

## Patient Information Booklet

# Important Information About: Topography- Assisted LASIK Treatment for Nearsightedness (Myopia) with Astigmatism using the Nidek EC-5000 Excimer Laser System

Surgical Laser Treatment for Vision Correction of Nearsightedness (Myopia) from -1.00D to -4.00D of sphere with astigmatic refractive errors from  $>-0.5$  to  $-2.0$  D with manifest refraction spherical equivalent (MRSE) of  $>-1.0$  to  $-5.0$  D

### PLEASE READ THIS ENTIRE BOOKLET

Discuss its contents with your doctor so that all of your questions are answered to your satisfaction before you agree to have LASIK surgery.

Some amounts of nearsightedness and astigmatism cannot be treated with the Nidek EC-5000 Excimer Laser System. Ask your doctor if the amount of your nearsightedness and astigmatism can be corrected by LASIK.

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Nidek Incorporated  
47651 Westinghouse Drive  
Fremont, California 94539  
Phone: (510)-226-5700  
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## GLOSSARY

This section defines specialized technical words that are used in this booklet. Please ask your doctor any questions you may have about these words.

**Accommodation:** the process of changing the focus of the eye from distant objects to near objects.

**Acuity:** (see Visual Acuity)

**Antibiotic:** eye drops used before and/or after refractive surgery to treat or prevent infection.

**Anti-Inflammatory Drug:** eye drops used after refractive surgery to reduce or prevent inflammation.

**Astigmatism:** a refractive error in which the eye focuses light rays more strongly in one direction than another. For example, an eye with astigmatism might be more nearsighted for horizontal lines than for vertical lines.

**Collagen Vascular Disease:** a condition that may cause inflammation of parts of the body, such as muscles, joints, and blood vessels. Examples of this type of disease are lupus and rheumatoid arthritis.

**Contraindication:** a condition for a type of patient who should not have LASIK because it is not safe.

**Cornea:** the clear, front surface of the eye.

**Diopter:** a unit of measurement for refractive power, or the distance between the eye and an object in focus. An infinite (very large) focal distance is zero diopters, a one meter distance is one diopter, a one-half meter distance is two diopters, and so on. The diopter scale is used to measure the amount of myopia, hyperopia, or astigmatism of an eye.

**Dry Eye Syndrome:** a condition in which the eye does not produce enough tears to stay moist and comfortable. Symptoms of dry eye include pain, stinging, burning, scratchiness, and blurry vision.

**Epithelium:** the cells on the surface of your eye

**Excimer Laser:** the type of ultraviolet light laser used for LASIK.

**Farsightedness:** the common name for hyperopia.

**Ghost Image:** a fainter, displaced, second image of the object you are looking at.

**Glare:** scattered light in the eye from a very bright light source that makes nearby objects harder to see.

**Halos:** rings of light around lamps or other small bright lights.

**Haze:** corneal clouding that causes a sensation of looking through smoke or fog.

**Herpes (simplex or zoster):** a virus that permanently infects the nervous system and can cause recurring symptoms. Herpes simplex can cause genital sores or “cold sores” around the mouth. Herpes zoster causes chicken pox in children and shingles in adults.

**Hyperopia:** a refractive error that happens when the eye is too short and light rays focus behind the retina, causing images of near objects to be blurry.

**Immunodeficiency Disease:** a condition that reduces the body’s ability to fight infection. An example is autoimmune deficiency disease (AIDS).

**Inflammation:** the body’s reaction to injury, infection, allergy, or a foreign substance. Symptoms can include pain, heat, redness, swelling, and/or loss of function of the affected area.

**Informed Consent Form:** a printed description of LASIK that you have to read and sign before you can have LASIK. The informed consent form explains the risks and benefits of LASIK, and it gives all the other ways of correcting nearsightedness and astigmatism. You should not sign the informed consent form until you are sure that you understand the risks and benefits of LASIK and that you still want to have it done.

**In Situ:** a Latin term meaning “in place” or not removed.

**Iris:** the colored ring of tissue behind the cornea and immediately in front of the lens.

**Keratotomy:** the surgical removal of corneal tissue.

**Keratoconus:** a disorder that causes the cornea to get thinner and (often) cone-shaped.

**Keratomileusis:** carving of the cornea to reshape it.

**Lamellar keratitis:** sterile (non-infectious) inflammation underneath the flap

**Laser:** an instrument that produces a powerful beam of coherent light. The word “laser” stands for “light amplification by stimulated emission of radiation.” Some types of laser produce beams of light that are powerful enough to evaporate tissue.

**LASIK:** the word “LASIK” stands for “laser assisted in situ keratomileusis,” a type of refractive surgery in which the doctor first uses a microkeratome to cut a thin layer, or “flap”, from the front of the cornea. The doctor then peels back the flap, removes some

corneal tissue with an excimer laser, and puts the flap back in place. This procedure corrects refractive errors by changing the shape of the cornea.

**Lens (of the eye):** a part of the eye behind the iris that helps to focus light onto the retina. The lens is able to change shape allowing the eye to focus at different distances.

**Manifest Refraction:** a test to measure the refractive power of the eye by asking a patient to look at a visual acuity chart through different lenses to find the one that brings the chart into the best focus.

**Microkeratome:** a surgical tool that cuts a flap of tissue from the front surface of the cornea with a knife or laser.

**Myopia:** a refractive error in which the eye is too long and light rays focus in front of the retina, causing images of distant objects to be blurry.

**Nearsightedness:** the common name for myopia.

**Overcorrection:** too much refractive correction. For example, overcorrecting a nearsighted eye makes it farsighted.

**PRK:** PRK stands for photorefractive keratectomy, a type of refractive surgery in which no flap is cut, but the top layer of corneal cells is scraped away and the new surface is reshaped with the laser.

