Professional Use Information

VISX STAR S4 IR™ Excimer Laser System and WaveScan WaveFront® System

CustomVue™ Treatments for High Myopia and Myopic Astigmatism

For the reduction or elimination of myopia and myopic astigmatism from -6.00 to -11.00 D MRSE, with cylinder between 0.00 and -3.00 D

RESTRICTED DEVICE: U.S. Federal Law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed eye care practitioner. U.S. Federal Law restricts the use of this device to practitioners who have been trained in its calibration and operation and who have experience in the surgical management and treatment of refractive errors.

This document provides information concerning the intended clinical use of the STAR S4 IR Excimer Laser System. For complete information concerning system components, safety instructions, installation, maintenance, and troubleshooting, refer to the STAR S4 IR Excimer Laser System Operator's Manual.

Carefully read all instructions prior to use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to do so may result in patient and/or user complications.

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General Warnings

STAR S4 IR™ EXCIMER LASER SYSTEM

RESTRICTED DEVICE: U.S. Federal Law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed eye care practitioner. U.S. Federal Law restricts the use of this device to practitioners who have been trained in its calibration and operation and who have experience in the surgical treatment and management of refractive errors.

Performance of procedures, use of controls, or any other adjustments other than those specified herein may result in a hazardous condition.

Never operate the laser in the presence of flammable anesthetics or other volatile substances, such as alcohol.

GAS HANDLING: High-pressure gas cylinders are contained in a protected compartment within the STAR S4 IR™ Excimer Laser System. Storage of additional cylinders and the replacement of used cylinders must be done in accordance with "Gas Safety" (Section 4.5) and "Gas Maintenance" (Section 14.1) and must comply with all applicable Occupational Safety and Health Administration (OSHA), local, and national requirements for gas safety.

The premix (argon/fluorine) gas mixture used in this laser system is highly toxic. VISX, Incorporated, recommends that anyone working with the gas cylinders: 1) be trained in the proper handling of toxic and compressed gases, 2) know the location of the emergency exhaust fan/room purifier switch, 3) have easy access to all required protective equipment, and 4) be familiar with safety procedures and Materials Safety Data Sheets (MSDS) provided by the site's safety officer. Gas discharge into the atmosphere may be evidenced by a sharp, penetrating odor and by eye, nose, and throat irritation.

SKIN AND EYE EXPOSURE: The STAR S4 IR System contains a Class IV laser with an output at 193 nm, which is potentially hazardous to the skin and the surface layers of the cornea. This laser radiation will not enter the eye and poses no threat to retinal structures or the crystalline lens. The fixed optical system restricts the beam path, which is bounded by the operating table or the floor. Reflectivity from objects in operating rooms, including surgical instruments, is extremely low for 193 nm radiation.

The area of potential hazard (Nominal Hazard Zone) for production of a photochemical keratitis has been determined to be less than 40 cm from the primary beam. All healthcare personnel should avoid direct exposure to the skin or eye by the primary beam. While no hazard may exist farther than 40 cm from the beam, the use of protective eyewear is recommended if the possibility exists that healthcare personnel will approach closer than this distance from the primary beam.

PRECAUTIONS: Carefully read all instructions prior to use. The laser beam is invisible. The user cannot tell if the laser is emitting radiation by looking for the beam. Observe all contraindications, warnings, and precautions noted in this manual. Failure to do so may result in patient and/or user complications.

ELECTROMAGNETIC FIELD (EMF): The thyratron emits an electromagnetic pulse which is shielded by the metal coverings of the STAR S4 IR™ Excimer Laser System. This metal covering reduces the EMF below the limits set by applicable standards for electromagnetic compliance.

WARNING: The effects of electromagnetic emissions from the excimer laser system on other devices, such as cardiac pacemakers or implanted defibrillators, is unknown. Operation of the laser in proximity to such devices is not recommended.

AIRBORNE CONTAMINANTS: Airborne contaminants which are produced by the ablation process are captured in proximity to the cornea near the point of production and fed into an aspirator with a filter. This aspirator is designed to prevent any of the products of ablation from contaminating the surgical suite.

WAVESCAN WAVEFRONT® SYSTEM

PRECAUTIONS: The WaveScan WaveFront System is a Class III accessory device. It contains a Class IIIB laser with a 780 nm output. The light levels accessible with the covers off and the interlocks defeated are potentially hazardous to skin and eyes. Avoid direct exposure to these light levels. The covers should be removed only by trained service personnel. To avoid inadvertent exposure to laser radiation, never operate the system with the covers opened or removed. Doing so may expose the user or others to stray laser radiation.

Any service requiring access to the interior of the system should be performed only by VISX® service personnel or by qualified service technicians who have received specific system training. Never try to defeat safety interlocks after removing covers. The safety interlocks are there for user protection. All power cords must be connected to the medical grade isolation transformer in the system.

Carefully read all instructions prior to use. Retain all safety and operating instructions for future use. Observe all contraindications, warnings, and precautions noted in the WaveScan WaveFront Operator's Manual.

1.1 Device Description

1.1.1 STAR S4 IR™ Excimer Laser System

The STAR S4 IR System is designed to create a superficial lamellar keratectomy on exposed corneal tissue. Corneal tissue is removed by a process known as Ablative Photodecomposition. Ablative Photodecomposition occurs when far-ultraviolet radiation reacts with organic molecules, resulting in the photochemical breakdown of the molecular bonds without a significant local thermal effect. The source of the far-ultraviolet photons is a high-efficiency, gas-discharge excimer laser that electronically excites a combination of argon and fluorine, producing an ultraviolet wavelength of 193 nm. The STAR S4 IR Excimer Laser System combines submicron precision of tissue removal by an excimer laser with a sophisticated computer controlled delivery system.

Features and components of the STAR S4 IR System include:

Excimer Laser
An argon-fluoride excimer laser module, with an output wavelength of 193 nm.

Gas Management System
A gas cabinet containing a working gas cylinder for laser operation; a gas cleaning system; a gas leak audio alarm with a sensor to detect fluorine (one part-per-million); a gas discharge system, using an activated charcoal filter to absorb fluorine; an emergency safety system using a positive-action solenoid safety valve, which automatically seals the premix cylinder in the event of a power failure; and a second charcoal scrubber to neutralize fluorine in case of a leak. The STAR S4 IR laser software also contains a refinement to the method of STAR laser beam energy control by inclusion of an ozone compensation system.

Laser Beam Delivery System
The STAR S4 IR laser system delivers spatially scanning ultraviolet pulses of variable diameters and slits on to the cornea. The range of diameters and slits available during treatments are 0.65 mm to 6 mm. Beam shaping and homogenizing optics designed to produce a uniform, coaxial beam profile; a spatial integrator and beam rotator for temporal integration; and an iris diaphragm and rotating slit blades used to shape the beam. Conventional STAR treatments utilize sphere, cylinder and axis components which are entered manually into the laser by the operator to generate the ablation treatment. CustomVue™ treatment information is generated on the WaveScan® system and transferred to the STAR S4 IR Excimer Laser System. The transferred information includes patient information, eye and refraction information, image of the eye, eye alignment information, and ablation instructions to the laser for beam diameters and the exact locations of the beam on the cornea. The variable spot scanning (VSS™) feature of the laser, used for CustomVue™ treatments delivers variable diameter ultraviolet pulses to precise locations by the scanning delivery system. The VSS algorithm optimizes the ablation pattern by choosing the best combination of beam diameters and locations to achieve a target shape. VSS expands the laser capability to achieve a broader spectrum of ablation shapes than conventional treatments because the conventional algorithm optimizes only the diameter for myopic treatments and slits for hyperopic treatments.

Patient Management System
The ActiveTrak® System, which enables the laser beam to track the patient's eye movements during the treatment, an operating microscope with reticle, used to observe a patient procedure and to facilitate accurate focus and laser beam alignment; a debris-removal system designed to evacuate the debris plume that occurs during ablation; a patient operating chair used to align

the patient for treatment; a video camera and monitor used to record and monitor patient treatment; an illumination device used to illuminate the patient's eye for observation and treatment, and a fixation LED used by the patient to maintain proper alignment during treatment. Wavefront-guided treatments using the STAR S4 IR™ and WaveScan Systems utilize an automated iris registration system. The angle of rotation of the patient's eye under the laser is determined by comparing features of the iris on the WaveScan image to the same features located in the image of the iris taken using the STAR S4 IR camera. The treatment is rotated to align precisely with the rotation of the patient's eye under the laser.

Computer Control
A PC-compatible computer, video monitor, keyboard with touchpad for user interface (Windows®[1] standard), printer, a floppy drive to store patient information on floppy disks, a USB port, a VISX® treatment card driver, and system software.

VISX® Treatment Card
The VISX Treatment Card system comprises a card drive and treatment cards. The VISX treatment card defines the number and the types of treatments available.

1.1.2 WaveScan WaveFront® System

The WaveScan WaveFront System is a diagnostic instrument indicated for the automated measurement, analysis, and recording of refractive errors of the eye: including myopia, hyperopia, astigmatism, coma, spherical aberration, trefoil, and other higher order aberrations through sixth order, and for displaying refractive data of the eye to assist in prescribing refractive correction..

The WaveScan WaveFront System measures the refractive error and wavefront aberrations of the human eye using a Hartmann-Shack wavefront sensor. The measurements can be used to determine regular (sphero-cylindrical) refractive errors and irregularities (aberrations) that cause decreased or blurry vision in the human eye.

The function of the Hartmann-Shack sensor is to measure the refractive error of the eye by evaluating the deflection of rays emanating from a small beam of light projected onto the retina. To control the natural accommodation of the eye during WaveScan imaging, the system incorporates a fogged fixation target.

The WaveScan® System optical head projects a beam of light onto the retina. The light reflects back through the optical path of the eye and into the wavefront device. The reflected beam is imaged by a lenslet array onto the charge-coupled device (CCD). Each lens of the array gathers light information (deflection information) from a different region of the pupil to form an image of the light that passes through that region of the pupil. An array of spots are imaged on the CCD sensor. The system compares the locations of the array of spots gathered from the CCD to the theoretical ideal (the ideal plane wave).

The WaveScan System software uses these data to compute the eye's refractive errors and wavefront aberrations using a polynomial expansion. The system displays the refractive errors and wavefront aberrations as the optical path difference (OPD) between the measured outgoing wavefront and the ideal plane wave. The WaveScan system software subtracts the refractive errors from the wavefront errors map and displays the higher order aberrations as OPD errors. Regions of the pupil with positive OPD are in front of the ideal plane wave and areas with negative OPD are behind the ideal plane wave.

[1] Windows® is a registered trademark of Microsoft Corporation.

Features and components of the WaveScan WaveFront® System include:

Computer Control
The WaveScan WaveFront® System includes software to calculate the desired laser vision correction treatment (CustomVue™ treatment) from the WavePrint® measurement. The software generates two sets of laser instructions, one for PreVue® plastic and the other for the patient procedure. Both sets of instructions are loaded on to the STAR S4 IR™ System and are used to define the patient treatment.

PC and Monitor
The computer is PC-compatible. The monitor is a flat-panel LCD display. Keyboard and mouse (or glidepad) are Windows standard.

Isolation Transformer
The medical-grade isolation transformer complies with IEC 601-1 regulations. All power cords connect to the isolation transformer.

Power Supply
The power supply provides DC power to the video cameras (CCDs), and the superluminescent diode (SLD).

LED
Yellow (D3): Indicates SLD over-power fault. Located on back panel of power supply box.

Optical Head
The optical head includes two optical units for the precompensation of sphere and astigmatism, adjusted by three stepper motors, two CCD cameras, and a light source (the SLD). A circuit continuously measures the incident power of the light source and switches the SLD off if the incident power exceeds a defined threshold.

Printer
A high resolution color printer is included with the system.

Motorized table
The motorized table supports the WaveScan WaveFront System. Electrical ratings: 120 V ~, 50/60 Hz, 6 A. Vertical position is controlled by a rocker control switch (vertical height can range from 630 mm to 1030 mm). Table top supports the PC monitor, keyboard, mouse (or glidepad), and optical head. Shelves hold PC, printer, isolation transformer, and power supply.

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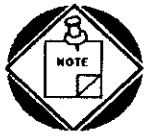
2.1 Indications, Contraindications, Warnings, Precautions, and Adverse Events

2.1.1 Indications for Use

The STAR S4 IR™ Excimer Laser System with Variable Spot Scanning (VSS™) and the WaveScan WaveFront® System is indicated for wavefront-guided laser assisted in situ keratomileusis (LASIK):

- for the reduction or elimination of myopia and myopic astigmatism from -6.00 to -11.00 D MRSE, with cylinder between 0.00 and -3.00 D;
- in patients 21 years of age or older; and
- in patients with documented evidence of a change in manifest refraction of no more than 1.0 D (in both cylinder and sphere components) for at least one year prior to the date of pre-operative examination.



Refer to the preceding General Warnings section of this Professional Use Information Manual, in addition to the warnings and precautions found in this section.

2.1.2 Contraindications

Laser refractive surgery is contraindicated:

- in patients with collagen vascular, autoimmune or immunodeficiency diseases.
- in pregnant or nursing women.
- in patients with signs of keratoconus or abnormal corneal topography.
- in patients who are taking one or both of the following medications: Isotretinoin (Accutane®[2]); Amiodarone hydrochloride (Cordarone®[3]).

