

Facts You Need to Know About CustomVue™ Laser Assisted In-Situ Keratomileusis (LASIK) Laser Treatment Patient Information Booklet

For Mixed Astigmatism (1 to 5 D of Cylinder)

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

VISX®, Incorporated
3400 Central Expressway
Santa Clara, CA 95051-0703
U.S.A.
Tel: 408.733.2020

© Copyright 2005 by VISX®, Incorporated
All Rights Reserved

VISX®, VisionKey®, ActiveTrak®, WaveScan®, WaveScan WaveFront®, and WavePrint® are registered trademarks of VISX, Incorporated.

CustomVue™ and STAR S4 IR™ are trademarks of VISX, Incorporated.

Accutane® is a registered trademark of Hoffmann-La Roche Inc. Cordarone® is a registered trademark of Sanofi-Synthelabo, Inc. Imitrex® is a registered trademark of GlaxoSmithKline.

No part of this publication may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying, recording, or any information storage and retrieval system, without permission in writing from VISX, Incorporated.

Table of Contents

Introduction	1
How Refractive (Wavefront) Errors Affect Your Vision	2
The VISX® STAR S4 IR™ Excimer Laser	4
How the CustomVue™ LASIK Procedure Works	4
The VISX WaveScan WaveFront® System	5
BENEFITS	6
Clinical Study to Evaluate Benefits	6
Study Patient Demographics	6
Visual Acuity Without Glasses After Treatment	7
Visual Acuity Without Glasses After Treatment and With Glasses Before Treatment	8
Patient Quality of Vision Comparison	9
Patient Satisfaction Comparison	10
RISKS	10
CONTRAINDICATIONS — When Can't You Have LASIK? ..	11
What Warnings and Other Information Do You Need to Know About?	12
Warnings	12
Precautions	13
Clinical Study to Evaluate Risks	14
Visual Acuity With Glasses After Treatment	14
Change in Visual Acuity With Glasses After Treatment	15
Contrast Sensitivity	16
Adverse Events and Complications	17
Patient Symptoms After CustomVue™ Treatment	18

Frequency of Patient Symptoms After CustomVue™ Treatment . . 19
The First Week Following Surgery 19
The First Two To Six Months Following Surgery 19
Are You A Good Candidate For CustomVue LASIK? 20
Before Surgery 20
The Day of Surgery 21
After Surgery 22
Questions to Ask Your Doctor 23
Self-Test 24
Summary of Important Information 25
Answers to Self-Test Questions 26
Glossary 26
Patient Assistance Information 32

Introduction

Your doctor and VISX, Incorporated provide the information in this booklet to help you decide whether to have a CustomVue™ LASIK treatment. CustomVue LASIK (laser assisted *in situ* keratomileusis) may be used to correct, or partly correct, naturally occurring mixed astigmatism. Mixed astigmatism means you have two kinds of astigmatism, myopic (nearsighted) and hyperopic (farsighted) in the same eye.

Some other ways to correct your vision are by wearing glasses or contact lenses, or by undergoing other kinds of laser refractive surgery such as non-custom LASIK or PRK (photorefractive keratectomy). Other surgical procedures that do not use a laser such as RK (radial keratotomy) and ALK (automated lamellar keratectomy) may also be an option.

Please read this booklet completely. Discuss any questions with your doctor before you decide if CustomVue LASIK is right for you. Only an eye care professional trained in laser vision correction can determine whether you are a suitable candidate. Some people, such as military pilots, have job-related vision requirements that cannot be met by having LASIK.

How Refractive (Wavefront) Errors Affect Your Vision

The cornea and lens of the eye focus rays of light by bending (or refracting) them to focus an image on the retina at the back of the eye, much like a camera focuses images onto film.

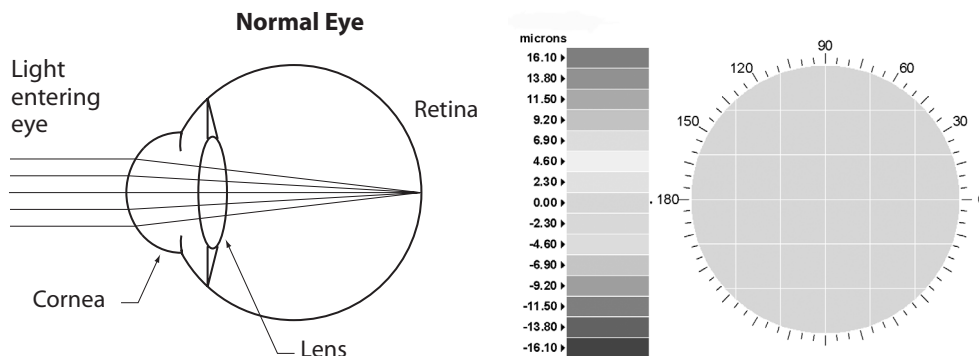


Figure 1: On the left is a diagram showing how the eye focuses light rays to create a sharp image on the retina. The corresponding wavefront map of an ideal eye is displayed on the right.