**Presbyopia:** the loss of the ability to focus on near objects, such as reading small print that naturally happens as we get older.

**Pupil:** the opening in the center of the iris that changes size to control the amount of light that enters the eye in response to changes in lighting. It gets larger in dim lighting conditions and gets smaller in brighter lighting conditions.

**Refract:** to bend or focus rays of light.

**Refractive Errors:** errors in the focusing power of the eye, for example, farsightedness, nearsightedness, and astigmatism.

**Refractive Power:** the ability of a lens system, such as the eye, to focus a beam of light that passes through it.

**Retina:** a layer of nerve tissue at the back surface of the eye that changes light images into electrical signals and sends these signals to the brain.

**Topography:** a map of the surface of the eye (cornea) that provides information about its shape and any irregularities (aberrations).

**Undercorrection:** not enough refractive correction. For example, undercorrecting a nearsighted eye leaves it still somewhat nearsighted.

**Visual Acuity:** the sharpness of vision; the ability to see small details.

## **1 INTRODUCTION**

Please read this booklet if you are thinking about having laser eye surgery to correct your nearsightedness and astigmatism. The NIDEK laser performs a special “custom” type of “Laser in situ Keratomileusis” (LASIK) that uses a map of the front surface of your eye to help plan the treatment. Other ways to correct myopia and astigmatism are glasses, contact lenses, and other kinds of surgery such as photorefractive keratectomy (PRK), non-custom LASIK and implantable lenses.

This booklet is intended to help you decide how to correct your nearsightedness. Please read this booklet completely. Discuss all of your questions with your doctor to decide if LASIK is the right choice for you. Only a trained and certified doctor can determine whether or not you are a good candidate for LASIK.

The goal of LASIK is to reduce your need for glasses or contact lenses by changing the shape of your cornea. However, LASIK may not correct your vision perfectly. The laser may undercorrect or overcorrect your vision so that you still need glasses to see clearly. Also, as you grow older, your vision is likely to change so that you need glasses to read, even if you can see clearly at large distances without glasses. In some cases LASIK can make your vision permanently worse, so that you cannot see clearly even with glasses.

Both of your eyes may need correction. It is up to you and your doctor to decide if it is better for you to have LASIK on both of your eyes or only on one.

## 2 HOW THE EYE WORKS

The cornea and lens of the eye work like a camera to form an image on the retina at the back of the eye. The sharpness of that image depends on the overall shape and size of your eye, the shape of the cornea, and the lens inside your eye.

When light enters the eye, it passes first through the cornea, then the pupil, then through the lens, and finally to the retina, as shown in Figure 1. The cornea and the lens bend the light rays so that they focus, or come together at a single point on the retina.

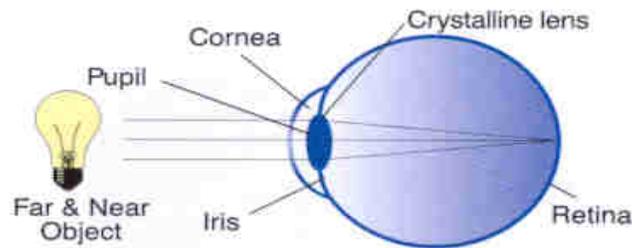


Figure 1: Normal Vision

When the light rays focus either in front or in back of the retina, the pictures that are formed on the retina are blurred and you are said to have a refractive error. Refractive errors are common in people around the world. The three main types of refractive errors are nearsightedness, farsightedness, and astigmatism.

Nearsightedness (myopia) occurs when the eye is too long. Nearsighted eyes can see clearly close up but distant objects look blurred because the images are focused in front of the retina, as shown in Figure 2. Nearsightedness can be corrected by glasses or contact lenses that move the distant image back onto the retina. Refractive surgery with a laser can also correct nearsightedness by removing tissue from the center of the cornea. This makes the cornea flatter so that the far object is in focus on the retina instead of in front of the retina.

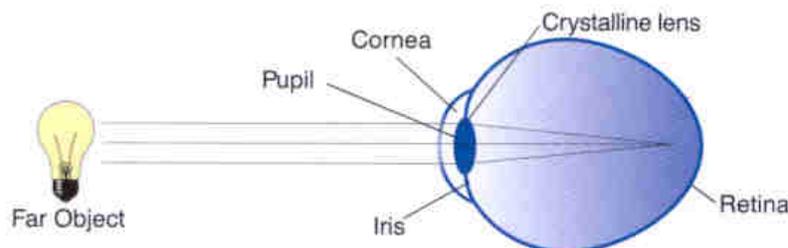


Figure 2: Nearsightedness (Myopia)

Farsightedness is the opposite of nearsightedness. The eye is too short and images are in focus behind the retina, as shown in Figure 3. Eyes that are farsighted have more difficulty seeing near objects than far away objects. The eye has the ability to adjust the shape of its lens to bring nearby objects into focus. This ability is called accommodation. How well the eye can accommodate, or adjust its focus from far to near objects also affects how well the farsighted eye can see far objects as well as near objects. Like nearsightedness, farsightedness can be corrected with glasses, contact lenses or laser surgery that moves the image to the retina. Laser surgery for the treatment of farsightedness removes more tissue in the outer edges of the cornea to make the cornea more curved, so that near objects are in focus on the retina instead of behind the retina.

