CATARACT & LASER
EYE SURGEONS

EYE SURGERY CENTER
of Westchester

PATIENT CONSENT FOR
PHOTOREFRACTIVE KERATECTOMY (PRK)

INTRODUCTION:

You have been diagnosed with myopia (nearsightedness) or hyperopia (farsightedness) with or without astigmatism, or astigmatism alone. Myopia is a result of light entering the eye and focusing in front of the retina instead of on the retina. Hyperopia is a result of light entering the eye and focusing behind the retina instead of on the retina. Astigmatism is a result of light entering the eye and focusing at several points on the retina instead of just one point, resulting in blurry and distorted vision. The treatment options for myopia, hyperopia and astigmatism include glasses, contact lenses, or refractive surgery. Glasses and contact lenses are adjustable options that may be worn without the surgical risks involved with refractive surgery.

The potential benefits of refractive surgery include the reduced dependency on glasses or contact lenses, permanent correction of myopia, hyperopia, and astigmatism, or an alternate approach for contact lens-intolerant persons. The material included in this consent form is intended to present information on Photorefractive Keratectomy (PRK) surgery. If you have any questions regarding information contained in the consent, please consult with your doctor prior to having the PRK procedure.

PROCEDURE BACKGROUND:

PRK is a two-step procedure involving the removal of epithelium from a thin layer of corneal tissue with either the VISX Star S4 IR computer controlled ultraviolet Excimer Laser, the Amoil's Brush, 20% Ethyl Alcohol or manual scrape and the application of the VISX Star S4 IR Excimer Laser. The Excimer Laser reshapes microscopic layers of corneal tissue. The surgeon uses a high power microscope to align the eye and to monitor the amount of tissue being removed. The procedure is performed with a topical anesthetic drop in the eye. A bandage contact lens is then placed onto the eye. There are no incisions or needles used during a PRK procedure.

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EXPECTATIONS:

Realistic expectations following the PRK procedure are important. The goal of PRK is to reduce the dependency on glasses or contact lenses. Reading glasses or glasses for driving at night may be needed. Enhancements may be performed only after the cornea has sufficiently healed and the vision has stabilized.

Although the goal of PRK is to improve vision to the point of not being dependent on glasses or contact lenses, this result is not guaranteed. Additional procedures, spectacles, or contact lenses may be required to achieve adequate vision. PRK does not correct the condition known as Presbyopia (inability to see close work from aging of the eye's lens). Presbyopia occurs in most people around age 40 and may require them to wear reading glasses for close-up work. If you presently need reading glasses, you will likely need them after this treatment.

FDA clinical results indicate that the majority of patients achieve 20/40 vision or better; however, there is no guarantee of final visual acuity. 20/40 vision is the standard to legally drive a vehicle without glasses or contact lenses. There is no guarantee what your PRK result will be. An examination with your surgeon will determine your anticipated outcome.

PRK will not prevent you from developing naturally occurring eye problems such as glaucoma, cataracts, retinal degeneration or retinal detachment.

CONTRAINDICATIONS:

Only patients in good general physical condition without the presence of active ocular diseases are candidates for PRK. PRK is a treatment option for patients with myopia, hyperopia and astigmatism. For nearsightedness (myopia) up to -6 Diopters (D) spherical equivalent at the corneal plane with up to 1 D of astigmatism, patients need to be 18 years old and have a stable refraction (within 0.5 diopter) for one year. For nearsightedness (myopia) up to -12 D at the spectacle plane with up to 4 D of astigmatism, patients need to be 21 years old and have a stable refraction (within 0.5 diopter) for one year. For farsightedness (hyperopia) with or without astigmatism, patients need to be 21 years old and have a stable refraction (within 0.5 diopter) for one year. PRK treatment can correct up to +6 D of farsightedness at the spectacle plane with up to +4 D of astigmatism with a maximum manifest refraction spherical equivalent (MRSE) of +6 D. Contraindications include, but are not limited to, pregnancy, uncontrolled diabetes, uncontrolled high blood pressure, keratoconous, herpes, keloid formations and collagen vascular (e.g., rheumatoid arthritis), autoimmune (e.g., lupus), or immunodeficiency diseases (e.g., AIDS). Medications with ocular side effects, such as Isotretinoin and Amiodarone Hydrochloride are contraindicated as well.

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PRECAUTIONS:

- You should inform your physician of any medications you are taking to reduce the risk of drug interactions during the PRK procedure and subsequent treatments. You should also alert your doctor to any drug allergies you may have to reduce the risk of an allergic reaction to medications used.

- Only persons able to cooperate during the treatment should be considered appropriate. Potential adverse results may occur from the misalignment of the VISX Excimer Laser due to noncompliance of the patient.

- Persons who have had Radial Keratotomy (RK) reportedly experienced a higher incidence of glare, haze or loss of best-corrected visual acuity.

