Patient Information Sheet

VISX® Wavefront-Guided LASIK for Correction of Hyperopic 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 hyperopic astigmatism up to +3.00 D MRSE, with cylinder between 0.00 and +2.00 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. 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 hyperopic astigmatism up to +3.00 D MRSE, with cylinder between 0.00 and +2.00 D." An acceptable alternate version of this official name is "wavefront-guided LASIK for correction of hyperopic 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 was based on a clinical trial of 144 eyes (74 primary and 70 secondary). Of all eyes treated, 134 were evaluated for effectiveness with 98.5% accountability at 3 months, 131 eyes with 97.0% accountability at 6 months, 118 eyes with 90.8% accountability at 9 months, and 27 eyes with 87.1% accountability at 12 months. The studies found that of the 131 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at 6 months, 97.3% were corrected to 20/40 or better, and 66.2% were corrected to 20/20 or better in 74 spherical hyperopia eyes; and 93.0% were corrected to 20/40 or better, and 56.1% were corrected to 20/20 or better in 57 astigmatic hyperopia eyes.

The study showed that at the 6 month stability time point: there was no 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 that can be obtained with spectacles in either 63 astigmatic hyperopia eyes or 74 spherical hyperopia eyes; none of the 63 astigmatic hyperopia or 74 spherical hyperopia eyes had best spectacle corrected visual acuity (BSCVA) worse than 20/25. During the course of the study, one in 63 eyes with astigmatic hyperopia lost >2 lines of BSCVA at 1 month, no eyes with spherical hyperopia 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.

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 9 mm. Long term risks of wavefront-guided LASIK for hyperopic 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 5 mm; for treatments greater than +3 diopters of MRSE or with greater than 2 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 144 eyes at any interval up to 6 months post-treatment: cells growing under the flap (2.1%); feeling of something in the eye (1.4%); double or ghost images (11.3%); and scratch on the surface of the eye (2.1%).

The following subjective symptoms rated "often or always" were increased in frequency in the effectiveness cohort at 6 months post-treatment on 131 eyes compared with pretreatment on 136 eyes: dryness (17% vs. 6%); blurry vision (10% vs. 7%); fluctuation of vision (14% vs. 6%); halos (10% vs. 5%); double or ghost images (7% vs.3%).

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

CustomVue®
INDIVIDUALIZED LASER VISION CORRECTION

VISX®
WE MAKE THINGS CLEAR