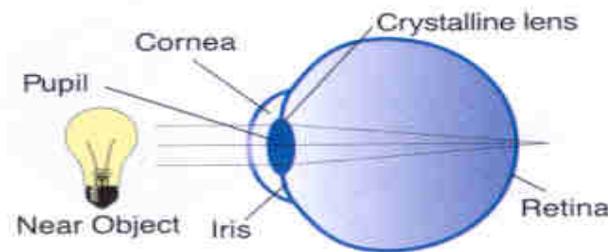


Figure 3: Farsightedness (Hyperopia)

An eye has astigmatism when the cornea is more curved in one direction than another. Some light rays focus in front of the retina and others focus behind it, as shown in Figure 4. Since the light rays are not all bent to a single point, the picture that is created on the retina is distorted or fuzzy. Glasses, contact lenses, and laser surgery each use a cylinder shaped correction that is tilted at an angle to match the angle at which the cornea is curved the least. With the correction, the images focus onto the retina in a single point instead of in scattered points.

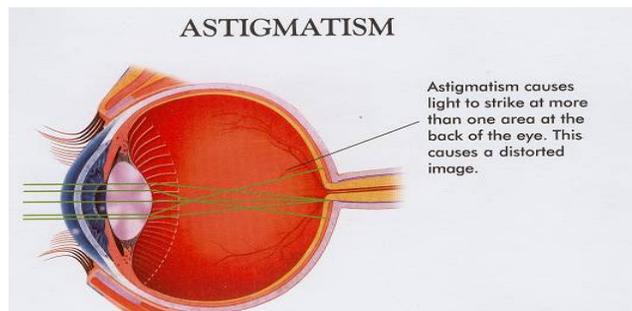


Figure 4: Astigmatism

The type of LASIK you need depends on the type of refractive error your eye has. Your doctor detects whether you are nearsighted, farsighted, or have astigmatism by determining where the light rays focus on your retina during a regular eye examination. This is done by adjusting your vision with different lenses until the image you see is correctly focused on the retina. This procedure (called a manifest refraction) is used to determine whether you have nearsightedness, farsightedness, or astigmatism and the amount of each refractive error that is present in the eye. The amount of refractive error present in the eye is measured in units called "diopters." In North America, about 25% of the population is nearsighted and about 10% is farsighted.

It is important for you to understand that LASIK cannot be undone or easily changed if your vision changes or if the first surgery is not successful. 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. Nearsightedness, farsightedness, and astigmatism can range from very mild to very strong. The Nidek Laser System does not cover the entire range of myopia and astigmatism. Whether you can have LASIK will depend on the type and amount of refractive error that you have as well as other important information about your eyes.

### **3 WHAT IS TOPOGRAHY-ASSISTED LASIK?**

LASIK corrects nearsightedness and astigmatism by changing the shape of the cornea. The laser fires a stream of up to 40 pulses of invisible ultraviolet light per second. Each pulse lasts only a few billionths of a second. Each pulse removes a tiny bit of tissue by evaporating it. To treat nearsightedness, the pulses are placed in a pattern that makes the cornea flatter. Excimer laser light does not penetrate the eye and does not harm the iris, lens, or retina. The laser produces very little heat and is controlled by the doctor during the operation.

Like regular LASIK, Topography-Assisted LASIK uses manifest refraction measurements of your nearsightedness and astigmatism to plan the treatment for your eye. In addition, however, it uses a corneal topography map of the shape of your cornea to treat small, local defects that cannot be corrected by glasses.

LASIK is done on one eye at a time. If all goes well with the first eye and you are having your second eye treated, the second eye may be treated on the same day or on a different day.

### **4 HOW MUCH VISION CORRECTION CAN YOU EXPECT WITH THE NIDEK LASER?**

You must have both nearsightedness and astigmatism to qualify for Topography-Assisted LASIK with the Nidek Laser. The laser can correct from one to four diopters of nearsightedness and one-half to two diopters of astigmatism. If you have nearsightedness and astigmatism within these ranges, LASIK may help you see distant objects more clearly without eyeglasses or contact lenses.

### **5 RISKS OF LASIK TREATMENT FOR NEARSIGHTEDNESS**

Most patients are very pleased with the results of their refractive surgery. However, like any other medical procedure, there are risks involved. That's why it is important for you to understand the limitations and possible complications of refractive surgery.

LASIK is a type of surgery and, like any surgery, there can be serious risks. Your vision may not be satisfactory after LASIK and you may need to have additional laser treatment in the same eye. Some possible problems that can be caused by LASIK are listed below. You should think carefully about whether you are willing to accept the risk that these problems could happen to you, and discuss them with your doctor before you decide to have LASIK surgery. You should also talk with your doctor about whether it would be better for you to have LASIK surgery in both of your eyes or only one eye.

Before undergoing a refractive procedure, you should carefully weigh the risks and benefits based on your own personal value system, and try to avoid being influenced by friends that have had the procedure or doctors encouraging you to do so.

- **Some patients lose vision.** Some patients lose lines of vision on the vision chart that cannot be corrected with glasses, contact lenses, or surgery as a result of treatment.
- **Some patients develop debilitating visual symptoms.** Some patients develop glare, halos, and/or double vision that can seriously affect nighttime vision. Even with good vision on the vision chart, some patients do not see as well in situations of low contrast, such as at night or in fog, after treatment as compared to before treatment.
- **You may be under treated or over treated.** Only a certain percent of patients achieve 20/20 vision without glasses or contacts. You may require additional treatment, but additional treatment may not be possible. You may still need glasses or contact lenses after surgery. This may be true even if you only required a very weak prescription before surgery. If you used reading glasses before surgery, you may still need reading glasses after surgery.
- **Some patients may develop severe dry eye syndrome.** As a result of surgery, your eye may not be able to produce enough tears to keep the eye moist and comfortable. Dry eye not only causes discomfort, but can reduce visual quality due to intermittent blurring and other visual symptoms. This condition may be permanent. Intensive drop therapy and use of plugs or other procedures may be required.
- **Results are generally not as good in patients with very large refractive errors of any type.** You should discuss your expectations with your doctor and realize that you may still require glasses or contacts after the surgery.
- **For some farsighted patients, results may diminish with age.** If you are farsighted, the level of improved vision you experience after surgery may decrease with age. This can occur if your manifest refraction (a vision exam with lenses before dilating drops) is very different from your cycloplegic refraction (a vision exam with lenses after dilating drops).
- **Long-term data are not available.** The first laser was approved for LASIK eye surgery in 1998. Therefore, the long-term safety and effectiveness of LASIK surgery is not known.

