

# PHYSICIAN MANUAL

*LaserSight Technologies, Inc.*

## LSX

LASER SYSTEM  
for  
PHOTOREFRACTIVE KERATECTOMY (PRK)

## MYOPIA

**CAUTION:** Federal law restricts the sale of this device by or on the order of a physician.

**RESTRICTED DEVICE:** US Federal Law restricts the use of this device to practitioners who have been trained in its calibration and operation, and who have experience in the surgical treatment and management of refractive errors.

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# LaserSight Technologies, Inc.

## Physician Manual

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# LaserSight LSX EXCIMER LASER SYSTEM

## PHYSICIAN MANUAL PHOTOREFRACTIVE KERATECTOMY

### MYOPIA

#### I. Device Description

The LSX excimer laser is based on the principle that radiation at the 193 nm wavelength is highly absorbed by corneal tissue<sup>(1)</sup>, and that 193 nm wavelength photon energy disrupts the intramolecular collagen bonds of corneal tissue<sup>(2)</sup>, with the result being that the irradiated area is denatured. The 193 nm wavelength disruption is precise so that for any given intensity (or energy per pulse) the depth of an ablated area corresponds with the number of laser pulses and the area of tissue removal corresponds with the diameter of the incident laser beam on the tissue<sup>(3, 4)</sup>. It has also been shown that the non-thermal chemical bond breaking of the 193 nm wavelength results in minimal collateral damage to surrounding tissue<sup>(3, 4, 5, 6)</sup>.

To precisely control the ablation profile of the 193 nm beam on the corneal surface, the LSX excimer laser employs an optical scanning delivery system. Reports of the scanning technique for the delivery of laser radiation for photoablation of corneal tissue began to appear in 1992<sup>(7)</sup>. By 1993 the results from preclinical tissue studies demonstrated that optical scanning delivery of excimer laser energy produces smooth and gradual ablations without step-like transition zones, and without thermal damage<sup>(8, 9, 12)</sup>. These findings were replicated using a 213 nm ultraviolet solid state laser with a scanning delivery system in-vitro with human cadaver and rabbit eyes<sup>(10)</sup>, and in-vivo with pigmented rabbit eyes<sup>(11)</sup>.

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The LSX consists of the following system components:

1. Excimer Laser Head:

The laser head provides the following output characteristics:

Laser medium:	ArF
Laser wavelength:	193 nm
Gas mixture:	0.015 bar F2 / 0.40 bar Ar / 7.585 bar Ne 0.19% F2, 5% Ar, Balance Ne
Operating fill pressure:	7 bar
Pulse energy:	5 mJ
Repetition rate:	100 Hz
Power:	500 mW
Pulse width (duration):	2.5 to 3 ns
Emergent beam size (VxH):	3x2 mm
Beam divergence (VxH):	2.0 x 3.6 mrad

2. Laser Gas System:

Included in the laser system is a tank of the laser gas mixture with Argon, Neon, and Fluorine. The concentration of Fluorine is less than 0.2%. Additionally, there is another tank containing Helium gas, which is used for flushing the laser and gas system for installation and service. Components of the gas system include automatic valve manifold, vacuum pump, fluorine filter, computer controlled gas manifold drive, and valve position sensors.

3. System Control:

i) *Computer and software*

- An IBM computer and proprietary software are used to coordinate the control of the system, as well as determine the ablation profile and algorithm for each patient eye to be treated.

ii) *System Control Board*

The System Control Board receives and sends signals to the computer and the safety control, as well as controlling components of the system, such as turning on and off the laser radiation, opening and closing the shutter.

4. Laser Beam Delivery System

The laser beam delivery system consists of safety shutter, attenuator, focusing lens, galvanometers with scanning mirrors, and 45° deflection mirror. The main functions of the delivery system are to shape the laser beam to the proper size and

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beam profile, to attenuate the fluence to an appropriate level, and to scan the laser pulses to the locations on the eye determined by the computer and software.

5. Patient and Doctor Interface

The laser system components that comprise the patient-doctor interface include the patient chair and footswitch, operating microscope with centration reticule, illumination light, diode fixation light, footswitch for shutter control, computer keyboard, laser emission indicator, and emergency stop.

6. System Integration

The mechanical integrity of the system is provided by a welded metal frame with plastic covers bolted to the frame. All components and sub-components are fastened to the plates and the frame. Covers with specified interlocks are used to protect the users from electric and radiation hazards. The electronic components are connected with shielded cable. Isolation transformers and line filters are used for the electric power lines.

Electrical Safety:

The LSX excimer laser system is certified as meeting the UL 2601-1 electrical safety standard requirements.

Feature Disabling:

Laser radiation is prevented from exiting the laser system in certain situations, such as in the following cases: (1) the physician detects non-optimal event, i.e., eye movement, releasing the footswitch blocks the radiation, (2) when the surgery is completed laser radiation is blocked, (3) the system is equipped with an interlock that disables the laser when covers are removed, (4) emergency stop button disables the laser when pushed, and (5) a remote interlock is supplied which disables the laser when used.

Two redundant means are employed to block laser radiation. One uses a manual shutter consisting of an opaque, non-reflective metal blade that closes over the beam path; the second uses the scanning mirrors to deflect the beam so that it will not exit the system. The shutter has been tested to be able to block the laser radiation within 35 ms. The scanning mirrors have been tested to be able to deflect the laser beam within 3 ms. In addition, there are two shutter position sensors, one for the "open" and another for the "closed" position. If the computer receives an incorrect position signal, the laser head is shut down.

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## II. INDICATIONS FOR USE

The LaserScan LSX Excimer Laser is intended for myopic photorefractive keratectomy:

- For the reduction or elimination of myopia ranging from  $-1.0$  to less than  $-6.0$  diopters (D) with less than or equal to 1.0 D of astigmatism;
- In patients with documentation of a stable manifest refraction ( $\pm 0.5D$ ) over the prior one year; and in patients who are 18 years of age or older.

## III. CONTRAINDICATIONS

Patients with the following conditions should not be considered for PRK surgery:

- Active ocular / systemic infection
- Fuch's corneal dystrophy
- Keratoconous
- Central corneal scars affecting visual acuity
- Autoimmune or immunodeficiency diseases.
- Pregnant or nursing women

Patients who are taking one or both of the following medications:

- Isotretinoin (Accutane)
- Amiodarone hydrochloride (Cordarone)

## IV. WARNINGS

1. Patients presenting with the following condition(s) should be considered for PRK surgery only after careful assessment of the potential risk and benefit to the specific patient:
  - Collagen vascular disorders
  - Myopia progressing at a rate greater than 0.5 diopters per year.
  - Active systemic disease.
2. PRK is not recommended in patients with a history of ophthalmic Herpes simplex or Herpes zoster.

