

VISX™ Wavefront-Guided LASIK for Correction of Myopic, Hyperopic, and Mixed 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 trials 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 are approved to perform wavefront-guided laser assisted *in-situ keratomileusis* (LASIK) treatments for the reduction or elimination of **low to moderate 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 low to moderate 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 low to moderate 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 study 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 IR™ Excimer Laser System with VSS™ and WaveScan WaveFront System are approved to perform wavefront-guided laser assisted *in-situ keratomileusis* (LASIK) treatments for the reduction or elimination of **high myopic astigmatism** from -6.00 D 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 1.00 D (in both cylinder and sphere components) for at least one year prior to the date of pre-operative examination.

Wavefront-guided LASIK for correction of high 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 application is based on a clinical trial of 184 eyes. Of all eyes treated, 180 were evaluated for effectiveness with 97.8% accountability at 3 months, 178 eyes with 96.7% accountability at 6 months, 170 eyes with 96.5% accountability at 9 months, and 107 eyes with 93.9% accountability at 12 months. The study found that of the 178 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at 6 months, 98.3% were corrected to 20/40 or better, 97.2% were corrected to 20/32 or better, and 84.3% were corrected to 20/20 or better without spectacles or contact lenses. The study showed that of 83 spherical and 101 astigmatic eyes, no eyes lost 2 or more lines of best corrected vision that can be obtained with spectacles (BSCVA) and none of the eyes had BSCVA worse than 20/40.

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 1.00 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 study 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.

The VISX STAR S4 IR Excimer Laser System with VSS and WaveScan WaveFront System are approved to perform wavefront-guided laser assisted *in-situ keratomileusis* (LASIK) treatments for the reduction or elimination of naturally occurring **mixed astigmatism** when the magnitude of cylinder (from 1.0 to 5.0 D) is greater than the magnitude of sphere and the cylinder and sphere have opposite signs; 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 the correction of mixed 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 mixed astigmatism application is based on a clinical trial of 86 eyes. Of all eyes treated, 86 were evaluated for effectiveness with 100.0% accountability at 3 months, 80 eyes with 95.2% accountability at 6 months, 69 eyes with 86.3% accountability at 9 months, and 63 eyes with 94.0% accountability at 12 months. The study found that of the 86 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at 3 months, 95.3% were corrected to 20/40 or better, 91.9% were corrected to 20/32 or better, and 61.6% were corrected to 20/20 or better without spectacles or contact lenses. The study showed that of 86 astigmatic eyes, one eye temporarily lost 2 lines of best corrected vision that can be obtained with spectacles at 1 month and at 6 months and none of the eyes had best spectacle corrected visual acuity (BSCVA) worse than 20/40.

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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. For the treatment of low to moderate myopic astigmatism, 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 have 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 and mixed astigmatism. Long term risks of wavefront-guided LASIK beyond 12 months have not been studied. The safety and effectiveness of the STAR S4™ Excimer Laser System have NOT been established for wavefront-guided treatment of low to moderate myopic astigmatism in patients: whose WaveScan™ wavefront diameter 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 the STAR S4 Excimer Laser System have NOT been established for wavefront-guided treatment of high myopic astigmatism in patients: whose WaveScan wavefront diameter is less than 5 mm, for treatments greater than -11 diopters of MRSE or with greater than 3 diopters of astigmatism. The safety and effectiveness of the STAR S4 Excimer Laser System have NOT been established for wavefront-guided treatment of hyperopic astigmatism in patients: whose WaveScan wavefront diameter 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. The safety and effectiveness of the STAR S4 IR™ Excimer Laser System have NOT been established for wavefront-guided treatment of mixed astigmatism in patients: whose WaveScan wavefront diameter is less than 5 mm, for treatments greater than 5 diopters or less than 1 diopter 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 for low to moderate myopic astigmatism, hyperopic astigmatism and mixed astigmatism, the average higher order aberration did not decrease after CustomVue treatment. In the clinical studies for high myopic astigmatism, the average higher order aberration increased 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 low to moderate 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 high myopic astigmatism showed that the following adverse events or complications occurred in at least 1% of the 184 eyes at one or more postoperative examinations up to 6 months post-treatment: epithelium in the interface (1.1%); peripheral corneal epithelial defect at 1 month or later (2.2%); corneal edema between 1 week and 1 month post-operatively (2.7%) and double vision (or "ghost images") in the operative eye (6.0%). The following subjective symptoms were reported as present "often or always" by a higher percentage of subjects 6 months after treatment than before treatment: dryness (10.8% vs. 9.3%); halos (21.6% vs. 15.4%); and ghosting or shadowing of images (2.8% vs. 1.1%).

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%).

The clinical trial for mixed astigmatism showed that the following adverse events or complications occurred in at least 1% of the 86 eyes at one or more postoperative examinations up to 3 months post-treatment: miscreated flap (1.2%); cells growing under the flap (4.7%); and double vision (or "ghost images") in the operative eye (8.1%). The following subjective symptoms were reported as present "often or always" by a higher percentage of subjects 3 months after treatment than before treatment: dryness (22% vs. 6%); halos (20% vs. 13%).

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