VISXPRESS®

THE LATEST NEWS FROM THE LEADER IN LASER VISION CORRECTION

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VISX CustomVue™ Hyperopia Procedure Approved by the FDA

First U.S. Custom Wavefront LASIK Approval for Farsightedness and Astigmatism

VISX announced today that it has received approval from the U.S. Food and Drug Administration (FDA) to treat hyperopia and hyperopic astigmatism with the VISX CustomVue Hyperopic LASIK procedure.

The FDA approval allows for WaveScan® diagnosis and CustomVue™ treatment of patients with farsightedness and astigmatism. This approval is specifically for wavefront-guided LASIK for correction of hyperopia with or without astigmatism up to +3.00D MRSE, with cylinder up to +2.00D.

The CustomVue procedure is the first U.S. approved wavefront-guided laser treatment for hyperopia.

Colman Kraff, M.D., principal investigator with the VISX® multi-center clinical study, stated, "VISX's new CustomVue Hyperopia procedure is a significant step forward in the treatment of farsightedness. The overall quality of vision with this new procedure is so superior that I plan to treat all of my qualified patients with CustomVue Hyperopia."

A six-month evaluation of clinical study participants showed that more than four times as many people were very satisfied with their night vision after the VISX CustomVue hyperopia procedure, compared to their night vision before with glasses or contacts. The VISX clinical study results also exceeded all of the FDA required parameters for safe and effective laser vision correction.

In order to perform VISX CustomVue hyperopic LASIK procedures, physicians must complete the CustomVue Hyperopic Certification Course.

Prerequisite: U.S. Physician CustomVue Certification Course for Myopia

Here are the steps:

1. Complete the CustomVue Hyperopia Certification Course which is being emailed to all CustomVue certified physicians.
2. Log onto the VISX website, www.visx.com and click on the CustomVue Certification button. Using your password from the U.S. CustomVue Physicians Certification Course for Myopia, you will be able to verify your course completion and print your Certificate. After completing this certification, CustomVue hyperopia treatment cards can be ordered.

Note, for additional information on CustomVue hyperopic certification, password retrieval, education, treatment card ordering and other questions, call the VISX Customer Response Center at 1-800-246-VISX or 1-800-246-8479.

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

Statements regarding the potential benefits of wavefront-guided LASIK (CustomVue) are based upon the results of clinical trials. 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 trials' treatment parameters and the clinical trials' 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, individual results may vary. You can find information about the clinical trial below and in the Professional Use Information Manual for the VISX STAR S4™ Excimer Laser System and WaveScan WaveFront® System (CustomVue Treatments).

As with any surgical procedure, there are risks associated with the CustomVue treatment. Before treating patients with the CustomVue procedure, you should carefully review the Professional Use Information Manual, complete the Physician CustomVue Certification Course, provide your patients with the Patient Information Booklet for CustomVue LASIK Laser Treatment, and discuss the risks associated with this procedure and questions about the procedure with your patients.

WAVEFRONT-GUIDED LASIK INDICATIONS AND INTENDED USES:

The VISX STAR S4 Excimer Laser System and WaveScan WaveFront System is 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.

Wavefront-guided LASIK for correction of myopic astigmatism 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 myopic astigmatism 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.

The VISX STAR S4 Excimer Laser System and WaveScan WaveFront System is 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 1.00 D (in both cylinder and sphere components) for at least one year prior to the date of pre-operative examination.

Wavefront-guided LASIK for the correction of hyperopic astigmatism 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 hyperopic astigmatism application is 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 either 63 astigmatic hyperopia eyes or 74 spherical hyperopia eyes; none of the 63 astigmatic hyperopia eyes or 74 spherical hyperopia eyes had best spectacle corrected visual acuity (BSCVA) worse than 20/25. During the course of study, one of 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. Lower uncorrected visual acuity may be anticipated in the treatment of higher degrees of myopia with and without astigmatism (>-5.0 D MRSE).

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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 for myopic astigmatism, and an optical zone of 6 mm and an ablation zone of 9 mm for hyperopic astigmatism. Long term risks of wavefront-guided LASIK beyond 12 months have not been studied. The safety and effectiveness of STAR S4 Excimer Laser System have NOT been established for wavefront-guided treatment of myopic astigmatism 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. The safety and effectiveness of STAR S4 Excimer Laser System have NOT been established for wavefront-guided treatment of hyperopic astigmatism 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 studies, 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.

The use of Percentage Nomogram Adjustment should be based upon careful consideration of patient and surgeon information, in addition to environmental conditions surrounding the surgery. The simultaneous use of the Percentage Nomogram Adjustment and the Physician Adjustment has not been studied in controlled investigations, and should not be attempted until the accuracy of the Nomogram setting has been verified for the same laser, treatment conditions and type of treatment. Therefore, the combined simultaneous use of the Percentage Nomogram Adjustment and the Physician Adjustment is not recommended without careful analysis of postoperative refractive results.

ADVERSE EVENTS AND COMPLICATIONS:
The clinical trial for myopic astigmatism 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 %).

The clinical trial for hyperopic astigmatism 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 the effectiveness cohort at 6 months post-treatment on 131 eyes compared with pre-treatment 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.

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