

**FACTS YOU NEED TO KNOW ABOUT
LADARVision®
LASER IN-SITU KERATOMILEUSIS (LASIK) SURGERY**

PATIENT INFORMATION BOOKLET

For:

For Farsightedness (Hyperopia) With or Without Astigmatism and Mixed Astigmatism
(Sphere up to +6.00D and Cylinder up to -6.00D)

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

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TABLE OF CONTENTS

| | |
|---|----|
| A. Glossary..... | 5 |
| B. Introduction | 10 |
| C. How Does LASIK Correct Hyperopia With or Without Astigmatism or Mixed Astigmatism?..... | 10 |
| D. What Are The Benefits Of LASIK? | 13 |
| E. Contraindications | 15 |
| F. Warnings | 15 |
| G. Precautions | 15 |
| H. What Are The Risks Of LASIK? | 16 |
| I. Are You A Good Candidate For LASIK? | 19 |
| J. What Should You Expect During LASIK Surgery? | 20 |
| K. Questions To Ask Your Doctor..... | 23 |
| L. Self-Test | 24 |
| M. Summary Of Important Information | 25 |
| N. Patient Assistance Information..... | 26 |
| O. Index..... | 27 |

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A. Glossary

This section contains definitions of terms used in this information booklet. Please discuss with your doctor any questions that you may have about these terms. Your doctor can provide you with answers to your medical questions.

Allergic Conjunctivitis: inflammation of the outer lining of the eye from an allergic reaction to the environment, such as hay fever.

Astigmatism: a condition of the eye that results in blurred distance and/or near vision. The surfaces of the eye focus the light rays at different points inside the eye. The different points of focus create a blur of parts of objects you see.

Antibiotic Medication: a drug used to treat or prevent infection. Your doctor may prescribe this type of medication after surgery.

Anti-inflammatory Medication: a drug that reduces inflammation or the body's reaction to injury or disease. Surgery that alters the eye, such as LASIK, can also cause inflammation. Your doctor may prescribe this type of medication after surgery.

Autoimmune Disease: a condition in which the body attacks itself that may result in inflammation or swelling of parts of the body; such as muscles, joints, and blood vessels. Examples of this condition are multiple sclerosis and myasthenia gravis. If you have this type of condition, you should not have LASIK surgery.

Bandage Contact Lens: a soft contact lens that may be placed on the cornea after surgery to cover the eye.

Cataract: an opacity, or clouding, of the lens inside the eye that can cause a loss of vision. This clouding tends to develop with older age and may affect different parts of the lens, which are categorized as nuclear sclerosis, cortical spoking, and posterior subcapsular cataract.

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 of this type of disease are lupus and rheumatoid arthritis. If you have this type of condition, you should not have LASIK surgery.

Conjunctiva: the outer lining of the eye that surrounds the cornea.

Conjunctival Injection: increased redness of the blood vessels in the front of the eye

Contraindications: any special condition that results in the treatment not being recommended.

Cornea: the clear front surface of the eye. Surgery such as LASIK, PRK and RK reshape or flatten this surface to correct distance vision.

Corneal Abrasion: a scratch in the outer layer of the cornea often from an eye injury.

Corneal Epithelium: the top layer of the cornea.

Corneal Flap: 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 is applied to the inner layers of the cornea.

Corneal Folds/Striae/Wrinkles: the temporary appearance of fine white lines in the back of the cornea as a result of corneal swelling.

Corneal Infiltrate: inflammation of the cornea.

Corneal Opacities: cloudy areas in the cornea.

Corneal Swelling: an accumulation of fluid in the cornea that is not normally present. This condition is usually temporary with no significant effect on vision.

Cotton Wool Spot: a small area in the back of the eye (retina) with a cotton-like appearance that develops when there is a lack of blood supply to the area. This spot does not typically affect vision may be associated with several types of conditions, such as diabetes or high blood pressure.

Diopter: a unit used to measure the amount of myopia and astigmatism of an eye.

Drusen: small deposits of cellular material in the back of the eye (retina), which is more common in older age. These deposits often have no affect on vision but may result in vision loss if they occur in the area responsible for central vision (macula).

Epithelial Defect: a piece of the outer layer of the cornea that has torn off leaving a defect. This defect could occur anywhere on the surface of the cornea. This condition is usually temporary and may result in some discomfort or pain.

Epithelial Irregularity: an area of the outer layer of the cornea that is not smooth.

Epithelium in the Interface: this condition can occur after LASIK surgery when epithelial cells from the surface of the cornea move or grow underneath the corneal flap. This can result in loss of vision.

Excimer Laser: a type of laser used in LASIK that removes tissue from the cornea.

Farsightedness: Another term for hyperopia. Farsightedness eyes may see better at distance than at near without glasses or contact lenses but usually require correction for both distances.

Glaucoma: a condition usually associated with high eye pressure. This condition results in damage to the nerve at the back of the eye and possible loss of vision.

Halos: circular flares or rings of light that may appear around a headlight or other lighted object. This symptom may occur after LASIK surgery.

Herpes Simplex: a type of infection caused by a virus 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 infection caused by a virus 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.

Hyperopia: a condition of the eye that results in blurred distance and near vision. The cornea and lens focus light rays from distant and near objects behind the retina.

Hyperopic Astigmatism: a condition of the eye that results in blurred distance and near vision. The cornea and the lens focus the light rays at different points behind the retina.

Immunodeficiency Disease: a condition that alters the body's ability to heal. An example is AIDS. If you have this type of condition, you should not have surgery.

Inflammation: the body's reaction to injury or disease. Surgery that alters the eye, such as LASIK, can also cause inflammation.

Interface Debris: cellular and foreign material underneath the flap after LASIK surgery.

Intralamellar Haze: cloudiness underneath the corneal flap.

Iritis: inflammation of the inside of the eye behind the cornea.

Iron Line or Ring: a deposit of iron in the cornea that has no effect on vision.

Keratoconus: a condition of the cornea that results in a thinning of the cornea. A change in corneal shape like a cone typically occurs. If you have this type of condition, you should not have LASIK surgery.

Lagophthalmos: failure to close eyes completely, which may result in irritation of the front of the eye due to dryness.

Laser In-Situ Keratomileusis (LASIK): a procedure where a device called a microkeratome is used to surgically create a thin, hinged flap of corneal tissue. The flap is folded back, the laser is directed to the corneal surface exposed beneath the flap and the flap is brought back into place.

Lens: a structure inside the eye that helps to focus light onto the back of the eye.

MRSE (Manifest Refraction Spherical Equivalent): the amount of hyperopia and astigmatism calculated based on the glasses prescription.

Microkeratome: a surgical instrument used to cut a flap of corneal tissue as the first step in the LASIK procedure.

