

**FACTS YOU NEED TO KNOW ABOUT WAVEFRONT-GUIDED LASER-ASSISTED IN SITU  
KERATOMILEUSIS (LASIK) SURGERY FOR THE REDUCTION OR ELIMINATION OF  
MYOPIC ASTIGMATISM WITH SPHERE UP TO -7.00 DIOPTERS OF NEARSIGHTEDNESS,  
ASTIGMATISM UP TO -3.00 DIOPTERS AND MRSE  $\leq$  -7.50D AT THE SPECTACLE PLANE  
WITH THE BAUSCH AND LOMB TECHNOLAS<sup>®</sup> 217z ZYOPTIX<sup>™</sup> SYSTEM FOR  
PERSONALIZED VISION CORRECTION**

**PATIENT INFORMATION BOOKLET**

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

Bausch & Lomb Incorporated  
180 E. Via Verde Drive  
San Dimas, California 91773

Refractive Hotline:  
(800) 496-7457  
(800) 4xmr-hlp

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## A. INTRODUCTION

This booklet contains information to help you decide whether or not to have Laser in situ Keratomileusis (LASIK) laser surgery for the correction of nearsightedness. Eye surgery can help you see more clearly by changing the shape of the front surface of your *cornea*, which is the clear layer at the front of your eye. RK uses a scalpel to make fine cuts in the cornea. PRK and LASIK use a laser to reshape the cornea. For LASIK, an instrument called a *microkeratome* first cuts a thin flap of tissue from the front of your cornea. This *corneal flap* is folded back and the laser removes tissue under the flap to change the shape of the front surface of your eye. Then the flap is put back in place for the eye to heal.

Your eyeglass prescription is the usual way to tell how nearsighted you are. Another way is to measure the shape of the *wavefront* of reflected light coming out of your eye. A wavefront measurement gives more information about your nearsightedness than an eyeglass prescription. A wavefront measures all of the *focusing errors* in your eye, including complex errors that eyeglasses cannot correct. These complex focusing errors are called "higher-order *aberrations*". The combination of simple and complex wavefront errors in any eye is unique, and measurement of your wavefront provides your doctor with individualized information on your eye that is not otherwise available.

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

Please read this booklet completely and discuss your questions with your doctor. Only your eye care professional can determine whether or not you are a suitable candidate. Some jobs, such as military pilots, have vision requirements that RK, PRK, and LASIK presently cannot meet.

Your doctor can use either your eyeglass prescription or a wavefront measurement to plan LASIK surgery. LASIK surgery based on the eyeglass prescription is called *Conventional LASIK*. LASIK surgery based on the wavefront is called wavefront-guided *LASIK*. Zyoptix LASIK is wavefront-guided surgery with the Bausch and Lomb **Technolas 217z Zyoptix System for Personalized Vision Correction**.

### PERSONALIZED VISION CORRECTION.

LASIK surgery is permanent. You can have LASIK surgery on one eye at a time. The second eye may have surgery on the same day or later, depending upon your choice and your doctor's advice. Discuss with your doctor whether you are a good candidate for Zyoptix LASIK surgery.

## **HOW THE EYE FUNCTIONS**

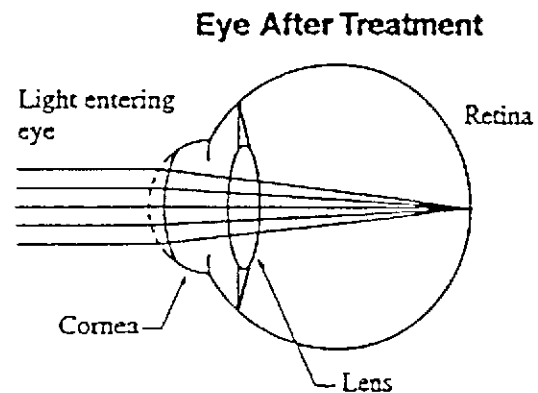
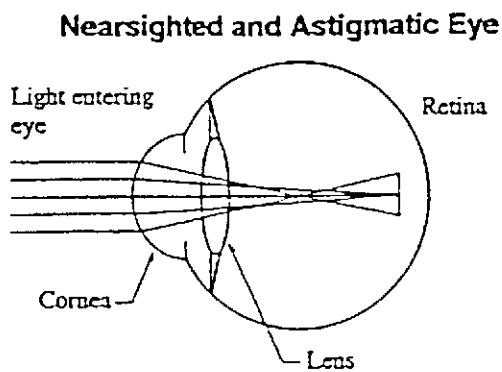
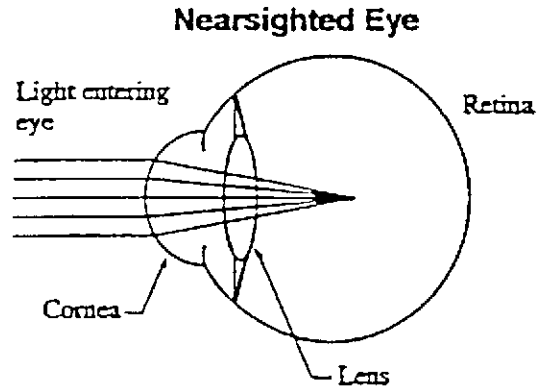
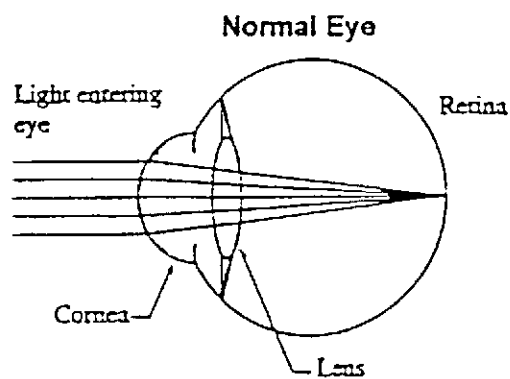
Your eye focuses light to form images or "pictures" much like a camera. Your eye changes the images into electrical signals and sends them to the brain. If your eye is out of focus, what you see is blurred.

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

## **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 exactly on the retina. You will see a clear image. However, if the light focuses either in front of or behind the retina, the image you see will be blurred. Depending on where the image focuses, you will be nearsighted, farsighted, or astigmatic.

