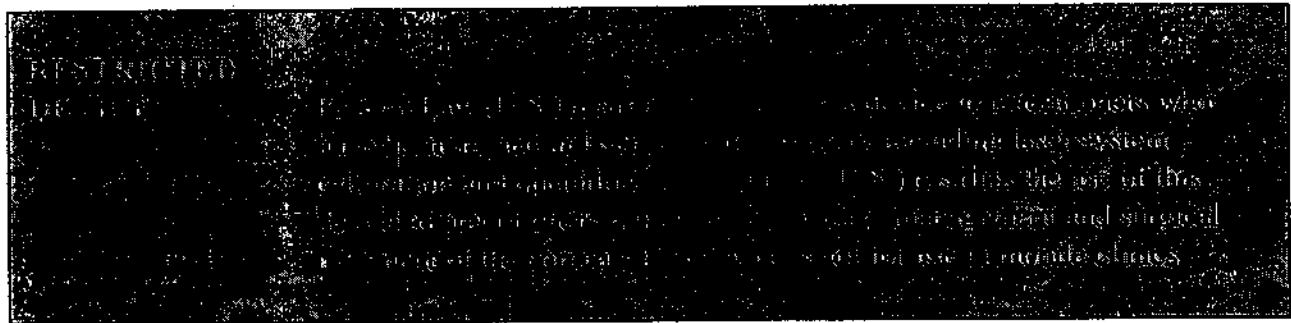
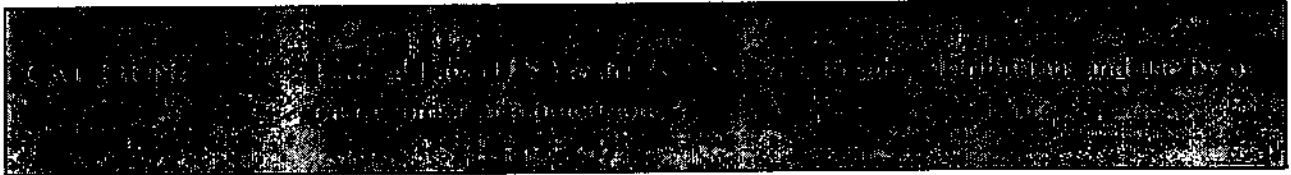


## PHYSICIAN INFORMATION

Dishler Excimer Laser  
for  
Laser Assisted-In-Situ Keratomileusis (LASIK)  
Treatment of Myopia and Myopic Astigmatism



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## **INTRODUCTION**

This physician information booklet has been developed based on the experience with the Dishler Excimer Laser System for the treatment of myopia and myopic astigmatism. This booklet provides information on patient selection, possible risks, and probable outcome. All surgeons should read this information closely before using the Dishler Excimer Laser System for LASIK surgery.

Each patient must have the opportunity to read and understand the Patient Information brochure for the LASIK treatment of myopia and myopic astigmatism. Be certain that each patient is advised of the risks inherent in the use of this medical device and in the outcomes of the myopic LASIK procedures before treating that patient.

In addition to reading the Patient Information brochure, all patients must have the opportunity to read, understand and sign an Informed Consent Document for LASIK treatment with the Dishler Excimer Laser System before the LASIK treatment is administered.

If in doubt about the correct way to operate this medical device, seek help from a trained, authorized user of this device. Improper use of this device may result in physical harm to a patient. Adhere to all warnings, cautions and contraindications in the following Physician Information document.

## 1.0 DEVICE DESCRIPTION

The Dishler Excimer Laser uses a commercially available embedded Lambda Physik COMPex 201 excimer laser engine, which emits energy at a wavelength of 193 nanometers. The laser engine is air-cooled and uses argon fluoride (ArF) as the halogen source. The beam exits the laser and expands into a 25 mm x 25 mm homogenous area of energy. The software algorithm uses the clinical patient data to calculate the appropriate ablation algorithm. The sculpting device is software controlled. The iris is rotated and tilted appropriately to image the masked beam onto the eye. The expanded beam is concentrated to a maximum diameter of 7 mm. The laser produces its ablations intrastromally in a 7 mm or smaller diameter optical zone. The laser is a masked beam for the treatment of myopia and astigmatism.

The Dishler Excimer Laser System is available in two models: A and B. Model A was technologically upgraded to the same specifications as Model B for the treatment of myopia and myopic astigmatism. The energy output and delivery mechanism for both models are the same, except that the laser beam delivery heads for the two models are designed as mirror images of each other. The Dishler Excimer Laser System consists of the following components:

1. **Excimer Laser:** The excimer laser beam emitted from the treatment aperture has the following specifications:

Wavelength	193 nm
Maximum Peak Power	1 X 10 <sup>6</sup> W
Maximum Average Power	200 mW
Pulse Duration	10-30 ns
Pulse Rise Time	5 ns
Pulse Fall Time	7 ns
Maximum Pulse Rate Frequency	10 Hz
Integrated Radiance	12 J/(cm <sup>2</sup> sr)
Beam divergence	4°

Maximum voltage used to charge the laser capacitors is 30 KV. For myopia, the laser is run at 10 Hz but the voltage is reduced to 85% of maximum.

2. **Gas Management System**
3. **Laser Beam Delivery System**
4. **Patient Management System**
5. **Computer Control and Software System**

Please refer to the Operator's Manual for a complete description of the Dishler Excimer Laser System.

## **2.0 INTENDED USE/INDICATIONS**

The Dishler Excimer Laser is intended for use for Laser Assisted-In-Situ Keratomileusis (LASIK) treatment of myopia (-0.5 diopters to -13.0 diopters MRSE) with or without astigmatism ( between -0.5 and - 4.0 diopters), in patients who are 21 years of age or older and who have documented evidence of a change in manifest refraction of less than or equal to 0.5 diopters per year for at least one year prior to the date of preoperative examination.

### 3.0 CONTRAINDICATIONS

Do not use this device on patients with the following:

- diagnosed autoimmune disease, uncontrolled vascular disease, or immunodeficiency diseases.
- signs of keratoconus.
- Fuchs' corneal dystrophy or other significant central corneal pathology.
- lactating or who are known to be pregnant.
- history of long-term use of oral or injected steroids (such as prednisone), drugs to prevent organ transplant rejection, anti-cancer drugs, or other drugs which affect wound healing.
- taking one or more of the following medications: isotretinoin (Accutane™), amiodarone hydrochloride (Cordarone™), and/or sumatriptan succinate (Imitrex™).

#### 4.0 WARNINGS

- The decision to perform LASIK surgery in a patient with systemic disease likely to affect wound healing, such as connective tissue disease, diabetes, severe atopic disease, or an immunocompromised status, should be approached cautiously. The safety and effectiveness of the Dishler Excimer Laser System have not been established in patients with these conditions.
- LASIK surgery is not recommended in patients who have *Herpes simplex* or *Herpes zoster* infections of the eye or other active ocular or systemic infections.
- Lower rate of achieving postoperative uncorrected visual acuity of 20/20 and 20/40 may be anticipated for eyes that have a higher degree of correction for myopia and astigmatism. Although there are no difference in loss of greater than 2 lines of BSCVA, eyes which require higher degrees of correction of myopia and astigmatism may have a higher incidence of losing 1 or 2 lines of BSCVA.
- LASIK surgery is not recommended for patients whose myopia is documented as progressing at a rate of greater than 0.5 diopters per year, because they are more likely to be undercorrected, resulting in blurred vision without glasses.



## 5.0 PRECAUTIONS

- To avoid corneal ectasia, the posterior 250 microns of corneal stroma should not be violated by the laser or the microkeratome.
- Although the effects of LASIK on visual performance under poor lighting conditions have not been determined, it is possible that the patient will 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.
- Significant visual symptoms, such as glare and halos, may be worse in patients with larger pupil sizes or patients functioning under conditions which cause larger pupils (e.g., night driving).
- The safety and effectiveness of the Dishler Excimer Laser System have not been established:
  - In patients with progressive or unstable myopia, ocular disease (such as glaucoma, uveitis, dry eyes), corneal abnormality, previous corneal surgery, or significant anterior segment pathology.
  - In patients who are under 21 years of age.
  - In patients who are blind in the fellow eye.
  - In patients who have a history of keloid scar formation.
  - For the use of this laser for photorefractive keratectomy (PRK).
  - For refractive laser treatments greater than -13.0 diopters MRSE or cylinder greater than 4.0 diopters.
  - beyond 12 months after LASIK treatment.

## **6.0 PATIENT SELECTION CONSIDERATIONS**

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

- Complete examination of the eye must be performed, including manifest refraction and visual acuity testing. Cycloplegic refractions should be performed when clinically indicated. Baseline evaluations should be performed within 30 days of the LASIK surgery.
- Intraocular pressure measurements by applanation must be performed to rule out glaucoma. Patients with glaucoma and/or evidence of glaucomatous damage to the optic nerve should not undergo LASIK surgery.
- Contact lens wearers should discontinue wearing soft lenses for at least 2 days, gas permeable lenses for at least 2 weeks, and hard lenses for at least 4 weeks prior to the preoperative eye examination and the surgery. Patients wearing hard contact lenses should have two refractions taken at least one week apart that are within 0.5 diopters of each other for both sphere and cylinder.
- Preoperative corneal topography must be performed to exclude topographical abnormalities.
- The patient should be able to tolerate topical anesthesia and oral or intravenous anxiolytics.
- The patient should not have a history of allergic response or known intolerance to any of the medications used in the surgical procedure or postoperatively, unless an alternate medication can be substituted to which the patient has no known allergy or tolerance.
- The patient must be able to understand and give an informed consent for the LASIK procedure and be clearly informed of all alternatives for the correction of their refractive error. Correction alternatives include, but are not limited to, spectacles, contact lenses, and other refractive surgeries such as radial keratotomy (RK) and photorefractive keratectomy (PRK).

## 7.0 CLINICAL SAFETY RESULTS

### 7.1 Adverse Events and Complications

The adverse events and complications that occurred in a clinical study of 839 eyes that underwent LASIK treatment for myopia with or without astigmatism are summarized below. The primary treatment for all eyes treated, including those that were later retreated, were included in the evaluation.