Misaligned Flap: the flap created with the microkeratome has not returned to its correct position after the ablation is complete. It is sometimes possible to reposition the flap.

Miscreated Flap: the flap created with the microkeratome was of poor quality (e.g. too small or irregular) and the laser ablation was not attempted. In this situation, a new flap can usually be created 3 months after the first attempt and LASIK surgery completed.

Mixed Astigmatism: a condition of the eye that results in blurred distance and near vision. The cornea and the lens focus the light rays at different points with one point focused in front of the retina and the other point focused behind the retina.

Mono vision: optical correction of one eye so that it sees clearly in the distance and the other eye sees clearly up close.

Non-Steroidal Anti-inflammatory Drug (NSAID): a type of drug that reduces inflammation or the body's reaction to injury or disease. Your doctor may prescribe this type of medication after surgery.

Ocular Hypertension: an increase in the pressure inside the eye.

Photorefractive Keratectomy (PRK): a type of surgery used to correct vision by reshaping the surface of the cornea using an excimer laser. Tissue is removed from the outermost surface of the cornea just beneath the epithelium.

Regression: a decrease in the amount of vision correction after LASIK surgery.

Retina: the back surface of the eye. The retina takes focused light and transfers it to the brain.

Sterile Interface Inflammation: an inflammatory reaction underneath the corneal flap after LASIK surgery that is not due to bacteria. This condition may result in loss of vision.

Steroid Medication: a type of drug that reduces inflammation or the body's reaction to injury or disease. Your doctor may prescribe a steroid for use in the eye after surgery to modify the healing of the cornea. If you are taking this drug for a disease condition, you should not have LASIK surgery.

Subconjunctival Hemorrhage : an area of bleeding in the outer lining of the eye next to the cornea. This bleeding has no adverse effects and resolves on its own.

Superficial Punctate Keratitis (SPK) : surface irritation in the outer layer of the cornea.

Trichiasis: misdirected eyelashes that may turn inward toward the eye.

Vacuoles: small round areas of cellular debris in the cornea that typically has no effect on vision.

Vitreous Floater: a strand or spot in the fluid inside the eye that may appear as floating spot in the vision. The appearance of floaters is normal and more common with age.

B. Introduction

Do you need to wear glasses or contact lenses to help you to see clearly? One option to see more clearly is to correct your vision with surgery. Some types of surgery correct vision by shaping the front surface of the eye, the cornea. A recent type of surgery that reshapes the cornea is Photorefractive Keratectomy (PRK). PRK uses a laser instead of a scalpel to carefully shape the corneal surface. Another procedure, which uses the laser is called Laser In-Situ Keratomileusis (LASIK). In the LASIK procedure, the laser energy is applied to the inner layers of the cornea. LASIK may help you to see more clearly by partially or fully correcting vision.

The LADARVision[®] Excimer Laser System is a unique system that tracks all movements of the eye during surgery. Tracking movements of the eye allows the system to accurately place the laser beam. The system applies hundreds to thousands of laser beam pulses to the cornea to correct vision. Accurate placement of these laser beam pulses provides precise shaping of the cornea. The purpose of this booklet is to inform you about LASIK with the tracker-guided LADARVision[®] system. Please read this information carefully and discuss any questions with your doctor. It is important that you make an informed decision about LASIK with the help of your doctor.

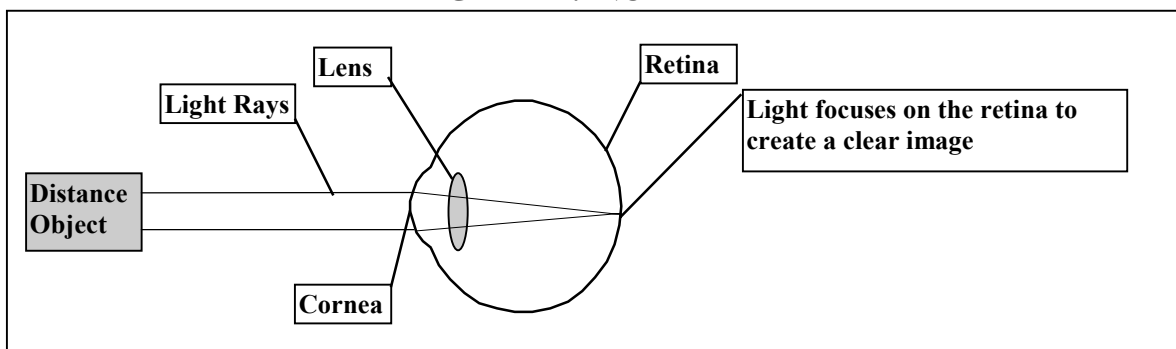
Although vision without glasses improved for all eyes, some people still needed glasses or contact lenses for some tasks after LASIK. LASIK does not eliminate the need for reading glasses. In addition, the vision requirements of some occupations, such as military pilots, cannot be met by having PRK or LASIK.

NOTE: You may need reading glasses after LASIK even if you did not wear them before.

C. How Does LASIK Correct Hyperopia With or Without Astigmatism or Mixed Astigmatism?

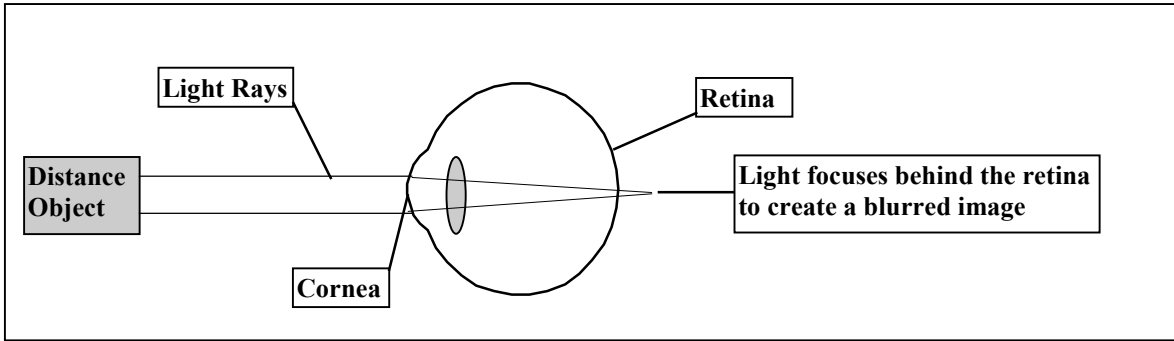
The human eye functions like a camera. The lens in a camera focuses light into images on to film. In the same way, the cornea and the lens inside the eye focus light into images on to the retina, the back surface of the eye (Diagram 1). Blurred vision occurs when the light does not focus precisely on the retina.

