

## **FACTS YOU NEED TO KNOW ABOUT LASER IN SITU KERATOMILEUSIS (LASIK)**

**A SURGERY TO REDUCE OR ELIMINATE MYOPIA  
WITH OR WITHOUT ASTIGMATISM USING THE  
CARL ZEISS MEDITEC MEL 80 EXCIMER LASER SYSTEM**

### **PATIENT INFORMATION BOOKLET**

Please read this entire booklet. If you have any questions about it, discuss them with your doctor before you agree to the surgery.

The MEL 80 Excimer Laser is indicated for use in primary **LASIK** treatments for the reduction or elimination of **myopia** of less than or equal to -7.0 D with or without refractive **astigmatism** of less than or equal to -3.0 D, with a maximum manifest refraction spherical equivalent (**MRSE**) of -7.00 D, in patients who are 21 years of age or older with documentation of stable manifest refraction over the past year as demonstrated by change in sphere and cylinder of  $\leq 0.5$  D.

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**CARL ZEISS MEDITEC, INC.  
MEL 80 EXCIMER LASER SYSTEM  
PATIENT INFORMATION BOOKLET**

**TABLE OF CONTENTS**

	<b><u>PAGE</u></b>
<b>A. INTRODUCTION.....</b>	<b>5</b>
1. HOW THE EYE FUNCTIONS.....	5
2. FOCUSING WITH YOUR EYE.....	5
3. CHECKING YOUR FOCUS.....	6
4. THE NEARSIGHTED EYE.....	6
<b>B. WHAT IS LASIK?.....</b>	<b>7</b>
<b>C. WHAT ARE THE BENEFITS OF LASIK SURGERY?.....</b>	<b>7</b>
1. CLINICAL STUDY TO EVALUATE BENEFITS.....	8
STUDY PATIENT DEMOGRAPHICS.....	8
VISUAL ACUITY WITHOUT GLASSES AFTER SURGERY.....	9
VISUAL ACUITY AFTER SURGERY (WITHOUT GLASSES) COMPARED TO VISUAL ACUITY BEFORE SURGERY (WITH GLASSES).....	10
<b>D. WHAT ARE THE RISKS OF LASIK SURGERY?.....</b>	<b>10</b>
1. CONTRAINDICATIONS – WHEN CAN’T YOU HAVE LASIK?.....	13
2. WHAT WARNINGS AND OTHER INFORMATION DO YOU NEED TO KNOW ABOUT?.....	13
3. PRECAUTIONS.....	14
EARLY COMPLICATIONS (DURING THE FIRST FEW WEEKS AFTER LASIK).....	15
MEDIUM-TERM COMPLICATIONS (3 MONTHS AFTER SURGERY).....	15
LONG-TERM COMPLICATIONS (6 MONTHS AFTER SURGERY).....	16
4. CLINICAL STUDY TO EVALUATE RISKS.....	16
VISUAL ACUITY WITH GLASSES AFTER SURGERY.....	17
CHANGE IN VISUAL ACUITY WITH GLASSES AFTER SURGERY.....	17
ADVERSE EVENTS AND COMPLICATIONS.....	17
5. PATIENT SELF-EVALUATION BEFORE AND AFTER LASIK.....	18
PATIENT SYMPTOMS GRADED AS WORSE OR SIGNIFICANTLY WORSE AFTER SURGERY.....	19
SYMPTOM SEVERITY BEFORE AND AFTER SURGERY.....	20
PATIENT SELF –EVALUATION OF VISION QUALITY.....	23
FACTORS ASSOCIATED WITH OUTCOMES.....	25

**E. INDICATIONS FOR USE .....26**

**F. ARE YOU A GOOD CANDIDATE FOR LASIK? .....26**

**G. WHAT YOU NEED TO KNOW ABOUT THE SURGERY.....26**

**H. QUESTIONS TO ASK YOUR DOCTOR.....28**

**I. SUMMARY OF IMPORTANT INFORMATION .....29**

**J. GLOSSARY OF TERMS.....30**

**K. PATIENT ASSISTANCE INFORMATION.....32**

**L. INDEX.....33**

**CARL ZEISS MEDITEC, INC.  
MEL 80 EXCIMER LASER SYSTEM  
PATIENT INFORMATION BOOKLET**

**INDEX OF TABLES**

	<b><u>PAGE</u></b>
<b>TABLE 1. DEMOGRAPHICS OF 360 EYES OF 182 PATIENTS .....</b>	<b>8</b>
<b>TABLE 2 VISUAL ACUITY WITHOUT GLASSES AFTER SURGERY (N=360 EYES TESTED) .....</b>	<b>9</b>
<b>TABLE 3. VISUAL ACUITY WITH NO GLASSES AFTER SURGERY COMPARED TO VISUAL ACUITY WHILE WEARING GLASSES BEFORE SURGERY .....</b>	<b>10</b>
<b>TABLE 4 VISUAL ACUITY WITH GLASSES (BEST VISION) AFTER SURGERY .....</b>	<b>17</b>
<b>TABLE 5 CHANGE IN VISUAL ACUITY WITH GLASSES AFTER SURGERY COMPARED TO BEFORE SURGERY (N=360 EYES TESTED) .....</b>	<b>17</b>
<b>TABLE 6 ADVERSE EVENTS REPORTED AT ANY POSTOPERATIVE VISITS ALL TREATED EYES .....</b>	<b>18</b>
<b>TABLE 7 COMPARISON OF SYMPTOMS BEFORE AND AFTER SURGERY .....</b>	<b>19</b>
<b>TABLE 8A CHANGE IN GRADING OF SYMPTOMS BEFORE AND AFTER SURGERY .....</b>	<b>21</b>
<b>TABLE 8B CLINICALLY SIGNIFICANT PATIENT SYMPTOMS .....</b>	<b>22</b>
<b>TABLE 9 PATIENT EVALUATION OF SATISFACTION AND VISION QUALITY IMPROVEMENT .....</b>	<b>24</b>

## A. INTRODUCTION

This booklet is written to help you decide whether to have **LASIK** surgery to correct your **nearsightedness**. (**LASIK** stands for Laser in situ Keratomileusis.) Glasses and contact lenses also correct **nearsightedness**, as do the surgeries known as **PRK** and **RK**. (**PRK** stands for photorefractive keratectomy and **RK** for radial keratotomy.) This booklet refers to **LASIK** using the Carl Zeiss Meditec MEL 80 Excimer Laser System. It is completely different than **RK**, but somewhat similar to **PRK**.

If you are nearsighted in both eyes, you may want to treat both eyes with **LASIK**. Sometimes, it is better to treat only one eye with **LASIK**. Talk with your doctor about whether it would be better to treat one eye or both eyes.

Please read this whole booklet. Discuss your questions with your doctor. Your doctor can determine whether or not you are medically suitable for **LASIK**, but only you can decide whether the expected benefits are worth the risks. Some jobs have vision requirements that **RK**, **PRK**, or **LASIK** do not meet. For example, military pilots.

### 1. HOW THE EYE FUNCTIONS

Your eye focuses light to form images or "pictures" much like a camera. Your eye changes the images into nerve signals. Then it sends them to the brain. If your eye is out of focus, what you see is blurred.

The **cornea** at the front of the eye bends the light toward your retina. The clear tissue of the **cornea** provides two-thirds of the focusing power of the eye. The **lens** within the eye finishes the job of focusing the light onto your retina.