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



**Light focuses on the retina after surgery. Vision is clearer.**

### CHECKING YOUR FOCUS

Your doctor checks where your eye focuses light. When your vision is corrected, a lens or a combination of lenses is added to move the point where the light focuses so that the focal point strikes your retina perfectly. The lens or combination of lenses used to correct the focus of your eye has a numerical value that is called the “manifest refraction spherical equivalent” or MRSE. MRSE is a measurement that describes the total refractive error of the eye.

Good focus depends on the shape and size of your eyeball, the shape of your cornea, and the power of your natural lens.

### THE NEARSIGHTED EYE

One in four people in North America are nearsighted. They see near objects clearly, but distant objects are blurry. Light rays focus in front of the retina instead of directly on it. Nearsightedness tends to run in families. It usually starts in childhood and stabilizes in the late

teens or early adulthood. Nearsightedness can be corrected by glasses, contact lenses or refractive surgery.

Glasses and contact lenses can be adjusted if vision changes over time. Wearing glasses and contact lenses help your eye focus light properly on the retina. LASIK surgery focuses light properly by reshaping the cornea. LASIK surgery uses an *excimer laser* to remove a tiny amount of tissue from the cornea. This type of laser does not change any other parts of the eye. The diagram of the eye after the Treatment shows that distant vision is clearer after LASIK.

## **B. WHAT IS WAVEFRONT GUIDED LASER IN SITU KERATOMILEUSIS (ZYOPTIX LASIK)?**

### **BEFORE THE PROCEDURE**

Before surgery, your doctor will determine your specific correction by measuring the wavefront of your eye, to capture all of the *focusing errors* in your eye and determine the amount of correction needed. This is accomplished by projecting light into your eye and measuring the reflected light that comes out to determine your wavefront. Zyoptix LASIK uses the wavefront to guide the laser in reshaping the cornea to correct focusing errors, in the manner described below.

Your doctor has the choice of setting the diameter of the area of the central cornea to which the LASIK treatment is delivered. This area is called the *Optic Zone*. The doctor will choose the optic zone best suited for you on the basis of providing the largest zone for the amount of correction needed that still leaves the appropriate amount of corneal tissue after the procedure.

### **THE PROCEDURE**

A small surgical instrument called a microkeratome, which works much like a miniature carpenter's plane, is used to make a very thin flap of tissue on the cornea (the clear part on the front of the eye). This flap is then folded out of the way, and an excimer laser is used to flatten the front surface of the cornea below the flap. The laser removes small amounts of tissue with ultraviolet light. After the laser treatment is finished, the corneal flap is placed back into its original position on the cornea. This is different from RK (radial keratotomy). In RK, a surgical knife is used to make deep cuts around the center of the cornea to cause it to flatten.

An excimer laser is a piece of medical equipment that produces and aims a powerful beam of ultraviolet light. The excimer laser produces a brief, intense pulse that lasts only a few billionths of a second. These laser pulses remove small and precise amounts of corneal tissue based on your individual wavefront analysis. The excimer laser produces little heat and leaves the tissue beneath unchanged.



The Zyoptix laser system also includes an active eye tracker system that automatically adjusts the laser beam to bring the laser pulses to the desired position in the event your eye moves during Zyoptix LASIK surgery

LASIK surgery is performed on one eye at a time. The second eye can be treated if all goes well with the first eye. Laser surgery on the second eye can usually be done on the same day as the first eye, or may be done later, depending on your doctor's evaluation of your particular case.

### **C. WHAT ARE THE BENEFITS OF ZYOPTIX LASIK?**

Zyoptix LASIK surgery can correct up to  $-7$  diopters (D) of nearsightedness with up to  $-3.00$  D of *astigmatism*, and  $MRSE \leq 7.50D$  at the spectacle plane. If you have nearsightedness within this range, Zyoptix<sup>®</sup> LASIK surgery may allow you to see clearly at long distances without eyeglasses or contact lenses.

### **CLINICAL STUDY TO EVALUATE BENEFITS**

A clinical study was conducted to evaluate the benefits and risks of Zyoptix LASIK. The study included 342 eyes to determine benefits and risks. The study results are shown below and in "What are the Risks of Zyoptix LASIK." In the study the doctor made a choice of what the optic zone size should be based on the eye's wavefront measurement and the individual diameter of the pupil in low light conditions.

### **STUDY PATIENT DEMOGRAPHICS**

Most patients in the study were Caucasian. No patients were under 21 years of age or over 61 years old. Table 1 shows ~~the~~ age, race, and gender of patients in the study. (Please note that in all tables, "N" or "n" represents the number of eyes treated in each category.)

**TABLE 1. DEMOGRAPHICS OF 342 EYES OF 191 STUDY PATIENTS**

			<b>Total</b>
<b>Number of Eyes</b>			342
<b>Number of Enrolled Subjects</b>			191
<b>Age (yrs)</b>	Mean		34.4
	SD		8.29
	Range		21-61
<b>Gender</b>	Male	% (n)	46.07% (88)
	Female	% (n)	53.93% (103)
<b>Race</b>	White	% (n)	90.58% (173)
	Black	% (n)	1.05% (2)
	Asian	% (n)	5.24% (10)
	Other	% (n)	3.14% (6)
<b>Operative Eye</b>	Right	% (n)	49.71% (170)
	Left	% (n)	50.29% (172)

Two eyes were unable to have the procedure completed. Therefore the results are based on the 340 eyes that successfully completed the procedure.

**VISUAL ACUITY *WITHOUT* GLASSES AFTER SURGERY**

In the clinical study of the Bausch & Lomb TECHNOLAS 217z Zyoptix Excimer Laser System, 91.5% of all treated eyes had 20/20 vision or better without glasses after a single LASIK procedure, and 99.4% had 20/40 vision or better at the 6-month visit. Most states require that your vision be 20/40 or better for you to drive **without** any glasses or contact lenses.