DIAGRAM 1: NORMAL EYE



Hyperopia (farsightedness) is a condition of the eye where people usually see better in the distance than near. The cornea and lens focus light rays from a distant and near object behind the retina. Diagram 2 shows how light from a distant object focuses behind the retina to cause a blurred image.

DIAGRAM 2: HYPEROPIA



Astigmatism is a condition of the eye that also results in blurred vision. In this case, the cornea and the lens focus the light rays at different points. In eyes with hyperopic astigmatism, both points focus behind the retina. In eyes with mixed astigmatism, one point focuses in front of the retina and the other point focuses behind the retina. The different points of focus create blur of parts of the images. For example, a person with astigmatism might confuse an “R” with a “P” or an “F” on a sign. This confusion about the letter occurs because only part of the letter is in focus. Diagrams 3 and 4 show how light rays focus at different points in an eye with astigmatism causing a blurred image.

DIAGRAM 3: HYPEROPIA WITH ASTIGMATISM

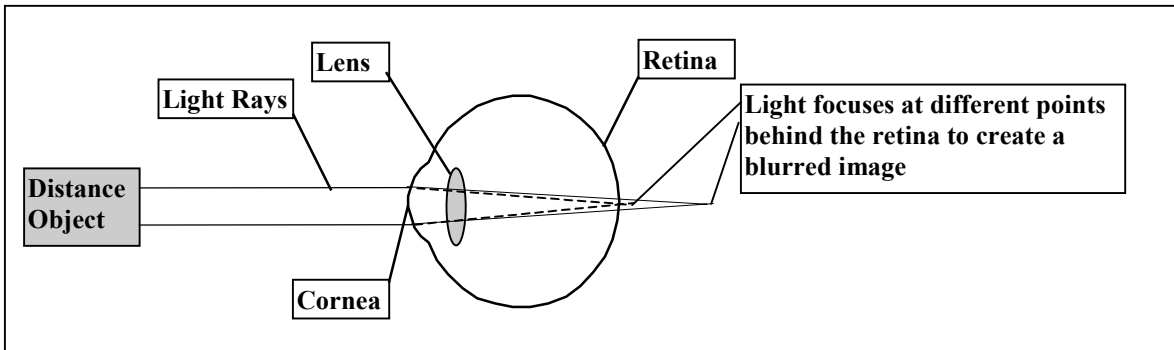
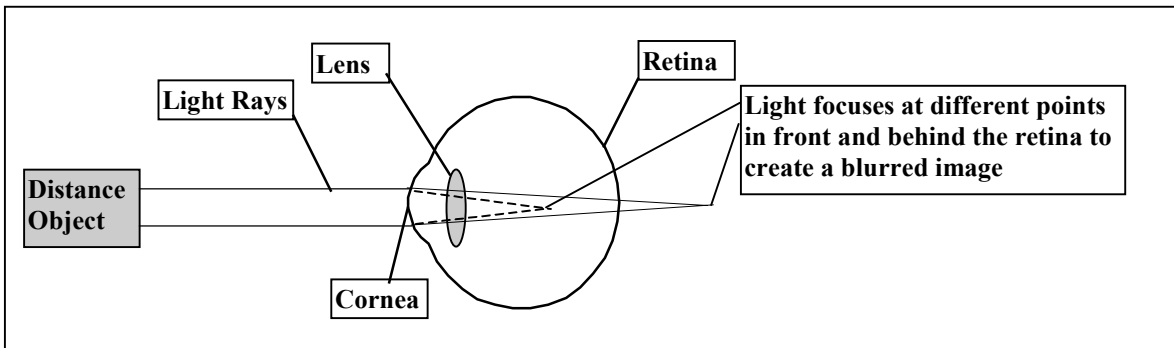
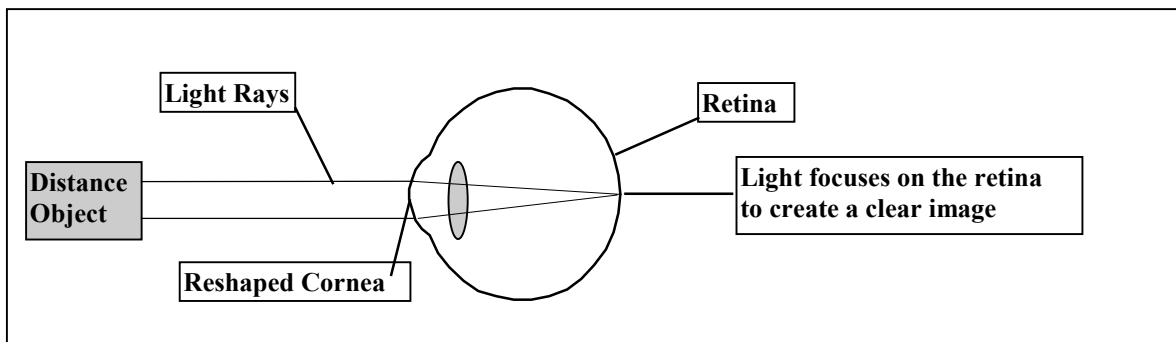


DIAGRAM 4: MIXED ASTIGMATISM



Glasses and contact lenses help focus all of the light rays on to the retina. By focusing all of the light rays properly, the vision in the distance is clear. Another way to change the way the eye focuses light is to reshape the cornea. For treatment of hyperopia, this is done by reshaping the periphery of the cornea. LASIK sculpts the cornea by removing a tiny amount of the tissue with a laser. An excimer laser is a type of laser used in LASIK that removes tissue from the cornea. This type of laser reshapes the cornea without changing any other parts of the eye. Diagram 5 shows how these LASIK can reshape the cornea to provide clearer vision.

DIAGRAM 5: CORRECTION OF VISION AFTER LASIK



The LADARVision[®] System incorporates an active eye tracking mechanism (LADARTracking), which compensates for eye movement during the surgery. The measurement speed of the LADARTracker (4000 measures/second) allows the system to detect eye movement and move the laser beam to compensate for this movement.

A very small laser beam is used to shape your cornea with this system. Therefore, precise shaping of the cornea depends on accurate placement of the laser beam. Without a system to track eye movements, any movement of the eye could affect the placement of the laser beam. Your eyes are constantly making fine eye movements even though you may not be aware of the movement. Many of these movements are beyond your control. In addition, you would not be able to hold your eye perfectly still even if you tried. By tracking all eye movements, the LADARVision[®] system maintains accurate placement of the laser beam.

Analysis of eye movement data gathered electronically during the surgical procedures of 554 eyes treated in the clinical study on myopia and astigmatism demonstrated that:

- All eyes moved during surgery.
- The LADARTracker compensated for this eye movement so that eyes with large movements and eyes with small movements had similar results.
- Active eye tracking with LADARTracking improves the accuracy of corneal shaping.