The risks listed below are based on problems that have happened to other LASIK patients and on problems that doctors believe could happen for this kind of eye surgery. Some risks are related to the corneal flap and not to the laser treatment itself. Some possible problems with the corneal flap are:

- Cutting an incomplete flap, irregularly shaped flap, or a flap that is completely free of the cornea;
- Not properly aligning the flap when it is replaced; or,
- Cutting all the way through the cornea during the flap cutting procedure.

- Repositioning of the flap after the LASIK surgery
- Accidentally loosening, tearing off, or losing the flap altogether after the surgery is finished and you have gone home.
- Flap defect, including wrinkles in the flap

Other possible corneal flap complications may not be listed here. If a flap complication occurs, you may postpone your LASIK surgery until the flap heals. A flap complication may also result in a corneal irregularity that permanently blurs your vision and prevents you from having LASIK surgery.

You should be aware of complications that may occur after LASIK, which may need long term medical attention. Current medical technology may not be able to resolve these complications. These complications may or may not affect your vision. Some may cause pain or discomfort. These complications may be permanent. Ask your doctor to explain to you the short term and long term risks of each:

- Swelling of the cornea
- Epithelium, or the cells on the surface of your eye, in between the flap and the area of the cornea where the laser pulses were applied
- A feeling as if something is in your eye
- Pain in the eye
- Eye dryness that affects your vision. If your eyes are dry after LASIK you may have moderate to severe pain, burning, foreign body sensation (feeling like something is in your eye) and/or blurred vision
- Blurred vision
- Tearing or watery eyes
- Sensitivity to lights
- Difficulty reading without wearing reading glasses
- Ghost images
- Double vision
- Lamellar keratitis, or inflammation between the flap and where the laser pulses were applied
- Fluctuation in your vision
- Vision with glasses that is worse than before LASIK
- Glare
- Halos
- Starbursts

Other complications that may occur after LASIK are more serious. These complications most likely will need long-term medical attention. Current medical technology may not be able to resolve these complications. These serious complications most likely will

affect your vision. Some may cause pain or discomfort. These complications may be permanent.

- Severe dry eye which affects your vision. If your eyes are severely dry after LASIK you will have moderate to severe pain, burning, foreign body sensation (feeling like something is in your eye) and/or blurred vision.
- Lamellar keratitis with progressive melting of the cornea
- Corneal ulcer
- Vision after LASIK with your glasses on that is 2 lines or more (on the Snellen Eye chart) worse than before LASIK.
- Increased pressure in the eye.
- Hazy vision lasting longer than 6 months.
- Retinal detachment
- Serious flap cutting complication.

Complications that were seen in the Nidek clinical study can be found on page 25 in SECTION 17: CLINICAL STUDY OF BENEFITS and on page 26 in SECTION 18: CLINICAL STUDY OF RISKS of this patient information booklet.

**CAUTION**

You may need reading glasses after LASIK even if you did not wear them before. You may need to wear glasses or contact lenses for some activities after LASIK, such as driving at night or reading small print

## 6 CONTRAINDICATIONS – WHEN YOU SHOULD NOT HAVE LASIK

You should **not** have LASIK surgery if:

- You have severe dry eye.
- The top layer of your cornea (epithelium) does not properly adhere to the layer underneath (corneal erosion).
- You have advanced Glaucoma.
- You have collagen vascular, auto or immunodeficiency diseases (for example: rheumatoid arthritis, lupus or AIDS). These conditions may result in scarring or poor healing after LASIK treatment resulting in reduced vision.
- You show signs of thinning of the cornea (keratoconus). This condition can lead to serious cornea problems that require additional surgical repair and result in poor vision.
- Your cornea is too thin to allow your doctor to properly cut a corneal flap. LASIK cannot be performed unless a corneal flap is created. You may be able to have other types of refractive surgery that do not require a corneal flap to perform the procedure.
- You have uncontrolled eye movements (nystagmus) 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 cannot keep your eyes still during treatment.
- You are pregnant or nursing. These conditions may affect your preoperative refraction making it difficult to choose the correct amount of LASIK treatment.
- You have uncontrolled diabetes. Uncontrolled diabetes will affect the healing process and may cause you to have poor results and complications.

## 7 WARNINGS

Some medical conditions can affect your eyes. If you have vision problems from any of these diseases, your vision after LASIK may not be good. Discuss these conditions with your doctor if:

- You have diabetes or connective tissue disease. These conditions may also involve your eyes. Eyes that have vision problems from these diseases may affect the accuracy of your refractive results.

- You have a condition or are taking medication that affects the immune system.
- You have any disease that may affect wound healing. Such diseases may include connective tissue disease, severe atopic disease or the lack of an adequate immune response.
- You are taking isotretinoin (Accutane®) to treat severe acne. This may affect your refractive outcome and possibly result in reduced vision after LASIK treatment.
- You have ocular Herpes Simplex or ocular Herpes Zoster. Herpes infections are caused by viruses that stay in your body permanently but are usually not active. Laser treatment may make the virus active again.
- You have dry eyes not responsive to treatment. LASIK can make the dryness in your eyes worse and affect your vision. These effects may be permanent.
- 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 moisture of your eye, the accuracy of your refractive results may be affected.
- You now have or previously had glaucoma or high pressure in your eyes. It is not known whether LASIK is safe and effective for you.