**TABLE 2. VISUAL ACUITY *WITHOUT* GLASSES AFTER SURGERY (N=340 Eyes Tested)**

<b>Time after Surgery</b>	<b>1 Month</b>	<b>3 Months</b>	<b>6 Months</b>
<b>Percent of eyes with 20/16 or better</b>	61%	69%	70%
<b>Percent of eyes with 20/20 or better</b>	86%	90%	92%
<b>Percent of eyes with 20/25 or better</b>	94%	95%	95%
<b>Percent of eyes with 20/40 or better</b>	99%	99%	99%

LASIK to correct distance vision does not eliminate the need for reading glasses. It is possible that you may need reading glasses after laser surgery even if you did NOT wear them before.

### INFLUENCE OF OPTIC ZONE SIZE

The clinical results at 6 months were also analyzed by the size of the optic zone used in the treatment. This information is found in the table below. Larger optic zones tended to have better outcomes.

**TABLE 3. SUMMARY OF KEY EFFICACY VARIABLES AT 6 MONTHS BY OPTICAL ZONE SIZE**

KEY EFFICACY VARIABLES	OPTICAL ZONE SIZE (mm)		
	5.75-6.24 % (n)	6.25-6.74 % (n)	6.75-7.24 % (n)
<b>Total Eyes Reported*</b>	73	246	20
<b>UCVA 20/16 or Better</b>	60.3% (44)	73.6% (181)	65.0% (13)
<b>UCVA 20/20 or Better</b>	83.6% (61)	93.5% (230)	95.0% (19)
<b>UCVA 20/25 or Better</b>	90.4% (66)	96.7% (238)	95.0% (19)
<b>UCVA 20/32 or Better</b>	94.5% (69)	99.6% (245)	100.0% (20)
<b>UCVA 20/40 or Better</b>	97.3% (71)	100.0% (246)	100.0% (20)

\*One eye did not have optic zone size documented

### VISUAL ACUITY AFTER SURGERY (NO GLASSES) COMPARED TO VISUAL ACUITY BEFORE SURGERY (WITH GLASSES)

Table 4 shows that at 6 months after the surgery, about 78% of the patients saw as well *without* glasses after Zyoptix surgery as *with* glasses before surgery. A gain of lines means that patients could read 1 or more rows of letters on the eye chart (visual acuity chart) after surgery that they could not read before surgery.

**TABLE 4. VISUAL ACUITY WITH NO GLASSES AFTER SURGERY COMPARED TO VISUAL ACUITY WHILE WEARING GLASSES BEFORE SURGERY (N=340 Eyes Tested)**

Time after Surgery	3 Months % (n)	6 Months % (n)
<b>Percent of eyes with 2 or more lines better vision than with glasses</b>	13.5% (46)	14.1% (48)
<b>Percent of eyes with 1 line better vision than with glasses</b>	25.6% (87)	27.9% (95)
<b>Percent of eyes with the same vision as with glasses</b>	38.2% (130)	36.2% (123)
<b>Percent of eyes with 1 line worse vision than with glasses</b>	15.3% (52)	14.7% (50)
<b>Percent of eyes with 2 or more lines worse vision than with glasses</b>	7.4% (25)	7.1% (24)

## D. WHAT ARE THE RISKS OF ZYOPTIX LASIK?

If you are not satisfied with your surgery results, your doctor may suggest another surgery. No data are available for Zyoptix LASIK retreatments.

Zyoptix LASIK does not take away the need for reading glasses. You may need reading glasses after Zyoptix LASIK even if you did not need them before.

In some cases, your best vision *with* your glasses or contact lenses may be worse after Zyoptix LASIK surgery than it was before surgery.

A number of risks from LASIK surgery are related to the corneal flap rather than the laser treatment. Some specific problems include: cutting an incomplete or irregular flap, loss of the flap, misalignment of the flap, and cutting all the way through the cornea with the microkeratome. These problems can lead to other complications, such as infections, *cataracts*, and permanent scarring or deformity of the eye.

### CONTRAINDICATIONS

You should **NOT** have Zyoptix<sup>®</sup> LASIK surgery if you:

- are pregnant or nursing because these conditions may cause temporary and unpredictable changes in your cornea that may interfere with getting the right measurement of your cornea before the LASIK procedure.
- show signs of *keratoconus*. This is a condition of the cornea that results in a change in the shape of the cornea as well as thinning of the cornea. The unstable condition of the cornea makes it unsafe to do LASIK procedures on eyes with this condition.
- are taking medications with ocular side effects [for example, isotretinoin (Accutane<sup>1</sup>) for acne treatment or amiodarone hydrochloride (Cordarone<sup>2</sup>) for normalizing heart rhythm]. Such medications may affect the accuracy of the LASIK procedure or the way the cornea heals after surgery. This may result in poor vision after LASIK.
- have a *collagen vascular, autoimmune, or immunodeficiency disease*. These are conditions that affect your immune response (your body's ability to heal), or result in inflammation or swelling of parts of the body, such as muscles, joints, and blood vessels. Examples are AIDS, lupus, and rheumatoid arthritis. These conditions affect the body's ability to heal properly.

### WARNINGS

Discuss with your doctor if you have:

- diabetes. Diabetes may interfere with the healing of the cornea after LASIK.

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<sup>1</sup> Accutane Reg TM of Hoffmann-LaRoche, Inc.

<sup>2</sup> Cordarone Reg TM of Sanofi Corp.

- severe allergies. The medications taken for severe allergies may interfere with the ability of the eye to heal after LASIK.
- significant dry eye that is unresponsive to treatment. LASIK may increase the dry eye condition. This may or may not go away.
- a history of *herpes simplex* or *herpes zoster* infection that has affected your eyes. LASIK may be more risky for patients who have had herpes infections that affected their eyes.
- You have a systemic disease likely to affect wound healing, such as connective tissue disease, diabetes, severe atopic disease or an immunocompromised status.

