

**SightLine Laser Eye Center, LLC**  
**INFORMED CONSENT FOR ADVANCED SURFACE TREATMENT (AST)**  
**A.K.A. PHOTOREFRACTIVE KERATECTOMY (PRK)**

**I. INTRODUCTION**

➤ This information is being provided to you so that you can make an informed decision about the use of a device known as an excimer laser, to perform Advanced Surface Treatment (AST), also known as PRK. The outer layer of the cornea (the epithelium) is removed and the excimer laser's cold beam is then used to remove ultra-thin layers from the cornea to reshape it in order to reduce the refractive error. A contact lens is placed on the surface of the cornea to aid in comfort while the epithelium regenerates.

AST is an elective procedure: There is no emergency condition or other reason that requires or demands that you have either performed. You could continue wearing contact lenses or glasses and have adequate visual acuity. While most patients will never have a serious complication and most patients are excited about their results, this procedure, like all surgery, presents some risks. It is not our intention to alarm you or dissuade you from having this procedure, but we must attempt to inform you to the best of our ability of the possible complications so you can make an informed decision about proceeding with AST. It is impossible to inform you of every conceivable complication. You should also understand that there might be other risks not known to your doctor, which may become known later. Despite the best of care, complications and side effects may occur. Should this happen in your case, the outcome could be affected even to the extent of making your vision worse. The only way to completely eliminate the possibility of complications is by not having this procedure.

**ALTERNATIVES TO ADVANCED SURFACE TREATMENT (AST)**

There are methods, other than AST, of correcting your vision. Alternatives for nearsightedness, farsightedness and astigmatism include, among others, eyeglasses, contact lenses, Astigmatic Keratotomy, clear lens extraction with the implantation of an intra ocular lens (IOL), and Laser In Situ Keratomileusis (LASIK).

**II. PATIENT CONSENT**

In giving my permission for AST, I will declare that I understand the following: The long-term risks and effects of AST are unknown. I have received no guarantee as to the success of my particular case. I understand that the following risks are associated with the procedure:

**VISION RISKS**

1. There may be increased sensitivity to light, glare, and fluctuations in the sharpness of vision. These conditions usually occur during the normal stabilization period of from one to three months, but they may also be permanent.
2. **Glare:** At night there may be a "star-burst" or halo effect around lights. This condition usually diminishes with time. However, **this glare could be permanent and may be serious enough to prevent you from driving or performing other activities at night.** You should not drive until your vision is adequate both during the day and at night.

**Over/Under Correction & Enhancement**

3. Over or under correction could occur, requiring future enhancement procedures, such as more laser treatment, Astigmatic Keratotomy, or the use of glasses or contact lenses.

Patient initials \_\_\_\_\_

- 4. Under some circumstances only one eye may be treated even if the pre-operative plan is to treat both eyes. The surgeon may elect not to proceed with the second eye because of unanticipated problems with the first eye. There may be a "balance" problem between the two eyes if AST is performed on one eye, but not the other. This phenomenon is called anisometropia. This could cause eyestrain and make judging distance or depth perception more difficult. If that eye takes longer to heal than usual, this would prolong the time the imbalance symptoms could persist.
- 5. Following surgery, if the uncorrected refractive error is significant and causing vision distress, enhancement surgery may be performed when vision is stable UNLESS it is unwise or unsafe. If you are not seeing adequately, an assessment of the need for an enhancement will be made by your doctor, and then the risks and possible benefits of an enhancement will be discussed. Enhancement carries an increased risk of corneal haze.
- 6. There may be pain or a foreign body sensation, particularly during the first 72 hours after the procedure. This pain could be severe and prevent normal activity.
- 7. This procedure may cause or exacerbate eye dryness that can result in significant discomfort. This dryness could be severe enough to cause vision decrease. This condition could require therapy, which could be expensive and ineffective.
- 8. Temporary glasses either for distance or reading may be necessary while healing occurs and more than one pair of glasses may be needed.
- 9. The effects of AST beyond ten years presently are unknown. Unforeseen complications or side effects could occur in the future.
- 10. The visual acuity initially gained from AST could regress, and vision could drift away from the original result over time requiring the use of glasses, contacts, or additional surgery in the future.
- 11. You may be given medication in conjunction with the procedure and your eye may be patched afterward. You must not drive for at least three days following the procedure and not until your doctor determines that your vision is adequate for driving.
- 12. If you currently need reading glasses or bifocals, you will still likely need reading glasses after this treatment if both eyes are corrected for distance. It is possible that dependence on reading glasses may increase or that reading glasses may be required at an earlier age if you have AST. By correcting one eye for distance and the other eye for near vision (monovision) you likely will reduce your dependence on reading glasses. If you do not need reading glasses now, and have both eyes treated for distance, you will need reading glasses in the future.

