PHYSICIAN MANUAL

LaserSight Technologies, Inc.

LSX

LASER SYSTEM

for

Laser Assisted In-Situ Keratomileusis (LASIK)

MYOPIA with and without astigmatism

Myopia from –0.5 to less than - 6.0 diopters spherical equivalent with astigmatism less than or equal to 4.5 diopters

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.

Carefully read all instructions prior to use. Observe all contraindications, warnings and precautions noted in these instructions. Failure to do so may result in patient and/or user complications

LaserSight Technologies, Inc.

Physician Manual

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EXCIMER LASER SYSTEM

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Laser Assisted In-Situ Keratomilieusis (LASIK)

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I. Device Description

The LaserSight LaserScan LSX Excimer Laser System (henceforth, to be called the LSX) that is the subject of this supplement differs from the unit previously approved for PRK in the amount of correction to be provided for a given refractive error (i.e., different treatment nomograms for LASIK and PRK). Except for that one nomogram difference, the other ablation characteristics (e.g., fluence, repetition rate, shot placement, etc.) remained the same.

The operative laser parameters are summarized as follows.

LaserScan LSX Excimer Laser Parameters		
Pulse Rate: 100 Hz Fluence: 80 - 100 mJ/cm		
Ablation Zone Size		
SER	Maximum Ablation Zone (mm)	Maximum Transition Zone (mm)
< 6.0 D	6.0	7.0

The LASIK procedure requires the use of a commercially available microkeratome that has been cleared for marketing via premarket notification. The device used in this study consists of a sterilization/storage tray, which includes the shaper head, a left/right eye adapter, suction ring, suction handle, blade handling pin, and corneal reference marker. The instrument motor, tonometer, cleaning brush, disposable blades, power/suction supply unit with vacuum and motor footswitches and power cords are provided as separate components in an accessory stand and equipment suitcase which complete the system.

II. INDICATIONS FOR USE

The LaserScan LSX Excimer Laser is intended for Laser Assisted In-Situ Keratomilieusis (LASIK):

- For the reduction or elimination of myopia ranging from –0.5 to less than –6.0 diopters (D) spherical equivalent, with astigmatism less than or equal to 4.5 D, as measured at the spectacle plane;

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- In patients with documentation of a stable manifest refraction defined as ≤ 0.50 D, or ≤10% of preoperative spherical equivalent refraction (SER) shift over one year prior to surgery; and,
- In patients who are 18 years of age or older.

III. CONTRAINDICATIONS

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

- Active ocular / systemic infection in operative eye
- Fuch's corneal dystrophy in either eye
- Keratoconous in either eye
- 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 LASIK surgery only after careful assessment of the potential risk and benefit to the specific patient:

    - Collagen vascular disorders
    - An unstable refraction defined as > 0.5 D or >10% of preoperative SER shift over one year prior to surgery
    - Active systemic disease

2. LASIK is not recommended in patients with a history of ophthalmic Herpes simplex or Herpes zoster.

V. PRECAUTIONS

A. General

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

- Severe dry eye
- Immunosuppression
- Glaucoma
- Uveitis
- Blepharitis
- Psoriasis

- Systemic or topical use of steroids
- For patients under 18 years of age
- Use of medications or systemic diseases likely to affect wound healing
- In patients with corneal neovascularization (abnormal blood vessels) within 1.0 mm of the area of the cornea where LASIK will be performed
- In patients with progressive myopia or astigmatism, ocular disease, corneal abnormality, and previous corneal surgery or trauma in the ablation zone
- In patients with myopia of 6.0 or more diopters spherical equivalent or astigmatism more than 4.5 diopters of astigmatism

In the clinical study, the number of retreated eyes was too small (11 eyes) to draw any definitive conclusions regarding safety and effectiveness.

Treatments for nearsightedness without astigmatism may result in undercorrections (reduced effectiveness of the procedure). In the clinical trial, 24% of eyes (treated for sphere only) were undercorrected by greater than 1.0 diopter at 6 months.

The effects of LASIK on the patient's vision under poor lighting conditions have not been determined. Following LASIK the patient may find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog or glare from bright lights at night. The patient's pupil should be measured in dim conditions. If the patient's pupil size is greater than the area of the cornea where LASIK will be performed, 6 mm, the patient may experience problems with their vision after surgery.

B. Patient Selection- Inclusion/Exclusion Criteria

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

- 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 or gas permeable lenses and at least 3 weeks for hard (PMMA) lenses. Prior to treatment, patients must have a stable manifest refraction and keratometry of $\leq$ 0.5D over 1 week of discontinued lens wear.

- Evaluation of the optic nerve and measurement of the intraocular pressure are necessary prior to surgery. 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 LASIK 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 LASIK 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 with and without astigmatism. These alternatives corrections include, but are not limited to spectacles, contact lenses, and other refractive surgeries such as photorefractive keratectomy (PRK), radial keratotomy, astigmatic keratometry, implantable contact lenses (ICL) or automated lamellar keratoplasty.

C. Potential Hazards to Health Care Personnel

- 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.

VI. ADVERSE EVENTS

The following transient complications might be expected with patients undergoing the LASIK 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 LASIK procedure are loss of best spectacle corrected visual acuity, overcorrection, increase in refractive cylinder, abnormal glare, double vision, sensitivity to bright lights, difficulty with night vision, increase in intraocular pressure, corneal haze, corneal infection/ulcer/infiltrate, corneal decompensation/edema, lens abnormality and secondary surgical intervention, problems associated with the flap, including a lost, misplaced or misaligned flap, retinal detachment, and retinal vascular accidents.