### PRECAUTIONS

The safety and effectiveness of Bausch and Lomb Personalized Vision Correction System for Zyoptix LASIK have **NOT** been established in patients:

- with unstable or worsening nearsightedness. Eyes with unstable nearsightedness are unable to be correctly measured to determine the right amount of the vision correction to provide.
- with a cornea that is too thin for LASIK to be completed safely. A flap needs to be cut into the cornea for the LASIK procedure. Thin corneas cannot have a proper flap cut done.
- with a history of *glaucoma* (a condition usually associated with high eye pressure with damage to the nerve in the eye and possible loss of vision). It is unknown whether LASIK is safe for eyes with glaucoma.
- who are taking the medication sumatriptan (Imitrex<sup>3</sup>) for migraine headaches. It is unknown whether the use of this medication will interfere with the measurement prior to LASIK or the healing of the eye after LASIK.
- under 21 because it is unknown if the eye has reached its adult vision refraction. This may result in measurement of the amount of correction to provide being incorrect.
- over the long term (more than 6 months).
- with greater than 7D of nearsightedness with greater than -3.00D of astigmatism and greater than -7.50D MRSE. Corrections falling outside of the approved range have not been studied.
- for retreatment with Zyoptix LASIK. Retreatments have not been done enough times to allow an understanding of whether it is safe and effective.
- The following conditions may interfere with the ability to properly measure the eye to determine the right amount of vision correction to provide and the may also affect the way the eye would heal after the procedure. Eyes with:
  - with disease or corneal condition (for example, scar, infection, etc.).
  - with injury to the center of the cornea where Zyoptix LASIK will reshape the cornea.
  - with previous surgery on the cornea or inside the eye (for example, cataract surgery).
  - with prior history of surgery to correct vision (for example, RK, PRK, LASIK).

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<sup>3</sup> Imitrex Reg TM of Glaxo Group Limited

Before surgery, your doctor should evaluate your pupil size under dim lighting conditions. If your pupils in dim light are greater than the optical zone (which ranges from 6.0mm to 7.0mm) proposed by your doctor, consult with your doctor about the risk that the surgery may cause negative effects on your vision, such as glare, halos, and night driving difficulty.

Bausch & Lomb recommends selection of the largest optical zone between 6.0 and 7.0 mm, while ensuring residual stromal thickness of at least 250 microns.

Your doctor should also evaluate you for dry eyes before surgery. You may have dry eyes after LASIK surgery even if you did not have dry eyes before surgery.

Patients 50 years of age and older may be likely to experience a reduction in predictability of outcomes (as compared to younger patients).

Lower uncorrected visual acuity and accuracy of MRSE within  $\leq \pm 0.5D$  of emmetropia (no remaining refraction error) may be anticipated following treatment of eyes that have higher levels of preoperative MRSE (greater than or equal to  $-7.00D$  MRSE). This means that outcomes were not as good in eyes with high refractive error, i.e., MRSE of  $-7.00D$  or greater.

#### **During the first week following surgery**

- You may feel pain, discomfort, or the sensation of something in your eye. This may last up to 7 days after surgery.
- Your vision may be blurry or you may become more sensitive to light as your eye heals.
- You may have temporary swelling of the front surface of your eye.
- The pressure inside your eye may increase, usually due to the use of *anti-inflammatory medication* (eye drops) after surgery. Using another medication or stopping the anti-inflammatory medication can control the abnormal increase in eye pressure.

#### **During one to three months following surgery**

- Your vision should be stable 3 to 6 months after surgery. Some patients may notice that their vision improves or worsens. These small changes may occur up to 3 months or more after surgery. You should contact your doctor if you notice any change or loss of vision.
- You may become more sensitive to light. You may notice glare or have difficulty in driving at night.

**CLINICAL STUDY TO EVALUATE RISKS**

In the clinical study on Zyoptix® LASIK, vision **without** glasses improved for all eyes. Some people still needed glasses or contact lenses after surgery, but in general, measuring vision with glasses is a good safety measure since it allows the number of eyes whose vision was worse after Zyoptix LASIK to be identified. Table 4 above, provided a comparison if vision without glasses after surgery to vision with glasses before surgery, while Table 5 and Table 6 compares vision with glasses after surgery to vision with glasses before surgery.

**VISUAL ACUITY WITH GLASSES AFTER SURGERY**

Table 5 shows that all eyes with nearsightedness saw 20/25 or better **with** glasses at 3 and 6 months and that all eyes with nearsightedness with astigmatism saw 20/32 or better **with** glasses at 3 and 6 months. (Please note that in all tables, “N” or “n” represents the number of eyes treated in each category.) As mentioned on an earlier page of this document, a gain of lines means that patients could read 1 or more rows of letters on the eye chart (visual acuity chart) after surgery than they could read before surgery.

**TABLE 5. VISUAL ACUITY WITH GLASSES (BEST VISION) AFTER SURGERY**

	Nearsightedness		Nearsightedness With Astigmatism	
	3 Months (N=117)	6 Months (N=117)	3 Months (N=223)	6 Months (N=223)
<b>20/16 or better</b>	86.3%	93.2%	85.2%	86.1%
<b>20/20 or better</b>	98.3%	99.1%	98.2%	100.0%
<b>20/25 or better</b>	100.0%	100.0%	99.6%	100.0%
<b>20/32 or better</b>	100.0%	100.0%	100.0%	100.0%
<b>20/40 or better</b>	100.0%	100.0%	100.0%	100.0%

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

Table 6 compares the change in vision **with** glasses at 3 and 6 months to vision before surgery for the patients from the clinical study. At 6 months after the procedure, best vision with glasses was unchanged or improved in 94.1% of eyes. No eyes lost more than 2 lines, and two eyes lost 2 lines. One of these eyes was 20/12.5 before surgery and 20/20 at 6 months; the other was 20/16 before surgery and 20/25 at 6 months.

**TABLE 6. CHANGE IN VISUAL ACUITY WITH GLASSES AFTER SURGERY COMPARED TO BEFORE SURGERY (N=340 Eyes Tested)**

PROPORTION OF THE POPULATION WITH CHANGE TO VISION WITH GLASSES	Time after surgery	
	3 Months	6 Months
% of eyes with loss of more than 2 lines	0.0%	0.0%
% of eyes with loss of 2 lines	1.2%	0.6%
% of eyes with loss of 1 line	6.9%	5.3%
% of eyes with no change	38.8%	33.8%
% of eyes with gain of 1 line	35.6%	41.5%
% of eyes with gain of 2 lines	15.3%	17.4%
% of eyes with gain of more than 2 lines	1.2%	1.5%

**ADVERSE EVENTS AND COMPLICATIONS**

Some patients from the clinical study experienced adverse events and complications after Zyoptix® LASIK surgery as shown below.

**TABLE 7  
ADVERSE EVENTS SUMMARY  
ALL TREATED EYES**

ALL REPORTED ADVERSE EVENTS	VISITS		
	1 MONTH	3 MONTHS	6 MONTHS
Total Eyes Reported	340	340	340
Not Reported	0	0	0
Distribution of Scores	% (n)	% (n)	% (n)
Decrease in best vision with glasses of $\geq 2$ lines at $\geq 6$ months	0.0% (0)	0.0% (0)	0.6% (2)
Lamellar keratitis	0.0% (0)	0.0% (0)	0.3% (1)

Adverse events and complications that occurred during the study included

- A decrease of 2 or more lines of vision in 2/340 eyes (0.6%) at 6 months
- Lamellar keratitis (inflammation of the cornea under the flap) in 1/340 eyes (0.3%) at 3 months
- Epithelium (cells) under the flap in 1/340 eyes (0.3%)
- Misplaced or loose flap or free cap in 1/340 eyes (0.3%)
- Foreign body sensation (feeling of something in the eye) in 1/340 eyes (0.3%)

Other complications included allergies, conjunctivitis (inflammation of the outer lining of the eye), abrasion of the cornea, inflammation under the flap, episcleritis, chalazion, and Bowman’s wrinkle; all of these complications occurred at an incidence of less than 1%.



The following complications did not occur during the clinical trial: recurrent corneal erosions, size and shape of flap not as intended, corneal epithelial defect either on the flap or off the flap and epithelial in-growth.

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

At each scheduled postoperative visit, patients were asked to complete a questionnaire that allowed them to report any findings they had regarding their vision or ocular comfort following the surgery in each eye. Patients were also asked to grade the severity of any symptoms they reported, as compared to the same symptoms before surgery. As shown in Table 8, a number of symptoms were graded as “worse” or “significantly” worse after surgery than before surgery.

**TABLE 8  
COMPARISON OF SYMPTOMS BEFORE AND AFTER SURGERY  
(AT 6 MONTHS, N = 340 EYES TESTED)**

Symptom	Worse	Significantly Worse
Dryness	28.8%	2.4%
Fluctuation of Vision*	20.0%	4.2%
Variation in Vision***		
In Dim Light	14.7%	2.7%
In Bright Light	10.3%	0.3%
In Normal Light	8.8%	2.4%
Blurring of Vision	14.7%	3.8%
Glare	12.1%	3.2%
Halos	11.8%	2.6%
Redness	9.7%	1.2%
Night Driving Difficulty	9.1%	1.2%
Burning	7.6%	0.3%
Light Sensitivity	7.1%	0.6%
Gritty Feeling	6.2%	0.0%
Headache	4.1%	1.2%
Ghost Images**	3.5%	0.9%
Excessive Tearing	3.2%	0.6%
Pain	2.1%	0.0%
Double Vision	0.9%	2.4%

\* Fluctuation in vision only reported on for n= 335 eyes at 6 months

\*\*Ghost images was reported on for n=339 eyes at 6 months

\*\*\*Variation in vision was reported on for only n=339 eyes at 6 months

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, < stage 2 lamellar keratitis, debris in interface & episcleritis, 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  $\leq 2$  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.

## **PATIENT SELF-EVALUATION BEFORE AND AFTER LASIK**

Patients in the study were asked to grade symptoms and to grade the overall quality of their vision both before and after surgery, to allow a comparison to be made.

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

Some symptoms were reported as better or significantly better after Zyoptix LASIK surgery and some symptoms were reported as worse or significantly worse after Zyoptix LASIK surgery, as shown in Table 9 below. (Symptoms described as worse or significantly worse were also shown in Table 8, above).

Six months after surgery, the majority of symptoms were reported as better or significantly better, however a number of symptoms were described as worse or significantly worse. Symptoms that were described as better after surgery include light sensitivity, headache, pain, redness, tearing, burning, and night driving difficulties. Symptoms reported as worse after surgery were dryness, halos, double vision, and fluctuation of vision.

**TABLE 9**  
**CHANGE IN GRADING OF SYMPTOMS BEFORE AND AFTER SURGERY**  
**(AT 6 MONTHS, N = 340 EYES TESTED)**

Symptom	Significantly Better	Better	No Change	Worse	Significantly Worse
Light Sensitivity	9.4%	27.4%	55.6%	7.1%	0.6%
Headache	5.9%	19.4%	69.4%	4.1%	1.2%
Pain	2.4%	3.8%	91.8%	2.1%	0.0%
Redness	1.8%	21.5%	65.9%	9.7%	1.2%
Dryness	2.9%	16.8%	49.1%	28.8%	2.4%
Excessive Tearing	2.1%	10.0%	84.1%	3.2%	0.6%
Burning	1.2%	13.2%	77.6%	7.6%	0.3%
Gritty Feeling	0.6%	7.9%	85.3%	6.2%	0.0%
Glare	3.5%	17.4%	63.8%	12.1%	3.2%
Halos	1.8%	11.8%	72.1%	11.8%	2.6%
Blurring of Vision	8.5%	13.8%	59.1%	14.7%	3.8%
Double Vision	0.3%	1.2%	95.3%	0.9%	2.4%
Ghost Images**	0.3%	4.1%	91.2%	3.5%	0.9%
Fluctuation of Vision*	0.0%	7.5%	68.4%	20.0%	4.2%
<b>Variation in Vision***:</b>					
<b>In Bright Light</b>	3.8%	20.1%	65.5%	10.3%	0.3%
<b>In Normal Light</b>	0.9%	8.6%	79.4%	8.8%	2.4%
<b>In Dim Light</b>	5.0%	20.4%	57.2%	14.7%	2.7%
<b>Night Driving Difficulty</b>	11.2%	29.1%	49.4%	9.1%	1.2%

\* Fluctuation in vision only reported on for n=336 eyes at 3 months and n=335 eyes at 6 months

\*\* Ghost images was reported on for n=339 eyes at 6 months

\*\*\* Variation in vision was reported on for only n=339 eyes at 6 months

**PATIENT SELF-EVALUATION OF VISION QUALITY**

Patient self-evaluation of postoperative vision quality was evaluated in the study on the question of quality of vision, whether the patient would choose to have the procedure again, and how satisfied they were with the results. The data from the patient responses is found in Table 10 below:

**TABLE 10  
SELF-EVALUATION  
OVERALL QUALITY OF VISION  
ALL TREATED EYES**

Overall Quality Of Vision After Excimer Laser?	VISITS		
	1 MONTH	3 MONTH	6 MONTH
Total Eyes Reported	340	340	340
Not Reported	0	0	0
Distribution Of Scores	% (n)	% (n)	% (n)
Extreme improvement	80.6 % (274)	81.8 % (278)	84.7 % (288)
Marked improvement	16.2 % (55)	14.1 % (48)	12.1 % (41)
Moderate improvement	2.4 % (8)	2.1 % (7)	1.8 % (6)
Slight improvement	0.9 % (3)	1.8 % (6)	1.2 % (4)
No improvement	0.0 % (0)	0.3 % (1)	0.3 % (1)

Choose Excimer Laser Again?	VISITS		
	1 MONTH	3 MONTH	6 MONTH
Total Eyes Reported	337	338	340
Not Reported	3	2	0
Distribution Of Scores	% (n)	% (n)	% (n)
Yes	97.0 % (327)	97.3 % (329)	98.2 % (334)
Unsure	3.0 % (10)	2.7 % (9)	1.2 % (4)
No	0.0 % (0)	0.0 % (0)	0.6 % (2)

How satisfied with the Excimer Laser Results?	VISITS		
	1 MONTH	3 MONTH	6 MONTH
Total Eyes Reported	340	337	340
Not Reported	0	3	0
Distribution Of Scores	% (n)	% (n)	% (n)
Very Satisfied	89.7 % (305)	91.1 % (307)	90.9 % (309)
Moderately Satisfied	8.8 % (30)	7.1 % (24)	7.9 % (27)
Neutral	0.9 % (3)	1.8 % (6)	1.2 % (4)
Dissatisfied	0.6 % (2)	0.0 % (0)	0.0 % (0)
Very Dissatisfied	0.0 % (0)	0.0 % (0)	0.0 % (0)

## **E. INDICATIONS FOR USE**

The Bausch & Lomb Zyoptix System is indicated for laser in-situ keratomileusis (LASIK) treatments:

- for the reduction or elimination of myopic astigmatism, with sphere up to -7.00 D, cylinder up to -3.00 D with MRSE  $\leq$  -7.50D at the spectacle plane;
- in patients with documented evidence of a change in manifest refraction of less than or equal to  $\pm$  0.50 diopters (in both cylinder and sphere components) for at least one year prior to the date of the pre-operative examination; and,
- in patients who are 21 years of age or older.

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

If you are considering Zyoptix LASIK, you must:

- be at least 21 years of age.
- have a healthy eye with no eye disease or corneal condition (for example, scar, infection, retinal problems, etc.)
- have up to -7D of nearsightedness with up to -3.50D of astigmatism.
- have less than or equal to 0.50D change each year in your nearsightedness for at least one year before your eye examination before surgery.
- be able to lie flat on your back without difficulty
- be able to look at a red blinking fixation light during the entire surgery.
- be able to have eye drops that numb your eye and enlarge your pupil.
- understand the risks and benefits of Zyoptix LASIK compared to other available treatments for nearsightedness.

## **G. WHAT SHOULD YOU EXPECT DURING ZYOPTIX LASIK SURGERY?**

<b>BEFORE THE SURGERY</b>
---------------------------

Before surgery, your doctor needs to determine your complete medical and eye history and check the health of both your eyes. As part of this exam, your doctor will use a computed program to map the front surface of your eye. This exam will determine if your eyes are healthy and if you are a good candidate for Zyoptix<sup>®</sup> LASIK.

**WARNING:** You must stop wearing any soft contact lenses at least 1 week and any hard or gas permeable lenses at least 3 weeks before this eye examination. Failure to do this may affect surgical results.

Tell your doctor if you take any medications or have any allergies. Ask your doctor if you should eat or drink right before the surgery. **You should also arrange for transportation since you must not drive right after the surgery.** Your doctor will let you know when your vision is good enough to drive again.

### THE DAY OF SURGERY

To prepare for surgery, your doctor will use the wavefront system to take a picture of your eye. This helps to determine where the laser should treat your cornea. Your doctor will put eye drops to dilate (enlarge) the pupil in your eye(s). After 30-40 minutes, your doctor will measure the wavefront of your eye to determine the amount of laser treatment you need.

Your doctor will then place numbing eye drops and ask you to lie on your back on the laser bed. The laser bed is a flat cushioned surface that can be moved to position you for surgery. Your doctor will instruct you to watch a blinking fixation light. Your doctor will place an instrument between your eyelids to hold them open during the surgery. A temporary shield will cover the eye that is not having surgery.

When the surgery begins, the surgeon will use a small instrument to create a thin flap of corneal tissue that is folded away from the cornea. The doctor will then reposition your head under the microscope. You will be asked to look directly at the red light. Even though the eye not having the surgery may be covered by a drape or a patch, try to keep both eyes open without squinting. This makes it easier to keep looking at the red light. You will then hear the noise the laser makes when it is delivering the laser energy.

**WARNING:** It is very important that you keep looking directly at the red light, even if the light fades or dims. Your results depend on how well you look directly at this red light throughout the treatment.

After the surgery is complete, your doctor will place some eye drops in your eye. Your doctor may cover your eye with a *bandage contact lens* to help heal the eye. For your eye protection and comfort, your doctor may apply a patch or shield over your eye. The surgery is painless because of the numbing eye drops. The effects of the numbing eye drops will wear off after about 45-60 minutes.

### THE FIRST DAYS AFTER SURGERY

You may be mildly sensitive to light and have a feeling that something is in your eye. Sunglasses may make you more comfortable. Also, your eye may hurt. Your doctor can prescribe pain

medication to make you more comfortable during the first few days after the surgery. A plastic shield may be used to protect your eye after LASIK. You will need to use lubricants, *antibiotic*, and *anti-inflammatory medications* in the first few days.

**IMPORTANT:** Use the lubricants and eye medications as directed by your doctor. Your results depend upon you following your doctor's instructions.

**WARNING:** Your doctor will monitor you for any side effects if you need to use a topical *steroid medication*. Possible side effects of prolonged topical steroid use are:

- *ocular hypertension* (an increase in the eye pressure);
- *glaucoma* (a condition usually associated with high eye pressure that results in damage to the nerve in the eye and possible loss of vision);
- *cataract formation* (an opacity or clouding of the lens inside the eye that can cause a loss of vision).