**My doctor has discussed mono vision with me and I have elected:**

**\_\_\_\_\_to have mono vision treatment    \_\_\_\_\_not to have mono vision treatment.**

- 13. The correction that you can expect to gain from AST may not be perfect. It is not realistic to expect that this procedure will result in perfect vision, at all times, under all circumstances, for the rest of your life. You may need glasses to refine your vision for some purposes. In the future your vision might change, increasing the need for glasses. Vision after surgery might not reach pre-surgery corrected levels.
- 14. 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 the body. Because it is impossible to state every complication that may occur as a result of any surgery, the list of complications in this form may not be complete.

**Patient initials\_\_\_\_\_**

15. The use of certain medications in conjunction with AST can increase the inner eye pressure, which is usually resolved by drug therapy or discontinuation of post-treatment medications.
16. You must make your doctor aware of electronic implants such as a cardiac pacemaker, insulin pump etc.
17. You must inform your eye doctor if you are pregnant or nursing. If you are pregnant or nursing, you should delay AST.

## EYE THREATENING COMPLICATIONS

1. The excimer laser could malfunction, requiring the procedure to be stopped before completion. Depending on the type of malfunction, this may or may not be accompanied by visual loss.
- 2. In the AST procedure there is more healing response of the eye than with LASIK. Irregular healing of the cornea could result in a distorted cornea. This would mean that glasses or contact lenses might not correct vision to the level possible before undergoing AST. If this distortion in vision is severe, a partial or complete corneal transplant might be necessary to repair the cornea.
- 3. Rapid healing following AST can cause hazing of the corneal tissue. This usually does not affect vision. In some cases however, the haze can be dense enough to cause vision reduction. Corneal haze is more likely to occur with higher amounts of treatment. This haze can also occur later due to extensive exposure to sunlight or eye injury. For this reason, patients having AST are encouraged to wear sun protection during long exposure to sunlight as well as safety goggles in situations with high potential for eye injury.
4. Mild or severe infection is possible. Mild infection can usually be treated with antibiotics and usually does not lead to permanent visual loss. Severe infection, even if successfully treated with antibiotics, could lead to permanent scarring and loss of vision that may require corrective laser surgery or, if very severe, corneal transplantation. Other very rare complications threatening vision include, but are not limited to, cataract formation, total blindness and even loss of your eye.

## TREATMENT OF BOTH EYES AT THE SAME TIME

I understand that I can elect to have both eyes treated at one time or one eye at a time. There are advantages and disadvantages to both. The imbalance between the two eyes while waiting to have the second eye done is the major disadvantage of doing one eye at a time. Patients usually prefer having both eyes done together for reasons of convenience. However, treating both eyes together exposes both eyes to the risk of infection at the same time. While very unlikely, infection can cause severe vision loss. It is possible that any of the above complications could occur in both eyes, if both eyes are done simultaneously. Treating one eye also allows for adjustment to the treatment level of the second eye based on the first eye's result.

## DRIVING RESTRICTION

The above conditions if severe enough, could cause best corrected vision to drop below 20/40. If this occurs in both eyes, your license to drive a car could be limited or revoked. Glare could be severe enough to prevent you from driving at night. In some patients healing is slow and the return to good vision is delayed. Driving could be restricted during this period. If, prior to AST, you already have reduced vision in one eye, you must seriously consider the risk of licensure loss if AST is being performed on your best eye.

Patient initials \_\_\_\_\_

**EXPECTATIONS**

I understand that laser vision correction is intended to reduce my dependence on glasses or contact lenses. There have been no guarantees or promises made to me that this procedure will eliminate my need for glasses or contact lenses. I also understand that I could experience any of the above complications and these could cause a reduction in my best corrected vision.

Patient initials \_\_\_\_\_

**MEDICATION & HEALTH HISTORY DISCLOSURE**

Certain medications, as well as certain eye and general health conditions can affect the outcome of the procedure. If you are pregnant or nursing you should not have this procedure. You must inform your eye doctor of all medications you are taking and of any history of eye or general health problems.

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

**MANAGEMENT OF CARE**

I understand that my referring eye doctor (optometrist / ophthalmologist) will direct my care both before and after the procedure. This care arrangement has been approved by the surgeon. I understand that my eye doctor accepts the responsibility for the pre- and post-operative care and will notify SightLine Laser Eye Center of any complications and will provide periodic written reports on my post-operative progress. The SightLine Laser Eye Center staff and surgeon will manage my care during the time of my procedure at the Center. I understand that both my eye doctor and the SightLine surgical staff are available to me for care throughout the pre- and post-procedure period.

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

**PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING**

The procedure known as AST has been presented to me in detail in this document and explained to me by my eye doctor. My eye doctor has answered all my questions to my satisfaction. I therefore consent to AST. I give my permission to use data about my procedure and subsequent treatment to further understand AST. 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 AST procedure will be performed.

Eye(s) To Be Treated:            Right eye (OD)            Left eye (OS)            Both (OU)

Print Name \_\_\_\_\_

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

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

(I have reviewed this consent document with the patient, and I agree to fulfil my responsibilities as the case managing doctor.)

Eye Doctor Signature \_\_\_\_\_ Date \_\_\_\_\_

Surgeon Signature \_\_\_\_\_ Date \_\_\_\_\_

I have been offered a copy of this consent form (patient initials) \_\_\_\_\_