

# WAKE FOREST BAPTIST HEALTH EYE CENTER

## LASIK Consent Form

### 1. GENERAL INFORMATION

The following information is intended to help you make an informed decision about having Laser In-Situ Keratomileusis (LASIK). The purpose of the informed consent is to inform you of the side effects, limitations, and complications of LASIK surgery to the best of our ability. The first important message to understand is that it is impossible to perform any form of surgery without accepting a certain degree of risk and responsibility.

However, people take risks every day. Every time you drive your car you take a chance that despite your best efforts you may be seriously injured in an accident. Yet you take this risk, because it saves us time, and the chance of an accident is very small.

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 not commonly known are not discussed. In addition, because LASIK is a relatively recent surgery, there may be long term effects not yet known or anticipated at the present time. It is not our intention to frighten or dissuade someone from pursuing laser surgery, as most of our patients will never encounter any serious complications. The vast majority are pleased with the improvement that they achieve. It is our intention; however, to actually outline the associated risks to all candidates so that they may either elect not to accept the risks associated or be better prepared to deal with any unexpected complications or side effects. The only guaranteed way to not encounter any surgical risks is by staying in your glasses or contact lenses.

### 2. AN OVERVIEW OF THE LASIK PROCEDURE

The Food and Drug Administration (FDA) has fully approved LASIK. LASIK combines two already approved procedures, automated lamellar keratoplasty (ALK) and photorefractive keratectomy (PRK). The Wake Forest Baptist Health Eye Center uses the Allegretto Wavelight laser, which was approved by the FDA in 1995 and is the most technologically advanced laser on the market. In addition, we use the Alcon FS200 femtosecond laser to make the protective flap. Nearly one million LASIK procedures are performed in the United States each year.

### 3. BACKGROUND

The Excimer laser reshapes the cornea in order to reduce or eliminate the need for glasses or contact lenses in cases of myopia (nearsightedness) and astigmatism (ovalness of the cornea) and for hyperopia (farsightedness). The Excimer laser can be delivered to reshape the cornea in two ways: (1) on the surface known as PRK or photorefractive keratectomy or (2) beneath the surface of the cornea as with LASIK. The surface cells of the eye called epithelium are very reactive to trauma. When these cells are removed as with PRK, they cause more pain, greater chance of infection, and a greater healing response which may lead to scarring. By creating a flap of tissue, as with the LASIK procedure, and applying the laser beneath this flap, the risks associated with healing are reduced. The intraoperative risks, however, are greater with LASIK than with PRK alone. Although LASIK affords a much quicker healing response and quicker return to work with better initial acuity, it does have disadvantages that are unique to this procedure which have to do with cutting the flap using a femtosecond laser.

### 4. LASIK SURGERY DESCRIBED

The surgery is performed under topical anesthesia (numbing drops in the eye). This will completely numb the eye so that you will not experience any pain during the operative procedure. A suction ring is attached to the eye securing the eye in position for the femtosecond laser. When the suction is applied, the vision will appear completely gray or black. Patients cannot see or feel the incision. The femtosecond laser separates the top 15% percent of the cornea from the deeper layers below. Once this flap has been made, this thin layer of corneal tissue is folded back so the Excimer laser can finely sculpt the corneal tissue. It effectively puts your contact lens prescription in your cornea. After this tissue has been removed, the flap is replaced back into position and bonds back into place in just a few minutes without the need for stitches. Removal of thin layers 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, which changes the focusing power of the cornea.

### 5. RISKS AND COMPLICATIONS

The majority of reactions or complications with the LASIK procedure occurs in association with the healing process that takes place after the procedure and are usually resolved within one to three months after the procedure. However, it is possible that some of these risks/complications could be long term or permanent.

- **PAIN** – The risk of pain is approximately 1 in 1000 with LASIK. It is common to feel a slight “eyelash” foreign body sensation immediately after

the procedure which may last for 2 to 4 hours. Patients are almost always light sensitive with tearing immediately after the procedure. This may last up to 1 week.

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- **INFECTION** – The risk of a corneal infection is approximately 1 in 20,000 with LASIK. This risk of infection is greatest within the first 24 to 72 hours immediately following LASIK surgery. Makeup, swimming, and vigorous activities should be avoided during this time. A serious corneal infection can result in scarring, a permanent reduction in vision, and even complete loss of vision. However, the risk of severe corneal infection is rare and is significantly reduced in the LASIK procedure as compared to PRK or RK. Most corneal infections can be treated with antibiotic drops. If scarring should occur, this could be remedied with a corneal transplant.

