

# Alcon®

## LADARVISION®4000

Excimer Laser System

### FACTS YOU NEED TO KNOW ABOUT CustomCornea® LASER ASSISTED IN-SITU KERATOMILEUSIS (LASIK) SURGERY

#### PATIENT INFORMATION BOOKLET

For Nearsightedness (Myopia) up to -7D with less than -0.50D Astigmatism

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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## A. Introduction

The purpose of this booklet is to provide you with information on laser eye surgery. Please read this entire booklet carefully. See the “Glossary” (Section M) for an explanation of words shown in *italics*. Discuss your questions with a doctor trained in laser eye surgery. You need to understand the benefits and risks of this surgery before making a decision to have surgery.

You may have nearsightedness if you have trouble seeing objects clearly when they are far away. *Nearsightedness*, which is also called *myopia*, is a type of condition that causes blurred vision. Glasses, contact lenses, or eye surgery can correct nearsightedness and help you see distant objects more clearly.

The types of eye surgeries that are available to correct nearsightedness are *Radial Keratotomy* (RK), *Photorefractive Keratectomy* (PRK), and *Laser Assisted In-Situ Keratomileusis* (LASIK). These surgeries may not meet the vision requirements for some careers, such as military service.

Eye surgery can help you see more clearly by changing the shape of the front surface of your *cornea*, which is the clear layer at the front of your eye. RK uses a scalpel to make fine cuts in the cornea. PRK and LASIK use a laser to reshape the cornea. For LASIK, an instrument called a *microkeratome* first cuts a thin flap of tissue from the front of your cornea. This *corneal flap* is folded back and the laser removes tissue under the flap to change the shape of the front surface of your eye. Then the flap is put back in place for the eye to heal.

Your eyeglass prescription is the usual way to tell how nearsighted you are. Another way is to measure the shape of the *wavefront* of reflected light coming out of your eye. A wavefront measurement gives more information about your nearsightedness than an eyeglass prescription. A wavefront measures all of the *focusing errors* in your eye, including complex errors that eyeglasses cannot correct. These complex focusing errors are called “higher-order *aberrations*”.

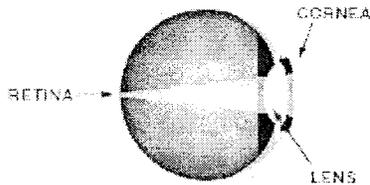
Your doctor can use either your eyeglass prescription or a wavefront measurement to plan LASIK surgery. LASIK surgery based on the eyeglass prescription is called *Conventional LASIK*. LASIK surgery based on the wavefront is called wavefront-guided *LASIK*. CustomCornea® LASIK is wavefront-guided surgery with the LADARVision® 4000 Excimer Laser System.

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

## B. How Does CustomCornea® LASIK Correct Nearsightedness (Myopia)?

You see objects because your eye focuses light into images. Your eye works like a camera. The camera lens focuses light to form clear images onto film. Both the cornea and lens in the eye focus light onto the back surface of the eye, called the *retina*. Diagram 1 shows that distant vision is clear when light focuses correctly.

**DIAGRAM 1: NORMAL EYE**

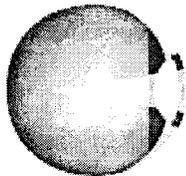


**Light focuses on the retina.  
Vision is clear.**

A NORMAL EYE

Nearsightedness is a type of focusing error that results in blurry distant vision. Light from a distant object focuses in front of the retina, rather than on the retina. Diagram 2 shows that distant vision is blurry when light focuses incorrectly in a nearsighted eye.

**DIAGRAM 2: NEARSIGHTED EYE**

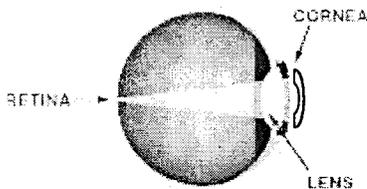


**Light focuses in front of the retina. Vision is blurry.**

A NEARSIGHTED or MYOPIC EYE

Wearing glasses and contact lenses help your eye focus light properly on the retina. LASIK surgery focuses light properly by reshaping the cornea. LASIK surgery uses an *excimer laser* to remove a tiny amount of tissue from the cornea. This type of laser does not change any other parts of the eye. Diagram 3 shows that distant vision is clearer after LASIK.

**DIAGRAM 3: CORRECTION OF VISION AFTER LASIK**



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

CustomCornea® LASIK uses the wavefront to guide the laser in reshaping the cornea to correct focusing errors. The doctor measures the wavefront by projecting light into your eye and measuring the reflected light that comes out.

The LADARVision® 4000 system uses a very small laser beam to reshape the cornea. To correct for nearsightedness, the cornea receives hundreds to thousands of laser pulses during LASIK surgery. The system must place the laser pulses accurately to precisely reshape the cornea. Precise shaping of the cornea requires tracking and compensating for eye movement during surgery.

Your eyes are constantly making small movements. Some of these movements are involuntary and you do not notice them. You cannot hold your eye perfectly still even if you try. The LADARVision® 4000 system tracks and adjusts for eye movement during surgery. A high-speed active eye tracking system, called the LADARTracker®, measures the eye position 4000 times a second.

In a clinical study<sup>1</sup>, eye movement during surgery using the LADARVision® 4000 system was evaluated for 554 eyes. This study showed that:

- All eyes moved during surgery.
- The LADARTracker® system adjusted for this eye movement. The results of the surgery were about the same for eyes with large or small eye movements.
- Active eye tracking with LADARTracker® system improves the accuracy of corneal shaping.

Without a system to track eye movements, any movement of the eye during surgery could move it away from its correct position under the laser beam. Before each laser pulse, the LADARTracker® system calculates where the eye has moved since the last pulse and moves the beam in exactly the same way, so the laser beam hits the cornea in the same place as if the eye had not moved.

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<sup>1</sup> LADARVision® System PRK Myopia and Astigmatism study

**C. What Are the Benefits of CustomCornea® LASIK?**

CustomCornea® LASIK surgery can correct up to  $-7$  diopters (D) of nearsightedness with less than  $-0.50D$  of astigmatism. If you have nearsightedness within this range, CustomCornea® LASIK surgery may allow you to see clearly at long distances without eyeglasses or contact lenses.

**Clinical Study to Evaluate Benefits**

A clinical study was done to evaluate the benefits and risks of CustomCornea® LASIK. The study included 139 eyes to determine benefits and 426 eyes to determine risks. The study results are shown below and in “What are the Risks of CustomCornea® LASIK” (Section D).

**Study Patient Demographics**

Most patients were Caucasian. No patients were over 65 years old. Table 1 shows the age, race, gender and contact lens history of patients in the study.

Table 1. Demographics of 426 Eyes of 264 Study Patients						
Age	Race		Gender		Contact Lens History	
Average: $38 \pm 8$ years Range: 20 to 64 years	Asian	2.3%	Female	43.2%	None	22.8%
	Black	0.2%	Male	56.8%	Hard	4.7%
	Caucasian	96.5%			Soft	72.5%
	Other*	0.9%				

\*2 eyes (1 patient) Philippino; 2 eyes (1 patient) Guyanese.

### Visual Acuity *without* Glasses After Surgery

*Visual acuity* measures the sharpness of vision using a letter chart. Table 2 shows that at least 98% of study patients saw 20/40 or better **without** glasses after surgery. Most states require that your vision be 20/40 or better if you drive **without** any glasses or contact lenses.

<b>Table 2. Visual Acuity <i>without</i> Glasses After Surgery (N=139)</b>			
<b>Time after Surgery</b>	<b>1 Month</b>	<b>3 Months</b>	<b>6 Months</b>
% of eyes with 20/20 or better	86%	81%	80%
% of eyes with 20/25 or better	94%	94%	91%
% of eyes with 20/40 or better	99%	98%	99%

### Visual Acuity *without* Glasses After Surgery and *with* Glasses Before Surgery

Table 3 shows that about half of the patients saw as well **without** glasses after CustomCornea<sup>®</sup> surgery as **with** glasses before surgery.

<b>Table 3. Visual Acuity <i>without</i> Glasses After Surgery Compared to <i>with</i> Glasses Before Surgery (N=139)</b>			
<b>Time after Surgery</b>	<b>1 Month</b>	<b>3 Months</b>	<b>6 Months</b>
% of Eyes 2 Lines Better	2.2%	1.4%	2.2%
% of Eyes 1 Line Better	12.2%	13.7%	15.1%
% of Eyes Equal	44.6%	40.3%	35.3%
% of Eyes 1 Line Worse	26.6%	23.7%	23.7%
% of Eyes 2 Lines Worse	8.6%	11.5%	14.4%
% of eyes >2 Lines Worse	5.8%	9.4%	9.4%

After surgery, 95.6% of patients at 3 months and 94.1% at 6 months did not wear glasses or contact lenses.

## Patient Symptoms After Surgery

Patients rated the change in the following symptoms after surgery. Table 4 shows that more than half of the patients reported that their symptoms were the same 3 and 6 months after CustomCornea® LASIK surgery as before surgery.

<b>Table 4. Comparison of Symptoms Before and After Surgery</b>					
<b>Symptom</b>	<b>Significantly Better</b>	<b>Better</b>	<b>No Change</b>	<b>Worse</b>	<b>Significantly Worse</b>
<b>3 Months (N=137)</b>					
Blurring of Vision	6.6%	12.4%	58.4%	21.2%	1.5%
Burning	2.2%	6.6%	84.7%	5.8%	0.7%
Double Vision	0.7%	0.0%	91.2%	7.3%	0.7%
Dryness*	5.9%	17.0%	48.1%	21.5%	7.4%
Excessive Tearing	0.7%	8.0%	91.2%	0.0%	0.0%
Fluctuation of Vision	2.2%	11.7%	60.6%	24.1%	1.5%
Glare	1.5%	13.1%	68.6%	16.8%	0.0%
Gritty Feeling	5.1%	9.5%	73.7%	10.9%	0.7%
Halos†	2.9%	12.4%	65.0%	19.0%	0.7%
Headache	2.9%	5.8%	86.1%	5.1%	0.0%
Light Sensitivity	0.0%	13.9%	78.1%	7.3%	0.7%
Night Driving Difficulty	5.1%	12.4%	65.0%	13.9%	3.6%
Pain	2.9%	3.6%	88.3%	5.1%	0.0%
Redness	3.6%	13.1%	75.2%	8.0%	0.0%
<b>6 Months (N=136)</b>					
Blurring of Vision	7.4%	11.0%	62.5%	16.2%	2.9%
Burning	2.9%	10.3%	79.4%	5.9%	1.5%
Double Vision	1.5%	3.7%	88.2%	5.9%	0.7%
Dryness	8.1%	12.5%	56.6%	20.6%	2.2%
Excessive Tearing*	1.5%	5.2%	93.3%	0.0%	0.0%
Fluctuation of Vision	3.7%	7.4%	71.3%	16.9%	0.7%
Glare	2.9%	12.5%	69.9%	14.7%	0.0%
Gritty Feeling	8.1%	8.8%	72.8%	8.8%	1.5%
Halos †	5.1%	6.6%	75.0%	13.2%	0.0%
Headache	2.9%	5.9%	89.7%	1.5%	0.0%
Light Sensitivity	3.7%	10.3%	81.6%	4.4%	0.0%
Night Driving Difficulty	6.6%	12.5%	61.8%	18.4%	0.7%
Pain	4.4%	5.9%	89.0%	0.7%	0.0%
Redness	4.4%	16.2%	73.5%	5.9%	0.0%

\*N=135 eyes

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

## D. What Are the Risks of CustomCornea® LASIK?

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

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

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

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

### During the first week following surgery

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

### During one to three months following surgery

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

**Clinical Study to Evaluate Risks**

In the clinical study on CustomCornea® LASIK, vision **without** glasses improved for all eyes. Some people still needed glasses or contact lenses after surgery.

**Visual Acuity *with* Glasses After Surgery**

Table 5 shows that all patients from the study saw 20/32 or better **with** glasses at 3 and 6 months.

<b>Table 5. Visual Acuity <i>with</i> Glasses (Best Vision) After Surgery</b>				
	<b>Nearsightedness</b>		<b>Nearsightedness With Astigmatism</b>	
	<b>3 Months (N=139)</b>	<b>6 Months (N=139)</b>	<b>3 Months (N=426)</b>	<b>6 Months (N=424)</b>
20/20 or better	100%	100%	99.8%	99.5%
20/25 or better	100%	100%	100%	99.8%
20/32 or better	100%	100%	100%	100%

**Change in Visual Acuity *with* Glasses After Surgery**

Under dim room lighting conditions, the best vision with glasses was measured using a standard (high-contrast) visual acuity chart and a 10% *low contrast visual acuity* chart. A standard chart has black letters on a white background. A 10% low contrast visual acuity chart has gray letters on a white background. Black letters are easier to see than gray letters. Low contrast acuity testing is another way to determine how well patients can see in poor contrast conditions such as very dim light, rain, snow, and fog. Table 6 compares the change in vision **with** glasses at 3 and 6 months before and after surgery for the patients from the clinical study.

<b>Table 6. Change in Visual Acuity <i>with</i> Glasses After Surgery Compared to Before Surgery (N=139)</b>				
	<b>Standard Chart</b>		<b>10% Low Contrast Chart</b>	
	<b>3 Months</b>	<b>6 Months</b>	<b>3 Months</b>	<b>6 Months</b>
% of eyes with loss of more than 2 lines	0.0%	0.0%	0.0%	0.0%
% of eyes with loss of 2 lines	1.4%	0.0%	7.2%	2.2%
% of eyes with loss of 1 line	15.1%	8.6%	15.1%	18.7%
% of eyes with no change	52.5%	53.2%	42.4%	40.3%
% of eyes with gain of 1 line	28.8%	35.3%	30.2%	30.2%
% of eyes with gain of 2 lines	2.2%	2.9%	4.3%	6.5%
% of eyes with gain of more than 2 lines	0.0%	0.0%	0.7%	2.2%

## Adverse Events and Complications

Some patients from the clinical study experienced adverse events and complications after CustomCornea<sup>®</sup> LASIK surgery as shown below.

Greater than or equal to 1% of eyes (N=426) had:

- *Inflammation* of the cornea under the flap 3.5%
- Cells growing under the flap 3.3%
- Double or ghost images 2.1%
- *Corneal swelling* between 1 week and 1 month 1.9%

Less than or equal to 1% of eyes (N=426) had:

- Inflammation under the flap and of the eyelids 0.5%
- Feeling of something in the eye at 1 month or later 0.5%
- *Corneal wrinkle* in the flap 0.5%
- Irregular flap creation with the microkeratome 0.2%
- Scratch on the surface of the eye with the microkeratome 0.2%
- Local inflammation under the flap 0.2%
- Inflammation of the outer lining of the eye 0.2%
- Tear in the retina at 6 months (unrelated to the device) 0.2%
- Pain at 1 month or later 0.2%

In addition, two systemic adverse events were unrelated to the device or the CustomCornea<sup>®</sup> LASIK surgery. These events were a death of one patient due to colon cancer and the diagnosis of multiple sclerosis in another patient after the 3-month visit.

## Worse and Significantly Worse Patient Symptoms After Surgery

Some symptoms were reported as worse or significantly worse after CustomCornea® LASIK surgery than before surgery (Table 7). A complete listing of the patient symptoms is detailed in “What Are the Benefits of CustomCornea® LASIK” (Section C).

<b>Table 7. Comparison of Symptoms Before and After Surgery</b>		
<b>Symptom</b>	<b>Worse</b>	<b>Significantly Worse</b>
<b>3 Months after Surgery (N=137)</b>		
Blurring of Vision	21.2%	1.5%
Burning	5.8%	0.7%
Double Vision	7.3%	0.7%
Dryness*	21.5%	7.4%
Excessive Tearing	0.0%	0.0%
Fluctuation of Vision	24.1%	1.5%
Glare	16.8%	0.0%
Gritty Feeling	10.9%	0.7%
Halos†	19.0%	0.7%
Headache	5.1%	0.0%
Light Sensitivity	7.3%	0.7%
Night Driving Difficulty	13.9%	3.6%
Pain	5.1%	0.0%
Redness	8.0%	0.0%
<b>6 Months after Surgery (N=136)</b>		
Blurring of Vision	16.2%	2.9%
Burning	5.9%	1.5%
Double Vision	5.9%	0.7%
Dryness	20.6%	2.2%
Excessive Tearing*	0.0%	0.0%
Fluctuation of Vision	16.9%	0.7%
Glare	14.7%	0.0%
Gritty Feeling	8.8%	1.5%
Halos	13.2%	0.0%
Headache	1.5%	0.0%
Light Sensitivity	4.4%	0.0%
Night Driving Difficulty	18.4%	0.7%
Pain	0.7%	0.0%
Redness	5.9%	0.0%

\*N=135 eyes

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

## E. Contraindications

You should **NOT** have wavefront-guided LASIK surgery if you:

- are pregnant or nursing.
- show signs of *keratoconus*. (This is a condition of the cornea that results in a change in the shape of the cornea.)
- are taking medications with ocular side effects [for example, Isotretinoin (Accutane<sup>2</sup>) and Amiodarone hydrochloride (Cordarone<sup>3</sup>)]
- have a *collagen vascular, autoimmune, or immunodeficiency disease*. [These are conditions that affect your immune response (your body's ability to heal), or result in inflammation or swelling of parts of the body, such as muscles, joints, and blood vessels. Examples are AIDS, lupus, , and rheumatoid arthritis.]

## F. Warnings

Discuss with your doctor if you have:

- diabetes.
- severe allergies.
- significant dry eye that is unresponsive to treatment.
- a history of *herpes simplex* or *herpes zoster* infection that has affected your eyes.

You will need eye drops to enlarge your pupil to at least 7mm to 11mm before surgery so the tracking system can more easily follow your eye during surgery. This effect of eye drops is only temporary.

## G. Precautions

The safety and effectiveness of LADARVision®4000 System for wavefront-guided LASIK have **NOT** been established in patients:

- with unstable or worsening nearsightedness.
- with disease or corneal condition (for example, scar, infection, etc.).
- with injury to the center of the cornea where wavefront-guided LASIK will reshape the cornea.
- with previous surgery on the cornea or inside the eye (for example, cataract surgery).
- with prior history of surgery to correct vision (for example, RK, PRK, LASIK).
- with a cornea that is too thin for LASIK to be completed safely.

<sup>2</sup> Accutane Reg TM of Hoffmann-LaRoche, Inc.

<sup>3</sup> Cordarone Reg TM of Sanofi Corp.

- with a history of *glaucoma* (a condition usually associated with high eye pressure with damage to the nerve in the eye and possible loss of vision).
- who are taking the medication Sumatriptin (Imitrex<sup>4</sup>).
- under 21 or over 65 years of age.
- over the long term (more than 6 months).
- with greater than 7D of nearsightedness with less than –0.50D of astigmatism.
- for retreatment with CustomCornea® LASIK.

Before surgery, your doctor should measure your pupil size under dim lighting conditions. If your pupils in dim light are  $\geq 6.5\text{mm}$ , consult with your doctor about the risk that the surgery may cause negative effects on your vision, such as glare, halos, and night driving difficulty.

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

There were not enough patients in the clinical study with more than –6D of nearsightedness to determine the effectiveness and complication rates of CustomCornea® LASIK with the same reliability as for eyes with less than –6D of nearsightedness.

In the clinical study, contrast sensitivity was measured in daylight and in dim light to determine how well patients can see in poor contrast conditions such as very dim light, rain, snow, and fog. The results are shown below.

Under daylight testing conditions, contrast sensitivity after CustomCornea® LASIK surgery as compared to before surgery showed a:

- gain in 4.3% of patients at 3 months and 2.2% at 6 months.
- loss in 2.2% of patients at 3 months and 0.7% at 6 months.

Under dim light testing conditions, contrast sensitivity after CustomCornea® LASIK surgery as compared to before surgery showed a:

- gain in 10.1% of patients at 3 months and 15.2% at 6 months.
- loss in 5.8% of patients at 3 months and 5.8% at 6 months.

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<sup>4</sup> Imitrex Reg TM of Glaxo Group Limited

## H. Are You A Good Candidate For CustomCornea<sup>®</sup> LASIK?

If you are considering CustomCornea<sup>®</sup> LASIK, you must:

- be at least 21 years of age.
- have a healthy eye with no eye disease or corneal condition (for example, scar, infection, etc.).
- have up to  $-7D$  of nearsightedness with less than  $-0.50D$  of astigmatism.
- have less than or equal to  $0.50D$  change each year in your nearsightedness for at least one year before your eye examination before surgery.
- be able to lie flat on your back.
- be able to look at a blinking fixation light during the entire surgery.
- be able to have eye drops that numb your eye and enlarge your pupil.
- understand the risks and benefits of CustomCornea<sup>®</sup> LASIK compared to other available treatments for nearsightedness.
- be willing to sign an Informed Consent Form, if provided by your doctor.

## I. What Should You Expect During CustomCornea<sup>®</sup> LASIK Surgery?

### Before The Surgery

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

**WARNING:** You must stop wearing any contact lenses at least 3 weeks before this eye examination. Failure to do this may affect surgical results.

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

### The Day Of Surgery

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

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

An instrument called the microkeratome creates a flap of tissue in the cornea. Then, your doctor will reposition your head and activate the LADARTracker® system to track your eye movement. Your doctor will ask you to look directly at the blinking light. The laser in the LADARVision®4000 system will remove small amounts of tissue from your cornea. During the laser treatment, you will hear a “clicking” sound of laser pulses. The tracking system will follow eye movements and allow the laser to continue the treatment. **Still, you MUST continue looking at the blinking light throughout the treatment, even if your vision begins to become cloudy during the procedure.** You will be under the laser for several minutes. The use of the laser will take about one minute. Overall, the surgery takes about 10 minutes.

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

### The First Days After Surgery

You may be mildly sensitive to light and have a feeling that something is in your eye. Sunglasses may make you more comfortable. Also, your eye may hurt. Your doctor can prescribe pain medication to make you more comfortable during the first few days after the surgery. A plastic shield may be used to protect your eye after LASIK. You will need to use lubricants, *antibiotic*, and *anti-inflammatory medications* in the first few days.

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

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

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

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

## J. Questions To Ask Your Doctor

You may want to ask the following questions to help you decide if CustomCornea® LASIK with the LADARVision®4000 System 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 CustomCornea® LASIK for my amount of nearsightedness?
- What vision can I expect in the first few months after surgery?
- If CustomCornea® 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 CustomCornea® LASIK if I need them?
- How is CustomCornea® 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 CustomCornea® LASIK?
- Should I have CustomCornea® 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 CustomCornea® LASIK only on one eye?
- Do I have significant dry eye or large pupils that could produce undesirable side effects and decrease my satisfaction after surgery?

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

**K. Self-Test****Are You An Informed And Educated Patient?**

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

	TRUE	FALSE
1. Excimer laser surgery is risk-free.	<input type="checkbox"/>	<input type="checkbox"/>
2. Excimer laser surgery is the same as Radial Keratotomy (RK).	<input type="checkbox"/>	<input type="checkbox"/>
3. It does not matter if I wear my contact lenses before surgery when my doctor told me not to wear them.	<input type="checkbox"/>	<input type="checkbox"/>
4. Since the LADARVision®4000 system tracks my eye movements, I do not have to fixate on the blinking light.	<input type="checkbox"/>	<input type="checkbox"/>
5. After the surgery, there is a good chance that I will depend less on eyeglasses or contact lenses.	<input type="checkbox"/>	<input type="checkbox"/>
6. I may need reading glasses after LASIK surgery, even if I did not need them before.	<input type="checkbox"/>	<input type="checkbox"/>
7. There is a risk that I may lose some vision after LASIK surgery.	<input type="checkbox"/>	<input type="checkbox"/>
8. It does not matter if I am pregnant.	<input type="checkbox"/>	<input type="checkbox"/>
9. If I have an autoimmune disease, I am still a good candidate for LASIK surgery.	<input type="checkbox"/>	<input type="checkbox"/>
10. Significant dry eye or large pupils may produce undesirable side effects and decrease my satisfaction after LASIK surgery.	<input type="checkbox"/>	<input type="checkbox"/>

You can find the answers to Self-Test at the bottom of the next page.

## L. Summary Of Important Information

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

### Answers to Self-Test Questions:

- |  |   |
|--|---|
| 1. False (see Section D: Risks)              | 6. True (see Section D: Risks)              |
| 2. False (see Section A: Introduction)       | 7. True (see Section D: Risks)              |
| 3. False (see Section I: Before the Surgery) | 8. False (see Section E: Contraindications) |
| 4. False (see Section I: The Day of Surgery) | 9. False (see Section E: Contraindications) |
| 5. True (see Section C: Benefits)            | 10. True (see Section G: Precautions)       |

## M. Glossary

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

**Aberration:** focusing errors in the eye detectable by wavefront measurements. Examples are nearsightedness and astigmatism (lower-order) and complex errors (higher-order).

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

**Anti-inflammatory Medication:** a drug that reduces inflammation or the body's reaction to injury or disease. Any eye surgery can cause inflammation. Your doctor may prescribe this medication after LASIK surgery.

**Astigmatism:** a focusing error that results in blurred distant and/or near vision. The cornea is more curved in some directions than others, and causes light rays to focus at different points inside the eye. Parts of objects appear clearer than other parts.

**Autoimmune Disease:** a condition in which the body attacks itself and results in inflammation or swelling of parts of the body, such as muscles, joints, and blood vessels. If you have this type of condition, you should not have LASIK surgery.

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

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

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

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

**Contrast Sensitivity:** a measure of the ability of the eye to detect small lightness differences between objects and the background in daylight and in dim light. For example, black lines on a gray background are easier to see than gray lines on a gray background. Objects in daylight are also easier to see than in dim light. Contrast sensitivity testing is a way to determine how well patients can see in poor contrast conditions such as very dim light, rain, snow, and fog.

**Conventional LASIK:** LASIK surgery that uses an eyeglass prescription to plan the surgery.

**Cornea:** the clear front layer of the eye. Surgery such as PRK, LASIK and RK reshapes the front surface of the cornea to improve distant vision.

**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 shapes the inner layers of the cornea.

**Corneal Swelling:** abnormal fluid build-up in the cornea. This condition is usually temporary with no significant effect on vision.

**Corneal Wrinkle:** temporary appearance of fine white lines in the cornea due to swelling.

**CustomCornea® LASIK:** LASIK surgery that uses the wavefront to plan the surgery.

**Diopter:** a unit of focusing power, used to describe the amount of nearsightedness and astigmatism of an eye. Abbreviated as “D”.

**Excimer Laser:** a type of laser used in conventional and CustomCornea® LASIK to remove tissue from the cornea.

**Focusing Error:** a condition in which your eye forms a blurred image on your retina. Examples are nearsightedness, astigmatism, and higher-order aberrations (complex focusing errors).

**Glaucoma:** an eye disease usually associated with high eye pressure. Glaucoma damages the optic nerve of the eye and usually causes a progressive loss of vision.

**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 viral infection that can recur. This virus typically causes cold sores and/or vesicles to appear on the face or other parts of the body. You should discuss any history of this condition with your doctor before having LASIK surgery.

**Herpes Zoster:** a type of viral infection that can recur. This condition is a reactivation of the chicken pox virus as an adult. Vesicles appear on only one side of the body. You should discuss any history of this condition with your doctor before having LASIK surgery.

**Immunodeficiency Disease:** a condition that compromises the body’s ability to heal. An example is acquired immunodeficiency syndrome (AIDS). If you have this type of condition, you should not have LASIK surgery.

**Inflammation:** the body’s reaction to injury or disease. Eye surgery, such as PRK and LASIK, can cause inflammation.

**Keratoconus:** a condition of the cornea that results in a change in the shape of the cornea with thinning. If you have this condition, you should not have LASIK surgery.

**Laser Assisted In-Situ Keratomileusis (LASIK):** a type of eye surgery that uses a microkeratome and a laser to improve vision. The microkeratome creates a thin, hinged flap of tissue on the cornea and folded back. The laser shapes the tissue under the flap and the flap is put back on the eye so the tissue heals.

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

**Low Contrast Visual Acuity:** a measure of the sharpness of vision using a 10% low contrast chart with gray letters on a white background. Low contrast acuity testing is another way to determine how well patients can see in poor contrast conditions such as very dim light, rain, snow, and fog.

**Microkeratome:** a surgical instrument used in LASIK to cut a thin flap of tissue from the front surface of the eye before the laser treatment is applied.

**Myopia:** a focusing error that results in blurrier vision at distance than near. Myopia is also called nearsightedness.

**Nearsightedness:** a focusing error that results in blurrier vision at distance than near. Nearsightedness is also called myopia.

**Ocular Hypertension:** increased eye pressure.

**Photorefractive Keratectomy (PRK):** a type of eye surgery that uses an excimer laser to reshape the front surface of the eye to improve vision. After the epithelium (outermost layer) of the cornea is first scraped away, the laser removes tissue from the exposed surface. After the surgery, the epithelium grows back.

**Radial Keratotomy (RK):** a type of eye surgery that changes the shape of the front surface of the eye by making a special pattern of cuts in the cornea to correct nearsightedness.

**Retina:** the layer of nerve tissue at the back of the eye that captures images, similar to film in a camera, and sends information about those images to the brain. Light must be focused correctly on the retina to form clear images.

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

**Visual Acuity:** a measure of the sharpness of vision using a letter chart.

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

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

CustomCornea® LASIK Doctor

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

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

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

Treatment Location

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

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

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

Laser Manufacturer

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