**DO NOT** rub your eyes for the first 3 to 5 days. Rubbing your eye may move the flap. If you notice any sudden decrease in your vision, you should contact your doctor immediately. The flap may have moved and the doctor may need to reposition the flap.

## H. QUESTIONS TO ASK YOUR DOCTOR

You may want to ask the following questions to help you decide if Zyoptix LASIK with the Bausch and Lomb Technolas 217z System for Personalized Vision Correction is right for you:

- What are my other options to correct my nearsightedness?
- Will I have to limit my activities after surgery and for how long?
- What are the benefits of Zyoptix LASIK for my amount of nearsightedness?
- What vision can I expect in the first few months after surgery?
- If Zyoptix LASIK does not correct my vision, what is the possibility that my glasses would need to be stronger than before? Could my need for glasses increase over time?
- Will I be able to wear contact lenses after Zyoptix LASIK if I need them?
- How is Zyoptix LASIK likely to affect my need to wear glasses or contact lenses as I get older?
- Will my cornea heal differently if injured after having Zyoptix LASIK?
- Should I have Zyoptix LASIK surgery in my other eye?
- How long will I have to wait before I can have surgery on my other eye?
- What vision problems might I experience if I have Zyoptix LASIK only on one eye?
- Do I have significant dry eye or large pupils that could produce undesirable side effects and decrease my satisfaction after surgery?



Discuss the cost of surgery and follow-up care needs with your doctor. Most health insurance policies do not cover laser vision correction.

## I. SELF-TEST

### ARE YOU AN INFORMED AND EDUCATED PATIENT?

Take the test below to see if you can answer the following questions after reading this booklet.

	TRUE	FALSE
1. Excimer laser surgery is risk-free.	___	___
2. Excimer laser surgery is the same as Radial Keratotomy (RK).	___	___
3. It does not matter if I wear my contact lenses before surgery when my doctor told me not to wear them.	___	___
4. After the surgery, there is a good chance that I will depend less on eyeglasses or contact lenses.	___	___
5. I may need reading glasses after LASIK surgery, even if I did not need them before.	___	___
6. There is a risk that I may lose some vision after LASIK surgery.	___	___
7. It does not matter if I am pregnant.	___	___
8. If I have an autoimmune disease, I am still a good candidate for LASIK surgery.	___	___
9. Significant dry eye or large pupils may produce undesirable side effects and decrease my satisfaction after LASIK surgery.	___	___

You can find the answers to Self-Test on the following page.

## J. SUMMARY OF IMPORTANT INFORMATION

- Zyoptix LASIK is a permanent surgery to the cornea.
- Zyoptix LASIK does not eliminate the need for reading glasses, even if you have never worn them before.
- Your vision must be stable before Zyoptix LASIK surgery. You must provide written evidence that your nearsightedness has changed less than or equal to 0.50D each year for at least 1 year.
- Pregnant and nursing women should wait until they are not pregnant and not nursing to have the surgery Zyoptix LASIK.
- You would not be a good candidate if you have collagen vascular or autoimmune diseases. If you have a condition that makes wound healing difficult, you would not be a good candidate.
- Zyoptix LASIK surgery has some risks. Please read and understand this entire booklet before you agree to the surgery. The sections on Benefits and Risks are especially important to read carefully.
- Zyoptix LASIK is not a laser version of RK. These surgeries are entirely different.
- Some other options to correct nearsightedness include glasses, contact lenses, RK, PRK, and Conventional LASIK.
- RK, PRK, Conventional LASIK or Zyoptix LASIK may not meet the vision requirements of some occupations, such as military service.
- Before considering Zyoptix LASIK surgery you should:
  - a. have a complete eye examination.
  - b. talk with at least one eye care professional about Zyoptix LASIK, especially the potential benefits, risks, and complications. You should discuss the time needed for healing after Zyoptix LASIK.

### ANSWERS TO SELF-TEST QUESTIONS:

1. False (see Section D: Risks)
2. False (see Section A: Introduction)
3. False (see Section I: Before the Surgery)
4. True (see Section C: Benefits)
5. True (see Section D: Risks)
6. True (see Section D: Risks)
7. False (see Section E: Contraindications)
8. False (see Section E: Contraindications)
9. True (see Section G: Precautions)

## K. GLOSSARY OF TERMS

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

- Aberration:** Focusing errors in the eye detectable by wavefront measurements. Examples are nearsightedness and astigmatism (lower-order) and complex errors (higher-order).
- Antibiotic Medication:** A drug used to treat or prevent infection. Your doctor may prescribe this medication after LASIK surgery.
- Anti-inflammatory Medication:** A drug that reduces inflammation or the body's reaction to injury or disease. Any eye surgery can cause inflammation. Your doctor may prescribe this medication after LASIK surgery.
- Astigmatism:** Refractive error that prevents light rays from coming to a single point of focus on the retina because of different degrees of bending of light by the various meridians of the eye.
- Autoimmune Disease:** A condition in which the body attacks itself and results in inflammation or swelling of parts of the body, such as muscles, joints, and blood vessels. If you have this type of condition, you should not have LASIK surgery.
- Bandage Contact Lens:** A soft contact lens placed on the cornea after surgery to cover the area that was treated with the laser.
- Cataract** An opacity, or clouding, of the lens inside the eye that can blur vision.
- Collagen Vascular Disease:** A condition that may result in inflammation or swelling of parts of the body, such as muscles, joints, and blood vessels. Examples are lupus and rheumatoid arthritis. If you have this type of condition, you should not have LASIK surgery.
- Contraindications:** Any special condition that results in the treatment not being recommended.
- Contrast Sensitivity:** A measure of the ability of the eye to detect small lightness differences between objects and the background in daylight and in dim light. For example, black lines on a gray background are easier to see than gray lines on a gray background. Objects in daylight are also easier to see than in dim light. Contrast sensitivity testing is a way to determine how well patients can see in poor contrast conditions such as very dim light, rain, snow, and fog.

