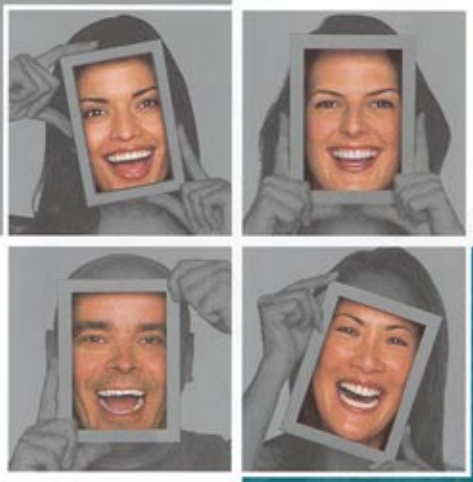
CustomVue™
INDIVIDUALIZED LASER VISION CORRECTION

Live your best life with your Personal Best Vision



The Fingerprint of Your Vision™

Providing a precise, unique, and more detailed analysis of your vision

Prepared for you by the company recognized worldwide for bringing innovation and breakthrough technology to laser vision correction

VISX
WE MAKE THINGS CLEAR

Look Better, Feel Better, See Better in a Whole New World

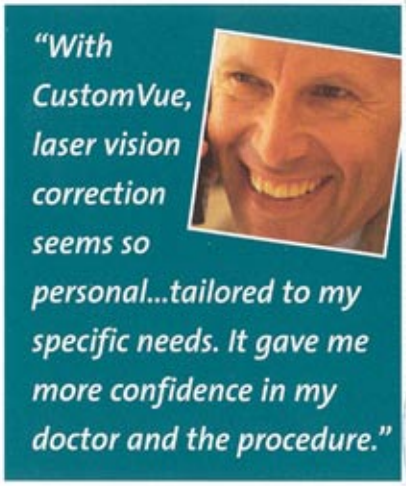
Chances are, several of your friends or family members are experiencing the joys of living without glasses and contact lenses as a result of laser vision correction. You've heard the excitement in their voices, noticed the boost in their confidence levels, and watched the quality of their lives improve with new-found freedoms.

Millions of Americans are enjoying these life-enhancing benefits and millions more, just like you, are exploring the procedure that could free them from the worries of glasses and contact lenses.

"Having clear vision is like waking up to a new world."

VISX CustomVue™ Improves the View of Laser Vision Correction

CustomVue™ Individualized Laser Vision Correction was developed by VISX, the company recognized world-wide for bringing innovation and breakthrough technology to laser vision correction. With CustomVue, a new standard in laser vision correction is established, providing a precise level of measurement and correction never before possible.



Using WaveScan®-based digital technology, originally developed for use in high-powered telescopes to reduce distortions when viewing distant objects in space, doctors can now identify, measure, and correct imperfections in an individual's eyes *25 times more precisely than with standard methods used for glasses and contact lenses.* This information is transferred to the laser, providing a new level of precision and accuracy.

Reach the Full Potential of Your Vision—Your Personal Best Vision

Just like a fingerprint, each person's vision is 100 percent unique to their eyes. Before the recent advancements in technology, doctors were only able to use standard measurements to correct vision, meaning that prescriptions could only provide a certain level of correction regardless of an individual's needs.

Now, VISX CustomVue™ can measure and correct the unique imperfections of each individual's vision and provide them with the potential to experience better vision than is possible with glasses or contact lenses—Personal Best Vision.

Taking the Mystery out of Laser Vision Correction

The laser vision correction process begins with a consultation with your doctor where a patient can learn about the technology and the procedure. An evaluation follows to assess a patient's overall health and to measure and create a detailed and unique map of their eyes. Once it's confirmed that an individual is a good candidate for laser vision correction, the procedure can be scheduled.

"I can see the alarm clock! I can see highway signs! I can even see individual leaves on the trees and flowers to the smallest detail!"

On the day of the procedure, anesthetic drops are placed into the patient's eyes. The patient's unique correction information is transferred from the WaveScan® to the laser. Laser vision correction works by gently reshaping the cornea with the cool beam from the laser to remove microscopic amounts of tissue—less than the thickness of a human hair in most cases—to create a new curvature. The procedure typically takes several seconds and the majority of individuals feel no discomfort. Many patients notice immediate results after CustomVue™ and vision continues to improve over several days. Routine follow-up visits complete the process.

Great Results by Day and by Night

One year after the CustomVue™ procedure, patients in a clinical study reported these great results without glasses and contact lenses:

- 100% could pass a driving test
- 98% could see 20/20 or better
- 70% could see better than 20/20

In a clinical study, four times as many people were very satisfied with their night vision after the procedure as compared to their night vision before with glasses or contact lenses.

"Laser vision correction truly changed my life. I'm a lot more involved in outdoor activities, especially water sports. Now I jump right in instead of watching from the sidelines!"

Clear Vision—Anytime, Anywhere!

VISX® lasers have been used to perform millions of laser vision correction procedures in the U.S. and around the world. If you're over the age of 21, and are nearsighted and/or astigmatic, you may be a candidate for the CustomVue™ procedure.

"I can see the television!
I can do anything.
It's amazing!
I still can't believe it!"