Table 7.1-1: Adverse Events Summary

ADVERSE EVENT	1 Month N = 758	3 Months N = 779	6 Months N = 815	12 Months N = 582
Moderate to marked corneal haze	2 (0.3%)	2 (0.3%)	1 (0.1%)	2 (0.3%)
Overcorrected by more than 1 D	37 (4.9%)	24 (3.1%)	15 (1.8%)	10 (1.7%)
Overcorrected by more than 2 D	16 (2.1%)	8 (1.0%)	7 (0.9%)	5 (0.9%)
Loss of more than 2 lines of BSCVA beyond 6 months	N/A	N/A	N/A	1 (0.2%)

"N" is the number of eyes evaluated at the specified visit; not all eyes were eligible for the 12 month visit

Other adverse events that could have occurred, but did not occur in any of the eyes evaluated in the study, include: corneal infiltrate or ulcer; persistent central corneal epithelial defect at 1 month or later; any corneal epithelial defect involving the keratectomy site at 1 month or later; corneal edema at 1 month or later; epithelium in the interface; lost, misplaced, or misaligned flap; melting of the flap; uncontrolled IOP with increase of > 5 mm Hg above baseline and any reading above 25 mm Hg; late onset of haze beyond 6 months with loss of 2 lines (10 letters) or more BSCVA; decrease in BSCVA of > 10 letters not due to irregular astigmatism as shown by hard contact lens refraction at 6 months or later; retinal detachment; retinal vascular accidents; and, corneal infiltrate or ulcer at < 1 month.

The only complications that occurred at any time during the study were two reports of ghost/double images (2/758; 0.26%) in the LASIK-treated eyes that were evaluated at 1 month post-LASIK. Other complications that could have occurred, but did not occur in any of the eyes evaluated in the study, included: corneal edema between 1 week and 1 month after the procedure; peripheral corneal epithelial defect at 1 month or later; epithelium in the interface;

recurrent corneal erosion at 1 month or later; foreign body sensation at 1 month or later; and, pain at 1 month or later.

Two microkeratome complications occurred during the 839 LASIK surgical procedures; both (2/839; 0.24%) were cases of an insufficient flap being created. In each case the cap was repositioned and no laser treatment was performed. There were no other cases of the flap not being of the size and shape as initially intended nor were there any cases where the microkeratome stopped mid-cut.

### 7.2 Subjective Patient Adverse Events

The incidence of subjective patient adverse events were evaluated in 839 eyes treated in a clinical study with LASIK for myopia with or without astigmatism in a clinical study. All 839 eyes enrolled in the study completed the preoperative questionnaire; however, only 376 eyes completed the 12-month postoperative questionnaire. The preoperative and 12-month postoperative results for these 376 eyes are summarized below. Visual symptoms were rated in severity using a 5 point scale. Visual symptoms were rated as being none (1), mild (2), moderate (3), marked (4), or severe (5). The incidence of visual symptoms that were self-rated as marked or severe is summarized below.

Table 7.2-1: Patient Visual Symptoms (Subjective Adverse Events) at 12 Months Post-LASIK

	Marked				Severe				TOTAL			
	Preop		12 Mo		Preop		12 Mo		Preop		12 Mo	
	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%
N	376		376		376		376		376		376	
Light Sensitivity	19	5.1	11	2.9	2	0.5	0	0.0	21	5.6	11	2.9
Night Driving	25	6.6	21	5.6	0	0.0	6	1.6	25	6.6	27	7.2
Reading Difficulty	16	4.3	11	2.9	2	0.5	3	0.8	18	4.8	14	3.7
Double Vision	6	1.6	2	0.5	0	0.0	0	0.0	6	1.6	2	0.5
Fluctuation in Vision	5	1.3	14	3.7	0	0.0	1	0.3	5	1.3	15	4.0
Glare	0	0.0	8	2.1	2	0.5	0	0.0	2	0.5	8	2.1
Halos	6	1.6	17	4.5	0	0.0	0	0.0	6	1.6	17	4.5
Dryness	30	8.0	16	4.3	4	1.1	10	2.7	34	9.0	26	6.9
Pain	0	0.0	2	0.5	0	0.0	0	0.0	0	0.0	2	0.5

"N" is the number of eyes evaluated at the specified visit.

The most common subjective adverse events reported at 12 months post-LASIK were those related to dim lighting conditions (problems with night driving), bright lights (glare, halos, light sensitivity), dryness, fluctuation in vision, and reading difficulty.

## 8.0 CLINICAL STUDY RESULTS

### 8.1 Introduction

There were 839 eyes treated in a prospective, non-randomized study using two lasers at a single site for LASIK treatment of myopia with or without astigmatism

### 8.2 Data Analysis and Results

The clinical results for the 839 eyes that were enrolled in the study are summarized in the various sections below. All evaluations are calculated on a per eye basis and not per patient.

#### 8.2.1 Accountability

At 6 months post-LASIK, 815 of the 839 eyes (97.1%) enrolled in the study were available for analysis. Accountability for these 839 eyes at 6 months post-LASIK is summarized below.

Table 8.2.1-1: Accountability for All Eyes Treated

Status	1 Month		3 Months		6 Months	
	N		N		N	
	n/N	%	n/N	%	n/N	%
Available for Analysis	758	90.3	779	92.8	815	97.1
Discontinued	0	0.0	0	0.0	0	0.0
Not Yet Eligible for the Interval	0	0.0	0	0.0	2	0.2
Lost to Follow-up	0	0.0	0	0.0	0	0.0

"N" is the number of eyes evaluated at the specified visit

#### 8.2.2 Safety and Efficacy Outcome

A summary of the key safety and efficacy variables for this study for eyes treated for spherical myopia only (sphere) and for those eyes treated for myopic astigmatism (spherocylinder) are

provided in Tables 8.2.2-1 and 8.2.2-2 below. The results for the 815 eyes that completed the 6 month post-LASIK visit are stratified by MRSE diopter in Tables 8.2.2-3 and 8.2.2-4, respectively, for eyes treated for sphere and spherocylinder. These results include the primary treatment for eyes that were later retreated.

Table 8.2.2-1: Outcome for Eyes Treated for Sphere Only

Preoperative MRSE	1 Month		3 Months		6 Months		12 Months	
	n/N	%	n/N	%	N/N	%	n/N	%
<b>EFFICACY VARIABLES</b>								
UCVA 20/20 or better	206	61.3	188	55.5	186	52.7	135	54.9
UCVA 20/25 to 20/40	101	30.1	105	31.0	112	31.7	95	38.6
UCVA 20/40 or better (cumulative)	307	91.4	293	86.4	298	84.4	230	93.5
MRSE $\leq$ +0.50 D	247	73.5	242	71.4	232	65.7	170	69.1
MRSE $\leq$ +1.00 D	58	17.3	44	13.0	65	18.4	56	22.8
MRSE $\leq$ +2.00 D	26	7.7	50	14.7	49	13.9	16	6.5
MRSE $\leq$ +1.00 D (cum.)	305	90.8	286	84.4	297	84.1	226	91.9
MRSE $\leq$ +2.00 D (cum.)	331	98.5	336	99.1	346	98.0	242	98.4
<b>Eyes Without Monovision</b>								
# Non-Monovision (N)	313		315		328		232	
UCVA 20/20 or better	206	65.8	183	58.1	184	56.1	132	56.9
UCVA 20/25 to 20/40	89	28.4	101	32.1	107	32.6	88	37.9
UCVA 20/40 or better (cumulative)	295	94.2	284	90.2	291	88.7	220	94.8
<b>SAFETY VARIABLES</b>								
Loss of > 2 lines BSCVA	2	0.6	2	0.6	0	0.0	1	0.4
BSCVA worse than 20/40	0	0.0	0	0.0	0	0.0	0	0.0
Increase > 2 D cylinder	1	0.3	1	0.3	1	0.3	0	0.0
BSCVA worse than 20/25 if 20/20 or better preop	9	2.7	13	3.8	5	1.4	1	0.4

"N" is the number of eyes evaluated at the specified visit.

Table 8.2.2-2: Outcome for Eyes Treated for SpheroCylinder

Preoperative MRSE	1 Month		3 Months		6 Months		12 Months	
N	422		440		462		336	
	n/N	%	n/N	%	N/N	%	n/N	%
<b>EFFICACY VARIABLES</b>								
UCVA 20/20 or better	213	50.5	210	47.7	201	43.5	156	46.4
UCVA 20/25 to 20/40	174	41.2	179	40.7	184	39.8	142	42.3
UCVA 20/40 or better (cumulative)	387	91.7	389	88.4	385	83.3	298	88.7
MRSE <u>+</u> 0.50 D	254	60.2	262	59.5	272	58.9	215	64.0
MRSE <u>+</u> 1.00 D	98	23.2	105	23.9	102	22.1	71	21.1
MRSE <u>+</u> 2.00 D	57	13.5	59	13.4	75	16.2	39	11.6
MRSE <u>+</u> 1.00 D (cum.)	352	83.4	367	83.4	374	81.0	286	85.1
MRSE <u>+</u> 2.00 D (cum.)	409	96.9	426	96.8	449	97.2	325	96.7
<b>Eyes Without Monovision</b>								
# Non-Monovision (N)	382		399		420		306	
UCVA 20/20 or better	202	52.9	205	51.4	194	46.2	151	49.3
UCVA 20/25 to 20/40	151	39.5	156	39.1	170	40.5	128	41.8
UCVA 20/40 or better (cumulative)	353	92.4	361	90.5	364	86.7	279	91.2
<b>SAFETY VARIABLES</b>								
Loss of > 2 lines BSCVA	4	0.9	1	0.2	1	0.2	0	0.0
BSCVA worse than 20/40	2	0.5	2	0.5	2	0.4	0	0.0
Increase > 2 D cylinder	0	0.0	0	0.0	0	0.0	0	0.0
BSCVA worse than 20/25 if 20/20 or better preop	16	3.8	7	1.6	4	0.9	5	1.5

"N" is the number of eyes evaluated at the specified visit.