The above figure shows an ideal eye with no focusing imperfections. All of the rays of light traveling through the eye focus to a single point on the retina at the back of the eye.

In reality, all eyes have some degree of imperfections. One way to measure the focusing errors of an eye is to measure the *wavefront* of the eye. This can be done with an instrument like the VISX WaveScan WaveFront® System. The wavefront map is a picture of the rays of light as they travel through the eye. The WaveScan® System measures the wavefront errors by measuring light as it reflects out of the eye with a camera sensor.

The wavefront of a perfect eye has a flat surface because all of the light rays travel uniformly through the eye, as shown in figure 1. The wavefront of an eye with imperfections is curved or wavy because some light rays reach the retina before others, and some rays strike different locations on the retina than others. Wavefront errors include both simple and complex focusing errors. The simple wavefront errors, which can be corrected with curved lenses (e.g., glasses or contact lenses), are also called *refractive errors* and include *mixed astigmatism*.

Astigmatism is usually caused by a misshapen cornea. Instead of being perfectly spherical, like a basketball, a cornea with astigmatism is more sharply curved in one direction than the other, like a football. The different curvatures of the cornea focus the light unequally so that they do not ever form a single point. Things look blurry because images are not ever focused clearly on the retina (the back of the eye).

There are two types of astigmatism. Hyperopic (farsighted) astigmatism causes some rays to focus behind the retina and myopic (nearsighted) astigmatism causes some rays to focus in front of the retina. Mixed astigmatism is when an eye has both types of astigmatism at the same time.

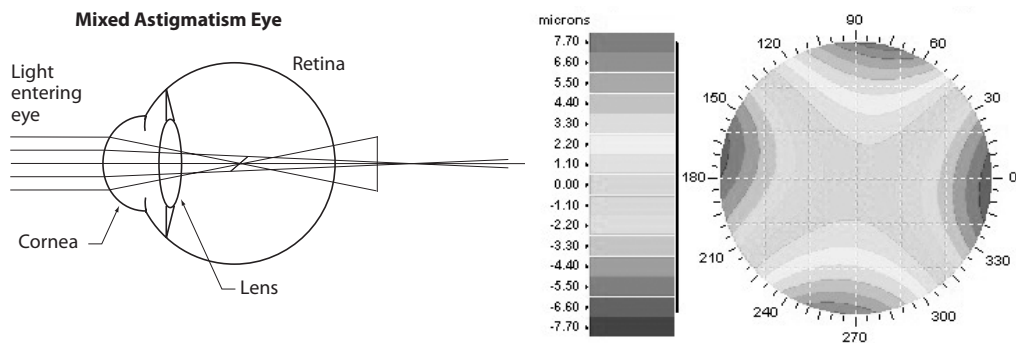


Figure 2: On the left is a diagram of an eye with mixed astigmatism showing that light entering the eye through different regions of the cornea focuses in two points, but neither point is on the retina. The corresponding wavefront map shows a surface that curves forward in one direction, and backward in the other, much like the shape of a saddle.

The WaveScan® System can also measure complex focusing errors. On the left in figure 3 is a map of all wavefront errors and on the right is a map showing just the complex errors. The combination of simple and complex wavefront errors in any eye is unique. The CustomVue™ treatment is “custom” because it includes information from the WaveScan System that is more individualized than what a doctor uses to create a non-custom treatment.

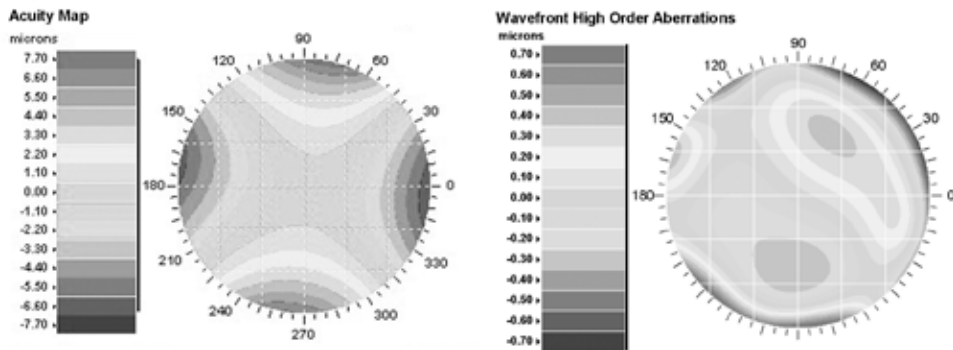


Figure 3: On the left is a wavefront map of all wavefront errors and on the right is a wavefront map showing only the complex errors.