You may have LASIK if you have one or more of these conditions but you and your doctor both agree that the expected benefit is worth the extra risk.

You should also understand that your results may not be as good as the results from the clinical study.

## **8 PRECAUTIONS**

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

- You have undiagnosed dry eyes. 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.
- Your vision or glasses prescription has changed within the last 12 months. Your eyes are not stable if in the past 12 months they are > 0.50 Diopter 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. 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.
- You now have or previously had, an injury or surgery of 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 taking amiodarone hydrochloride (Cordaron®) to treat certain recurrent irregular heartbeats (ventricular arrhythmias). This may affect your refractive outcome and possibly result in reduced vision after LASIK treatment.
- History of glaucoma, increased pressure inside your eyes, have been diagnosed with ocular hypertension, or are being followed for possible glaucoma (glaucoma suspect), because it is unknown whether Topo-guided LASIK is safe and effective for you.
- 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. Many medications can affect the way your cornea is changed by the laser and the way it heals after LASIK surgery.
- You take medicines that may affect wound healing. One such medicine is Sumatriptan, or Imitrex, 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 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. Research has not shown what effects LASIK has on vision performance in poor lighting.

- You have a history of forming keloid scars when you heal from injuries.
- You need spherical correction of more than -5.00 D, astigmatism correction of more than -2.00 D, or MRSE correction of more than -6.00 D, as insufficient safety and effectiveness data are available for eyes in this range.
- If your eyes have large pupils (greater than 8mm diameter) in darkness or dim light, you may have more problems driving at night or seeing clearly in dim lighting after LASIK. Your doctor should measure your pupils in dim light to determine if you have large pupils.
- If you have any problems with the iris (colored part) of your eye or have had previous surgery on this part of your eye, then the eye-tracker on the laser may not work properly; and Topo-guided LASIK may not be safe and effective for you.
- History of crossed eyes (strabismus). It is unknown whether Topo-guided LASIK is safe and effective under this condition.

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

If you have any of these conditions or situations, you may still decide to have LASIK if your doctor explains the amount of extra risk to you, and you and your doctor both agree that the expected benefit is still worth the risk.

You should also understand that your results may not be as good as the results from the clinical study.

## **9 ARE YOU A GOOD CANDIDATE FOR LASIK?**

Please read carefully the RISKS, CONTRAINDICATIONS, WARNINGS and PRECAUTIONS sections of this information booklet before you consider having LASIK. If you have any concerns please discuss those concerns with your doctor.

To have LASIK with the Nidek EC-5000 laser, you must:

- Be at least 21 years of age and have both nearsightedness and astigmatism.
- Not have had any previous eye surgery.

- Have nearsightedness more than -0.75D but not more than -5.0D, astigmatism more than -0.50 D but not more than -2.0 D, and spherical equivalent refraction more than -1.0D but not more than -6.0 D, based on your screening manifest refraction before the surgery.
- Have visual acuity that is 20/25 or better in each eye with your glasses on.
- Understand the risks and benefits of LASIK for your nearsightedness and astigmatism compared to other methods for correcting your vision.
- Be able to lie flat on your back without difficulty.
- Be able to look steadily at a light without moving your eyes during the surgery.
- Be able to tolerate all of the medications (including the numbing drops) that will be used before, during, or after LASIK. If you have any allergies to any medications, please make sure you tell your doctor.
- Sign an informed consent form given to you by your doctor or his/her staff that you have been informed of and understand the risks and benefits of LASIK and that you agree to have the surgery.

## 10 WHAT CAN YOU EXPECT BEFORE LASIK?

Before you have LASIK, you will need to have a complete eye examination. Your doctor will do several different tests to see whether your eyes are healthy enough to have LASIK. These tests also tell your doctor how much treatment your eyes will need to correct your vision. You will also be asked questions about your medical history and any medicines you are taking. It is important for you to be truthful with your doctor when you are answering these questions. You will also need to have someone drive you home after LASIK because you should not drive right after the surgery.

### CAUTION

If you wear contact lenses, you must stop wearing them before the screening eye examination and leave them out of your eyes until you have LASIK. Not doing this could cause poor results or complications.

The time you must stop wearing contact lenses before your first examination depends upon the type of lens. The shortest times for stopping are:

- Soft lenses 3 days
- Soft extended wear lenses 7 days
- Soft toric (astigmatism) lenses 14 days
- Hard gas permeable lenses 4 weeks

Your doctor may ask you to stop wearing your contact lenses for longer than the time given for your type of lens. You will also need to come back for a second visit before LASIK or be examined on the day of surgery to make sure that your vision has not changed since you stopped using your contact lenses.

## 11 WHAT HAPPENS DURING LASIK?

You will be taken into the laser room and asked to lie on your back in a reclining chair that is located under the part of the laser that shines the laser beam. Before LASIK, numbing (anesthetic) drops will be placed into the eye to be treated. An instrument will be placed between your eyelids to hold them open. The eye that is not having LASIK will be covered during the surgery. Surgical draping may be placed over your face, exposing only the eye to be treated, to keep the area around the eye as clean as possible. Your doctor may briefly fire the laser onto a piece of plastic so you can hear what the laser will sound like during the treatment.

If your corneal flap is being cut with a microkeratome, a suction ring will be placed on the eye to increase the pressure in the eye. Your vision in that eye will go black temporarily as the pressure is increased. The doctor will attach the microkeratome to the suction ring and cut the corneal flap. The doctor will then release the suction and you should be able to see again. The doctor will line up your head under the laser. The doctor will then lift the flap and fold it back, like opening a hinged cabinet door. This exposes the part of the cornea where LASIK will be performed.

