



INFORMED CONSENT TO HAVE PHOTOREFRACTIVE KERATECTOMY (PRK)

This information is to help you make an informed decision about having photorefractive keratectomy (PRK), an elective laser vision correction procedure to treat your nearsightedness, farsightedness, and/or astigmatism. Only you and your doctor can determine if you should have PRK surgery based upon your own visual needs and medical considerations. Any questions you have regarding PRK or other alternative therapies for your case should be directed to your doctor. Take as much time as you wish to make a decision about signing this form. You are encouraged to ask any questions and have them answered to your satisfaction before you give your permission for surgery. Every procedure has risks as well as benefits and each person must evaluate this risk/benefit ratio for himself/herself in light of the information that follows. The only way to avoid all of the risks of PRK is to not have the surgery. Spectacles and contact lenses are the most common methods of correcting nearsightedness (myopia), farsightedness (hyperopia), and astigmatism. When tolerated well, they are a good alternative to PRK. PRK is an elective surgery and is not reversible.

PRK permanently changes the shape of the anterior central cornea using an excimer laser to ablate (remove by vaporization) a small amount of tissue from the corneal stroma at the front of the eye, just under the corneal epithelium. The outer layer of the cornea is removed prior to the ablation. The Visx Star 4 LASER will automatically center on the patient's visual axis and will pause if the eye moves out of range and then resume ablating at that point after the patient's eye is re-centered. The outer layer of the cornea, or epithelium, is a soft, rapidly regrowing layer in contact with the tear film that can completely replace itself from limbal stem cells within a few days with no loss of clarity. The proper and timely use of prescribed eye drops and strict adherence to the post-operative visit schedule are essential to minimize complications such as infection and pain or discomfort.

The goal of PRK is to improve vision to the point of not being dependent on glasses or contact lenses, or to the point of wearing thinner (or weaker) glasses, however this result is not guaranteed. Refractive surgery is continually evolving and other procedures may be available as an alternative to PRK.

You should understand that PRK would not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, retinal degeneration or detachment. After the procedure you should avoid rubbing the eye. Your eyes may be more susceptible to traumatic injury after PRK and protective eyewear is recommended for all contact and racquet sports where a direct blow to the eye could occur. PRK does not correct the condition known as presbyopia (or aging of the eye), which occurs to most people around age 40 and may require them to wear reading glasses for close-up work. People over 40 that have their nearsightedness corrected may find that they need reading glasses for clear, close vision. You should also be aware that having any refractive procedure could potentially disqualify you from some professions, including the military and certain law enforcement agencies.

During pregnancy your refractive error can fluctuate which could influence your results. If you know you are pregnant or attempting to become pregnant within the next three months, it is important that you advise your doctor immediately. Be sure that you have fully disclosed to your doctor your medical history, current conditions and any medications that you are taking prior to your surgical procedure, even conditions that may seem unrelated to your eyes. Certain conditions and/or medications may increase the risk of complications from the procedure.

POTENTIAL RISKS AND OTHER CONSIDERATIONS OF PRK INCLUDE:

1. OVER-RESPOND AND UNDER-RESPOND. It may be that laser vision correction will not give you the result you desired. Everyone's eye heals differently and our best efforts/calculations do not always predict your precise treatment. Your vision may fluctuate up to 6 months post-operatively. Some procedures result in the eye under-responding, in which case it may be possible or necessary to have additional surgery to fine tune or enhance the initial result. Results from any surgery cannot be guaranteed. It is also possible that your eye may over-respond, leaving you farsighted. It

is possible that your initial results could regress over time, especially if eye drops are used incorrectly. In some, but not all cases, re-treatment could be considered.

2. COMPLICATIONS AND SIDE EFFECTS. I have been informed and I understand that certain complications and side effects have been reported in the post-treatment period by patients who have had PRK, including the following:

- Possible short and long-term effects of PRK surgery: The following have been reported in the short-term post treatment period and are associated with the normal post-treatment healing process: mild discomfort or pain (first 72 to 96 hours), corneal swelling, double vision, feeling something is in the eye, ghost images, light sensitivity, and tearing.
- Haze: Loss of clarity of the cornea, usually not affecting vision, which usually resolves over time.
- Starbursting: After refractive surgery, a certain number of patients experience glare, a “starbursting” or halo effect around lights or other low-light vision problems that may interfere with the ability to drive at night or see well in dim light. Although there are several possible causes for these difficulties, the risk may be increased in patients with large pupils or high degrees of correction. For most patients this is a temporary condition that diminishes with time or is correctable by wearing glasses at night or taking eye drops. For some patients, however, these visual problems are permanent. Your vision may not seem as sharp at night as during the day and you may need to wear glasses at night or take eye drops. It is not possible to predict whether you will experience these night vision or low light problems and you may permanently lose the ability to drive at night or function in dim light because of them. You should not drive unless your vision is adequate. These risks in relation to your particular pupil size and amount of correction have been discussed with you. If they have not been, please discuss with your surgeon.
- Loss of Best Vision: A decrease in my best vision even with glasses or contacts.
- IOP Elevation: An increase in the inner eye pressure due to post-treatment medications, which is usually resolved by drug therapy or discontinuation of post-treatment medications.

- Mild or severe infection: Mild infection can 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.
- Keratoconus: Some patients develop keratoconus, a degenerative corneal disease affecting vision that occurs in approximately 1/2000 in the general population. While there are several tests that suggest which patients might be at risk, this condition can develop in patients who have normal preoperative topography (a map of the cornea obtained before surgery) and pachymetry (corneal thickness measurement). Since keratoconus may occur on its own, there is no absolute test that will ensure a patient will not develop keratoconus following laser vision correction. Severe keratoconus may need to be treated with a corneal transplant while mild keratoconus can be corrected by glasses or contact lenses.
- Infrequent complications. The following complications have been reported infrequently by those who have had PRK surgery: itching, dryness of the eye or foreign body feeling in the eye, double or ghost images, patient discomfort, inflammation of the cornea or iris, persistent corneal surface defect, persistent corneal scarring severe enough to affect vision, ulceration/infection, irregular astigmatism (warped corneal surface which causes distorted images), cataract, drooping of the eyelid, loss of bandage contact lens with increased pain (usually corrected by replacing with another contact lens), and a slight increase of possible infection due to use of a bandage contact lens in the immediate post-operative period.

3. LOSS OF VISION. There is a remote chance that PRK could cause partial or complete loss of vision or loss of best-corrected vision. This can be due to infection, inflammation or irregular scarring or other causes, and unless successfully controlled by antibiotics, steroids or other necessary treatment, could result in the loss of functional vision in one or both eyes. This can also be due to corneal perforation, which can result in the loss or damage of the natural lens, infection, and/or the need for an intraocular lens implant, corneal transplant or, rarely, blindness. Vision loss can be due to the cornea healing irregularly which could result in irregular astigmatism, making it necessary for you to wear glasses or contact lenses that still may not fully

correct your vision. It is also possible that you may not be able to successfully wear contacts after PRK.

4. OTHER RISKS: There are potential complications due to anesthesia and medications which may involve other parts of your body. It is also possible that the excimer laser could malfunction and the procedure would need to be stopped. Since it is impossible to state all potential risks of any surgery, this form is incomplete.

5. FUTURE COMPLICATIONS: You should also be aware that there are other complications that could occur that have not been reported before the creation of this consent form, as PRK has been performed only since the early 1990's and longer-term results may reveal additional risks and complications.

6. OFF-LABEL:

Use of the excimer laser for PRK to correct refractive errors in excess of FDA approved parameters is considered an "off-label" use of an approved medical device. Off-label usage of FDA approved devices and drugs is commonly practiced by physicians without interference from the FDA and allows physicians to practice medicine in a manner they feel most beneficial to their patients.

- Consent Statement: I understand that while the latest "Custom Wavefront" technology has been approved for use with LASIK, it has not been approved for PRK. Nonetheless, non-FDA sponsored studies have shown safety and efficacy that are comparable to results for LASIK patients, and InSight LASIK & Refractive Group routinely performs "Wavefront PRK" on its patients who have PRK. This is technically not an FDA-approved device and technology, and by signing this consent form, I am acknowledging this fact and giving my consent to the Wavefront PRK procedure.

Signature

Date

7. PRE-PROCEDURE INSTRUCTIONS: It is imperative that you follow the physician's instructions to stare at the fixating light during the procedure due to the sophisticated computerized eye tracking feature.

8. POST-PROCEDURE INSTRUCTIONS: After your procedure you will be given medications and instructions to help prevent infection and control healing. You may experience mild to moderate discomfort. It is imperative that you follow instructions exactly as they are given to you. It is also imperative that all follow-up visits be kept as directed.

Daniel V. Zimmer, M.D. will be performing your surgery. You will be released to _____ or your regular optometrist for post-operative care. To ensure the best care, both doctors will be available by appointment or by phone to address any questions or problems related to the surgery. This care relating to the surgery will be provided at no additional charge during a full one-year postoperative period.

