IMPORTANT SAFETY INFORMATION

VISX Wavefront-Guided LASIK for Correction of Myopic Astigmatism, Hyperopic Astigmatism 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, your results may vary. You can find information about the clinical trials 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 ***CustomVue*** *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 (LOW TO MODERATE MYOPIC ASTIGMATISM):
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 preoperative 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.

WAVEFRONT-GUIDED LASIK INDICATIONS AND INTENDED USES (HIGH MYOPIC ASTIGMATISM):
The ***VISX STAR S4*** 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 preoperative examination. Note that the complete name for this ophthalmic laser is "***STAR S4 IR*** Excimer Laser System for wavefront-guided laser assisted *in-situ* keratomileusis (LASIK) treatments of myopic astigmatism from -6.00 to -11.00 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 high myopia with or without astigmatism."

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 studies 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.

WAVEFRONT-GUIDED LASIK INDICATIONS AND INTENDED USES (HYPEROPIC ASTIGMATISM):
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 preoperative 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 for 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 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.

WAVEFRONT-GUIDED INDICATIONS AND INTENDED USES (MIXED ASTIGMATISM):
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; and in patients 21 years of age or older 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 preoperative examination. Note that the complete name for this ophthalmic laser is "***STAR S4 IR*** Excimer Laser System" for wavefront-guided laser assisted *in-situ* keratomileusis (LASIK) treatments 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. An acceptable alternate version of this official name is "wavefront-guided LASIK for correction of mixed astigmatism."

Wavefront-guided LASIK for 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 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 studies 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.

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:
Long term risks of wavefront-guided LASIK beyond 12 months have not been studied. 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 treatments, and an ablation zone of 9 mm for hyperopic and mixed astigmatism treatments. The safety and effectiveness of the ***STAR S4*** Excimer Laser System have NOT been established for wavefront-guided surgery in patients with low to moderate myopic astigmatism: 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 surgery in patients with high myopic astigmatism: 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 surgery in patients with hyperopic astigmatism: 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 surgery in patients with mixed astigmatism: whose ***WaveScan WaveFront*** diameter is less than 5.00 mm; for treatments greater than 5.00 D or less than 1.00 D 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.

ADVERSE EVENTS AND COMPLICATIONS (LOW TO MODERATE MYOPIC ASTIGMATISM):
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%).

ADVERSE EVENTS AND COMPLICATIONS (HIGH MYOPIC ASTIGMATISM):
The clinical trial 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: cells growing under the flap (1.1%); scratch on the surface of the eye at 1 month or later (2.2%); swelling of the cornea between 1 week and 1 month postoperatively (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%).

ADVERSE EVENTS AND COMPLICATIONS (HYPEROPIC ASTIGMATISM):
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%).

ADVERSE EVENTS AND COMPLICATIONS (MIXED ASTIGMATISM):
The clinical trials 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%).

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

References
1. Market Scope Q1 2009 Quarterly Estimate.
2. Durrie DS. Randomized prospective clinical study of LASIK: ***IntraLase*** versus mechanical keratome. Subsets presented at: Meeting of the International Society of Refractive Surgery of the American Academy of Ophthalmology; November 14-15, 2003; Anaheim, CA; American Society of Cataract and Refractive Surgery Symposium; May 1-5, 2004; San Diego, CA; Refractive Surgery 2004; International Refractive Surgery: Science and Practice; October 22-23, 2004; New Orleans, LA; American Society of Cataract and Refractive Surgery Symposium; April 15-20, 2005; Washington, DC.
3. Data on file. AMO Development, LLC. ***CustomVue*** Procedure clinical trials submitted to the FDA; 2003, 2004, 2005 & 2007.

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Thinking About Laser Vision Correction?

The iLASIK Procedure Means Your Wait is Over

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Ask your physician if the ***iLASIK*** Procedure is right for you.

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The Time is Right for the iLASIK Procedure

Now that the ***iLASIK*** Procedure is available, there's really no reason to put off having laser vision correction. Doctors have been performing laser vision correction procedures for over a decade and 31.4 million procedures have been performed worldwide to date,[1] making it the most common elective vision procedure in the U.S. In fact, all branches of the U.S. military and NASA recently allowed the treatment of LASIK for their servicemen and women thanks to studies using ***iLASIK*** Technology.

The introduction of the ***iLASIK*** Procedure (the combination of today's most innovative laser vision correction technologies) means the wait is over and it's simple:

1. Most people are candidates — make an appointment and have an exam
2. ***iLASIK*** Technology is safe and effective
3. The ***iLASIK*** Procedure is fast and simple

Laser assisted *in-situ* keratomileusis (LASIK) can only be performed by a trained physician and is specified for reduction or elimination of myopia, hyperopia, and astigmatism as indicated within the product labeling. Laser refractive surgery is contraindicated for patients: a) with collagen vascular, autoimmune, or immunodeficiency diseases; b) who are pregnant or nursing women; c) with signs of keratoconus or abnormal corneal topography; d) who are taking one or both of the following medications: Isotretinoin (Accutane) and Amiodarone hydrochloride (Cordarone). Potential side effects to laser refractive surgery may include glare, dry eye, as well as other visual anomalies. LASIK requires the use of a microkeratome that cuts a flap on the surface of the cornea, potential side effects may include flap related complications. Consult with your eye care professional and *Patient Information Booklet* regarding the potential risks and benefits for laser refractive surgery, results may vary for each individual patient.