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- **NIGHT VISION DIFFICULTIES** - Night glare/ blurriness or halo is very common in nearsighted individuals even before any refractive procedure is performed. LASIK patients often experience an increase in starburst halos, etc. for 1 to 2 weeks after surgery. It is more common when only one eye has been treated. Typically, 2 months after both eyes have been treated only 0.1% of patients still experience significant night glare which seriously interferes with their night driving. As the pupil dilates with reduced lighting conditions, patients with this problem may note blurriness, ghosting, or halos around lights.

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- **BLURRINES/LOSS OF BEST CORRECTED VISUAL ACUITY** – Blurriness is very common during the healing process. After LASIK, there is considerable improvement in the vision within the first 24 hours. It generally takes 1 to 2 days until vision is clear enough to drive. However, it may take longer in rare cases. Approximately 90% of the visual recovery occurs within the first day while the last 10% of vision improves over 1 week to 3 months and even up to a year. Approximately 1 in 500 patients independent of the procedure performed will develop corneal irregularities reducing the sharpness, crispness, and clarity of their vision preventing them from reading the bottom 2 or more lines of an eye chart even with glasses, contact lenses, or laser enhancement surgery. The initial blurriness resolves in approximately 99% of patients over 6 to 12 months. However, it may be permanent in approximately 0.5% of treated patients. There is no way of determining who will be in this 0.5%. A patient who loses sharpness will have vision that is permanently worse. All forms of eye surgeries possess the same or even

higher risk. Some of these patients, however, would benefit from wearing a rigid gas-permeable contact lens if their eye could tolerate it.

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- **SCAR TISSUE OR HEALING HAZE** – Healing haze occurs as collagen proteins try to rebuild the damaged structural surface of the cornea. This is very common in the PRK procedure. With LASIK, it is abnormal for the cornea to heal in such a manner. Mild haze is not usually noticed by the patient, and usually clears over time. However, less than 1 in 5,000 patients may have severe haze which will appear to be as if you are looking through a dirty windshield. Haze is not the initial blurriness that you will experience. The chance of healing haze or scar tissue is about 1 in 5,000 with LASIK.

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- **OVER CORRECTION** – LASIK may result in over correction of the desired treatment with the eye becoming farsighted or hyperopic as a result. Fortunately, the incidents of overcorrection are 1% or less. If this occurs and you are annoyed by the over correction, you may desire to wear a thin pair of glasses to help you see at a distance, at near, and/or elect to have an additional laser procedure to alleviate the correction.

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- **UNDER CORRECTION** – A patient may not get the full correction desired from LASIK and some degree of nearsightedness could remain as a result of the healing process of the eye. A patient may need to continue to use glasses or contact lenses. The enhancement rate at the Wake Forest University Eye Center has historically been between 5 to 10% depending on your initial correction. You may elect to undergo an enhancement procedure 3 months following your initial procedure to further improve your vision. While an enhancement procedure does not guarantee improvement, it very often does significantly improve your distance vision.

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- **FLAP COMPLICATIONS** – One of the benefits of LASIK over PRK is the speed at which the vision recovers and the lack of pain as compared to PRK. This benefit is directly attributable to the use of the corneal flap. The entire incision time in making this flap is only a few seconds during the LASIK procedure. During this brief interval there is a very small risk that you might experience a corneal flap complication, and a smaller risk that the complication will be severe. For example, inadequate suction pressure could result in a corneal flap that is too thin which may result in (1) postponing the procedure for several months, (2) performing the procedure, but experiencing a prolonged recovery, and/or (3)

temporary or permanent blurred vision. If the femtosecond laser malfunctions before completion of the LASIK procedure, the corneal flap would have to be replaced without completing the procedure of the LASIK procedure, the corneal flap would have to be replaced without completing the procedure and the eye would have to be allowed to heal for 3 to 6 months before the entire LASIK procedure could be performed again to completion. In most cases this type of complication does not result in permanent damage to the eye. In the LASIK procedure instead of making a hinged flap as intended the entire portion of the corneal disc would be removed which is known as “free flap”. In that case, the physician may elect to proceed with the Excimer laser portion of the procedure and replace the free flap or replace the disc, and wait 3 to 6 months before performing the procedure again. It is possible that irregular healing of the corneal flap after the LASIK procedure could result in a distorted cornea. This would mean that glasses or contact lenses may not correct the patient’s vision to the level that existed before surgery. The risk for a corneal flap complication is approximately 1 in 5,000.