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3. PRK treatment of myopia from -6.0 to -10.0 D with this device has demonstrated risk of a loss of 2 lines or more of BSCVA approximately ten times that below -6.0 D at  $\geq 12$  months (5.9% vs. 0.6%). For treatment of myopic sphere between -6.0 and -10.0 D effectiveness is also reduced compared to treatments less than -6.0 D. No safety and effectiveness data above -10.0 D are available.

## V. PRECAUTIONS

### A. General

The safety and effectiveness of the LaserScan LSX excimer laser have not been established in patients presenting the following conditions:

- Severe dry eye
- Immunosuppression
- Glaucoma
- Uveitis
- History of keloid formation
- Blepharitis
- Psoriasis
- Systemic or topical use of steroids
- For patients under 18 years of age
- In patients who are taking sumatriptan (Imitrex)
- Use of medications likely to affect wound healing
- In patients with corneal neovascularization within 1.0 mm of the ablation zone
- In patients with progressive myopia or astigmatism, ocular disease, corneal abnormality, and previous corneal surgery or trauma in the ablation zone
- For PRK treatment of  $\leq -1.0$  diopters

### B. Patient Selection- Inclusion/Exclusion Criteria

Consideration should be given to the following in determining the appropriate patients for PRK:

- Complete examination, including cycloplegic evaluation, must be performed. The lens must be evaluated, especially in the older patient, to assure that nuclear sclerosis or any other lens opacity is not present prior to laser surgery. Myopic patients will have a higher incidence of retinal pathology, and indirect ophthalmoscopy through a dilated pupil is essential.

To obtain accurate refractive information, contact lens wearers must be examined after a period of abstinence from contact lens use for at least 2 weeks for soft lenses and at least 3 weeks for rigid gas permeable or hard (PMMA) lenses. Prior to treatment, patients must have 3 separate central keratometry readings and

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manifest refractions each taken at one (1) week intervals, of which the last two must not differ by more than 0.5 diopter in either meridian. All mires must be regular.

- Glaucoma is more common in myopia patients than in the general population. Evaluation of the optic nerve and measurement of the intraocular pressure are necessary. If elevated intraocular pressure and/or evidence of glaucomatous damage are found, topical steroids should only be used with careful medical supervision or the patient should not undergo PRK surgery.
- Pre-operative corneal mapping is essential on all patients to exclude topographical abnormalities. This is especially important when astigmatism or steep keratometry readings are present, which may indicate the presence of keratoconus or other irregularities.
- The patient should have the ability to tolerate local or topical anesthesia.
- The patient should have the ability to lie flat without difficulty.
- The patient should be able to fixate steadily and accurately for the duration of the PRK procedure.
- The patient must be able to understand and give an informed consent.
- Patients must be clearly informed of all alternatives for the correction of myopia. These alternatives corrections include, but are not limited to spectacles, contact lenses, and other refractive surgeries such as radial keratotomy or automated lamellar keratoplasty.

### C. Procedure

- The output of the laser is potentially hazardous only to the skin and the surface layers of the cornea. This radiation has not been shown to pose a threat to retinal structures or the crystalline lens.
- All healthcare personnel should avoid direct exposure to the skin or eye by the laser beam. The use of protective eyewear is recommended.

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#### D. Post Procedure

- A slit lamp examination should be performed on the postoperative day one and as needed thereafter to ensure that healing of the cornea is complete. After re-epithelialization, the following examinations are recommended at a schedule of at least 1,3, and 6 months:
  - Uncorrected Visual Acuity (UCVA or VA-sc)
  - Manifest refraction with the Best Spectacle Corrected Visual Acuity (BSCVA or VA-cc)
  - Intraocular pressure (IOP)
  - Slit lamp examination, including corneal clarity evaluation
  - If topical steroids are used post-operatively, patients should be monitored for development of possible steroid side effects, including but not limited to ocular hypertension, glaucoma, and/or cataract.

#### VI. ADVERSE EVENTS

The following transient complications might be expected with patients undergoing the PRK procedure: pain (24-48 hours), foreign body sensation, tearing, photophobia, redness, itching, burning, dryness, headache, blurred vision, corneal swelling and pupil enlargement.

Other adverse events that might be expected with patients undergoing the PRK procedure but have not been observed in the LaserSight clinical study are corneal perforations, intraocular infections, hyphemas, hypopyon, post-traumatic lens abnormalities with vision loss, persistent corneal edema, or cystoid macular edema.

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A. Adverse Events and Complications

**Table 1. All Eyes Treated – Initial Treatment (%)**

<i>Adverse Events / Complications</i>	< 1 month <sup>1</sup>	1 month	3 months	6 months	12 months
Corneal infiltrate/ulcer > 1 mo		2/340 (0.6)	0/318 (0)	0/275 (0)	0/162 (0)
Corneal edema > 1 mo		0/340 (0)	0/318 (0)	1/275 (0.4)	0/162 (0)
Persistent Central Epithelial Defect		1/340 (0.3)	0/318 (0)	0/275 (0)	0/162 (0)
Retinal detachment		0/340 (0)	0/318 (0)	0/275 (0)	0/162 (0)
Corneal Edema < 1 mo	0/373 (0)				
Corneal Infiltrate/ulcer < 1 mo	5/373 (1.3)				
Late onset haze beyond 6 months with loss of > 2 lines <sup>2</sup>				0/275 (0)	1/162 (0.6)
Loss >2 lines beyond 6 months <sup>2</sup>				0/275 (0)	1/162 (0.6)
IOP Increase > 5 mmHg above baseline, and any reading above 25 mmHg		1/340 (0.3)	1/318 (0.3)	0/275 (0)	0/162 (0)
IOP increase 6 to 10 mmHg		11/340 (3.2)	15/318 (4.7)	7/275 (2.5)	3/162 (1.9)
IOP increase > 10 mmHg		1/340 (0.3)	1/318 (0.3)	0/275 (0)	0/162 (0)
Retinal Detachment		0/340 (0)	0/318 (0)	0/275 (0)	0/162 (0)
Retinal Vascular Accidents		0/340 (0)	0/318 (0)	0/275 (0)	0/162 (0)
Recurrent Corneal Erosion		0/340 (0)	1/318 (0.3)	0/275 (0)	1/162 (0.6)
Foreign Body Sensation		0/340 (0)	0/318 (0)	4/275 (1.5)	0/162 (0)
Pain/Discomfort		0/340 (0)	1/318 (0.3)	2/275 (0.7)	2/162 (1.2)
Corneal Haze (Moderate to Marked)		4/340 (1.2)	2/318 (0.6)	0/275 (0)	2/162 (1.2)
Overcorrection > 1 D <sup>3</sup>				12/275 (4.4)	8/162 (4.9)
Overcorrection > 2 D <sup>3</sup>				1/275 (0.4)	1/162 (0.6)