### 2. FOCUSING WITH YOUR EYE

The eye focuses light by bending all light rays to meet at a single point. If it works perfectly, a sharp image of the object you look at will be focused on the retina (Fig. 1). You will see a clear image. But, if the light focuses in front of or behind the retina, the image you see will be blurred. Whether you are nearsighted, farsighted, or astigmatic (Fig.2, Fig.3) depends on where the image focuses.

The shape of the **cornea** determines the focusing power of the eye. The more curved the **cornea**, the more that light rays are bent. If the **cornea** is too flat, the image focuses behind the retina. The eye then is farsighted. If the **cornea** is curved too much, the image focuses in front of the retina. The eye then is nearsighted (Fig. 2). If the **cornea** shape is irregular (like a football rather than a basketball), it is called astigmatic (Fig. 3).

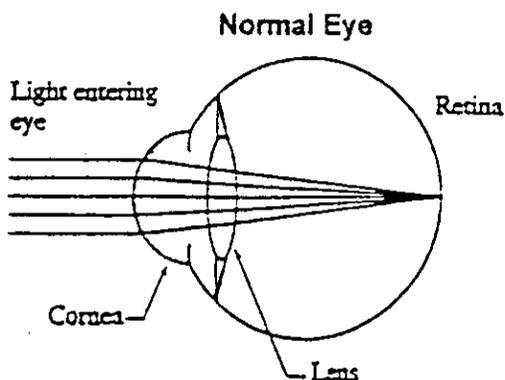


Fig. 1

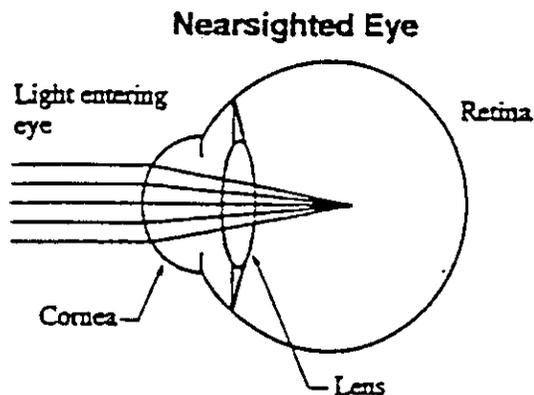


Fig. 2

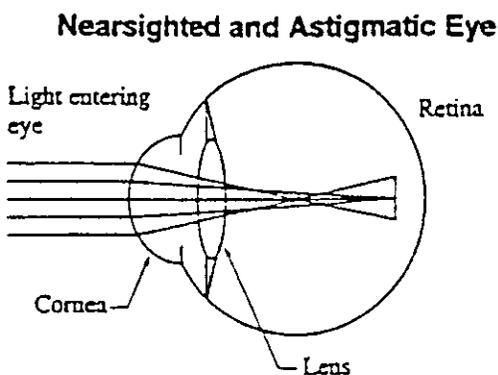


Fig. 3

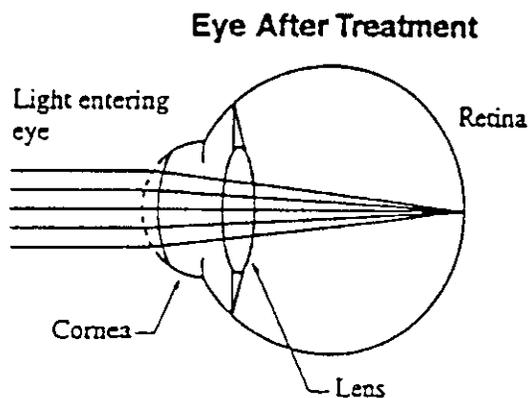


Fig. 4

### 3. CHECKING YOUR FOCUS

Your doctor checks where your eye focuses light. When he corrects your vision, he adds a **lens** to move the focal point. (Sometimes he combines more than one lens.) Now the focal point strikes your retina perfectly. Good focus depends on the shape and size of your eyeball, the shape of your **cornea**, and the power of your natural **lens**.

### 4. THE NEARSIGHTED EYE

In North America, one in four people are **nearsighted**. They see near objects clearly, but far objects are blurry. Light rays focus in front of the retina, not directly on it. It tends to run in families. More often than not, it starts in childhood and becomes stable in the late teens or early twenties. Glasses, contact lenses or **refractive surgery** can correct **nearsightedness**.

If your vision changes over time, you can change glasses or contact lenses. Changes due to **refractive surgery** cannot be reversed. Sometimes the first surgery doesn't correct your vision enough or corrects it too much. Sometimes your vision changes as time passes. In either case, your doctor can try to improve it with added treatments.

## B. WHAT IS LASIK?

**LASIK** is a surgical treatment for **nearsightedness**. A device called a microkeratome, which is like a carpenter's plane, cuts a thin flap of tissue from the front of the **cornea**. (The cornea is the clear part on the front of the eye.) The doctor then folds the flap out of the way. Next, an **excimer laser** removes some tissue from the front surface of the **cornea** to make it less curved. After the laser treatment, the doctor replaces the corneal flap. This is different from **RK**. In **RK**, a doctor makes deep cuts around the center of the **cornea** with a surgical knife.

An **excimer laser** is a machine that aims a strong beam of UV light at your eye. (UV stands for ultraviolet.) The machine creates a brief, intense pulse that lasts just a few billionths of a second. Each pulse removes a tiny amount of tissue from the surface of the **cornea**. It makes little heat and does not change the tissue beneath.

Doctors perform **LASIK** surgery on one eye at a time. If all goes well with the first eye, he can treat the second eye. Often he does the second eye on the same day. He can also do it later. It depends on his judgment of your particular case.

**LASIK** corrects your vision so you can see distant objects better. It does not take away the need for reading glasses. You may need reading glasses after laser surgery even if you did NOT wear them before.

## C. WHAT ARE THE BENEFITS OF LASIK SURGERY?

Using the MEL 80, your doctor can correct your distance vision. It also may reduce or end your need to use contact lenses or glasses. Doctors can use it on nearsighted patients up to these limits.

- Patients who are **nearsighted** up to **-7.0 Diopters**, with **astigmatism** up to **-3.0 Diopters**, with a maximum manifest refraction spherical equivalent (**MRSE**) of **-7.0 Diopters**.

The clinical study described below found that **LASIK** surgery with the MEL 80 Excimer Laser System is a reasonably safe and effective way to correct **nearsightedness**.

**1. CLINICAL STUDY TO EVALUATE BENEFITS**

Researchers did a study to evaluate the benefits and risks of **LASIK** with the MEL 80. They studied 360 eyes. The results are below and in the section named "What are the Risks of **LASIK** surgery."

**STUDY PATIENT DEMOGRAPHICS**

Most patients in the study were Caucasian. No patients were under 21 years old or over 60 years old. Table 1 shows the age, race, and gender of patients in the study. Please note: In all tables, "N" or "n" stands for the number of eyes treated in each category.

**TABLE 1. DEMOGRAPHICS OF 360 EYES OF 182 PATIENTS**

			<b>Total</b>
<b>Number of Eyes</b>			360
<b>Number of Enrolled Subjects</b>			182
<b>Age (yrs)</b>		<b>Average</b>	33.5
		<b>Standard Deviation</b>	8.8
		<b>Range</b>	21-60
<b>Gender</b>	Male	% (n)	55.5% (101)
	Female	% (n)	44.5% (81)
<b>Race</b>	White	% (n)	79.7% (145)
	Black	% (n)	3.3% (6)
	Asian	% (n)	4.9% (9)
	Other	% (n)	12.1% (22)
<b>Treated Eye</b>	Right	% (n)	50.0% (180)
	Left	% (n)	50.0% (180)

**VISUAL ACUITY WITHOUT GLASSES AFTER SURGERY**

In the study, doctors gave each eye one LASIK treatment with the MEL 80. Then they measured the vision of each eye without glasses after 1, 3 and 6 months. After 3 and 6 months, more than 92% of eyes had 20/20 vision or better. More than 99% had 20/40 vision or better. Most states require your vision to be 20/40 or better for you to drive **without** glasses or contacts.