Table 8.2.2-3: Outcome at 6 Months Post-LASIK Stratified by Preoperative MRSE for Eyes Treated for Sphere Only

Preoperative MRSE	-1.0 to -1.99		-2.0 to -2.99		-3.0 to -3.99*		-4.0 to -4.99		-5.0 to -5.99		-6.0 to -6.99	
N	26		56		67		59		47		25	
	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%
<b>EFFICACY VARIABLES</b>												
UCVA 20/20 or better	24	92.3	43	76.8	41	61.2	27	45.8	19	40.4	10	40.0
UCVA 20/25 to 20/40	2	7.7	13	23.2	21	31.3	23	39.0	14	29.8	9	36.0
UCVA 20/40 or better (cumulative)	26	100.0	56	100.0	62	92.5	50	84.7	33	70.2	19	76.0
MRSE $\pm$ 0.50 D	25	96.2	47	83.9	53	79.1	36	61.0	29	61.7	8	32.0
MRSE $\pm$ 1.00 D	1	3.8	6	10.7	10	14.9	15	25.4	7	14.9	8	32.0
MRSE $\pm$ 2.00 D	0	0.0	3	5.4	4	6.0	8	13.6	11	23.4	9	36.0
MRSE $\pm$ 1.00 D (cum.)	26	100.0	53	94.6	63	94.0	51	86.4	36	76.6	16	64.0
MRSE $\pm$ 2.00 D (cum.)	26	100.0	56	100.0	67	100.0	59	100.0	47	100.0	25	100.0
<b>Eyes Without Monovision</b>												
# Non-Monovision (N)	26		55		64		57		42		22	
UCVA 20/20 or better	24	92.3	43	78.2	41	64.1	27	47.4	19	45.2	10	45.5
UCVA 20/25 to 20/40	2	7.7	12	21.8	20	31.3	23	40.4	14	33.3	8	36.4
UCVA 20/40 or better (cumulative)	26	100.0	55	100.0	61	95.3	50	87.7	33	78.6	18	81.8
<b>SAFETY VARIABLES</b>												
Loss of > 2 lines BSCVA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
BSCVA worse than 20/40	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Increase > 2 D cylinder	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
BSCVA worse than 20/25 if 20/20 or better preop	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	8.0

\*"N" is the number of eyes evaluated at the specified visit.



Table 8.2.2-3: Outcome at 6 Months Post-LASIK Stratified by Preoperative MRSE for Eyes

Treated for Sphere Only (continued)

Preoperative MRSE	-7.0 to -7.99		-8.0 to -8.99		-9.0 to -9.99		-10.0 to -10.99		-11.0 to -11.99		-12.0 to -12.99	
	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%
<b>EFFICACY VARIABLES</b>												
UCVA 20/20 or better	8	32.0	5	29.4	3	18.8	2	50.0	3	75.0	0	0.0
UCVA 20/25 to 20/40	12	48.0	8	47.1	6	37.5	0	0.0	1	25.0	3	60.0
UCVA 20/40 or better (cumulative)	20	80.0	13	76.5	9	56.3	2	50.0	4	100.0	3	60.0
MRSE $\leq$ +0.50 D	16	64.0	8	47.1	5	31.3	2	50.0	2	50.0	1	20.0
MRSE $\leq$ +1.00 D	6	24.0	4	23.5	4	25.0	0	0.0	2	50.0	1	20.0
MRSE $\leq$ +2.00 D	1	4.0	5	29.4	6	37.5	1	25.0	0	0.0	1	20.0
MRSE $\leq$ +1.00 D (cum.)	22	88.0	12	70.6	9	56.3	2	50.0	4	100.0	2	40.0
MRSE $\leq$ +2.00 D (cum.)	23	92.0	17	100.0	15	93.8	3	75.0	4	100.0	3	60.0
<b>Eyes Without Monovision</b>												
# Non-Monovision (N)	24		15		13		4		3		3	
UCVA 20/20 or better	8	33.3	5	33.3	3	23.1	2	50.0	2	66.7	0	0.0
UCVA 20/25 to 20/40	12	50.0	8	53.3	6	46.2	0	0.0	1	33.3	1	33.3
UCVA 20/40 or better (cumulative)	20	83.3	13	86.7	9	69.2	2	50.0	3	100.0	1	33.3
<b>SAFETY VARIABLES</b>												
Loss of > 2 lines BSCVA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
BSCVA worse than 20/40	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Increase > 2 D cylinder	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	20.0
BSCVA worse than 20/25 if 20/20 or better preop	1	4.0	2	11.8	0	0.0	0	0.0	0	0.0	0	0.0

"N" is the number of eyes evaluated at the specified visit.

Table 8.2.2-3: Outcome at 6 Months Post-LASIK Stratified by Preoperative MRSE for Eyes

Treated for Sphere Only (continued)

Preoperative MRSE	-13.0 to -13.99		CUM TOTAL < -7D		CUM TOTAL ≥ -7D		CUM TOTAL ALL EYES	
	n/N	%	n/N	%	n/N	%	n/N	%
N	1		280		72		352	
<b>EFFICACY VARIABLES</b>								
UCVA 20/20 or better	1	100.0	164	58.6	22	30.6	186	52.8
UCVA 20/25 to 20/40	0	0.0	82	29.3	30	41.7	112	31.8
UCVA 20/40 or better (cumulative)	1	100.0	246	87.9	52	72.2	298	84.7
MRSE + 0.50 D	0	0.0	198	70.7	34	47.2	232	65.9
MRSE + 1.00 D	1	100.0	47	16.8	18	25.0	65	18.5
MRSE + 2.00 D	0	0.0	35	12.5	14	19.4	49	13.9
MRSE + 1.00 D (cum.)	1	100.0	245	87.5	52	72.2	297	84.4
MRSE + 2.00 D (cum.)	1	100.0	280	100.0	66	91.7	346	98.3
<b>Eyes Without Monovision</b>								
Non-Monovision (N)	0		266		62		328	
UCVA 20/20 or better	0	0.0	164	61.7	20	32.3	184	56.1
UCVA 20/25 to 20/40	0	0.0	79	29.7	28	45.2	107	32.6
UCVA 20/40 or better (cumulative)	0	0.0	243	91.4	48	77.4	291	88.7
<b>SAFETY VARIABLES</b>								
Loss of > 2 lines BSCVA	0	0.0	0	0.0	0	0.0	0	0.0
BSCVA worse than 20/40	0	0.0	0	0.0	0	0.0	0	0.0
Increase > 2 D cylinder	0	0.0	0	0.0	1	1.4	1	0.3
BSCVA worse than 20/25 if 20/20 or better preop	0	0.0	2	0.7	3	4.2	5	1.4

"N" is the number of eyes evaluated at the specified visit.

Table 8.2.2-4: Outcome at 6 Months Post-LASIK Stratified by Preoperative MRSE for Eyes Treated for SpheroCylinder

Preoperative MRSE	-1.0 to -1.99		-2.0 to -2.99		-3.0 to -3.99		-4.0 to -4.99**		-5.0 to -5.99		-6.0 to -6.99	
N	7		29		61		60		68		74	
	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%
<b>EFFICACY VARIABLES</b>												
UCVA 20/20 or better	5	71.4	24	82.8	33	54.1	32	53.3	30	44.1	32	43.2
UCVA 20/25 to 20/40	2	28.6	5	17.2	21	34.4	16	26.7	26	38.2	33	44.6
UCVA 20/40 or better (cumulative)	7	100.0	29	100.0	54	88.5	48	80.0	56	82.4	65	87.8
MRSE + 0.50 D	5	71.4	26	89.7	44	72.1	38	63.3	46	67.6	40	54.1
MRSE + 1.00 D	2	28.6	3	10.3	15	24.6	9	15.0	10	14.7	26	35.1
MRSE + 2.00 D	0	0.0	0	0.0	2	3.3	13	21.7	12	17.6	7	9.5
MRSE + 1.00 D (cum.)	7	100.0	29	100.0	59	96.7	47	78.3	56	82.4	66	89.2
MRSE + 2.00 D (cum.)	7	100.0	29	100.0	61	100.0	60	100.0	68	100.0	73	98.6
<b>Eyes Without Monovision</b>												
# Non-Monovision (N)	7		29		54		57		60		66	
UCVA 20/20 or better	5	71.4	24	82.8	30	55.6	32	56.1	30	50.0	29	43.9
UCVA 20/25 to 20/40	2	28.6	5	17.2	19	35.2	15	26.3	23	38.3	31	47.0
UCVA 20/40 or better (cumulative)	7	100.0	29	100.0	49	90.7	47	82.5	53	88.3	60	90.9
<b>SAFETY VARIABLES</b>												
Loss of > 2 lines BSCVA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
BSCVA worse than 20/40	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Increase > 2 D cylinder*	N/A	####	N/A	####	N/A	####	N/A	####	N/A	####	N/A	####
BSCVA worse than 20/25 if 20/20 or better preop	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0

\*"N" is the number of eyes evaluated at the specified visit.

Table 8.2.2-4: Outcome at 6 Months Post-LASIK Stratified by Preoperative MRSE for Eyes

Treated for Sphero-cylinder (continued)

Preoperative MRSE	-7.0 to -7.99		-8.0 to -8.99		-9.0 to -9.99		-10.0 to -10.99		-11.0 to -11.99		-12.0 to -12.99	
N	60		28		30		19		10		8	
	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%
<b>EFFICACY VARIABLES</b>												
UCVA 20/20 or better	21	35.0	7	25.0	10	33.3	3	15.8	0	0.0	1	12.5
UCVA 20/25 to 20/40	30	50.0	14	50.0	12	40.0	11	57.9	6	60.0	4	50.0
UCVA 20/40 or better (cumulative)	51	85.0	21	75.0	22	73.3	14	73.7	6	60.0	5	62.5
MRSE $\pm$ 0.50 D	31	51.7	10	35.7	14	46.7	6	31.6	4	40.0	2	25.0
MRSE $\pm$ 1.00 D	12	20.0	8	28.6	4	13.3	6	31.6	2	20.0	3	37.5
MRSE $\pm$ 2.00 D	17	28.3	10	35.7	8	26.7	4	21.1	2	20.0	0	0.0
MRSE $\pm$ 1.00 D (cum.)	43	71.7	18	64.3	18	60.0	12	63.2	6	60.0	5	62.5
MRSE $\pm$ 2.00 D (cum.)	60	100.0	28	100.0	26	86.7	16	84.2	8	80.0	5	62.5
<b>Eyes Without Monovision</b>												
# Non-Monovision (N)	58		24		27		17		7		8	
UCVA 20/20 or better	21	36.2	7	29.2	9	33.3	3	17.6	0	0.0	1	12.5
UCVA 20/25 to 20/40	29	50.0	12	50.0	12	44.4	10	58.8	5	71.4	4	50.0
UCVA 20/40 or better (cumulative)	50	86.2	19	79.2	21	77.8	13	76.5	5	71.4	5	62.5
<b>SAFETY VARIABLES</b>												
Loss of > 2 lines BSCVA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	12.5
BSCVA worse than 20/40	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	25.0
Increase > 2 D cylinder*	N/A	####	N/A	####	N/A	####	N/A	####	N/A	####	N/A	####
BSCVA worse than 20/25 if 20/20 or better preop	1	1.7	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0

\*"N" is the number of eyes evaluated at the specified visit.