D. What Are the Benefits of LASIK?

LASIK may reduce overall farsightedness (hyperopia). LASIK may also reduce or eliminate the need to wear glasses or contact lenses to see clearly.

- LASIK surgery performed with the LADARVision[®] system is effective in reducing hyperopia between 0 and +6.0 Diopters. The LASIK procedure is also effective in correcting up to 6 Diopters of astigmatism in eyes with hyperopic or mixed astigmatism.

The results listed in the following section are from U.S. clinical studies of the LADARVision[®] system for LASIK. The clinical results are arranged by the type of condition: hyperopia without astigmatism, hyperopic astigmatism, and mixed astigmatism. It is important that you know which type of condition you have to determine which results represent your condition. Please discuss which type of condition you have with your doctor prior to reading this information.

Listed in the table below are the clinical results of vision with and without glasses at 6 months after surgery, which is the time point of stability of the refractive outcome of the procedure.

| U.S. CLINICAL STUDY RESULTS AT 6 MONTHS AFTER LASIK SURGERY | | | | | | |
|---|-------------------------------|-------------|-----------------------|-------------|-------------------|-------------|
| | Hyperopia without astigmatism | | Hyperopic Astigmatism | | Mixed Astigmatism | |
| | n/N | % | n/N | % | n/N | % |
| Visual Acuity 20/20 or better without glasses** | 57/115 | 49.6 | 38/88 | 43.2 | 18/40 | 45.0 |
| Visual Acuity 20/20 or better without glasses* | 59/121 | 48.8 | 41/110 | 37.3 | 25/54 | 46.3 |
| Visual Acuity 20/25 or better without glasses* | 83/121 | 68.6 | 66/110 | 60.0 | 40/54 | 74.1 |
| Visual Acuity 20/40 or better without glasses* | 113/121 | 93.4 | 100/110 | 90.9 | 50/54 | 92.6 |
| Visual Acuity 20/20 or better with glasses** | 115/132 | 87.1 | 88/101 | 87.1 | 37/41 | 90.2 |
| Visual Acuity 20/20 or better with glasses | 121/141 | 85.8 | 94/124 | 75.8 | 47/56 | 83.9 |
| Visual Acuity 20/40 or better with glasses | 141/141 | 100 | 124/124 | 100 | 56/56 | 100 |
| Loss of 2 lines of visual acuity with glasses | 5/141 | 3.5 | 7/121 | 5.8 | 1/52 | 1.9 |
| Loss of more than 2 lines of visual acuity with glasses | 0/141 | 0.0 | 0/121 | 0.0 | 0/52 | 0.0 |

*Not including eyes treated for monovision

**If vision with glasses was 20/20 or better before surgery

At 6 months after surgery, patients completed a questionnaire for the following symptoms, which were rated as significantly better, better, unchanged, worse or significantly worse than before surgery. For information on the symptoms rated as worse or significantly worse, please refer to the section entitled “What are the risks of LASIK?” The table below displays the percentage of patients who rated the symptoms as unchanged, better or significantly better than before surgery. Note that this data reflects the percentage of patients who did not report worsening of these symptoms after surgery.

| U.S. CLINICAL STUDY PATIENT QUESTIONNAIRE RESULTS AT 6 MONTHS | | | | | | |
|---|--------------------------------------|----------|------------------------------|----------|--------------------------|----------|
| Subjective responses rated as unchanged, better, or significantly better than before surgery | | | | | | |
| | Hyperopia without astigmatism | | Hyperopic Astigmatism | | Mixed Astigmatism | |
| | <i>N</i> | <i>%</i> | <i>N</i> | <i>%</i> | <i>N</i> | <i>%</i> |
| Blurring of vision | 132 | 88.6 | 111 | 82.9 | 53 | 88.7 |
| Burning | 133 | 97.0 | 113 | 90.3 | 53 | 92.5 |
| Double vision | 132 | 90.2 | 111 | 90.1 | 53 | 98.1 |
| Dryness | 132 | 80.3 | 113 | 77.0 | 53 | 73.6 |
| Excessive tearing | 132 | 98.5 | 111 | 98.2 | 52 | 100 |
| Feeling of something in eye | 133 | 93.2 | 113 | 92.0 | 53 | 94.3 |
| Fluctuation of vision | 133 | 78.2 | 111 | 77.5 | 53 | 88.7 |
| Glare | 133 | 77.5 | 113 | 79.6 | 53 | 77.4 |
| Halos | 132 | 84.8 | 111 | 74.8 | 53 | 73.6 |
| Headache | 132 | 97.0 | 110 | 95.5 | 53 | 96.2 |
| Light sensitivity | 133 | 72.2 | 112 | 76.8 | 53 | 79.2 |
| Night driving difficulty | 133 | 88.7 | 113 | 84.1 | 53 | 79.2 |
| Pain | 132 | 96.2 | 110 | 94.5 | 53 | 96.2 |
| Quality of vision | 132 | 95.5 | 115 | 94.8 | 53 | 94.3 |
| Redness | 133 | 88.0 | 112 | 92.0 | 53 | 96.2 |

Patients also reported on a questionnaire their satisfaction with their results at 6 months after surgery, which was rated as extremely satisfied, satisfied, not sure, unsatisfied or extremely unsatisfied, as shown in the table below.

| U.S. CLINICAL STUDY PATIENT SATISFACTION RESULTS AT 6 MONTHS | | | | | | |
|---|--------------------------------------|----------|------------------------------|----------|--------------------------|----------|
| | Hyperopia without astigmatism | | Hyperopic Astigmatism | | Mixed Astigmatism | |
| | <i>N</i> | <i>%</i> | <i>N</i> | <i>%</i> | <i>n/N</i> | <i>%</i> |
| Extremely Satisfied | 53/133 | 39.8 | 31/112 | 27.7 | 21/53 | 39.6 |
| Satisfied | 48/133 | 36.1 | 45/112 | 40.2 | 20/53 | 37.7 |
| Not Sure | 16/133 | 12.0 | 22/112 | 19.6 | 6/53 | 11.3 |
| Unsatisfied | 16/133 | 12.0 | 11/112 | 9.8 | 5/53 | 9.4 |
| Extremely Unsatisfied | 0/133 | 0.0 | 3/112 | 2.7 | 1/53 | 1.9 |

E. Contraindications

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

- **You are pregnant or nursing**
- **You show signs of keratoconus** (This is a condition of the cornea that results in a change in the shape of the cornea.)
- **You are taking medications with ocular side effects** (for example, Isotretinoin (Accutane[®]) and Amiodarone hydrochloride (Cordarone[®]))
- **You 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 of these diseases are AIDS, lupus, rheumatoid arthritis, multiple sclerosis and myasthenia gravis.