The doctor will then focus the laser microscope on your cornea. You will be asked to look directly at a blinking light and LASIK will begin. It is important for you to look directly at the blinking light without moving your eyes during the entire surgery. Relax the muscles of your face and forehead and try to keep both eyes open without squinting. While you are looking at the blinking light, the laser will remove small amounts of tissue from your cornea.

#### **CAUTION**

It is very important that you keep looking at the blinking fixation light without moving your eyes during LASIK, even if the light fades or becomes dim. If you do not, the surgery may not be successful.

After LASIK is complete, the doctor will fold the corneal flap back into place and smooth the surface. Some drops will be placed in your eye and the instrument holding your eye open and any surgical draping over your face will be removed. You will be allowed to stand up and will be taken to another area where you will wait for a short time to make sure there are no immediate problems from the surgery. After your doctor checks your eye and makes sure everything is satisfactory, you will be allowed to go home.

LASIK usually lasts 10 to 15 minutes from start to finish and you are only exposed to the laser beam for a minute or less. The surgery itself is painless because your eye is numb from anesthetic drops. The numbing drops will wear off in about 30 to 60 minutes and your eye may hurt, or feel a “sandy sensation”, for 1 to 3 days. Your doctor can prescribe pain medicine to make you more comfortable during this time. It is important that you **DO NOT RUB** the eye for the first 5 days after LASIK. Rubbing the eye can damage the cornea, move the corneal flap, cause infection, and make the eye take longer to heal. You will be given written instruction about how to take care of your eye after LASIK. It is important that you (and a family member) make sure that you understand these instructions before you leave the surgery clinic.

## 12 WHAT CAN YOU EXPECT AFTER LASIK

Sunglasses may make you more comfortable during the first few days after LASIK. Your doctor may give you a shield to place over your eye while you are sleeping to protect your eye from accidental injury. Your doctor may give you drops to use in your eyes after the surgery. It is important to follow the directions for using the drops to help your eye to heal and keep it from getting infections. **DO NOT RUB** your eye for at least 5 days after LASIK. Rubbing your eye can damage the cornea, move the corneal flap, cause infection, and make the eye take longer to heal.

### CAUTION

Use the moistening eye drops and anti-inflammatory and antibiotic eye drops prescribed by your doctor. Your results depend upon you following your doctor's instructions.

### The first week following surgery:

You may have any of the following symptoms up to several weeks after LASIK. Except for the ones related to the corneal flap, they are part of normal healing after LASIK.

- Feelings of pain, pressure, scratchiness, burning sensations, and dryness in your eye for 1 to 3 days after LASIK, for which your eye doctor can provide medicine.
- The feeling that something is in your eye.
- Swelling of the cornea.
- Blurred vision and tearing or watery eyes.
- Sensitivity to bright lights.
- Problems with healing of the corneal flap:
  - damage to the flap,
  - loss of the flap,
  - misalignment of the flap, or
  - growth of cornea surface cells under the flap.

If needed to improve healing, the doctor may lift the flap, clean the surfaces under it, and put it back in position.

## **The first one to six months after LASIK:**

You may have the following symptoms for up to six months after LASIK while your eye continues to heal:

- Eye dryness;
- fluctuation in your vision or;
- a feeling that something is in your eye

### **CAUTION**

You should see your doctor if you notice any pain, sudden change, or loss of vision in your eye. Eye pain or sudden loss of vision can be a sign of a serious problem that your doctor should look at right away.

## 13 QUESTIONS TO ASK YOUR DOCTOR

You may want to ask the following questions to help you decide if LASIK is right for you:

- What other ways are there for correcting my nearsightedness and astigmatism?
- Will I have to give up some of my activities after LASIK, and for how long?
- What are the benefits of LASIK for my amount of nearsightedness and astigmatism?
- How good can I expect my vision to be in the first few months after LASIK?
- If LASIK does not correct my vision, what is the chance that my glasses would need to be stronger than before? Could I need glasses more and more as time goes by?
- Will I be able to wear contact lenses after LASIK if I need them?
- How is LASIK likely to affect my need to wear glasses or contact lenses as I get older?
- Will my cornea heal differently if I injure it after I have LASIK?
- Should I have LASIK surgery in my other eye?
- How long will I have to wait before I can have LASIK in my other eye?
- What vision problems might I have if I have LASIK only on one eye?

Talk about the cost of surgery and follow-up care with your doctor, because your health insurance may not cover LASIK.

## 14 SELF-TEST

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

- |   |   |                          |      |                          |       |
|---|---|--------------------------|------|--------------------------|-------|
| 1 | LASIK is risk free.   | <input type="checkbox"/> | TRUE | <input type="checkbox"/> | FALSE |
| 2 | It does not matter if I wear my contact lenses when my doctor told me not to.       | <input type="checkbox"/> | TRUE | <input type="checkbox"/> | FALSE |
| 3 | The laser does all the work, I just have to lie on the chair and close my eyes.     | <input type="checkbox"/> | TRUE | <input type="checkbox"/> | FALSE |
| 4 | After the surgery, there is a good chance that I will be less dependent on glasses. | <input type="checkbox"/> | TRUE | <input type="checkbox"/> | FALSE |
| 5 | I may need reading glasses after laser surgery.                                     | <input type="checkbox"/> | TRUE | <input type="checkbox"/> | FALSE |
| 6 | There is a risk that I may lose some vision after laser surgery.                    | <input type="checkbox"/> | TRUE | <input type="checkbox"/> | FALSE |
| 7 | It does not matter if I am pregnant.  | <input type="checkbox"/> | TRUE | <input type="checkbox"/> | FALSE |
| 8 | If I have an autoimmune disease, I am still a good candidate for LASIK.             | <input type="checkbox"/> | TRUE | <input type="checkbox"/> | FALSE |

The answers to the SELF-TEST are on page 24, in Section 16: ANSWERS TO SELF TEST.