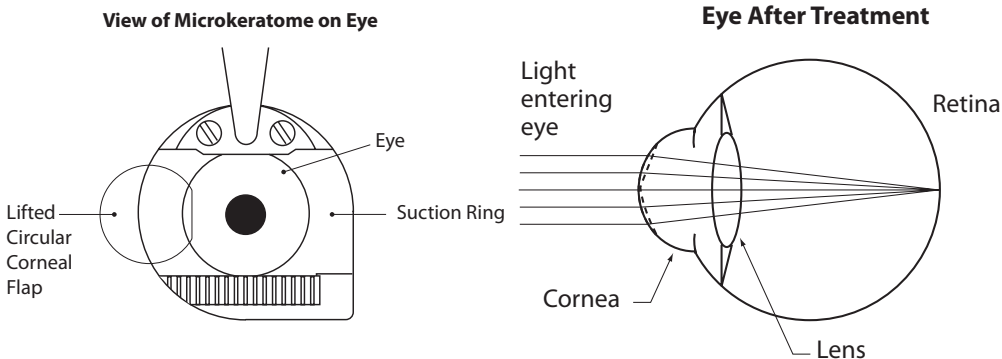
The VISX STAR S4 IR™ Excimer Laser

The excimer laser produces a beam of cool ultraviolet light. The doctor programs your information into a computer that controls the laser. The laser produces a series of rapid pulses that remove small and precise amounts of corneal tissue. Excimer laser light does not penetrate into the eye and leaves other eye structures (iris, lens, retina) undisturbed.

The laser also contains an auto-centering eye tracking system which will automatically align the treatment to your eye and compensate for many of your eye movements during the CustomVue™ treatment.

How the CustomVue LASIK Procedure Works

LASIK is a laser surgery technique used to correct refractive errors of the eye including nearsightedness, farsightedness, and astigmatism. Before activating the laser, the doctor creates a flap on your cornea using a *microkeratome*. A microkeratome is an instrument that creates a circular flap of tissue from the surface of the cornea using a blade or a laser. The doctor lifts the flap and folds it out of the way of the laser. After the laser treatment finishes, the doctor repositions the flap. VISX does not manufacture the microkeratome that your surgeon uses.



View (from above) of microkeratome on the eye.

Diagram of an eye after treatment showing where tissue is removed.

To correct mixed astigmatism, the cornea is flattened along one axis (e.g., vertical) and steepened along the other (e.g., horizontal). The doctor creates a unique treatment plan from the WaveScan[®] System to guide the laser. The laser removes tissue from the eye according to the treatment plan.

The VISX WaveScan WaveFront[®] System

Before your CustomVue[™] LASIK treatment is programmed into the laser, you must have one or more WavePrint[®] measurements taken by the WaveScan[®] System. The WaveScan System is a tabletop diagnostic system that measures your eyes with specialized cameras. You will sit in front of the WaveScan System and look toward a light through an opening in the system while it scans your eye. Your doctor may take more than one measurement and then choose the most appropriate measurement to use as the basis for the CustomVue LASIK treatment. The doctor will also take other routine measurements of your vision to help design your treatment.

BENEFITS

CustomVue™ LASIK treatment can correct up to 5 diopters (D) of mixed astigmatism. If you have mixed astigmatism within this range, CustomVue LASIK treatment may help you to see distant objects clearly without eyeglasses or contact lenses.

Clinical Study to Evaluate Benefits

A clinical study was conducted to evaluate the benefits and risks of CustomVue LASIK for mixed astigmatism. This study involved 86 eyes of 44 patients. This study was initiated at six centers in January, 2003. The last patient in this study was treated in November 2003. The study results shown in this booklet include all the available reported outcomes on these patients through November 2004. Each table lists the number of eyes (N) for which data were available at the reported time point.

Study Patient Demographics

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

Table 1 — Demographics of 86 Eyes of 44 Patients

Age	Average Range	41 ± 11 years 23 to 66 years
Gender	Male	66%
	Female	34%
Race	Caucasian	69%
	Asian/Pacific Islander	2%
	African American	1%
	Hispanic	28%
Contact Lens History	None	97%
	Soft	3%
	Hard	0%

Visual Acuity Without Glasses After Treatment

Visual acuity measures the sharpness of vision using a letter chart. Table 2 shows that six months after treatment, 60% of study patients saw 20/20 or better *without* glasses. At 12 months, 97% of study patients saw 20/40 or better. A visual acuity of 20/40 or better is the standard requirement in most states for you to drive without any glasses or contact lenses.

Table 2 — Visual Acuity *Without* Glasses After Treatment (N=86)

Time After Treatment	1 Month n=84	3 Months n=86	6 Months n=80	9 Months n=69	12 Months n=63
% of eyes with 20/20 or better	67%	62%	60%	74%	75%
% of eyes with 20/25 or better	85%	84%	85%	87%	87%
% of eyes with 20/40 or better	94%	95%	96%	99%	97%

Visual Acuity Without Glasses After Treatment and With Glasses Before Treatment

Table 3 shows that 56% of the patients saw as well or better *without* glasses 6 months after CustomVue™ treatment as *with* glasses before treatment.

