

INFORMED CONSENT FOR PHOTO-REFRACTIVE KERATECTOMY (PRK)

FOR THE CORRECTION OF NEARSIGHTEDNESS, FARSIGHTEDNESS, AND
ASTIGMATISM

Patient Name: _____
Patient Last Four SS# : 20/ _____

Date of Birth: _____

Washington State law guarantees that you have both the right and the obligation to make decisions regarding your health care. Your physician can provide you with the necessary information and advice, but as a member of the health care team, you must participate in the decision making process. This form will acknowledge your consent to treatment recommended by your physician.

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 PRK. PRK is one of a number of alternatives for correcting nearsightedness, farsightedness, and astigmatism. In PRK, the excimer laser is used to remove ultra-thin layers from the cornea to reshape it to reduce nearsightedness, farsightedness, and astigmatism.

PRK is an elective procedure: There is no emergency condition or other reason that requires or demands that you have it performed. You could continue wearing contact lenses or glasses and have adequate visual acuity. This procedure, like all surgery, presents some risks, many of which are listed below. You should also understand that there might be other risks not known to your doctor, which might become known later. Despite the best of care, complications and side effects might occur; should this happen in your case, the result might be affected even to the extent of making your vision worse or very rarely partial or complete loss of vision.

ALTERNATIVES TO PRK

If you decide not to have PRK, there are other methods of correcting your nearsightedness, farsightedness, and astigmatism. These alternatives include, among others, eyeglasses, contact lenses, radial keratotomy, Automated Lamellar Keratoplasty (ALK), and LASER IN-SITU KERATOMILEUSIS (LASIK).

PATIENT CONSENT

In giving my permission for the use of an FDA-approved excimer laser for PRK, I understand the following: although PRK has been approved by the FDA after extensive investigational trials, it is still new surgery, and, as such, it has not as yet been completely and exhaustively studied by medical researchers in this country. 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 THREATENING COMPLICATIONS

1. **I understand** that irregular healing of the cornea surface could result in a distorted cornea. This would mean that glasses or contact lenses might not correct my vision to the level possible before undergoing PRK. If this distortion in vision is severe, a partial or complete corneal transplant might be necessary to repair the cornea.
2. **I understand** that it is possible, for example from an infection, that a perforation of the cornea could occur, causing devastating complications, including loss of some or all of my vision.

3. **I understand** that other very rare complications threatening vision include, but are not limited to, corneal swelling, retinal detachment, hemorrhage, venous and arterial blockage, cataract formation, total blindness, and even loss of my eye.