A. Adverse Events and Complications

The analysis of safety was based on the cohort of all 204 eyes treated in the clinical study. Those adverse events occurring at 6 months after treatment included 0.7% eyes that had an

IOP increase of > 10 mm Hg above baseline, and any reading above 25 mm Hg. (Table 1). Intraoperative complications are presented in Table 2. These include 2.8 % eyes that had epithelium in the interface/ingrowth at 6 months. Overall, the incidence of complications in this study were quite low.

Table 1
Adverse Events

Adverse Events	1 Month		3 Months		6 Months	
	n/N	%	n/N	%	n/N	%
Macerated Flap	0/202	0.0	0/204	0.0	0/143	0.0
Perforated Cornea	0/202	0.0	0/204	0.0	0/143	0.0
Incorrect manifest entered into laser	0/202	0.0	0/204	0.0	0/143	0.0
Corneal Infiltrate, ulcer or perforations	0/202	0.0	0/204	0.0	0/143	0.0
Epithelial Defect involving keratectomy	0/202	0.0	0/204	0.0	0/143	0.0
Corneal edema	0/202	0.0	0/204	0.0	0/143	0.0
Epithelium in interface w/loss > 2 lines BSCVA	0/202	0.0	0/204	0.0	0/143	0.0
Intraocular Infection	0/202	0.0	0/204	0.0	0/143	0.0
Uncontrolled IOP with increase of > 10 mm Hg above baseline and any reading above 25 mmHg	0/202	0.0	0/204	0.0	1/143	0.7
Lost ,misplaced, misaligned, or dislocated flap	0/202	0.0	0/204	0.0	0/143	0.0
Melting of the flap	0/202	0.0	0/204	0.0	0/143	0.0
Flap Necrosis	0/202	0.0	0/204	0.0	0/143	0.0
Decrease of > 10 letters BSCVA at 6 months not due to irregular astigmatism	0/202	0.0	0/204	0.0	0/143	0.0
Loss of > 2 lines BSCVA at 6 months	0/202	0.0	0/204	0.0	0/143	0.0
Perforation of cornea into anterior chamber	0/202	0.0	0/204	0.0	0/143	0.0
Retinal detachment	0/202	0.0	0/204	0.0	0/143	0.0
Retinal vascular accidents	0/202	0.0	0/204	0.0	0/143	0.0

Table 2
Complications

Complications	1 Month		3 Months		6 Months	
	n/N	%	n/N	%	n/N	%
Keratectomy Irregular	0/202	0.0	0/204	0.0	0/143	0.0
Epithelial Defect	0/202	0.0	0/204	0.0	0/143	0.0
Cap Striae	1/202	0.5	0/204	0.0	0/143	0.0
Free Cap	0/202	0.0	0/204	0.0	0/143	0.0
Decentered Ablation	0/202	0.0	0/204	0.0	0/143	0.0
Interrupted Treatment	0/202	0.0	0/204	0.0	0/143	0.0
Persistent Subject Movement	0/202	0.0	0/204	0.0	0/143	0.0
Epithelium in the Interface/Ingrowth	9/202	4.5	5/204	2.5	4/143	2.8
Corneal Erosion	0/202	0.0	2/204	1.0	0/143	0.0
Foreign Body Sensation	0/202	0.0	0/204	0.0	0/143	0.0
Pain	0/202	0.0	0/204	0.0	0/143	0.0
Ghosts/Double Images	0/202	0.0	2/204	1.0	0/143	0.0
Flap not the Size Intended	1/202	0.5	0/204	0.0	0/143	0.0
Corneal Edema	4/202	2.0	0/204	0.0	0/143	0.0
Peripheral Epithelial Defect	1/202	0.5	0/204	0.0	0/143	0.0
Flap Tear/Defect	0/202	0.0	0/204	0.0	0/143	0.0
Lamellar Keratitis (SOS/DLK)	0/202	0.0	0/204	0.0	0/143	0.0
Debris in the Interface	0/202	0.0	0/204	0.0	0/143	0.0

B. Subjective Patient Adverse Events

In the clinical study, at baseline and 6 months after surgery, patients were asked to rate a series of subjective events. The most frequent events, reported as "often" or "always", were night vision problems and clarity changes over time. The exact percentages are listed below:

Table 3
Patient Events at Preop and 6 months

PATIENT SYMPTOMS	Eyes Without astigmatism		Eyes With astigmatism	
	PREOP n/N (%)	6 MO N/N (%)	PREOP n/N (%)	6 MO n/N (%)
Foreign Body Sensation	0/52 (0.0)	2/24 (8.3)	3/144 (2.1)	5/55 (9.1)
Burning Feeling	1/52 (1.9)	0/24 (0.0)	5/144 (3.5)	3/55 (5.5)
Watery Eyes	5/52 (9.6)	0/24 (0.0)	9/144 (6.3)	3/55 (5.5)
Halos/Starbursts	5/52 (9.6)	3/24 (12.5)	18/144 (12.5)	2/55 (3.6)
Double Vision	0/52 (0.0)	0/23 (0.0)	1/144 (0.7)	0/54 (0.0)
Clarity Changes	5/52 (9.6)	7/24 (29.2)	9/144 (6.3)	5/55 (9.1)
Night Vision Problems While Driving	12/52 (23.1)	9/24 (37.5)	40/144 (27.8)	14/55 (25.5)

VII. Clinical Results

A prospective clinical trial in healthy eyes was performed at ten US clinical sites under investigational device exemption (IDE) application # G980248. The data from this study served as the basis for the approval decision. Specifically, safety and effectiveness outcomes at 6 months postoperatively were assessed as stability was reached by that time. Outcomes at 12 months postoperatively were also evaluated for confirmation of stability. The IDE study is described in detail as follows:

A. Study Objectives

The objectives of the study were to determine the safety and effectiveness of the LSX for LASIK treatment of spherical equivalent refraction (SER) of up to -15.00 D (–0.50 to –15.00 D of myopia with and without astigmatism of –0.50 to –6.00 D) and to assess stability of the achieved visual outcome.

