

# **PATIENT INFORMATION BOOKLET**

**Photorefractive Keratectomy  
for Moderate Myopia (Nearsightedness)  
with Astigmatism**

**Nidek EC-5000  
Excimer Laser System**

**Nidek Inc.**

**47651 Westinghouse Drive  
Fremont, California 94539  
(510) 226-5700**

**[www.nidek.com](http://www.nidek.com)**

**SURGICAL LASER TREATMENT FOR NEARSIGHTED PATIENTS WITH  
VISION CORRECTION FROM  $-1.00^*$  TO  $-8.00$  DIOPTERS SPHERICAL  
EQUIVALENT AND HAVING ASTIGMATISM FROM  $-0.50$  TO  $-4.00$   
DIOPTERS OF CYLINDER**

\*Ask your doctor about certain limitations in the lower range of correction. You may not be qualified for treatment with certain amounts of astigmatism.

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

**Laser Manufacturer:**  
Nidek Co., Ltd.  
Gamagori, Japan

**U.S.A. Offices:**  
Nidek Inc.  
47651 Westinghouse Drive  
Fremont, California 94539  
(510) 226-5700

Part Number 16006-P812A 10.99

## TABLE OF CONTENTS

|   |    |
|---|----|
| 1. INTRODUCTION .....   | 2  |
| 2. HOW THE EYE FUNCTIONS .....  | 3  |
| 3. WHAT IS PRK FOR MYOPIA WITH <u>ASTIGMATISM</u> ? .....                         | 7  |
| 4. CONTRAINDICATIONS .....  | 8  |
| 5. WARNINGS .....   | 9  |
| 6. PRECAUTIONS .....  | 10 |
| 7. RISKS .....  | 11 |
| 8. BENEFITS .....   | 14 |
| 9. ARE YOU A GOOD CANDIDATE FOR PRK FOR<br>MYOPIA WITH <u>ASTIGMATISM</u> ? ..... | 15 |
| 10. BEFORE THE SURGERY .....  | 18 |
| 11. THE DAY OF SURGERY .....  | 19 |
| 12. THE FIRST DAYS AFTER SURGERY .....  | 22 |
| 13. QUESTIONS TO ASK YOUR DOCTOR .....  | 23 |
| 14. SELF-TEST .....   | 24 |
| 15. SUMMARY OF IMPORTANT INFORMATION .....  | 26 |
| 16. SUMMARY TABLES .....  | 29 |
| 17. GLOSSARY .....  | 31 |

## 1. Introduction

Please read the following information if you are thinking about having Photorefractive Keratectomy (PRK) for myopia with astigmatism laser surgery to correct nearsightedness (myopia) with treatment for astigmatism<sup>1</sup>. The options for correction of myopia and astigmatism now include glasses, contact lenses, and different kinds of refractive surgery such as radial keratotomy (RK), automated lamellar keratoplasty, excimer laser in situ keratomileusis (LASIK), and PRK for myopia with astigmatism using excimer lasers, including the Nidek EC-5000 Excimer Laser System.

This information can help you make an informed decision when selecting a method to correct your nearsightedness. If both of your eyes are nearsighted, your doctor may recommend PRK for myopia with astigmatism surgery for both eyes to achieve satisfactory vision or to treat only one eye. For example, one reason for treating only one eye is that you may use one eye for looking close up and one eye for looking far away.

Please read this booklet completely. Discuss any questions you may have with your doctor in order to decide if PRK for myopia with astigmatism is the right choice for you. Only a trained and certified practitioner

---

<sup>1</sup> Underlined terms are contained in the Glossary.

can determine whether or not you are a suitable candidate for PRK for myopia with astigmatism. You should be aware that a small percentage of patients treated with excimer lasers experience permanent vision reduction. The goal of PRK for myopia with astigmatism is to reduce your need for glasses or contact lenses by changing the shape of the cornea through PRK for myopia with astigmatism laser surgery.

## **2. How the Eye Functions**

The cornea and lens of the eye focus light like a camera lens to form an image on the retina at the back of the eye. The cornea, where light first enters the front of the eye, provides about two thirds of the eye's focusing power, and the lens inside the eye provides the other third. Normally, in relatively young persons (i.e., less than 50 years of age) the lens of the eye can adjust its focusing power somewhat, so you can see objects clearly both near and far away.