1. Adverse events occurring operatively and up to 1 month postoperatively.
2. These events were reported 6 and 12 months after final treatment.
3. Cycloplegic refractions taken at 6 and 12 months postoperative.

i) Adverse Events

Adverse events data are presented in Table 1 for "All Eyes Treated- Initial Treatment". One investigational site accounted for nearly half the incidence of early corneal ulcer, and was subsequently discontinued from the study. At any time period there were few adverse events. Those adverse events occurring at 1 month of treatment included 0.6% with a corneal infiltrate, 3.2% had an IOP increase of 6 to 10 mm Hg, 1.2% had moderate to marked corneal haze and 0.3% had an IOP increase of > 10 mm Hg. No adverse events were reported after any retreatment procedure.

ii) Complications

Complications data are presented in Table 1 for "All Eyes Treated-Initial Treatment". Recurrent corneal erosion was reported at 3-months (0.3%) and at 1-year (0.6%) postoperatively. Foreign body sensation was reported at 6-months (1.5%) and pain / discomfort was recorded at 3-months (0.23), 6-months (0.7%) and at 1-year (1.2%) postoperatively. Overall the incidence of complications in this study were quite low,

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with the patient report of foreign body sensation and pain / discomfort being the most frequent complaints. No complications occurred after any retreatment procedure.

B. Subjective Patient Adverse Events

Table. 2  
Patient Events at Preop and 6 months

Eyes with Preop SER < -6.00D  
All Eyes Treated - Initial Treatment

SUBJECTIVE PATIENT ADVERSE EVENTS	Preop	6 Months
Burning, Gritty Feeling <sup>1</sup>	12/338 (3.6%)	15/183 (8.2%)
Halos, Startbursts <sup>1</sup>	46/335 (13.7%)	43/184 (23.4%)
Watery Eyes <sup>1</sup>	10/337 (3.0%)	6/184 (3.3%)
Double Vision / Ghosts <sup>1</sup>	2/337 (0.6%)	6/182 (3.2%)
Clarity Changes Day to Day <sup>1</sup>	10/335 (3.0%)	22/182 (12.1%)
Night Vision Problems <sup>2</sup>	80/336 (23.8%)	43/173 (24.9%)
Problems with Colors <sup>2</sup>	9/336 (2.7%)	3/175 (1.7%)

1. Rated as "Never", "Rarely", "Often" or "Always". Percent reported as "Often" or "Always" included here.  
2. Rated as "Yes" or "No". Percent reporting "Yes" included here.

Patient events are reported in Table 2 for "All Eyes Treated-Initial Treatment". Patient events were recorded on a self-administered questionnaire preoperatively and at 3 or 6 months post-treatment. Patients were asked to subjectively rate the presence or absence of these events. The most frequent events were halos, double vision, clarity changes over time, and night vision problems.

VII. Clinical results

A. Study Design

The study was a prospective, non-randomized clinical trial. 373 eyes were enrolled at eleven US sites and one foreign site.

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B. Data Analysis and Results

i.) Accountability

**Table. 3  
Accountability**

**Eyes < -6.00 D Preop  
Initial Treatment**

	1 Month	3 Months	6 Months	12 Months	≥ 12 Months
Available for Analysis n/N (%)	340/ 373 ( 91.2%)	318/ 373 ( 85.3%)	275/ 373 (73.7%)	162/ 373 (43.4%)	181/ 373 (48.5%)
Not yet due for the interval n/N (%)	7/ 373 ( 1.9%)	29/ 373 ( 7.8%)	66/ 373 (17.7%)	<del>142/ 373</del> (38.1%)	142/ 373 (38.1%)
Lost to Follow-up <sup>1</sup> n/N (%)	0/ 373 ( 0.0%)	0/ 373 ( 0.0%)	3/ 373 ( 0.8%)	38/ 373 (10.2%)	44/ 373 (11.8%)
Discontinued n/N (%)	1/ 373 ( 0.3%)	1/ 373 ( 0.3%)	10/ 373 (2.7%)	8/ 373 (2.1%)	4/ 373 (1.1%)
Missed Visit n/N (%)	25/ 373 ( 6.7%)	25/ 373 ( 6.7%)	19/ 373 ( 5.1%)	23/ 373 (6.2%)	6/ 373 (1.6%)
% Accountability = Available for Analysis	340/ 365 ( 93.2%)	318/ 343 ( 92.7%)	275/ 297 (92.6%)	162/ 223 (72.6%)	181/ 227 (79.7%)
(Enrolled - Discontinued - Not yet due)					

\* N = Total eyes enrolled

1. A patient is considered lost to follow-up after 12 months from the last visit.

Accountability of Initial Treatment eyes was calculated for each study visit and for ≥ 12 months. (Initial Treatment eyes are all eyes just prior to any retreatments.)

Accountability for Initial Treatment Eyes was 92.6% at 6-months and 79.7% at the ≥ 12 month interval.

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ii.) Summary of Key Safety and Efficacy Variables

a.) All Eyes Treated - Initial Treatment

**Table. 4**  
**Safety and Efficacy Variables**  
**Preop SER < -6.00D**  
**All Eyes Treated - Initial Treatment**

	1 Month n/N (%)	3 Months n/N (%)	6 Months n/N (%)	12 Months n/N (%)	≥ 12 Months n/N (%)
<b>Efficacy Variables</b>					
UCVA 20/20 or better*	113/327 (34.6)	143/308 (46.4)	147/265 (55.5)	83/159 (52.2)	94/177 (53.1)
UCVA 20/40 or better*	268/327 (82.0)	268/308 (87.0)	232/265 (87.5)	133/159 (83.6)	151/177 (85.3)
MRSE ± 0.50 D	170/340 (50.0)	165/318 (52.9)	161/275 (58.5)	91/162 (56.2)	105/181 (58.0)
MRSE ± 1.00 D	266/340 (78.2)	254/318 (79.9)	224/275 (81.5)	124/162 (76.5)	140/181 (77.3)
MRSE ± 2.00 D	320/340 (94.1)	307/318 (96.5)	266/275 (96.7)	158/162 (97.5)	177/181 (97.8)
<b>Safety Variables</b>					
Loss of > 2 lines BSCVA	4/340 (1.2)	0/318 (0.0)	0/275 (0.0)	1/162 (0.6)	1/181 (0.6)
BSCVA worse than 20/40	0/340 (0.0)	0/318 (0.0)	0/275 (0.0)	0/162 (0.0)	0/181 (0.0)
Increase of > 2 D cylinder	3/340 (0.9)	1/318 (0.3)	1/275 (0.4)	0/162 (0.0)	0/181 (0.0)
BSCVA worse than 20/25 if 20/20 or better preoperatively	12/340 (3.5)	1/318 (0.3)	3/275 (1.1)	1/162 (0.6)	2/181 (1.1)

\* For all eyes minus those intentionally undercorrected (defined as greater than 0.5 D myopia).