## 15 SUMMARY OF IMPORTANT INFORMATION

- LASIK is permanent. It changes your cornea in ways that cannot be undone.
- LASIK will not take away your need for reading glasses. In fact, you will probably need them after LASIK even if you never have worn them before. As you get older, your eyes lose the ability to focus on nearby objects. When you are nearsighted, you don't have to focus your eyes to see clearly up close, but after LASIK, you will have to focus to read easily. *You should talk to your doctor about the possibility that you may not be able to read without glasses after LASIK before you decide to have LASIK.*
- Your vision must stay the same for at least one year before LASIK. You will need to prove that your nearsightedness and astigmatism have changed less than 1.0 diopter over the past year.
- Pregnant or nursing women should not have LASIK.
- You should not have LASIK if you have degenerative or autoimmune diseases, or have a condition that keeps wounds from healing normally.
- LASIK may be painful and uncomfortable while your eye is healing. It could make your vision worse or permanently damage your eye. Please read this entire booklet and make sure you understand it, especially page 25, Section 17 on the Clinical Study of Benefits and page 26, Section 18 on the Clinical Study of Risks before you agree to the surgery.
- Besides LASIK, nearsightedness and astigmatism can be corrected with glasses, contact lenses, and PRK.
- Some people, such as military pilots, have job-related vision requirements that cannot be met by having LASIK.
- Before agreeing to have LASIK, you should:
  - Have a complete eye examination.
  - Read this booklet.
  - Talk with one or more eye doctors about how LASIK could make your vision worse instead of better.
  - Understand that your eye(s) will need up to six months to heal after LASIK.

## 16 ANSWERS TO SELF-TEST QUESTIONS

1. False (see Section 5: Risks of LASIK Treatment for Nearsightedness on page 10); 2. False (see Section 10: What Can You Expect Before LASIK? on page 18); 3. False (see Section 11: What Happens During LASIK on page 18); 4. True (see Section 4: How Much Vision Correction Can You Expect with the Nidek Laser? on page 10); 5. True (see Section 5: Risks of LASIK Treatment for Nearsightedness on page 10); 6. True (see Section 5: Risks of LASIK Treatment for Nearsightedness on page 10); 7. False (see Section 7: Warnings on page 14); 8. False (see Section 6: Contraindications – When You Should NOT Have LASIK on page 14).

## **17 CLINICAL STUDY OF BENEFITS**

Nidek did a clinical study to measure the benefits of having Topography-Assisted LASIK. They treated 135 eyes of 74 patients for nearsightedness with astigmatism. The study was done at three centers in the United States and one center in Mexico. Patients in the study were treated between December 2005 and September 2006. This part of the booklet discusses the main results of the study.

### **Demographics**

Of the 74 patients in the study, 32 were men and 42 were women. Racial distribution consisted of 42 Caucasian; 24 Hispanic; 3 Black; 4 Asian; and, 1 Caucasian-Asian, mixed. The patients had an average age of 35 years with a range of 21 to 64 years.

### **Vision Without Glasses After LASIK**

A letter chart tested how well patients could see without glasses or contact lenses before and after LASIK. One month after LASIK four out of five eyes could see 20/20 or better without glasses or contact lenses and all eyes could see 20/40 or better. Most states have a law that you have to see 20/40 or better to get a driver's license without wearing glasses or contact lenses.

### **Vision Without Glasses After LASIK Compared to Vision With Glasses Before LASIK**

More than three-fourths of the eyes (80%) had vision without glasses or contact lenses at 3 months after LASIK that was at least as good as their vision before LASIK with glasses or contact lenses. However, 5% of the eyes had vision without glasses or contact lenses at 3 months after LASIK that was 2 or more lines worse than vision with glasses or contact lenses before LASIK.

### **Changes in Quality of Vision Without Glasses After LASIK Compared to Vision With Glasses Before LASIK**

Patients rated their visual symptoms before LASIK with glasses or contact lenses and after LASIK without using glasses or contact lenses. The ratings before and three months after LASIK were compared. The improved visual symptoms (>10% of eyes) were:

- Difficulty Driving at Night (47%)

- Light Sensitivity (23%)
- Glare (10%)

The worsened visual symptoms (>10% of eyes) were:

- Dryness (50%)
- Halos (21%)
- Reading Difficulty (20%)
- Glare (20%)
- Light Sensitivity (18%)
- Starbursts (16%)
- Fluctuation in Vision (13%)
- Foreign Body Sensation (10%)

## **18 CLINICAL STUDY OF RISKS**

Nidek's clinical study tested the safety of having Topography-Assisted LASIK for nearsightedness with astigmatism.

The clinical study tested the effects of LASIK on the ability to see under poor lighting conditions such as very dim light, rain, snow, fog or glare from bright lights at night. Overall, the eyes tested had an improvement in vision when tested in lighting conditions that were similar to these low lighting situations.

### **Vision With Glasses Before and After LASIK**

At 3 months after LASIK, 57% of the patients saw better than before LASIK and 35% of the patients saw no difference. One patient, in both eyes, lost 2 lines **with** glasses beginning at 3 months, but this reduction in vision was due to his eyes being dry and very tired at his examination.

## Adverse Events and Complications

Table 1 shows the percentages of patients who had adverse events during or after LASIK for up to 24 months. Only the adverse events with at least 4 patients (5%) are presented.