The eye focuses light by refracting all light rays to meet at a single point. If the focusing process works perfectly, a sharp image of the object you are looking at will be focused exactly on the retina and you will see a clear image. However, if the light focuses either in front of or behind the retina, the image on the retina (and the image you see) will be blurred, and you are said to have a refractive error. Refractive errors are not diseases, but

are common variations observed in human beings across the world.

There are three main types of refractive error. They are called nearsightedness (myopia), farsightedness (hyperopia) and astigmatism. The amount of refractive error present in the eye is measured in units called "diopters." When your eye cannot focus correctly, it is said to have one of the main refractive errors: myopia or hyperopia.

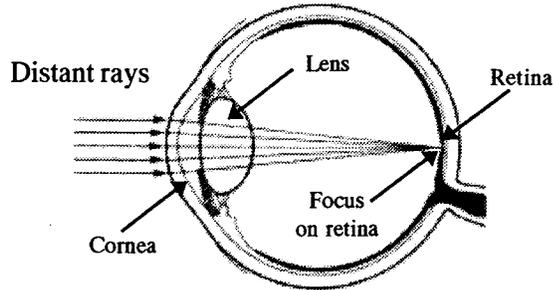
Myopia usually starts in childhood and typically stabilizes in the late teens or early adulthood. The tendency to develop myopia also runs in families. Myopia can range from a very mild to a very strong nearsighted effect. The range of treatment with the Nidek EC-5000 covers a large part of that range.

Hyperopia is also very common, and is especially problematic in older persons who have difficulty in focusing on objects up close. The Nidek EC-5000 is not approved for treating hyperopia.

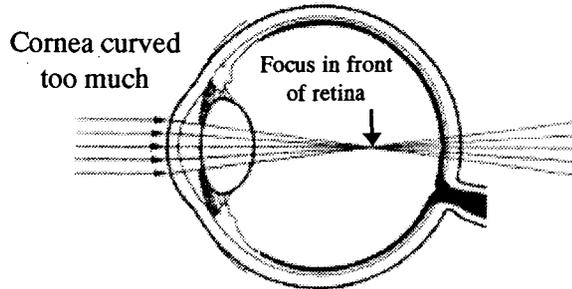
Astigmatism occurs when the refractive error is stronger in a particular direction. Astigmatism may occur with either myopia or hyperopia.

The pictures on the following page emphasize the role of the cornea in determining the focusing power of the eye. They show that the more sharply the cornea is curved, the more the light rays are bent. If the cornea is curved too much, the image focuses in front of the retina and the eye is

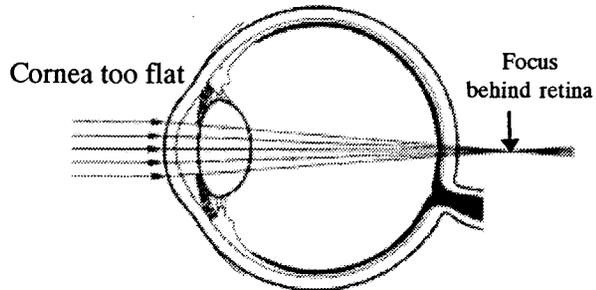
### PROPER FOCUS



### NEARSIGHTED EYE



### FARSIGHTED EYE



nearsighted. If the cornea is too flat, the image focuses behind the retina and the eye is farsighted. When the cornea shape is just right, the image from a distant object is focused exactly on the retina. This proper focus for distance vision is called emmetropia.

Good focus depends on three factors, the overall shape and size of your eye, the shape of the cornea, and your lens power. During a regular eye examination, your doctor checks your vision to determine where the eye focuses light relative to your retina. When your doctor adjusts your vision with different lenses, he correctly focuses light on the retina.

Myopia affects about 25% of the population in North America. Myopic individuals see near objects clearly, but distant objects are blurry. Nearsightedness and astigmatism can be corrected by any method that reduces the total refractive power of the eye, and includes the use of glasses, contact lenses and refractive surgery. With glasses or contacts, changes in your vision that occur slowly over time can be corrected by simply adjusting the lens prescription of your glasses or contacts. Refractive surgery, on the other hand, produces changes that are permanent and cannot be undone or easily modified if your vision changes or if the initial surgery is not successful (2.4% of initial surgeries were found to be greater than 2.0 diopters from intended correction at 6 months after surgery).