[2] Accutane ® is a registered trademark of Hoffmann-La Roche Inc.
[3] Cordarone® is a registered trademark of Sanofi-Synthelabo, Inc

2.1.3 Warnings

LASIK is not recommended in patients who have:

- diabetes.
- a history of *Herpes simplex* or *Herpes zoster* keratitis.
- significant dry eye that is unresponsive to treatment.
- severe allergies.

2.1.4 Precautions

A. General

To avoid corneal ectasia, the posterior 250 microns (µm) of corneal stroma should not be violated.

The treatment of highly myopic eyes necessitates the removal of significant amounts of corneal tissue. The WaveScan calculates the estimated residual bed depth using the pachymetry and intended flap thickness entered by the user. Actual flap thicknesses may vary. All users should be aware that during the FDA clinical trial for highly myopic eyes, an "in the bed" pachymetric measurement was performed to assure a minimum residual stromal bed of 250 microns. If the corneal flap was thicker than intended and the 250 micron minimum would have been violated by a CustomVue treatment, users were instructed not to perform a CustomVue treatment on that eye.

The safety and effectiveness of this laser for LASIK correction have **NOT** been established in patients:

- with progressive myopia, hyperopia, myopic or hyperopic astigmatism; ocular disease; corneal abnormality; previous corneal or intraocular surgery; or trauma in the ablation zone.
- with a residual corneal thickness less than 250 microns at the completion of ablation.
- with a history of glaucoma.
- who are taking the medication Sumatriptan (Imitrex®[4]).

The effects of laser refractive surgery on visual performance under poor lighting conditions have not been determined. It is possible, following LASIK treatment, that patients will find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog, or glare from bright lights at night. Visual performance possibly could be worsened by large pupil sizes or decentered pupils.

Pupil size should be evaluated under mesopic illumination conditions. Patients with large mesopic pupil size (≥6.6 mm) should be advised of the potential for negative effects on vision after surgery, such as increased frequency of glare and halos, and decreased satisfaction at night under conditions with glare, such as night driving.

Pre-operative evaluation for dry eye should be performed. Patients should be advised of the potential for dry eye post-LASIK surgery.

[4] Imitrex® is a registered trademark of GlaxoSmithKline.

Pre-operative ultrasonic pachymetry measurement must be performed.

The physician's adjustment of defocus was used in the clinical study to implement standard nomogram adjustment to the wavefront-guided treatments. No other uses of the physician's adjustment of defocus have been studied, and their effects on the safety and effectiveness outcomes for wavefront-guided LASIK are unknown.

The safety and effectiveness of wavefront-guided LASIK surgery has **ONLY** been established with an optical zone of 6 mm and an ablation zone of 8 mm.

The WaveScan® sensor measures the higher order aberrations only over the diameter of the patient's pupil, to a maximum of 7.0 mm. No optical zone diameters other than 6 mm were studied in the U.S. wavefront-guided clinical trial for high myopia.

No higher order aberrations can be measured or treated outside the wavefront measurement region. If the surgeon extends the optical zone beyond the measured wavefront diameter, the nonuniform wavefront transition zone will overlie the attempted spherocylindrical treatment. Some treatments based on WaveScan measurement diameters of less than 6.0 mm were used to establish the safety and effectiveness of wavefront-guided high myopia treatments with 6.0 mm optical zones. A comparison of results from these treatments and treatments based on measurements that were 6.0 mm or larger showed that outcomes were similar.

It is important to maintain a carefully controlled surgical environment. VISX recommends that all CustomVue™ treatments be performed in surgical environments where the humidity is between 40-45% and the temperature is between 68-72° F for best results.

The safety and effectiveness of the STAR S4 IR™ System have **NOT** been established for wavefront-guided LASIK surgery in patients:

- with corneal neovascularization within 1.0 mm of the ablation zone.
- under 21 years of age.
- over the long term (more than 1 year after surgery).
- with prior intraocular or corneal surgery of any kind.
- For eyes with high myopia or myopic astigmatism:
  - whose difference between WaveScan and manifest sphere or cylinder powers is more than ±0.75 diopters, or whose difference between WaveScan and manifest cylinder axes is >15 degrees (for eyes with manifest cylinder power greater than 0.50 D).
  - whose difference between manifest and cycloplegic sphere powers is more than ±0.75 diopters, or whose difference between manifest and cycloplegic cylinder axes is >15 degrees (for eyes with manifest cylinder power greater than 0.50 D).
  - whose difference between WaveScan and cycloplegic sphere or cylinder powers is more than ±0.75 diopters, or whose difference between WaveScan and cycloplegic cylinder axes is >15 degrees (for eyes with manifest cylinder power greater than 0.50 D).
  - whose BSCVA is worse than 20/20.
  - whose WaveScan® wavefront measurement diameter is < 5 mm.
  - for treatments greater than -11 diopters of MRSE or greater than -3 diopters of astigmatism.
  - for retreatment with CustomVue™ LASIK.
  - who were wearing contact lenses unless they had evidence of stability.

- with anticipated postoperative keratometry reading <33 diopters. Anticipated post-operative keratometry values can be calculated by multiplying the magnitude of the MRSE by 0.8, and subtracting that value from the average pre-operative keratometry value. In other words, [((K1 + K2) x 0.5) - (|MRSE| x 0.8)] > 33 D.

B. Patient Selection

Consideration should be given to the following in determining the appropriate patients for CustomVue™ treatment:

- All patients must be given the opportunity to read and understand the Patient Information Booklet and to have all their questions answered to their satisfaction before giving consent for Laser Assisted In Situ Keratomileusis (LASIK).

- Complete examination, including but not limited to, cycloplegic evaluation, must be performed. The lens must be evaluated, especially in the older patient, to assure that nuclear sclerosis or any other lens opacity is not present prior to laser surgery. Myopic patients will have a higher incidence of retinal pathology, and indirect ophthalmoscopy through a dilated pupil is essential.

- To obtain accurate refractive information, contact lens wearers must be examined after abstaining from contact lens use for at least 2 weeks for soft lenses and at least 3 weeks for hard lenses. Prior to treatment and after at least 3 weeks of contact lens abstinence, patients who wear rigid gas permeable or hard (PMMA) lenses must have 3 central keratometry readings and manifest refractions taken at 1 week intervals, the last 2 of which must not differ by more than 0.50 diopter in either meridian. All mires must be regular. Any patient with keratometry or a clinical picture that is suggestive of keratoconus is specifically contraindicated as described above.

- Glaucoma is more common in myopic patients than in the general population. Evaluation of the optic nerve and measurement of the intraocular pressure are necessary. If there are any concerns regarding the appearance of the optic nerve, a Humphrey 24-2 Fastpac or equivalent threshold test of the visual field should be performed. If elevated intraocular pressure and/or evidence of glaucomatous damage are found, topical steroids should be used only with careful medical supervision or the patient should not undergo laser refractive surgery.

- Pre-operative corneal mapping is essential on all patients to exclude topographical abnormalities. This is especially important when astigmatism or steep keratometry readings are present, which may indicate the presence of keratoconus or other irregularities.

- Baseline evaluation of patients requesting CustomVue treatments should be performed within 30 days of the laser refractive surgery. This evaluation should address agreement between the manifest, cycloplegic, and the WaveScan® refraction and the limits for peak to valley higher order aberrations, BSCVA, and pupil size, as outlined in the previous section of these Precautions.

- The minimum size of the wavefront measurement must be ≥5 mm to calculate a CustomVue treatment.

- If a PreVue® lens is used in the baseline evaluation of patients requesting CustomVue™ treatments, the vision obtained by the patient through the PreVue lens is not meant to be predictive of the end result that a patient might achieve. In situations where there is a clinical question regarding the applicability of the computer-generated treatment, a PreVue lens can be ablated to assist both the practitioner and the patient in evaluating the appropriateness of this generated treatment.

- The patient should have the ability to tolerate local or topical anesthesia.

- The patient should have the ability to lie flat without difficulty.

- The patient should be able to fixate steadily and accurately for the duration of the laser refractive procedure.

- The patient must be able to understand and give an informed consent.

- Patients must be clearly informed of all alternatives for the correction of myopia, hyperopia, and myopic and hyperopic astigmatism. These alternative corrections include but are not limited to spectacles, contact lenses, and other refractive surgeries.

C. Procedure

The output of the laser is potentially hazardous only to the skin and the surface layers of the cornea. This radiation has not been shown to pose a threat to retinal structures or the crystalline lens. The area of potential hazard (Nominal Hazard Zone) for production of a photochemical keratitis has been determined to be less than 40 cm from the primary beam.

All healthcare personnel should avoid direct exposure to the skin or eye by the primary beam. While no hazard may exist farther than 40 cm from the beam, the use of protective eyewear is recommended if the possibility exists that healthcare personnel will approach closer than this distance to the primary beam.

D. Post-Procedure

The following post-operative examinations are recommended on day 1, and at 1, 3, and 6 months:

- WaveScan® measurement at 1, 3, and 6 months.
- Uncorrected Visual Acuity (UCVA or VA-sc).
- Best Spectacle-Corrected Visual Acuity (BSCVA or VA-cc).
- Manifest refraction.
- Intraocular pressure (Goldmann applanation) at 1, 3, and 6 months.
- Slit-lamp examination.
- Keratometry and videokeratography at 1, 3, and 6 months.

2.1.5 Adverse Events

One hundred eighty-four (184) eyes were used for safety analyses. A summary of adverse events at 1 month and later are provided in Table 2-1. Complications are presented in Table 2-2.

Table 2-1: Summary of Adverse Events (N=184)

	<1 Month (n=184)		1 Month (n=184)		3 Months (n=180)		6 Months (n=178)		9 Months (n=170)		12 Months (n=107)	
	n	%	n	%	n	%	n	%	n	%	n	%
Corneal Infiltrate/Ulcer	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Corneal epithelial defect involving the keratectomy at 1 month or later	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Corneal edema at 1 month or later	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Epithelium in the interface with loss of 2 or more lines of BSCVA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Miscreated Flap	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Melting of the flap	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Uncontrolled IOP >10 mm Hg or any reading > 25 mm Hg	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Late onset of haze beyond 6 months with loss of 2 lines (10 letters) or more BSCVA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Decrease in BSCVA of > 10 letter not due to irregular astigmatism as shown by hard contact lens refraction, at 6 months or later	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Retinal Detachment	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Retinal Vascular Accidents	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Other: Two eyes of two separate subjects developed trace diffuse lamellar keratitis (DLK) prior to the 1-month visit. One eye of one subject experienced a metallic foreign body with subsequent rust ring. This event occurred at an interim 1-month visit and resolved by the 3-month visit. At the 9-month visit, one subject reported having undergone excision of a benign parotid gland tumor.

Table 2-2: Summary of Complications (N=184)												
	<1 Month (n=184)		1 Month (n=184)		3 Months (n=180)		6 Months (n=178)		9 Months (n=170)		12 Months (n=107)	
	n	%	n	%	n	%	n	%	n	%	n	%
Misaligned flap	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Corneal edema between 1 week and 1 month after the procedure	5	2.7	1	0.5	0	0.0	0	0.0	0	0.0	0	0.0
Peripheral corneal epithelial defect at 1 month or later	4	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Epithelium in the interface[5]	1	0.5	2	1.1	0	0.0	0	0.0	0	0.0	0	0.0
Foreign body sensation at 1 month or later	0	0.0	1	0.5	0	0.0	0	0.0	0	0.0	0	0.0
Pain at 1 month or later	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Diplopia (ghost images) in the operative eye[6]	0	0.0	11	6.0	9	5.0	6	3.4	5	2.9	4	3.7

[5] Overall, 3 eyes (3/184, 1.6%) experienced epithelium in the interface.
[6] Overall, 16 eyes (16/184, 8.7%) experienced diplopia.

3.1 Clinical Results

3.1.1 High Myopia With and Without Astigmatism

A prospective, non-randomized, unmasked, multicenter clinical study was conducted. The refractive inclusion criteria specified that the patient have myopic astigmatism with cylinder between -3.0 and -6.0 D, or myopia from -6.0 D to -14.0 D MRSE with or without astigmatism up to -6.0 D. To qualify for the study, patients also had to demonstrate agreement between the manifest and WaveScan® refraction, and a wavefront measurement size ≥5 mm. All study treatments were conducted using a 6 mm optical zone and an 8 mm ablation zone with intention of full correction to emmetropia. In the trial for high myopia, a standardized physician adjustment of -0.5D sphere offset and +4% nomogram boost were used by all sites to increase the ablation efficiency by approximately 10% for all eyes. One hundred and eighty-four (184) eyes comprised the cohort used for both safety and effectiveness evaluations. Results from eyes with spherical myopia (n=83) and myopic astigmatism (n=101) are presented separately. Spherical myopia is defined as ≤ 0.5 D of astigmatism by manifest refraction. Patients who exhibited any of the following conditions were excluded: anterior segment pathology; residual, recurrent, or active ocular disease; previous intraocular or corneal surgery in the operative eye; history of herpes keratitis; or autoimmune disease, systemic connective tissue diseases, or atopy.

A. About the Study

Analyses of results were performed at 1, 3, 6, 9, and 12 months post-treatment. Effectiveness analyses included uncorrected visual acuity, accuracy of manifest refraction, and stability. Safety analyses included change in best spectacle-corrected visual acuity (BSCVA), change in intraocular pressure, adverse events, and complications. The post-operative spectacle/contact lens wear frequency was not assessed.