B. Study Design

The study was a prospective, non-randomized, 10 center, and 23 surgeon study where the primary control was the preoperative state of the treated eye (i.e., comparison of pretreatment and post-treatment visual parameters in the same eye).

C. Inclusion and Exclusion Criteria

Study subjects were 18 years or older and had signed an informed consent. Enrollment occurred if the subject met these conditions: -0.50 to –15.00 D SER and spherical myopia with up to 6.0 D astigmatism; best spectacle corrected visual acuity of 20/25 or better in the operative eye, normal corneal topography, and stable manifest refraction as documented by $\leq$ 0.5 D change or $\leq$10% of (SER) shift within twelve months prior to surgery. Contact lens wearers had to refrain from contact lens use prior to baseline examination (2 weeks for soft / gas permeable lenses, 3 weeks for hard lenses).

Subjects not meeting the above inclusion criteria were excluded from the study. In addition, subjects who exhibited any of the following conditions were excluded: keratoconus, active ocular disease or corneal abnormality, corneal neovascularization within 1 mm of the intended ablation zone, systemic disease likely to affect wound healing, unstable keratometry readings with irregular shaped mires or corneascope photographs with broken central rings, use of systemic medications likely to affect wound healing, immunodeficiency, previous intraocular or corneal surgery, glaucoma or glaucoma suspect, corneal thickness that would require ablation within 250 microns of endothelium, sensitivity to study medications, pregnancy/lactation and participation in another ophthalmic trial within the past 30 days.

D. Study Plan, Patient Assessments and Efficacy Criteria

Subjects were evaluated pre-operatively and post-operatively at day and week one and at months 1, 3, 6, and 12. Pre-operative objective measurements included: uncorrected and best corrected visual acuity, manifest or cycloplegic refraction, keratometry, intraocular pressure,

pachymetry, clinical assessment of corneal clarity, clinical assessment of anterior chamber, vitreal, retinal and lens status, assessment of complications and adverse reactions, and assessment of pupil size in mesopic (dim) lighting conditions.

Additionally, corneal topography was performed pre-operatively to rule out corneal abnormalities, such as keratoconus.

Subjects were permitted to have second eyes (fellow eyes) treated at the same time as the first eye (primary eye) In addition, subjects were eligible for retreatment if the treated eye remained undercorrected and /or regression decreased the uncorrected vision to 20/30 or worse and the eye had a stable refraction.

Effectiveness was evaluated based on improvement in uncorrected visual acuity, reduction in mean spherical equivalent refractive error, stability of refractive outcome through the post-operative period, and accuracy of correction. Descriptive statistics were provided on data up to 6 months.

The primary efficacy variables for this study were improvement of UCVA and accuracy of manifest refraction spherical equivalent (MRSE).

E. Study Period, Investigational Sites and Demographic Data

1. Study Period

   A total of 204 eyes in 109 subjects were treated between August 17, 1999 and June 20, 2000.

2. Demographics and Baseline Characteristics

The demographics of this study population are very typical of a contemporary refractive surgery trial performed in the US. The cohort consists primarily of Caucasians. The majority of subjects were male. The mean age was 39.8 years at the time of surgery.

Table 4 Demographic Characteristics 109 subjects (204 eyes)	
	109 subjects (204 eyes)
Male	60
Female	49
Race	
Caucasian	101
Hispanic	2
Asian	3
Black	3
Contact Lens History	
None	85
Soft	107
RGP	12
PMMA	0
Mean Age (Range)	39.8 20- 68

F. Data Analysis and Results

1. Baseline Characteristics

Table 5 contains a summary of the preoperative refractive errors of the entire cohort. Note that the evaluation of the effectiveness (see section 2e. below) concerns the subset of eyes with treatment less than 6.0 diopters spherical equivalent refraction (SER). Baseline characteristics were as follows:

Table 5 Baseline Characteristics	
Spherical equivalent refraction (SER)	All Eyes (N=204) Number (%)
0.00 - 0.99 D	6/204 (2.9)
1.00 - 1.99 D	45/204 (22.1)
2.00 - 2.99 D	44/204 (21.6)
3.00 - 3.99 D	35/204 (17.2)
4.00 - 4.99 D	37/204 (18.1)
5.00 - 5.99 D	16/204 (7.8)
6.00 - 6.99 D	11/204 (5.4)
7.00 - 7.99 D	1/204 (0.5)
8.00 - 8.99 D	3/204 (1.5)
9.00 - ≤15 D	6/204 (2.9)
TOTAL	204 (100.0)
Cylinder	
≤ 0.75D	98 (48.0)
1.00D	25 (12.3)
1.25D	17 (8.3)
1.50D	9 (4.4)
1.75D	9 (4.4)
2.00D	7 (3.4)
2.25D	7 (3.4)
2.50D	6 (2.9)
2.75D	5 (2.5)
3.00D	5 (2.5)
>3.00D	16 (7.8)
TOTAL	204 (100.0)