### **3. What is PRK for myopia with astigmatism?**

PRK for myopia with astigmatism is laser surgery to correct near-sightedness (myopia) with astigmatism. An excimer laser beam is used to flatten the front of the cornea. The laser beam removes microscopic amounts of tissue from the front of the cornea, precisely reshaping the cornea.

The excimer laser produces a beam of ultraviolet light in a series of rapid pulses. Each pulse lasts only a few billionths of a second and removes a microscopic amount of tissue by evaporating it. Excimer laser light does not penetrate the eye and leaves other eye structures (iris, lens, and retina) undisturbed. The laser produces very little heat and is controlled by the doctor during the operation.

Prior to PRK for myopia with astigmatism, some anesthetic drops are placed on the eye to numb it. Your doctor then begins the PRK for myopia with astigmatism procedure by gently removing the outermost layer of the cornea where the laser treatment will be performed. These cells are usually scraped away using a small instrument. This part usually takes a couple of minutes. After that, your doctor uses the laser beam to complete the PRK for myopia with astigmatism procedure. The laser treatment usually lasts only about 15-40 seconds. This procedure is performed on one eye at a time even if both are to be

treated. If all goes well with the first eye, and your vision stabilizes without complication or adverse reactions, then the second eye can be treated later. PRK for myopia with astigmatism laser surgery on the second eye is usually done three months after the first eye, if needed.

#### 4. Contraindications

You should **NOT** have PRK for myopia with astigmatism surgery if:

- You have collagen vascular, autoimmune or immunodeficiency diseases (for example: rheumatoid arthritis, lupus or AIDS). These conditions may result in scarring or poor healing after PRK for myopia with astigmatism treatment resulting in reduced vision.
- You are pregnant or nursing. These conditions may affect your preoperative refraction making it difficult to choose the correct amount of PRK for myopia with astigmatism treatment.
- You show signs of thinning of the cornea (keratoconus) or corneal disease. This condition can lead to serious cornea problems that require additional surgical repair and result in poor vision.
- You are taking prescription medications that affect corneal healing or your refraction. You

should discuss all medications you take, even over-the-counter medications, with your eye doctor. Many medications can affect the way your cornea is changed by the laser and the way it heals after PRK for myopia with astigmatism treatment. These may affect your refractive outcome and possibly result in reduced vision after PRK for myopia with astigmatism treatment.

## 5. Warnings

Discuss with your doctor if:

- Your nearsightedness is changing. If your vision is unstable, then you should not be treated. Treatment of unstable vision may affect the accuracy of your refractive results.
- You have severe allergies. Your medications may have to change before or after your eye surgery. These medications may change the wetness (moisture level) in your eye. If the medication changes the wetness of your eye, the accuracy of your refractive results may be affected.
- You have been diagnosed with ocular *Herpes simplex* or ocular *Herpes zoster*. Herpes are viral infections. Laser treatment may reactivate the infection.

- You have nystagmus (uncontrolled eye movements) or another condition that prevents a steady gaze. You need to be able to keep your eyes still during treatment. The accuracy of your refractive results will be affected if you can not keep your eyes still during treatment.

## 6. Precautions

The safety and effectiveness of the Nidek EC-5000 Excimer Laser has **NOT** been evaluated in patients with the following conditions or situations. Therefore, no statement regarding the safety and effectiveness can be made about the effect these situations may have on PRK for myopia with astigmatism refractive surgery with the EC-5000:

- Eyes with disease or corneal abnormality (for example: scar, infection, corneal dystrophies, etc.).
- Eyes with previous surgery or injury to the center of the cornea where PRK for myopia with astigmatism will be performed.
- Patients under 21 years of age.
- Patients over the long term (more than 2 years after the surgery).

## 7. Risks

PRK for myopia with astigmatism is a laser surgical procedure involving your eyes and has potentially serious risks. You should consider and discuss with your doctor the risks that are noted in this booklet. These are based on clinical experience with PRK for myopia with astigmatism cases and the possible concerns that doctors believe should be considered for this kind of eye surgery.

See the information listed below for details on risks of complications and adverse events.

- Although the effects of PRK for myopia with astigmatism on visual performance under poor lighting conditions (dim illumination) have not been determined, it is possible that you will find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog or glare from bright lights at night. These effects have been reported as being more common in persons with large pupils (over 6 mm). It is possible that these may be permanent effects.
- Up to six months following surgery:**
  - Your intraocular pressure may increase due to use of steroid or anti-inflammatory medications (the worst case was 0.9% of the eyes at 3 months after surgery had a significant elevation in intraocular pressure).