For All Eyes Treated - Initial Treatment at 6 months, 87.5% had an UCVA of 20/40 or better, 55.5% were 20/20 or better and 81.5% were within ± 1.0 D SER.

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b.) All Eyes Retreated - Last Treatment

**Table. 5**  
**Safety and Efficacy Variables**  
**Eyes with Preop < -6.00 D**  
**All Eyes Retreated - Last Treatment**

All retreatments performed were for undercorrection of myopia. No retreatments were performed secondary to overcorrection. Overall, there were 20 retreatments performed (5.4%)

For All Eyes Retreated - Last Treatment, retreated eyes had no safety events (0.0%) at any interval. At 6 months 100 % eyes were 20/40 or better (UCVA). After retreatment all eyes had a BSCVA of 20/40 or better.

	1 Month n/N (%)	3 Months n/N (%)	6 Months n/N (%)	12 Months n/N (%)	≥ 12 Months n/N (%)
<b>Efficacy Variables</b>					
UCVA 20/20 or better*	5/14 (35.7)	5/11 (45.5)	4/7 (57.1)	1/1 (100)	1/1 (100)
UCVA 20/40 or better*	11/14 (78.6)	9/11 (81.8)	7/7 (100)	1/1 (100)	1/1 (100)
MRSE ± 0.50 D	9/14 (64.3)	5/11 (45.5)	2/7 (28.6)	0/1 (0.0)	0/1 (0.0)
MRSE ± 1.00 D	12/14 (85.7)	9/11 (81.8)	6/7 (85.7)	1/1 (100)	1/1 (100)
MRSE ± 2.00 D	12/14 (85.7)	10/11 (90.9)	7/7 (100)	1/1 (100)	1/1 (100)
<b>Safety Variables</b>					
Loss of > 2 lines BSCVA	0/14 (0.0)	0/11 (0.0)	0/7 (0.0)	0/1 (0.0)	0/1 (0.0)
BSCVA worse than 20/40	0/14 (0.0)	0/11 (0.0)	0/7 (0.0)	0/1 (0.0)	0/1 (0.0)
Increase of > 2 D cylinder	0/14 (0.0)	0/11 (0.0)	0/7 (0.0)	0/1 (0.0)	0/1 (0.0)
BSCVA worse than 20/25 if 20/20 or better preoperatively	0/14 (0.0)	0/11 (0.0)	0/7 (0.0)	0/1 (0.0)	0/1 (0.0)

\* For all eyes minus those intentionally undercorrected (defined as greater than 0.5D myopia)

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- c.) All Eyes Treated - Initial Treatment, Stratified by Preop MRSE (Manifest Refraction Spherical Equivalent)

**Table. 6**  
**Safety and Efficacy Variables**  
**At ≥ 12 Months (Stratified by Preop MRSE)**  
**Eyes with Preop < -6.00D**  
**All Eyes Treated - Initial Treatment**

	<-1.0 D	-1.0 to -1.99 D	-2.0 to -2.99 D	-3.0 to -3.99 D	-4.0 to -4.99 D	-5.0 to -5.99 D	CUM TOTAL < 6 D
	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
<b>Efficacy Variables</b>							
UCVA 20/20 or better*	----	5/9 (55.6)	17/33 (51.5)	36/53 (67.9)	21/46 (45.7)	15/36 (41.7)	94/177 (53.1)
UCVA 20/40 or better*	----	9/9 (100)	29/33 (87.9)	48/53 (90.6)	37/46 (80.4)	28/36 (77.8)	151/177 (85.3)
MRSE ± 0.50 D	----	8/9 (88.9)	25/33 (75.8)	35/55 (63.6)	18/46 (39.1)	19/38 (50.0)	105/181 (58.0)
MRSE ± 1.00 D	----	9/9 (100)	29/33 (87.9)	47/55 (85.5)	31/46 (67.4)	24/38 (63.2)	140/181 (77.3)
MRSE ± 2.00 D	----	9/9 (100)	33/33 (100)	54/55 (98.2)	44/46 (95.7)	37/38 (97.4)	177/181 (97.8)
<b>Safety Variables</b>							
Loss of > 2 lines BSCVA	----	0/9 (0.0)	0/33 (0.0)	0/55 (0.0)	1/46 (2.2)	0/38 (0.0)	1/181 (0.6)
BSCVA worse than 20/40	----	0/9 (0.0)	0/33 (0.0)	0/55 (0.0)	0/46 (0.0)	0/38 (0.0)	0/181 (0.0)
Increase of > 2 D cylinder	----	0/9 (0.0)	0/33 (0.0)	0/55 (0.0)	0/46 (0.0)	0/38 (0.0)	0/181 (0.0)
BSCVA worse than 20/25 if 20/20 or better preoperatively	----	0/9 (0.0)	0/33 (0.0)	0/55 (0.0)	1/46 (2.2)	1/38 (2.6)	2/181 (1.1)

\* For all eyes minus those intentionally undercorrected (defined as greater than 0.5 D myopia).

Results for UCVA of 20/40 or better varied from a high of 100 % for the -1.00 to -1.99 D to 77.8% for the -5.00 to -5.99 D group. There were no safety events that occurred for treatments of < -4.00 diopters. For treatments of -4.00 to -4.99 diopters, 2.2% had a loss of > 2 lines of BSCVA and 2.2% had a BSCVA worse than 20/25 if 20/20 or better preoperatively. For treatments of -5.00 to -5.99 diopters, 2.6% had a BSCVA worse than 20/25 if 20/20 or better preoperatively.

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iii.) Stability of Manifest Refraction

Stability was reached between 6 and 12 months. In Table. 7 for those eyes available for their 1,3,6 and 12 month visits, 94.3% and 95.0% changed  $\leq 1$  diopter at 6 and 12 months, respectively.