2. Postoperative Characteristics and Results

a. Patient Accountability

There were 210 eyes enrolled and 204 eyes treated. Accountability for all eyes treated was 86.8% at month 3 and 84.2% at month 6. The following cohorts were used for analysis:

- Safety—all eyes (n=204)
- Effectiveness—eyes with treatment of 0.5 to less than 6.0 diopters SER (n=183)

Stability—subset of all eyes seen at any two consecutive visits, and subset of all eyes seen at all visits (1,3,6 and 12 months)

b. Stability of Outcome

In the 3-6 month window, greater than 95% of eyes experienced a change of MRSE not exceeding ± 1.0D. Furthermore, the mean of the paired-difference of MRSE progressively decreased over time, and reached a change of less than 0.02 D in the 3-6 months window (Tables 6 to 7). The changes in the 6-12 months window for the entire cohort remained at less than 0.05 D; thus, stability was demonstrated by 6 months postoperative.

Table 6
Stability of Manifest Refraction
(Eyes with two consecutive visits through 12 Months)

Change in Spherical Equivalent	1 and 3 Months n/N (%)	3 and 6 Months n/N (%)	6 and 12 Months n/N (%)
≤ 1.00 D	164/168 (97.6)	103/106 (97.2)	79/79 (100.0)
Mean Difference	-0.13	-0.02	0.03
SD	0.37	0.42	0.38
95% CI (Mean)	(-0.15, -0.11)	(-0.05, 0.01)	(-0.00,0.06)

Table 7
Stability of Manifest Refraction
Eyes that had every exam through 12 Months

Change in Spherical Equivalent Between	1 and 3 Months n/N (%)	3 and 6 Months n/N (%)	6 and 12 Months n/N (%)
≤ 1.00 D	71/72 (98.6)	70/72 (97.2)	72/72 (100.0)
Mean Difference	-0.11	0.02	0.05
SD	0.35	0.37	0.38
95% CI (Mean)	(-0.14, -0.08)	(-0.01, 0.05)	(0.02, 0.08)

c. Effectiveness Outcomes

The analysis of effectiveness was based on the 111 eyes evaluable at the 6 month stability timepoint for the cohort of subjects with preoperative SER 0.5 to less than 6.0 D. This analysis includes eyes where the cylinder treatment differed from the full

preoperative cylinder. Key efficacy outcomes over the course of the study and at the point of stability stratified by diopter of MRSE are presented in tables 8 and 9. At 6 months, 93.5% of eyes had UCVA 20/40 or better and 49.5% of eyes had UCVA 20/20 or better.

Treatments for nearsightedness without astigmatism resulted in undercorrection for some eyes.

Table 8
Summary of Key Effectiveness Variables Over Time
Eyes with Preop MRSE <6D

	1 Month n/N (%)	3 Months n/N (%)	6 Months n/N (%)	12 Months n/N (%)
Efficacy Variables				
UCVA 20/20 or better*	89/167 (53.3)	73/150 (48.7)	53/107 (49.5)	43/83 (51.8)
UCVA 20/40 or better*	154/167 (92.2)	136/150 (90.7)	100/107 (93.5)	81/83 (97.6)
MRSE ± 0.50 D	124/175 (70.9)	105/155 (67.7)	72/111 (64.9)	57/84 (67.9)
MRSE ± 1.00 D	164/175 (93.7)	139/155 (89.7)	98/111 (88.3)	73/84 (86.9)
MRSE ± 2.00 D	174/175 (99.4)	153/155 (98.7)	109/111 (98.2)	83/84 (98.8)

*For all eyes minus those intentionally treated for monovision.

Table 9
Summary of Key Efficacy Variable
At 6 months (Stratified by Pre-op MRSE)

	< -1.0 D n/N (%)	-1.0 to -1.99 D n/N (%)	-2.0 to -2.99 D n/N (%)	-3.0 to -3.99 D n/N (%)	-4.0 to -4.99 D n/N (%)	-5.0 to -5.99 D n/N (%)	CUM TOTAL < 6 D n/N (%)
Efficacy Variables							
UCVA 20/20 or better*	3/3 (100)	16/29 (55)	10/20 (50)	8/17 (47)	13/25 (52)	3/13 (23)	53/107 (50)
UCVA 20/40 or better*	3/3 (100)	29/29 (100)	20/20 (100)	15/17 (88)	22/25 (88)	11/13 (85)	100/107 (93)
MRSE ± 0.50 D	1/3 (33)	23/30 (77)	13/20 (65)	11/19 (58)	15/26 (58)	9/13 (69)	72/111 (65)
MRSE ± 1.00 D	3/3 (100)	29/30 (97)	19/20 (95)	16/19 (84)	21/26 (81)	10/13 (77)	98/111 (88)
MRSE ± 2.00 D	3/3 (100)	30/30 (100)	20/20 (100)	18/19 (95)	25/26 (96)	13/13 (100)	109/111 (98)

* For all eyes minus those treated for monovision.

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Analysis of the correction of the cylindrical component of the astigmatic eyes is presented in Tables 10 and 11.

There was a mean reduction in absolute cylinder of 63.2% at 6 months.