B. Patient Accountability

One hundred and eighty-four (184) eyes of 94 subjects treated at seven centers in the United States were evaluated for safety and effectiveness. The mean age of the 94 subjects participating in this trial was 35.8 ± 7.4 years (range 23 to 55). There were 51 women and 43 men. Table 3-1 presents the demographic characteristics of the patient population. Table 3-2 presents the percent accountability for all eyes treated in the study. Over 93% accountability was achieved at the 1, 3, 6, 9, and 12-month visits.

Table 3-1: Demographics (N=184)			
Age (in Years)	Average + Standard Deviation Minimum to Maximum	35.8 ± 7.4 23 to 55	
		Number	**% of Eyes**
Gender	Male	86	46.7
	Female	98	53.3
Race	Caucasian	135	73.4
	Asian/ Pacific Islander	18	9.8
	African American	4	2.2
	Native American/ Alaskan Native	0	0.0
	Hispanic	20	10.9
	Other*	7	3.8
Eyes	Right	92	50.0
	Left	92	50.0
Contact Lens History	None	25	13.6
	Soft	137	74.5
	RGP/PMMA	22	12.0

*"Other" classifications of race include: Hispanic/American Indian, Persian, and Indian

Table 3-2: Patient Accountability (N=184)										
	1 Month		**3 Months**		**6 Months**		**9 Months**		**12 Months**	
	n	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Available for Analysis	184	100	180	97.8	178	96.7	170	92.4	107	58.2
Discontinued	0	0.0	0	0.0	0	0.0	0	0.0	2	1.1
Missed Visit	0	0.0	2	1.1	4	2.2	4	2.2	1	0.5
Not yet eligible	0	0.0	0	0.0	0	0.0	6	3.3	68	37.0
Lost to Follow-Up	0	0.0	2	1.1	2	1.1	4	2.2	6	3.3
% Accountability*	**100%**		**97.8%**		**96.7%**		**96.5%**		**93.9%**	

*Percent accountability = [available for analysis/(enrolled – discontinued – not yet eligible)] x 100.

C. Data Analysis and Results

1) Pre-Operative Characteristics

All refractions were tested at four meters and converted to optical infinity for data analysis and presentation. Table 3-3 presents pre-operative refractive error stratified by manifest sphere and cylinder, while Table 3-4 presents pre-operative refractive error stratified by manifest spherical equivalent and cylinder, expressed in minus cylinder notation.

Table 3-3: Pre-Operative Refractive Error Stratified by Sphere and Cylinder: (N=184)

	Manifest Cylinder (D)													
Manifest Sphere (D)	**0 to -0.5**		**<-0.5 to -1**		**<-1 to -2**		**<-2 to -3**		**<-3 to -4**		**<-4 to -5.25**		**Total**	
	n	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
<-5 to -6	0	0.0	0	0.0	3	1.6	1	0.5	2	1.1	2	1.1	8	4.3
<-6 to -7	13	7.1	11	6.0	7	3.8	10	5.4	3	1.6	0	0.0	44	23.9
<-7 to -8	30	16.3	6	3.3	14	7.6	4	2.2	2	1.1	0	0.0	56	30.4
<-8 to -9	23	12.5	8	4.3	7	3.8	2	1.1	0	0.0	0	0.0	40	21.7
<-9 to -10	8	4.3	4	2.2	7	3.8	1	0.5	0	0.0	0	0.0	20	10.9
<-10 to -11.25	9	4.9	4	2.2	3	1.6	0	0.0	0	0.0	0	0.0	16	8.7
Total	83	45.1	33	17.9	41	22.3	18	9.8	7	3.8	2	1.1	184	100

Table 3-4: Pre-Operative Refractive Error Stratified by Spherical Equivalent and Cylinder (N=184)														
	Manifest Cylinder (D)													
Manifest Spherical Equivalent (D)	0 to -0.5		<-0.5 to -1		<-1 to -2		<-2 to -3		<-3 to -4		<-4 to -5.25		Total	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
<-6 to -7	9	4.9	8	4.3	3	1.6	1	0.5	0	0.0	0	0.0	21	11.4
<-7 to -8	27	14.7	7	3.8	8	4.3	9	4.9	2	1.1	1	0.5	54	29.3
<-8 to -9	26	14.1	5	2.7	16	8.7	2	1.1	3	1.6	1	0.5	53	28.8
<-9 to -10	12	6.5	7	3.8	5	2.7	5	2.7	2	1.1	0	0.0	31	16.8
<-10 to -11	7	3.8	3	1.6	6	3.3	1	0.5	0	0.0	0	0.0	17	9.2
<-11 to -12	2	1.1	3	1.6	3	1.6	0	0.0	0	0.0	0	0.0	8	4.3
Total	83	45.1	33	17.9	41	22.3	18	9.8	7	3.8	2	1.1	184	100.0

2) Uncorrected Visual Acuity (UCVA)

All eyes were targeted for emmetropia. At the 6 month visit, 84.3% (150/178) of all eyes achieved UCVA of 20/20 or better, and 98.3% achieved 20/40 or better. Tables 3-5 to 3-7 present UCVA over time for the cohorts of all eyes, eyes with spherical myopia, and eyes with astigmatic myopia, respectively.

Table 3-5: UCVA Over Time: All Eyes (N=184)

	Pre-Op (n=184)		1 Month (n=184)		3 Months (n=180)		6 Months (n=178)		9 Months (n=170)		12 Months (n =107)	
	n	%	n	%	n	%	n	%	n	%	n	%
20/12.5 or better	0	0.0	7	3.8	12	6.7	26	14.6	18	10.6	10	9.3
20/16 or better	0	0.0	95	51.6	101	56.1	116	65.2	103	60.6	63	58.9
20/20 or better	0	0.0	157	85.3	147	81.7	150	84.3	145	85.3	92	86.0
20/25 or better	0	0.0	170	92.4	168	93.3	166	93.3	162	95.3	103	96.3
20/32 or better	0	0.0	175	95.1	176	97.8	173	97.2	165	97.1	107	100.0
20/40 or better	0	0.0	182	98.9	177	98.3	175	98.3	169	99.4	107	100.0
20/80 or better	0	0.0	184	100.0	180	100.0	178	100.0	170	100.0	107	100.0
20/100 or better	0	0.0	184	100.0	180	100.0	178	100.0	170	100.0	107	100.0
Worse than 20/100	184	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 3-6: UCVA Over Time: Spherical Myopia (N=83)												
	Pre-Op (n=83)		1 Month (n=83)		3 Months (n=82)		6 Months (n=83)		9 Months (n=73)		12 Months (n=46)	
	n	%	n	%	n	%	n	%	n	%	n	%
20/12.5 or better	0	0.0	4	4.8	8	9.8	16	19.3	6	8.2	7	15.2
20/16 or better	0	0.0	55	66.3	62	75.6	70	84.3	59	80.8	35	76.1
20/20 or better	0	0.0	79	95.2	77	93.9	82	98.8	72	98.6	45	97.8
20/25 or better	0	0.0	82	98.8	80	97.6	82	98.8	72	98.6	46	100.0
20/32 or better	0	0.0	82	98.8	80	97.6	82	98.8	72	98.6	46	100.0
20/40 or better	0	0.0	82	98.8	81	98.8	82	98.8	72	98.6	46	100.0
20/80 or better	0	0.0	83	100.0	82	100.0	83	100.0	73	100.0	46	100.0
20/100 or better	0	0.0	83	100.0	82	100.0	83	100.0	73	100.0	46	100.0
Worse than 20/100	83	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 3-7: UCVA Over Time: Myopic Astigmatism (N=101)												
	Pre-Op (n=101)		1 Month (n=101)		3 Months (n=98)		6 Months (n=95)		9 Months (n=97)		12 Months (n=61)	
	n	%	n	%	n	%	n	%	n	%	n	%
20/12.5 or better	0	0.0	3	3.0	4	4.1	10	10.5	12	12.4	3	4.9
20/16 or better	0	0.0	40	39.6	39	39.8	46	48.4	44	45.4	28	45.9
20/20 or better	0	0.0	78	77.2	70	71.4	68	71.6	73	75.3	47	77.0
20/25 or better	0	0.0	88	87.1	88	89.8	84	88.4	90	92.8	57	93.4
20/32 or better	0	0.0	93	92.1	96	98.0	91	95.8	93	95.9	61	100.0
20/40 or better	0	0.0	100	99.0	96	98.0	93	97.9	97	100.0	61	100.0
20/80 or better	0	0.0	101	100.0	98	100.0	95	100.0	97	100.0	61	100.0
20/100 or better	0	0.0	101	100.0	98	100.0	95	100.0	97	100.0	61	100.0
Worse than 20/100	101	100	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 3-8 presents post-operative uncorrected visual acuity compared to pre-operative best spectacle-corrected visual acuity. At six months, 78% of eyes were able to achieve a post-operative uncorrected vision that was either the same or better than their pre-operative best-corrected vision.

Table 3-8: Post-Operative Uncorrected Visual Acuity Compared to Pre-Operative Best Spectacle-Corrected Visual Acuity: All Eyes (N=184)

	1 Month (n=184)		3 Months (n=180)		6 Months (n=178)		9 Months (n=170)		12 Months (n=107)	
	n	%	n	%	n	%	n	%	n	%
> 2 lines better	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
2 lines better	2	1.1%	3	2.2%	7	3.9%	5	2.9%	2	1.9%
1 line better	38	20.7%	42	23.3%	60	33.7%	49	28.8%	28	26.2%
< 1 line change	91	49.5%	83	46.1%	72	40.4%	74	43.5%	52	48.6%
1 line worse	34	18.5%	32	17.8%	18	10.1%	29	17.1%	18	16.8%
2 lines worse	10	5.4%	13	7.2%	15	8.4%	7	4.1%	5	4.7%
> 2 lines worse	9	4.9%	6	3.3%	6	3.4%	6	3.5%	2	1.9%

Note: "< 1 line change" means "less than 1 line better or worse"; "1 line better" means "equal to or greater than 1 line better, but less than 2 lines better"; "2 lines better" means "equal to 2 lines better"; "> 2 lines better" means "greater than 2 lines better"; and so on.

3) Accuracy of MRSE Over Time

At 6 months post-operatively, 77.0% (137/178) of eyes were within 0.50 D and 95.5% (170/178) were within 1.0 D of attempted correction. Tables 3-9 to 3-11 present the accuracy of MRSE over time.

Table 3-9: Accuracy of Manifest Refraction Attempted vs. Achieved All Eyes (N=184)

	Pre-Op (n=184)		1 Month (n=184)		3 Months (n=180)		6 Months (n=178)		9 Months (n=170)		12 Months (n=107)	
	n	%	n	%	n	%	n	%	n	%	n	%
MRSE												
± 0.50 D	0	0.0	146	79.3	140	77.8	137	77.0	137	80.6	88	82.2
± 1.00 D	0	0.0	177	96.2	171	95.0	170	95.5	162	95.3	102	95.3
± 2.00 D	0	0.0	184	100.0	179	99.4	178	100.0	170	100.0	107	100.0
Overcorrected												
> 1.00 D			7	3.8	6	3.3	4	2.2	4	2.4	1	0.9
> 2.00 D			0	0.0	1	0.6	0	0.0	0	0.0	0	0.0
Undercorrected												
< -1.00			0	0.0	3	1.7	4	2.2	4	2.4	4	3.7
< -2.00			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 3-10: Accuracy of Manifest Refraction: Attempted vs. Achieved: Spherical Myopia (N=83)												
	Pre-Op (n=83)		1 Month (n=83)		3 Months (n=82)		6 Months (n=83)		9 Months (n=73)		12 Months (n=46)	
	n	%	n	%	n	%	n	%	n	%	n	%
MRSE												
± 0.50 D	0	0.0	71	85.5	69	84.1	68	81.9	62	84.9	42	91.3
± 1.00 D	0	0.0	80	96.4	81	98.8	82	98.8	72	98.6	46	100.0
± 2.00 D	0	0.0	83	100.0	81	98.8	83	100.0	73	100.0	46	100.0
Overcorrected												
> 1.00 D			3	3.6	1	1.2	1	1.2	1	1.4	0	0.0
> 2.00 D			0	0.0	1	1.2	0	0.0	0	0.0	0	0.0
Undercorrected												
< -1.00			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
< -2.00			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 3-11: Accuracy of Manifest Refraction: Attempted vs. Achieved: Myopic Astigmatism (N=101)												
	Pre-Op (n=101)		1 Month (n=101)		3 Months (n=98)		6 Months (n=95)		9 Months (n=97)		12 Months (n=61)	
	n	%	n	%	n	%	n	%	n	%	n	%
MRSE												
± 0.50 D	0	0.0	75	74.3	71	72.4	69	72.6	75	77.3	46	75.4
± 1.00 D	0	0.0	97	96.0	90	91.8	88	92.6	90	92.8	56	91.8
± 2.00 D	0	0.0	101	100.0	98	100.0	95	100.0	97	100.0	61	100.0
Not Reported	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Overcorrected												
> 1.00 D			4	4.0	5	5.1	3	3.2	3	3.1	1	1.6
> 2.00 D			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Undercorrected												
< -1.00			0	0.0	3	3.1	4	4.2	4	4.1	4	6.6
< -2.00			0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

4) Stability of Outcome

Stability of outcome is evaluated both by the cohort of eyes with a refraction at each visit (n=164), as well as the cohort of eyes who were available for two consecutive visits, but not for all visits. Refractive stability is reached at 6 months and confirmed at the 9-month visit. Tables 3-12 and 3-13 present refractive stability over time.