Table 8.2.2-4: Outcome at 6 Months Post-LASIK Stratified by Preoperative MRSE for Eyes Treated for Spherocylinder (continued)

Preoperative MRSE	-13.0 to -13.99		CUM TOTAL < -7D		CUM TOTAL ≥ -7D		CUM TOTAL ALL EYES	
	n/N	%	n/N	%	n/N	%	n/N	%
N	4		299		159		458	
<b>EFFICACY VARIABLES</b>								
UCVA 20/20 or better	1	25.0	156	52.2	43	27.0	199	43.4
UCVA 20/25 to 20/40	2	50.0	103	34.4	79	49.7	182	39.7
UCVA 20/40 or better (cumulative)	3	75.0	259	86.6	122	76.7	381	83.2
MRSE + 0.50 D	3	75.0	199	66.6	70	44.0	269	58.7
MRSE + 1.00 D	1	25.0	65	21.7	36	22.6	101	22.1
MRSE + 2.00 D	0	0.0	34	11.4	41	25.8	75	16.4
MRSE + 1.00 D (cum.)	4	100.0	264	88.3	106	66.7	370	80.8
MRSE + 2.00 D (cum.)	4	100.0	298	99.7	147	92.5	445	97.2
<b>Eyes Without Monovision</b>								
Non-Monovision (N)	2		273		143		416	
UCVA 20/20 or better	1	50.0	150	54.9	42	29.4	192	46.2
UCVA 20/25 to 20/40	1	50.0	95	34.8	73	51.0	168	40.4
UCVA 20/40 or better (cumulative)	2	100.0	245	89.7	115	80.4	360	86.5
<b>SAFETY VARIABLES</b>							0	
Loss of > 2 lines BSCVA	0	0.0	0	0.0	1	0.6	1	0.2
BSCVA worse than 20/40	0	0.0	0	0.0	2	1.3	2	0.4
Increase > 2 D cylinder*	N/A	####	####	####	####	####	####	####
BSCVA worse than 20/25 if 20/20 or better preop	1	25.0	1	0.3	3	1.9	4	0.9

\*"N" is the number of eyes evaluated at the specified visit.

### 8.2.3 Refractive Stability

Time to refractive stability was evaluated from 1 to 3 months and from 3 to 6 months post-LASIK and is summarized in Tables 8.2.3-1 and 8.2.3-2 below. Only eyes that had refractive data at 1, 3, and 6 months post-LASIK were included in the analysis. The point of stability is considered to be the last timepoint in the range when at least 95% of the treated eyes reach stability. Eyes treated for sphere attain refractive stability by 3 months post-LASIK, while eyes treated for spherocylinder do not attain refractive stability until 6 months post-LASIK.

Table 8.2.3-1: Refractive Stability for Eyes Treated for Sphere

	1 and 3 Months		3 and 6 Months	
	n/N	%	n/N	%
≤ 1.00 D Difference in MRSE	287/300	95.7	291/300	97.0
Mean Difference	-0.187		-0.074	
Std. Dev.	0.469		0.402	
95% C.I. for the Mean	0.0533		0.0456	

Table 8.2.3-2: Refractive Stability for Eyes Treated for SpheroCylinder

	1 and 3 Months		3 and 6 Months	
	n/N	%	n/N	%
≤ 1.00 D Difference in MRSE	367/398	92.2	380/398	95.5
Mean Difference	-0.265		-0.173	
Std. Dev.	0.517		0.495	
95% C.I. for the Mean	0.0510		0.0488	

#### 8.2.4 Accuracy of Cylinder Treatment

The mean percent reduction of absolute cylinder that was attained at 6 months post-LASIK for all 461 eyes treated for spherocylinder versus the amount of preoperative manifest cylinder is summarized in Table 8.2.4-1 below.

Table 8.2.4-1: Mean Percent Reduction in Absolute Cylinder in Eyes Treated for SpheroCylinder

Preoperative Manifest Cylinder	Number of Eyes Evaluated (n/N)	Mean % Reduction of Absolute Cylinder
≤ 1.0 Diopters	178/461	56.9 %
>1.0 to ≤ 2.0 Diopters	222/461	67.8 %
>2.0 to ≤ 3.0 Diopters	45/461	74.9 %
>3.0 to ≤ 4.0 Diopters	16/461	79.8 %

Of the 461 eyes included in this analysis, 16 eyes (3.47%) had residual postoperative cylinder that was of a greater magnitude than the preoperative cylinder.

#### 8.2.5 Retreatments

The retreatment rate for the 839 eyes treated in the study was 3% (n = 25) at 6 months post-LASIK and 11.6% (n = 97) at 12 months post-LASIK. The higher retreatment rate at 12 months is reflective of the investigator's usual practice of waiting at least 6 months or longer to perform retreatments.

No adverse events, complications, or microkeratome-related complications occurred in the 25 retreated eyes. Prior to retreatment, the most common subjective adverse events reported by the patients were marked or severe were reading difficulty (4/25 eyes; 16%) and problems with night driving or night vision (8/25; 32.0%). After retreatment, the only marked to severe subjective adverse events were two reports of problems with night driving (2/25; 8.0%).

A summary of the key safety and efficacy variables after the retreatments were performed is provided in Table 8.2.5-1 below.

Table 8.2.5-1: Outcome AFTER Retreatment for All Eyes Retreated

Preoperative MRSE	1 Month		3 Months		6/12 Months		Last Available Visit	
	n/N	%	n/N	%	n/N	%	n/N	%
N	22		23		21		25	
<b>EFFICACY VARIABLES</b>								
UCVA 20/20 or better	11	50.0	16	69.6	12	57.1	14	56.0
UCVA 20/25 to 20/40	11	50.0	6	26.1	9	42.9	11	44.0
UCVA 20/40 or better (cumulative)	22	100.0	22	95.7	21	100.0	25	100.0
MRSE + 0.50 D	17	77.3	18	78.3	17	81.0	19	76.0
MRSE + 1.00 D	4	18.2	3	13.0	3	14.3	4	16.0
MRSE + 2.00 D	1	4.5	2	8.7	1	4.8	2	8.0
MRSE + 1.00 D (cumulative)	21	95.5	21	91.3	20	95.2	23	92.0
MRSE + 2.00 D (cumulative)	22	100.0	23	100.0	21	100.0	25	100.0
<b>Eyes Without Monovision</b>								
# Non-Monovision (N)	21		22		20		24	
UCVA 20/20 or better	10	47.6	14	63.6	12	60.0	14	58.3
UCVA 20/25 to 20/40	8	38.1	5	22.7	8	40.0	10	41.7
UCVA 20/40 or better (cumulative)	18	85.7	19	86.4	20	100.0	24	100.0
<b>SAFETY VARIABLES</b>								
Loss of > 2 lines BSCVA	0	0.0	0	0.0	0	0.0	0	0.0
BSCVA worse than 20/40	0	0.0	0	0.0	0	0.0	0	0.0
Increase > 2 D cylinder	0	0.0	0	0.0	0	0.0	0	0.0
BSCVA worse than 20/25 if 20/20 or better preop	0	0.0	0	0.0	0	0.0	0	0.0

"N" is the number of eyes evaluated at the specified visit



## **9.0 PREOPERATIVE EXAMINATION AND SURGICAL PLANNING**

Patients should be scheduled for an initial screening examination to determine whether the patient is a candidate for LASIK surgery. A complete medical and ocular history should be obtained and the health of the patient's eye(s) should be evaluated, taking into account the contraindications, precautions, and warnings listed above. Preoperative tests and measurements should include:

- Uncorrected and best corrected visual acuity using a Snellen chart
- Manifest refraction (performed manually and noted in plus cylinder notation)
- Cycloplegic refraction (if clinically indicated)
- Central keratometry
- Intraocular pressure by applanation
- Pupil size measured in dim light
- Slit lamp examination
- Dilated fundus examination
- Computerized corneal topography
- Central pachymetry
- Evaluation of corneal haze

A medical history should be obtained from the patient, including both systemic and ophthalmic medications. The patient should be given a visual symptom questionnaire to complete.

If the patient is a suitable candidate for LASIK surgery, the patient should be given a patient information booklet and an informed consent document to review. The consent form must be signed prior to performing LASIK surgery. The patient information booklet includes discussions of refractive error, the LASIK procedure, and the risks and benefits of the LASIK procedure. It also provides instructions that the patient should follow preoperatively, on the day of surgery, and postoperatively. This information should be reviewed in detail with the patient.

Individualized instructions for prescription and nonprescription medications and postoperative care of the operated eye will need to be given after the LASIK surgery.

Contact lens wearers should discontinue wearing soft lenses for at least 2 days, gas permeable lenses for at least 2 weeks, and hard lenses for at least 4 weeks prior to the preoperative eye examination and the surgery. Patients wearing hard contact lenses should have two refractions taken at least one week apart that are within 0.5 diopters of each other for both sphere and cylinder.

Patients may be evaluated for LASIK surgery by a referral optometrist or ophthalmologist. The screening data obtained by the referring doctor should be reviewed closely; however, the measurements that are necessary to calculate the appropriate treatment algorithm should be repeated by the LASIK surgeon or his/her staff prior to finalizing the LASIK surgical plan. Complete instructions for calculating the treatment plan and for operating the Dishler Excimer Laser System are provided in the operator's manual.