Table 10
Cylinder Correction Efficacy Stratified by Pre-Operative Cylinder
(N=88)

Pre-Operative Cylinder	6 Months Reduction of Absolute Cylinder	
	% Reduction[1] Mean	**Ratio[2] Mean**
≤ 1.0D	-49.8	0.50
> 1.0 to ≤ 2.0D	-66.3	0.34
> 2.0 to ≤ 3.0D	-78.4	0.22
> 3.0 to ≤ 4.0D	-94.8	0.05
> 4.0 to ≤ 4.5D	-86.5	0.14
Total	-63.2	0.37

1. [(Post-op cylinder - Pre-op cylinder) / Pre-op cylinder] x 100
2. Post-op cylinder / Pre-op cylinder

The Intended Refractive Correction ("IRC") had a mean of 1.50 D with a median of 1.25 D (range –1.50 to 4.50 D). The Surgically Induced Refractive Correction ("SIRC") had a mean of 1.41 D with a median of 1.00 D (range –1.50 to 5.50 D). The vector magnitude ratio (SIRC/IRC) was 0.77 at 6 months.

Table 11
Cylinder Correction Efficacy Stratified by Pre-Operative Cylinder
(N=90)

Pre-Operative Cylinder	6 Months Achieved vs Intended Vector Magnitude Ratio (Achieved/Intended) Mean
≤ 1.0D	0.62
> 1.0 to ≤ 2.0D	0.82
> 2.0 to ≤ 3.0D	0.98
> 3.0 to ≤ 4.0D	1.03
> 4.0 to ≤ 4.5D	1.04
Total	0.77

d. Key Safety Results

The analysis of safety was based on the cohort of all 204 eyes treated in the clinical study. Safety was evaluated based on maintenance of BSCVA, surgical induction of additional refractive cylinder, and adverse events, complications and other clinical findings were noted as appropriate.

Table 12 presents a summary of key safety variables for all eyes treated at the 1, 3 and 6 month visits. The proportion of eyes at 1 month with a BSCVA worse than 20/25 if 20/20 or better preoperatively was 2.1%. No eyes were reported to have a BSCVA worse than 20/40 or a loss of >2 lines of BSCVA at any visit.

Table 12

Summary of Key Safety Variables Over Time
(all eyes treated)

Safety Variable	1 Month N= 192 n (%)	3 Months N= 174 n (%)	6 Months N=123 n (%)
Loss of >2 lines BSCVA.	0 (0.0)	0 (0.0)	0 (0.0)
Loss of ≥ 2 Lines BSCVA	4 (2.1)	1 (0.6)	1 (0.8)
BSCVA worse than 20/40.	0 (0.0)	0 (0.0)	0 (0.0)
Increase of > 2D cylinder#	0/52 (0.0)	0/44 (0.0)	0/33 (0.0)
BSCVA worse than 20/25 if 20/20 or better preoperatively	4 (2.1)	0 (0.0)	0 (0.0)

e. Retreatment

Fourteen eyes were retreated with the study laser due to undercorrection and/or regression. Table 13 contains the outcomes of the retreated eyes. There were insufficient data to form any definitive conclusions regarding the safety and effectiveness of retreatment with this device.

Table 13
Summary of Key Safety and Efficacy Variables
Eyes Retreated – Last Treatment

	1 Month n/N (%)	3 Months n/N (%)	6 Months n/N (%)
Efficacy Variables			
UCVA 20/20 or better*	13/14 (92.9)	8/10 (80.0)	---
UCVA 20/40 or better*	14/14 (100)	10/10 (100)	---
MRSE ± 0.50 D	11/13 (84.6)	10/11 (90.9)	---
MRSE ± 1.00 D	13/13 (100)	10/11 (90.9)	---
MRSE ± 2.00 D	13/13 (100)	11/11 (100)	---
Safety Variables			
Loss of > 2 lines BSCVA	0/13 (0.0)	0/11 (0.0)	---
BSCVA worse than 20/40	0/13 (0.0)	0/11 (0.0)	---
Increase of > 2 D cylinder#	0/3 (0.0)	0.3 (0.0)	---
BSCVA worse than 20/25 if 20/20 or better preoperatively	0/13 (0.0)	0/11 (0.0)	---

*For all eyes minus those intentionally treated for monovision.
For eyes treated for spherical correction only.

f. Patient Satisfaction

Subjects were asked to rate their satisfaction with the surgery on a scale of 1-10, 1 "being very disappointed" and 10 "being very satisfied". The results of the questionnaire are listed below:

Table 14
Patient Satisfaction at 6 Months

	N	Mean	Median	Std	Range
Patient Satisfaction (1-10)	77	8.7	10	2	3.0 - 10.0

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 to document the history of hypertension, heart/lung or breathing problems, thyroid or kidney problems or diabetes mellitus, autoimmune diseases and collagen vascular disorders. Complete medical evaluation for pharmaceutical agents is reviewed as well as any known allergies to medications.

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.

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.

As with any refractive surgical procedure, the patient's pupil should be measured in dim lighting conditions. If the pupil size is greater than the optical zone, 6mm the patient may experience qualitative visual symptoms post-operatively. The physician should use their clinical judgement to make this determination.

F. STABILITY OF CONTACT LENS WEARERS

All patients who wear contact lenses will be asked to discontinue wearing them prior to the LASIK 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.

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

IX. Treatment Procedure

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

The LASIK surgical technique consists of ablating a lens shaped volume of tissue from the cornea, after a corneal flap has been created with a manual or automated microkeratome. 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 ablation area. The required depth of ablation is proportional to the number of diopters to be corrected.

A. Enter the patient's name and gender.
B. Enter eye to be treated, average keratometry reading and vertex distance.
C. Enter the spectacle refraction (sphere and/or cylinder with axis) into the computer.
D. Enter patient pachymetry and LASIK cap depth into computer.
E. Align patient under the laser and get patient in focus (for detailed description refer to operator's manual)
F. Apply a topical anesthetic agent into the operative eye.
G. Use a sterile eye lid speculum to keep the eye open for surgery.
H. Mark the cornea with an optical zone marker (typically 7.0 mm). The corneal flap is created with the microkeratome and afterwards the flap is lifted.
I. The patient is instructed to fixate on the flashing light immediately after the flap has been lifted. 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.
J. 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.
K. After surgery is complete apply an antibiotic, steroid and or a non-steroidal eye drop, (at the physician's discretion).
L. A bandage soft contact lens may be placed and the patient is instructed to wear a protective shield or sunglasses.
M. The patient is given post operative instructions and a follow up appointment.

Note: For a more detailed explanation of the operator's procedure refer to the operator's manual.

X. References

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Patient Information

Laser Assisted In-Situ Keratomilieusis (LASIK) for the correction of:

Myopia with and without astigmatism

Nearsighted patients from –0.5 to less than - 6.0 diopters spherical equivalent with astigmatism less than or equal to 4.5 diopters

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 System
LaserSight Technologies, Inc.
3300 University Blvd., Suite 140
Winter Park, Florida 32792

Table of Contents

Introduction

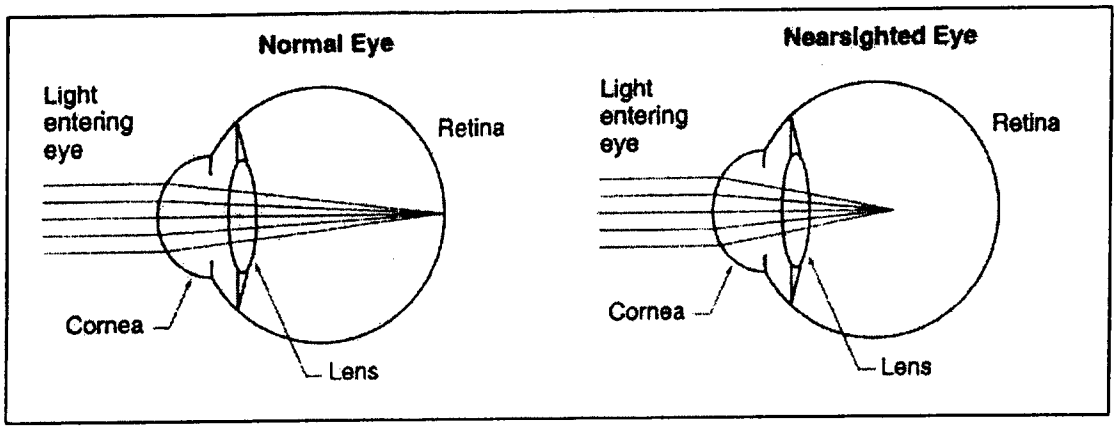
The information in this booklet is provided so you are able to make an intelligent, informed decision about having LASIK eye surgery. Some other ways to correct nearsightedness and astigmatism are glasses, contact lenses, and other kinds of refractive surgery. Your doctor can explain these alternatives.

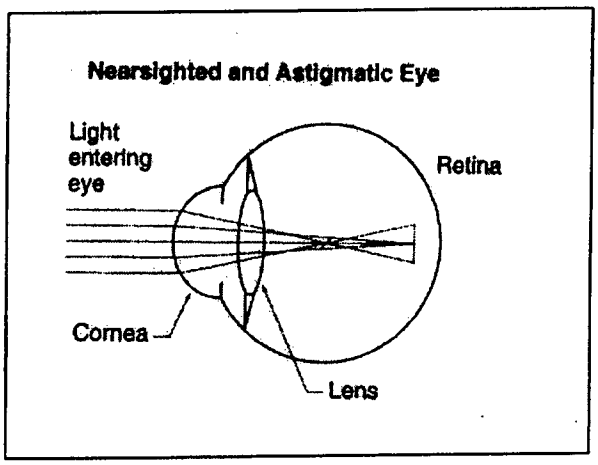
Should you require LAISK in both eyes, your doctor may recommend LASIK for both eyes at the same time. Sometimes it is better to have LASIK done on only one eye. You and your doctor should decide whether it would be better to treat one eye or both eyes at the same time.

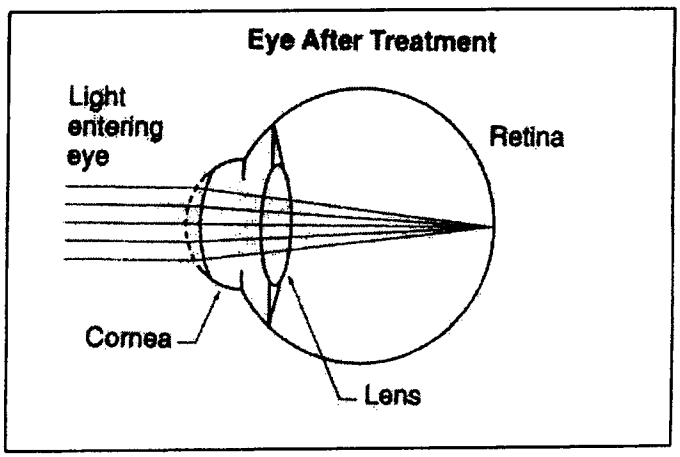
Please note that no guarantees can be made as to the exact result of any surgical operation. Take as much time as you need to review this information before making your decision to have this surgery. You may decide not to make any decision at this time. Please ask any questions you have after reading this information. Some people, such as military pilots, have job-related vision requirements that cannot be met by having refractive surgery such as LASIK.