This is usually resolved by drug therapy or by stopping the use of the steroid or anti-inflammatory medication.

- Your cornea may become hazy or cloudy enough to affect your vision (0.9% of eyes had mild or moderate haze at 6 months after surgery, 0.3% had mild to moderate haze with significant loss of vision). This haze typically disappears over time, but some patients continue to experience a small amount of haze over 1-2 years (0.6%).
- An increase in fluctuation of vision (40.5% pre-operatively vs. 45.7% post-operatively).
- Glare (27.7% pre-operatively vs. 31.4% post-operatively).
- Difficulty in night driving (24.3% pre-operatively vs. 43.9% post-operatively).

#### **CAUTION**

**You should contact your doctor if you notice any pain or change or loss of vision in the eye. Eye pain or sudden loss of vision can indicate a serious problem that requires immediate medical attention.**

□ **More than one year after surgery:**

Nidek clinical studies showed that at one or two years after PRK for myopia with astigmatism surgery the following vision-threatening events happened less than approximately 1% of the time:

- Losing a significant amount of vision (more than 2 lines worse on the eye chart) even with glasses.
- Corneal haze (that causes significant loss of vision).

Too large a correction (causing farsightedness more than +2.0 diopters) was observed in 2.5% (12 months) to 3.8% (24 months) of the clinical study group.

If the results of the surgery are not satisfactory, you may need to have additional refractive surgery in the same eye.

## 8. Benefits

- PRK for myopia with astigmatism surgery, as performed with the Nidek EC-5000 Excimer Laser, may be effective in reducing nearsightedness requiring correction from  $-1.00$  to  $-8.00$  diopters spherical equivalent in patients with  $-0.50$  to  $-4.00$  diopters of astigmatism (86.1% of treated eyes were within 1.0 diopter of intended correction at 6 months).
- PRK for myopia with astigmatism may reduce your overall nearsightedness (93.5% significantly improved uncorrected vision to the level of 20/40 or better at 6 months).
- PRK for myopia with astigmatism may reduce or eliminate your dependency upon contact lenses or glasses (64.3% could see 20/20 or better without glasses or contacts at 6 months).
- PRK for myopia with astigmatism should be considered a permanent surgical procedure, in that the refractive result changes little after the first few months. If your refractive result is unsatisfactory, your doctor may recommend further surgical treatments, or correcting your remaining refractive error with glasses or contacts.

**9. Are You a Good Candidate for PRK for myopia with astigmatism?**

If you are considering PRK for myopia with astigmatism, you must:

- Be at least 21 years of age.
- Have healthy eyes which are free from eye disease or corneal abnormality (for example: scar, infection, etc.).
- Have nearsightedness (myopia) requiring vision correction between  $-1.00$  and  $-8.00$  diopters spherical equivalent, with  $-0.50$  to  $-4.00$  diopters of astigmatism. Ask your doctor about certain limitations in the lower range of correction. You may not be qualified for treatment with certain amounts of astigmatism.
- Be sure your eye doctor has satisfactory evidence that your refraction has been stable over the past year (changed by  $\leq 0.5$  diopters in your vision correction, and  $\leq 0.5$  diopters in your astigmatism correction).
- Be informed of PRK for myopia with astigmatism risks and benefits as compared to other available treatments for nearsightedness (myopia) and astigmatism.

- Be willing to sign an informed consent form, as provided by your eye care professional.

**Why PRK for myopia with astigmatism may not be right for you:**

- *If you expect perfect results.* No surgical procedure can assure you perfect results or can guarantee that your expectations will be met.
- *If you expect perfect vision under all conditions.* At night, eyes that have been reshaped by refractive procedures such as PRK for myopia with astigmatism may experience glare and a variety of visual effects. The PRK for myopia with astigmatism procedure only reshapes the central portion of the cornea and does not reshape the entire cornea. As a result, when the pupil of the eye dilates (over 6 mm) under low light conditions, it may open past the boundaries of the treated area producing unwanted changes in vision, such as halos and hypersensitivity to light. You may find that you will need to wear corrective lenses to drive at night.

PRK for myopia with astigmatism treatment is not intended to eliminate the need for reading glasses. In some patients, reading glasses may be required after treatment even if they were not worn before treatment. As patients get to age 40 and beyond, they are more and more likely to require reading glasses when their distance vision is otherwise excellent. Nearly all older patients require reading glasses if their distance vision is fully corrected.