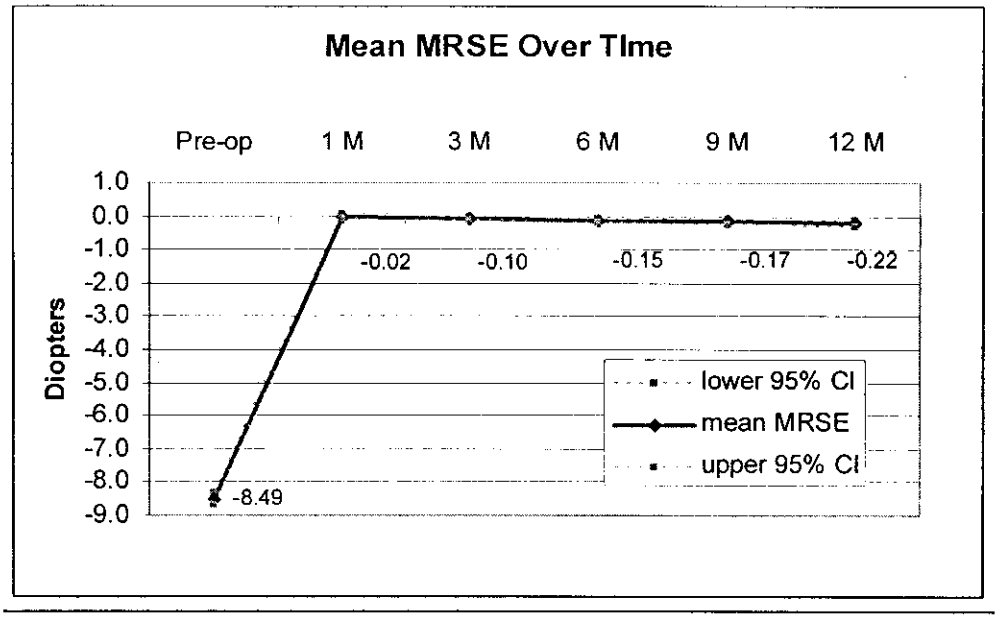
Table 3-12: Stability of MRSE for Eyes that Underwent 1, 3, 6, and 9-Month Exams

	Between 1 and 3 Months	Between 3 and 6 Months	Between 6 and 9 Months
All Eyes (n=164)			
Change in MRSE by ≤ 1.0 D, n	161	163	163
%	98.2	99.4	99.4
Mean Change in MRSE ± SD	-0.08 ± 0.39	-0.04 ± 0.31	-0.02 ± 0.28
95% CI	(-0.14, -0.02)	(-0.09, 0.01)	(-0.07, 0.02)
Spherical Myopia (n=72)			
Change in MRSE by ≤ 1.0 D, n	70	71	72
%	97.2	98.6	100.0
Mean Change in MRSE ± SD	-0.08 ± 0.39	-0.07 ± 0.34	-0.04 ± 0.29
95% CI	(-0.17, 0.01)	(-0.15, 0.01)	(-0.11, 0.03)
Myopic Astigmatism (n=92)			
Change in MRSE by ≤ 1.0 D, n	91	92	91
%	98.9	100.0	98.9
Mean Change in MRSE ± SD	-0.08 ± 0.40	-0.02 ± 0.29	-0.01 ± 0.28
95% CI	(-0.17, 0.00)	(-0.08, 0.04)	(-0.07, 0.05)

Table 3-13: Stability of MRSE for Eyes that Underwent Two Consecutive Visits				
	Between 1 and 3 Months	**Between 3 and 6 Months**	**Between 6 and 9 Months**	**Between 9 and 12 Months**
All Eyes	**n=180**	**n=176**	**n=166**	**n=107**
Change in MRSE by ≤ 1.0 D, n	177	174	165	107
%	98.3	98.9	99.4	100.0
Mean Change in MRSE ± SD	-0.09 ± 0.38	-0.04 ± 0.32	-0.02 ± 0.28	0.00 ± 0.28
95% CI	(-0.14, -0.03)	(-0.09, 0.01)	(-0.07, 0.02)	(-0.05, 0.05)
Spherical Myopia	**n=82**	**n=82**	**n=73**	**n=46**
Change in MRSE by ≤ 1.0 D, n	80	80	73	46
%	97.6	97.6	100.0	100.0
Mean Change in MRSE ± SD	-0.09 ± 0.37	-0.05 ± 0.35	-0.04 ± 0.28	-0.02 ± 0.30
95% CI	(-0.17, -0.01)	(-0.13, 0.02)	(-0.11, 0.03)	(-0.10, 0.07)
Myopic Astigmatism	**n=98**	**n=94**	**n=93**	**n=61**
Change in MRSE by ≤ 1.0 D, n	97	94	92	61
%	99.0	100.0	98.9	100.0
Mean Change in MRSE ± SD	-0.08 ± 0.40	-0.03 ± 0.29	-0.01 ± 0.28	0.01 ± 0.26
95% CI	(-0.16, 0.00)	(-0.08, 0.03)	(-0.07, 0.05)	(-0.05, 0.08)

When plotted over time, the mean manifest spherical equivalents illustrate that stability is achieved by the 6-month visit.

Figure 3-1 — MRSE Over Time (All Eyes, N=184)



5) Efficacy of Correction of Astigmatism

Efficacy of correction of astigmatism was evaluated at the point of stability (6 months) for eyes with myopic astigmatism. Table 3-14 displays the mean percent reduction of cylinder for eyes with myopic astigmatism, stratified by pre-operative cylinder.

Table 3-14: Reduction of Absolute (Non-Vector) Cylinder at 6 Months: Myopic Astigmatism (N=95)

Preoperative Cylinder	Mean % Reduction	Range
All (n=95)	70.0%	-33.0% to 100%
< -0.50 to -1.0 D (n=33)	60.1%	-33.3% to 100%
< -1.0 to -2.0 D (n=39)	72.2%	12.5% to 100%
< -2.0 to -3.0 D (n=16)	79.6%	49.8% to 100%
< -3.0 to -4.0 D (n=7)	81.9%	53.1% to 100%

Table 3-15 presents a summary of the vector analysis which includes mean Intended Refractive Change (IRC), Surgically Induced Refractive Change (SIRC), correction Ratio (CR), and Error Ratio (ER), at the point of stability (6 months).

Table 3-15: Vector Analysis at Stability (6 Months): Eyes with Myopic Astigmatism (N=95)

Preoperative Cylinder	IRC* Mean ± SD	SIRC^ Mean ± SD	CR† Mean ± SD	ER◊ Mean ± SD
All (n=95)	-1.34 ± 0.71	-1.19 ± 0.71	0.91 ± 0.32	-0.37 ± 0.43
< -0.50 to -1.0 D (n=33)	-0.69 ± 0.11	-0.69 ± 0.31	0.99 ± 0.37	-0.48 ± 0.57
< -1.0 to -2.0 D (n=39)	-1.27 ± 0.24	-1.08 ± 0.41	0.86 ± 0.32	-0.34 ± 0.34
< -2.0 to -3.0 D (n=16)	-2.13 ± 0.26	-1.81 ± 0.52	0.85 ± 0.24	-0.25 ± 0.24
< -3.0 to -4.0 D (n=7)	-3.01 ± 0.17	-2.79 ± 0.37	0.93 ± 0.14	-0.22 ± 0.23

*IRC-*Intended Refractive Change* – vector difference between target refraction and preoperative refractions
^SIRC-*Surgically Induced Refractive Error* – difference between postoperative and preoperative vectors
†CR-*Correction Ratio* – ratio of achieved versus intended vector magnitude
CR mathematical definition: |SIRC| divided by |IRC|
◊ER-*Error Ratio* – ratio of Error Vector and IRC magnitudes
Error Vector mathematical definition: vector difference between |SIRC| and |IRC|
ER mathematical definition: |Error Vector| divided by |IRC|

6) Higher Order Aberrations

Although the WaveScan WaveFront® System measures the refractive error and wavefront aberrations of the human eyes, including myopia, hyperopia, astigmatism, coma, spherical aberration, trefoil, and other higher order aberrations through sixth order, in the clinical study for this PMA, the average higher order aberrations increased after CustomVue™ treatment. The most noticeable increases were in coma and spherical aberration. The clinical data over 9 months showed that the changes in all higher order aberrations were stable post-operatively.

Table 3-16 presents mean root-mean-square (RMS) value for higher order aberrations over time for all eyes with eligible wavefront exams.

Table 3-16: RMS Over Time (N=184^)						
	Pre-Op Mean ± SD	1 Month Mean ± SD	3 Months Mean ± SD	6 Months Mean ± SD	9 Months Mean ± SD	12 Months Mean ± SD
	n=184	n=174	n=174	n=169	n=162	n=101
All higher order	0.17 ± 0.06	0.32 ± 0.10	0.33 ± 0.10	0.33 ± 0.10	0.34 ± 0.10	0.35 ± 0.10
Coma	0.10 ± 0.06	0.24 ± 0.12	0.26 ± 0.12	0.26 ± 0.12	0.27 ± 0.12	0.28 ± 0.12
Trefoil	0.08 ± 0.05	0.10 ± 0.05	0.09 ± 0.05	0.09 ± 0.06	0.10 ± 0.05	0.09 ± 0.05
Spherical Aberration	0.06 ± 0.04	0.11 ± 0.07	0.10 ± 0.07	0.11 ± 0.08	0.11 ± 0.07	0.11 ± 0.08
Secondary Astigmatism	0.03 ± 0.02	0.05 ± 0.03	0.06 ± 0.03	0.06 ± 0.03	0.06 ± 0.03	0.05 ± 0.03
Tetrafoil	0.03 ± 0.02	0.05 ± 0.03	0.05 ± 0.03	0.05 ± 0.03	0.05 ± 0.03	0.06 ± 0.04
5^{th} order	0.02 ± 0.02	0.05 ± 0.03	0.04 ± 0.02	0.04 ± 0.02	0.04 ± 0.02	0.04 ± 0.03
6^{th} order	0.02 ± 0.01	0.04 ± 0.02	0.04 ± 0.02	0.03 ± 0.02	0.03 ± 0.02	0.03 ± 0.03
Signed Value of Spherical Aberration	0.04 ± 0.06	0.07 ± 0.11	0.09 ± 0.09	0.10 ± 0.09	0.10 ± 0.09	0.10 ± 0.09
Min, Max	(-0.13, 0.18)	(-0.22, 0.29)	(-0.14, 0.29)	(-0.11, 0.31)	(-0.18, 0.38)	(-0.14, 0.31)
	n=184	n=181	n=177	n=175	n=164	n=102
WaveScan SE*	-8.24 ± 1.40	0.22 ± 0.78	0.16 ± 0.68	0.00 ± 0.70	-0.02 ± 0.70	-0.16 ± 0.57
Astigmatism Magnitude*	1.24 ± 1.00	0.59 ± 0.51	0.56 ± 0.36	0.56 ± 0.32	0.59 ± 0.31	0.53 ± 0.29

^Wavefront aberrations are calculated over a 5 mm area. Eyes with wavefront measurements of ≥ 5 mm are included in this analysis.

*WaveScan spherical equivalent and astigmatism analyses are calculated over a 4 mm area. Eyes with wavefront measurements of ≥ 4 mm are included in this analysis.

7) WaveScan Wavefront Diameter

A minimum wavefront diameter of 5 mm is required for treatment with CustomVue™ LASIK for high myopia. In the clinical trial, all treatments used an optical zone of 6 mm and ablation zone of 8 mm. Some of the eyes in the study (47/184, 25.5%) had 6 mm treatments based on wavefront diameters that were smaller than 6 mm. The results of these eyes were compared to results of eyes with treatments based on wavefront measurements of 6 mm or greater. Both groups of eyes had similar results. Table 3-17 presents key safety and effectiveness results for the two groups at 6 months postoperatively.

Table 3-17: Summary of 6 Month Key Safety and Effectiveness Variables For All Eyes Stratified by WaveScan Diameter

Wavefront Diameter	**< 6 mm**		**≥ 6 mm**	
	n	**%**	**n**	**%**
EFFECTIVENESS VARIABLES	**n=45**		**n=133**	
UCVA 20/16 or better	31	68.9	85	63.9
UCVA 20/20 or better	39	86.7	111	83.5
UCVA 20/25 or better	43	95.6	123	92.5
UCVA 20/32 or better	43	95.6	130	97.7
UCVA 20/40 or better	44	97.8	131	98.5
MRSE ± 0.50 D	30	66.7	107	80.5
MRSE ± 1.00 D	41	91.1	110	97.0
MRSE ± 2.00 D	45	100.0	133	100.0
Cylinder ± 0.50 D	33	73.3	102	76.7
Cylinder ± 1.00 D	41	91.1	128	96.2
SAFETY VARIABLES	**n=45**		**n=133**	
BSCVA worse than 20/25	0	0.0	0	0.0
BSCVA worse than 20/40	0	0.0	0	0.0
Loss ≥ 2 lines BSCVA	0	0.0	0	0.0
Loss up to 1 line BSCVA	1	2.2	8	6.0
No Change in BSCVA	13	28.9	34	25.6
Gain up to 1 line BSCVA	21	46.7	73	54.9
Gain ≥ 2 lines BSCVA	10	22.2	18	13.6

8) Best Spectacle-Corrected Visual Acuity (BSCVA)

No eye lost 2 or more lines of BSCVA at any visit. Table 3-18 presents the change in lines of BSCVA over time.