The first step is to call an eye care center to schedule a doctor's consultation. During the consultation you can review the details of the technology and the procedure ***and*** be that much closer to living your best life with your **Personal Best Vision.**

VISX® Wavefront-Guided LASIK for Correction of Myopic Astigmatism (CustomVue™ LASIK Laser Treatment)

Statements regarding the potential benefits of wavefront-guided LASIK (CustomVue) are based upon the results of a clinical trial. These results are indicative of not only the CustomVue treatment but also the care of the clinical physicians, the control of the surgical environment by those physicians, the clinical trial's treatment parameters and the clinical trial's patient inclusion and exclusion criteria. Although many clinical trial patients after the CustomVue procedure saw 20/20 or better and/or had or reported having better vision during the day and at night, compared to their vision with glasses or contact lenses before the procedure, your results may vary. You can find information about the clinical trial below and in the CustomVue *Patient Information Booklet*.

Only an eye care professional trained in laser vision correction can determine whether you are a suitable candidate for the CustomVue procedure. As with any surgical procedure, there are risks associated with the CustomVue treatment. Before deciding whether to have the CustomVue procedure, you should ask your doctor for and carefully review the *Patient Information Booklet*. It is important to discuss the risks associated with the procedure and any questions you may have about the procedure with your doctor.

WAVEFRONT-GUIDED LASIK INDICATIONS AND INTENDED USES: The VISX STAR S4™ Excimer Laser System and WaveScan WaveFront® System are approved to perform wavefront-guided laser assisted *in-situ keratomileusis* (LASIK) treatments for the reduction or elimination of myopic astigmatism up to -6.00 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 0.50 D (in both cylinder and sphere components) for at least one year prior to the date of pre-operative examination. Note that the complete name for this ophthalmic laser is "STAR S4™ ActiveTrak® Excimer Laser System for wavefront-guided laser assisted *in-situ keratomileusis* (LASIK) treatments of myopic astigmatism up to -6.00 D MRSE, with cylinder between 0.00 and -3.00 D." An acceptable alternate version of this official name is "wavefront-guided LASIK for correction of myopic astigmatism."

Wavefront-guided LASIK is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, photorefractive keratectomy (PRK), conventional LASIK, and other refractive surgeries. Approval of the application is based on a clinical trial of 351 eyes (189 primary and 162 secondary). Of all eyes treated, 318 were evaluated for effectiveness with 98.8% accountability at 3 months, 277 eyes with 96.9% accountability at 6 months, 102 eyes with 95.3% accountability at 9 months, and 86 eyes with 95.6% accountability at 12 months. The studies found that of the 277 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at 6 months, 100% were corrected to 20/40 or better, and 95.8% were corrected to 20/20 or better in 71 spherical myopia eyes; and 99.5% were corrected to 20/40 or better, and 93.2% were corrected to 20/20 or better in 206 astigmatic myopia eyes.

The study showed that at the 3 month stability time point: there was a loss of ≥ 2 lines of best corrected vision that can be obtained with spectacles in 1 of 239 astigmatic myopia eyes and there was no loss of ≥ 2 lines of best corrected vision in 79 spherical myopia eyes; there was 1 of 239 astigmatic myopia eyes with best spectacle corrected visual acuity (BSCVA) worse than 20/25 and none in 79 spherical myopia eyes with BSCVA worse than 20/25. During the course of study, no eye lost >2 lines of BSCVA and no eye had a BSCVA worse than 20/40.

CONTRAINDICATIONS: Wavefront-guided LASIK is contraindicated in patients with collagen vascular, autoimmune or immunodeficiency disease, signs of keratoconus or abnormal corneal topography, patients taking isotretinoin (Accutane®*) or amiodarone hydrochloride (Cordarone®†) or are pregnant or nursing.

WARNINGS: Wavefront-guided 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, or severe allergies. Lower uncorrected visual acuity may be anticipated in the treatment of higher degrees of myopia with and without astigmatism (>-5.0 D MRSE).

PRECAUTIONS: 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. Long term risks of wavefront-guided LASIK for myopic astigmatism beyond 12 months have not been studied. The safety and effectiveness of STAR S4 Excimer Laser System have NOT been established for wavefront-guided surgery in patients: whose WaveScan®-measured pupil size is less than 6 mm; for treatments greater than -6 diopters of MRSE or with greater than 3 diopters of astigmatism and for retreatment with CustomVue LASIK.

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 aberration did not decrease after CustomVue treatment.

It is possible, after wavefront-guided 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.

ADVERSE EVENTS AND COMPLICATIONS: The clinical trial showed that the following adverse events or complications occurred in at least 1% of the 351 eyes at any interval up to 6 months post-treatment: inflammation of the cornea under the flap (1.4%); double or ghost images (1.4%); and scratch on the surface of the eye (1.4%).

The following subjective symptoms frequency rated "often or always" were increased in the effectiveness cohort at 6 months post-treatment on 258 eyes compared with pre-treatment on 332 eyes: dryness (9% vs. 6%); fluctuation of vision (3% vs. 2%); glare (4% vs. 2%) and halos (7% vs. 5%).

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

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