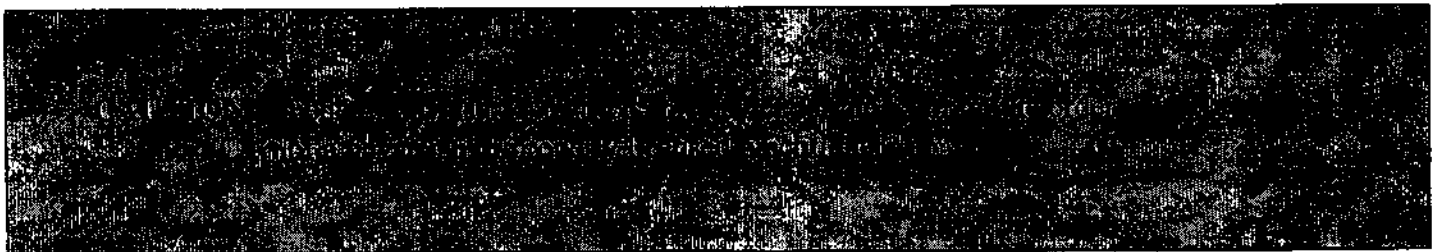
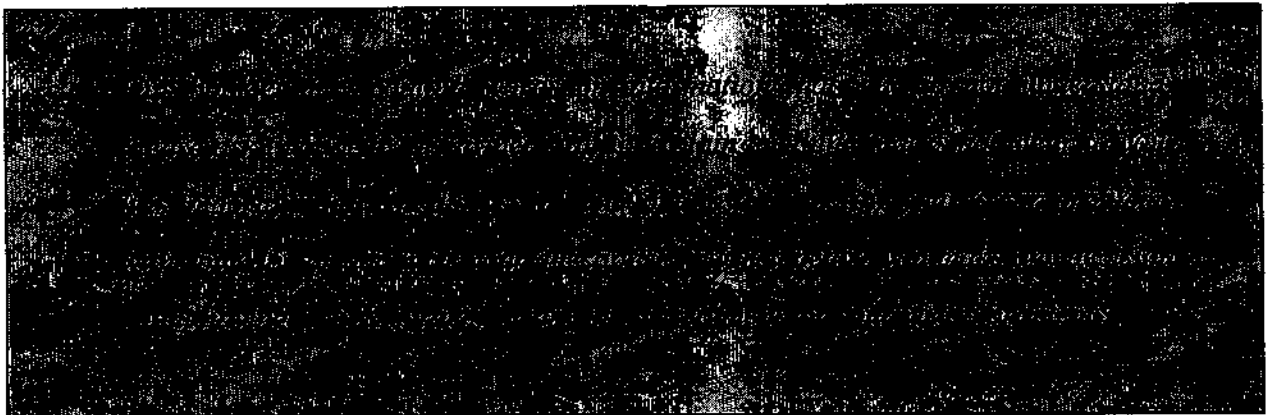
#### **10.0 OPERATOR'S MANUAL**

The Operator's Manual includes information regarding safety, system operation, maintenance, checking the emitted pulse energy and stability, changing the laser gas fill, checking the laser beam profiles, calibrating the energy meter, and calibrating the system detector. Please refer to the Operator's Manual for a complete description of the device and instructions for operating the Dishler Excimer Laser System.

# *Patient Information Booklet*

## **LASIK (Laser Assisted in-situ Keratomileusis) SURGERY**

For  
Nearsightedness With or Without Astigmatism



Dishler Excimer Laser System  
Laser Institute of the Rockies/DTC Eye Surgery Center  
8400 Prentice Avenue, Suite 1200  
Englewood, Colorado 80111  
Telephone: (303)-793-3000 or 1-800-905-2745

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## *Glossary*

<b>AK</b>	An abbreviation for "astigmatic keratotomy." Surgical procedure where cuts are place in the cornea (clear, glassy outermost covering of the eye) to make it more circular or rounded. Used for treating astigmatism.
<b>ALK</b>	An abbreviation for "automated lamellar keratoplasty." Surgical procedure using a special knife to cut part way through the top of the cornea so a "flap" can be laid back and a second layer of corneal tissue may be removed.
<b>Astigmatism</b>	Vision problem that results from an oval shaped cornea, rather than the normal circular shape.
<b>Cornea</b>	The clear, glassy outermost covering of the eye.
<b>Corneal swelling</b>	Swollen eye due to inflammation caused by surgery.
<b>Dilation</b>	The opening up of a part of the body. The dilation of blood vessels means to open up the blood vessels. The dilation of the pupil means to open up the pupil.
<b>Diopter</b>	This is a unit of measurement the doctor uses to determine how much correction you need to see clearly.
<b>Double vision</b>	Seeing an image as two images
<b>Drooping of eyelid</b>	Sagging of the upper eyelid
<b>Epithelium</b>	The outermost layer of cells on the cornea.
<b>Excimer laser</b>	A medical device that produces a very powerful, pure beam of light of a single and specific wavelength (or color) that is used to remove tissue from the cornea (the clear part of the eye). This removal of tissue is performed with a computer and re-shapes the cornea to correct refractive errors. The re-shaping allows incoming light rays to focus more accurately on the retina.

<b>Farsightedness</b>	The inability to see objects that are close. Another word for farsightedness is hyperopia.
<b>Foreign body sensations</b>	A feeling that there is something in your eye.
<b>Fuch's corneal dystrophy</b>	A disorder of the cornea that results in a cloudy waterlogged cornea, painful blisters on the corneal surface, and reduced vision.
<b>Ghost images</b>	This occurs when you see a shadow around objects.
<b>Glare</b>	A sensation produced by bright lights that causes greater discomfort than normal, even annoyance.
<b>Halos</b>	Hazy rings around bright lights that are seen by some patients.
<b>Hyperopia</b>	The inability to see objects that are close. Another word for hyperopia is farsightedness.
<b>Iris</b>	The colored part of the eye.
<b>Keratoconus</b>	A hereditary, degenerative corneal disease characterized by generalized thinning and cone-shaped protrusion of the central cornea.
<b>LASIK</b>	This is an abbreviation for Laser Assisted In-Situ Keratomileusis or Laser Assisted Intrastromal Keratoplasty. This laser procedure is used to reshape the cornea.
<b>Lens</b>	The part of the eye that bends incoming light to focus on a single point on the retina.
<b>Light sensitivity</b>	When light hurts your eyes.
<b>Microkeratome</b>	A surgical instrument that makes very small incisions on the eye.
<b>Myopia</b>	Not able to see objects that are far away. Another word for myopia is nearsightedness.
<b>Nearsightedness</b>	The inability to see objects that are far away. Another word for nearsightedness is myopia.
<b>Nominally</b>	A very small amount.

<b>Permeable</b>	Gas is able to get into a part of the body.
<b>PRK</b>	An acronym for "photorefractive keratectomy." A surgical procedure where a thin portion of the cornea (the clear, front part of the eye) is removed using an excimer laser to re-shape the cornea.
<b>Pupil</b>	The black center of the eye. It regulates the amount of light that can enter the eye.
<b>Refraction</b>	Bending of light rays as they travel from a clear medium of one density to another medium of different density. The test to determine the best corrective lenses to be prescribed. The prescription for eyeglasses or contact lenses resulting from this test.
<b>Refractive Error</b>	A defect that occurs when parallel light rays are not brought to a sharp focus precisely on the retina, producing a blurred image.
<b>Retina</b>	The part of the eye located behind the lens upon which images are focused in order to see.
<b>RK</b>	An acronym for "radial keratotomy." A surgical procedure where radial cuts are made in the cornea (the clear, front part of the eye).
<b>Sclera</b>	The white part of the eye.
<b>Steroid</b>	A class of drugs used to reduce swelling and scarring.
<b>Tearing</b>	Excessive watering of the eye.
<b>Vitreous</b>	A clear, gel-like substance that fills the eye's cavity and provides spherical shape to the eye.

## *Introduction*

Please read this booklet carefully so that you understand the risks and benefits of having LASIK surgery. Before you have LASIK surgery, you should talk with your eye doctor, family, or other people who have had LASIK surgery to decide whether LASIK surgery is right for you. Vision problems of nearsightedness, farsightedness, and astigmatism can be corrected by wearing glasses or contact lenses (corrective lenses) outside of the eye or by having some type of eye surgery to change the shape of the eye. The overall goal of any of these methods is to change the way the light rays are bent and focused so that they hit the retina in the proper position.

As an alternative to corrective lenses, surgery can be performed upon the eye to change the way the eye bends the light through the cornea and lens. Surgery is a permanent operation to the cornea and cannot be reversed. Different methods of surgery use different approaches to change the shape of the cornea and correct the refractive error. These different types of eye surgery include: Radial Keratotomy (RK); Astigmatic Keratotomy (AK); Automated Lamellar Keratoplasty (ALK); Photorefractive Keratectomy (PRK); and, Laser Assisted In-Situ Keratomileusis (LASIK). Please make sure you discuss all of your options with your eye doctor.

Some agencies or particular employers (such as the military, Federal Aviation Agency (FAA), police departments, etc.) may have physical and/or visual requirements or limitations that cannot be met with LASIK surgery.



### *Summary of Important Information*

- LASIK surgery is not risk-free. Please read this booklet carefully so that you understand the risks and benefits of having LASIK surgery. LASIK surgery may cause some discomfort or undesired vision changes.
- LASIK surgery is a permanent operation to the cornea and cannot be reversed.
- Before considering LASIK surgery, you should talk with your eye doctor, family, or other people who have had LASIK surgery to help you decide whether LASIK surgery is right for you.
- You should have a complete eye examination before LASIK surgery and discuss the complications, risks, and the time required for healing with one or more eye surgeons.
- You may still need to wear corrective lenses after LASIK surgery for reading or even if you did not wear them before surgery.
- Alternatives to LASIK surgery include, but are not limited to, eye glasses, contact lenses, RK, and PRK.
- Your vision must be stable at least 1 year before LASIK surgery. You will need written proof that your nearsightedness and/or astigmatism has changed less than -0.5 diopters during the year.
- LASIK surgery is not a laser version of alternative surgeries (RK, PRK, etc.). It is completely different .
- Some agencies or particular employers (such as the military, Federal Aviation Agency (FAA), police departments, etc.) may have physical and/or visual requirements or limitations that cannot be met with LASIK surgery. You may still need to wear glasses.
- You are not a good candidate for LASIK surgery if you have any condition that makes wound healing difficult, such as autoimmune diseases.
- You should not have LASIK surgery while you are pregnant or nursing

### *Indications for LASIK Surgery*

Dishler Excimer Laser for LASIK treatment may be considered if:

- You need correction of nearsightedness (myopia) between -0.5 diopters and -13.0 diopters (MRSE) with or without astigmatism (between -0.5 and -4.0 diopters).
- You are 21 years of age or older.
- You have written proof from your eye doctor that the shape of your eye's cylinder or sphere has changed less than or equal to 0.5 diopters in the last year.