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- **EPITHELIAL INGROWTH** – During the first 24 hours the epithelial protective layer grows over the corneal flap. There is a small risk of about 1 in 1,000 that these epithelial cells may grow underneath the flap. This is much more common in people with weak epithelial layers and poor bonding to the eye surface for which age and diabetes is a factor. Most commonly epithelial ingrowth is seen during retreatments or enhanced procedures following the initial LASIK procedure. Untreated epithelial ingrowth may distort vision and damage the flap if severe or progressive. Small ingrowths do not usually present any visual problems and need only to be monitored.

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- **EPITHELIAL DISPLACEMENT/ABRASION** – Occasionally the pressure of the suction ring will cause the epithelial layer to slide out of position temporarily in a small area over the flap. This is much more common in people with weak epithelial layers and poor bonding to the eye surface for which age and diabetes is a factor. Your surgeon will reposition this loose epithelium if this should occur. Typically this will delay recovery of your vision, but does not permanently affect your vision. The chance of epithelial displacement occurring is about 1%. If the displacement is severe, it may be torn and cause a small abrasion. Corneal abrasions are rare with LASIK (<1 in 200) and typically heal in 24 to 48 hours without consequence.

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- **DIFFUSE LAMELLAR KERATITIS (DLK)** – In the first week following surgery, you may develop an inflammatory condition known as Diffuse Lamellar Keratitis (DLK). This probably represents an aggressive healing

response that occurs in less than 1% of patients and can be controlled with topical steroids. Wake Forest University Eye Center data shows our DLK rate as less than the national average by 100 fold. DLK typically will cause light sensitivity on the second or third day after LASIK, followed by blurred vision. If left untreated, it could cause permanent damage to your vision. Fortunately, in most cases it is easily treated with topical steroid drops and resolves in one to two weeks.

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- **DRY EYE** – Most people will have “dry eyes” following LASIK that lasts up to two weeks or more. You will be instructed on how to use artificial tears to prevent this during your postoperative period. Less than 1% of patients will have a dry eye for longer than 3 months. Your doctor may recommend silicone plugs which may be beneficial in helping a dry eye retain more moisture, and thus resolve more quickly.

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- **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 checkups to assess the condition of your eyes.

6. **RISK OF SEVERE COMPLICATIONS** – Less than 0.1% of patients may develop severe complications, no one ever believes that they will be in that 0.1%. Theoretical risks mean they have just not happened yet. There are no guarantees of perfect vision, no guarantees of zero glasses or contacts, and no guarantees that you will not be among the few people that have significant complications. Remember you would not buy that airline ticket if you knew the flight was going to crash.

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7. **LIMITS OF LASIK** – The goal of LASIK is to improve vision to the point of not being dependent on glasses or contact lenses or to the point of wearing thinner glasses. This result is not guaranteed. Additional procedures, spectacles, or contact lenses may be required to achieve adequate vision for your needs. LASIK does not completely correct the condition known as presbyopia (aging of the eye) which occurs for most people around age 40 and may require them to wear reading glasses for close work. If you presently need reading glasses, you will likely still need reading glasses after treatment. If you do not need reading glasses, you may need them at a later age. LASIK surgery will not prevent you

from developing natural occurring eye problems such as glaucoma, cataracts, retinal degeneration, or detachment.

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- 8. ENHANCEMENTS** – The goal is to achieve the best visual result the safest way. The goal is not to eliminate glasses and contacts completely, but to dramatically reduce the dependency upon them and attempt to help improve quality of life. Night driving glasses and reading glasses may always be needed. Even 90% clarity of vision is 10% blurry. Enhancement surgeries can be performed when stable, unless unwise or unsafe. Typically if vision is 20/30 or worse, then an enhancement may be performed. Enhancement surgeries cannot be performed for at least 12 weeks and usually after healing and stability has occurred. If there is inadequate tissue, it may not be possible to perform an enhancement. Your surgeon can discuss with you the benefits and risks of enhancement surgery if necessary.

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- 9. IMPROVEMENT OF VISUAL POTENTIAL** – Patients who do not see 20/20 before surgery even with the strongest prescription cannot expect or anticipate 20/20 after surgery. After surgery the best vision the patient can obtain is the vision that they experienced preoperatively with their glasses or contacts. Rigid gas-permeable contact lenses may actually provide certain patients with better vision than glasses, soft contact lenses, or refractive surgery. The surgery does not improve visual potential.

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- 10. DRIVING PRECAUTIONS** – After surgery, you may experience starburst like images or halos around lights. Your depth perception may be slightly altered and image size 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 your vision is adequate. Ask your physician when it is appropriate for you to drive. On the day of surgery, you should arrange to be driven home after the procedure.

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- 11. RISKS OF NOT UNDERGOING LASIK** – 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 your glasses or contact lenses in the event of an emergency, the risk 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.

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## **12. ALTERNATE TREATMENT**

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

- Eyeglasses/spectacles
- Contact lenses
- Photorefractive keratectomy or PRK
- Radial keratotomy or RK
- Automated lamellar keratoplasty or ALK
- Orthokeratology
- Corneal relaxing incision or AK
- Implantable contact lens
- Laser thermal keratoplasty (LTK for hyperopia only)
- Clear lens extraction with intraocular lens

You should discuss these options with your physician.

### **Contraindications for all patients**

By initialing below, you are certifying that you are at least 18 years of age. You have also confirmed that you understand that the following conditions may present a reason not to undergo LASIK surgery. You have agreed to disclose these or other medical conditions to your eye doctor.

- Uncontrolled vascular disease
- Autoimmune disease
- Immune compromise or on drugs or therapy which suppress the immune system
- Signs of keratoconus (steepening of the cornea)
- Pregnant, nursing, or expecting to become pregnant within 6 months following the LASIK procedure
- Residual recurrent or active ocular disease or abnormality except for myopia or hyperopia in either eye
- Active or residual diseases likely to affect wound healing capability
- Unstable or uncontrolled diabetes
- Progressive myopia or hyperopia
- Amblyopia
- Obsessive-compulsive disorder

If you know that you have any of these conditions, you must inform your physician. In addition, if you have any other concerns or possible conditions which may affect your

decision to undergo LASIK surgery, you must discuss them with your physician prior to the procedure.

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## **PATIENT STATEMENT**

I have read this informed consent form or it has been read to me. The LASIK 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 LASIK. I understand that it is impossible for my physician to inform me of every conceivable complication that may occur. Because LASIK 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 that I have asked.

1. Please write the following below: "I may not achieve the result I hope for."
2. I understand that correction obtained may not eliminate all my myopia or astigmatism and that additional correction with glasses, contact lenses, or further surgery may be needed. Please write the following below: "I may still need to wear glasses."
3. Presbyopia is typically present in people over 45. By fully correcting both eyes for distance, I will need to wear reading glasses for near work such as reading fine print. If you are over 45 and are having both eyes fully corrected, please write the following: "I will still need reading glasses."
4. I understand the basic nature of the procedure as well as the possible risks and benefits of LASIK. I have decided to undergo Laser In-Situ Keratomileusis with the Excimer laser and femtosecond laser. Although vision-threatening complications are quite rare, it is possible that significant reduction in vision is produced as a result of complication and may require a corneal transplant. Blindness resulting from LASIK may occur as a result of infection or other sight threatening conditions under very rare condition. I understand that partially and fully sighted eyes have been treated with the Excimer worldwide since 1987. The very long-term effects associated with the procedure are not known. Please write the following below: "There are many risks and there are no guarantees."

5. I have been informed of alternate treatments of myopia and/or astigmatism including glasses, contact lenses, and other surgical procedures such as PRK and AK. I understand that I do not have to have the LASIK procedure and that it is not a reversible procedure. A copy of this consent form is available to me upon request. All my questions have been answered to my satisfaction. Please write the following below: "All my questions have been satisfactorily answered."

### **VOLUNTARY CONSENT**

In signing this form I certify that I have read the preceding information and understand the contents. I fully understand the possible risks, complications, and benefits that can result from Excimer and femtosecond laser surgery. My decision to proceed with Laser In-Situ Keratomileusis (LASIK) is voluntary and freely given.

<b>Diagnosis:</b>	<b>Myopia/Hyperopia</b>	<b>Astigmatism</b>
<b>Plan:</b>	<b>LASIK Right eye</b>	<b>Left eye      Both Eyes</b>

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

\_\_\_\_\_  
Date

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

\_\_\_\_\_  
Date

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

\_\_\_\_\_  
Date