**TABLE 2 VISUAL ACUITY WITHOUT GLASSES AFTER SURGERY (N=360 EYES TESTED)**

VISUAL ACUITY WITHOUT GLASSES	TIME AFTER SURGERY		
	1 MONTH	3 MONTHS	6 MONTHS
Percent of eyes with 20/20 or better	91.6%	92.5%	92.7%
Percent of eyes with 20/40 or better	99.7%	99.7%	99.4%

**VISUAL ACUITY AFTER SURGERY (WITHOUT GLASSES) COMPARED TO VISUAL ACUITY BEFORE SURGERY (WITH GLASSES)**

The study compared the vision of each eye with glasses before LASIK and without glasses 3 and 6 months after LASIK. Table 3 shows the results. At 3 months, 70.1% saw as well *without* glasses as they did before *with* glasses. At 6 months, it was 72.9%. This was measured in terms of a gain of lines on the eye chart. (The eye chart is the visual acuity chart. A line is a row of letters on it. Each line on the chart has smaller letters than the lines above it.) A gain of lines means a patient could read lines of smaller letters after LASIK than they could read before. Please note that the “N” at each exam is different because different numbers of patients came back at 3 and 6 months.

**TABLE 3. VISUAL ACUITY WITH NO GLASSES AFTER SURGERY COMPARED TO VISUAL ACUITY WHILE WEARING GLASSES BEFORE SURGERY**

Visual Acuity Without Glasses	Time after Surgery	
	3 Months % (n/N)	6 Months % (n/N)
Percent of eyes with 2 or more lines better vision than with glasses before surgery	2.5% (9/358)	4.0% (14/354)
Percent of eyes with 1 line better vision than with glasses before surgery	21.5% (77/358)	29.4% (104/354)
Percent of eyes with the same vision as with glasses before surgery	46.1% (165/358)	39.5% (140/354)
Percent of eyes with 1 line worse vision than with glasses before surgery	21.5% (77/358)	17.5% (62/354)
Percent of eyes with 2 or more lines worse vision than with glasses before surgery	8.4% (30/358)	9.6% (34/354)

**D. WHAT ARE THE RISKS OF LASIK SURGERY?**

Sometimes **LASIK** does not give you the best vision the first time. To get the best vision you can, you may need to have **LASIK** surgery again.

**LASIK** can sometimes leave your vision worse than before, even with glasses or contacts.

After **LASIK**, you may need to wear glasses or contacts to see clearly up close, even if you did not need to wear them before.

**LASIK** can give you vision problems or symptoms that you did not have before. It can also cause vision problems or symptoms that you had before to become worse. (For example, dry eye, halos, glare, etc.)

**LASIK** has the following risks:

- The **cornea** or other parts of the eye can become infected because the cornea has been cut and tissue has been removed from it.
- The microkeratome that is used to make the corneal flap can cut all the way through the front part of the eye. This is called perforation of the eye, which can lead to loss of fluid from inside the eye, cataract formation, and infection of the eye.
- The corneal flap can come loose, or can be torn or cut off the eye completely and be lost, making your vision much worse.

The following possibilities are also considered risk factors:

- Retreatment with the MEL 80. It is not known whether **LASIK** is safe and effective to repeat on the same eye.
- Undiagnosed dry eyes. Your doctor should test you for dry eyes before you have **LASIK**. **LASIK** can make dry eyes worse, and it can give you dry eyes even if you did not have them before.
- Large pupils. Before **LASIK**, your doctor should measure your **pupil** size under dim light. Pupils too large under dim light can lead to bad effects from **LASIK**. "Too large" means more than 7 mm. These effects include glare, **halos**, and problems driving at night. If your pupils are too large, talk with your doctor about the risks.

#### During the First Week Following Surgery

- You may have pain and discomfort for up to 7 days after surgery.
- You can expect to have blurred vision and tearing as the **cornea** heals.
- You may be sensitive to bright lights.
- You may have short-term swelling of the front surface of your eye.
- The pressure in your eye may increase. This is often due to the use of eye drops to control inflammation. To control this, your doctor may prescribe another kind of eye drop, or stop giving you such drops. An increase in eye pressure does not usually cause any symptoms. But to make sure, you must see your doctor as directed to check for an increase in eye pressure. A severe increase in eye pressure could cause eye pain or nausea. If you have these symptoms, you should contact your doctor.
- You must not rub your eye. This can cause a shift of the flap, which leads to bad effects. These can include blurred vision, risk of infection, inflammation, edema or epithelial in-growth.

**During the First Week to One Month following surgery**

- The pressure in your eye may increase. This is often due to the use of eye drops to control inflammation. When you stop the drug therapy, the pressure goes back to normal.
- Your **cornea** may become so hazy or cloudy that it affects your vision. This haze disappears over time. Some patients see haze up to 6 months after **LASIK**.

**3 months or Longer After Surgery**

- Some patients have vision complaints. These are discussed in the clinical results section D.4 (see Table 7).

## 1. CONTRAINDICATIONS – WHEN CAN'T YOU HAVE LASIK?

You should **NOT** have **LASIK** if any of the things below apply. In these cases, the risk is greater than the benefit.

- You have a disease that makes your body less able to heal. These include collagen vascular (e.g., rheumatoid arthritis), autoimmune (e.g., lupus), or immunodeficiency diseases (e.g., AIDS).
- You are pregnant or nursing, which can cause short-term changes in your **cornea**. Such changes cannot be predicted. In such cases, **LASIK** might change the shape of your **cornea** in a way that would harm your vision.
- You show signs of a condition that causes a thinning of your **cornea**. **Keratoconus** is one such condition. It can lead to serious problems during and after **LASIK**. It may result in poor vision after **LASIK**. It may cause the need for additional surgery.
- You are taking medicines that have side effects on your eyes. Such medicines include: Accutane<sup>1</sup> to treat acne and Cordarone<sup>2</sup> to normalize heart rhythm. These may affect the accuracy of **LASIK** or the way the **cornea** heals after **LASIK**. This may yield poor vision after **LASIK**.

## 2. WHAT WARNINGS AND OTHER INFORMATION DO YOU NEED TO KNOW ABOUT?

If you have any of the conditions below, talk to your doctor before you have **LASIK**. In these cases, your doctor must judge whether the benefits of **LASIK** outweighs the risks.

- You have a disease likely to affect wound healing. Such types of disease include connective tissue disease, severe atopic disease or the lack of an adequate immune response. In these cases, **LASIK** may be risky for you. This is because it may impede the healing of your eyes.
- You have diabetes. If you depend on insulin, **LASIK** may be risky for you. This is because it may impede the healing of your eyes.
- You have or had a *Herpes* infection that affected your eyes. *Herpes simplex* or *Herpes zoster* can affect your eyes. If you have now—or had before—such an infection, **LASIK** is more risky for you.
- You have dry eyes. If you have very dry eyes, **LASIK** may increase dryness. This may or may not go away. This dryness may delay healing of the flap. It may interfere with the surface of the eye after **LASIK**.
- You have severe allergies. If you do and take medicines for them, **LASIK** is more risky for you.