Table 3 — Visual Acuity *Without* Glasses After Treatment Compared to *With* Glasses Before Treatment

Time After Treatment	1 Month n=84	3 Months n=86	6 Months n=80	9 Months n=69	12 Months n=63
% of eyes 2 lines better	0.0%	0.0%	1.3%	0.0%	3.2%
% of eyes 1 line better	21.4%	18.6%	13.8%	15.9%	23.8%
% of eyes equal	28.6%	32.6%	41.3%	42.5%	42.9%
% of eyes 1 line worse	29.8%	29.1%	22.5%	29.0%	14.3%
% of eyes 2 lines worse	9.5%	10.5%	11.3%	7.2%	9.5%
% of eyes >2 lines worse	10.7%	9.3%	10.0%	4.3%	6.3%

Patient Quality of Vision Comparison

Patients were asked to evaluate the quality of their vision both before and after the CustomVue™ treatment. Table 4 lists the patient responses reported at 3 months after treatment on 86 eyes and at 6 months after treatment on 80 eyes.

Table 4 — Comparison of Quality of Vision *Without* Glasses After Treatment Compared to *With* Glasses Before Treatment

	3 Months (n=86)			6 Months (n=80)		
	Improve (% of Eyes)	No Change (% of Eyes)	Worsen (% of Eyes)	Improve (% of Eyes)	No Change (% of Eyes)	Worsen (% of Eyes)
Sharpness and Clarity	14.0%	77.9%	8.1%	16.3%	78.8%	5.0%
Consistency of Vision	19.8%	70.9%	9.3%	18.8%	76.3%	5.0%
Daylight Driving	20.9%	67.4%	11.6%	20.0%	72.5%	7.5%
Night Driving	30.2%	64.0%	5.8%	31.3%	62.5%	6.3%
Night Vision With Glare	36.0%	64.0%	0.0%	36.3%	63.8%	0.0%

Patient Satisfaction Comparison

Patients were asked to evaluate their satisfaction with the quality of their vision both before and after the CustomVue™ treatment. Table 5 lists the patient responses reported before treatment on 86 eyes and at 6 months after treatment on 80 eyes.

Table 5 — Comparison of Patient Satisfaction of Vision Before and After Treatment

	Very Satisfied or Satisfied		Not Sure		Somewhat or Very Dissatisfied	
	Pre-Op	6 Months	Pre-Op	6 Months	Pre-Op	6 Months
Sharpness and clarity	71%	85%	13%	9%	16%	6%
Consistency of vision	67%	85%	9%	5%	23%	10%
Daylight vision	74%	93%	12%	0%	14%	8%
Night vision	54%	89%	15%	5%	31%	6%
Night vision with glare	38%	76%	24%	16%	37%	8%

RISKS

As with any surgical procedure there are risks associated with CustomVue™ treatments. It is important to discuss these risks with your doctor before you make the decision to have the surgery. If the results of the surgery are not satisfactory, you may need to have additional laser treatment in the same eye. Your doctor may perform CustomVue LASIK for both eyes. However, sometimes it is better to have this procedure done on only one eye. Talk with your doctor about whether it would be better to treat one or both of your eyes.

Some risks are related to the creation of the corneal flap. Corneal flap complications include but are not limited to: cutting an incomplete, irregular flap or free flap; misalignment of the flap; and perforation of the cornea. Corneal flap complications range in severity from those that simply require the treatment to be postponed for several months, to those which create corneal irregularities resulting in permanently blurred vision.

IMPORTANT:

You may need reading glasses after laser surgery even if you did not wear them before. Your vision may not be perfect, and you may need to wear glasses or contact lenses for some activities even after laser vision correction.

CONTRAINDICATIONS — When Can't You Have LASIK?

If you have any of the following situations or conditions you should not have LASIK because the risk is greater than the benefit:

- You are pregnant or nursing, because these conditions may cause temporary and unpredictable changes in your cornea and a LASIK treatment may improperly change the shape of your cornea.
- You have collagen vascular disease (e.g., rheumatoid arthritis), autoimmune disease (e.g., lupus), or immunodeficiency disease (e.g., AIDS), because these conditions affect the body's ability to heal.
- You show signs of keratoconus or any other condition that causes a thinning of your cornea. This condition can lead to serious corneal problems during and after LASIK surgery. It may result in need for additional surgery and may result in poor vision after LASIK.

- You are taking medications with ocular side effects, e.g., isotretinoin (Accutane®*) for acne treatment or amiodarone hydrochloride (Cordarone®†) for normalizing heart rhythm, because they may affect the accuracy of the LASIK treatment or the way your cornea heals after LASIK. This may result in poor vision after LASIK.
- Your corneas are thin. If your corneas are too thin to allow your doctor to cut a proper flap in the LASIK procedure, you can't have LASIK because it is necessary to have a flap.

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

Warnings

If you have more severe mixed astigmatism, your results may not be as good as those reported in this clinical study.