If the thought of occasionally wearing eye wear is uncomfortable, then PRK for myopia with astigmatism may not be right for you.

- *If you expect an instant change in vision.* The visual results are not instant, even for patients with less than 4 diopters of correction. It may take up to 3 months, sometimes longer, for the shape of the cornea to stabilize following surgery. You must be patient and be willing to wait until the healing process finishes. You may need to temporarily wear corrective lenses.

Please note that various occupations may have certain restrictions regarding refractive surgery. Therefore, you should check with the appropriate people before having refractive surgery.

#### **10. Before the Surgery**

If you are interested in having PRK for myopia with astigmatism, you will need to have a pre-surgical examination to determine if your eye is healthy and suitable for PRK for myopia with astigmatism. This will include a complete eye history, and a thorough examination of both eyes. In addition, computerized mapping of your cornea will be done to determine if it is smooth and properly shaped.

#### **WARNING**

**If you wear contact lenses, it is very important to stop wearing them 2-4 weeks before the evaluation. Failure to do this can affect the quality of your vision and the accuracy of your refractive result.**

Before the surgery, please tell your doctor well in advance whether you take any medications or have any allergies. Also, talk with your doctor about whether you can eat or drink immediately before the surgery. You should also arrange for transportation, since you must not drive immediately after the surgery. You can resume driving only after receiving permission from your doctor.

### **11. The Day of Surgery**

Before the surgery, (numbing) anesthetic drops will be placed into the eye to be treated and you will be escorted into the room with the laser. You will lie on your back in a reclining chair and look up at a microscope that will deliver the laser light to your cornea. An instrument will be placed between your eyelids to hold them open during the surgery. For protection and comfort, a temporary shield will cover the eye not having surgery.

- Your doctor may perform a brief practice treatment so you can hear and smell what the laser will be like during the treatment.

- Using a small instrument, the surgeon begins the procedure by removing the outermost layer of the cornea. Next, the doctor repositions your head in the chair, and refocuses the microscope on your cornea. You will then be asked to look directly at a blinking light. Relax the muscles of your face and forehead and try to keep both eyes open without squinting. As you continue to look at the blinking light, small amounts of tissue will be removed from your cornea using the Nidek EC-5000 Excimer Laser.

#### **PRECAUTION**

**It is very important that you keep looking at the blinking light during the procedure, even if the light fades or becomes dim. The quality of vision and accuracy of your refractive result after PRK for myopia with astigmatism can depend on you looking straight at this blinking light throughout the treatment.**

- You will be exposed to the laser energy for less than 1 minute. However, the entire surgical procedure takes about 10 to 15 minutes.

- After the laser surgery is complete, some drops or ointment will be placed into your eye. Then it will be covered and patched for your protection and comfort. The surgery itself is painless because of the numbing actions of the anesthetic drops that were applied to your eye at the beginning of the procedure.
- After 45 to 60 minutes, the anesthetic will wear off and your eye may hurt for 1 to 3 days. Most patients describe this pain as moderate to severe. Do **NOT** rub your eyes for the first 3 to 5 days. Rubbing your eyes can damage the cornea and will delay healing. Your doctor can prescribe pain medication to make you more comfortable during the first week after the surgery.

**WARNING**

**Your doctor will monitor you for any side-effects if topical steroids were used. The possible side-effects from prolonged use of topical steroids are an increase of pressure in the eye (ocular hypertension), glaucoma or cataract formation.**

## **12. The First Days After Surgery**

In your doctor's office, your eye patch will be removed the following day. You will be mildly sensitive to light and have the feeling that something is in your eye for the first few days. Sunglasses may make you more comfortable during this time.

- Your vision should become stable within the first several weeks after surgery. Some patients may experience some small changes (for example, improvement or worsening of their vision). These changes may occur up to six months or more after surgery.
- A haze or cloudiness is typically seen in the cornea following surgery, but usually does not affect your vision. This haze tends to decrease over time and usually disappears completely over a 1 to 2 year period.

### **IMPORTANT**

**Use anti-inflammatory eye drops and lubricants as directed by your doctor. The quality of your vision and the accuracy of your refractive result depend upon you following your doctor's directions.**

### 13. Questions to Ask Your Doctor

You may want to ask the following questions to help you decide if PRK for myopia with astigmatism is right for you:

- What other options are available for correcting my nearsightedness with astigmatism?
- Will I have to limit my activities after surgery, and for how long?
- What are the benefits of PRK for myopia with astigmatism for my amount of nearsightedness with astigmatism?
- What quality of vision can I expect in the first few months after surgery?
- If PRK for myopia with astigmatism 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 PRK for myopia with astigmatism if I need them?
- How is PRK for myopia with astigmatism likely to affect my need to wear glasses or contact lenses as I get older?