<sup>1</sup> Accutane (isotretinoin) is the registered trademark of Hoffman La Roche Inc.

<sup>2</sup> Cordarone (amiodarone hydrochloride) is the registered trademark of Sanofi-Synthlabo.

- You have blepharitis, or have had it in the past. (Blepharitis is redness on the line of the eyelash. It includes crusting of the lashes, often with burning, itching and irritation of the eyes.) It can increase the risk of infection of the flap after LASIK. It also can increase the risk of inflammation of the flap.

### 3. PRECAUTIONS

If you have any of the conditions below, talk to your doctor before you have **LASIK**. In these cases, it is not known whether **LASIK** is safe and effective.

- Your vision has not been stable in the last 12 months. Your eyes are not stable if in 12 months they are  $> 0.50$  **Diopters** more **nearsighted** or **astigmatic**. In this case, your doctor cannot know how much treatment to apply. This may result in poor vision after **LASIK**.
- Your cornea, lens, or vitreous are not normal due to disease or other factors. (Other factors might be a scar, infection, cataract, etc.) Things like corneal scars may affect the accuracy of **LASIK** or the way your eye heals. This may result in poor vision after **LASIK**.
- You have or had uveitis/iritis of the eye. In such cases, it is not known whether **LASIK** is safe and effective. Such diseases are often treated with steroids, which can affect wound healing. While these diseases are active or resolving, they could affect the accuracy of **LASIK**. They also could affect the healing process.
- You now have or previously had an injury or surgery on your eye. It could have been refractive surgery such as **RK**, **PRK**, **LASIK**, or another type. In these cases, it is not known whether **LASIK** will weaken the **cornea** too much. This may result in poor vision after **LASIK**.
- You are less than 21 years of age. It is not known whether **LASIK** is safe and effective for you.
- You are taking medicines. Let your doctor know of any medicines you are taking, with or without a prescription.
- You take medicines that may affect wound healing. One such medicine is Imitrex<sup>3</sup>, used for migraine headaches, and others include hormone replacement therapy and antihistamines. It is not known whether **LASIK** is safe and effective for you.
- You now have or previously had glaucoma or high pressure in your eyes. High pressure in your eyes is more than 23 mmHg. It is not known whether **LASIK** is safe and effective for you.
- Your corneas are too thin. In this case, your doctor cannot cut a proper flap to do **LASIK**.

<sup>3</sup> Imitrex (sumatriptan succinate) is a registered trademark of Glaxo Group Limited.

- Over the long term (> 6 months after LASIK), it is not known whether **LASIK** is safe and effective.
- You are in dim lighting, rain, snow, fog, or bright glare. In these cases, you might have problems seeing after **LASIK**. Whether you will or not is hard to predict because it has been studied so little.
- You have a history of keloid formation.
- You have a **MRSE** of -7.25 to -8.00 D, as insufficient safety and effectiveness data are available for eyes in this range.

Research has not shown what effects **LASIK** has on vision performance in poor lighting. After **LASIK**, some patients may find it harder than before to see in dim light, rain, snow, fog, or glare from lights at night. Vision performance could be worsened by large **pupil** size.

Speak with your doctor about the risk that **LASIK** may cause bad effects on your vision. These include glare, **halos**, and problems driving at night.

Your doctor should test you for dry eyes before **LASIK**. **LASIK** may make dry eyes worse. You may have dry eyes after **LASIK** even if you did not before.

Compared to younger patients, it is harder to predict outcomes for those 50 years and older.

#### **TYPICAL COMPLICATIONS THAT MAY OCCUR AFTER THE LASIK PROCEDURE ARE:**

##### **EARLY COMPLICATIONS (DURING THE FIRST FEW WEEKS AFTER LASIK)**

- Epithelium in the interface with loss of  $\leq 2$  lines of best vision with glasses
- Corneal edema
- Less than stage 2 lamellar keratitis
- Corneal erosion
- Debris in interface & episcleritis
- Allergies
- Chalazion
- Conjunctivitis
- Episcleritis
- Inflammation
- Lamellar keratitis
- Lamellar keratitis & debris in interface
- Superficial punctate keratitis
- Subconjunctival hemorrhage

##### **MEDIUM-TERM COMPLICATIONS (3 MONTHS AFTER SURGERY)**

- Corneal flap complication with loss of < 2 lines of best vision with glasses
- Ghost images

- Allergies
- Chalazion
- Conjunctivitis
- Debris in interface

**LONG-TERM COMPLICATIONS (6 MONTHS AFTER SURGERY)**

- Recurrent corneal erosion
- Bowman's wrinkle
- Conjunctivitis
- Corneal abrasion
- Debris in interface
- Debris in interface & Bowman's wrinkle
- Lamellar keratitis

**4. CLINICAL STUDY TO EVALUATE RISKS**

In the study on **LASIK** using the Carl Zeiss MEL 80 Excimer Laser System, vision **without** glasses improved for all eyes. Some people still needed glasses or contact lenses after **LASIK**. To measure vision with glasses gives you the eye's best vision. The study showed best vision before and after **LASIK**. In this way, you can know how many eyes got worse. The study also reports adverse events after **LASIK**. This is to assess risks besides worse vision.

Table 4 shows the best vision after **LASIK**. Table 5 shows the change in best vision after **LASIK**. Table 6 shows the percent and number of eyes that had adverse events after **LASIK**. Change in best vision was measured in terms of a gain or loss of lines on the eye chart. (The eye chart is the visual acuity chart. A line is a row of letters on it. Each line on the chart has smaller letters than the lines above it.) A gain of lines means a patient could read lines of smaller letters after **LASIK** than they could read before. Please note that the "N" at each exam is different because different numbers of patients came back at 3 and 6 months.

**VISUAL ACUITY WITH GLASSES AFTER SURGERY**

The study measured vision with glasses 3 and 6 months after LASIK. Table 4 shows that all nearsighted and all nearsighted and astigmatic eyes saw 20/20 or better.

**TABLE 4 VISUAL ACUITY WITH GLASSES (BEST VISION) AFTER SURGERY**

	Nearsightedness		Nearsightedness With Astigmatism	
	3 Months % (n/N)	6 Months % (n/N)	3 Months % (n/N)	6 Months % (n/N)
20/20 or better	100.0% (88/88)	100.0% (88/88)	100.0% (270/270)	100.0% (266/266)
20/40 or better	100.0% (88/88)	100.0% (88/88)	100.0% (270/270)	100.0% (266/266)

**CHANGE IN VISUAL ACUITY WITH GLASSES AFTER SURGERY**

Table 5 shows the change in best vision after LASIK. The study measured vision with glasses 3 and 6 months after LASIK. At 3 months, best vision did not change or improve in 91.6% of eyes compared with best vision with glasses before LASIK. Only 2 eyes lost 2 or more lines of vision in the study.