Table 3-18: Change in BSCVA Over Time: All Eyes (N=184)

	1 Month n=184		3 Months n=180		6 Months n=178		9 Months n=170		12 Months n=107	
	n	%	n	%	n	%	n	%	n	%
Decrease ≥ 2 Lines	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Decrease > 1 to < 2 Lines	1	0.5	3	1.7	0	0.0	0	0.0	0	0.0
Decrease > 0 to ≤ 1 Line	18	9.8	14	7.8	9	5.1	11	6.5	16	15.0
No Change	69	37.5	55	30.6	46	26.4	47	27.6	27	25.2
Increase >0 to ≤ 1 Line	89	48.4	94	52.2	94	52.8	96	56.5	59	55.1
Increase > 1 to ≤ 2 Lines	7	3.8	13	7.2	27	15.2	14	8.2	5	4.7
Increase > 2 Lines	0	0.0	1	0.6	1	0.6	2	1.2	0	0.0

9) Contrast Sensitivity Analysis

Table 3-19 presents the results of the contrast sensitivity analysis include mean change, standard error, and p-value from paired t-test. Patient responses to the four spatial frequencies (3, 6, 12 and 18 cycles per degree (CPD)) were measured with the patient's best corrected vision using the VectorVision CSV-1000 and converted from contrast levels to log units. A positive mean change reflects an improvement in contrast sensitivity, while a negative mean change reflects a decrease.

Table 3-19: Contrast Sensitivity: All Eyes (N=184)												
	Pre-Op (n=184)				Change from Pre-Op to 1 Month (n=178)				Change from Pre-Op to 3 Months (n=178)			
CPD	3	6	12	18	3	6	12	18	3	6	12	18
Dim w/ Glare												
Mean	1.52	1.52	1.00	0.54	-0.01	-0.05	-0.08	-0.01	0.00	-0.02	-0.07	0.00
SE	0.017	0.023	0.030	0.032	0.018	0.028	0.033	0.033	0.019	0.029	0.037	0.040
P Value*					0.622	0.065	0.023	0.789	0.923	0.441	0.084	0.973
Dim w/o Glare												
Mean	1.59	1.63	1.12	0.65	0.00	-0.03	-0.08	-0.03	-0.02	-0.06	-0.08	-0.04
SE	0.020	0.023	0.033	0.035	0.018	0.024	0.033	0.036	0.020	0.028	0.037	0.040
P Value* ≤					0.972	0.165	0.012	0.471	0.362	0.033	0.038	0.338
Bright w/o Glare												
Mean	1.76	1.95	1.61	1.14	-0.02	-0.06	-0.09	-0.05	-0.04	-0.06	-0.10	-0.08
SE	0.013	0.014	0.019	0.019	0.015	0.019	0.029	0.026	0.015	0.023	0.029	0.027
P Value* ≤					0.256	0.001	0.004	0.041	0.016	0.005	0.001	0.003

*Two tailed paired t test for the means.

Table 3-19: Contrast Sensitivity: All Eyes (N=184) (continued)								
	Change from Pre-Op to 6 Months (n=178)				Change from Pre-Op to 12 Months (n=107)			
CPD	3	6	12	18	3	6	12	18
Dim w/ Glare								
Mean	0.01	0.01	0.04	0.06	0.01	0.05	0.12	0.14
SE	0.020	0.026	0.035	0.037	0.026	0.036	0.041	0.04
P Value*	0.497	0.610	0.263	0.131	0.720	0.155	0.004	0.001
Dim w/o Glare								
Mean	-0.01	0.02	0.02	0.05	-0.01	0.02	0.08	0.08
SE	0.018	0.023	0.033	0.034	0.028	0.035	0.044	0.048
P Value* ≤	0.716	0.390	0.602	0.111	0.696	0.604	0.085	0.091
Bright w/o Glare								
Mean	-0.02	-0.01	-0.02	0.00	-0.03	-0.06	-0.06	-0.01
SE	0.017	0.017	0.024	0.023	0.023	0.025	0.036	0.032
P Value* ≤	0.255	0.480	0.448	0.894	0.230	0.018	0.110	0.830

*Two tailed paired t test for the means.

Table 3-20 presents the change in contrast sensitivity from baseline of more than 2 lines (>0.30 log levels) at 2 or more spatial frequencies, at 3, 6 and 12-months post-operatively for all eyes.

Table 3-20: Change in Contrast Sensitivity: All Eyes (N=184)									
	3 Months (n=178)			6 Months (n=178)			12 Months (n=107)		
	Decrease n %	No Change n %	Increase n %	Decrease n %	No Change n %	Increase n %	Decrease n %	No Change n %	Increase n %
Bright without Glare	25 14.0%	146 82.0%	7 3.9%	19 10.7%	143 80.3%	16 9.0%	15 14.0%	83 77.6%	9 8.4%
Dim without Glare	37 20.8%	112 62.9%	29 16.3%	28 15.7%	111 62.4%	39 21.9%	17 15.9%	62 57.9%	28 26.2%
Dim with Glare	34 19.1%	114 64.0%	30 16.9%	40 22.5%	90 50.6%	48 27.0%	14 13.1%	64 59.8%	29 27.1%

10) Retreatments

At the time of database closure, 4 eyes (4/184, 2.2%) had undergone retreatment in the study. Two eyes were retreated after completing the 9-month visit, and two eyes were retreated after completing the 12-month visit. Data for these eyes prior to retreatment are included in all analyses.

11) Patient Symptoms

Patient questionnaires reflected the following patient responses pre-operatively and at 1, 3, and 6 months post-operatively. Table 3-21 present a summary of patient symptoms and table 3-23 presents summary of patient satisfaction with visual quality for eyes with a preoperative questionnaire (n=182). Change in symptoms is presented in table 3-22 and change in satisfaction with visual quality is presented in table 3-24. Patients rated their vision on a 5 level scale. An improvement or worsening represents a change of at least two levels.

Table 3-21: Summary of Subject Symptoms: All Eyes (n=182*)																		
	Never			Rarely			Sometimes			Often			Always			Not Reported		
	Pre n=182	3M n=178	6M n=176	Pre n=182	3M n=178	6M n=176	Pre n=182	3M n=178	6M n=176	Pre n=182	3M n=178	6M n=176	Pre n=182	3M n=178	6M n=176	Pre n=182	3M n=178	6M n=176
	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%
Dryness	14.8	7.9	8.0	40.1	33.1	51.1	35.7	43.3	30.1	8.2	14.6	9.7	1.1	1.1	1.1	0.0	0.0	0.0
Blurry Vision	25.3	27.0	30.7	37.4	39.9	45.5	29.7	26.4	18.2	5.5	3.9	2.8	2.2	2.8	2.8	0.0	0.0	0.0
Fluctuation of Vision	40.7	38.8	35.2	32.4	29.8	44.3	23.1	24.2	18.2	3.8	6.2	1.1	0.0	1.1	1.1	0.0	0.0	0.0
Glare	23.1	23.6	26.1	35.2	36.0	40.9	30.8	29.8	26.1	11.0	7.3	5.1	0.0	3.4	1.7	0.0	0.0	0.0
Halos Around Lights	26.4	18.5	22.2	36.3	29.8	33.5	22.0	33.7	22.7	13.2	11.2	13.1	2.2	6.7	8.5	0.0	0.0	0.0
Difficulty at Night W/Glare	16.5	16.3	18.8	34.6	39.9	43.8	28.0	27.0	23.9	15.4	10.7	6.8	5.5	6.2	6.8	0.0	0.0	0.0
Ghosting or Shadowing of Images	62.1	57.9	65.9	28.6	26.4	22.2	8.2	11.8	9.1	0.0	3.4	1.7	1.1	0.6	1.1	0.0	0.0	0.0
Double Images	81.9	86.0	89.8	17.0	8.4	7.4	1.1	5.6	2.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

*Eyes with pre-operative questionnaire.

Table 3-22: Change in Patient Symptoms: Comparison of Pre-Operative Best-Corrected Vision to Post-Operative Uncorrected Vision: All Eyes (N=182)						
	3 Months N=178			6 Months N=176		
	Improve 2 or more levels %	Change less than 2 levels %	Worsen 2 or more levels %	Improve 2 or more levels %	Change less than 2 levels %	Worsen 2 or more levels %
Dryness	4.5	84.8	10.7	4.5	89.8	5.7
Blurry Vision	9.6	79.2	11.2	13.1	81.3	5.7
Fluctuation of vision	7.9	78.1	14.0	4.0	88.6	7.4
Glare	6.2	88.2	5.6	10.8	84.1	5.1
Halos Around Lights	6.2	77.5	16.3	6.3	81.3	12.5
Difficulty at Night W/Glare	12.4	75.8	11.8	11.9	81.3	6.8
Ghosting or Shadowing of Images	6.2	82.6	11.2	6.8	84.7	8.5
Double Images	1.1	93.3	5.6	1.1	96.0	2.8

Table 3-23: Summary of Patient Satisfaction for All Eyes (N=182*)																		
	Very Satisfied			Satisfied			Not Sure			Somewhat Dissatisfied			Very Dissatisfied			Not Reported		
	Pre n=182	3M n=178	6M n=176	Pre n=182	3M n=178	6M n=176	Pre n=182	3M n=178	6M n=176	Pre n=182	3M n=178	6M n=176	Pre n=182	3M n=178	6M n=176	Pre n=182	3M n=178	6M n=176
	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%
Sharpness and Clarity	20.9	65.5	60.8	58.8	24.3	26.7	4.9	3.4	3.4	12.1	6.8	9.1	3.3	0.0	0.0	0.0	0.6	0.0
Consistency of Vision	21.4	55.6	61.4	56.6	33.7	31.3	3.3	3.4	2.8	16.5	7.3	4.5	2.2	0.0	0.0	0.0	0.0	0.0
Daylight Vision	23.1	70.8	67.6	64.3	23.6	24.4	2.2	1.1	2.8	9.9	4.5	5.1	0.5	0.0	0.0	0.0	0.0	0.0
Night Vision	12.6	31.5	39.2	50.5	48.9	41.5	7.7	8.4	6.8	22.5	10.7	11.9	6.6	0.6	0.6	0.0	0.0	0.0
Night Vision with Glare	9.9	24.2	26.7	42.3	46.1	41.5	11.5	10.7	13.1	23.1	18.0	15.9	13.2	1.1	2.8	0.0	0.0	0.0

*Eyes with pre-operative questionnaire.

Table 3-24: Change in Patient Satisfaction: Comparison of Pre-Operative Best-Corrected Vision to Post-Operative Uncorrected Vision: All Eyes (N=182)						
	3 Months N=178			6 Months N=176		
	Improve 2 or more levels %	Change less than 2 levels %	Worsen 2 or more levels %	Improve 2 or more levels %	Change less than 2 levels %	Worsen 2 or more levels %
Sharpness and Clarity	18.1	76.3	5.6	16.5	75.6	8.0
Consistency of Vision	16.3	77.5	6.2	17.6	78.4	4.0
Daylight Driving	11.2	85.4	3.4	10.2	85.2	4.5
Night Driving	24.7	66.9	8.4	26.1	64.2	9.7
Night Vision with Glare	23.0	68.0	9.0	25.0	65.3	9.7

12) Summary of Key Safety and Effectiveness Variables

The key safety and effectiveness variables over time for all eyes, eyes with spherical myopia, and eyes with myopic astigmatism are presented in Tables 3-25 to 3-27. The key safety and effectiveness variables at the point of stability, stratified by pre-operative manifest refraction spherical equivalent, are presented in Tables 3-28 to 3-30.