QUESTIONS ON PRK INFORMED CONSENT

The following questions cover important information. **Please mark the correct answer.**

1. **TRUE OR FALSE:** PRK and use of the excimer laser to correct myopia in excess of FDA-approved guidelines is considered an “off-label” use of approved excimer lasers by the Food and Drug Administration.
2. **TRUE OR FALSE:** There are no guarantees as to exactly how well you will see after the procedure.
3. **TRUE OR FALSE:** PRK is the only way to correct your refractive error(s).
4. **TRUE OR FALSE:** You may experience vision irregularities such as halos and glare after your surgery and you may be more sensitive to light, which in some cases could be permanent.
5. **TRUE OR FALSE:** After the surgery, follow-up visits are not important.
6. **TRUE OR FALSE:** It is possible that another operation may be necessary after PRK to obtain the best level of vision correction.
7. **TRUE OR FALSE:** It is very important that you look at the fixating light during the laser treatment.
8. **TRUE OR FALSE:** There is the possibility that the PRK procedure could cause loss of vision.
9. **TRUE OR FALSE:** You may experience mild to moderate discomfort for several days after the procedure.
10. **TRUE OR FALSE:** PRK will eliminate the need for reading glasses when you are over 40 years of age.

Please check your answers with the correct answers on the following page. Mark any that you missed. If you are still unsure as to why you missed any of these questions, take the form to the doctor or staff member for an explanation.

ANSWERS:

1. **TRUE.** The FDA considers PRK and use of the excimer laser to correct myopia in excess of FDA-approved guidelines to be “off label: uses of the excimer laser in the United States.
2. **TRUE.** There are no guarantees as to how well you will see after PRK.
3. **FALSE.** In addition to glasses and contact lenses, there may be other surgical procedures to treat your refractive error(s).
4. **TRUE.** Halos, glare, and light sensitivity can be experienced and may not go away completely.
5. **FALSE.** Follow up visits are extremely important to monitor your the healing process.
6. **TRUE.** Re-treatment may be required to obtain the best level of corrected vision.
7. **TRUE.** Not looking at the fixation light during treatment with the excimer laser could cause a poor result.
8. **TRUE.** Some patients have had their vision made worse.
9. **TRUE.** Some patients report mild to moderate pain for a short time after the procedure.
10. **FALSE.** PRK does not treat “presbyopia” which occurs to most people above the age of 40 and requires them to wear reading glasses for close work.

1. Please use this space to write any questions or concerns you still wish to ask the doctor or a staff member prior to your surgery.
2. Please state in your own words what your expectations are for refractive surgery. For example: To wake up in the morning and see the alarm clock and/or to see my children at the pool.

MONOVISION CORRECTION

After the age of 40, many people begin to notice a decrease in their ability to read or focus on close up objects. This condition, called presbyopia, is a natural consequence of the aging of the eye. Monovision correction is a way to help compensate for this condition. In monovision, one eye, usually the dominant eye, is corrected fully for distance vision. The other eye is slightly undercorrected to help reading vision. The undercorrected eye then has less sharpness for distance viewing. While monovision correction is helpful for situations like reading a menu at a restaurant or looking at one's wristwatch, individuals may still require glasses for night driving or reading a phone book (fine print). Individuals over the age of 35 may want to consider monovision correction as a way to compensate for presbyopia. People who require the best distance vision possible should avoid monovision and recognize that after surgery they will need to wear reading glasses for close up vision.

By signing below you acknowledge your doctor has discussed this matter with you and you consent to have monovision correction: I wish to have monovision correction with my:

☐ **Right eye** ☐ **Left eye** corrected for **DISTANCE**.

Patient Signature_____

In signing this form, you are stating that you have read this consent form and although it contains medical terms, which you may not completely understand, you have had the opportunity to ask questions and have had them answered to your satisfaction.

To assure that you have understood the information presented, **please copy the following statement in your own handwriting: "I understand the information presented and am willing to accept the fact that I may need glasses or contact lenses or further procedures following PRK to achieve my best possible level of vision."**

I am making an informed decision in giving my permission to have PRK performed on my

☐ **Right eye** ☐ **Left eye** ☐ **Both eyes.**

Signature of Patient: _____ Date: _____

Signature of Witness: _____ Date: _____
(Staff Member)

Signature of Optometrist: _____ Date: _____

Signature of Surgeon: _____ Date: _____

Surgeon's Notes: _____