**Table. 7**  
**Stability of Manifest Refraction Through 12 Months**

**Eyes with Preop SER < -6.00 D**  
**All Eyes Treated - Initial Treatment**

Change in Spherical Equivalent Between	1 and 3 Months n/N (%)	3 and 6 Months n/N (%)	6 and 12 Months n/N (%)
$\leq 1.00$ D	122/140 ( 87.1)	132/140 ( 94.3)	133/140 ( 95.0)
Mean Difference	0.50	0.42	0.38
SD	0.48	0.49	0.50
95% CI (Mean)	( 0.47 - 0.52)	( 0.40 - 0.45)	( 0.35 - 0.41)
95% CI (Individual)	(-0.45 - 1.44)	(-0.55 - 1.39)	(-0.59 - 1.36)

Only those patients with 1,3,6, and 12 months are included in the analysis.

## VIII. Pre-operative Examination and Surgical Planning:

### Ocular Examination and History

#### A. HISTORY

Complete ocular and medical histories are obtained from the patient including primary reason for desiring the evaluation, patient's occupation, hobbies or activities patient enjoys. Work requirements on a visual basis, previous ocular history including the role of previous ocular injuries, ocular infections or previous ocular surgery. Contact lens history is taken detailing type of previous contact lens wear, how long the patient has continuously been wearing contact lenses and when the lenses were last worn, as well as documentation of absence or presence of contact lens intolerance or other complications. Complete medical history is obtained with specific rule outs for hypertension, heart/lung or breathing problems, thyroid or kidney problems or diabetes mellitus. Complete medical evaluation for pharmaceutical agents is reviewed as well as any known allergies to medications.

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B. VISUAL ACUITY MEASUREMENTS

The patient is seated at 6 optical meters distance from the acuity chart. A standard occluder is held by the patient to block out the eye not being tested and the examiner must constantly ensure that the untested eye is completely covered to avoid inadvertent peeking. The patient is instructed to read the smallest line on the chart that is easily visible. This saves the monotonous reading of the entire chart.

When the patient cannot read a letter they are encouraged to guess at it. If the patient states that the letter is one of two letters, they are asked to choose only one letter, and if necessary, to guess. The patient may neither squint to achieve pinhole nor lean forward.

Visual Acuity and Refraction will be performed with the Snellen Eye Charts.

C. METHOD OF REFRACTION

The trial frame or phoropter is placed and adjusted in front of the patient's face so that the lens cells are parallel to the anterior plane of the orbits and centered in front of the pupils. Manifest retinoscopy is performed to obtain initial objective refraction prior to beginning subjective refraction. The left eye is occluded and subjective refraction begun on the right eye.

The patient is then asked to look at and read a Snellen acuity chart in the light box at an optical distance of 6 meters either directly or with a mirror.

Each refraction should be done without knowledge of the previous refraction results.

The refraction should be performed until neither the power nor the axis of the cylinder can be improved. The power of the sphere is rechecked by adding +0.25 and -0.25 spheres and changing the spherical power by quarter diopter increments of the appropriate sign until the patient can perceive no improvement in vision. If the sphere is changed at this point, the cylinder should be rechecked. This process is repeated until no further significant lens changes are made. The lens corrections obtained in this way for the right eye are recorded. The entire process is repeated for the left eye and the lens corrections are recorded on the examination form.

D. CYCLOPLEGIC REFRACTION

For Cycloplegic Refraction, Retinoscopy and Refraction are carried out as described above in the Section "Manifest Refraction". Cycloplegia is obtained by instilling 1 drop of 1% Mydriacyl in each eye, three times each separated by 5 minutes. Cycloplegic refraction is performed 30 to 45 minutes after the last instillation of 1% Mydriacyl.

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E. NATURAL PUPIL

Pupil examination is performed at pre-op, or as needed based on symptoms from the patient or signs found within the clinical examination. Pupil findings are recorded on the chart in the standard PERRLA format.

F. STABILITY OF CONTACT LENS WEARERS

All patients who wear contact lenses will be asked to discontinue wearing them prior to the PRK refractive evaluation and to continue absence of lens wearing prior to any surgical treatment.

- Soft lenses - discontinue wear for minimum of 2 weeks
- Hard lenses - (including PMMA and all rigid gas permeable materials) discontinue wear for a minimum of 3 weeks

Review contact lens history with patient including total time wearing contact lenses, when last worn, and type of lenses worn, any complications with contact lens wear recorded.

G. INTRAOCULAR PRESSURE

For measurement of intraocular pressure Goldmann Applanation Tonometry is performed after instillation of 1 drop 0.5% Proparacaine and application of fluorescein.

H. CORNEAL TOPOGRAPHY

Corneal mapping is performed.

I. CORNEAL THICKNESS TESTING

Corneal thickness testing is performed with an ultrasonic pachymetry.

J. HAZE GRADING

A detailed evaluation of the cornea in terms of the presence of haze will be performed.

K. SUMMARY OF PRE-OPERATIVE REPORT

Includes a detailed discussion involving refractive options for the patient including contact lenses, spectacle lenses, refractive surgeries involving PRK and keratophakia or other procedures that may be available to the patient on a case-specific basis.

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L. INFORMED CONSENT

The patient, upon deciding to have refractive surgery, is to review and sign an informed consent.

## IX. PATIENT INSTRUCTIONS

### Pre-operative

Pre-operative PRK patients are notified the day prior to surgery to review pre-operative instructions. Pre-operative instructions include the following:

1. No food after midnight.
2. May have clear liquids up to 2 hours prior to arrival.
3. Patients are to take regular medication prior to arrival.
4. Patient is instructed to shower, shampoo hair and wash face with soap the morning of surgery.
5. Verify telephone number where patient may be reached evening of surgery for post-surgical follow-up call.
6. Name and telephone number of person to contact in case of emergency.
7. One day post-operative appointment given to patient.

### Day of Surgery

The patient is instructed to arrive at the physician's office on the day of the surgery. At this time any additional pre-operative testing may be performed, if needed (i.e., repeat manifest refraction, corneal topography, etc.).

The pre-operative PRK patient is then taken to the laser room. (A disposable surgical jump suit may or may not be worn over their street clothes and as well as shoe covers and a hair bonnet.) It is recommended that identification stickers be placed over the eye or eyes to be treated. The staff may then prepare the eye or eyes to be treated by cleaning around them prior to surgery. The patient is now ready for the treatment procedure.

## X. Treatment Procedure

For a more detailed description on how to use and program the LaserSight LSX laser please refer to the US PRK Operator's Manual.