Table 3-25: Summary of Key Safety and Effectiveness Variables: All Eyes (N=184)					
	1 Month n % (95% CI)	3 Months n % (95% CI)	6 Months n % (95% CI)	9 Months n % (95% CI)	12 Months n % (95% CI)
EFFECTIVENESS VARIABLES*					
	n=184	**n=180**	**n=178**	**n=170**	**n=107**
UCVA 20/20 or better	157 85.3 (79.4, 90.1)	147 81.7 (75.2, 87.0)	150 84.3 (78.1, 89.3)	145 85.3 (79.1, 90.3)	92 86.0 (77.9, 91.9)
UCVA 20/40 or better	182 98.9 (96.1, 99.9)	177 98.3 (95.2, 99.7)	175 98.3 (95.2, 99.7)	169 99.4 (96.8, 100.0)	107 100.0 (97.2, 100.0)
Sphere ± 0.50 D	144 78.3 (71.6, 84.0)	145 80.6 (74.0, 86.1)	141 79.2 (72.5, 84.9)	140 82.4 (75.8, 87.8)	93 86.9 (79.0, 92.7)
Sphere ± 1.00 D	173 94.0 (89.6, 97.0)	171 95.0 (90.7, 97.7)	170 95.5 (91.3, 98.0)	162 95.3 (90.9, 97.9)	103 96.3 (90.7, 99.0)
MRSE ± 0.50 D	146 79.3 (72.8, 85.0)	140 77.8 (71.0, 83.6)	137 77.0 (70.1, 82.9)	137 80.6 (73.8, 86.2)	88 82.2 (73.7, 89.0)
MRSE ± 1.00 D	177 96.2 (92.3, 98.5)	171 95.0 (90.7, 97.7)	170 95.5 (91.3, 98.0)	162 95.3 (90.9, 97.9)	102 95.3 (89.4, 98.5)
MRSE ± 2.00 D	184 100.0 (98.4, 100.0)	179 99.4 (96.9, 100.0)	178 100.0 (98.3, 100.0)	170 100.0 (98.3, 100.0)	107 100.0 (97.2, 100.0)
	n = 101	**n = 98**	**n = 95**	**n = 97**	**n=61**
Cylinder^ ± 0.50 D	74 73.3 (63.5, 81.6)	65 66.3 (56.1, 75.6)	62 65.3 (54.8, 74.7)	68 70.1 (60.0, 79.0)	41 67.2 (54.0, 78.7)
Cylinder^ ± 1.00 D	96 95.0 (88.8, 98.4)	94 95.9 (89.9, 98.9)	87 91.6 (84.1, 96.3)	90 92.8 (85.7, 97.0)	59 96.7 (88.7, 99.6)
STABILITY OF MRSE**		**n=180**	**n=176**	**n=166**	**n=107**
Change ≤ 1.00 D MRSE		177 98.3 (95.2, 99.7)	174 98.9 (96.0, 99.9)	165 99.4 (96.7, 100.0)	107 100.0 (97.2, 100.0)
Mean Change in MRSE ± SD		-0.09 ± 0.38 (-0.14, -0.03)	-0.04 ± 0.32 (-0.09, 0.01)	-0.02 ± 0.28 (-0.07, 0.02)	0.00 ± 0.28 (-0.05, 0.06)
STABILITY OF CYLINDER^		**n=98**	**n=94**	**n=93**	**n=61**
Change ≤ 1.00 D Cylinder		98 100.0 (97.0, 100.0)	94 100.0 (96.9, 100.0)	93 100.0 (96.8, 100.0)	61 100.0 (95.2, 100.0)
Mean Change in Cylinder ± SD		-0.02 ± 0.28 (-0.08, 0.04)	-0.05 ± 0.32 (-0.12, 0.02)	0.01 ± 0.24 (-0.04, 0.06)	-0.06 ± 0.24 (-0.12, 0.00)
SAFETY VARIABLES	**n=184**	**n=180**	**n=178**	**n=170**	**n=107**
Loss of ≥ 2 lines BSCVA	0 0.0 (0.0, 1.6)	0 0.0 (0.0, 1.7)	0 0.0 (0.0, 1.7)	0 0.0 (0.0, 1.7)	0 0.0 (0.0, 2.8)
BSCVA worse than 20/25	0 0.0 (0.0, 1.6)	0 0.0 (0.0, 1.7)	0 0.0 (0.0, 1.7)	0 0.0 (0.0, 1.7)	0 0.0 (0.0, 2.8)
BSCVA worse than 20/40	0 0.0 (0.0, 1.6)	0 0.0 (0.0, 1.7)	0 0.0 (0.0, 1.7)	0 0.0 (0.0, 1.7)	0 0.0 (0.0, 2.8)

*Manifest refractions and visual acuity were measured at 4 meters. Refractions were converted to optical infinity.
**Analysis of stability is limited to eyes with two consecutive visits.
^Analysis of cylinder was limited to those eyes with a preoperative manifest cylinder <-0.5D.

Table 3-26: Summary of Key Safety and Effectiveness Variables: Spherical Myopia (N=83)					
	1 Month	3 Months	6 Months	9 Months	12 Months
	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)
EFFECTIVENESS VARIABLES*					
	n=83	**n=82**	**n=83**	**n=73**	**n=46**
UCVA 20/20 or better	79 95.2	77 93.9	82 98.8	72 98.6	45 97.8
	(88.1, 98.7)	(86.3, 98.0)	(93.5, 100.0)	(92.6, 100.0)	(88.5, 99.9)
UCVA 20/40 or better	82 98.8	81 98.8	82 98.8	72 98.6	46 100.0
	(93.5, 100.0)	(93.4, 100.0)	(93.5, 100.0)	(92.6, 100.0)	(93.7, 100.0)
Sphere ± 0.50 D	70 84.3	72 87.8	71 85.5	62 84.9	40 87.0
	(74.7, 91.4)	(78.7, 94.0)	(76.1, 92.3)	(74.6, 92.2)	(73.7, 95.1)
Sphere ± 1.00 D	79 95.2	81 98.8	81 97.6	71 97.3	45 97.8
	(88.1, 98.7)	(93.4, 100.0)	(91.6, 99.7)	(90.5, 99.7)	(88.5, 99.9)
MRSE ± 0.50 D	71 85.5	69 84.1	68 81.9	62 84.9	42 91.3
	(76.1, 92.3)	(74.4, 91.3)	(72.0, 89.5)	(74.6, 92.2)	(79.2, 97.6)
MRSE ± 1.00 D	80 96.4	81 98.8	82 98.8	72 98.6	46 100.0
	(89.8, 99.2)	(93.4, 100.0)	(93.5, 100.0)	(92.6, 100.0)	(93.7, 100.0)
MRSE ± 2.00 D	83 100.0	81 98.8	83 100.0	73 100.0	46 100.00
	(96.5, 100.0)	(93.4, 100.0)	(96.5, 100.0)	(96.0, 100.0)	(93.7, 100.0)
STABILITY OF MRSE**		**n=82**	**n=82**	**n=73**	**n=46**
Change ≤ 1.00 D MRSE		80 97.6	80 97.6	73 100.0	46 100.0
		(91.5, 99.7)	(91.5, 99.7)	(96.0, 100.0)	(93.7, 100.0)
Mean Change in MRSE ± SD		-0.09 ± 0.37	-0.05 ± 0.35	-0.04 ± 0.28	-0.02 ± 0.30
		(-0.17, -0.01)	(-0.13, 0.02)	(-0.11, 0.03)	(-0.10, 0.07)
SAFETY VARIABLES	**n=83**	**n=82**	**n=83**	**n=51**	**n=46**
Loss of ≥ 2 lines BSCVA	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
	(0.0, 3.5)	(0.0, 5.6)	(0.0, 3.5)	(0.0, 4.0)	(0.0, 6.3)
BSCVA worse than 20/25	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
	(0.0, 3.5)	(0.0, 5.6)	(0.0, 3.5)	(0.0, 4.0)	(0.0, 6.3)
BSCVA worse than 20/40	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
	(0.0, 3.5)	(0.0, 5.6)	(0.0, 3.5)	(0.0, 4.0)	(0.0, 6.3)

*Manifest refractions and visual acuity were measured at 4 meters. Refractions were converted to optical infinity.
**Analysis of stability is limited to eyes with two consecutive visits.

Table 3-27: Summary of Key Safety and Effectiveness Variables: Myopic Astigmatism (N=101)					
	1 Month	3 Months	6 Months	9 Months	12 Months
	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)	n % (95% CI)
EFFECTIVENESS VARIABLES*					
	n=101	**n=98**	**n=95**	**n=97**	**n=61**
UCVA 20/20 or better	78 77.2	70 71.4	68 71.6	73 75.3	47 77.0
	(67.8, 85.0)	(61.4, 80.1)	(61.4, 80.4)	(65.5, 83.5)	(64.5, 86.8)
UCVA 20/40 or better	100 99.0	96 98.0	93 97.9	97 100.0	61 100.0
	(94.6, 100.0)	(92.8, 99.8)	(92.6, 99.7)	(97.0, 100.0)	(95.2, 100.0)
Sphere ± 0.50 D	74 73.3	73 74.5	70 73.7	78 80.4	53 86.9
	(63.5, 81.6)	(64.7, 82.8)	(63.6, 82.2)	(71.1, 87.8)	(75.8, 94.2)
Sphere ± 1.00 D	94 93.1	90 91.8	89 93.7	91 93.8	58 95.1
	(86.2, 97.2)	(84.5, 96.4)	(86.8, 97.6)	(87.0, 97.7)	(86.3, 99.0)
Cylinder^ ± 0.50 D	74 73.3	65 66.3	62 65.3	68 70.1	41 67.2
	(63.5, 81.6)	(56.1, 75.6)	(54.8, 74.7)	(60.0, 79.0)	(54.0, 78.7)
Cylinder^ ± 1.00 D	96 95.0	94 95.9	87 91.6	90 92.8	59 96.7
	(88.8, 98.4)	(89.9, 98.9)	(84.1, 96.3)	(85.7, 97.0)	(88.7, 99.6)
MRSE ± 0.50 D	75 74.3	71 72.4	69 72.6	75 77.3	46 75.4
	(64.6, 82.4)	(62.5,81.0)	(62.5, 81.3)	(67.7, 85.2)	(62.7, 85.5)
MRSE ± 1.00 D	97 96.0	90 91.8	88 92.6	90 92.8	56 91.8
	(90.2, 98.9)	(84.5, 96.4)	(85.4, 97.0)	(85.7, 97.0)	(81.9, 97.3)
MRSE ± 2.00 D	101 100.0	98 100.0	95 100.0	97 100.0	61 100.0
	(97.1, 100.0)	(97.0, 100.0)	(96.9, 100.0)	(97.0, 100.0)	(95.2, 100.0)
STABILITY**		**n= 98**	**n= 94**	**n= 93**	**n=61**
Change ≤ 1.00 D MRSE		97 99.0	94 100.0	92 98.9	61 100.0
		(94.4, 100.0)	(96.9, 100.0)	(94.2, 100.0)	(95.2, 100.0)
Mean Change in MRSE ± SD		-0.08 ± 0.40	-0.03 ± 0.29	-0.01 ± 0.28	0.01 ± 0.26
		(-0.16, 0.00)	(-0.09, 0.04)	(-0.07, 0.05)	(-0.05, 0.08)
Change ≤ 1.00 D Cylinder^		98 100.0	94 100	93 100.0	61 100.0
		(97.0, 100.0)	(96.9, 100.0)	(96.8, 100.0)	(95.2, 100.0)
Mean Change in Cylinder ± SD		-0.02 ± 0.28	-0.05 ± 0.32	0.01 ± 0.24	-0.06 ± 0.24
		(-0.08, 0.04)	(-0.12, 0.02)	(-0.04, 0.06)	(-0.12, 0.00)
SAFETY VARIABLES	**n= 101**	**n =98**	**n= 95**	**n= 97**	**n= 61**
Loss of ≥ 2 lines BSCVA	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
	(0.0, 2.9)	(0.0, 3.0)	(0.0, 3.1)	(0.0, 3.0)	(0.0, 4.8)
BSCVA worse than 20/25	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
	(0.0, 2.9)	(0.0, 3.0)	(0.0, 3.1)	(0.0, 3.0)	(0.0, 4.8)
BSCVA worse than 20/40	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
	(0.0, 2.9)	(0.0, 3.0)	(0.0, 3.1)	(0.0, 3.0)	(0.0, 4.8)

*Manifest refractions and visual acuity were measured at 4 meters. Refractions were converted to optical infinity.
**Analysis of stability is limited to eyes with two consecutive visits.
^Analysis of cylinder was limited to those eyes with a preoperative manifest cylinder <-0.5D.