F. Warnings

Discuss with your doctor if:

- You are an insulin dependent diabetic
- You have severe allergies
- You have had a Herpes simplex or Herpes zoster infection that has affected your eyes

It will be necessary to use eye drops to enlarge your pupil to a certain size (7mm to 11mm) before surgery to optimize the tracker operation. This effect is only temporary.

A microkeratome, used to create the corneal flap prior to laser treatment, should create a flap large enough to allow for a treatment zone of 9.0mm needed for this procedure.

G. Precautions

The safety and effectiveness of the LADARVision[®] system have **NOT** been established:

- In eyes with disease or corneal condition (for example, scar, infection, etc.)
- In eyes with previous surgery or injury to the center of the cornea where LASIK will reshape the cornea
- In patients with a cornea that is too thin for the procedure to be completed safely
- In patients with a history of glaucoma (a condition usually associated with high eye pressure that results in damage to the nerve in the eye and possible loss of vision)
- In patients who are taking the medication Sumatriptan (Imitrex[®])

- In patients under 21 years of age
- In patients over the long term (beyond 9 months)
- In eyes with previous corneal or intraocular surgery (for example, cataract surgery)
- In non-Caucasian patients
- For the treatment of astigmatism less than 0.50 Diopters
- For treatments greater than +6.0D of hyperopia or –6.0D of astigmatism
- For retreatments of hyperopia, hyperopic astigmatism or mixed astigmatism

Eye with greater than 5.0D of hyperopia may have lower predictability of refractive outcome and improvement in uncorrected visual acuity (vision without glasses or contact lenses) than eyes with lower levels of hyperopia.

Hyperopic astigmatism eyes with greater than 4.0D MRSE before surgery may have lower predictability of refractive outcome and improvement in uncorrected visual acuity (vision without glasses or contact lenses) than eyes with lower levels of MRSE. MRSE is the amount of hyperopic astigmatism calculated based on the glasses prescription. These eyes may be more likely to experience a reduction of two lines in their best corrected visual acuity (vision with glasses or contact lenses) and to require additional treatment (retreatment).

Older patients and women on hormone replacement therapy may be less likely to achieve uncorrected visual acuity (vision without glasses or contact lenses) of 20/20 or better.

The effects of LASIK on visual performance under poor lighting conditions have not been effectively determined. Following LASIK treatment, some patients may find it more difficult to see in conditions such as very dim light, rain, snow, fog, and glare from bright lights at night.

H. What Are the Risks of LASIK?

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

On the day of LASIK Surgery

In clinical studies of the LADARVision® system for LASIK surgery, each of the following complications was reported on the day of surgery (n=360) at a rate of 0.3%: epithelial defect and misaligned flap. The following adverse event was reported on the day of surgery at a rate of 0.8%: miscreated flap related to use of the microkeratome. In the situation of a miscreated flap, laser ablation is not attempted. A new flap can usually be created 3 months after the first attempt and LASIK surgery completed.

The First Week Following LASIK Surgery

- Pain, discomfort and a feeling of something in the eye may last from 1 up to 3 days after surgery.
- Blurred vision may be present for the first week as the corneal flap settles. Best-corrected vision (vision with glasses or contact lenses) may be reduced in this early time period after surgery.
- Do not rub your eye as this may move the corneal flap. If you notice any sudden decrease in your vision, the corneal flap may have moved and you should contact your doctor immediately. The doctor may have to re-position the flap.
- Swelling of the eye may occur.
- You will use antibiotic and anti-inflammatory drops in the first few days. You may also use a prescription drop and a bandage contact lens for management of pain in the first few days.
- The pressure inside your eye may increase. Anti-inflammatory medications prescribed by your doctor may cause an increase in pressure in the eye. Your doctor may need to treat a pressure increase with drug therapy or by stopping the anti-inflammatory medication. An increase in the eye pressure does not usually cause any symptoms. Therefore, it is essential that you see your doctor as directed to check for an increase in the eye pressure. A severe increase in eye pressure could cause eye pain or nausea. If you notice these symptoms, you should contact your doctor.
- In clinical studies of the LADARVision[®] system for LASIK surgery, each of the following complications was reported at the 1 week visit (n=354) at a rate of 0.6% or less: corneal folds/striae, corneal swelling, epithelium in interface, and intralamellar haze. The complication of sterile interface inflammation was reported at 1 week at a rate of 2.0%. Each of the following adverse reactions was reported at 1 week at a rate of 0.8% or less: corneal infiltrate and increase in intraocular pressure.
- The following complications were reported only at unscheduled visits within the first two weeks after primary treatment or retreatment: corneal swelling (4 eyes), epithelium in the interface (1 eye), and sterile interface inflammation (2 eyes). In addition, one patient with a history of heart disease experienced a myocardial infarction (heart attack) two weeks after surgery, which was not related to the LASIK procedure or to the LADARVision system.

The First One Month Following LASIK Surgery

- You should contact your doctor if you notice any pain or change or loss of vision in the eye.
- You may notice glare, sensitivity to light and difficulty in driving at night.
- Your vision should become stable within the first few weeks after surgery. Some patients may experience some small changes in their vision. For example, their vision may improve or worsen. These changes may occur up to 3 months or more after surgery.

In U.S. clinical studies of the LADARVision® system, the following adverse events and complications related to LASIK surgery have occurred at 1 month or later. These events may result in a loss of vision.

Summary of LASIK Adverse Events and Complications

| | 1 Month | | 3 Months | | 6 Months | | 9 Months | |
|--|---------|-----|----------|-----|----------|-----|----------|-----|
| | n/N | % | n/N | % | n/N | % | n/N | % |
| ADVERSE EVENTS | | | | | | | | |
| Rolled flap edge with trace corneal melt | 0/353 | 0.0 | 0/344 | 0.0 | 1/324 | 0.3 | 0/265 | 0.0 |
| COMPLICATIONS | | | | | | | | |
| Corneal abrasion | 0/353 | 0.0 | 0/344 | 0.0 | 1/324 | 0.3 | 0/265 | 0.0 |
| Corneal folds/Striae/Wrinkles | 3/353 | 0.8 | 0/344 | 0.0 | 0/324 | 0.0 | 1/265 | 0.4 |
| Corneal opacities | 3/353 | 0.8 | 6/344 | 1.7 | 1/324 | 0.3 | 2/265 | 0.8 |
| Double/ghost images | 2/353 | 0.6 | 2/344 | 0.6 | 5/324 | 1.5 | 2/265 | 0.8 |
| Epithelium in the interface | 6/353 | 1.7 | 7/344 | 2.0 | 5/324 | 1.5 | 3/265 | 1.1 |
| Feeling of something in the eye | 2/353 | 0.6 | 2/344 | 0.6 | 1/324 | 0.3 | 0/265 | 0.0 |
| Interface debris | 10/353 | 2.8 | 7/344 | 2.0 | 5/324 | 1.5 | 1/265 | 0.4 |
| Irregular epithelium | 1/353 | 0.3 | 0/344 | 0.0 | 0/324 | 0.0 | 0/265 | 0.0 |
| Iron line or ring | 0/353 | 0.0 | 0/344 | 0.0 | 1/324 | 0.3 | 2/265 | 0.8 |
| Isolated cells in interface | 0/353 | 0.0 | 1/344 | 0.3 | 2/324 | 0.6 | 1/265 | 0.4 |
| Lagophthalmos | 1/353 | 0.3 | 0/344 | 0.0 | 0/324 | 0.0 | 0/265 | 0.0 |
| Pain | 1/353 | 0.3 | 0/344 | 0.0 | 0/324 | 0.0 | 0/265 | 0.0 |
| Sterile Interface Inflammation | 1/353 | 0.3 | 0/344 | 0.0 | 0/324 | 0.0 | 0/265 | 0.0 |
| Superficial punctate keratitis (SPK) | 20/353 | 5.7 | 17/344 | 4.9 | 10/324 | 3.1 | 14/265 | 5.3 |