NON-VISION THREATENING SIDE EFFECTS

1. **I understand** that there might be increased sensitivity to light, glare, and fluctuations in the sharpness of vision. I understand these conditions usually occur during the normal stabilization period from one to three months, but they might also be permanent.
2. **I understand** that an over-correction could occur, causing me to become farsighted, and that this farsightedness could be either permanent or treatable. I understand an over correction is more symptomatic in people over the age of 40 years and might require the use of glasses for reading or for distance vision or all of the time.
3. **I understand** that at night there might be a “star bursting” or halo effect around lights. I understand that this condition usually diminishes with time, but could be permanent. I understand that my vision might not seem as sharp at night as during the day and that I might need to wear glasses at night. I understand that I should not drive until my vision is adequate both during the day and at night.
4. **I understand** that I might not get a full correction from my PRK procedure and this might require future enhancement procedures, such as more laser treatment, RK or Astigmatic Keratotomy (a technique similar to RK for correcting astigmatism), or the use of glasses or contact lenses.
5. **I understand** that there might be a “balance” problem between my two eyes after PRK has been performed on one eye, but not the other. This phenomenon is called anisometropia. I understand this would cause eyestrain and make judging distance or depth perception more difficult. I understand that my first eye might take longer to heal than is usual; prolonging the time I could experience anisometropia.
6. **I understand** that there is a natural tendency of the eyelids to droop with age and that eye surgery might hasten this process.
7. **I understand** that there might be pain or a foreign body sensation, particularly during the first 4 to 6 days after surgery.
8. **I understand** that temporary glasses either for distance or reading might be necessary while healing occurs and that more than one pair of glasses might be needed.
9. **I understand** that the follow-up effects of PRK beyond 7 years presently are unknown and that PRK has not been in use long enough to measure long-term effects (those occurring after 10 years or more) following the procedures, and that unforeseen complications or side effects could occur.
10. **I understand** that visual acuity I initially gain from PRK could regress, and that my vision might go partially or completely back to the level it was immediately prior to having the procedure.
11. **I understand** that the correction that I can expect to gain from PRK might not be perfect. I understand that it is not realistic to expect that this procedure will result in perfect vision, at all times, under all circumstances, for the rest of my life. I understand I might need glasses to refine my vision for some purposes requiring fine detailed vision after some point in my life, and that this might occur soon after surgery or years later.
12. **I understand** that I might be given medication in conjunction with the procedure and that my eye might be patched afterward. I, therefore, understand that I must not drive for at least one day following the procedure and not until I am certain that my vision is adequate for driving.
13. **I understand** that if I currently need reading glasses, I will still likely need reading glasses after this treatment. It is possible that dependence on reading glasses might increase or that reading glasses might be required at an earlier age if I have this surgery.
14. Even 90% clarity of vision is still slightly blurry. Enhancement surgeries can be performed when vision is stable UNLESS it is unwise or unsafe. Typically if -1.00 diopter or greater correction remains or vision is 20/40 or worse, an enhancement might be performed.
15. **I understand** that, as with all types of surgery, there is a possibility of complications due to anesthesia, drug reactions, or other factors that might involve other parts of my body. I understand that, since it is impossible

to state every complication that might occur as a result of any surgery, the list of complications in this form might not be complete.

Although these risks and complications might occur only very rarely, they do sometimes occur and cannot be predicted or prevented by the physician performing the procedure. Although most procedures have good results, I acknowledge that no guarantee has been made to me about the results of this procedure.

These potential risks and complications could result in the need to repeat the procedure; wearing of glasses or contact lenses, additional medical or surgical treatment or procedures; hospitalization; blood transfusions; or very rarely permanent total blindness, loss of an eye, permanent disability or death. I recognize that during the course of treatment, unforeseeable conditions might require additional treatment or procedures. I request and authorize my physician and other qualified medical personnel to perform such treatment or procedures as required.

PATIENT'S STATEMENT OF ACCEPTANCE AND UNDERSTANDING

The details of the procedure known as PRK have been presented to me in detail in this document and explained to me by my ophthalmologist. My ophthalmologist has answered all my questions to my satisfaction. I, therefore, request and authorize **Dr.** _____ or his/her associates or assistants to perform a PRK upon me.

I consent to the administration of anesthesia or other medications before, during or after the procedure by qualified medical personnel.

I give permission for my ophthalmologist to record on video or photographic equipment my procedure, for purposes of education, research, or training of other health care professionals. I also give my permission for my ophthalmologist to use data about my procedure and subsequent treatment for research purposes.

I certify that I have read or had read to me the contents of this form. I have read or had read to me and will follow any patient instructions related to this procedure. I understand the potential risks and complications involved with any medical or surgical treatment or procedure and have decided to proceed with this procedure after considering the possibility of both known and unknown risks, complications and alternatives to the procedure. I declare that I have had the opportunity to ask questions and all of my questions have been answered to my satisfaction.

IMPORTANT

Female Patients ONLY, Please RE-WRITE The Following:

No, I am NOT Pregnant , Breast fed or had a Miscarriages in the last 6 Months

Patient Signature: _____ **Date:** _____

PRINT PATIENT NAME: _____ 20/ _____ (S.S.# Last Four)

PATIENT'S SIGNATURE: _____ DATE: _____

WITNESS SIGNATURE: _____ DATE: _____

SURGEON SIGNATURE: _____ DATE: _____