**TABLE 5 CHANGE IN VISUAL ACUITY WITH GLASSES AFTER SURGERY COMPARED TO BEFORE SURGERY (N=360 EYES TESTED)**

PROPORTION OF THE POPULATION WITH CHANGE TO VISION WITH GLASSES	Time after surgery	
	3 Months % (n/N)	6 Months % (n/N)
% of eyes with loss of 2 or more lines	0.6% (2/358)	0.3% (1/354)
% of eyes with loss of 1 line	7.8% (28/358)	5.6% (20/354)
% of eyes with no change	46.6% (167/358)	47.5% (168/354)
% of eyes with gain of 1 line	38.3% (137/358)	40.4% (143/354)
% of eyes with gain of 2 or more lines	6.7% (24/358)	6.2% (22/354)

**ADVERSE EVENTS AND COMPLICATIONS**

Table 6 shows the percent and number of eyes that had adverse events after LASIK.

**TABLE 6 ADVERSE EVENTS REPORTED AT ANY POSTOPERATIVE VISITS  
ALL TREATED EYES**

<b>Adverse Event</b>	<b>%</b>	<b>n/N</b>
Corneal infiltrate or ulcer	0.3%	1/360
Dry eye	0.3%	1/360
Epithelium in the interface	0.3%	1/360
Eye irritated	0.3%	1/360
Punctal plug inserted	0.3%	1/360
Vision blurry	0.6%	2/360
Vision decrease due to head trauma	0.3%	1/360

Adverse events that occurred during the study were as follows.

- A decrease of 2 or more lines of vision due to head trauma in 1 eye (0.3%). Visit at 6 months.
- Epithelium (cells) under the flap in 1 eye (0.3%). Visit at 1 month.
- Blurry vision in 2 eyes (0.6%). Visit at 1 month.
- Corneal infiltrate/ulcer in 1 eye (0.3%). Visit was not scheduled.
- Dry eye in 1 eye (0.3%). Visit was not scheduled.
- Eye irritated in 1 eye (0.3%). Visit was not scheduled.
- Punctal plug inserted in 1 eye (0.3%). Visit was not scheduled.

Complications that occurred at 3 months after LASIK in this study were as follows.

- Double/ghost images in the eye (0.6%) and epithelium in the interface (2.2%).

Complications that did **not** occur at 3 months after LASIK in this study were as follows.

- Recurrent corneal erosion
- Corneal edema
- Pain
- Size and shape of flap not as intended
- Corneal epithelial defect, either on the flap or off the flap
- Diffuse lamellar keratitis
- Foreign body sensation

## 5. PATIENT SELF-EVALUATION BEFORE AND AFTER LASIK

Patients were asked to grade their symptoms compared to the same symptoms before **LASIK**. Patients were asked to grade the overall quality of their vision before and after **LASIK**.

**PATIENT SYMPTOMS GRADED AS WORSE OR SIGNIFICANTLY WORSE AFTER SURGERY**

At each scheduled visit after LASIK, patients were asked to complete a survey. Through it they could report on their vision and eye comfort in each eye. Patients were asked to grade their symptoms compared to the same symptoms before LASIK according to their severity as either none, mild, moderate, marked, or severe. Table 7 shows the following problems were worse 3 months after LASIK for more than 1% of patients. Any symptom for which there is a one grade increase from baseline is considered “worse”, and at least a two grade increase is considered “significantly worse”. Symptoms that had the highest percentage of “significantly worse” grading were dryness (7.6%), blurred vision (4.8%), variation in dim light (5.3%), and night driving (7.3%).

**TABLE 7 COMPARISON OF SYMPTOMS BEFORE AND AFTER SURGERY  
(AT 3 MONTHS, N = 356 EYES TESTED)**

<b>SYMPTOM</b>	<b>WORSE % (n)</b>	<b>SIGNIFICANTLY WORSE % (n)</b>
Light sensitivity	13.2% (47)	3.4% (12)
Headaches	3.7% (13)	2.5% (9)
Pain/burning	3.9% (14)	1.4% (5)
Dryness	33.1% (118)	7.6% (27)
Excessive tearing	2.2% (8)	0.0% (0)
Gritty, scratchy	8.7% (31)	2.0% (7)
Glare	17.7% (63)	3.4% (12)
Halos	20.8% (74)	3.7% (13)
Blurred vision	12.6% (45)	4.8% (17)
Double vision	6.7% (24)	2.2% (8)
Fluctuation of vision	16.3% (58)	3.7% (13)
Variation - bright light	7.9% (28)	0.8% (3)
Variation - normal light	5.6% (20)	1.7% (6)
Variation - dim light	11.8% (42)	5.3% (19)
Night driving vision	13.8% (49)	7.3% (26)
Other	0.0% (0)	0.6% (2)

### **SYMPTOM SEVERITY BEFORE AND AFTER SURGERY**

Patients graded symptoms 3 and 6 months after **LASIK**. Patients described some symptoms as better, while some symptoms were worse. Table 8A shows the symptoms described as better or worse. Any symptom for which there is at least a one grade increase from baseline is considered “worse”, and at least a one grade decrease is considered “better”.

At 3 months, a higher percentage of patients reported the following symptoms as “better” than reported them as “worse” after **LASIK**.

- Light sensitivity
- Headaches
- Pain
- Tearing
- Night driving vision

At 3 months, a higher percentage of patients reported the following symptoms as “worse” than reported them as “better” after **LASIK**.

- Dryness
- Gritty feeling
- Glare
- Halos
- Blurred vision
- Double vision
- Fluctuation of vision
- Variation of vision in bright, normal, and dim light

Clinically significant symptoms were those rated moderate to severe. Those with statistically significant change from baseline to month 3 are as follows (see Table 8B below).

- Dryness (increased 6% to 12%)
- Tearing (decreased 2% to 0%)
- Blurred vision (increased 2% to 7%)
- Fluctuation of vision (increased 1% to 4%)

**TABLE 8A CHANGE IN GRADING OF SYMPTOMS BEFORE AND AFTER SURGERY  
(AT 3 AND 6 MONTHS)**

Patient Symptom	3 Months % (n/N)			6 Months % (n/N)		
	Better	No Change	Worse	Better	No Change	Worse
Light sensitivity	18.5 (66/356)	64.9 (231/356)	16.6 (59/356)	22.7 (80/352)	63.4 (223/352)	13.9 (49/352)
Headaches	9.8 (35/356)	84.0 (299/356)	6.2 (22/356)	8.8 (31/352)	85.8 (302/352)	5.4 (19/352)
Pain/burning	5.9 (21/356)	88.8 (316/356)	5.3 (19/356)	7.4 (26/352)	88.4 (311/352)	4.3 (15/352)
Dryness	10.1 (36/356)	49.2 (175/356)	40.7 (145/356)	12.8 (45/352)	59.7 (210/352)	27.6 (97/352)
Excessive tearing	5.3 (19/356)	92.4 (329/356)	2.2 (8/356)	7.4 (26/352)	90.9 (320/352)	1.7 (6/352)
Gritty, scratchy	9.6 (34/356)	79.8 (284/356)	10.7 (38/356)	9.4 (33/352)	83.2 (293/352)	7.4 (26/352)
Glare	15.4 (55/356)	63.5 (226/356)	21.1 (75/356)	17.6 (62/352)	65.6 (231/352)	16.8 (59/352)
Halos	8.1 (29/356)	67.4 (240/356)	24.4 (87/356)	11.4 (40/352)	71.9 (253/352)	16.8 (59/352)
Blurred vision	7.6 (27/356)	75.0 (267/356)	17.4 (62/356)	8.8 (31/352)	77.3 (272/352)	13.9 (49/352)
Double vision	1.1 (4/356)	89.9 (320/356)	9.0 (32/356)	1.1 (4/352)	94.3 (332/352)	4.5 (16/352)
Fluctuation of vision	1.4 (5/356)	78.7 (280/356)	19.9 (71/356)	2.8 (10/352)	81.0 (285/352)	16.2 (57/352)
Variation - bright light	7.9 (28/356)	83.4 (297/356)	8.7 (31/356)	7.7 (27/352)	81.8 (288/352)	10.5 (37/352)
Variation - normal light	1.1 (4/356)	91.6 (326/356)	7.3 (26/356)	1.7 (6/352)	90.9 (320/352)	7.4 (26/352)
Variation - dim light	9.8 (35/356)	73.0 (260/356)	17.1 (61/356)	11.1 (39/352)	73.6 (259/352)	15.3 (54/352)
Night driving vision	23.0 (82/356)	55.9 (199/356)	21.1 (75/356)	20.7 (73/352)	64.2 (226/352)	15.1 (53/352)
Other	0.6 (2/356)	98.9 (352/356)	0.6 (2/356)	0.6 (2/352)	97.4 (343/352)	2.0 (7/352)