The PRK (Photorefractive Keratectomy) surgical technique consists of ablating a lens shaped volume of tissue from the cornea, after manually removing the epithelium from the area to be treated. For example, the shape of the ablated area for myopia is achieved by allowing more laser energy to strike the central than the peripheral portion of the

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ablation area. The required depth of ablation is proportional to the number of diopters to be corrected.

- A. Enter the patient's name
- B. Enter eye to be treated, average keratometry reading and vertex distance
- C. Enter the spectacle refraction (sphere only) into the computer
- D. Align patient under the laser and get patient in focus ( for detailed description refer to operator's manual)
- E. Apply a topical anesthetic agent into the operative eye
- F. Use a sterile eye lid speculum to keep the eye open for surgery
- G. Mark the cornea with an optical zone marker (typically 7.0 mm) that is approximately 1.0 mm larger than the treatment area. Manually remove the epithelium out to the limit of the optical zone marker with a Paton spatula or similar surgical instrument. Gently wipe away any loose epithelium within the optical area with a dry Weck or Merocell sponge. It is important to remove all the epithelium within the ablation zone otherwise an irregular ablation may result. The time period from the start of epithelium removal and the start of laser delivery should be 5 minutes or less to avoid dehydration of the cornea.
- H. The patient is instructed to fixate on the flashing light immediately above them. The patient is instructed to keep looking straight ahead even if they lose sight of the fixation light. The physician must monitor the patient's fixation to ensure the ablation is well centered.
- I. Start up the laser and begin treatment by pushing on the footswitch, keeping the footswitch pressed during the treatment. If the patient should move, release the footswitch, realign the patient and restart surgery by pressing on the footswitch. It is important to realign the patient if they should become decentered during the treatment, otherwise a decentered ablation may result causing induced or irregular astigmatism.
- J. After surgery is complete apply an antibiotic, steroid and or a non-steroidal eye drop, (at the physician's discretion).
- K. Patch the operative eye or place a bandage soft contact lens
- L. Give patient post operative instructions and a follow up appointment

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# Patient Information

## Photorefractive keratectomy (PRK) for the correction of myopia without astigmatism

Mild to moderately nearsighted patients (-1.0 to less than -6.0 diopters) with less than or equal to 1.00 diopters of astigmatism.

*Please read this entire booklet.  
Discuss its contents with your doctor so that all your  
questions are answered to your satisfaction. Ask any  
questions you may have before you agree to the surgery.*

LaserScan LSX Excimer Laser  
LaserSight Technologies, Inc.  
3300 University Blvd., Suite 140  
Winter Park, Florida 32792

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## Introduction

The information in this booklet is provided so you are able to make an intelligent, informed decision about having PRK (Photorefractive Keratectomy) eye surgery. Some other ways to correct nearsightedness are glasses, contact lenses, and other kinds of refractive surgery such as radial keratotomy (RK) or lamellar keratectomy (ALK).

If you are nearsighted in both eyes, your doctor may recommend PRK surgery for both eyes. Sometimes it is better to have PRK done on only one eye. Talk to your doctor about whether it would be better to treat one or both eyes.

Please note that the practice of surgery can make no guarantees as to the exact result of an operation. Please take as much time as you wish to review this information before making your decision to have this surgery. You may decide not to make any decision at this time. We encourage you to ask any questions you have after reading this information.

## How The Eye Works

In a normal eye, light is focused directly on the retina (the back of the eye). If light is focused in front of or behind the back of the eye, it is referred to as a refractive error. Myopia or nearsightedness is caused by light focusing in front of the back of the eye. In general, nearsighted people can see close but far objects are blurry. Eyeglasses and contact lenses correct nearsightedness by putting lenses in front of the eye that are thicker at the edge than in the center. PRK corrects nearsightedness by flattening the central part of the cornea. All of these methods of corrections move the point where the light focuses so that it is focused directly on the retina. This allows you to see a clear image. The LSX Excimer Laser System is indicated for treating eyes with myopia ranging from  $-1.0$  to less than  $-6.0$  diopters (D) with less than or equal to  $1.0$  D of astigmatism.

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## What is PRK ?

PRK is a surgical procedure for nearsightedness. An excimer laser reshapes the cornea so that light can focus properly on the back of the eye.

The PRK procedure uses an excimer laser to re-shape the surface of the cornea (the clear covering over the colored part of the eye). The laser reshapes the eye by using ultraviolet light to sculpt the cornea.

The PRK is performed on one eye at a time. The second eye can be treated if all goes well and vision stabilizes without complications or adverse reactions. When to treat the second eye should be discussed with your doctor.

PRK is generally associated with a quick visual recovery and only minor discomfort, which is controlled with pain medication, in the first 24 hours after the procedure.

In the U.S. clinical studies, 53.1 % of all treated eyes could see 20/20 or better without glasses after a single PRK procedure and 85.3 % could see 20/40 or better. Even though their vision without glasses improved, some patients still needed glasses or contact lenses after PRK. PRK does not eliminate the need for reading glasses after laser surgery. It is possible that you may need glasses after laser surgery even if you did not wear them before.

## What Is An Excimer Laser?

An excimer laser is a unique laser, which removes extremely thin layers of corneal cells without damaging the adjacent layers. It does this by using a wavelength of light that breaks the molecular (very small) bonds of the cornea. By breaking these molecular bonds the laser is able to reshape the cornea.

The laser is controlled by a computer program, which tells the laser how much tissue to remove to correct a given refractive error.

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# Risks of PRK Surgery

## Risks:

As with any surgical procedures there are risks associated with PRK surgery. It is important to discuss these risks with your doctor before you make the decision to have the surgery. If the results of the surgery are not satisfactory, you may need to have additional PRK surgery in the same eye. Approximately 5 % of patients in the clinical study needed to have additional surgery in the same eye.

## The first week following surgery:

During the first 2 - 3 days following surgery, your eye will be patched or a bandage soft contact lens will be worn while the epithelium (top cell layers of cornea) grows back. During this period you may experience pain, discomfort, tearing, sensitivity to bright lights and blurred vision. Once the epithelium has grown back these symptoms often will resolve though your vision may continue to be blurry.

## The first two to six months following surgery:

During the two to six months following surgery, your vision may continue to be blurry as your eye (cornea) continues to heal. Your intraocular pressure may increase due to the use of anti-inflammatory medications. This is usually resolved by drug therapy or by stopping the anti-inflammatory medications. Your cornea may become hazy or cloudy enough to affect your vision. This haze typically disappears over time, but some patients continue to experience haze over 2-3 years.