Table 3-28: Summary of Key Safety and Effectiveness Variables at Stability Endpoint of 6 Months Stratified by Pre-Operative MRSE: All Eyes (N=178)

CRITERIA	-6.0 to –7.0 n, % (95% CI)	<–7.0 to –8.0 n, % (95% CI)	<–8.0 to –9.0 n, % (95% CI)	<–9.0 to –10.0 n, % (95% CI)	<–10.0 to –11.0 n, % (95% CI)	<–11.0 to –12.0 n, % (95% CI)	Cum Total n, % (95% CI)
	n=21	n=53	n=50	n=29	n=17	n=8	n=178
EFFECTIVENESS VARIABLES*							
UCVA 20/20 or better	16 76.2 (52.8, 91.8)	44 83.0 (70.2, 91.9)	43 86.0 (73.3, 94.2)	24 82.8 (64.2, 94.2)	15 88.2 (63.6, 98.5)	8 100.0 (68.8, 100.0)	150 84.3 (78.1, 89.3)
UCVA 20/40 or better	21 100.0 (86.7, 100.0)	52 98.1 (89.9, 100.0)	48 96.0 (86.3, 99.5)	29 100.0 (90.2, 100.0)	17 100.0 (83.8, 100.0)	8 100.0 (68.8, 100.0)	175 98.3 (95.2, 99.7)
MRSE ± 0.50 D	17 81.0 (58.1, 94.6)	43 81.1 (68.0, 90.6)	38 76.0 (61.8, 86.9)	21 72.4 (52.8, 87.3)	10 58.8 (32.9, 81.6)	8 100.0 (68.8, 100.0)	137 77.0 (70.1, 82.9)
MRSE ± 1.00 D	21 100.0 (86.7, 100.0)	52 98.1 (89.9, 100.0)	47 94.0 (83.5, 98.7)	28 96.6 (82.2, 99.9)	14 82.4 (56.6, 96.2)	8 100.0 (68.8, 100.0)	170 95.5 (91.3, 98.0)
MRSE ± 2.00 D	21 100.0 (86.7, 100.0)	53 100.0 (94.5, 100.0)	50 100.0 (94.2, 100.0)	29 100.0 (90.2, 100.0)	17 100.0 (83.8, 100.0)	8 100.0 (68.8, 100.0)	178 100.0 (98.3, 100.0)
SAFETY VARIABLES							
Loss of ≥ 2 lines BSCVA	0 0.0 (0.0, 13.3)	0 0.0 (0.0, 5.5)	0 0.0 (0.0, 5.8)	0 0.0 (0.0, 9.8)	0 0.0 (0.0, 16.2)	0 0.0 (0.0, 31.2)	0 0.0 (0.0, 1.7)
BSCVA worse than 20/25	0 0.0 (0.0, 13.3)	0 0.0 (0.0, 5.5)	0 0.0 (0.0, 5.8)	0 0.0 (0.0, 9.8)	0 0.0 (0.0, 16.2)	0 0.0 (0.0, 31.2)	0 0.0 (0.0, 1.7)
BSCVA worse than 20/40	0 0.0 (0.0, 13.3)	0 0.0 (0.0, 5.5)	0 0.0 (0.0, 5.8)	0 0.0 (0.0, 9.8)	0 0.0 (0.0, 16.2)	0 0.0 (0.0, 31.2)	0 0.0 (0.0, 1.7)
Increase > 2D cylinder^	0 0.0 (0.0, 13.3)	0 0.0 (0.0, 5.5)	0 0.0 (0.0, 5.8)	0 0.0 (0.0, 9.8)	0 0.0 (0.0, 16.2)	0 0.0 (0.0, 31.2)	0 0.0 (0.0, 1.7)

*Manifest refractions and visual acuity were measured at 4 meters. Refractions were converted to optical infinity.
^Analysis limited to eyes with spherical myopia (N=83).

Table 3-29: Summary of Key Safety and Effectiveness Variables at Stability Endpoint of 6 Months Stratified by Pre-Operative MRSE: Spherical Myopia (N=83)							
CRITERIA	-6.0 to –7.0 n, % (95% CI)	<–7.0 to –8.0 n, % (95% CI)	<–8.0 to –9.0 n, % (95% CI)	<–9.0 to –10.0 n, % (95% CI)	<–10.0 to –11.0 n, % (95% CI)	<–11.0 to –12.0 n, % (95% CI)	Cum Total n, % (95% CI)
	n=9	n=27	n=26	n=12	n=7	n=2	n=83
EFFECTIVENESS VARIABLES*							
UCVA 20/20 or better	9 100.0 (71.7, 100.0)	26 96.3 (81.0, 99.9)	26 100.0 (89.1, 100.0)	12 100.0 (77.9, 100.0)	7 100.0 (65.2, 100.0)	2 100.0 (22.4, 100.0)	82 98.8 (93.5, 100.0)
UCVA 20/40 or better	9 100.0 (71.7, 100.0)	26 96.3 (81.0, 99.9)	26 100.0 (89.1, 100.0)	12 100.0 (77.9, 100.0)	7 100.0 (65.2, 100.0)	2 100.0 (22.4, 100.0)	82 98.8 (93.5, 100.0)
MRSE ± 0.50 D	9 100.0 (71.7, 100.0)	21 77.8 (57.7, 91.4)	21 80.8 (60.6, 93.4)	10 83.3 (51.6, 97.9)	5 71.4 (29.0, 96.3)	2 100.0 (22.4, 100.0)	68 81.9 (72.0, 89.5)
MRSE ± 1.00 D	9 100.0 (71.7, 100.0)	26 96.3 (81.0, 99.9)	26 100.0 (89.1, 100.0)	12 100.0 (77.9, 100.0)	7 100.0 (65.2, 100.0)	2 100.0 (22.4, 100.0)	82 98.8 (93.5, 100.0)
MRSE ± 2.00 D	9 100.0 (71.7, 100.0)	27 100.0 (89.5, 100.0)	26 100.0 (89.1, 100.0)	12 100.0 (77.9, 100.0)	7 100.0 (65.2, 100.0)	2 100.0 (22.4, 100.0)	83 100.0 (96.5, 100.0)
SAFETY VARIABLES							
Loss of ≥ 2 lines BSCVA	0 0.0 (0.0, 28.3)	0 0.0 (0.0, 10.5)	0 0.0 (0.0, 10.9)	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 34.8)	0 0.0 (0.0, 77.6)	0 0.0 (0.0, 3.5)
BSCVA worse than 20/25	0 0.0 (0.0, 28.3)	0 0.0 (0.0, 10.5)	0 0.0 (0.0, 10.9)	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 34.8)	0 0.0 (0.0, 77.6)	0 0.0 (0.0, 3.5)
BSCVA worse than 20/40	0 0.0 (0.0, 28.3)	0 0.0 (0.0, 10.5)	0 0.0 (0.0, 10.9)	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 34.8)	0 0.0 (0.0, 77.6)	0 0.0 (0.0, 3.5)
Increase > 2D cylinder	0 0.0 (0.0, 28.3)	0 0.0 (0.0, 10.5)	0 0.0 (0.0, 10.9)	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 34.8)	0 0.0 (0.0, 77.6)	0 0.0 (0.0, 3.5)

*Manifest refractions and visual acuity were measured at 4 meters. Refractions were converted to optical infinity.

Table 3-30: Summary of Key Safety and Effectiveness Variables at Stability Endpoint of 6 Months Stratified by Pre-Operative MRSE: Myopic Astigmatism (N=95)

CRITERIA	-6.0 to –7.0 n, % (95% CI)	<–7.0 to –8.0 n, % (95% CI)	<–8.0 to –9.0 n, % (95% CI)	<–9.0 to –10.0 n, % (95% CI)	<–10.0 to –11.0 n, % (95% CI)	<–11.0 to –12.0 n, % (95% CI)	Cum Total n, % (95% CI)
	n=12	n=26	n=24	n=17	n=10	n=6	n=95
EFFECTIVENESS VARIABLES*							
UCVA 20/20 or better	7 58.3 (27.7, 84.8)	18 69.2 (48.2, 85.7)	17 70.8 (48.9, 87.4)	12 70.6 (44.0, 89.7)	8 80.0 (44.4, 97.5)	6 100 (60.7, 100)	68 71.6 (61.4, 80.4)
UCVA 20/40 or better	12 100 (77.9, 100)	26 100 (89.1, 100)	22 91.7 (73.0, 99.0)	17 100 (83.8, 100)	10 100 (74.1, 100)	6 100 (60.7, 100)	93 97.9 (92.6, 99.7)
MRSE ± 0.50 D	8 66.7 (34.9, 90.1)	22 84.6 (65.1, 95.6)	17 70.8 (48.9, 87.4)	11 64.7 (38.3, 85.8)	5 50.0 (18.7, 81.3)	6 100 (60.7, 100)	69 72.6 (62.5, 81.3)
MRSE ± 1.00 D	12 100 (77.9, 100)	26 100 (89.1, 100)	21 87.5 (67.6, 97.3)	16 94.1 (71.3, 99.9)	7 70.0 (34.8, 93.3)	6 100 (60.7, 100)	88 92.6 (85.4, 97.0)
MRSE ± 2.00 D	12 100 (77.9, 100)	26 100 (89.1, 100)	24 100 (88.3, 100)	17 100 (83.8, 100)	10 100 (74.1, 100)	6 100 (60.7, 100)	95 100 (96.9, 100)
SAFETY VARIABLES							
Loss of ≥ 2 lines BSCVA	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 10.9)	0 0.0 (0.0, 11.7)	0 0.0 (0.0, 16.2)	0 0.0 (0.0, 25.9)	0 0.0 (0.0, 39.3)	0 0.0 (0.0, 3.1)
BSCVA worse than 20/25	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 10.9)	0 0.0 (0.0, 11.7)	0 0.0 (0.0, 16.2)	0 0.0 (0.0, 25.9)	0 0.0 (0.0, 39.3)	0 0.0 (0.0, 3.1)
BSCVA worse than 20/40	0 0.0 (0.0, 22.1)	0 0.0 (0.0, 10.9)	0 0.0 (0.0, 11.7)	0 0.0 (0.0, 16.2)	0 0.0 (0.0, 25.9)	0 0.0 (0.0, 39.3)	0 0.0 (0.0, 3.1)

*Manifest refractions and visual acuity were measured at 4 meters. Refractions were converted to optical infinity.

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

Patient Information Booklet

For High Myopia (Nearsightedness) from -6 to -11 D MRSE with up to -3 D Astigmatism

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.

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Table of Contents

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, high levels of myopia (nearsightedness) with and without astigmatism.

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.

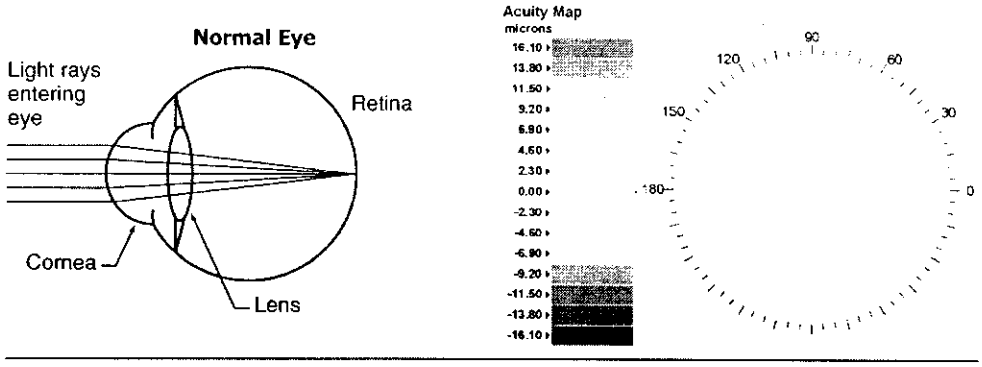

Figure 1: On the left is a diagram showing how the eye focuses light rays to create a sharp image on the retina. The corresponding wavefront map of an ideal eye is displayed on the right.

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 *myopia and astigmatism*.

Myopia (nearsightedness) usually starts in childhood and gets progressively worse through adolescence. It usually stops changing by the late teens, but it can sometimes continue to get worse into the mid-twenties. Nearsighted (or myopic) eyes bend light too much so that light rays focus to a single spot in front of the retina. Things that are far away look blurry because the rays are spread apart instead of focused when they strike the retina.

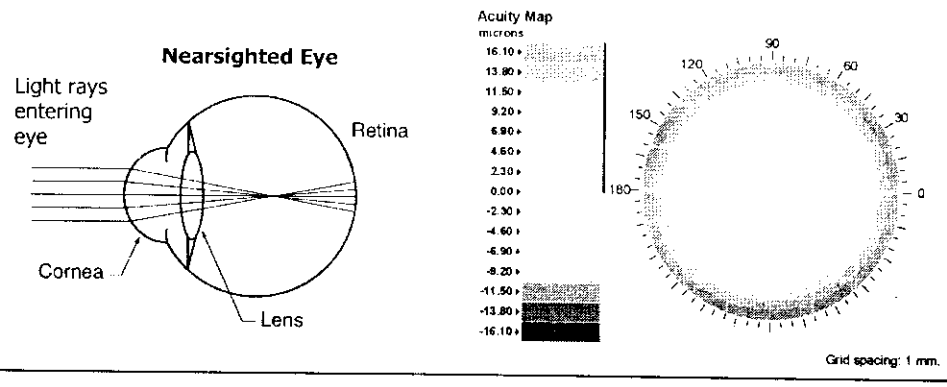

Figure 2: On the left is a diagram of a nearsighted eye showing the light rays focusing in front of the retina. The corresponding wavefront of a myopic eye shows a curved wavefront surface. The height difference between center and edge is indicated by the change in grayscale.

Astigmatism causes the rays of light entering through different parts of the eye to focus unequally so that they do not ever form a single spot. Some rays may focus on the retina, but other rays focus in front of the retina. Things look blurry because images are not ever focused clearly on the retina.

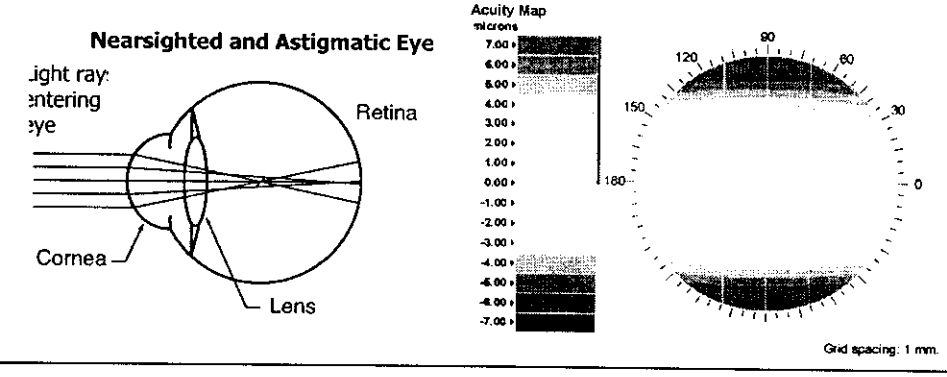

Figure 3: On the left is a diagram of an astigmatic eye showing light rays that do not ever come to a focus at one point. The corresponding wavefront map for this eye shows a surface that is curved more in one direction than the other.