**TABLE 8B CLINICALLY SIGNIFICANT PATIENT SYMPTOMS**  
**ALL TREATED EYES**

Symptom	Preop. Versus 3 Months N = 356		Preop. Versus 6 Months N = 352	
	Preop (%)	3 Months (%)	Preop n (%)	6 Months n (%)
Light sensitivity	10.4%	6.7%	10.5%	4.8%
Headaches	3.7%	3.7%	3.7%	2.3%
Pain/burning	2.2%	2.0%	2.3%	0.9%
Dryness	5.6%	12.1%	5.7%	9.9%
Excessive tearing	2.2%	0.0%	2.3%	0.6%
Gritty, scratchy	1.7%	2.0%	1.7%	0.3%
Glare	7.0%	5.6%	7.7%	4.3%
Halos	7.0%	5.9%	7.1%	7.7%
Blurred vision	2.0%	6.7%	2.0%	7.1%
Double vision	1.7%	2.8%	1.7%	3.4%
Fluctuation of vision	0.6%	3.9%	0.6%	3.7%
Variation - bright light	2.2%	1.4%	2.3%	1.7%
Variation - normal light	0.6%	1.7%	0.6%	1.7%
Variation - dim light	3.9%	5.9%	4.0%	4.0%
Night driving vision	11.0%	10.1%	11.1%	9.4%
Other	0.0%	0.6%	0.0%	1.1%

### **PATIENT SELF –EVALUATION OF VISION QUALITY**

As part of the study, patients were asked to assess their vision quality after LASIK. They were asked to assess it in these terms.

- Quality of vision
- Whether he or she would choose to have LASIK done again
- How satisfied they are with the results

Table 9 reports the data from the patient replies.

Table 9 shows that at 3 months, only 1.1% reported that they were not satisfied with their outcome. This includes 4 eyes of 2 subjects. Both were farsighted at month 6 (MRSE was +1.00 D in the right eye and +0.50 D in the left eye for one subject, and it was +1.12 D in the right eye and +1.87 D in the left eye for the other subject.) Only 1.1% would not select **refractive surgery** again. Only 0.6% reported no improvement in overall quality of vision. (Includes 1 eye of one subject. At 3 months, this eye was 20/80 without glasses, and 20/12 with glasses, with an MRSE of +1.87 D).

**TABLE 9 PATIENT EVALUATION OF SATISFACTION AND VISION QUALITY IMPROVEMENT  
ALL TREATED SUBJECTS (SUBJECT BASIS)**

<b>Self-evaluation</b>	<b>Response</b>	<b>3 Months % (n/N)</b>	<b>6 Months % (n/N)</b>
Overall Vision Quality	No Improvement	0.6% (1/180)	0.6% (1/178)
	Slight Improvement	1.1% (2/180)	0.0% (0/178)
	Moderate Improvement	1.1% (2/180)	1.7% (3/178)
	Marked Improvement	14.4% (26/180)	16.3% (29/178)
	Extreme Improvement	82.8% (149/180)	81.5% (145/178)
	Not reported*	0	0
	Total†	180	178
Would Select Refractive Surgery Again	No	1.1% (2/180)	2.2% (4/178)
	Yes	94.4% (170/180)	94.4% (168/178)
	Unsure	4.4% (8/180)	3.4% (6/178)
	Not reported*	0	0
	Total†	180	178
Satisfaction	Very Satisfied	90.6% (163/180)	88.8% (158/178)
	Moderately Satisfied	7.8% (14/180)	8.4% (15/178)
	Neutral	0.6% (1/180)	1.7% (3/178)
	Dissatisfied	1.1% (2/180)	0.6% (1/178)
	Very Dissatisfied	0.0% (0/180)	0.6% (1/178)
	Not reported*	0	0
	Total†	180	178

### **FACTORS ASSOCIATED WITH OUTCOMES**

The study tried to find factors that might predict LASIK outcomes. Outcomes here mean measured vision quality. The study assessed the factors that follow.

- Gender
- Preoperative refraction
- Age
- Baseline refraction
- Primary vs. fellow eye
- Study site

The study found that study site, age and baseline refraction are predictors.

There were four study sites. Outcomes at each site were compared for nearness to the attempted correction. The norm used was percent of eyes with refractions within  $\pm 0.50$  D of the attempted correction. Statistics showed that outcomes varied by site more than they should if site did not matter (at 3 months, 77% of eyes were within 0.50 D of intended outcome at site #2, compared with 83%, 87%, and 92% at the other three study sites. At 6 months, 67% of eyes were within 0.50 D of intended outcome at site #1, compared with 76%, 80%, and 86% at the other three study sites). At 6 months, this difference was ascribed to a change in refraction method at site #1.

To test for the effects of age, the study analyzed age subgroups. For each group, it compared outcomes to attempted correction. It applied a threshold of  $\geq 50\%$  to each age group (that is, were at least 50% of eyes within  $\pm 0.50$  D of that attempted?) At 3 months, all age groups met the 50% threshold, and at 6 months, the only age group that did not meet the 50% threshold was the age group  $\geq 50$  years.

The study found baseline refraction predicts outcomes of LASIK. Baseline refraction is the amount of nearsightedness and astigmatism in each eye before LASIK. The study grouped eyes by refraction before LASIK. It then compared groups for nearness to the intended outcome. The norm used was percent of eyes within  $\pm 0.50$  D. The most nearsighted group of eyes had a smaller percentage within  $\pm 0.50$  D of the intended outcome. These were eyes more than -7.00 D before LASIK. That is, eyes with baseline refraction (MRSE) up to -7.00 D had statistically higher MRSE accuracy outcome at 6 months (79% were within 0.50 D of intended outcome), than eyes with baseline refraction (MRSE) greater than -7.00 D (45% within 0.50 D of intended outcome). This difference was not observed at 3 months.

The study showed no link between baseline refraction and outcomes of 20/40 or better, without glasses. However, eyes with baseline refraction (MRSE) -7.00 D or lower had better uncorrected vision better than 20/40 (i.e., 20/12.5 to 20/16 at 3 months, and 20/16 to 20/32 at 6 months) than eyes with baseline refraction (MRSE) higher than -7.00 D. In addition, subjects  $\geq 50$  years had fewer eyes 20/40 or better at 6 months, without glasses (this difference was not observed at 3 months). This is compared to those  $< 50$  years old.