- Information is available on post-operative outcomes; however, the long -term safety and effectiveness of the Excimer Laser has not been established in patients taking hormone replacement therapy or antihistamines; in patients who are taking Sumatriptan for migraine headaches; and on patients with a history of glaucoma.

RISKS:

As with any surgical procedure there are risks associated with laser vision correction. Most complications are transient conditions that occur in the normal corneal healing process. Since it is impossible to state all potential risks of any surgical procedure, this form does not provide a comprehensive listing of every conceivable risk or problem. It is important to discuss these risks with your doctor before you make the decision to have the surgery.

Keratoconus

Keratoconus is a hereditary, degenerative disease characterized by generalized thinning (ectasia) and cone-shaped protrusion of the corneal area. The protrusion is caused by the normal pressure of the eye pushing out on the thinned areas of the cornea. Since the cornea is responsible for refracting most of the light coming into your eye, an abnormal-shaped cornea can create reduced visual acuity and affect the way you see. This reduced visual acuity can make even simple daily tasks, such as driving, watching television or reading, difficult to perform. Keratoconus normally affects both eyes, though it typically progresses at different rates. In most people, keratoconus begins during their teen years and slowly worsens before stabilizing in their 30s or 40s. Keratoconus is estimated to affect one in 2,000 people across all races. While there are several tests that suggest which patients might be at risk, this condition can develop in patients who have normal pre-operative 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.

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The following adverse events and complications were reported in the LASEK clinical trials.

Immediate/Short Term Post-treatment Complications:
The following are the most common complications that have been reported in the first month after PRK. They are associated with the normal healing process and include: post treatment pain (first 24 - 48 hours), blurred vision, corneal swelling, inflammation, foreign body sensation, tearing or dryness of the eye, double vision, and light sensitivity. These symptoms are transient conditions that occur during the normal corneal healing period.

Long Term Adverse Reactions:
The following complications were reported in less than 3% of patients participating in the FDA clinical trials: haze, glare or halos, blurry vision, inflammation, scarring, improper correction (under/over correction), loss of Best Spectacle Corrected Visual Acuity, induced astigmatism, increased Intra-Ocular Pressure (IOP), night vision strain, or dryness of the eye.

- **Reticular Haze:** Haze decreases the clarity of the cornea usually without affecting the quality of vision.
- **Corneal Scarring:** Corneal scarring is cloudiness usually severe enough to affect the quality of vision.
- **Glare:** Glare, especially from bright lights, may be seen particularly in the early months following treatment.
- **Halo:** Halos or hazy rings surrounding bright light may be seen after the treatment, particularly at night.
- **Improper Correction:** Surgical under correction or over correction may require an enhancement, glasses or contact lenses. It is possible that improper correction may increase dependence on reading glasses or requires the use of reading glasses at an earlier age.
- **Induced Regular/Irregular Astigmatism:** PRK treatment may cause a distortion of astigmatism that requires the use of glasses or contact lenses. Astigmatism may require further treatment only after the eye has healed and stabilized.
- **Intra-ocular Pressure Elevation:** Medications used post-operatively may temporarily increase the intra-ocular pressure. The discontinuation of the medication will decrease the pressure or drug therapy may be used to reduce ocular pressure.
- **Night Vision Difficulties:** Most patients experience night vision strain as a transient complication with a small percentage needing temporary spectacle assistance for low light conditions or night driving. Persons with large pupils may experience difficulty in night driving due to significant night glare.

The following adverse events occurred long term post-treatment in clinical trials in less than 1% of patients: epithelial defects and foreign body sensation.

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_____is scheduled for outpatient surgery at

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PRK Operative Eye: OD (right)_____ OS (left)_____ OU (both)_____

CONSENT:

By signing below, I acknowledge that I have read the preceding consent. I understand that it is impossible for my doctor to inform me of every conceivable complication that may occur and that there may be unforeseen risks. I have been informed of and understand the possible consequences, risks, complications and benefits associated with the VISX Excimer Laser, the Amoil's Brush, 20% Ethyl Alcohol, manual scrape and PRK.

I enter into this procedure voluntarily without duress and informed that PRK is a surgical procedure. I have had a consultation with my surgeon. I have been given the opportunity to ask questions and received satisfactory answers to any questions I have asked. I understand that there is no guarantee of a particular outcome.

I have disclosed all medical information necessary to determine that I am an appropriate candidate in good general health possessing no contraindicating conditions. Transportation arrangements have been made so I will not be operating a vehicle until given medical clearance by my doctor. Post-operative instructions have been given to me in writing and I understand the responsibility of following these instructions.

I hereby consent to the proposed operation performed by the surgeon listed below. I consent to the administration of the necessary pre-operative and post-operative medications.

_____	_____	_____
Patient's Name	Patient's Signature	Date

I hereby consent to the observation of my surgical procedure at New Jersey Eye Laser Centers.

_____	_____	_____
Patient's Name	Patient's Signature	Date
_____	_____	_____
Name of Witness	Signature of Witness	Date
_____		_____
Surgeon's Signature		Date