<b>Conventional</b>	LASIK surgery that uses an eyeglass prescription to plan the LASIK: surgery.
<b>Cornea:</b>	Transparent front portion of the eye that covers the iris, pupil, and anterior chamber, and provides most of an eye's optical focusing power.
<b>Corneal Flap:</b>	A thin slice of tissue on the surface of the cornea made with a microkeratome at the beginning of the LASIK procedure. This flap is folded back before the laser shapes the inner layers of the cornea.
<b>Corneal Swelling:</b>	Abnormal fluid build-up in the cornea. This condition is usually temporary with no significant effect on vision.
<b>Corneal Wrinkle:</b>	Temporary appearance of fine white lines in the cornea due to swelling.
<b>Diopter:</b>	Unit of measurement of optical strength or refractive power of lenses.
<b>Excimer laser:</b>	A medical device that produces a very powerful and pure beam of light of a single specific wavelength (color) that is used to remove tissue from the clear front part of the eye (cornea). This is done in a computer-controlled fashion to re-shape the cornea to correct refractive errors. This re-shaping allows incoming light rays to be more accurately focused on the retina.
<b>Farsightedness/ Hyperopia:</b>	Condition in which the eye is "under-powered," so that parallel light rays from a distant object strike the retina before coming to a sharp focus; true focal point is said to be "behind the retina." Corrected with additional optical power, supplied by a "plus" lens or by additional use of the eye's own focusing ability.
<b>Focusing Error:</b>	A condition in which your eye forms a blurred image on your retina. Examples are nearsightedness, astigmatism, and higher-order aberrations (complex focusing errors).
<b>Glaucoma:</b>	An eye disease usually associated with high eye pressure. Glaucoma damages the optic nerve of the eye and usually causes a progressive loss of vision.
<b>Halos:</b>	Hazy ring around bright lights seen by some patients with refractive error or optical defects (e.g., cataracts or corneal swelling).
<b>Herpes Simplex:</b>	A type of viral infection that can recur. This virus typically causes cold sores and/or vesicles to appear on the face or other parts of the body. You should discuss any history of this condition with your doctor before having LASIK surgery.

- Herpes Zoster:** A type of viral infection that can recur. This condition is a reactivation of the chicken pox virus as an adult. Vesicles appear on only one side of the body. You should discuss any history of this condition with your doctor before having LASIK surgery.
- Immunodeficiency Disease:** A condition that compromises the body's ability to heal. An example is acquired immunodeficiency syndrome (AIDS). If you have this type of condition, you should not have LASIK surgery.
- Inflammation:** The body's reaction to injury or disease. Eye surgery, such as PRK and LASIK, can cause inflammation.
- Keratoconus:** Hereditary, degenerative corneal disease characterized by generalized thinning and cone-shaped protrusion of the central cornea.
- LASIK:** An acronym for "laser in situ keratomileusis." This is a surgical procedure in which a very thin flap of tissue on the clear front part of the eye (cornea) is made using a small surgical instrument called a microkeratome, which is much like a carpenter's plane. The flap is then folded out of the way and an excimer laser is used to flatten the front surface of the cornea below the flap.
- Lens:** A transparent, colorless body located in the front third of the eyeball, between the aqueous and the vitreous, the function of which is to help bring rays of light to focus on the retina.
- Low Contrast Visual Acuity:** A measure of the sharpness of vision using a 10% low contrast chart with gray letters on a white background. Low contrast acuity testing is another way to determine how well patients can see in poor contrast conditions such as very dim light, rain, snow, and fog.
- MRSE** Manifest Refraction Spherical Equivalent is a measurement that describes the total refractive error of the eye. It is comprised of the myopia and one half of the astigmatism.
- Microkeratome:** A surgical instrument used in LASIK to cut a thin flap of tissue from the front surface of the eye before the laser treatment is applied.

**Nearsightedness/  
Myopia:**

“Overpowered” eye in which parallel light rays from a distant object are brought to focus in front of the retina. Requires “minus” lens correction to “weaken” the eye optically and permit clear distance vision.

**Ocular  
Hypertension:**

Increased eye pressure.

**Optic Zone:**

This is the diameter of the area of the central cornea to which the LASIK treatment is delivered.

**Pupil:**

The opening at the center of the iris of the eye for the transmission of light, which varies in diameter depending upon the brightness of the light coming into the eye.

**PRK:**

An acronym for “photorefractive keratectomy.” This is a surgical procedure in which a thin portion of the clear front part of the eye (cornea) is removed by the excimer laser in a predetermined manner to re-shape the cornea to correct refractive errors of the eye.

**Refractive surgery:**

Several different procedures used for altering the shape of the cornea and thus how it bends light, in order to change or correct the eye’s refractive error.

**Retina:**

The thin lining of the back of the eye that converts images from the eye’s optical system into electrical impulses sent to the brain.

**RK**

An acronym for “radial keratotomy.” This is a surgical procedure in which a predetermined number of radial cuts are made in the periphery of the cornea. This allows the central cornea to flatten and thereby reduces nearsightedness.

**Steroid**

**Medication:**

A drug that reduces inflammation or the body’s reaction to injury or disease. Your doctor may prescribe this medication after LASIK surgery for a short time to modify the healing of your eye. If you are taking this medication for a disease condition, you should not have LASIK surgery.

**Visual Acuity:**

A measure of the sharpness of vision using a letter chart.

**Wavefront:**

A measure of the total focusing errors (aberrations) including nearsightedness, astigmatism, and complex focusing errors (higher-order aberrations). Light is projected into your eye and focused on the retina. Part of this light is reflected back out of your eye to form the wavefront.

**L. PATIENT ASSISTANCE INFORMATION**

**PRIMARY EYE CARE PROFESSIONAL**

Name:

Address:

Telephone Number:

**LASIK DOCTOR**

Name:

Address:

Telephone Number:

**LOCATION WHERE TREATMENT WAS DONE**

Name:

Address:

Telephone Number:

**LASER MANUFACTURER**

Bausch & Lomb TECHNOLAS GmbH  
Hans-Riedl-Strasse 7-9  
D-85622 Feldkirchen/Munchen  
Germany

(011) 498994004-0

**SALES AND SERVICE**

Bausch & Lomb Incorporated  
180 E. Via Verde Drive  
San Dimas, California 91773  
United States of America

Refractive Hotline:

(800) 496-7457

(800) 4xmr-hlp

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