## E. INDICATIONS FOR USE

The MEL 80 Excimer Laser is indicated for use in primary Laser Assisted *in situ* Keratomileusis (LASIK) treatments for the reduction or elimination of **myopia** of less than or equal to -7.0 D with or without refractive **astigmatism** of less than or equal to -3.0 D, with a maximum manifest refraction spherical equivalent (MRSE) of -7.00 D, in patients who are 21 years of age or older with documentation of stable manifest refraction over the past year as demonstrated by change in sphere and cylinder of  $\leq 0.5$  D.

## F. ARE YOU A GOOD CANDIDATE FOR LASIK?

To have **LASIK**, you must:

- Be 21 years of age or older.
- Have healthy eyes free from retinal problems, corneal scars, and any eye disease.
- Have **nearsightedness** within the range of treatment. The range is up to -7.0 D of sphere with up to -3.0 D of **astigmatism**. (The maximum manifest refraction spherical equivalent (MRSE) is -7.0 D.)
- Have proof your vision has not changed more than one half Diopter for at least one year before your pre-surgery exam.
- Be fully informed about the risks and benefits of **LASIK** as compared to other treatments for **nearsightedness**.
- Be able to lie flat without difficulty.
- Be able to keep your eye on the blinking fixation light during the whole **LASIK** process.
- Be willing to sign an Informed Consent Form provided by your doctor.
- Be able to tolerate eye drops to numb your eye.

## G. WHAT YOU NEED TO KNOW ABOUT THE SURGERY

### Before the Surgery

If you think you want **LASIK**, you will need an exam first to assess your eyes. This is to make sure your eyes are healthy and suitable for **LASIK**. This would include a medical exam and eye history. Both eyes will be checked.

**WARNING:** If you wear contact lenses, the doctor will ask you to stop wearing them before your exam. You must stop two weeks before for hard contact lenses, or one week before for soft contact lenses. This is so the doctor can get a stable eye measurement. Failure to do this may lead to poor results from **LASIK**.

Before **LASIK**, talk to your doctor if you take any medications or if you have any allergies. These may cause healing problems. Also discuss whether you should eat and drink just before surgery. You should arrange to have someone drive you home after surgery. Also have them drive you to your next doctor's visit. You should not drive after surgery until your doctor gives you permission.

### **The Day of Surgery**

Before the day of surgery, you will be given the chance to hear the sounds the laser makes. Thus you will be prepared for the noise. On the actual day of surgery, you will be given some numbing drops in the eye that will be treated. You will be shown into the surgery room. There you will see a large machine with a computer screen, a surgeon's chair and a patient bed. You will be asked to lie down on the bed. You will lay face up toward the laser's microscope and the ceiling. Your eye may be numbed with more drops. The eye not having surgery may be covered with a temporary shield.

The surgery takes 10 to 20 minutes in total. But the laser is used only about 30 to 60 seconds. The doctor will place a small spring-like device between your eyelids to hold them open.

When the surgery begins, the doctor will put a suction ring onto your eye. This will serve as a track for a small device called a microkeratome. This device will create a thin flap of corneal tissue. While this is done your vision will become blurry. This is due to the suction ring, which increases eye pressure to above 65mm Hg. After the flap is made, the suction will be switched off. Then the doctor will fold the flap away from the **cornea**. The doctor will then reposition your head under the microscope. You will be asked to look directly at the blinking light. Try to keep both eyes open without squinting. Try even though a drape or a patch may cover the eye not having **LASIK**. This makes it easier to keep looking at the blinking light. You will then hear the noise the laser makes when it does its work.

**WARNING: It is vital to keep looking right at the blinking light, even if the light fades or dims. Your results depend on how well you keep focus on this blinking light throughout the treatment.**

### **Immediately After the Surgery**

After it's done, your doctor will put medicine drops or ointment into your eye. Your doctor may apply a patch or shield to your eye for protection and comfort.

Numbing drops make the surgery painless. When these drops wear off, your eye will probably hurt for a day or two. Most patients describe the pain as moderate to severe. Your doctor may prescribe pain medicine to make you more comfortable. Do not remove the patch or shield until instructed to do so.

**WARNING: Do not rub or touch your treated eye for the first seven days after surgery. This can cause a shift of the flap, which leads to bad effects. These can include blurred vision, risk of infection, inflammation, edema or epithelial in-growth.**

### **First Days After Surgery**

The patch or shield is usually removed the next day. You may be mildly sensitive to light and glare. Wear sunglasses to ease your discomfort. You may also have the feeling that something is in your eye. This happens while the outer layer of your **cornea** is healing.

Your vision should stabilize within a few weeks. Some patients report small changes in vision. These could be better or worse. These may occur up to six months or more after **LASIK**.

You may see a haze or cloudiness in the **cornea** after **LASIK**. It usually will not affect your vision. This haze tends to decrease over time. Most often it ends by 12 to 24 months after **LASIK**. However, some patients continue to see haze.

Use as directed any drops and lubricants your doctor prescribes. Your results depend on you following your doctor's orders. If you use topical steroids, your doctor should watch you for side effects of long-term use. One side effect may be increased eye pressure. (This is called **ocular hypertension**.) This condition is often linked to bad effects. One such effect is **glaucoma**. It is marked by damage to the nerve fiber layer. It can cause loss of vision. Another bad effect of high eye pressure could be **cataract formation**. This is a clouding of the lens inside the eye. It also can cause a loss of vision.

**WARNING: You should contact your doctor if you notice any pain or change or loss of vision in the eye. These may be signs of a serious medical condition.**

## **H. QUESTIONS TO ASK YOUR DOCTOR**

You may want to ask the questions below to help you decide if **LASIK** with the MEL 80 is right for you.

- What are the other options to correct **nearsightedness**?
- Will I have to limit what I do after **LASIK**? If yes, for how long?
- What are the benefits of **LASIK** for my level of **nearsightedness**?
- What vision can I expect in the first few months after **LASIK**?
- If **LASIK** does not correct my vision, could my vision be worse than before? Could my need for glasses increase over time?
- Will I be able to wear contact lenses if I still need them after **LASIK**?
- How is **LASIK** likely to affect my need to use glasses or contact lenses as I get older?
- Will my **cornea** heal differently if I injure it after **LASIK**?

- Should I have **LASIK** surgery on my other eye?
- How long will I have to wait before I can have **LASIK** surgery on my other eye?
- What vision problems will I have if I have **LASIK** in only one eye?

Discuss the cost of surgery and follow-up care with your doctor. Most health **insurance** does not cover **LASIK** for vision correction.

## I. SUMMARY OF IMPORTANT INFORMATION

- **LASIK** is permanent. Once done, it cannot be reversed.
- **LASIK** does **NOT** end the need for reading glasses, even if you have never worn them.
- **LASIK** is used to treat **nearsightedness**.
- Your vision must be stable for at least one year before **LASIK**. You will need written proof that it has not changed by more than 0.50 **Diopters**.
- Pregnant and nursing women should wait to have **LASIK**. For these women, it may cause over- or under-correction as well as regression (reduction or loss of the correction over time).
- You should not have **LASIK** if you have a medical condition that impairs wound healing. (For example, corneal scars, uveitis, diabetes, dry eyes etc.)
- The **LASIK** treatment may cause you discomfort.
- **LASIK** is not risk-free. Please read this whole booklet before you agree to the treatment. Pay special heed to the sections on Benefits and Risks.
- **LASIK** is not a laser version of **RK**. (**RK** stand for radial keratotomy.) **LASIK** and **RK** are completely different from each other.
- Some alternatives to **LASIK** are glasses, contact lenses, **RK** and **PRK**. (**PRK** stands for photorefractive keratectomy.)
- Some jobs have vision requirements that **RK**, **PRK**, and **LASIK** do not meet. For example, military pilots.
- Before you decide to have **LASIK** you should do as follows.
  - Have a complete eye exam.
  - Talk with one or more doctors about **LASIK**. Discuss its benefits, complications, risks and time required to heal.