- Is it likely I will need reading glasses sooner than later?
- Will my cornea heal differently if injured after having PRK for myopia with astigmatism?
- Should I have PRK for myopia with astigmatism surgery in my other eye?
- How long will I have to wait before I can have PRK for myopia with astigmatism surgery on my other eye?
- What vision problems might I experience if I have PRK for myopia with astigmatism only on one eye?

Discuss the cost of surgery and follow-up care requirements with your doctor, as laser treatment is not covered by most health insurance policies.

#### **14. Self-Test**

##### **Are you an informed and educated patient?**

Take the following test and see if you can correctly answer these questions after reading this booklet.

**TRUE      FALSE**

1. Excimer laser refractive surgery is risk free.
2. Excimer laser surgery use pulses of invisible light.
3. It doesn't matter if I wear my contact lenses when  
my doctor told me not to.
4. The laser does all the work; I just have to lie on the  
chair and close my eyes.
5. After the surgery, there is a good chance that I will  
be less dependent on eye glasses.
6. I may need reading glasses after laser surgery.
7. There is a risk that I may lose some vision after  
laser surgery.
8. It doesn't matter if I am pregnant.
9. If I have an auto-immune disease, I am still a good  
candidate for PRK for myopia with astigmatism.

Answers to SELF-TEST questions are found on page 28.

## 15. Summary of Important Information

- PRK for myopia with astigmatism is a permanent operation to the cornea that cannot be easily changed.
- Alternatives to PRK for myopia with astigmatism include glasses, contact lenses and RK.
- PRK for myopia with astigmatism is not a laser version of RK; they are completely different from one another.
- Some occupations, such as pilots, may not accept applicants who have had any refractive surgery.
- Refractive error must be stable (within  $\leq 0.5$  diopters in your vision correction, and within  $\leq 0.5$  diopters in your astigmatism correction) for at least one year before surgery.
- The following risks of PRK for myopia with astigmatism surgery should be noted:
  - Temporary discomfort may be expected for 24 to 72 hours after surgery. If the discomfort persists, please contact your doctor.
  - Problems that may last several weeks: corneal swelling, blurred vision, feeling something in the eye, shadow images, light sensitivity, tearing, and pupil enlargement.

- Adverse events beyond the first few months: elevation of intraocular pressure (0.3% at 6 months); cloudy cornea affecting vision (0.3% at 6 months had mild to moderate haze with significant loss of vision); overcorrection by more than 2.0 diopters (2.1% at 6 months, 2.5% at 12 months); under correction or nearsighted by more than 2.0 diopters (0.3% at 6 months, 1.1% at 12 months); and loss of best vision that can be achieved with glasses (0.5% at 6 months).
- The following benefits of PRK for myopia with astigmatism surgery should be noted:
  - Nearsightedness with astigmatism may be reduced so that the amount of time contact lenses or glasses are used during the day is reduced or eliminated.
  - PRK for myopia with astigmatism may be an alternative to glasses in some patients who are intolerant of contact lenses.
  - PRK for myopia with astigmatism may be another alternative to correct nearsightedness and astigmatism.
- Patients considering PRK for myopia with astigmatism surgery should:
  - Discuss fully with one or more ophthalmic

surgeons the complications of PRK for myopia with astigmatism surgery, the risks and the time required for healing, and have a complete eye examination before making a final decision.

- Read both the Patient Information Booklet and the Informed Consent Document (ICD) provided by your doctor carefully before signing the ICD.