### *Contraindications for LASIK Surgery*

You should NOT have LASIK surgery if:

- You have autoimmune disease, uncontrolled vascular disease, or an immunodeficiency disease.
- You have a cone-shaped cornea (keratoconus).
- You have Fuchs' corneal dystrophy or other significant central corneal conditions which could cause damage to the cornea. You are nursing or are pregnant.
- You have a history of long-term use of oral or injected steroids (such as prednisone), drugs to prevent organ transplant rejection, anti-cancer drugs, drugs for HIV, or other therapies that affect the immune system, which affects wound healing.
- You are taking one or more of the following medications: isotretinoin (for example, Accutane™), amiodarone hydrochloride (for example, Cordarone™), and/or sumatriptan succinate (for example, Imitrex™).

### *Warnings*

LASIK surgery is NOT recommended for you, if you have any of the following:

- systemic diseases that are likely to affect wound healing, such as connective tissue disease, diabetes, severe atopic disease, or an immunocompromised status (or any other conditions listed under "Contraindications"). The safety and effectiveness of the Dishler Excimer Laser System has not been established for patients with these conditions.
- Herpes simplex or Herpes zoster infections of the eye. These types of infection could cause permanent damage to the cornea.
- a need for a higher degree of correction for nearsightedness (-7 diopters and above of correction) with or without astigmatism because you have a greater chance of having uncorrected vision after LASIK surgery that is worse than 20/20..
- changes in your nearsightedness that progress at a rate of greater than 0.5 diopters per year.

### *Precautions*

- You may not be able to have LASIK surgery if your eye has a thin cornea.
- You may find it more difficult than usual to see under poor lighting conditions such as very dim light, rain, snow, fog, or glare from bright lights at night after LASIK surgery.
- You may have significant visual symptoms, such as glare and halos, if your normal pupils are larger than average or under conditions which cause larger pupils (e.g., night driving).
- The safety and effectiveness of the Dishler Excimer Laser System have NOT been established:
  - In patients with progressive myopia or unstable myopia, ocular disease (such as glaucoma, uveitis, dry eye), corneal abnormality, previous corneal surgery, or significant anterior segment pathology.
  - In patients who are under 21 years of age.
  - In patients who are blind in the fellow eye.

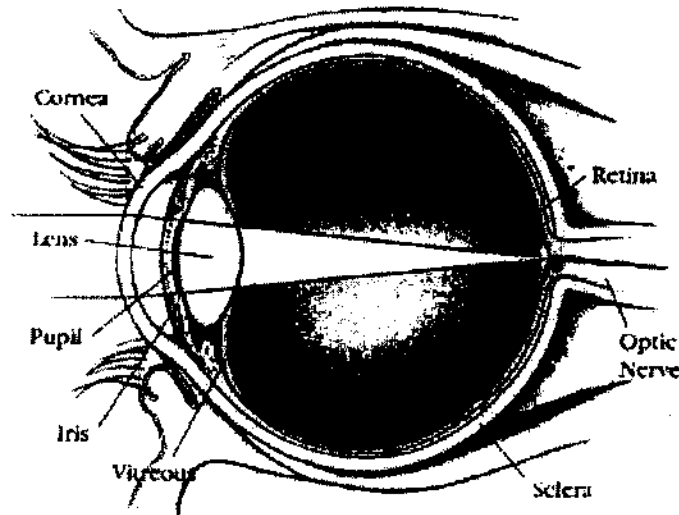
## ***Precautions (continued)***

- The safety and effectiveness of the Dishler Excimer Laser System have also NOT been established:
  - In patients who have a history of keloid scar formation (forming extra thick or bumpy scars).
  - For the use of this laser for photorefractive keratectomy (PRK).
  - For refractive laser treatments greater than -13.0 diopters MRSE or cylinder greater than 4.0 diopters.
  - Beyond 12 months after LASIK surgery.



### *How Does The Eye Work?*

Your eye is made up of many independent parts that are able to respond to changes in light, temperature, and the environment. These parts, working together, can change focus from nearby objects to distant objects in a fraction of a second.



The white part of the eye is the **sclera**. Light enters your eye first through the **cornea** that is made of transparent tissue. The cornea focuses and bends (or refracts) the light, which allows it to pass through the **pupil**. The pupil is the round opening in the center of the colored part of the eye that is called the **iris**. It is the pupil that becomes smaller in bright light and larger in dim light. The pupil works to allow the proper amount of light rays into the eye at all times.

Directly behind the pupil is the **lens**. Muscles in the eye adjust the lens to focus the light rays onto the **retina**, especially when you read. The retina is made of light sensitive cells that capture light images and translate them into electrical impulses that travel to the brain via the optic nerve. The eye's cavity is filled with a clear, gel-like substance, called **vitreous**, that provides the spherical shape to the eye.

The shape of your cornea, the power of the lens, and the length of the eyeball determine how clearly you see. If all three of these elements are matched together perfectly, the light rays can be focused properly and you can see clearly at all distances. If even one of these elements does not coordinate with the others, the light will not focus or bend (refract) correctly. These “refractive” problems are referred to as myopia, hyperopia, and astigmatism.

**Myopia** or nearsightedness occurs when the light focuses in front of the retina. Objects that are close can be seen but objects that are farther away are blurry. Nearsightedness is the most common refractive vision problem. It is caused by a cornea that is more curved than normal or by an eyeball that is too long. These conditions cause the light rays to focus at a point in front of the retina.



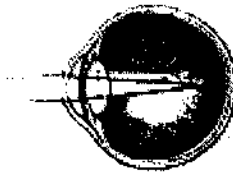
**MYOPIA** — Light focuses in front of the retina.

**Hyperopia** or farsightedness is the opposite of nearsightedness. Farsighted people have difficulty focusing on nearby objects. Farsightedness is caused by a cornea that is flatter than normal or by an eyeball that is too short. These conditions cause the light rays to focus at a point behind the retina.



**HYPEROPIA** — Light focuses behind the retina.

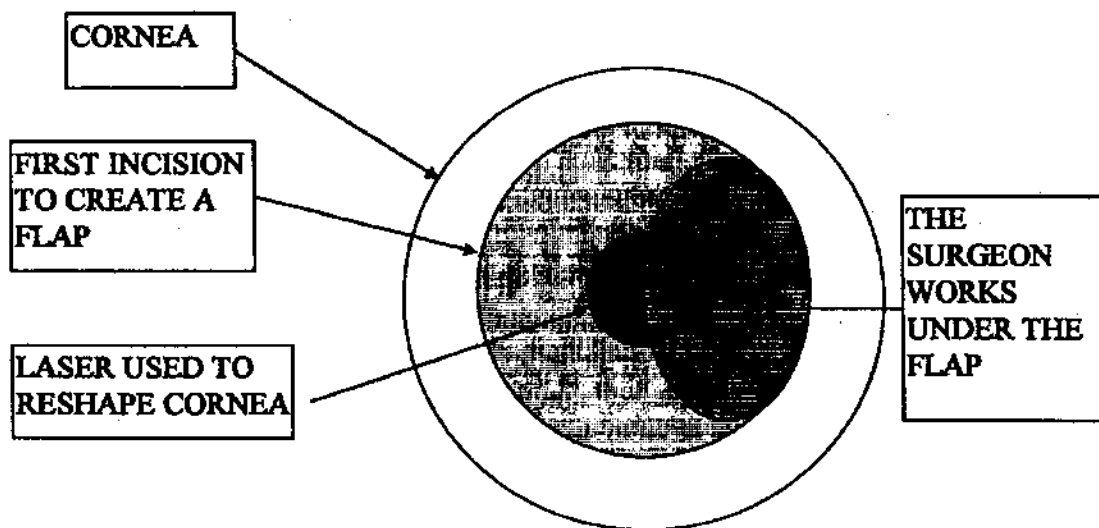
**Astigmatism** often occurs along with nearsightedness or farsightedness. This condition occurs when the cornea is oval or football-shaped instead of being circular. This football shape causes the light rays that pass through the cornea to the lens to be of different lengths. When the lens bends these rays of differing lengths, they focus on two different parts of the retina instead of a single point, causing a ghosting or doubling effect.



**ASTIGMATISM** — Light is focused unevenly

## ***What is LASIK?***

Laser Assisted In-situ Keratomileusis (LASIK) can be used to treat low, moderate, and high degrees of myopia and astigmatism. Its use for treating farsightedness is still being studied and has not been approved for general use. LASIK involves using a microkeratome (a special knife for cutting the cornea) to make a cut part way through the top of the cornea. This hinged cut piece is called the flap. The flap is laid back and an ultraviolet light beam (or laser) is used to remove a precise amount of tissue from underneath the flap in the center of the cornea and reshape the cornea. Operating under the flap leaves the surface of the cornea intact. As a result, many patients can see well within a few hours. There should be minimal pain after the procedure and vision generally becomes stable within a few weeks. Vision problems that may occur include fluctuating vision, scarring, flashes of light (starbursts), and rings of light around lights or bright objects (halos).



**Front View of Cornea**

There is no guarantee as to the success of your particular case, and there is a chance that you may have to use some sort of corrective lenses in the future. Some patients may not achieve their full

correction after the LASIK procedure and may decide to have a second procedure done on the same eye to further correct their vision. This second procedure to provide corrections is called an enhancement procedure. If this occurs and your surgeon decides an enhancement is in your best interest, you may decide to have a second surgery on the same eye. You will need to sign an additional consent form for a second surgery.

#### *Experience Record with the Dishler Excimer Laser*

In a clinical study of 839 eyes treated by Dr. Dishler, 87.2% (505/579) of eyes treated for less than -7.0 diopters of nearsightedness and 75.3% (174/231) of eyes treated for nearsightedness of -7.0 diopters or greater had vision of 20/40 or better without corrective lenses at six months after LASIK surgery. In 96.1% (671/698) of all patients treated, their vision was stable within 6 months after LASIK surgery and only 3.0% (25/839) of patients were retreated. Out of 461 eyes treated for myopic astigmatism, 3.47% (16/461) of the eyes had more astigmatism after surgery than before.

