

**FACTS YOU NEED TO KNOW ABOUT  
LADARVision<sup>®</sup>  
PHOTOREFRACTIVE KERATECTOMY (PRK) AND  
LASER IN-SITU KERATOMILEUSIS (LASIK) SURGERY**

**PATIENT INFORMATION BOOKLET**

For

For Nearsightedness (Myopia): up to  $-10.0D$  (PRK) or less than  $-9.0D$  (LASIK)  
With or Without Astigmatism:  $-0.50$  to  $-4D$  (PRK) or  $-0.50$  to less than  $-3.0D$  (LASIK)

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.

Summit Autonomous Inc.  
2501 Discovery Drive, Suite 500  
Orlando, FL 32826  
U.S.A.

Tel: (877) 523-2784  
Fax: (407) 384-1677

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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.

**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 PRK or 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 PRK or LASIK surgery.

**Bandage Contact Lens:** a soft contact lens placed on the cornea after surgery to cover the area that was treated with the laser.

**Blepharitis:** inflammation of the eyelid margins

**Cataract:** an opacity, or clouding, of the lens inside the eye that can cause a loss of vision.

**Collagen Vascular Disease:** a condition that may result in inflammation or swelling of parts of the body; such as muscles, joints, and blood vessels. Examples of this type of disease are lupus and rheumatoid arthritis. If you have this type of condition, you should not have PRK or LASIK surgery.

**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 PRK, LASIK 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. The doctor removes this layer during PRK surgery. The epithelium then grows back a few days after PRK surgery.

**Corneal Erosion:** a defect in the outer layers of the cornea that may occur without injury.

**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 Foreign Body:** foreign debris in outer layer of the cornea.

**Corneal Haze:** a cloudiness of the cornea that may occur after PRK.

**Corneal Infiltrate:** inflammation of 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.

**Corneal Ulcer:** an infection of the cornea that may result in a loss of vision.

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

**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 Dots:** small spots in the outer layer of the cornea, that have no effect on vision.

**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 PRK or LASIK that removes tissue from the cornea.

**Fibrotic Healing of Flap Edge:** slight scarring appearance of the edge of the corneal flap.

**Flap Distortion:** : irregular appearance of the corneal flap.

**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 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 PRK or 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 PRK or LASIK surgery.

**HSV Dendrite.:** a branching treelike lesion in the cornea due to herpes simplex infection.

**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.

**Induced Astigmatism:** the case when the eye has a greater amount of astigmatism after surgery than before surgery. This can happen if the corneal flap is created off-center (decentered flap) in LASIK.

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

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

**Interface haze/opacity:** a cloudiness of the cornea underneath the flap, either diffuse or localized areas that may occur after LASIK.

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

**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 PRK or LASIK surgery.

**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.

**Lattice Degeneration:** area of thinning in the back of the eye (retina), which is more common in nearsighted eyes and unrelated to surgery

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

**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.

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

**Myopia:** a condition of the eye that results in blurred distance vision. The cornea and lens focus light rays from distant objects in front of the retina. This incorrect focusing of light results in blurred images of objects at a distance.

**Nearsightedness:** another term for myopia. Nearsighted eyes see better at near than at a distance without glasses or contact lenses.

**Nebula After Foreign Body Removal:** area of haze in the outer layer of the cornea where foreign body was removed.

**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.

**Oil droplets/sheen:** oily appearance of the cornea

**Overcorrection:** too much correction after surgery that may cause blurred distance and/or near vision without glasses.

**Peau d' orange:** orange peel appearance of the cornea

**Peripheral Epithelial Defect:** a piece of the outer layer of the cornea that has torn off leaving a defect. This defect occurs in the periphery or outer part of the cornea.

**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.

**Radial Keratotomy (RK):** a type of surgery used to correct vision by flattening the cornea with a scalpel.

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

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

**Retinal Vascular Accident:** blockage of a blood vessel in the back of the eye.

**Retinal Vessel Tortuosity:** curving of blood vessels in the back of the eye unrelated to surgery

**Serous Macular Edema:** a sudden accumulation of fluid in the part of the retina responsible for central vision (macula) resulting in distortion of central vision.

**Starbursts:** flares of light seen around a lighted object that may appear like a star. This symptom is similar to halos and may occur after surgery.

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

**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 PRK or 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.

## B. Introduction

Do you need to wear glasses or contact lenses to help you to see clearly in the distance? One option to see more clearly at a distance is to correct your vision with surgery. Some types of surgery correct vision by shaping the front surface of the eye, the cornea. Radial Keratotomy (RK) is one type of surgery that uses a scalpel to make fine cuts in the cornea. A more recent type of surgery 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 LASIK. In the LASIK procedure, the laser energy is applied to the inner layers of the cornea. PRK or LASIK may help you to see more clearly by partially or fully correcting vision.

The LADARVision<sup>®</sup> 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 PRK and LASIK with the tracker-guided LADARVision<sup>®</sup> system. Please read this information carefully and discuss any questions with your doctor. It is important that you make an informed decision about PRK or LASIK with the help of your doctor.

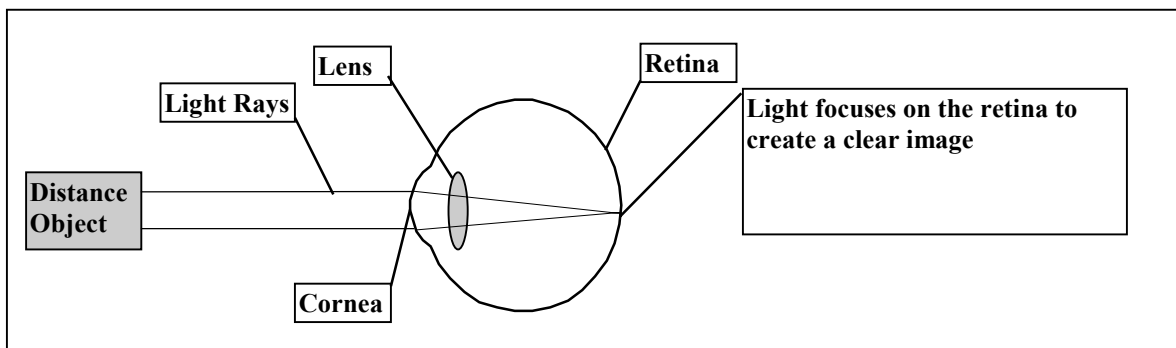
Although vision without glasses improved for all eyes, some people still needed glasses or contact lenses for some tasks after PRK or LASIK. PRK or LASIK does not eliminate the need for reading glasses. In addition, the vision requirements of some occupations, such as military pilots, cannot be met by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

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

## C. How Does PRK or LASIK Correct Myopia With or Without 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.

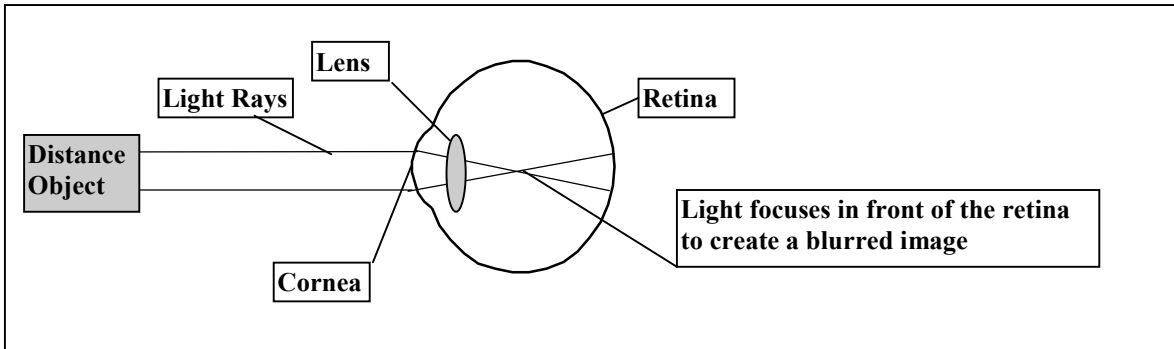
**DIAGRAM 1: NORMAL EYE**



Myopia (Nearsightedness) is a condition of the eye that results in blurred distance vision. The cornea and lens focus light rays from a distant object in front of the retina.

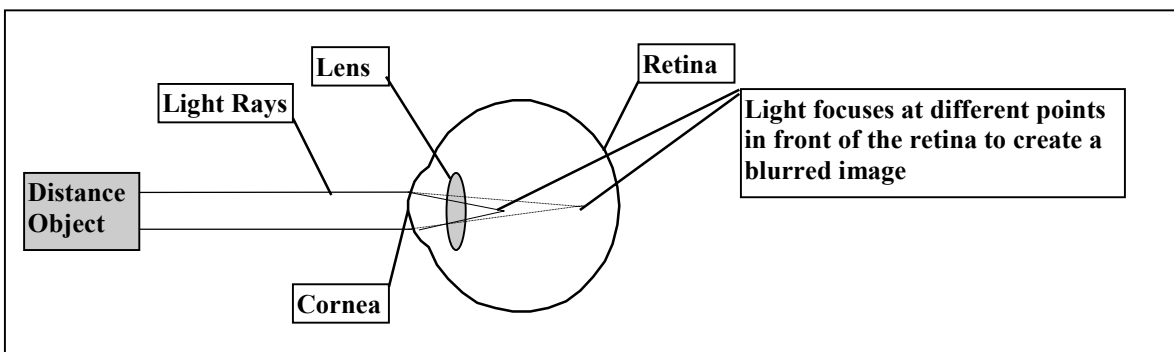
This incorrect focusing of light results in blurred images of objects at a distance. Diagram 2 shows how light focuses in front of the retina to cause a blurred image.

**DIAGRAM 2: MYOPIA**



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 front of 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. Diagram 3 shows how light rays focus at different points causing a blurred image.

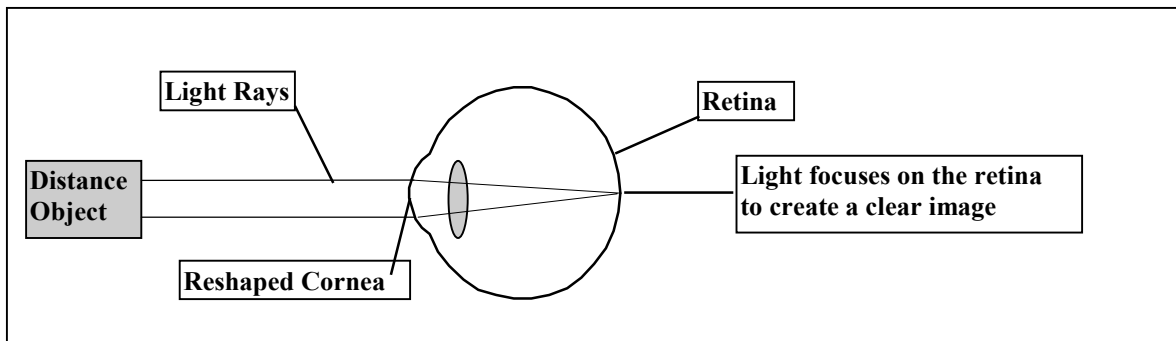
**DIAGRAM 3: MYOPIA WITH ASTIGMATISM**



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 myopia, flattening the center of the cornea helps to focus all of the light rays on to the retina to provide clear vision. PRK and LASIK flatten the cornea by removing a tiny amount of the tissue with a laser. An excimer laser is a type of laser used in PRK and 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 procedures can reshape the cornea to provide clearer vision.

**DIAGRAM 5: CORRECTION OF VISION AFTER PRK OR LASIK**



The LADARVision<sup>®</sup> 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<sup>®</sup> 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 Benefits Of PRK or LASIK?**

Either PRK or LASIK may reduce overall nearsightedness. PRK or LASIK may also reduce or eliminate the need to wear glasses or contact lenses to see clearly.

- PRK surgery performed with the LADARVision<sup>®</sup> system is effective in reducing myopia between -1.0 and -10.0 Diopters. In patients with myopia, the LADARVision<sup>®</sup> system is effective in reducing astigmatism of up to 4 Diopters.
- LASIK surgery performed with the LADARVision system is effective in reducing myopia less than -9.0 Diopters. In patients with myopia, the LADARVision system is effective in reducing astigmatism of 0.50 Diopters to less than 3.0 Diopters.

The results listed in the following section are from U.S. clinical studies of the LADARVision<sup>®</sup> system for PRK and LASIK.

<b>U.S. CLINICAL STUDY RESULTS AT 12 MONTHS AFTER PRK SURGERY</b>			
	Mildly Nearsighted	Mildly Nearsighted with Astigmatism	Highly Nearsighted with and without Astigmatism
Visual Acuity 20/20 or better <b>without</b> glasses*	72.0%	61.7%	61.2%
Visual Acuity 20/25 or better <b>without</b> glasses*	88.7%	82.6%	76.9%
Visual Acuity 20/40 or better <b>without</b> glasses*	98.1%	97.4%	93.4%
Visual Acuity 20/20 or better <b>with</b> glasses	97.0%	94.1%	92.4%
Visual Acuity 20/40 or better <b>with</b> glasses	100%	100%	100%
Loss of more than 2 lines of visual acuity <b>with</b> glasses	0.3%	0.0%	0.0%

\*not including eyes treated for monovision

<b>U.S. CLINICAL STUDY RESULTS AT 6 MONTHS AFTER LASIK SURGERY</b>				
	<b>Eyes without astigmatism</b>		<b>Eyes with astigmatism</b>	
	n/N	%	n/N	%
Visual Acuity 20/20 or better <b>without</b> glasses**	88/140	62.9%	47/89	52.8%
Visual Acuity 20/20 or better <b>without</b> glasses*	89/145	61.4%	47/94	50.0%
Visual Acuity 20/25 or better <b>without</b> glasses*	118/145	81.4%	69/94	73.4%
Visual Acuity 20/40 or better <b>without</b> glasses*	136/145	93.8%	88/94	93.6%
Visual Acuity 20/20 or better <b>with</b> glasses**	146/150	97.3%	88/98	89.8%
Visual Acuity 20/20 or better <b>with</b> glasses	148/155	95.5%	90/105	85.7%
Visual Acuity 20/40 or better <b>with</b> glasses	155/155	100.0%	105/105	100.0%
Loss of more than 2 lines of visual acuity <b>with</b> glasses	0/155	0.0%	0/105	0.0%

\*Not including eyes treated for monovision

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

### **E. Contraindications**

You should **NOT** have PRK or 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<sup>®</sup>) and Amiodarone hydrochloride (Cordarone<sup>®</sup>))
- **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.

## G. Precautions

The safety and effectiveness of the LADARVision<sup>®</sup> system have **NOT** been established:

- In eyes with unstable or worsening myopia (nearsightedness)
- In eyes with disease or corneal condition (for example, scar, infection, etc.).
- In eyes with injury to the center of the cornea where PRK or 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 with a tendency to form scars (PRK only)
- In patients who are taking the medication Sumatriptan (Imitrex<sup>®</sup>)
- In patients under 21 years of age
- For the treatment of astigmatism less than 0.50 Diopters
- In patients over the long term (more than 12 months for PRK; 6 months for LASIK)
- In eyes with previous corneal or intraocular surgery (for example, cataract surgery).
- For PRK refractive treatments greater than -10.0D of myopia combined with greater than -4.0D of astigmatism.
- For LASIK refractive treatments greater than or equal to -9.0D of myopia combined with greater than or equal to -3D of astigmatism.

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, or glare from bright lights at night.

In a contrast sensitivity study designed to assess the effects of LADARVision PRK surgery on how well patients can see in conditions such as very dim light, rain, snow, fog or glare from bright lights at night, the percentage of patients showing clinically significant losses were 10.6% at 6 months and 6.6% at 12 months after surgery, and the percentages of patients showing clinically significant improvements were 5.9% at 6 months and 3.3% at 12 months after PRK surgery.

In addition, U.S. clinical studies of the LADARVision® system have shown the following findings for PRK.

- Corneal infiltrates (inflammation) have been seen after PRK with the system in 1.6% of PRK eyes treated. All patients in the PRK study received bandage contact lenses and anti-inflammatory drops for pain management after surgery.
- Overcorrection of more than 1 Diopter with PRK has been associated with corrections of higher amounts of myopia, older patient age, and lower humidity in the laser room. An overcorrection is too much correction that may cause blurred distance and/or near vision without glasses.

## **H. What Are The Risks of PRK and of LASIK?**

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

### **PRK**

#### **The First Week Following PRK Surgery**

- Pain and discomfort may last from 1 up to 3 days after surgery.
- Blurred vision and tearing will occur as the cornea heals.
- You will be sensitive to bright lights.
- You may have difficulty seeing in low light conditions (e.g. rain, snow, fog or glare).
- 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 First One To Six Months Following PRK Surgery**

- 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.

- Your cornea may become hazy or cloudy enough to affect your vision. Haze may occur as the cornea heals. The haze typically goes away over time. Some patients continue to have some haze over a longer period of time.
- You may notice glare, sensitivity to light and difficulty in driving at night.
- You should contact your doctor if you notice any pain or change or loss of vision in the eye.

One or More Years After Surgery

Some patients report visual complaints at one or more years after surgery. These problems are discussed in detail in the following section. In U.S. clinical studies of the LADARVision® system, the following events related to the surgery have occurred. These events may result in a loss of vision.

**Summary of PRK Adverse Events<sup>1</sup> and Complications<sup>2</sup>**

	Mildly Nearsighted (n=386)	Mildly Nearsighted with Astigmatism (n=144)	Highly Nearsighted with and without Astigmatism (n=148)
Corneal Infiltrates (inflammation) <sup>1</sup>	1.3%	2.1%	2.0%
IOP increase above 25 mmHg <sup>1</sup>	0.5%	0.7%	2.7%
Feeling of something in the eye <sup>2</sup>	3.6%	7.6%	4.7%
Double or ghost images <sup>2</sup>	2.1%	5.6%	8.8%
Peripheral epithelial defect <sup>2</sup>	1.6%	1.4%	2.0%
Pain <sup>2</sup>	2.1%	2.1%	2.0%
Other <sup>2</sup>	3.9%	1.4%	4.1%

Other findings that occurred at a rate of less than or equal to 0.3% in all eyes treated (n=678) included:

- corneal edema (swelling in the cornea)
- corneal ulcer
- light sensitivity
- corneal erosion (a defect in the outer layer of the cornea that may recur)
- epithelial dots (small spots in the outer layer of the cornea with no adverse effects)
- epithelial irregularity (an area of the outer layer of the cornea that is not smooth)
- scratchiness (similar to a feeling of something in the eye)
- iritis (inflammation of the inside of the eye behind the cornea)
- ocular hypertension (an increase in the pressure inside the eye)
- 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 (surface irritation in the outer layer of the cornea)
- corneal foreign body (foreign debris in the outer layer of the cornea)
- nebula after foreign body removal (area of haze in outer layer of the cornea where foreign body was removed)
- retinal vascular accident (blockage of a blood vessel in the back of the eye unrelated to the surgery)

Other findings that occurred at a rate of less than or equal to 1.0% in all eyes treated (n=678) included:

- corneal abrasion (a scratch in the outer layer of the cornea often from an eye injury)
- halos/starbursts (circular or star-shaped flares of light that may appear around a headlight or other lighted object)

Other events that did not occur in this study that could occur following PRK include significant corneal haze and loss of best corrected visual acuity.

U.S. clinical studies of the LADARVision® system have shown the following conditions may occur after PRK surgery. At 12 months or more after surgery, some patients noted on a questionnaire that these conditions were significantly worse than before surgery, as shown in the table below.

	Mildly Nearsighted	Mildly Nearsighted with Astigmatism	Highly Nearsighted with and without Astigmatism
Difficulty with night driving	2.1%	6.8%	9.4%
Glare	1.0%	1.7%	5.5%
Halos*	1.7%	3.4%	7.0%
Feeling of something in eye	0.0%	1.7%	2.3%
Fluctuation of vision	1.7%	0.0%	2.3%
Blurring of vision	0.3%	0.9%	2.3%
Light sensitivity	1.0%	0.0%	0.8%
Headache	0.0%	0.0%	0.0%
Double vision	0.7%	0.0%	1.6%
Pain	0.3%	0.9%	0.0%
Excessive tearing	0.0%	0.0%	0.0%
Burning	0.0%	0.0%	0.0%

\* Halos are circular flares or rings of light that may appear around a headlight or other lighted object.

## LASIK

### On the day of LASIK Surgery

- In clinical studies of the LADARVision® system for LASIK surgery, the following adverse event was reported on the day of surgery (n=325) at a rate of 0.3%: miscreated flap (e.g. too small or irregular) related to use of the microkeratome. In this situation, 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.
- 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, the following complications were reported within 1 week (n=313) at a rate of less than 1.0%: corneal folds/striae, epithelium in the interface, misaligned flap and sterile interface inflammation.

### 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 (n=316)		3 Months (n=310)		6 Months (n=260)		9 Months (n=111)	
	n/N	%	n/N	%	n/N	%	n/N	%
Induced astigmatism-flap decentration	1/316	<b>0.3</b>	1/310	<b>0.3</b>	0/260	<b>0.0</b>	0/111	<b>0.0</b>
Feeling of something in the eye	1/316	<b>0.3</b>	0/310	<b>0.0</b>	0/260	<b>0.0</b>	0/111	<b>0.0</b>
Double/ghost images	2/316	<b>0.6</b>	1/310	<b>0.3</b>	1/260	<b>0.4</b>	0/111	<b>0.0</b>
Epithelium in the interface	3/316	<b>0.9</b>	3/310	<b>1.0</b>	1/260	<b>0.4</b>	0/111	<b>0.0</b>
Sterile Interface Inflammation	2/316	<b>0.6</b>	2/310	<b>0.6</b>	0/260	<b>0.0</b>	0/111	<b>0.0</b>
Serous Macular Edema	0/316	<b>0.0</b>	0/310	<b>0.0</b>	0/260	<b>0.0</b>	1/111	<b>0.9</b>
Corneal Folds/Striae/Wrinkle	4/316	<b>1.3</b>	2/310	<b>0.6</b>	2/260	<b>0.8</b>	0/111	<b>0.0</b>
Interface debris	10/316	<b>3.2</b>	12/310	<b>3.9</b>	11/260	<b>4.2</b>	0/111	<b>0.0</b>
Interface haze/opacity	7/316	<b>2.2</b>	10/310	<b>3.2</b>	1/260	<b>0.4</b>	1/111	<b>0.9</b>
Superficial punctate keratitis (SPK)	15/316	<b>4.7</b>	8/310	<b>2.6</b>	6/260	<b>2.3</b>	3/111	<b>2.7</b>
Oil droplets/sheen	5/316	<b>1.6</b>	0/310	<b>0.0</b>	2/260	<b>0.8</b>	0/111	<b>0.0</b>
Flap distortion	1/316	<b>0.3</b>	0/310	<b>0.0</b>	0/260	<b>0.0</b>	0/111	<b>0.0</b>
Fibrotic healing at flap edge	0/316	<b>0.0</b>	3/310	<b>1.0</b>	2/260	<b>0.8</b>	0/111	<b>0.0</b>
Epithelial defect	0/316	<b>0.0</b>	0/310	<b>0.0</b>	1/260	<b>0.4</b>	0/111	<b>0.0</b>
Conjunctival injection	0/316	<b>0.0</b>	0/310	<b>0.0</b>	2/260	<b>0.8</b>	0/111	<b>0.0</b>

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

- IOP increase >10 mmHg above baseline (3 eyes): increase in the pressure in the eye
- HSV dendrite (1 eye): a branching tree-like lesion on the cornea due to herpes simplex infection
- corneal folds/striae/wrinkles (2 eyes): the temporary appearance of fine white lines in the back of the cornea as a result of corneal swelling
- interface haze/opacity (3 eyes): a cloudiness of the cornea underneath the flap, either diffuse or in localized areas
- superficial punctate keratitis (13 eyes): surface irritation in the outer layer of the cornea
- peau d' orange (2 eyes): orange peel corneal appearance that typically does not affect vision
- flap distortion (1 eye): irregular appearance of the corneal flap
- vacuoles (1 eye): small round areas of cellular debris that typically does not affect vision
- conjunctival injection (2 eyes): increased redness of the blood vessels in the front of the eye

The following ocular findings were reported at 6 months (n=260) at a rate of 0.8%: blepharitis, retinal vessel tortuosity, and lattice degeneration with floaters.

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

Subjective Responses	Eyes Without Astigmatism		Eyes With Astigmatism	
	n/N	%	n/N	%
Difficulty with night driving	8/140	5.7	15/101	14.9
Glare	4/141	2.8	10/101	9.9
Halos*	5/141	3.5	7/101	6.9
Light sensitivity	4/141	2.8	6/101	5.9
Dryness	6/141	4.3	3/101	3.0
Fluctuation of vision	3/141	2.1	2/101	2.0
Blurring of vision	3/141	2.1	1/101	1.0
Redness	1/141	0.7	2/101	1.0
Headache	1/141	0.7	0/101	0.0
Double vision	1/139	0.7	0/101	0.0
Pain	0/141	0.0	0/101	0.0
Excessive tearing	0/141	0.0	0/100	0.0
Burning	0/141	0.0	0/100	0.0
Feeling of something in eye	0/141	0.0	0/101	0.0

\* Halos are circular flares or rings of light that may appear around a headlight or other lighted object.

## I. Are You A Good Candidate For PRK or LASIK ?

If you are considering PRK or 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 myopia between 0 to -10.0 diopters with no more than 4.0 diopters of astigmatism for PRK or have myopia less than -9.0D with less than -3.0D of astigmatism for LASIK
- Have documented evidence that the change in your nearsightedness is less than or equal to 0.50 diopter per year for corrections up to 7D, and less than or equal to 0.75D for corrections greater than 7D.
  - at least one year prior to your pre-operative exam
- Be able to lie flat without difficulty
- Be able to constantly look at a blinking light during the PRK or LASIK procedure
- Be able to tolerate eye drops to numb your eye and enlarge your pupil
- Be informed of PRK or LASIK risks and benefits as compared to other available treatments for myopia
- Be willing to sign an Informed Consent Form, if provided by your eye care professional

## **J. What Should You Expect During PRK or LASIK Surgery?**

PRK surgery is performed on one eye at a time. The second eye can be treated if all goes well and vision stabilizes in the first eye without complications or adverse reactions. Laser surgery of the second eye is usually done after the first eye if needed.

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 PRK or LASIK. This exam will help to determine if your eye is healthy and suitable for PRK or 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.

PRK surgery begins with removal of the outer layer of the cornea. Your doctor will remove this layer with a small spatula or a rotary brush. 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. For your eye protection and comfort, your doctor will cover your eye with a bandage contact lens in PRK. In some LASIK cases, a bandage contact lens is placed in your eye as well to help heal small abrasions. 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.

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.

A haze or cloudiness of the cornea will typically occur after PRK surgery. This haze usually does not affect vision. This haze tends to decrease over time and usually disappears completely over a 3 to 6 month period.

**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.

## **K. Questions To Ask Your Doctor**

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

- What are my other options to correct my nearsightedness?
- Will I have to limit my activities after surgery, and for how long?
- What are the benefits of PRK or LASIK for my amount of nearsightedness?
- What vision can I expect in the first few months after surgery?
- If PRK or 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 PRK or LASIK if I need them?
- How is PRK or 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 PRK or LASIK?
- Should I have PRK or 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 PRK or 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.		
2. Excimer laser surgery is the same as Radial Keratotomy (RK).		
3. It does not matter if I wear my contact lenses when my doctor told me not to wear them.		
4. Since the LADARVision <sup>®</sup> system tracks my eye movements, I do not have to fixate on the blinking light.		
5. After the surgery, there is a good chance that I will be less dependent on eye glasses.		
6. I may need reading glasses after laser surgery.		
7. There is a risk that I may lose some vision after laser surgery.		
8. It does not matter if I am pregnant.		
9. If I have an autoimmune disease, I am still a good candidate for PRK or LASIK.		

You can find the answers to Self-Test at the bottom of Page 26.

## **M. Summary Of Important Information?**

- PRK or LASIK are permanent operations to the cornea and are irreversible.
- PRK or LASIK do not eliminate the need for reading glasses, even if you never have worn them before.
- Your vision must be stable for at least one year before PRK or LASIK surgery. You will need written evidence that your nearsightedness has changed less than or equal to 0.50 Diopters.
- 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.
- PRK or 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.
- PRK or LASIK are not a laser version of Radial Keratotomy (RK). These surgeries are entirely different from each other.
- Alternatives to PRK or LASIK include, but are not limited to, glasses, contact lenses and RK.
- The vision requirements of some occupations, such as military pilots, cannot be met by having RK, PRK, or LASIK.
- Before considering PRK or LASIK surgery you should:
  - a. Have a complete eye examination.
  - b. Talk with one or more eye care professionals about PRK or LASIK. This talk should include the potential benefits, risks, and complications of PRK or LASIK surgery. In addition, you should discuss the time needed for healing after PRK or LASIK.

### Answers to Self-Test Questions:

1. False (see Risks on Page 16); 2. False (see Introduction on Page 10); 3. False (see Before the Surgery on Page 22); 4. False (see The Day of Surgery on Page 22); 5. True (see Benefits on Page 13); 6. True (see Introduction on Page 10); 7. True (see Risks on Page 16); 8. False (see Contraindications on Page 14); 9. False (see Contraindications on Page 14).

**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: \_\_\_\_\_

**PRK DOCTOR**

Name: \_\_\_\_\_

Address: \_\_\_\_\_

Phone: \_\_\_\_\_

**TREATMENT LOCATION**

Name: \_\_\_\_\_

Address: \_\_\_\_\_

Phone: \_\_\_\_\_

**LASER MANUFACTURER**

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