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 retina , it is referred to as a refractive error. Nearsightedness (Myopia) is caused by light focusing in front of the retina. In general, nearsighted people can see close but far objects are blurry. Many nearsighted patients, but not all, also have astigmatism, which means that the eye is shaped more like a football than a soccer ball and the cornea is irregularly shaped. These patients will see objects blurry near or far. Eyeglasses and contact lenses can correct all types of refractive error by putting lenses in front of the eye. Discuss with your doctor which procedure is more ideal for you. All methods of refractive correction move the point where the light focuses on the retina, allowing you to see a clearer image. The LSX Excimer Laser System is approved for treating eyes with myopia (-0.5 to less than -6.0 diopters spherical equivalent) with astigmatism less than or equal to 4.5 diopters.







What is LASIK?

LASIK is a surgical procedure to correct refractive errors of the eye. A thin flap of cornea (the clear covering over the colored part of the eye) will be created using a special instrument referred to as a microkeratome. The flap is lifted and the excimer laser beam reshapes the cornea so that light can focus properly on the retina. After the laser beam removes a thin layer of corneal tissue, the flap is put back into place. No stitches are required.

The LASIK procedure uses an excimer laser by using ultraviolet light to reshape the corneal surface.

LASIK is performed on one eye at a time. The second eye may be treated if you and your doctor consider it appropriate and safe. LASIK is generally associated with quick visual recovery and only minor discomfort, which may be controlled with pain medication, in the first 24 hours after the procedure.

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In the LaserSight U.S. clinical studies, 50% of all treated eyes could see 20/20 or better without glasses after a single LASIK procedure and 93% could see 20/40 or better six months after the procedure. Even though their vision without glasses improved, some patients still needed glasses or contact lenses after LASIK. LASIK may 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 remove tissue and reshape the cornea. The laser is controlled by computer software, which tells the laser how much tissue to remove to correct a given refractive error.

Risks of LASIK Surgery

As with any surgical procedures there are risks associated with LASIK 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 laser surgery on the same eye. In the clinical study 8.1% of eyes originally treated for nearsightedness without astigmatism had additional LASIK surgery on the same eye due to undercorrection of refractive error; 7.4% of eyes originally treated for nearsightedness with astigmatism had additional LASIK surgery on the same eye.

The first week following surgery:

During the first 4-7 days following surgery, you will be instructed to wear protective shields at night and sunglasses during the day. It may be that you experience some pain, discomfort, tearing, sensitivity to bright lights and blurred vision. Typically, after the first 24-48 hours these symptoms will resolve though your vision may continue to be blurry.

The first one to six months following surgery:

It is possible that during the first one to six months following surgery, your vision may be blurry as your eye (cornea) continues to heal. It is very important that you follow your doctor's orders, which will include follow-up office visits and possibly medications.

Six months to a year or more following surgery:

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

- 2.8 % had epithelial ingrowth (epithelium growing under the flap), this could result in astigmatism and the physician may need to lift the flap and scrape away the epithelial cells from underneath the flap.
- 0.7% had an uncontrolled intraocular pressure of > 10 millimeters of mercury above baseline and any reading above 25 millimeters of mercury. If the intraocular pressure remains elevated your doctor may need to treat you with a glaucoma medication.
- Some eyes treated (2.1%) had a slight decrease (loss of 1 line) of vision with glasses at 1 month after surgery, but no eyes showed a decrease of vision with glasses at 3 months or more after surgery.

In the clinical study, before and 6 months after surgery patients were asked to rate a series of subjective events. The most frequent events, reported as "often" or "always", were night vision problems and clarity changes over time. The exact percentages are listed below:

Patient Events at Preop and 6 months
All Eyes Treated

PATIENT SYMPTOMS	Without astigmatism		With astigmatism	
	PREOP n/N (%)	**6 MO** n/N (%)	**PREOP** n/N (%)	**6 MO** n/N (%)
Foreign Body Sensation	0/52 (0.0)	2/24 (8.3)	3/144 (2.1)	5/55 (9.1)
Burning Feeling	1/52 (1.9)	0/24 (0.0)	5/144 (3.5)	3/55 (5.5)
Watery Eyes	5/52 (9.6)	0/24 (0.0)	9/144 (6.3)	3/55 (5.5)
Halos/Starbursts	5/52 (9.6)	3/24 (12.5)	18/144 (12.5)	2/55 (3.6)
Double Vision	0/52 (0.0)	0/23 (0.0)	1/144 (0.7)	0/54 (0.0)
Clarity Changes	5/52 (9.6)	7/24 (29.2)	9/144 (6.3)	5/55 (9.1)
Night Vision Problems While Driving	12/52 (23.1)	9/24 (37.5)	40/144 (27.8)	14/55 (25.5)

Subjects were asked to rate their overall satisfaction with the surgery on a scale of 1-10, 1 "being very disappointed" and 10 "being very satisfied". The results of the questionnaire are listed below:

Patient Satisfaction
All Eyes Treated

	N	Mean	Median	Std Dev	Range
Patient Satisfiaction (1-10)	77	8.7	10	2	3.0 - 10.0

Contraindications

You should not have LASIK surgery if you have the following conditions:

- Active ocular or systemic infection in operative eye
- Fuch's corneal dystrophy in either eye
- Keratoconous in either eye
- Central corneal scars affecting visual acuity
- Autoimmune or immunodeficiency diseases.
- Pregnant or nursing women
- You are taking one or both of the following medications
  - Isotretinoin (Accutane)
  - Amiodarone hydrochloride (Cordarone)

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 refractive error is changing 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}).
- You have a history of Herpes simplex, Herpes zoster, or previous Herpetic keratitis (viral infections affecting the eye).