#### *Adverse Events*

The adverse event that was present at 6 months after LASIK surgery and occurred in more than 1% of the 839 eyes treated in the clinical study was: Overcorrection by more than 1.0 diopter in 1.8% (15/815) of the eyes evaluated. Adverse events that occurred in less than 1% of the eyes evaluated at 6 months in the clinical study included: overcorrection by more than 2 diopters in 0.9% (7/815) and moderate corneal haze in 0.1% (1/815) of the eyes. Other adverse events that could have occurred, but did not occur in any of the eyes evaluated in the study, include: loss of best corrected vision, detachment of the retina, haze or filminess on the cornea, problems with the corneal flap not being positioned properly after surgery or coming off and being lost or becoming deformed, swelling of the cornea, or changes in the pressure within the eye.

There are some serious potential complications (listed below) that could cause loss of SOME or ALL of the vision in the operated eye, because LASIK surgery involves making a cut in the



**cornea of the eye.** Please note that **NONE** of the potential problems listed below has occurred while performing LASIK surgery with the Dishler Excimer Laser System.

- Bacterial contamination of the surface of the eye or within the eye. This could cause an infection that may or may not be controlled with antibiotics or other means.
- Uneven healing of the corneal flap could result in a distorted cornea. This means that glasses or contact lenses could not correct your vision to what it was before the surgery.
- The laser could cut a hole in the cornea. This could result in distorted vision or require further surgery to restore useful vision.
- The microkeratome could cut the cornea too far and the entire corneal flap could come off. If this occurs, the corneal flap would be sewn back into place after the laser treatment is complete. There is a risk that the of cornea could be lost which could require further surgery and the use of donor corneal tissue to restore useful vision.

Some other potential problems which may occur after **any type of corrective eye surgery**, include but are not limited to:

- an imbalance between the two eyes that makes judging distance or depth more difficult. This could result in eyestrain.
- the natural tendency of the eyelids to droop with age which may be hasten by the surgical process.
- a rare possibility that corneal swelling, retinal detachment, hemorrhage, venous and arterial blood vessel blockage, or cataract formation could occur. These could lead to total blindness or even loss of an eye.
- The eye being more fragile to trauma from an impact. Protective eyewear is highly recommended during any active sport such as racquetball, tennis, softball, karate, etc., where a severe blow to the eye could result in damage to the operated eye.

### Subjective Adverse Events

About 200 patients (376 eyes) completed a questionnaire about their vision before (Pre-op) and 12 months (Mo.) after (Post-LASIK) LASIK surgery. Some of the patients had 1 eye treated and others had both eyes treated which resulted in a total of 376 eyes treated. Patients were asked to rate their vision problems in each of the treated eye(s) using the following scale: none = 1, mild = 2, moderate = 3, marked = 4, and severe = 5. For example, if a patient felt he/she had a great deal of difficulty reading, he/she would likely write 5 on his/her questionnaire for that question. Once all of the questionnaires were finished, they were grouped together and each visual symptom was counted (see table below). For example, out of the 376 eyes, 19 eyes had marked problems with light sensitivity before surgery and 11 eyes had this problem 12 months after surgery. Since all of the information was counted by visual symptoms and not by patients, there is no way to tell if any patient reported the same problem before and after surgery.

Patient Visual Symptoms (Subjective Adverse Events) at 12 Months Post-LASIK

	Marked				Severe				TOTAL			
	Preop		12 Mo		Preop		12 Mo		Preop		12 Mo	
	n	%	n	%	n	%	n	%	n	%	n	%
N	376		376		376		376		376		376	
Light Sensitivity	19	5.1	11	2.9	2	0.5	0	0.0	21	5.6	11	2.9
Night Driving	25	6.6	21	5.6	0	0.0	6	1.6	25	6.6	27	7.2
Reading Difficulty	16	4.3	11	2.9	2	0.5	3	0.8	18	4.8	14	3.7
Double Vision	6	1.6	2	0.5	0	0.0	0	0.0	6	1.6	2	0.5
Fluctuation in Vision	5	1.3	14	3.7	0	0.0	1	0.3	5	1.3	15	4.0
Glare	0	0.0	8	2.1	2	0.5	0	0.0	2	0.5	8	2.1
Halos	6	1.6	17	4.5	0	0.0	0	0.0	6	1.6	17	4.5
Dryness	30	8.0	16	4.3	4	1.1	10	2.7	34	9.0	26	6.9
Pain	0	0.0	2	0.5	0	0.0	0	0.0	0	0.0	2	0.5

"N" is the number of eyes evaluated at the specified visit

"n" is the number of eyes that had the specified symptom

% is calculated by dividing the number of eyes with the symptom by the total number of eyes evaluated and multiplying by 100.

The most common subjective adverse events reported at 12 months post-LASIK were those related to dim lighting conditions (problems with night driving), bright lights (glare, halos, light sensitivity), dryness, fluctuation in vision, and reading difficulty.



#### *LASIK Surgical Risks...*

Like any surgical procedure, some risk and discomfort may be associated with LASIK surgery. It is important that you discuss these risks with your doctor before making any decision about having laser surgery.

#### During the first month after Surgery:

- Your eyes may be watery or burn immediately following the surgery. This discomfort should go away within 12 to 24 hours after the surgery. Do NOT rub your eyes after the LASIK surgery; this could cause the corneal flap to move or rip.
- Your eyes may be dry for several weeks following the surgery. A lubricating eye drop (artificial tears) may be used to make your dry eyes feel better.
- There may be some pain, soreness, or a foreign body sensation after LASIK surgery, particularly during the first 48 hours following surgery. The eye drops given to you should minimize this. Pain medication (not containing aspirin) may be taken if needed.
- Some patients may notice a small broken blood vessel on the white part of the eye after the surgery. This is caused by the surgery and should disappear in the next few days to weeks after the surgery.

### During the first six months after Surgery:

- Your vision may NOT be as sharp as before surgery; you may be farsighted or more sensitive to light or glare right after surgery. These conditions usually occur during the normal stabilization period of one to three months after the surgery, but they may also be permanent. Vision may not seem as sharp at night as during the day and you may need some glasses at night.
- Undercorrection (where some degree of nearsightedness or astigmatism remains) or overcorrection (where some degree of farsightedness remains) may occur and may be permanent or may be treatable with future surgical “enhancement” procedures. An enhancement procedure is the same procedure performed again to make corrections.
- You may need to wear corrective lenses for reading or distance vision some or all of the time if your eye remains undercorrected or overcorrected after the surgery. Farsightedness is more likely in people over age 40. Moderate overcorrection has occurred in 1.8% (15/815) of the eyes treated with LASIK surgery.
- You may have more difficulty seeing in dim or fluorescent lights. Driving at night may be difficult right after the surgery because you may see “starburst” or “halo” effects around lights at night. A starburst is a momentary flash of light. A halo is a ring of light around any light or bright object. If halos are bothersome, they can sometimes be treated with medication or enhancement surgery. Halos usually diminish or disappear over time in most patients, but may be permanent. Halos that were marked in severity occurred in 4.5% (17/376) eyes in the clinical study. During LASIK surgery, some of the cells from the outer part of the eye could contaminate the area under the flap. If this happens, further surgery may be required to remove the cells.
- The laser, if not properly centered, could cause astigmatism and result in poorer vision than anticipated. This can occur if you do not look directly at the focusing (fixation) light during surgery.

*LASIK Surgery Benefits...*

- LASIK surgery performed with the Dishler Excimer Laser is effective in reducing or eliminating nearsightedness in the range of  $-0.5$  to  $-13.0$  diopters and nearsightedness with or without astigmatism up to  $-4.0$  diopters.
- LASIK surgery may reduce or eliminate dependency on eyeglasses and contact lenses.
- LASIK surgery may reduce overall nearsightedness and astigmatism.
- In a clinical study of 839 eyes treated by Dr. Dishler, 87.2% (505/579) of eyes treated for less than  $-7.0$  diopters of nearsightedness and 75.3% (174/231) of eyes treated for nearsightedness of  $-7.0$  diopters or greater had vision of 20/40 or better without corrective lenses at six months after LASIK surgery.



### *Are You A Candidate for LASIK Surgery?*

A brief screening eye exam by your eye surgeon or eye doctor can help determine if you are a good candidate for LASIK surgery. You may be a candidate if you:

- Are at least 21 years of age.
- Have between -0.5 and -13.0 diopters of nearsightedness with astigmatism between -0.5 and -4.0 diopters
- Have had little or no change in your vision over the past year (cylinder or sphere changing less than or equal to 0.5 diopters.
- Have healthy eyes with no eye disease or eye abnormalities.
- Are willing to sign an informed consent form for the surgery, provided by your doctor.

### *What Should You Do Before Surgery?*

Once you have determined that LASIK surgery is for you, then a complete eye examination must be performed to determine if your eye is healthy and suitable for LASIK surgery. The eye examination should include checking for defects or scratches on the cornea, measurements of the surface of your eyes, the pressure inside your eyes, etc. If this exam is performed by your own eye doctor, then the results of the eye exam should be forwarded to the eye surgeon's office before scheduling the LASIK surgery. Also, inform the eye surgeon of any allergies or medications you are taking.

Since contact lenses can change the shape of your eye, you will need to take the following actions if you wear contact lenses:

- Soft contact lens wearers - stop wearing the contacts at least 2 days before surgery.
- Gas permeable lens wearers - stop wearing the contacts a least 2 weeks before surgery.
- Hard contact lens wearers - stop wearing the contacts at least 4 weeks before surgery.
- Extended lens wearers - switch to only daytime use for 1 week (do not wear overnight) and stop wearing the contacts at least 2 days before surgery.

An additional eye exam may be necessary after you have stopped wearing your contact lenses and before your surgery date. Hard contact lens wearers should have two vision measurements taken at least one week apart before surgery.

If you are having surgery on both eyes, you should discuss with the surgeon or your eye doctor whether to have both eyes done on the same day, or, whether to come back on a different day to have the second eye treated. The risks of having both eyes treated on the same day could be greater than if they were treated on separate days.

You must have someone available to drive you home since you will not be allowed to drive until the effects of the medication given during the surgery wear off. You should not drive until your eye doctor gives you permission.