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.

- Diabetes. If you have diabetes, LASIK may be risky for you because your diabetes may interfere with the healing of your eyes.
- History of *Herpes simplex* or *Herpes zoster* infection that has affected your eyes. If you have had a *Herpes simplex* or a *Herpes zoster* infection that affected your eyes, and have an infection now, LASIK may be more risky for you.
- Symptoms of significant dry eye. If you have severely dry eyes, LASIK may increase the dryness. This 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. If you have severe allergies and take medicines for them, LASIK may be more risky for you.

* Accutane® is a registered trademark of Hoffmann-La Roche, Inc.

† Cordarone® is a registered trademark of Sanofi-Synthelabo, Inc.

Precautions

The safety and effectiveness of wavefront-guided LASIK with the STAR S4 IR™ Laser for mixed astigmatism has not been established in patients:

- With unstable eyes that have changed in their prescription more than 0.5 diopter in nearsightedness, farsightedness, or astigmatism in the last 12 months, and your nearsightedness, farsightedness, or astigmatism is getting worse. If your eyes are unstable, the right amount of treatment cannot be determined. This may result in poor vision after LASIK.
- With corneal disease or abnormality (e.g., scar, infection, etc.). If you have an abnormal corneal condition, such as corneal scars, it may affect the accuracy of the LASIK treatment or the way your cornea heals after LASIK. This may result in poor vision after LASIK. If your eyes have an active disease, it is unknown whether LASIK is safe and effective under this condition.
- With history of injury or surgery to the center of the cornea (for example, surgery to correct vision such as RK, PRK, LASIK), or other surgery on the eye. If your eyes are injured or you have had surgery, it is unknown whether LASIK will weaken the cornea too much. This may result in poor vision after LASIK.
- With large pupils. Before surgery, your doctor should measure your pupil size under dim lighting conditions and review how your pupil size may affect your vision after surgery.
- With history of glaucoma or have had pressure greater than 21 mmHg inside your eyes, because it is unknown whether LASIK is safe and effective for you.
- Who use medications that might make it harder for wounds to heal, such as sumatriptan (Imitrex®*) used for migraine headaches, because it is unknown whether LASIK is safe and effective for this condition.
- Who take other medications. Let your doctor know if you taking any prescription medicines or any medicines you bought without a prescription.

* Imitrex® is a registered trademark of GlaxoSmithKline.

- Who are younger than 21 years of age, because it is unknown whether LASIK is safe and effective for you.
- Who have astigmatism worse than 5 diopters, because it is unknown whether LASIK is safe and effective for you.
- Over the long term (more than 1 year), because the length of the clinical study was less than 1 year.
- Who are considering retreatment with this laser for LASIK, because it is unknown whether LASIK is safe and effective for repeating the LASIK procedure on the same eye.
- With undiagnosed dry eyes. 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.
- In the following conditions: dim lighting, rain, snow, fog, or bright glare. You might have difficulty seeing in dim lighting, rain, snow, fog, or bright glare. Whether you may have poor vision under these conditions is hard to predict because it has been studied so little.

Clinical Study to Evaluate Risks

In the clinical study on CustomVue™ LASIK for mixed astigmatism, visual acuity *with* glasses was the same or better for 87% of eyes treated.

Visual Acuity With Glasses After Treatment

Table 6 shows that all patients in the clinical study saw 20/25 or better *with* glasses at 1, 3, 6, and 9 months after treatment.

Table 6 — Visual Acuity *With* Glasses (Best Vision) After Treatment

	Pre-Op (n=86)	1 Month (n=84)	3 Months (n=86)	6 Months (n=80)	9 Months (n=69)	12 Months (n=63)
20/20 or better	85%	89%	93%	91%	91%	95%
20/25 or better	100%	100%	100%	100%	100%	100%
20/32 or better	100%	100%	100%	100%	100%	100%

Change in Visual Acuity With Glasses After Treatment

Table 7 shows the change in visual acuity *with* glasses at 1, 3, 6, 9, and 12 months after treatment for the patients in the clinical study.

Table 7 — Change in Visual Acuity *With* Glasses After Treatment Compared to Before Treatment

	1 Month (n=84)	3 Months (n=86)	6 Months (n=80)	9 Months (n=69)	12 Months (n=63)
Eyes with loss of >2 lines	0%	0%	0%	0%	0%
Eyes with loss of >1 to 2 lines	2%	0%	1%	0%	0%
Eyes with loss of >0 to 1 line	13%	13%	14%	16%	5%
Eyes with no change	43%	44%	36%	36%	35%
Eyes with gain of >0 to 1 line	39%	40%	43%	42%	49%
Eyes with gain of >1 to 2 lines	2%	4%	6%	6%	8%
Eyes with gain of >2 lines	0%	0%	0%	0%	3%

Contrast Sensitivity

Unlike normal vision tests that measure the ability to see a black and white eye chart, contrast sensitivity measures how well one sees in low contrast conditions such as driving in rain or fog. While most eyes in the study achieved the same or better contrast sensitivity post-operatively as they did pre-operatively, at 3 months post-operatively, 4% experienced a significant loss in bright conditions. In dim conditions, 7% experienced a similar loss, and with the addition of glare in dim conditions, 5% experienced such a loss. Table 8 shows the change in contrast sensitivity 3 months after treatment in 86 patients.