Precautions

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

- Severe dry eye

- Immunosuppression
- Glaucoma
- Uveitis
- Blepharitis
- Psoriasis
- Systemic or topical use of steroids
- For patients under 18 years of age
- Use of medications likely to affect wound healing
- In patients with corneal neovascularization (abnormal blood vessels) within 1.0 mm of the area of the cornea where LASIK will be performed
- In patients with progressive myopia or astigmatism, ocular disease, corneal abnormality, and previous corneal surgery or trauma in the ablation zone
- In patients with nearsightedness with or without astigmatism with 6.0 or more diopters spherical equivalent or more than 4.5 diopters of astigmatism.

In the clinical study, the number of retreated eyes was too small (11 eyes) to draw any definitive conclusions regarding safety and effectiveness

Treatments for nearsightedness without astigmatism may result in undercorrections (reduced effectiveness of the procedure). In the clinical trial, 24% of eyes were undercorrected by more than 1.0 diopter.

The effects of LASIK on your vision under poor lighting conditions have not been determined. Following LASIK you may find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog or glare from bright lights at night. Your pupil should be measured in dim conditions. If your pupil size is greater than the area of the cornea where LASIK will be performed, 6 mm, you may experience problems with your vision after surgery.

Who Is Eligible For LASIK Surgery

If you are considering the LASIK procedure, you must:

- Be at least 18 years of age;
- Have documented evidence that your refraction 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;
- Be informed of LASIK risks and benefits as compared to other available treatments for refractive errors
- 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 LASIK procedure.
- Be willing to sign an informed consent form.

What You Need To Know Before The Surgery

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

You will first have pre-operative testing. This testing will include a complete medical history, a vision check, and mapping of the cornea. This will require your eyes to be dilated, so you may prefer to have someone drive you to and from this appointment.

During your pre-operative testing, you will discuss your case with a healthcare professional who 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.
You will be given instructions to follow before having the surgery.

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. Because following surgery it may be difficult to drive.

WARNING **– If you wear contact lenses, it is very important to stop wearing soft and gas permeable lenses 2 weeks and hard lenses 3 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 and be taken to the pre-operative area. Here you will be given eye drops to numb your eyes and you will be taken into the surgery suite. The nurses will help you into the patient chair and ensure your proper alignment. Then you will receive more drops to numb your eye.

The surgery typically takes about 10-20 minutes per eye. Your eye will be held open by an instrument. The doctor will place a suction ring on your eye and then the corneal flap will be made with a surgical instrument (a microkeratome). The flap will be lifted and after you have been positioned under the microscope the laser beam is then applied to the cornea. At this time you will be asked to look straight ahead at a small beam of light. The laser beam will reshape the cornea by breaking the molecular (small) bonds of the tissue that make up the cornea.

During the procedure you must stare at the small beam of light until the doctor tells you that the surgery is over, this will assure that the treatment is well centered.

After the procedure, you will wear a protective eye shield during the first 24 -48 hours after the procedure. Once the anesthetic (numbing) drops wear off a few hours after surgery you may experience mild pain.

WARNING *- Do not rub or touch the treated eye for the first month after surgery.*

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

After Surgery

The eye shield may 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 may give you prescriptions for eye drops and a pain medication to use after your surgery.

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. Wearing sunglasses will help protect the eye as well as help with any light sensitivity that may occur.

During your healing period you may experience glare around lights and/or starbursting at night (a noticeable streaking of lights) as well as other subjective visual symptoms (see table page 4) These side effects often decrease over time.

Your eye(s) will be examined post-operatively, per your doctor's instructions.

IMPORTANT – Your doctor will monitor you for any side effects if topical steroids were used.

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

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Questions To Ask Your Doctor

1. Is the LASIK 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 LASIK procedure?

5. What about eye shields or contact lenses?

6. Will I need glasses after the procedure?

7. Can the LASIK procedure be done on both eyes on the same day?

8. What vision problems might I experience if I have laser surgery on only one eye?

9. How is LASIK likely to affect my need to wear glasses or contact lenses as I get older?

[redacted]Are my pupils too large for LASIK?

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

SUMMARY OF IMPORTANT INFORMATION

- *LASIK is a permanent operation to the cornea and is irreversible.*
- *LASIK does not necessarily eliminate the need for reading glasses, even if you have never worn them before.*
- *Your vision must be stable for at least one year before LASIK 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 or 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.*
- *LASIK 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.*
- *Alternatives to LASIK include, but are not limited to, glasses, contact lenses, and other refractive procedures.*
- *Some people, such as military pilots, have job related vision requirements that cannot be met by having LASIK.*
- *Before considering LASIK surgery you should:*

  a. *Have a complete eye examination*

  b. *Talk with one or more eye care professionals about the potential benefits of LASIK surgery, complications, and risks.*

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