## Six months to a year or more following surgery:

At 6 months after surgery the following events were reported in the clinical study:

- 4.4% were overcorrected (made farsighted) by > 1.0 diopter
- 2.5% had an increase of intraocular pressure of 6 -10 millimeters of mercury
- 1.5% reported a foreign body sensation
- 0.4% were overcorrected (made farsighted) by > 2.0 D
- 0.7% reported a foreign body sensation
- 0.4 % had swelling (edema) of the cornea

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At 12 months or longer after surgery the following events were reported:

- 17.9% were undercorrected by more than 1.0 diopter
- 4.9% were overcorrected (made farsighted) by more than 1.0 diopter
- 1.9% had an increase of intraocular pressure of 6 -10 millimeters of mercury
- 1.2% had moderate corneal haze
- 1.2% experienced pain or discomfort
- 1.1% had BSCVA (vision with spectacles) worse than 20/25 after surgery, when they had BSCVA 20/20 or better before surgery
- 0.6% had >2 lines loss of best corrected vision
- 0.6% had late onset of haze with a loss of >2 lines of best corrected vision
- 0.6 % had a recurrent corneal erosion (loss of top layer of cells from cornea)

**Subjective patient questionnaire:**

Before and 6 months after surgery patients were asked to rate a series of subjective events. The most frequent events reported were halos, double vision, clarity changes over time and night vision problems.

The exact percentages are listed as below:

Subjective Patient Adverse Events	Preop (Before Surgery)	6 months
Burning, Gritty Feeling <sup>1</sup>	12/338 (3.6%)	15/183 (8.2%)
Halos, Startbursts <sup>1</sup>	46/335 (13.7%)	43/184 (23.4%)
Watery Eyes <sup>1</sup>	10/337 (3.0%)	6/184 (3.3%)
Double Vision / Ghosts <sup>1</sup>	2/337 (0.6%)	6/182 (3.2%)
Clarity Changes Day to Day <sup>1</sup>	10/335 (3.0%)	22/182 (12.1%)
Night Vision Problems <sup>2</sup>	80/336 (23.8%)	43/173 (24.9%)
Problems with Colors <sup>2</sup>	9/336 (2.7%)	3/175 (1.7%)

1. Rated as "Never", "Rarely", "Often" or "Always". Percent reported as "Often" or "Always" included here.
2. Rated as "Yes" or "No". Percent reporting "Yes" included here.

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## Additional Clinical Observations:

- Some eyes treated (10.2%) had a slight worsening of vision with glasses ( loss of 1 line of vision) at 6 months. Some (8.6%) had the same loss at 12 months after surgery.
- Patients who had nearsightedness of -4.00 to -6.00 diopters had poorer results than patients with less nearsightedness (-1.50 to -4.00 diopters). For example, 70-80% of eyes in the -4.00 to -6.00 diopter range could see 20/40 or better without glasses after the operation, whereas 88-100% of eyes in the -1.50 to -4.00 diopter range could see 20/40 or better.
- Patients whose eyes were not optimally corrected (to within 0.5 diopters of the intended correction) experienced more symptoms, including burning, gritty feeling; halos, starbursts, watery eyes; double vision, ghosts; clarity changes day to day as well as night vision problems and problems with colors.

## Contraindications

**Patients with the following conditions should not be considered for PRK surgery:**

- Active ocular / systemic infection
- Fuch's corneal dystrophy
- Keratoconous
- Central corneal scars affecting visual acuity
- Autoimmune or immunodeficiency diseases.
- Pregnant or nursing women

**Patients who are taking one or both of the following medications:**

- Isotretinoin (Accutane)
- Amiodarone hydrochloride (Cordarone)

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## Warnings

*Discuss with your doctor if you have any of the following conditions. You can be considered for this treatment only after you have discussed the risks and benefits with your doctor.*

- Your myopia is progressing at a rate greater than 0.5 diopters per year.
- Active systemic disease (any disease affecting multiple organs or systems of the body {for example diabetes or severe allergies}).
- Herpes simplex, Herpes zoster, or previous Herpetic keratitis (viral infections affecting the cornea).

PRK treatment of myopia (nearsightedness) from -6.0 to -10.0 diopters with this device has demonstrated risk of a loss of 2 lines or more of BCVA; approximately ten times that below -6.0 diopters at 12 months or more (5.9% vs. 0.6%). For treatment of myopic sphere between -6.0 and -10.0 diopters effectiveness is also reduced compared to treatments less than -6.0 diopters. No safety and effectiveness data above -10.0 diopters are available.

## Precautions

The safety and effectiveness of the LaserScan LSX excimer laser have not been established in patients presenting the following conditions:

- In patients with nearsightedness less than 1.0 diopters
- Severe dry eye (an eye requiring frequent eye lubricant drops to eliminate dryness or a foreign body sensation)
- Immunocompromised patients (lacking a proper immune response)
- Glaucoma (increased eye pressure)
- Uveitis (inflammation of the inside of the eye)
- Blepharitis (Inflammation of the eyelids)
- Psoriasis (dry, scaling skin)
- Systemic or topical use of steroids
- Pregnancy
- For patients under 18 years of age
- In patients who are taking sumatriptan (Imitrex)
- In patients with corneal neovascularization (blood vessels) within 1.0 mm of ablation zone
- In patients with progressive myopia (nearsightedness) or astigmatism, ocular disease, corneal abnormality, and previous corneal surgery or trauma in the ablation zone.

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Use of medications likely to affect wound healing (such as steroids orally {by mouth} or anti-cancer medication)

The effects of PRK on visual performance under poor lighting conditions have not been determined. Following PRK treatment, you may find it more difficult than usual to see in conditions such as very dim light, snow, or glare from bright lights at night.

## Who Is Eligible For PRK Surgery

People considering the PRK procedure should:

- Be at least 18 years of age;
- Have documented evidence that your nearsightedness has been stable (not changed by more than 0.5 diopters) for at least one year prior to your pre-operative exam;
- Have no current eye infection or disease or corneal abnormality;
- Have nearsightedness ranging from  $-1.0$  to less than  $-6.0$  diopters, with no more than 1.0 diopters of astigmatism.
- Be informed of PRK risks and benefits as compared to other available treatments for nearsightedness.
- Be able to lie flat without difficulty.
- Be able to tolerate local or topical anesthesia.
- Be willing to keep your eye on the fixation light for the entire PRK procedure.
- Be willing to sign an informed consent form, if provided by your eyecare professional.

## What You Need To Know Before The Surgery

If you are interested in having PRK surgery, first discuss it with your eye care provider.