*Answers to Self-Test Questions:*

1. False (see Risks on page 11)
2. True (see What is PRK for myopia with astigmatism? on page 7)
3. False (see Before The Surgery on page 18)
4. False (see The Day of Surgery on page 19)
5. True (see Benefits on page 14)
6. True (see Why PRK for myopia with astigmatism may not be right for you? on page 16)
7. True (see Risks on page 11)
8. False (see Contraindications on page 8)
9. False (see Contraindications on page 8)

## 16. Summary Tables

The following tables provide additional information. If you have any questions, please discuss them with your doctor.

| <b>Summary of Key Safety and Efficacy Variables at 6 months after Surgery</b>                   |       |
|---|-------|
| <i>Efficacy Variables</i>   |       |
| Visual acuity without glasses or contacts:  |       |
| 20/20 or better   | 64.3% |
| 20/40 or better   | 93.5% |
| Treated eyes within range of target correction ( <u>MRSE</u> ):                                 |       |
| ±0.50 diopters  | 62.3% |
| ±1.00 diopters  | 86.1% |
| ±2.00 diopters  | 97.6% |
| <i>Safety Variables</i>   |       |
| Visual acuity with glasses being 20/40 or worse   | 0.0%  |
| Loss of more than 2 lines on vision chart with glasses on                                       | 0.5%  |
| Visual acuity with glasses on is worse than 20/25, when it was better than 20/20 before surgery | 0.6%  |

| Complications and Adverse Events                     |                              |             |
|--|------------------------------|-------------|
| Description  | Immediate Post-op to 1 Month | At 6 Months |
| <i>Complications—</i>                                |                              |             |
| Haze (mild to moderate)                              | 2.2%                         | 0.9%        |
| <u>Corneal edema</u>                                 | 0.3%                         | -----       |
| <u>Recurrent erosions</u>                            | 0.0%                         | 0.0%        |
| <i>Adverse events—</i>                               |                              |             |
| Persistent corneal defect                            | 0.3%                         | 0.1%        |
| <u>Corneal infiltrate</u>                            | 0.0%                         | 0.0%        |
| Elevated intraocular pressure (relative or absolute) | 0.6%                         | 0.3%        |
| Loss of visual acuity after 6 months                 | -----                        | 0.4%        |
| Late onset haze with decreased vision                | -----                        | 0.0%        |
| Retinal accidents/detach.                            | 0.0%                         | 0.1%        |

See Glossary on page 31 for an explanation of underlined terms.

## 17. Glossary

**Astigmatism:** A refractive error that is stronger in one direction than others, usually corrected by glasses or contacts with a slight cylinder shape.

**Automated lamellar keratoplasty:**

An older surgical technique to remove a thin layer of the cornea and reshape it to correct refractive error.

**Collagen vascular disease:**

Any of several conditions that alter the way your body creates and metabolizes normal connective tissue like collagen. The cornea is made mostly of collagen. Some common examples include lupus, scleroderma, and rheumatoid arthritis.

**Corneal dystrophies:**

Any of several abnormal conditions in the cornea that represent an unusual growth pattern in the surface cells or other layers of the cornea.

**Corneal edema:**

A swelling of the cornea, common in response to eye surgery or injury, that some times causes temporary clouding of the cornea.

**Corneal infiltrate:**

An infection or inflammatory response that penetrates into the cornea, often more difficult to treat than a surface problem.

**Cylinder:** Describes the barrel shaped lens required to fix your astigmatic refractive error.

**Efficacy:** How well or effectively a treatment performs.

**Excimer laser in situ keratomileusis (LASIK):**

Use of an excimer laser to treat refractive error under a thin flap of the cornea. The flap is made first, moved out of the way for laser treatment, then replaced to cover the treatment area.

**Increase in fluctuation of vision:**

Variations in vision more than usual or normal that are easily noticed by a person when lighting conditions change (e.g., daytime compared to nighttime vision).

**Intraocular pressure (IOP):**

The normally constant fluid pressure inside the eye. When too high, it can cause glaucoma.

**MRSE:** The manifest refraction spherical equivalent; a measure of the overall lens power of the refractive correction needed by your eye.

**Radial keratotomy (RK):**

A surgical treatment to correct refractive error using small cuts to change the shape of the cornea.

**Recurrent erosions:**

A repeated uncovering of the corneal epithelial cells that protect the cornea.

**Refractive surgery:**

Surgery to change how the eye focuses to correct refractive error. This includes the use of laser surgery or cuts to alter the shape of the cornea, implantation of small lenses or rings, or surgical removal of a clear lens.

**Sphere:**

Describes the round shaped lens required to fix your refractive error when you do not have astigmatism.

## **INFORMATION CENTER**

### **Primary Eye Care Professional**

(This information can be pre-printed by the physician's office)

Name:

Address:

Phone:

### **Doctor Performing PRK for myopia with astigmatism**

Name:

Address:

Phone:

### **Treatment Location**

Name:

Address:

Phone: