

# Alcon®

## LADAR6000™

EXCIMER LASER

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

#### PATIENT INFORMATION BOOKLET

For Mixed Astigmatism of 1.00D to less than 5.00D cycloplegic cylinder magnitude

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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### REVISION CONTROL SHEET

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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 J) 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.

*Mixed astigmatism* is a condition that causes blurred distant and near vision because the eye is both *nearsighted* and *farsighted*. If you have mixed astigmatism, you may have difficulty seeing clearly at distance and near. Glasses, contact lenses, or eye surgery can correct mixed astigmatism to help you see more clearly.

*Laser Assisted In-Situ Keratomileusis (LASIK)* is a type of eye surgery available to correct mixed astigmatism. Other eye surgeries that may be an option to correct vision are *Automated Lamellar Keratoplasty (ALK)* and *Radial Keratotomy (RK)*. These surgeries may not meet the vision requirements for some careers, such as military service.

LASIK surgery can help you see more clearly by changing the shape of the *cornea*, the clear front surface of your eye. LASIK surgery uses an *excimer laser* to remove tissue to reshape the cornea. 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 cornea. Then the flap is put back in place for the eye to heal.

Your eyeglass prescription is the usual way to tell how much mixed astigmatism you have. 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 mixed astigmatism 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*”.

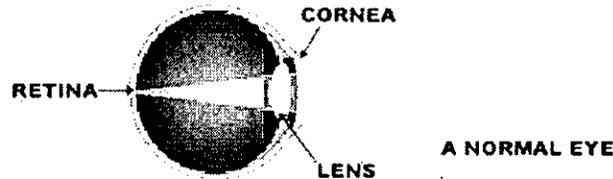
Your doctor can use either your eyeglass prescription or a wavefront measurement to plan LASIK surgery. LASIK surgery based on the eyeglass prescription is called *Conventional LASIK*. LASIK surgery based on the wavefront is called wavefront-guided LASIK. *CustomCornea® LASIK* is wavefront-guided surgery with the LADAR6000™ Excimer Laser System or the LADARVision®4000 System. The LADARVision®4000 System and LADAR6000™ System have comparable functions. Clinical studies done with the LADARVision®4000 System are applicable to the LADAR6000™ 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 Mixed Astigmatism?**

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 on film. Both the cornea and lens in the eye focus light on the *retina*, the back surface of your eye. Diagram 1 shows that distant vision is clear when light focuses correctly.

**DIAGRAM 1: NORMAL EYE**



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

Astigmatism is a focusing error that results in blurred distant and near vision. The cornea is more curved in some directions than others causing light to focus at different points from the retina. Vision is blurred because light does not focus correctly on the retina. When light focuses at a point in front of the retina, the eye is nearsighted. When light focuses at a point behind the retina, the eye is farsighted. An eye with mixed astigmatism is both nearsighted and farsighted. Diagram 2 shows how light focusing at different points from the retina causes blurred vision in an eye with mixed astigmatism.

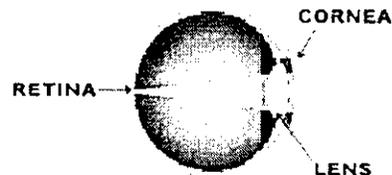
**DIAGRAM 2: EYE WITH MIXED ASTIGMATISM**



**Light focuses in front of and  
behind the retina.  
Vision is blurred.**

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 clear.**

CustomCornea® LASIK uses a wavefront unique to your eye for treatment. This wavefront is used to guide the laser that reshapes 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 of your eye.

The LADAR6000™ System uses a very small laser beam to reshape the cornea. To correct for mixed astigmatism, 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 LADAR6000™ System tracks and adjusts for eye movement during surgery. A high-speed active eye tracking system, called the LADARTracker® system, measures the eye position 4000 times a second.

In a clinical study<sup>1</sup>, eye movement during surgery using the LADARVision® 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 the 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. Benefits of CustomCornea® LASIK**

CustomCornea® LASIK surgery can correct between 1.00 to less than 5.00 *diopters (D)* of mixed astigmatism. If you have mixed astigmatism within this range, CustomCornea® LASIK surgery may help you clearly see distant objects without eyeglasses or contact lenses.

**Clinical Study to Evaluate Benefits**

A clinical study using the LADARVision®4000 System was done to evaluate the benefits and risks of CustomCornea® LASIK. The study included 110 eyes to determine benefits and risks. The study results are shown below and in “Risks of CustomCornea® LASIK” (Section D).

**Patient Demographics**

Table 1 shows the age, race, gender, and contact lens history of patients in the study.

Table 1. Demographics of 110 Eyes of 63 Study Patients						
Age	Race		Gender		Contact Lens History	
Average: 40.6 ± 10.7 years	Caucasian	94.5%	Female	53.6%	None	64.5%
Range: 20 to 60 years	Hispanic	3.6%	Male	46.4%	Hard	2.7%
	Indian	1.8%			Soft	32.7%

**Visual Acuity Measurement**

*Visual acuity* is a measure of the sharpness of vision using a letter chart. Diagram 4 shows an example of a visual acuity chart consisting of lines of letters. Each line of letters becomes smaller from top to bottom on the chart. Vision is sharper as smaller letters are correctly read from top to bottom. The chart is read at a distance to measure the sharpness of distant vision. Visual acuity is shown by two numbers: the first number is the distance and the second number is the smallest line of letters read correctly. As the second number becomes smaller, the vision is sharper. For example, a smaller line of letters is read correctly for a visual acuity of 20/20 compared to 20/40.

**DIAGRAM 4: EXAMPLE OF VISUAL ACUITY CHART**



### Visual Acuity without Glasses

The clinical study evaluated visual acuity **without** glasses at a distance using a letter chart. Table 2 shows that at least 93.5% of patients treated for mixed astigmatism 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.

Table 2. Visual Acuity without Glasses					
% of Eyes With:	Before Surgery (N=110)	1 Month (N=110)	3 Months (N=110)	6 Months (N=110)	9 Months (N=108)
20/20 or better*	1.1%	72.3%	63.8%	71.3%	69.6%
20/20 or better	0.9%	63.6%	56.4%	63.6%	61.1%
20/25 or better	3.6%	86.4%	80.9%	87.3%	84.3%
20/40 or better	35.5%	96.4%	95.5%	98.2%	93.5%

\* if visual acuity was 20/20 or better with glasses or contact lenses before surgery  
(N=94 eyes at all visits up to 6 months; N=92 at 9 months). N is the number of eyes studied.

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

The clinical study compared visual acuity **without** glasses at a distance after surgery to visual acuity **with** glasses before surgery using a letter chart. Table 3 shows that 56.4% of patients at 3 months and 60.0% at 6 months, saw as well or better **without** glasses after CustomCornea® surgery as **with** glasses before surgery.

Table 3. Visual Acuity without Glasses After Surgery Compared to with Glasses Before Surgery				
% of Eyes With:	1 Month (N=110)	3 Months (N=110)	6 Months (N=110)	9 Months (N=108)
2 lines better vision <i>without</i> glasses after LASIK than vision <i>with</i> glasses before surgery	0.0%	0.0%	1.8%	1.9%
1 line better vision <i>without</i> glasses after LASIK than vision <i>with</i> glasses before surgery	11.8%	16.4%	17.3%	18.5%
same vision* <i>without</i> glasses after LASIK as vision <i>with</i> glasses before surgery	48.2%	40.0%	40.9%	39.8%
1 line worse vision <i>without</i> glasses after LASIK than vision <i>with</i> glasses before surgery	23.6%	19.1%	26.4%	19.4%
2 lines worse vision <i>without</i> glasses after LASIK than vision <i>with</i> glasses before surgery	8.2%	11.8%	6.4%	10.2%
more than 2 lines worse vision <i>without</i> glasses after LASIK than vision <i>with</i> glasses before surgery	8.2%	12.7%	7.3%	10.2%

\* Same vision is within 2 or 3 letters on the same line of a visual acuity chart.  
N is the number of eyes studied.

### ***Patient Demographics and Surgery Outcomes***

Patient demographics were related to the following surgery outcomes in the clinical study at **3 months after surgery**.

- A visual acuity of 20/20 or better without glasses or contact lenses after surgery was more likely in younger patients and patients with lower amounts of astigmatism before surgery. A visual acuity of 20/40 or better without glasses or contact lenses after surgery was more likely in younger patients.
- Reduction of farsightedness or nearsightedness to 0.50D or less after surgery was more likely in younger patients, Caucasian patients\* and patients with lower amounts of astigmatism before surgery. Reduction of farsightedness or nearsightedness to 1.00D or less after surgery was more likely in patients with lower amounts of astigmatism before surgery.
- Reduction of astigmatism to 0.50D or less after surgery was more likely in patients with lower amounts of astigmatism before surgery. Reduction of astigmatism to 1.00D or less after surgery was more likely in females, Caucasian patients\* and patients with lower amounts of astigmatism before surgery.

Patient demographics were related to the following surgery outcomes in the clinical study at **6 months after surgery**.

- A visual acuity of 20/20 or better without glasses or contact lenses after surgery was more likely in patients with lower amounts of astigmatism before surgery.
- Reduction of farsightedness or nearsightedness to 0.50D or less after surgery was more likely in younger patients, Caucasian patients\* and patients with lower amounts of astigmatism before surgery. Reduction of farsightedness or nearsightedness to 1.00D or less after surgery was more likely in younger patients and patients with lower amounts of astigmatism before surgery.
- Reduction of astigmatism to 1.00D or less after surgery was more likely in females and patients with lower amounts of astigmatism before surgery.

Note that the clinical study included only 5.5% of patients of races other than Caucasian.

### ***Patient Questionnaire***

Patients in the clinical study were asked to rate the quality of vision after surgery compared to their recollection of quality of vision before surgery. Table 4 shows that compared to before surgery, quality of vision without glasses or contact lenses at 6 months after surgery was reported as better or significantly better in 86.3% of eyes, same in 4.5% and worse or significantly worse in 9.1%.

<b>Table 4. Quality of Vision <i>without</i> Glasses or Contact Lenses After Surgery Compared to Before Surgery*</b>		
	<b>3 MONTHS N=108</b>	<b>6 MONTHS N=110</b>
Significantly Better	54.6%	52.7%
Better	28.7%	33.6%
Same	7.4%	4.5%
Worse	7.4%	5.5%
Significantly Worse	1.9%	3.6%

N is the number of eyes studied.

\* Based on the patients' comparison of quality of vision after surgery as better or worse compared to their recollection of quality of vision before surgery.

Table 5 shows that satisfaction with surgery at 6 months was reported as satisfied or extremely satisfied in 73.7% of eyes, unsure in 10.9%, and unsatisfied or extremely unsatisfied in 15.4%.

<b>Table 5. Satisfaction with Surgery</b>		
	<b>3 MONTHS N=108</b>	<b>6 MONTHS N=110</b>
Extremely Satisfied	47.2%	48.2%
Satisfied	26.9%	25.5%
Not Sure	15.7%	10.9%
Unsatisfied	6.5%	11.8%
Extremely Unsatisfied	3.7%	3.6%

N is the number of eyes studied.

Table 6 shows that frequency of wearing glasses or contact lenses for distance vision at 6 months was reported as never in 81.8% of eyes and at least some of the time in 18.2% with frequent or constant use in 11.8%.

<b>Table 6. Frequency of Glasses or Contact Lens Wear for Distance After Surgery</b>		
	<b>3 MONTHS N=108</b>	<b>6 MONTHS N=110</b>
Never	85.2%	81.8%
Seldom	3.7%	6.4%
Frequently	1.9%	1.8%
Constantly	9.3%	10.0%

N is the number of eyes studied.

#### D. 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® LASIK retreatments.

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**IMPORTANT:** You may need to wear glasses or contact lenses for some activities after surgery. 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.

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In some cases, your best vision **with** 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.

#### Contraindications – When Can't You Have Surgery?

If you have any of the following situations or conditions, the risk of LASIK surgery is greater than the benefit. You should **NOT** have LASIK surgery if you:

- are pregnant or nursing. These conditions may cause temporary and unpredictable changes in your cornea that may interfere with the accuracy of the measurement of your cornea before the LASIK procedure.
- have a *collagen vascular* (e.g., rheumatoid arthritis), *autoimmune* (e.g., lupus), or *immunodeficiency disease* (e.g., AIDS). These conditions affect your body's ability to heal and may result in inflammation or swelling of parts of the body such as muscles, joints, and blood vessels.
- show signs of *keratoconus* or any other condition that causes a thinning of your cornea. This unstable condition of the cornea makes it unsafe to do LASIK procedures on eyes with this condition.
- are taking medications with ocular side effects, such as isotretinoin (Accutane<sup>2</sup>) for acne treatment or amiodarone hydrochloride (Cordarone<sup>3</sup>) for normalizing heart rhythm. These medications may affect the accuracy of the LASIK procedure or the way your cornea heals after surgery. This may result in poor vision after surgery.

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<sup>2</sup> *Accutane* Reg. TM of Hoffmann-La Roche Inc.

<sup>3</sup> *Cordarone* Reg. TM of Sanofi-Aventis

## What Warnings and Other Information Do You Need to Know About?

### Warnings

If you have any of the following conditions, you may have LASIK if your doctor evaluates the seriousness of your condition and believes the benefit of having LASIK is greater than the risk. Discuss with your doctor if you have:

- diabetes. Diabetes may interfere with the healing of the cornea after LASIK.
- a history of *herpes simplex* or *herpes zoster* infection that has affected your eyes. LASIK may be more risky for patients who have an active or previous herpes infection that has affected their eyes.
- significant dry eye that is unresponsive to treatment. LASIK may increase the dry eye condition, which may or may not go away. This dryness may delay healing of the flap or interfere with the surface of the eye after surgery.
- severe allergies. The medications taken for severe allergies may interfere with the ability of the eye to heal after LASIK.

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.

### Precautions

If you have any of the following conditions, you should discuss this with your doctor. The safety and effectiveness for LASIK have **NOT** been established in patients:

- with unstable mixed astigmatism. Eyes with unstable mixed astigmatism are unable to be measured correctly to determine the right amount of the vision correction to provide.
- with conditions that may interfere with the ability to properly measure the eye to determine the right amount of vision correction, and may also affect the healing of the eye after the surgery, such as:
  - disease or corneal condition (for example, scar, infection, etc.).
  - injury to the cornea where LASIK will reshape the cornea.
  - previous surgery on the cornea or inside the eye (for example, cataract surgery).
  - prior history of surgery to correct vision (for example, LASIK surgery).
- with a cornea that is too thin for LASIK to be completed safely. A flap needs to be cut into the cornea for the LASIK procedure. A proper flap cannot be created on a thin cornea.
- 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). It is unknown whether LASIK is safe for eyes with glaucoma.

- who are taking the medication sumatriptan succinate (Imitrex<sup>4</sup>) for migraine headaches. It is unknown whether the use of this medication will interfere with the accuracy of the measurement of your cornea prior to LASIK or the healing of the eye after LASIK.
- under 21 years of age because it is unknown if the eye has reached its adult vision refraction. This may result in measurement of the amount of correction to provide being incorrect.
- over the long term (more than 9 months).
- with mixed astigmatism less than 1.00D or for 5.00D or greater. Corrections falling outside of the approved range have not been studied.
- for retreatment with this laser for LASIK. Retreatments have not been done enough times to allow an understanding of whether it is safe and effective.

Let your doctor know if you are taking any prescription medicines or any medications you bought without a prescription. These medications may interfere with the measurement prior to LASIK or the healing of the eye after LASIK.

The safety and effectiveness of wavefront-guided LASIK have only been established with an optical zone of 6.5mm and a total treatment zone of 9.0mm.

Before surgery, your doctor should evaluate your pupil size under dim lighting conditions. If your pupils in dim light are greater than the optical zone (> 6.5mm) proposed by your doctor, 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.

### ***During the First Week Following Surgery***

- You may feel pain, discomfort, or have a feeling that something is 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.

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

### ***During One to Six Months Following Surgery***

- Your vision should be stable 3 months after surgery. Some patients may notice that their vision improves or worsens. These small changes may occur up to 6 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.
- You may experience some dryness.

### **Clinical Study to Evaluate Risks**

In the clinical study using the LADARVision®4000 System for CustomCornea® LASIK, some people still needed glasses or contact lenses after surgery.

Astigmatism remained after surgery for some patients. After surgery, 9.1% of patients at 3 months and 10.9% of patients at 6 months had astigmatism of more than 1D and 0.9% of patients at 3 and 6 months had astigmatism of more than 2D.

Farsightedness remained after surgery for some patients. After surgery, 5.5% of patients at 3 months and 7.3% of patients at 6 months had more than 1D of farsightedness and 0.9% of patients at 3 months had more than 2D of farsightedness. Older patients, primarily between 40 and 60 years, were more likely to have more than 1D of farsightedness at 3 and 6 months. Patients with higher amounts of astigmatism before surgery were more likely to have 1D of farsightedness at 3 months after surgery.

Nearsightedness remained after surgery for some patients. At 3 and 6 months, 1.8% of patients had more than 1D of nearsightedness. Younger patients were more likely to have more than 1D of nearsightedness at 3 and 6 months, which was observed in both eyes of a 20 year-old patient.

### ***Visual Acuity with Glasses***

The clinical study evaluated visual acuity **with** glasses at a distance using a letter chart. Table 7 shows that all patients in the study saw 20/25 or better **with** glasses before surgery and at 3 months or later after surgery.

<b>Table 7. Visual Acuity with Glasses (Best Vision)</b>					
<b>% of Eyes With:</b>	<b>Before Surgery (N=110)</b>	<b>1 Month (N=110)</b>	<b>3 Months (N=110)</b>	<b>6 Months (N=110)</b>	<b>9 Months (N=108)</b>
20/20 or better	85.5%	89.1%	89.1%	92.7%	93.5%
20/25 or better	100.0%	99.1%	100.0%	100.0%	100.0%
20/32 or better	100.0%	100.0%	100.0%	100.0%	100.0%

N is the number of eyes studied.

### Change in Visual Acuity with Glasses After Surgery

Under dim room lighting conditions, the change in best vision **with** glasses after surgery was compared to vision **with** glasses before surgery 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 visual acuity testing is a way to determine how well patients can see in poor contrast conditions such as very dim light, rain, snow, and fog. Table 8 compares the change in vision **with** glasses before surgery to 3 and 6 months after surgery.

<b>Table 8. Change in Visual Acuity <i>with</i> Glasses After Surgery Compared to Before Surgery</b>				
% of Eyes With:	Standard Chart		10% Low Contrast Chart	
	3 Months (N=110)	6 Months (N=110)	3 Months (N=108)	6 Months (N=110)
loss of more than 2 lines	0.0%	0.0%	0.9%	0.0%
loss of 2 lines	0.0%	0.0%	3.7%	2.7%
loss of 1 line	6.4%	3.6%	17.6%	19.1%
no change	53.6%	54.5%	39.8%	36.4%
gain of 1 line	39.1%	38.2%	30.6%	33.6%
gain of 2 lines	0.9%	3.6%	6.5%	7.3%
gain of more than 2 lines	0.0%	0.0%	0.9%	0.9%

N is the number of eyes studied.

### Contrast Sensitivity

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 majority of subjects reported no change before and after surgery. Table 9 compares the change in contrast sensitivity **with** glasses before surgery to 3 and 6 months after surgery.

<b>Table 9. Change in Contrast Sensitivity <i>with</i> Glasses After Surgery Compared to Before Surgery</b>				
% of Eyes With:	Daylight Conditions		Dim Light Conditions	
	3 Months (N=110)	6 Months (N=110)	3 Months (N=107)	6 Months (N=107)
Loss	6.4%	5.5%	11.2%	10.3%
No change	90.9%	89.1%	66.4%	63.6%
Gain	2.7%	5.5%	22.4%	26.2%

N is the number of eyes studied.

**Adverse Events and Complications**

Some patients from the clinical study experienced adverse events and complications after CustomCornea® LASIK surgery as shown in Table 10.

<b>Table 10. Adverse Events and Complications</b>	
<b>Greater than or equal to 1% of eyes (N=110) had:</b>	
Irritation on the front surface of the cornea at one month or later	10.0%
Cells growing under the corneal flap *	5.4%
<i>Inflammation</i> of the cornea under the corneal flap	4.5%
Problem with creation of the corneal flap *	1.8%
Pain at one month or later	1.8%
<b>Less than 1% of eyes (N=110) had:</b>	
Feeling of something in the eye at one month or later	0.9%
Viral infection in the cornea	0.9%

N is the number of eyes studied.

\* One eye did not receive laser ablation after a problem with the creation of the corneal flap and was not included in the analysis of eyes receiving laser surgery (N=111).

There were no reports of the following adverse events and complications in the clinical study:

- blockage of blood vessels in the retina;
- breakdown of the flap;
- corneal swelling;
- cells growing under the corneal flap with a loss of 2 or more lines of visual acuity **with** glasses;
- corneal scratch involving the treated area or outside the treated area at one month or later;
- corneal cloudiness at six months or later with a loss of 2 or more lines of visual acuity **with** glasses;
- eye pressure more than 25 mmHg;
- increase in eye pressure of more than 10 mmHg compared to before surgery;
- loss of more than 10 letters (more than 2 lines) of visual acuity **with** glasses at six months or later;
- poor alignment of the corneal flap; and
- separation of the retina from the back of the eye.

**Worse and Significantly Worse Symptoms After Surgery**

Patients who were treated for mixed astigmatism in the clinical study rated the change in the following symptoms shown in Table 11 as worse or significantly worse after surgery **without** glasses or contact lenses compared to their recollection of symptoms before surgery. The symptoms reported as “worse” or “significantly worse” in >10% of eyes at 6 months were dryness, light sensitivity, blurring of vision, fluctuation of vision, glare, halos, and night driving difficulty.

<b>Table 11. Worse or Significantly Worse Symptoms <i>without</i> Glasses After Surgery Compared to Before Surgery*</b>				
<b>Comfort Symptoms</b>	<b>3 Months (N=110)</b>		<b>6 Months (N=110)</b>	
	<b>Worse</b>	<b>Significantly Worse</b>	<b>Worse</b>	<b>Significantly Worse</b>
Burning	2.7%	0.9%	6.4%	0.9%
Dryness	40.0%	1.8%	36.4%	2.7%
Excessive Tearing	0.0%	0.0%	2.7%	0.0%
Gritty Feeling	6.4%	0.9%	6.4%	0.9%
Headache	4.5%	0.0%	4.5%	0.0%
Light Sensitivity	27.3%	0.0%	20.9%	1.8%
Pain	6.4%	1.8%	4.5%	0.0%
Redness	4.5%	1.8%	7.3%	0.0%
<b>Visual Symptoms</b>				
Blurring of Vision	20.0%	1.8%	13.6%	8.2%
Double Vision	8.2%	0.0%	4.5%	1.8%
Fluctuation of Vision	20.0%	3.6%	21.8%	4.5%
Glare	26.4%	0.0%	13.6%	0.0%
Halos §	27.3%	0.0%	19.1%	3.6%
Night Driving Difficulty	20.0%	0.0%	10.9%	3.6%

N is the number of eyes studied.

\* Based on the patients’ comparison of symptom severity after surgery as worse compared to their recollection of symptom severity before surgery.

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

## E. Are You a Good Candidate For CustomCornea® LASIK?

If you are considering CustomCornea® LASIK, you must:

- be at least 21 years of age.
- have a healthy eye with no eye disease or corneal condition (for example, scar or infection).
- have mixed astigmatism of 1.00D to less than 5.00D.
- have stable mixed astigmatism as documented by less than or equal to 0.50D change each year 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® LASIK compared to other available treatments for mixed astigmatism.
- be willing to sign an Informed Consent Form, if provided by your doctor.

## F. What Should You Expect During CustomCornea® 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 computer 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® 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.

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Tell your doctor if you take any prescription and non-prescription 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 unique to your eye to determine the amount of laser treatment you need.

Your doctor will then place numbing eye drops in the eye to be treated. Numbing drops are used to control pain during surgery. The effects of the numbing eye drops will wear off after about 45-60 minutes. Your doctor will 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 LADAR6000™ 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. 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.

---

**IMPORTANT:** You must continue looking at the blinking light throughout the treatment, even if your vision begins to become cloudy during the procedure.

---

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 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, you may experience pain. 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.

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**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.

## G. Questions to Ask Your Doctor

You may want to ask the following questions to help you decide if CustomCornea® LASIK with the LADAR6000™ System is right for you:

- What are my other options to correct my mixed astigmatism?
- Will I have to limit my activities after surgery and for how long?
- What are the benefits of CustomCornea® LASIK for my amount of mixed astigmatism?
- 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 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?
- Do I have significant dry eye or large pupils that could produce undesirable side effects after LASIK surgery?

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

**H. Self-Test**

**Are You An Informed And Educated Patient?**

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

	TRUE	FALSE
1. LASIK surgery is risk-free.	<input type="checkbox"/>	<input type="checkbox"/>
2. 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"/>
3. Since the LADAR6000™ 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 or contact lenses.	<input type="checkbox"/>	<input type="checkbox"/>
5. I may need reading glasses after LASIK surgery, even if I did not need them before.	<input type="checkbox"/>	<input type="checkbox"/>
6. There is a risk that I may lose some vision after LASIK 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 surgery.	<input type="checkbox"/>	<input type="checkbox"/>
9. Significant dry eye or large pupils may produce undesirable side effects after LASIK surgery.	<input type="checkbox"/>	<input type="checkbox"/>

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

## I. Summary of Important Information

- CustomCornea® LASIK is a permanent irreversible surgery to the cornea.
- You may need to wear glasses or contact lenses for some activities after surgery. CustomCornea® LASIK does not take away 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 mixed astigmatism 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 CustomCornea® LASIK surgery.
- You would not be a good candidate if you have *autoimmune or collagen vascular 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, especially the sections on Benefits and Risks before you agree to the surgery.
- Some other options to correct mixed astigmatism include glasses, contact lenses, and Conventional LASIK. Other surgical options that may be used to correct vision are ALK and RK.
- ALK, RK and LASIK surgery 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 F: Before the Surgery) | 7. False (see Section D: Contraindications) |
| 3. False (see Section F: The Day of Surgery) | 8. False (see Section D: Contraindications) |
| 4. True (see Section C: Benefits)            | 9. True (see Section D: Precautions)        |
| 5. True (see Section D: Risks)               |   |

## J. 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 mixed 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 near vision. The cornea is more curved in some directions than others causing light to focus at different points from the retina. Vision is blurred because light does not focus correctly on the retina. Types of astigmatism include nearsighted, farsighted and mixed.

**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. An example is lupus. If you have this type of condition, you should not have LASIK surgery.

**Automated Lamellar Keratoplasty (ALK):** a type of eye surgery that changes the shape of the front surface of the eye using a microkeratome. A flap is created and tissue is removed under the flap with the microkeratome. Then the flap is put back on the eye.

**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. An example is 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. LASIK surgery 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.

**CustomCornea® LASIK:** LASIK surgery that uses the wavefront to plan the surgery with the LADAR6000™ System.

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

**Excimer Laser:** a form of light energy used in Conventional and CustomCornea® LASIK to remove tissue from the cornea.

**Farsightedness:** a focusing error that results in blurred vision that is usually worse at near than at distance. The cornea and lens focus light at a point behind the retina resulting in blurred images. Farsightedness is also called hyperopia.

**Focusing Error:** a condition in which the eye forms a blurred image on the retina. Examples are mixed astigmatism, farsightedness, nearsightedness 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 before or 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 can also 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 that is 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.

**Mixed Astigmatism:** a focusing error that results in blurred distant and near vision. An eye with mixed astigmatism is both nearsighted and farsighted. The cornea is more curved in some directions than others causing light to focus at different points in front of and behind the retina. Vision is blurred because light does not focus correctly on the retina.

**Nearsightedness:** a focusing error that results in blurred vision that is usually worse at distance than at near. The cornea and lens focus light at a point in front of the retina resulting in blurred images. Nearsightedness is also called myopia.

**Ocular Hypertension:** increased eye pressure.

**Radial Keratotomy (RK):** a type of surgery that changes the shape of the front surface of the eye by creating cuts with a blade.

**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 mixed 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.

**K. 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, Inc. 2501 Discovery Drive, Suite 500 Orlando, FL 32826 Tel: (877) 523-2784      Fax: (407) 384-1677
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