The following other complications occurred at unscheduled visits at 1 month or later:

- superficial punctate keratitis (14 eyes)
- interface debris (8 eyes)
- corneal folds/striae/wrinkles (4 eyes)
- iron line/ring (3 eyes)
- corneal opacities (2 eyes)
- trichiasis (1 eye)
- subconjunctival hemorrhage (1 eye)
- conjunctival injection (1 eye)
- vacuoles (1 eye)

Each of the following ocular findings was reported at 6 months (n=265) at a rate of 0.6% or less: allergic conjunctivitis, vitreous floater, cotton wool spot, and drusen.

Lens findings (cataracts) were reported postoperatively in 14 eyes of 8 patients. All of these patients experienced lens changes due to age (range 59 to 73 years old). These findings included nuclear sclerosis, cortical spoking, and posterior subcapsular cataract. No eyes had a loss of more than 2 lines of best spectacle corrected visual acuity (with glasses). Only one eye had a related loss of 2 lines of best spectacle corrected visual acuity. All eyes had a last-reported best-corrected visual acuity of 20/32 or better.

The following other adverse events and complications occurred at 1 to 6 months after retreatment: epithelium in the interface (3 eyes) and double/ghost images (4 eyes.)

U.S. clinical studies of the LADARVision® system have shown the following symptoms may occur after LASIK surgery. At 6 months after surgery, patients noted on a questionnaire that these symptoms were worse or significantly worse than before surgery, as shown in the table below.

Subjective Symptoms at 6 Months

| Subjective Responses | Hyperopia without astigmatism | | | Hyperopic Astigmatism | | | Mixed Astigmatism | | |
|-----------------------------|-------------------------------|-------|---------------------|-----------------------|-------|---------------------|-------------------|-------|---------------------|
| | | Worse | Significantly Worse | | Worse | Significantly Worse | | Worse | Significantly Worse |
| | <i>N</i> | % | % | <i>N</i> | % | % | <i>N</i> | % | % |
| Blurring of vision | 132 | 9.8 | 1.5 | 111 | 15.3 | 1.8 | 53 | 7.5 | 3.8 |
| Burning | 133 | 2.3 | 0.8 | 113 | 8.0 | 1.8 | 53 | 7.5 | 0.0 |
| Double vision | 132 | 8.3 | 1.5 | 111 | 6.3 | 3.6 | 53 | 1.9 | 0.0 |
| Dryness | 132 | 16.7 | 3.0 | 113 | 17.7 | 5.3 | 53 | 24.5 | 1.9 |
| Excessive tearing | 132 | 1.5 | 0.0 | 111 | 1.8 | 0.0 | 52 | 0.0 | 0.0 |
| Feeling of something in eye | 133 | 5.3 | 1.5 | 113 | 5.3 | 2.7 | 53 | 5.7 | 0.0 |
| Fluctuation of vision | 133 | 15.8 | 6.0 | 111 | 20.7 | 1.8 | 53 | 11.3 | 0.0 |
| Glare | 133 | 21.8 | 0.8 | 113 | 18.6 | 1.8 | 53 | 22.6 | 0.0 |
| Halos | 132 | 12.9 | 2.3 | 111 | 20.7 | 4.5 | 53 | 26.4 | 0.0 |
| Headache | 132 | 3.0 | 0.0 | 110 | 2.7 | 1.8 | 53 | 3.8 | 0.0 |
| Light sensitivity | 133 | 26.3 | 1.5 | 112 | 21.4 | 1.8 | 53 | 20.8 | 0.0 |
| Night driving difficulty | 133 | 9.0 | 2.3 | 113 | 14.2 | 1.8 | 53 | 13.2 | 7.5 |
| Pain | 132 | 3.0 | 0.8 | 110 | 4.5 | 0.9 | 53 | 3.8 | 0.0 |
| Quality of vision | 132 | 4.5 | 0.0 | 115 | 5.2 | 0.0 | 53 | 1.9 | 3.8 |
| Redness | 133 | 11.3 | 0.8 | 112 | 5.4 | 2.7 | 53 | 3.8 | 0.0 |

I. Are You A Good Candidate for LASIK?

If you are considering LASIK, you must:

- Be at least 21 years of age
- Have healthy eyes that are free from eye disease or corneal condition (for example, scar, infection, etc.)
- Have hyperopia between 0 and +6.0D in combination with up to –6.0D of astigmatism
- Have documented evidence that the change in your farsightedness is less than or equal to 0.50 diopter per year for at least one year prior to your preoperative exam
- Be able to lie flat without difficulty
- Be able to constantly look at a blinking light during the LASIK procedure
- Be able to tolerate eye drops to numb your eye and enlarge your pupil
- Be informed of LASIK risks and benefits as compared to other available treatments for hyperopia
- Be willing to sign an Informed Consent Form, if provided by your eye care professional

J. What Should You Expect During LASIK Surgery?

LASIK surgery can be performed one eye at a time or on both eyes during the same surgical session.

Before The Surgery

First, you will need to have a pre-operative examination if you have an interest in LASIK. This exam will help to determine if your eye is healthy and suitable for LASIK. This exam will include a complete medical and eye history, and a complete evaluation of both eyes. In addition, this examination will involve mapping your cornea with a computer to determine if it is smooth and properly shaped.

WARNING:

If you wear contact lenses, it is very important to stop wearing them at least 3 weeks before the evaluation. Failure to do this will produce poor surgical results.