#### *What Happens On the Day Of Surgery?*

If you have scheduled a morning surgery, you should not eat or drink anything after midnight the night before surgery. If you have scheduled an afternoon surgery, then you may have a light breakfast with nothing to eat after that. You may drink clear liquids (e.g., water, apple juice) up to three hours before surgery.

You will come to the clinic at least one hour before your surgery time and will remain in the clinic until the eye surgeon determines that it is safe for you to go home. The average time from arrival to discharge is about two (2) hours.

You will be given an informed consent form to read and sign. An informed consent form is provided to advise you of possible surgical complications as well as tell you more about the surgical procedure. Please review the informed consent form carefully and ask the surgical staff any questions you have.

You may need to have an eye exam or vision test before your surgery. When it is time for your surgery, you will be given medication to take by mouth, or an intravenous line will be started and a small amount of medication will be given to you through your vein, to make you drowsy and relaxed during the surgery. Several drops of a local anesthetic eye solution will be placed in the eye to numb it. During the surgery, a cut will be made part way through the top of the cornea with the microkeratome. The cornea is the clear "glassy" part of the eye that covers the colored part of your eye. This cut piece of cornea (called a flap) will be laid back and the Dishler Excimer Laser beam will be used to remove ultra thin layers of the exposed cornea to change its shape. During the procedure, **it is very important that you do not move.** You should look at the light that helps focus your eye when instructed and follow all instructions given to you by the doctor or his staff. After the laser surgery is complete, the corneal flap is then returned to its original position. Antibiotic and anti-inflammatory eye drops will be put into the eye before and after the surgery to prevent infection and help the eye to heal. If you are having the second eye treated, the same procedures will be repeated on the second eye. At the end of the surgery, a clear shield will be taped over the eye(s) or wraparound sunglasses will be given to you to wear to protect the eye(s) from accidentally being bumped or touched. Do NOT rub your eye(s) as this could cause the corneal flap to move or tear. The surgical procedure takes about 2 to 5 minutes for each eye.

The following table gives you a brief outline of the surgical procedures.

Procedure	Purpose
Intravenous line started	To administer medicine for relaxation
Eye drops	To numb the eye
An incision is made in the cornea	A flap is created so the surgeon can reshape the cornea underneath the flap
Laser	Removes very thin layers of the cornea to reshape the cornea
Flap is returned and anchored to its original position. The flap is self-adhering, but may require a stitch to hold it in place.	To restore the eye to its normal state, protect the lasered area., and speed recovery.
Eye drops are instilled	To prevent infection and reduce redness



### *What To Do After The Surgery*

You will be given an eye care kit to use after the surgery. The kit contains plastic eye shields, tape, eye drops and pain medication.

- **Eye Shield:** An eye shield should be worn over each operated eye the first night after surgery. The next day you will wear the protective eye shield or the wraparound sunglasses over the operated eye(s) until you come to the clinic. **It is important that you do not rub the eye. You do not want to disturb the corneal flap, which could lead to distorted vision, or risk getting anything in the eye that might cause infection.**
- **Pain Medication:** The pain medication should be taken only if needed. Most patients experience little to no discomfort after the surgery. You may also take plain acetaminophen (for example, Tylenol®).
- **Eye Drops:** The eye drop is a combination antibiotic and steroid to prevent infections and help the eye to heal. You should put one drop in the operated eye four (4) times a day for one week or as instructed by the doctor.

Before you leave, one of the surgical staff members will review how to take care of your eye and will give you written instructions. Follow the written instructions if they are different from this booklet.

You will need to have follow-up visits at 1 day, 2 weeks, 3 months, and 1 year after the surgery. At each visit, your eyes will be examined and your vision will be tested. You may need to make additional visits to the clinic if you have any problem with your eye after the surgery. Your follow-up visits may be made to the surgical clinic or can be conducted by your own eye doctor

or another eye doctor who is trained in evaluating LASIK patients after surgery. The eye surgeon will work closely with your eye doctor to coordinate and evaluate your postoperative care.

The first week after surgery you should not use a hot tub or swim. Strenuous physical exercise and activity should be limited. It is important to protect your eyes from anything that might get in them and from being hit or bumped.

Do not wear eye makeup for one week after surgery. New mascara and eyeliner that wash off easily with water should be purchased for use after surgery. Avoid rubbing the eye when applying or removing eye makeup.

#### *When Should I Call The Doctor?*

You should call the eye surgeon or your eye doctor as soon as possible if either of the following occurs:

- You have any sudden changes in vision, especially after rubbing or bumping the eye.
- You develop sudden eye pain, redness, swelling, burning, or itching of the eye or eyelid.

#### *Are There Any Side Effects From The Medications?*

If fluorescein (a yellow eye drop) is put into the eye during the eye exam to check for defects or scratches, it will temporarily stain your tears yellow or orange. Fluorescein may stain soft contact lenses. You should wait at least one (1) hour before replacing contact lenses whenever fluorescein is used.

If eye drops are put in your eyes to dilate the pupil, your eyes will not respond normally to light and you may experience blurred vision and sensitivity to light until the effects of the eye drops

wear off. You should protect your eyes with sunglasses in bright light while your pupils are dilated. You should not drive or engage in any hazardous activity until your vision returns to normal.

A sedative may be given to you before the surgery to relax you. Common side effects include drowsiness, confusion, sleepiness, impaired coordination, slow reflexes, dry mouth, tiredness, and changes in heart rate or a drop in blood pressure. You may not remember things that happened, such as the surgery, after you take the sedative. You should not drive or engage in any activity that requires mental alertness for at least twelve (12) hours after the surgery or until the effects of the sedative have worn off. . You will not be allowed to drive yourself home after the surgical procedure and must have arranged for someone to drive you home.

Eye drops (for example, tetracaine or proparacaine) are usually used to anesthetize or numb the eye during the surgery. You should avoid touching or rubbing your eye until the anesthetic effect has worn off because the anesthetic temporarily eliminates the "blink" reflex. Your eye will be covered with a protective shield to keep you from accidentally touching or rubbing it. The numbing eye drops may cause some slight stinging or burning in the eye when they are applied and may cause some reddening of the white part of the eye. Rarely, they may cause an allergic reaction.

The eye drops used during and after the surgery contain an antibiotic and an anti-inflammatory agent. The side effects of the eye drops include eye irritation, redness, increased tearing or wateriness, swelling, and itching of the eyelid. Overuse of the eye drops may cause these same symptoms.

## *Questions to Ask Your Doctor*

This booklet explains the risks and benefits of having LASIK surgery. It is important that you talk with your doctor to obtain the information you need to make a decision about whether LASIK surgery is right for you. Please make sure you have asked your doctor all of the following questions:

- What does the LASIK procedure cost?
- Is the LASIK procedure generally covered by insurance?
- Will I be able to get rid of my glasses permanently?
- Does the refractive surgery fee include the cost of the surgery and all follow-up visits?
- If I am improperly corrected, will my enhancement procedure be free?
- How long am I actually under the laser?
- Can my own eye doctor care for me after the surgery? If so, how does he/she get paid?
- What are other options for correcting nearsightedness and astigmatism?
- What additional problems, if any, will I encounter if I have surgery performed on both eyes?
- If I have surgery performed on both eyes, will they heal the same?
- Will my cornea heal to its original condition?
- Can I take part in athletic activities (for example, running, swimming, etc.)?
- Will I experience any pain or discomfort?
- How long will it take for my eyes to heal?
- When can I expect to see results from the surgery?

*Lasik Self-Test Quiz*

Take the following test to see if you understand the information presented to you about LASIK. Circle either "true" or "false" to indicate your understanding of the statement. Answers are provided following the test. You should ask questions about anything you do not understand.

1. TRUE FALSE      The results of my LASIK have been guaranteed by the surgeon.
2. TRUE FALSE      LASIK is the only alternative to correct my vision problem.
3. TRUE FALSE      If my vision gradually gets worse after the surgery, I can always have an enhancement procedure.
4. TRUE FALSE      People over 40 years of age are more likely to have to wear reading glasses even after LASIK.
5. TRUE FALSE      The LASIK procedure involves the surgeon removing or lifting a portion of my cornea and later replacing it in the same position.
6. TRUE FALSE      Laser surgery is completely safe and not subject to the risks associated with other types of surgery.
7. TRUE FALSE      Even if my surgery does not eliminate all of my vision problems, glasses or contacts can always correct me to 20/20 vision.
8. TRUE FALSE      There is a good chance that my vision will gradually become as bad as it was before the surgery.
9. TRUE FALSE      Regardless of my occupation, I will be able to function at 100% capacity two to three days after my operation.
10. TRUE FALSE      At night I may experience a halo effect when looking at lights.
11. TRUE FALSE      My eyes may be unusually sensitive to light after the surgery.
12. TRUE FALSE      I will not experience noticeable changes in my vision during the months and years after the surgery.
13. TRUE FALSE      The doctors and staff have provided me with a complete list of possible complications associated with LASIK.

*Answers For LASIK Self-Test Quiz*

**Correct Answers**

1. FALSE It is impossible for any surgeon to guarantee a specific result for even the most ideal candidate.
2. FALSE Glasses and contact lenses are also alternatives
3. FALSE If there is a significant worsening or under-correction, you can have an enhancement procedure *only* if the surgeon determines it would be in your best interest.
4. TRUE People over 40 are more likely to need reading glasses, if only part-time.
5. TRUE The surgeon uses a microkeratome to create the corneal flap.
6. FALSE Laser surgery is associated with the same risks as any other surgery.)
7. FALSE In certain cases, it is possible to lose some best-corrected visual acuity. That is, you may not see as well as before, even with glasses or contacts.
8. FALSE There is practically no chance that your vision will regress completely.
9. FALSE You should not drive until your eye doctor gives you permission. You may be somewhat over-corrected initially afterwards, making reading difficult.
10. TRUE You may see a halo around lights at night, and this usually diminishes with time.
11. TRUE Your eyes may be light sensitive for some time after surgery.
12. FALSE LASIK will not prevent future changes in vision which may occur due to the aging process or other causes.
13. FALSE To state *all* complications of any surgery would be impossible. Therefore, you should ask questions if there is anything you do not understand.

*Index*

(This will be completed when the patient information is finalized.)