

# CLEAR SIGHT LASER CENTER

## PRK INFORMED CONSENT FORM

### PERFORMING PHOTOREFRACTIVE KERATECTOMY WITH AN EXCIMER LASER

- I. I, or the patient I represent, hereby consent to have \_\_\_\_\_, MD, perform excimer laser photorefractive keratectomy for nearsightedness (myopia), farsightedness (hyperopia) or astigmatism.

Place to be Administered: ClearSight Laser Center

- II. Background:  
The procedure (called photorefractive keratectomy or PRK) uses the excimer laser to potentially correct nearsightedness (myopia), farsightedness (hyperopia) or astigmatism. A laser produces a very intense beam of light at one wavelength. The excimer laser uses a mixture of gases to produce a narrow beam of invisible ultraviolet light energy, which when focused through a lens system, results in the removal of tissue, causing a change in the shape of the cornea to correct the refractive error.

The excimer laser photorefractive keratectomy procedure involves the removal of very small amounts of corneal (transparent outer layer of the eye) tissue to reduce the curvature of the central cornea. The cornea includes three key layers. The surgeon first gently removes the epithelium (the outermost layer of the cornea). Excimer laser energy is then delivered to the cornea (in order to flatten the central cornea to reduce the nearsightedness after the procedure). The epithelium (top layer of the cornea) grows back (in most cases during the first four days after the procedure). All excimer laser photorefractive keratectomy procedures will be performed under topical anesthesia (eyedrops).

- III. Expected Followup:

I have been asked to return one day, three days, one month, two months, three to four months, six months, and one year for examinations following the treatment. Additional visits might be necessary depending on examination results. During these visits, my eye will be given a thorough examination.

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- IV. I understand the procedures described above may have the following risks, possible side affects or discomforts:

The goal of the surgery is to improve my uncorrected visual acuity and to decrease my dependence on corrective lenses (glasses and/or contact lenses). As with all forms of surgery, the results in my case cannot be guaranteed; there is no guarantee that I will completely eliminate my reliance on corrective lenses.

I have been told that these excimer laser clinical procedures are designed to treat myopia (nearsightedness), hyperopia (farsightedness) or astigmatism. I have been told that if I currently need reading glasses, I will likely still need reading glasses after the procedure. I have also been told that if I do not currently need reading glasses, I still may need them as I get older.

The majority of adverse reactions/complications after excimer laser photorefractive keratectomy occur in association with the normal healing process that takes place after the clinical procedure. As a result of surgery which employs the excimer laser, it is possible that my vision could be made worse. Complications or risks may include improper correction (under or overcorrection), decrease in best corrected visual acuity, induced or irregular astigmatism, anterior stromal reticular haze, glare, halo, foreign body sensation, corneal scarring, a corneal ulceration or perforation, intraocular infection, persistent corneal edema, severe hyphema, guttata, intraocular pressure elevation, hypopyon, endophthalmitis, corneal infection, cataract (lens opacity), endothelial cell loss, double vision, ghost images, contrast sensitivity loss, tearing, iron lines, diffuse nebulae, lid droop, and difficulty wearing contact lenses after excimer laser surgery. Additional immediate/early postoperative symptoms which may occur include postoperative pain, corneal edema (swelling), double vision, ghost images, light sensitivity, contrast sensitivity loss, tearing, and pupil enlargement.

### Improper Correction:

I have been told of the possibility that the procedure will result in undercorrection where I will have some degree of nearsightedness and may need to continue to wear corrective lenses. I have also been told that improper correction may result in overcorrection resulting and my eye become farsighted or hyperopic which may or may not require me to wear corrective lenses. It is possible that improper correction may increase dependence on reading glasses or require use of reading glasses at an earlier age.

### Decrease in Best Correct Visual Acuity:

Although rare, a decrease in best correct visual acuity (vision with eyeglasses or contact lenses) may occur.

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### Glare:

Glare, especially from bright lights at night, may be experienced, particularly in the early months after the procedure.

### Halo:

Halos or hazy rings surrounding bright lights may be experienced particularly at night after the procedure.

### Foreign Body Sensations:

Patients may experience foreign body sensations or a feeling that something is in the eye. Over a period of a few weeks these foreign body sensations usually diminish.

### Corneal Scarring:

Although anticipated to be uncommon, a haze or scar dense enough to affect vision may occur after the procedure.

### Intraocular Pressure Elevation:

An increase in intraocular (inner eye) pressure due to usage of postoperative medication may occur which is usually resolved by drug therapy or discontinuation of postoperative medication.

### Difficulty Wearing Contact Lenses Postoperatively:

May occur after refractive surgery.

### Corneal Ulceration or Perforation:

An ulcer or perforation of the cornea which is the clear transparent outer layer of the eye.

### Intraocular Infection:

An eye infection may result as with any type of eye surgery.

### Corneal Decompensation:

Corneal decompensation represents a persistent disorder of the hydration of the cornea.

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### Persistent Cornea Edema:

During the healing processes, it is normal for a certain amount of swelling to occur. Persistent cornea edema represents prolonged swelling of the corneal tissues beyond the normal healing period.

### Diffuse Nebulae:

A scattered cloudiness of the cornea.

### Hyphema:

Hemorrhage in the anterior (front) chamber of the eye.

### Hypopyon:

Accumulation of white blood cells in the anterior (or front) chamber of the eye.

### Endophthalmitis:

Inflammation of tissues in the eye due to infection.

### Endothelial Cell Loss:

A loss of overall endothelial (the inner layer of the cornea) cell density, increase in cell irregularity or cell size, or change in cell shape could occur.

### Guttata:

Small whitish deposits on the inner layer of the cornea.

### Microbial Keratitis:

Inflammation of the cornea due to infection.

### Cataract:

Opacity or cloudiness of the lens of the eye that may prevent a clear image from forming on the retina.

### Iron Lines:

An epithelial iron line, iron stain or Hudson-Stahli line are commonly seen after any refractive surgery; with no observed reduction in vision.

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Lid Droop:

Some patients may experience temporary or permanent slight drooping of the eyelid.

Since it is impossible to state every complication that may occur as a result of surgery, I have been told that the list of complications stated in this form is not complete. There also may be risks and discomforts that are not yet known. I have also been told that the long-term safety and effectiveness of photorefractive keratectomy has not been established.

I have been told that some subjects may require a second excimer laser procedure or other procedure.

V. I understand the photorefractive keratectomy procedure may have the following benefits:

- 1) The potential to reduce the patient's overall myopia while also reducing the percentage of time during the day contact lenses or glasses are required or potentially eliminating the need for glasses or contact lenses in some patients.
- 2) An alternative to glasses for some patients intolerant of contact lenses.
- 3) Some patients who are reluctant to wear glasses, for occupational and life-style issues, may have a new option to reduce or correct their nearsightedness.

VI. I understand that the following alternatives of treatment that are available and possibly advantageous to me are:

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