Table 8 — Change in Contrast Sensitivity 3 Months After Treatment

	3 Months (n=86)		
	% of Eyes With Loss	% of Eyes That Stay The Same	% of Eyes With Gain
Bright conditions with no glare	4%	87%	9%
Dim conditions with no glare	7%	74%	19%
Dim conditions with glare	5%	78%	17%

Adverse Events and Complications

Some patients in the clinical study experienced adverse events and complications after CustomVue™ LASIK treatment, as shown in Table 9.

Table 9 — Adverse Events and Complications

	Less than 1 Month (n=86)		1 Month (n=84)		3 Months (n=86)		6 Months (n=80)		9 Months (n=69)		12 Months (n=63)	
	n	%	n	%	n	%	n	%	n	%	n	%
Greater than or equal to 1% of eyes had:												
Double or ghost images	0	0.0	3	3.6	7	8.1	4	5.0	2	2.9	4	6.3
Cells growing under the flap	0	0.0	4	4.8	4	4.7	2	2.5	2	2.9	2	3.2
Miscreated flap	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Scratch on outer surface of the eye	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
Blocked blood vessel in the back of the eye	0	0.0	0	0.0	0	0.0	1	1.3	0	0.0	0	0.0

Patient Symptoms After CustomVue™ Treatment

Patients were asked to evaluate the following visual symptoms without glasses after the CustomVue treatment at 3 months and again at 6 months compared to their vision with glasses before treatment.

Table 10 lists the reported responses at 3 months after treatment on 86 eyes and at 6 months after treatment on 80 eyes.

Table 10 — Comparison of Patient Symptoms of Vision *Without* Glasses After Treatment Compared to *With* Glasses Before Treatment

	3 Months (n=86)			6 Months (n=80)		
	Improve (% of Eyes)	No Change (% of Eyes)	Worsen (% of Eyes)	Improve (% of Eyes)	No Change (% of Eyes)	Worsen (% of Eyes)
Dryness	2.3%	79.1%	18.6%	1.3%	83.8%	15.0%
Blurry Vision	12.8%	70.9%	16.3%	13.8%	77.5%	8.8%
Fluctuation of Vision	8.1%	84.9%	7.0%	8.8%	83.8%	7.5%
Glare	15.1%	75.6%	9.3%	17.5%	73.8%	8.8%
Halos Around Lights	15.1%	75.6%	9.3%	17.5%	72.5%	10.0%
Difficulty at Night with Glare	27.9%	64.0%	8.1%	31.3%	62.5%	6.3%
Ghost or Double Images	9.4%	82.4%	8.2%	12.7%	81.0%	6.3%

Frequency of Patient Symptoms After CustomVue™ Treatment

Patients were asked to rank the frequency of their symptoms both before and after the CustomVue treatment. Table 11 lists the patient symptoms reported before treatment (Pre-Op) on 86 eyes and at 3 months after treatment on 86 eyes.

Table 11 — Comparison of Frequency of Symptoms Before and After Treatment

Symptom	Often or Always	
	Pre-Op	3 Months
Dryness	6%	22%
Blurry vision	16%	14%
Fluctuation of vision	9%	4%
Glare	8%	2%
Halos*	13%	20%
Difficulty at night with glare	16%	11%
Ghost or double images	7%	2%

*Halos are hazy rings around bright lights.

The First Week Following Surgery

- Moderate pain and discomfort may last for up to 3 days after surgery.
- Blurred vision and tearing will occur as the cornea heals.
- You will be sensitive to bright lights.

The First Two To Six Months Following Surgery

- Your vision may fluctuate during this time period. You may also experience some dryness.

Are You A Good Candidate For CustomVue™ LASIK?

If you are considering CustomVue LASIK, you must:

- Be at least 21 years of age and have mixed astigmatism.
- Have healthy eyes that are free from eye disease or corneal abnormality (e.g., scar, infection, etc.).
- Have documented evidence that your refraction did not change by more than 0.5 diopter during the year before your pre-operative examination.
- Be informed of LASIK risks and benefits as compared to other available treatments for mixed astigmatism.
- Be able to lie flat without difficulty.
- Be able to tolerate local or topical anesthesia.
- Be willing to sign an informed consent form as provided by your eye care professional.
- Be able to keep your eye accurately on the fixation light for the entire laser surgical procedure.

Before Surgery

If you are interested in having laser vision correction, you will need to have a pre-surgical examination to determine if your eye is healthy and suitable for surgery. This will include a complete medical and eye history, and thorough examination of both eyes, including WavePrint® refractions and computerized mapping of your cornea.