## J. GLOSSARY OF TERMS

This section explains important terms in this booklet. Please discuss any related questions with your doctor.

- Astigmatism:** Irregular shape of the cornea that keeps light rays from focusing on the retina.
- Cataract:** Cloudiness of the natural lens of the eye.
- Cornea:** Transparent front portion of the eye. It covers the iris and the **pupil**. It provides most of the eye's focusing power.
- Diopter:** Unit of measure for refractive power of lenses.
- Excimer Laser:** A medical device used to remove tissue from the **cornea**. It makes a powerful, pure beam of specific-wavelength light. It re-shapes the **cornea** to correct refractive errors. This allows light rays to better focus on the retina.
- Farsightedness or Hyperopia:** Defect in which light rays strike the retina before they come to a sharp focus. The true focal point is said to be "behind the retina." It is corrected by adding optical power. More optical power can come from a "plus" lens or from more of the eye's own power. (A "plus" lens is a convex lens that adds optical power.)
- Glaucoma:** Group of diseases marked by increased pressure in the eye. It results in damage to the optic nerve and retinal nerve fibers.
- Halos:** Hazy ring around bright lights. Some patients with refractive error or optical defects (e.g., cataracts or corneal swelling) see halos.
- Keratoconus:** An inherited disease of the cornea. It is progressive. It is marked by thinning and cone-shaped bulging of the central **cornea**.
- LASIK:** An acronym for "laser in situ keratomileusis." **LASIK** is a type of surgery to treat **nearsightedness**. A device called a microkeratome, which is like a carpenter's plane, cuts a thin flap of tissue from the front of the **cornea**. (The cornea is the clear part on the front of the eye.) The doctor then folds the flap out of the way. Next, an **excimer laser** removes tissue from the front surface of the **cornea** to make it less curved. After the laser treatment, the doctor replaces the corneal flap.

- Lens:** A clear organ found in the front third of the eyeball. It adds optical power to the eye to sharpen the image on the retina. (The retina is like the film of a camera.)
- MRSE:** Abbreviation for Manifest Refraction Spherical Equivalent, which is the average refractive power in **diopters** needed to correct the refractive error of the eye.
- Nearsightedness or Myopia:** Defect in which light rays come to a sharp focus in front of the retina. It is corrected by subtracting optical power using a “minus” **lens**. This type of lens is concave. It “weakens” the eye optically and permits clear distance vision.
- Ocular Hypertension:** Pressure inside the eye of more than 21 mmHg with no clear optic nerve damage or visual field defects.
- Pupil:** The dark circle in the center of the eye that transmits light. It adjusts in size to the brightness of the light coming into the eye. (It is like a camera f-stop.)
- PRK:** An acronym for “photorefractive keratectomy.” In this surgery, an **excimer laser** removes a thin portion of the clear front part of the eye (**cornea**). It is removed in a controlled manner. The goal is to re-shape the **cornea** to correct refractive errors of the eye.
- Refractive Surgery:** Surgery to change how the eye bends light. The goal is to repair the eye’s focusing errors.
- Retina:** The thin lining, or “film,” at the back of the eye. It converts light images into nerve signals sent to the brain.
- RK** An acronym for “radial keratotomy.” In this surgery, radial cuts are made near the edge of the **cornea**. This flattens the central **cornea** to reduce **nearsightedness**.

## **K. PATIENT ASSISTANCE INFORMATION**

### **PRIMARY DOCTOR**

Name:

Address:

Telephone Number:

### **LASIK DOCTOR**

Name:

Address:

Telephone Number:

### **LOCATION WHERE TREATMENT WAS DONE**

Name:

Address:

Telephone Number:

### **LASER MANUFACTURER**

Carl Zeiss Meditec AG  
Carl Zeiss Promenade 10  
Jena, Germany 07740

### **SALES AND SERVICE**

Carl Zeiss Meditec, Inc.  
5160 Hacienda Drive  
Dublin, California 94568 USA  
(925) 557-4651

## L. INDEX

### A

Age, patient 1, 8, 14, 26  
Alternatives 29  
Astigmatism 1, 7, 17, 25, 26, 30

### B

Benefits 5, 7, 8, 13, 26, 28, 29  
Blurry vision 18

### C

Candidate, suitable 26  
Cataract 11, 28, 30  
Cloudiness 28, 30  
Complications 15, 16, 18, 29  
Contraindications 12  
Contact lenses 5, 6, 7, 16, 26, 28, 29  
Cornea 5, 6, 7, 11, 12, 13, 14, 15, 16, 18, 26, 27, 28, 29, 30, 31  
Cost 29

### D

Diopter 7, 14, 26, 29, 30  
Discomfort 11, 28, 29  
Driving 11, 15, 19, 20, 21, 22

### E

Exam 10, 16, 26, 29  
Excimer laser 1, 5, 7, 26, 30, 31

### F

Farsighted 5, 23, 30  
Focus 5, 6, 27, 30, 31

### G

Glare 11, 15, 19, 20, 21, 22, 28  
Glasses 5, 6, 7, 9, 10, 15, 16, 17, 23, 25, 28, 29  
Glaucoma 14, 28, 30  
Gritty feeling 19, 20, 21, 22

### H

Halos 11, 15, 19, 20, 21, 22, 30  
Haze 12, 28

Headache 14, 19, 20, 21, 22

Healing 13, 14, 27, 28, 29

Herpes 13

## I

Infection 11, 13, 14, 28

Inflammation 11, 12, 14, 15, 28

Insurance 29

## J

Jobs 5, 29

## K

Keratoconus 13, 30

## L

Laser in situ keratomileusis (LASIK) 1, 5, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 23,  
25, 26, 27, 28, 29, 30, 32

Lens 5, 6, 28, 30, 31

Light sensitivity, 19, 20, 21, 22

Lighting conditions, vision in 15

## M

Medicines 13, 14, 27

Accutane 13

Cordarone 13

Imitrex, 14

lubricant 28

numbing drops 27

ointment 27

pain 27

## N

Nearsighted 5, 6, 7, 14, 17, 25, 26, 28, 29, 30, 31

Noise, during surgery 27

Nursing 13, 29

## O

Ocular Hypertension 28, 31

## P

Pain 11, 18, 19, 20, 21, 22, 27, 28

Precautions 14

Pregnant 13, 29

Pressure, intraocular 11, 12, 14, 27, 28, 30, 31

PRK 5, 14, 29, 31

Pupil 11, 15, 30, 31

## **R**

Radial keratotomy (RK) 5, 7, 14, 29, 31

Redness 14

Refractive surgery 6, 7, 14, 23, 24, 31

Results, clinical 8, 10, 12, 23

Retina 5, 6, 26, 30, 31

Risks 5, 8, 10, 11, 13, 16, 26, 29

## **S**

Safety (safe) 7, 11, 14

Scars 14, 26, 29

Second eye, treatment of 7

Stabilize, vision 28

Sunglasses 28

Swelling 11, 30

## **T**

Tearing 11, 19, 20, 21, 22

Treating both eyes 5

## **V**

Vision, blurred 11, 19, 20, 21, 22, 28

Vision, change 7

## **W**

Wound healing 13, 14, 29