The WaveScan® System can also measure complex focusing errors. On the left in Figure 4 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 program a non-custom treatment.

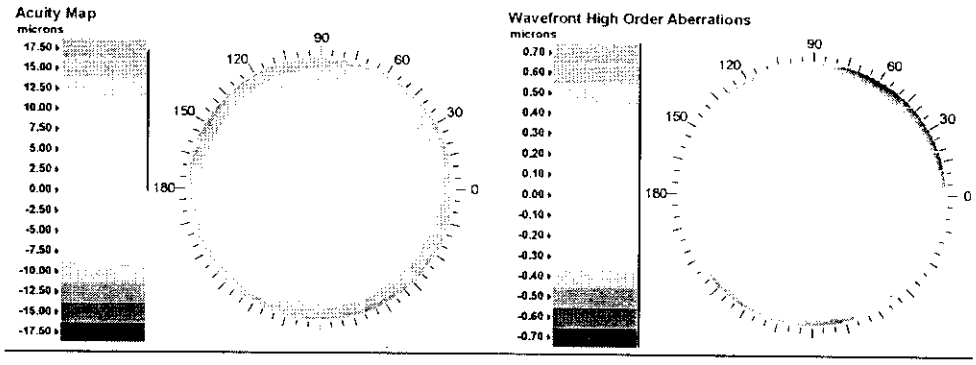

Figure 4: On the left is a wavefront map of all wavefront errors and on the right is a wavefront map showing only the complex errors.

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 align the treatment and automatically 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 and astigmatism. Before activating the laser, the doctor creates a flap on your cornea using a *microkeratome*. A microkeratome is a tool with a blade (or laser) that cuts a circular flap of tissue from the surface of the cornea. The doctor lifts the flap and folds it out of the way of the laser. After the laser finishes, the doctor repositions the flap. VISX does not manufacture the microkeratome that your surgeon uses.

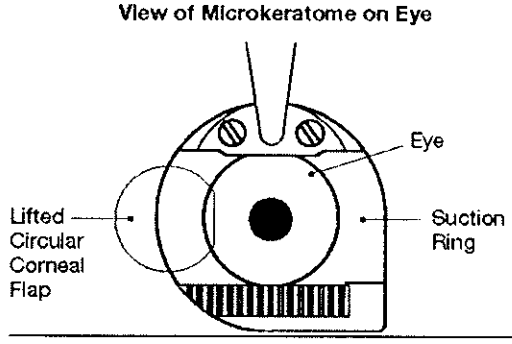

Figure 5: View (from above) of microkeratome on the eye.

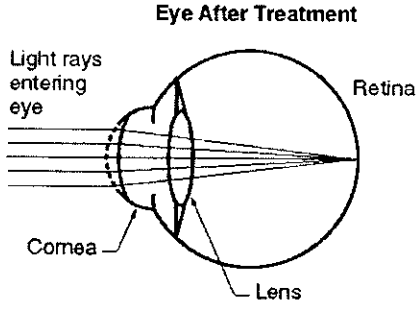

Figure 6: Diagram of an eye after treatment showing where tissue is removed.

To correct myopia, the cornea needs to be flatter, so the laser removes more tissue from the center than the edge. When there is astigmatism, the eye is flattened more along one axis (e.g., vertical) than in 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 at 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 for high myopia can correct from -6 to -11 diopters (D) of nearsightedness with up to -3 D of astigmatism. If you have nearsightedness within this range, CustomVue LASIK treatment may help you to see clearly distant objects without eyeglasses or contact lenses.

Clinical Study to Evaluate Benefits

A clinical study was conducted to evaluate the benefits and risks of CustomVue LASIK. This study involved 184 eyes of 94 patients. This study was initiated at seven U.S. centers in March 2004. The last patient in this study was treated in August 2004. The study results shown in this booklet include all the available reported outcomes on these patients through May 2005. 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 184 Eyes of 94 Patients

Age	Average	36 ± 7 years
	Range	23 to 55 years
Gender	Male	47%
	Female	53%
Race	Caucasian	73%
	Asian/ Pacific Islander	10%
	African American	2%
	Hispanic	11%
	Other*	4%
Contact Lens History	None	14%
	Soft	75%
	Hard	12%

*"Other" classifications of race include: Hispanic/American Indian, Persian, and Indian

Visual Acuity Without Glasses After Treatment

Visual acuity measures the sharpness of vision using a letter chart. Table 2 shows that six months after the treatment, 84% of study patients saw 20/20 or better *without* glasses while 98% 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=184)

Time After Treatment	1 Month (n=184)	3 Months (n=180)	6 Months (n=178)	9 Months (n=170)	12 Months (n=107)
20/16 or better	52%	56%	65%	61%	59%
20/20 or better	85%	82%	84%	85%	86%
20/25 or better	92%	93%	93%	95%	96%
20/40 or better	99%	98%	98%	99%	100%

Visual Acuity Without Glasses After Treatment and With Glasses Before Treatment

Table 3 shows the relative number of lines (rows of letters) on the eye chart that patients could see before and after surgery. 78% 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=184)	3 Months (n=180)	6 Months (n=178)	9 Months (n=170)	12 Months (n=107)
More than 2 lines better	0%	0%	0%	0%	0%
2 lines better	1%	2%	4%	3%	2%
1 line better	21%	23%	34%	29%	26%
Less than 1 line change	49%	46%	40%	44%	49%
1 line worse	18%	18%	10%	17%	17%
2 lines worse	5%	7%	8%	4%	5%
More than 2 lines worse	5%	3%	3%	4%	2%

Patient Quality of Vision Comparison

Patients were asked to evaluate their quality of vision before treatment with glasses and after the CustomVue™ treatment without glasses. Table 4 lists the patient responses reported before treatment on 182 eyes and at 6 months after treatment on 176 eyes.

Table 4 — Quality of Vision Before and After Treatment

	Very Satisfied / Satisfied		Not Sure		Somewhat Dissatisfied/ Very Dissatisfied	
	Pre-op	6 Months	Pre-op	6 Months	Pre-op	6 Months
Sharpness and Clarity	80%	88%	5%	3%	15%	9%
Consistency of Vision	78%	93%	3%	3%	19%	5%
Daylight Vision	87%	92%	2%	3%	10%	5%
Night Vision	63%	81%	8%	7%	29%	13%
Night Vision with Glare	52%	68%	12%	13%	36%	19%

Table 5 shows the percentage of eyes whose quality of vision improved, did not change, and worsened after treatment, for 176 patients at 6 months. Patients rated their satisfaction on a 5-level scale. An improvement or worsening reflects a change of 2 or more levels.

Table 5 — Change in Quality of Vision for Vision *without* Glasses After Treatment Compared to Vision *with* Glasses Before Treatment

	6 Months (n=176)		
	Improve	No Change	Worsen
Sharpness and Clarity	16%	76%	8%
Consistency of Vision	18%	78%	4%
Daylight Driving	10%	85%	5%
Night Driving	26%	64%	10%
Night Vision with Glare	25%	65%	10%

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 (e.g., rheumatoid arthritis), autoimmune (e.g., lupus), or immunodeficiency diseases (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 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 is 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 is more risky for you.

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* 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 high myopia with or without astigmatism has not been established in patients:

- With unstable eyes that have changed in their prescription more than 1.0 diopters in nearsightedness or astigmatism in the last 12 months, and your nearsightedness 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. If you have large pupils in dim light, there may be an increased possibility for negative effects on your vision after surgery, such as seeing glare and halos around lights, and being less satisfied with your vision when driving at night with oncoming headlights.
- 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.
- Who are younger than 21 years of age, because it is unknown whether LASIK is safe and effective for you.
- Who have nearsightedness worse than 11 diopters or astigmatism worse than 3 diopters, because it is unknown whether LASIK is safe and effective for you.
- Over the long term (more than 1 year), because it is unknown whether LASIK is safe and effective for periods longer 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

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* Imitrex® is a registered trademark of GlaxoSmithKline.

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 high myopia and myopic astigmatism, visual acuity *without* glasses improved for all 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 all time points after treatment.

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

	1 Month (n=184)	3 Months (n=180)	6 Months (n=178)	9 Months (n=170)	12 Months (n=107)
20/16 or better	80%	84%	91%	83%	80%
20/20 or better	98%	97%	100%	100%	99%
20/25 or better	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=184)	3 Months (n=180)	6 Months (n=178)	9 Months (n=170)	12 Months (n=107)
Eyes with loss ≥ 2 Lines	0%	0%	0%	0%	0%
Eyes with loss > 1 to < 2 Lines	1%	2%	0%	0%	0%
Eyes with loss > 0 to 1 Line	10%	8%	5%	6%	15%
Eyes with no change	38%	31%	26%	28%	25%
Eyes with gain of >0 to 1 line	48%	52%	53%	56%	55%
Eyes with gain > 1 to 2 Lines	4%	7%	15%	8%	5%
Eyes with gain > 2 Lines	0%	1%	1%	1%	0%

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 improved contrast sensitivity post-operatively as they did pre-operatively, at 6 months post-operatively, 11% experienced a significant loss in bright conditions. In dim conditions, 16% experienced a similar loss, and with the addition of glare in dim conditions, 23% experienced such a loss. Table 8 shows the change in contrast sensitivity 6 months after treatment in 178 patients.

Table 8 — Change in Contrast Sensitivity 6 Months After Treatment

Condition	6 Months (n=176)		
	% of Eyes With Loss	% of Eyes That Stay The Same	% of Eyes With Gain
Bright conditions with no glare	11%	80%	9%
Dim conditions with no glare	16%	62%	22%
Dim conditions with glare	23%	51%	27%

Adverse Events and Complications

~~Some~~ The overall percentage of eyes ~~patients~~ in the clinical study that experienced adverse events and complications after CustomVue™ LASIK treatment, ~~as~~ are shown in Table 9.

Table 9 — Adverse Events and Complications

Greater than or equal to 1% of eyes (n=184) had:	
Inflammation of the cornea under the flap	1.1%
Cells growing under the flap	1.6%
Scratch on the surface of the eye	2.2%
Swelling of the cornea	2.7%
Double or ghost images	8.7%
Less than or equal to 1% of eyes (n=184) had:	
Foreign body under flap	0.5%
Feeling of something in the eye	0.5%

Patient Symptoms After CustomVue™ Treatment

Patients were asked to rank the frequency of their symptoms both before and after the CustomVue treatment. Table 10 lists the patient symptoms reported as "often" or "always" before treatment (Pre-Op) on 182 eyes and at 6 months after treatment on 176 eyes.

Table 10 — Comparison of Symptoms Before and After Treatment

Frequency	**Often or Always**	
Symptom	**Pre-Op**	**6 Months**
Dryness	9%	11%
Blurry vision	8%	6%
Fluctuation of vision	4%	2%
Glare	11%	7%
Halos*	15%	22%
Difficulty at night with glare	21%	14%
Ghosting or shadowing of images	1%	3%
Double images	0%	0%

*Halos are hazy rings around bright lights.

Table 11 presents the percentage of eyes whose symptoms improved, did not change, or worsened 6 months after treatment, when vision without glasses after treatment was compared to vision with glasses before surgery. Patients rated their symptoms on a 5-level scale. An improvement or worsening reflects a change of 2 or more levels.

Table 11 — Change in Patient Symptoms for Vision *Without* Glasses After Treatment Compared to Vision *With* Glasses Before Treatment

Symptom	6 Months (n=176)		
	Improve	No Change	Worsen
Dryness	5%	90%	6%
Blurry vision	13%	81%	6%
Fluctuation of vision	4%	89%	7%
Glare	11%	84%	5%
Halos*	6%	81%	13%
Difficulty at night with glare	12%	81%	7%
Ghosting or shadowing of images	7%	85%	9%
Double images	1%	96%	3%

*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 myopia with or without 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 1.0 diopters during the year before your pre-operative examination.
- Be informed of LASIK risks and benefits as compared to other available treatments for nearsightedness with or without 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 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.	[]	[]
2.	It doesn't matter if I wear my contact lenses when my doctor told me not to.	[]	[]
3.	The laser does all the work; I just have to lie on the chair.	[]	[]
4.	After the surgery, there is a good chance that I will be less dependent on eyeglasses.	[]	[]
5.	I may need reading glasses after laser surgery.	[]	[]
6.	There is a risk that I may lose some vision after CustomVue LASIK surgery.	[]	[]
7.	It doesn't matter if I am pregnant.	[]	[]
8.	If I have an autoimmune disease, I am still a good candidate for laser vision correction.	[]	[]

Answers to Self-Test Questions are found on the next page.

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 nearsightedness with or without astigmatism has changed less than 1.0 diopters.
- 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 13); **2**. False (see Before Surgery on page 21); **3**. False (see The Day of Surgery on page 22); **4**. True (see Benefits on page 10); **5**. True (see Risks on page 13); **6**. True (see Risks on page 13); **7**. False (see Contraindications on page 13); **8**. False (see Contraindications on page 13).

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 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.

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.

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

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 tool that cuts a flap of tissue from the front surface of the eye with a blade or laser.

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