Before the surgery, please tell your doctor if you take any medications or have any allergies. Also, talk with your doctor about eating or drinking right before the surgery. You should also arrange for transportation, since **you must not drive right after the surgery. Your doctor will inform you of when you can resume driving.**

The Day of Surgery

Before the surgery, your doctor will ask you to lie on your back on the laser bed. The laser bed is a flat cushioned surface that does not recline or move. Your doctor will instruct you to watch a blinking light. Your doctor will take a picture of your eye to aid in determining the correct placement of the treatment on the cornea. Your doctor will not apply any laser pulses at this time. Your doctor will then put drops in your operative eye to dilate (enlarge) your pupil.

About 30-40 minutes later, your doctor will place anesthetic (numbing) drops into your eye. Your doctor will escort you back into the room with the laser. You will again lie on your back and look up at a microscope that will deliver the laser light to your cornea. Your doctor will place an instrument between your eyelids to hold them open during the surgery. A temporary shield will cover the eye not having surgery.

LASIK surgery begins with the creation of a corneal flap with a microkeratome. Then, your doctor will reposition your head and activate the tracker. Your doctor will ask you to look directly at a blinking light. The laser in the LADARVision[®] system will remove small amounts of tissue from your cornea. The tracker will follow eye movements and allow the laser to continue the treatment. Still, it is important to continue looking at the blinking light throughout the treatment.

You will be under the laser for several minutes. Overall, the surgery takes about 10 minutes. After the laser surgery is complete, your doctor will place some drops into your eye. In some LASIK cases, a bandage contact lens is placed in your eye as well to

help heal small abrasions. You may be provided with a plastic shield for eye protection after LASIK for the first few days. The surgery is painless because of the numbing drops. The numbing drops will wear off in about 45-60 minutes. After this time, your eye may hurt for 1 to 3 days.

WARNING:

Your doctor will monitor you for any side effects if you need to use topical steroids. Possible side effects of extended 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).

The First Days After Surgery

If a bandage contact lens was applied to the eye after surgery, your doctor will remove the bandage contact lens on the day the surface of your eye has recovered. 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.

DO NOT rub your eyes for the first 3 to 5 days. You may be provided with a plastic shield for eye protection after LASIK for the first few days. Your doctor can also prescribe pain medication to make you more comfortable during this time after the surgery.

IMPORTANT:

Use the antibiotic eye drops, anti-inflammatory eye drops and lubricants as directed by your doctor. Your results depend upon your following your doctor's directions.

Please refer to the section entitled "What are the risks of LASIK?" for information on the complications and adverse reactions that may occur in the first few weeks after surgery.

You may also experience blurred vision with or without glasses in the first week to one month after surgery. Some patients may experience a reduction in their best-corrected vision (with glasses) in the first week to one month as compared to before surgery, which tends to improve over the time. The following table displays the vision with and without glasses at one month for patients in the U.S. clinical study.

Some patients may experience some small changes or fluctuations in their vision. For example, their vision may improve or worsen. These changes may occur up to 3 months or more after surgery. Your vision with and without glasses should become stable within the first few weeks after surgery. Please refer to the section entitled "What are the benefits of LASIK?" for information on visual outcomes in the clinical study at 6 months, the time point of stability of the refractive outcome of the procedure.

| U.S. CLINICAL STUDY RESULTS AT 1 MONTH AFTER LASIK SURGERY | | | | | | |
|---|--------------------------------------|-------------|------------------------------|-------------|--------------------------|-------------|
| | Hyperopia without astigmatism | | Hyperopic Astigmatism | | Mixed Astigmatism | |
| | n/N | % | n/N | % | n/N | % |
| Visual Acuity 20/20 or better without glasses** | 45/118 | 38.1 | 33/101 | 32.7 | 20/46 | 43.5 |
| Visual Acuity 20/20 or better without glasses* | 46/124 | 37.1 | 34/124 | 27.4 | 23/61 | 37.7 |
| Visual Acuity 20/25 or better without glasses* | 74/124 | 59.7 | 52/124 | 41.9 | 33/61 | 54.1 |
| Visual Acuity 20/40 or better without glasses* | 114/124 | 91.9 | 104/124 | 83.9 | 55/61 | 90.2 |
| Visual Acuity 20/20 or better with glasses** | 104/138 | 75.4 | 82/114 | 71.9 | 37/48 | 77.0 |
| Visual Acuity 20/20 or better with glasses | 108/149 | 72.4 | 86/138 | 62.3 | 44/62 | 71.0 |
| Visual Acuity 20/40 or better with glasses | 149/149 | 100 | 137/138 | 99.3 | 62/62 | 100 |
| Loss of 2 lines of visual acuity with glasses | 14/149 | 9.4 | 16/135 | 11.9 | 1/58 | 1.7 |
| Loss of more than 2 lines of visual acuity with glasses | 3/149 | 2.0 | 3/135 | 2.2 | 1/58 | 1.7 |

*Not including eyes treated for monovision

**If vision with glasses was 20/20 or better before surgery

K. Questions To Ask Your Doctor

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

- Which type of refractive condition do I have: hyperopia without astigmatism, hyperopic astigmatism, or mixed astigmatism?
- What are my other options to correct my farsightedness (hyperopia)?
- Will I have to limit my activities after surgery, and for how long?
- What are the benefits of LASIK for my amount of farsightedness (hyperopia)?
- What vision can I expect in the first few months after surgery?
- If 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 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 injured after having LASIK?
- Should I have 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 LASIK only on one eye?

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

L. Self-Test

Are You An Informed And Educated Patient?

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

| | TRUE | FALSE |
|--|--------------------------|--------------------------|
| 1. Excimer laser surgery is risk free. | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. It does not matter if I wear my contact lenses when my doctor told me not to wear them. | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Since the LADARVision [®] system tracks my eye movements, I do not have to fixate on the blinking light. | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. After the surgery, there is a good chance that I will be less dependent on eyeglasses. | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. I may need reading glasses after laser surgery. | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. There is a risk that I may lose some vision after laser surgery. | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. It does not matter if I am pregnant. | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. If I have an autoimmune disease, I am still a good candidate for LASIK. | <input type="checkbox"/> | <input type="checkbox"/> |

You can find the answers to Self-Test at the bottom of Page 25.

