **Pregnancy**

During pregnancy, normal body changes can cause the refractive error of your eyes to fluctuate. Vision measurements made at this time will therefore not be reliable and cannot be used to guide LASIK surgery. If you are pregnant notify your doctor and do not have the procedure at this time.

### **Side Effects, Risks, and Complications**

Like all surgical procedures, LASIK is not absolutely safe. A list of possible side effects, risks, and complications follows. This list does not include every possible complication that may occur as a result of the LASIK procedure. There may also be unknown complications of LASIK. Risks include:

#### Unexpected Vision Correction Results

It is not possible to precisely predict how your eye will respond to the LASIK procedure. Any of the following outcomes may occur:

- **Undercorrection or Overcorrection** – LASIK surgery may result in undercorrection or overcorrection of the refractive error of the eye. Consequently, you may still need eyeglasses after this procedure to obtain good vision because of nearsightedness, farsightedness or astigmatism.
- **Decrease in Sharpness of Best Corrected Vision** – After LASIK, some patients find that their best vision with eyeglass or contact lens correction is not as good as it was before the procedure. This occurs as a result of irregularity in the shape of the surface of the eye. This may not improve with time.
- **Glare, Starbursts, and Visual Fluctuations** – Particularly in the first few months after the LASIK procedure, you may experience increased sensitivity to light, visual halos and/or starbursts around light sources, glare, double vision, or daily fluctuations in vision quality. Night vision may be impaired. This can limit your ability to drive, especially at night. These symptoms generally resolve themselves in three to six months, but they can persist indefinitely.
- **Inability to Wear Contacts** – If you want to wear contact lenses after the procedure, you may not be able to do so because of surgical changes to the shape of the eye. It may be difficult or impossible to fit contact lenses after LASIK surgery. In addition, certain types of lenses, such as extended wear contact lenses, may be prohibited.
- **Long-Term Changes** – Your eyes may change over time, partially reversing the LASIK correction. This may result in a decline in vision that requires the use of eyeglasses or contact lenses.
- **Later-Discovered Complications** – LASIK is a relatively recent technique. 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.

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### **Medical Complications of Surgery, Anesthetics, or Medicines**

Rarely, a serious medical complication may occur as a result of the LASIK procedure. These include:

- **Infection or Ulceration** – Infection inside the eye (endophthalmitis), corneal infection, corneal ulcer, or inflammation or infection outside the eye.
- **Irregular Healing** – Healing defects on the outer corneal layer (epithelium), irregular healing causing distortion of the corneal surface (irregular astigmatism), ingrowth of the surface corneal cells into the space between the flap and the bed of the flap (epithelialization of the interface), or increased blood vessel formation in the front part of the eye (corneal vascularization).
- **Irritability** – Recurrent erosions of the corneal surface with episodes of a sharp, gritty feeling in the eye; drooping of the upper eyelid (ptosis); or a feeling of eyestrain.
- **Impaired Vision or Blindness** – Scratch on the cornea (superficial corneal abrasion), wrinkling or tearing of the corneal flap, or excessive thinning of the cornea due to tissue removal can all impair vision and may be impossible to correct. Other complications may or may not be treatable with restoration of good vision. Consequently, LASIK can result in partial or complete loss of vision in the eye.
- **Reaction to Medication** – Certain complications may result from the use of topical anesthetics and oral sedatives during the LASIK procedure. These include discomfort, nausea, headache, vomiting, and mild to severe drug or allergic reactions resulting in stroke or even death.

In many cases of complication, but not all, an enhancement procedure may be done at the discretion of the surgeon and the patient. However, additional surgery may or may not achieve the desired result.

### **Videotape and Observer Policy**

Advanced Ophthalmology Institute conducts research into refractive surgery procedures and outcomes and presents findings at seminars and professional colloquia around the world. To facilitate these activities, it is the policy of Advanced Ophthalmology Institute to inform you when videotaping and/or audio taping any refractive surgery procedures. In addition, at the surgeon's discretion, properly scrubbed and attired observers may be allowed into the laser surgery suite for demonstration or training purposes. Your identity will not be disclosed without your prior written authorization.

### **Consent for Surgery**

In signing this consent form for LASIK surgery, I am stating that I have read this Informed Consent document (or it has been read to me), and I understand the basic procedure for LASIK surgery, and its advantages, disadvantages, risks, possible complications, and alternative treatments. Furthermore, I have had all of my questions about the procedure answered to my satisfaction.

I understand that the results of the surgery cannot be guaranteed and that no warranty or guarantee has been made to me regarding the results of the LASIK procedure.

If any unforeseen conditions are observed during the course of the surgery I do hereby authorize and request the surgeon and/or his/her associates to take whatever steps and to perform whatever procedure(s) they deem advisable, which may be in addition to or different than those now planned (e.g., PRK performed instead of the scheduled LASIK).

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I realize that the laser center is not a hospital, and that if a condition develops that warrants hospitalization as deemed necessary by my surgeon, I will be transferred to the nearest hospital for further treatment.

I hereby authorize Advanced Ophthalmology Institute and my surgeon to permit one or more observers to be present in the operating room and to observe the surgery to be performed on me. I also release the surgeon from any and all liability that may result from the presence of observers in said operating room.

I am aware that I will be sedated for the procedure, and I agree not to drive the day of the surgery. In addition, I will refrain from driving until I am comfortable with my vision during the day and night.

I understand that after this procedure, I should wear safety glasses to play racquet or contact sports.

I understand and agree that if I do not take all medications after surgery as directed, or if I fail to return for all scheduled postoperative appointments, the surgeon and Advanced Ophthalmology Institute cannot be responsible for the outcome of my surgery.

I will need to be seen at Advanced Ophthalmology Institute for my first day post-operative visit. I would like Dr. \_\_\_\_\_ to provide my pre- and post-operative care instead of Advanced Ophthalmology Institute (AOI). My eye doctor will be responsible for my pre-operative evaluation and my post-operative care for up to 12 months after surgery. I understand that I may return to AOI if I have any questions or concerns with my eyes.

Additional Consent:

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I hereby give my permission to Dr. \_\_\_\_\_ to perform LASIK (Laser In-Situ Keratomileusis) to correct my myopia (nearsightedness), hyperopia (farsightedness), and/or astigmatism on my \_\_\_\_\_ eye(s)

Patient's Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
(or legal representative if under 18 years of age)

Witness's Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
(Institute employee)

Surgeon's Certification: I hereby certify that the patient, or one authorized to act in his or her behalf, has been fully informed in lay terms understandable to the patient the nature of the surgical procedure, the alternatives as to treatment, and the consequences of and risks to the patient inherent or associated with the procedure and the patient (or authorized person) has authorized the performance of the procedure.

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