WARNING:

If you wear contact lenses, it is very important to stop wearing them 2 – 4 weeks before examination and treatment for the doctor to obtain a stable eye measurement. Failure to do this might produce suboptimal surgical results.

Before the surgery, please tell your doctor whether you take any medications or have any allergies. Also, talk with your doctor about eating or drinking immediately before the surgery. You should also arrange for transportation, since you must not drive immediately after the surgery. You may resume driving only after receiving permission from your doctor.

The Day of Surgery

Before the surgery, local anesthetic (numbing) drops will be placed into the eye to be treated and you will be escorted into the room with the laser. You will lie on your back in a reclining chair and look up. An instrument will be placed between your eyelids to hold them open during the surgery. There will also be a temporary shield covering the eye not having surgery. You will be asked to listen to the sounds of the treatment so that you will be prepared for the noise the laser makes during the surgery.

The surgery begins with the placement of a suction ring that elevates the pressure in the eye. The vision in the eye will go black as the suction increases the pressure in the eye. The microkeratome creates a circular corneal flap. The doctor will lift this flap of tissue after the suction is released. Vision will return to the eye after the suction is released.

The doctor will then reposition your head in the chair and refocus the microscope. You will be asked to look directly at a blinking light while the laser is running. It is important to fix your gaze on the light for the entire laser procedure. Try to keep both eyes open without squinting, as this makes it easier to keep looking at the light. Small amounts of tissue will then be removed from your cornea using the VISX STAR S4 IR™ Excimer Laser system.

PRECAUTION:

It is very important that you keep looking at the flashing fixation light during the procedure, even if the light fades or becomes dim. You need to concentrate on looking at this light throughout the treatment to ensure the best results possible.

Typically, the laser beam will be applied to your eye less than 2 minutes and, overall, the surgery may last about 10 minutes.

After the laser surgery is complete, some eye drops may be placed on your eye. The surgery is painless because of the anesthetic drop. When the anesthetic drops wear off (about 30 to 60 minutes), your eye may hurt moderately for 1 to 2 days. The discomfort is typically described as “a sandy sensation.” Your doctor can prescribe pain medication to make you more comfortable during this time after the surgery. To promote healing and lessen the risk of infection, do **NOT** rub your eye after surgery.

After Surgery

You will be mildly sensitive to light and have the feeling that something is in your eye for 1 to 2 days. Sunglasses may make you more comfortable during this time.

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).**

Questions to Ask Your Doctor

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

- What other options are available for correcting my vision?
- Will I have to limit my activities after surgery, and for how long?
- What are the benefits of CustomVue LASIK for my amount of refractive error?
- What vision can I expect in the first few months after surgery?
- If CustomVue LASIK does not correct my vision, what is the possibility that my glasses will need to be stronger than before? Could my need for glasses increase over time?
- Will I be able to wear contact lenses after laser surgery if I need them?
- How is CustomVue 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 laser surgery?
- Should I have CustomVue LASIK 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 CustomVue™ LASIK only on one eye?

Discuss the cost of surgery and follow-up care requirements with your doctor, as CustomVue LASIK is not covered by most health insurance policies.

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. CustomVue™ LASIK surgery is risk free.	<input type="checkbox"/>	<input type="checkbox"/>
2. It doesn't matter if I wear my contact lenses when my doctor told me not to.	<input type="checkbox"/>	<input type="checkbox"/>
3. The laser does all the work; I just have to lie on the chair.	<input type="checkbox"/>	<input type="checkbox"/>
4. After the surgery, there is a good chance that I will be less dependent on eyeglasses.	<input type="checkbox"/>	<input type="checkbox"/>
5. I may need reading glasses after laser surgery.	<input type="checkbox"/>	<input type="checkbox"/>
6. There is a risk that I may lose some vision after CustomVue LASIK surgery.	<input type="checkbox"/>	<input type="checkbox"/>
7. It doesn't 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 laser vision correction.	<input type="checkbox"/>	<input type="checkbox"/>

Answers to SELF-TEST are found on page 26.

Summary of Important Information

- CustomVue™ LASIK is a permanent operation to the cornea and is irreversible.
- CustomVue LASIK may 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 CustomVue LASIK. You will need written evidence that your mixed astigmatism has changed less than 0.5 diopter.
- Pregnant and nursing women should wait until they are not nursing and not pregnant to have the surgery.
- You are not a good candidate if you have degenerative or autoimmune diseases, or have a condition that makes wound healing difficult.
- CustomVue LASIK may result in some discomfort. The surgery is not risk-free. Please read this entire booklet, especially the sections on Benefits and Risks before you agree to the surgery.
- Alternatives to CustomVue LASIK include, but are not limited to, glasses, contact lenses, non-custom LASIK and PRK, RK, and ALK.
- Some people, such as military pilots, have job-related vision requirements that cannot be met by having CustomVue LASIK.
- Before considering laser vision correction you should:
 - a. Have a complete eye examination.
 - b. Talk with one or more eye care professionals about the potential benefits of laser refractive surgery, and the complications, risks, and time required for healing.