M. Summary Of Important Information

- LASIK is a permanent operation to the cornea and is irreversible.
- LASIK does not eliminate the need for reading glasses, even if you never have worn them before.
- Your vision must be stable for at least 1 year before LASIK surgery. You will need written evidence that your farsightedness has changed less than or equal to 0.50 D.
- Pregnant and nursing women should wait until they are not nursing and not pregnant to have the surgery.
- 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.
- LASIK surgery may result in some discomfort. The surgery is not risk-free. Please read this entire booklet before you agree to the surgery. The sections on Benefits and Risks are especially important to read carefully.
- Alternatives to LASIK include, but are not limited to, glasses and contact lenses.
- The vision requirements of some occupations, such as military pilots, cannot be met by having LASIK.
- Before considering LASIK surgery you should:
 - a. Have a complete eye examination.
 - b. Talk with one or more eye care professionals about LASIK. This talk should include the potential benefits, risks, and complications of LASIK surgery. In addition, you should discuss the time needed for healing after LASIK.
- If you are older or are a woman on hormone replacement therapy, you may be less likely than other patients to achieve a visual acuity of 20/20 or better without glasses or contact lenses.
- If you have hyperopia greater than 5.0D, your outcome may be less predictable and your visual acuity may be less likely to reach 20/20 or better without glasses or contact lenses.
- If you have hyperopic astigmatism greater than 4.0D MRSE before surgery (amount of hyperopic astigmatism based on your glasses prescription), your outcome may be less predictable and your visual acuity may be less likely to reach 20/20 or better without glasses or contact lenses. In addition, you may be more likely to experience a reduction of 2 lines of visual acuity with glasses or contact lenses. You may also be more likely to need additional treatment. The safety and effectiveness of retreatments has not yet been established.

Answers to Self-Test Questions:

1. False (see Risks on Page 16); 2. False (see Before the Surgery on Page 20); 3. False (see The Day of Surgery on Page 20); 4. True (see Benefits on Page 13); 5. True (see Introduction on Page 10); 6. True (see Risks on Page 16; also see The First Days After Surgery on Page 21); 7. False (see Contraindications on Page 15); 8. False (see Contraindications on Page 15).

N. Patient Assistance Information

To be completed by you or your Primary Eye Care Professional as a reference.

PRIMARY EYE CARE PROFESSIONAL

Name: _____

Address: _____

Phone: _____

LASIK DOCTOR

Name: _____

Address: _____

Phone: _____

TREATMENT LOCATION

Name: _____

Address: _____

Phone: _____

LASER MANUFACTURER

| |
|--|
| Summit Autonomous Inc. 2501 Discovery Drive, Suite 500 Orlando, FL 32826 U.S.A. Tel: (877) 523-2784 Fax: (407) 384-1677 |
|--|

O. Index

A

Allergic Conjunctivitis · 5, 18
Allergies · 15
Astigmatism
 Definition · 5, 11
Autoimmune Disease · 5, 24, 25
 Example
 Multiple Sclerosis · 5, 15
 Myasthenia Gravis · 5, 15

B

Burning · 14, 19

C

Cataract · 5, 21
 Age-related · 18
Collagen Vascular Disease · 5, 25
 Example
 Lupus · 5, 15
 Rheumatoid Arthritis · 5, 15
Conjunctiva · 5
 Injection · 5, 18
Contact Lenses
 Bandage · 5, 17, 21
 Discontinue wear before surgery · 20
Cornea
 Abrasion · 6, 18
 Definition · 5, 10
 Edema · 6
 Epithelial Defect · 6, 16
 Epithelial Irregularity · 6, 18
 Epithelium · 6
 Epithelium in the Interface · 6, 17, 18
 Flap · 6
 Folds · 6, 17, 18
 Infiltrate · 6, 17
 Iron Line · 7
 Iron Ring · 7
 Opacities · 6, 18
 Striae · 6, 17, 18
 Superficial Punctate Keratitis · 8
 Swelling · 6, 17
 Vacuoles · 9, 18
 Wrinkles · 6, 18
Corneal flap
 Misaligned · 16
 Miscreated · 16
Cotton wool spot · 6, 18

D

Diabetes · 15

Diopter

Definition · 6

Double or ghost images · 18, 19

Driving

After Surgery · 20

Difficulty at Night · 14, 19

Drusen · 6, 18

Dryness · 14, 19

E

Epithelial defect · 16

Epithelial Irregularity · *See Cornea:Epithelial Irregularity*

Epithelium · *See Cornea:Epithelium*

Epithelium in the interface · 19. *See Cornea:Epithelium in the interface*

Excimer Laser · 8, 10, 12

Definition · 6

Eye Pressure

Increase · 17

Eye Tracking · 12

F

Farsightedness · *See Also Hyperopia*

Definition · 6

Feeling of something in eye · 14, 18, 19, 21

G

Glare · 14, 19

Glaucoma · 6, 15, 21

H

Halos · 7, 14, 19

Haze

Intralamellar · 7, 17

Headache · 14, 19

Herpes Simplex · 7, 15

Herpes Zoster · 7, 15

Hyperopia · *See Also Farsightedness*

Definition · 7

Hyperopic Astigmatism

Definition · 7, 11

I

Immunodeficiency Disease · 7

Example

AIDS · 7

Inflammation

Definition · 7

Interface debris · 18

Definition · 7

Iritis · 7

Iron line or ring · 7, 18

K

Keratoconus · 7, 15

L

LADARVision® System · 13

Definition · 10

Tracking Eye Movements · 12, 20, 24

U.S. Clinical Studies · 13, 18, 19

Lagophthalmos · 7, 18

Laser In-Situ Keratomileusis (LASIK)

Are You A Good Candidate For LASIK? · 19

Benefits of LASIK · 13

Contraindications · 5, 15

Definition · 7

Glossary · 5

How Does LASIK Correct Hyperopia and Astigmatism · 10

Introduction · 10

Patient Assistance Information · 26

Precautions · 15

Questions To Ask Your Doctor · 23

Risks of LASIK · 16

Self-Test · 24

Summary Of Important Information · 25

Warnings · 15

What To Expect During LASIK Surgery? · 20

LASIK · See *Laser In-Situ Keratomileusis*

Lens

Definition · 7, 10

Light Sensitivity · 14, 19, 21

M

Medication

Amiodarone hydrochloride (Cordarone) · 15

Antibiotic · 5, 17

Anti-inflammatory · 5, 17, 21

Isotretinoin (Accutane) · 15

Non-Steroidal Anti-inflammatory Drug · 8

Steroid · 8

Sumatriptan (Imitrex) · 15

Microkeratome

Definition · 8

Misaligned Flap · 16

Definition · 8

Miscreated Flap · 16

Definition · 8

Mixed Astigmatism

Definition · 8, 11

Monovision · 13, 14, 22

Definition · 8

O

Ocular Hypertension · 8, 21

P

Pain · 14, 17, 18, 19

Photorefractive Keratectomy (PRK)

Definition · 8

Pregnancy · 15, 24, 25

R

Redness · 14, 19

Regression · 8

Retina

Definition · 8, 10

S

Sterile Interface Inflammation · 17, 18

Definition · 8

Subconjunctival hemorrhage · 8, 18

Superficial Punctate Keratitis (SPK) · 8, 18

T

Tearing · 14, 19

Trichiasis · 9, 18

V

Vacuoles · 9

Vision

Blurring · 14, 17, 19

Double · 14, 19

Fluctuation · 14, 19

Vitreous floater · 9, 18