You will first have pre-operative testing for surgery. This testing will include a complete medical history of the eye, a vision check, a mapping of the cornea and eye muscle movements. This will require your eyes to be dilated, so you may prefer to have someone drive you to this appointment. Other tests will be performed including determination of eye dominance, tear function and brightness testing.

During your pre-operative testing, you will discuss your case with the surgeon who will be performing your surgery. The surgeon will also review the risks and benefits associated with the surgery. Should you decide to go ahead with the surgery, your doctor will schedule a date for you to return for your surgery.

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You will be given instructions to follow before having the surgery. These instructions will also be told to you while at your pre-operative testing. These instructions include:

- You should have no food after midnight.
- You may have clear liquids up to 2 hours prior to arrival.
- You are to take your regular medications prior to arrival.
- You are instructed to shower, shampoo your hair, and wash your face with soap the morning of surgery.
- You are to provide a telephone number where you may be reached the evening of surgery for post-surgical call.
- You are to provide a name and a telephone number of a person to contact in case of an emergency.
- You will be given your one day post-operative appointment once your surgery has been scheduled.

Please arrange for a friend or family member to bring you to and from the surgery center on the day of your procedure. You will also need someone for your one-day follow up appointment. This is necessary because after surgery you may have a bandage soft contact lens in the operative eye and for a day or two you may experience light sensitivity and watering of the eye making driving difficult.

**WARNING** – If you wear contact lenses, it is very important to stop wearing them 2 – 4 weeks before the preoperative testing. Failure to do this will produce poor surgical results.

## The Day Of Surgery

When you arrive at the surgery center, you will check in. You will be taken to the pre-operative area. Here you will be given eye drops to numb your eyes. You will be taken into the surgery suite on a wheelchair. You will be helped onto the patient chair. The nurses will help you to lay face up on the chair. You will receive more eye drops.

The surgery takes about 10-20 minutes per eye. Your eye(s) will be held open by an instrument. You will be asked to look straight ahead at a light on the microscope. The doctor will gently wipe away the top layer cells (epithelium) prior to applying the laser. The layer of cells will grow back within 2 to 3 days after surgery. Once the doctor has removed this top layer of the eye he/she will position you under the microscope. After you have been positioned under the microscope the laser is then applied to the cornea.

The laser will reshape the cornea by breaking the molecular bonds (small bonds) of the tissue that make up the cornea.

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During the procedure you must stare at the light in the microscope until the doctor tells you that the surgery

is over, this will assure that the treatment is well centered.

After the procedure, your eye(s) will be covered with either a contact lens or a clear eye shield for protection during the first 24 hours after the procedure. Once the anesthetic (numbing) drops wear off a few hours after surgery you may experience a mild pain for up to 24 hours after surgery.

Do not rub or touch the treated eye for the first 3-5 days after surgery.

***WARNING*** – *It is very important that you keep looking at the green light during the procedure, even if the light fades or dim. Your surgical results depend on looking at his green light throughout treatment .*

## After Surgery

The bandage contact lens(es) or eye shield(s) will be removed at your one day follow up appointment. However, you will be asked to wear an eye shield at bedtime for the first week after your surgery for protection.

Your doctor will give you prescriptions for eye drops and a pain medication to use after your surgery as follows:

- An antibiotic eye drop which will help prevent infection
- An anti-inflammatory eye drop will control inflammation
- A prescription for oral (taken by mouth) pain medication in case it is needed.

The antibiotic drops will be used until the top layer of the eye has healed over, and the anti-inflammatory drops will be tapered off. After you finish these drops you can use artificial tears to help lubricate your eyes, if needed.

You will also be given a prescription for a stronger pain medication. This prescription is given because some patients with higher amounts of nearsightedness may have little more discomfort after surgery. This discomfort may last longer and be slightly more painful when more nearsightedness is corrected, since in these cases more corneal tissue was removed to reshape the eye.

Your vision after surgery will be changing over the next few weeks. Usually by 4-6 weeks after surgery, your vision will be stable. However, generally you can expect to return to normal daily activities within 1-2 days of your surgery. During these first few days it is recommended that you wear a pair of non-prescription sunglasses. By wearing sunglasses this will help protect the eye as well as help with any light

sensitivity that may occur. Some patients take longer so we ask that you keep your schedule flexible after your surgery.

During your healing period you may experience glare around lights and/or starbursting at night (a noticeable streaking of lights). These side effects will decrease over time and usually eventually stop.

Your eye(s) will be examined post-operatively at the following intervals: 1 day, 1 week, 1 month, 3 months, 6 months, 12 months.

***IMPORTANT – Your doctor will monitor you for any side effects if topical steroids were used. Possible side effects of prolonged topical steroids are ocular hypertension, glaucoma, or cataract formation.***

***IMPORTANT – Use eye drops and lubricants as directed by your doctor. Your surgical results depend upon the following your doctor's instructions.***

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## *Questions To Ask Your Doctor*

1. **Is the PRK procedure painful?**
2. **How long is the healing process?**
3. **When can I return to work following the procedure?**
4. **Are eye drops required after the PRK procedure?**
5. **What about eye shields or contact lenses?**
6. **Will I need glasses after the procedure?**
7. **Can the PRK procedure be done on both eyes on the same day?**

You may want to discuss these questions and any other concerns you may have with you doctor.

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## SUMMARY OF IMPORTANT INFORMATION

- *PRK is a permanent operation to the cornea and is irreversible.*
- *PRK does not eliminate the need for reading glasses, even if you never have worn them before.*
- *Your vision must be stable for at least one year before PRK surgery. You will need written evidence that your nearsightedness and/or astigmatism has changed less than 0.5 diopters.*
- *Pregnant and nursing women should wait until they are not nursing and not pregnant to have the surgery.*
- *You are not a good candidate if you have auto-immune diseases, or have a condition that makes wound healing difficult.*
- *PRK surgery may result in some discomfort. The surgery is not risk free. Please read this entire booklet, especially the section "Risks" before you agree to the surgery.*
- *PRK is not a laser version of radial keratotomy (RK) or automated lamellar keratectomy (ALK). These operations are completely different from each other.*
- *Alternatives to PRK include, but are not limited to, glasses, contact lenses, RK, and ALK.*
- *Some people, such as military pilots, have job related vision requirements that cannot be met by having RK or PRK.*
- *Before considering PRK surgery you should:*
  - Have a complete eye examination*
  - Talk with one or more eye care professionals about the potential benefits of PRK surgery, and the complications, risks, and time required for healing.*

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