Answers to Self-Test Questions

1. False (see Risks on page 10);
2. False (see Before Surgery on page 20);
3. False (see The Day of Surgery on page 21);
4. True (see Benefits on page 6);
5. True (see Risks on page 10);
6. True (see Risks on page 10);
7. False (see Contraindications on page 20);
8. False (see Contraindications on page 20).

Glossary

This section contains definitions of terms used in this information booklet. Please discuss with your doctor any questions you may have about these terms.

Antibiotic Medication: a drug used to treat or prevent infection.

Anti-inflammatory Medication: a drug that reduces redness and swelling associated with inflammation. May be a corticosteroid, or a nonsteroidal anti-inflammatory drug.

Astigmatism: The cornea and lens focus light rays from horizontal and vertical lines at different distances from the retina. The multiple focal distances result in blurred vision. Astigmatism may occur alone or along with nearsightedness, farsightedness, and other refractive errors.

Automated Lamellar Keratectomy (ALK): a type of surgery used to correct vision by removing a cap of cornea using a microkeratome (an automated instrument), reshaping or flattening the cap of cornea, and then replacing the cap on the corneal bed.

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.

Contraindications: any special condition that results in the treatment being inadvisable.

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

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 Haze: a cloudiness of the cornea that may occur after PRK and rarely after LASIK.

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

Diopter (D): a unit used to measure the amount of myopia, hyperopia, or astigmatism of any eye.

Farsightedness: a refractive error in which the cornea and lens focus light rays from objects behind the retina, causing images of near and distant objects to appear blurry. Hyperopia is another term for farsightedness.

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.

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.

Herpes Zoster: a type of infection caused by a virus that can recur. Vesicles typically appear on only one side of the body.

Hyperopia: a refractive error in which the cornea and lens focus light rays from objects behind the retina, causing images of near and distant objects to appear blurry. Farsightedness is another term for hyperopia.

Immunodeficiency Disease: a condition that alters the body's ability to fight infection. An example is AIDS.

Intraocular lens (IOL) implantation: A refractive surgery procedure that replaces the natural lens in the eye with an artificial one that has a different focusing strength.

Intracorneal ring segments: Surgical implants that correct myopia and astigmatism by deforming the cornea.

Intraocular Pressure (IOP): fluid pressure inside the eye. Your doctor measures the pressure inside the eye with a tonometer.

Keratoconus: a condition of the cornea that results in a thinning of the cornea. A change in corneal shape like a cone typically occurs.

LASIK: a type of surgery used to correct vision by raising a flap of cornea using a microkeratome (an automated instrument), then reshaping the cornea underneath using an excimer laser, and then replacing the flap on the corneal bed.

Lens: a structure inside the eye that helps to focus light onto the back of the eye, or an optical instrument for forming an image by focusing rays of light.

Microkeratome: an automated surgical instrument that creates a flap of tissue from the front surface of the eye.

Mixed Astigmatism: a refractive error in which the eye has both hyperopic (farsighted) astigmatism and myopic (nearsighted) astigmatism.

Moderately Farsighted: farsightedness between +1.0 and +6.0 diopters.

Myopia: a refractive error in which the cornea and lens focus light rays from distant objects in front of the retina, causing images of distant objects to appear blurry. Nearsightedness is another term for myopia.

Nearsightedness: a refractive error in which the cornea and lens focus light rays from distant objects in front of the retina, causing images of distant objects to appear blurry. Myopia is another term for nearsightedness.

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

Photorefractive Keratectomy (PRK): a type of surgery used to correct vision by reshaping the top surface of the cornea using an excimer laser.

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

Refract: to bend or focus rays of light.

Refraction: the focusing power of a lens or eye.

Refractive Error: a focusing error of the eye, in which parallel light rays are not brought to a sharp focus precisely on the retina, producing a blurred image. Refractive errors can be myopic, astigmatic, or hyperopic.

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

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

Wavefront: a surface representing the cross-section of the paths that light rays follow as they travel through the eye.

Wavefront error: simple and complex focusing errors in the eye that are revealed by differences in the paths of light rays as they are bent by the eye.

WavePrint®: a color map that displays wavefront errors measured by the VISX WaveScan WaveFront® System.

WaveScan®: the VISX WaveScan WaveFront System is a diagnostic instrument to objectively measure the refractive errors of the eye.

NOTES

NOTES

Patient Assistance Information

Primary Eye Care Professional

Name:

Address:

Phone:

Laser Vision Correction Doctor

Name:

Address:

Phone:

Treatment Location

Name:

Address:

Phone:

Laser Manufacturer:

VISX, Incorporated
3400 Central Expressway
Santa Clara, CA 95051
U.S.A.
Tel: 408.733.2020