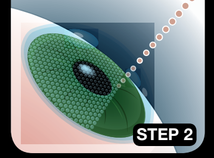
Restricted Device: U.S. Federal Law restricts this device to sale, distribution, and use by or on the order of a physician or other licensed eye care practitioner. U.S. Federal Law restricts the use of this device to practitioners who have been trained in its calibration and operation and who have experience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

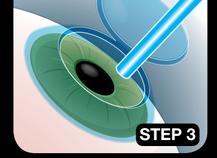
You're Probably a Candidate

The reality is that the majority of people who meet the age and general health requirements are in fact good candidates for the ***iLASIK*** Procedure. There are some conditions that exclude certain patients, but whether you have nearsightedness, farsightedness or an astigmatism, there's a good chance you can still have the ***iLASIK*** Procedure.

If you meet the basic criteria below, you should find an ***iLASIK*** surgeon and have a personal consultation.

- You are at least 21 years old
- You are in good general health
- You have had a stable vision prescription for at least one year
- You have no existing eye disease





What are the Advantages of the iLASIK Procedure?

With the ***iLASIK*** Procedure, your wait is over because:

- **Laser Vision Correction Has Never Been Better**
  The ***iLASIK*** Procedure is the result of over a decade's worth of technical refinement — it combines all of the latest all-laser LASIK technology in one efficient LASIK procedure. It simply doesn't get any better, so now's the time.

- **There's No Mystery**
  You've heard thousands of LASIK ads touting thousands of different things, but the ***iLASIK*** Procedure delivers outstanding results, one integrated technology solution and one easy way to better vision.

- **It's Truly Personalized**
  The ***iLASIK*** Procedure is truly customized just for you. Everything is based on your individual vision dynamics, so it's all about you.

Exceptional Vision Correction Technology at Every Step

When you have the ***iLASIK*** Procedure, you'll get a completely integrated, completely personalized procedure based on advanced vision correction technology at every step.

- **Step 1 — Creating Your Personal Vision Profile**
  The first step in the ***iLASIK*** Procedure is to perform a series of tests to determine the individual characteristics of your vision, including the use of our ***WaveScan*** Technology. The ***WaveScan*** System creates a 3-D map of the unique imperfections of your eyes. Then our ***Advanced CustomVue*** treatment uses the digital information from that map to design a custom treatment for each of your eyes.

- **Step 2 — Making The iLASIK Flap**
  The ***iLASIK*** Procedure exclusively uses an advanced technology called the ***IntraLase*** Method. The ***IntraLase*** Method is a 100% blade-free approach to creating your LASIK flap, the thin flap of tissue that the doctor folds back in order to perform your ***iLASIK*** Procedure. In a clinical survey of LASIK patients who had their LASIK flaps created using a blade in one eye and the ***IntraLase*** Method in the other, the vision in the ***IntraLase***-treated eye was preferred 3-to-1 (among those who stated a preference).[2]

- **Step 3 — Your Laser Vision Correction**
  Now that you've had your personal vision profile using ***WaveScan*** Technology and your blade-free LASIK flap using the exclusive ***IntraLase*** Method, your vision can be corrected using the ***Advanced CustomVue*** treatment within the ***iLASIK*** Procedure. The ***Advanced CustomVue*** Procedure has earned FDA approval to treat the broadest range of vision imperfections possible, including mild-to-severe nearsightedness, farsightedness and all types of astigmatism. Clinical studies showed that one year after treatment:[3]

  - 100 percent of nearsighted patients and more than 95 percent of all clinical study patients could pass a driving test without glasses or contact lenses
  - 98 percent of mild-to-moderate nearsighted patients and almost three-quarters of all clinical study patients could see 20/20 or better without glasses or contact lenses
  - Four times as many mild-to-moderate nearsighted participants were very satisfied with their night vision after treatment compared to their night vision before treatment with glasses or contacts

Take the Next Step

Now that you've learned the basics about the ***iLASIK*** Procedure, you should:

1. Schedule a consultation with your ***iLASIK*** surgeon to determine if you are a good candidate for the ***iLASIK*** Procedure *(typically this evaluation is free)*
2. Get comfortable with the procedure by getting answers to all of your questions and carefully reviewing the *Patient Information Booklet*
3. Schedule your ***iLASIK*** Procedure and understand the post-surgery treatment regimen