**Table 1: Adverse Events in Descending Order of Overall Incidence for All Treated Patients with Incidence Rate of at Least 5%**

Preferred Term	Overall (N=74)
Any Adverse Event	59 (80%)
Dry eye	36 (49%)
Halo vision	19 (26%)
Glare	15 (20%)
Wrinkles in the flap	12 (16%)
Inflammation on the surface of the cornea	12 (16%)
Starbursts	10 (14%)
A feeling as if something is in the eye	9 (12%)
Hazy vision	8 (11%)
Vision blurred	8 (11%)
Eye pain	7 (9%)
Fluctuating vision	6 (8%)
Eyelid discharge	5 (7%)
Corneal deposits	4 (5%)
Double vision	4 (5%)
Headache	4 (5%)
Eye sensitivity to light	4 (5%)

Overall, 59 (80%) patients reported adverse events (AE) from surgery-day through 24-months postop. The most common AEs with an overall rate greater than 10%, are:

- dry eye (49%)
- halo vision (26%)
- glare (20%)
- wrinkles in the flap (16%)
- inflammation on the surface of the cornea (16%)
- starbursts (14%)
- foreign body sensation in eyes (12%)
- haze (11%)
- blurred vision (11%)

Each of these AEs is common to any LASIK procedure.

The most common AEs related to the topography-assisted LASIK treatment occurring in over 5% of study patients overall reported at the 3-month visit are:

- dry eye (14%)
- halo vision (9%)
- glare, (7%)
- inflammation of the cornea

At the 6-month visit,

- dry eye decreases to 8%
- halo vision decreases to 0%
- glare decreases to 1%
- inflammation on the surface of the cornea decreases to 1%

At the 9-month visit,

- dry eye decreases to 6%
- halo vision increases to 5%
- glare increases to 3%
- inflammation on the surface of the cornea decreases to 3%

At the 12-month visit,

- dry eye further decreases to 5%
- halo vision decreases to 0%
- glare decreases to 0%
- inflammation on the surface of the cornea remains at 3%

Overall, 39 (53%) patients reported complications from surgery-day through 24-months postop. The most common complication at 1-month or later was:

- dry eye requiring chronic artificial tears or the insertion of plugs (punctal plugs) into the tear ducts to keep moisture on the eye

The postop complication of dry eye is common to the routine LASIK procedure and not unique to the topography-assisted treatment. In the clinical study, the incidence of dry eye was:

- 7% at 1-week
- 14% at 1-month
- 8% at 6-months

The incidence of the complication of dry eye requiring chronic artificial tears or punctal plugs in the clinical study was 5% at 1-month and 4% at 6-months. All complications observed in the clinical study are common to the LASIK procedure and are not unique to the topography-assisted LASIK procedure.

## **Patient Symptoms after LASIK Without Glasses Compared to Before LASIK With Glasses**

Patients rated their visual symptoms before and 6 months after LASIK.

Fewer patients reported light sensitivity, night driving problems, and starbursts after LASIK than before. However, more patients reported dryness after LASIK than before. About 7% of the patients reported moderate to marked difficulty reading at 6 months after LASIK compared to 4% before LASIK, probably because these patients had presbyopia (natural loss of ability to focus close that occurs with age) that they didn't notice until their eyes were corrected for good distance vision. Before you decide to have LASIK, you should ask your doctor whether LASIK is likely to make it harder for you to read without glasses.

Eye dryness is known to occur after LASIK, but it usually improves over time. In the clinical study, eye dryness was worst at 3 months after LASIK, with the patients reporting moderate to severe dry eye in about 26% of the LASIK eyes. At 6 months after LASIK, 16% of the eyes had moderate or marked dryness and about a third of the eyes had mild dryness. It is important for you to use eye drops after LASIK to treat or prevent dry eye symptoms.

## **Patient Quality of Vision after LASIK Without Glasses Compared to Before LASIK With Glasses or Contact Lenses**

The Refractive Status Vision Profile (RSVP) questionnaire was given to patients before LASIK and at each visit after LASIK, beginning with Month 1, to rate the patient's satisfaction, use of glasses or contact lenses, and the patient's quality of vision and quality of life. The subscales that were evaluated are:

- Concern: worry, concern or frustration about vision; afraid to do activities because of vision.
- Expectations: patients' ability to accept less-than-perfect vision.
- Physical/social functioning: watching TV or movies, seeing alarm clock, caring for or playing with children, doing one's job, playing sports or recreation.
- Driving: driving at night, during rain.
- Symptoms: eyes are irritated, pain, light sensitivity.
- Optical problems: change in vision during day; depth perception; seeing in dim light.
- Glare: seeing or driving under glare conditions.
- Problems with glasses or contact lenses: lenses are bothersome; cannot wear lenses; lenses get fogged up, wet or lost.

The RSVP shows an improvement in all topics but 1 (expectations) at most of the postoperative visits and in the total score for each visit. A difference of 6 points or more

on the total score is a clinically significant change. The difference in total score from before LASIK to each visit after LASIK showed clinically significant improvements in the RSVP profile for all visits, with an average improvement of approximately 13 points at each visit.

### **Patient Satisfaction after LASIK Without Glasses Compared to Before LASIK With Glasses**

At 3 months after LASIK, 94% of patients said they were either satisfied or very satisfied with their vision without glasses. At 3 months after LASIK, 3% of patients said they were very dissatisfied with their vision without glasses. At 6 months after LASIK, 92% of patients said they were either satisfied or very satisfied with their vision without glasses. At 6 months after LASIK, 5% of patients said they were very dissatisfied with their vision without glasses.

### **Accuracy of LASIK**

With LASIK, there is a risk that your vision will be corrected either too much or not enough. In the clinical study at 3 months after LASIK, 93% of all the eyes treated were within  $\pm 0.5$  D and 100% of the eyes were within  $\pm 1.0$  D of the attempted amount of correction. None of the eyes (0%) were overcorrected or undercorrected by more than 1.0 D of nearsightedness and astigmatism after LASIK.