



Advanced CustomVue™ Patient Key Messages and FAQs

Advanced CustomVue Laser Vision Correction The Most Advanced Custom Wavefront-Driven Treatment Available

Your choice to undergo laser vision correction with the VISX™ Advanced CustomVue procedure from AMO puts you in good company. More physicians in the U.S. choose VISX™ lasers to perform laser vision correction than all other lasers combined. That's because VISX has led the industry since the beginning and continues to provide innovative advances that improves outcomes and ensures patient satisfaction.

The Advanced CustomVue procedure offers the broadest range of treatment available

The Advanced CustomVue procedure represents many years of research, testing and clinical trials to secure approval from the U.S. Federal Drug Administration (FDA). Today, Advanced CustomVue stands in a class of its own, offering:

- The broadest range of FDA-approved indications. Now, more than 94 percent* of eligible candidates may potentially benefit from the Advanced CustomVue procedure.
- Advanced CustomVue procedure has earned FDA approvals to treat nearsightedness ranging from mild to severe (up to 11 diopters of correction), farsightedness, and all forms of astigmatism.

*Market Scope Data, U.S. Vision Population, 21 Years of Age or Older, 2005

The Advanced CustomVue procedure delivers exceptional outcomes

The Advanced CustomVue procedure is now a potentially superior vision correction alternative to glasses and contact lenses. Clinical studies have shown that 91 percent of all patients treated were as satisfied or more satisfied with their vision after the Advanced CustomVue procedure than they were before the procedure with glasses or contact lenses. Clinical studies also showed high participant satisfaction with night vision after the Advanced CustomVue procedure.

Many surgeons agree that the new level of measurement accuracy possible with the VISX system makes the Advanced CustomVue procedure the most effective laser corrective procedure available for the broadest range of vision imperfections.

How is this possible?

Advanced CustomVue™ laser vision correction combines a number of technology innovations into a laser vision correction procedure individually customized to each eye.

WaveScan WaveFront™ System with Fourier Algorithms

Your eyes are as unique as your fingerprint. Advanced CustomVue addresses your eyes' distinct characteristics using the WaveScan WaveFront System and VISX™ Technology's exclusive mathematical rules (Fourier algorithms) to capture each eye's unique imperfections with far greater accuracy than ever before possible. Like a topographical map showing the surface features of a landscape, WaveScan™ technology creates a detailed map of your eye's optical system. The system translates that information into completely personalized digital treatment instructions and sends them directly to the STAR S4 IR™ Excimer Laser System.

VISX Iris Registration

The Advanced CustomVue procedure provides a new level of precision in treatment alignment with VISX Iris Registration, the first FDA-approved, fully automated method of aligning treatment. It's normal for the pupil to shift positions from the time an eye is measured to the time of treatment. Iris registration technology centers the treatment correctly, regardless of the amount of time between wavefront measurement and laser treatment and independent of changes in the pupil center from measurement to treatment.

VISX STAR S4 IR™ Excimer Laser System

The VISX STAR S4 IR Excimer Laser system represents the most advanced laser technology platform available today. Integrating data collected by the WaveScan WaveFront System, the STAR S4 IR utilizes VISX Iris Registration and other exclusive VISX technologies to deliver advanced precision and enhanced safety. The Advanced CustomVue procedure is not affected by the patient's eye movement during treatment and minimizes correction to only those areas of the cornea that require reshaping.

Facts to Remember

- Advanced CustomVue is FDA-approved to potentially treat more than 94 percent* of patients eligible for laser vision correction.
- Advanced CustomVue represents the next generation of laser vision correction, combining the technologies of the WaveScan Wave Front System and the VISX STAR S4 IR Excimer Laser with Iris Registration (IR).
- Advanced CustomVue has established a new standard in laser vision correction by earning FDA approval to treat mild to severe nearsightedness with or without astigmatism, farsightedness with or without astigmatism, and mixed astigmatism.
- The Advanced CustomVue procedure is wavefront-driven and features VISX's exclusive, proven mathematical formulas, enabling doctors to measure and correct the unique imperfections in each individual's eyes.

*Market Scope Data, U.S. Vision Population, 21 Years of Age or Older, 2005

- Wavefront-guided Advanced CustomVue™ treatment tailors a distinct correction for each individual eye. In fact, each treatment is “designed” by the unique characteristics of the individual’s eyes.
- Advanced CustomVue is the wavefront-guided laser vision correction procedure with the broadest range of FDA-approved treatments.
- As demonstrated in clinical trials, the Advanced CustomVue procedure can potentially produce better vision than is possible with glasses or contact lenses.

Notable Outcomes

During clinical trials for FDA approval, participants undergoing Advanced CustomVue treatment for all indications achieved the following outcomes:

- More than 95 percent of all clinical study participants could pass a driving test without glasses or contact lenses one year after treatment.
- Almost three quarters of all clinical study participants could see 20/20 or better without glasses or contact lenses one year after treatment.
- Clinical study results showed high participant satisfaction with night vision after the VISX™ Advanced CustomVue procedure compared to night vision before with glasses or contact lenses.

Study participants achieved notable outcomes in each of the indications, including these highlights:

Myopia

- 98 percent of participants could see 20/20 or better one year after the procedure.
- 70 percent of participants could see 20/16 or better one year after the procedure.
- Nearly 80 percent of participants saw as well or better without glasses after treatment as they did with glasses before treatment.

High Myopia

- One year after treatment, 86 percent of participants could see 20/20 or better and 100 percent could pass a driving test without glasses or contact lenses.
- 59 percent could see 20/16 or better one year after the procedure.
- 88 percent of participants were as satisfied or more satisfied with the sharpness and clarity of their vision after Advanced CustomVue treatment than they were wearing glasses or contact lenses before treatment.

Hyperopia

- More than 95 percent of participants could see well enough to pass a driving test – without glasses or contact lenses – nine months after their Advanced CustomVue procedure.
- Six months after treatment, 89 percent of participants said they were as satisfied or more satisfied with their daylight vision without glasses or contact lenses as they were with glasses before treatment.

Mixed Astigmatism

- More than 95 percent of participants could see well enough to pass a driving test a year after treatment.
- Nearly twice as many participants were very satisfied with their night vision without glasses as they were with glasses before treatment.

These are not all of the clinical study results. For more information, please review the *Advanced CustomVue™ Patient Information Booklet* for your condition, and the *Patient Information Sheet*.

Facts and FAQs about Advanced CustomVue

What is laser vision correction?

Laser vision correction is a procedure that improves vision by using a laser to permanently change the shape of the cornea. Often referred to as LASIK (an acronym for the medical term *laser assisted in-situ keratomileusis*), it is the most commonly performed laser vision correction procedure and is an effective treatment for a wide range of vision problems.

What is VISX™ Advanced CustomVue laser vision correction?

Advanced CustomVue is an individualized laser vision correction procedure that combines the WaveScan WaveFront™ System and the VISX STAR S4 IR™ Excimer Laser with Iris Registration (IR), enabling a doctor to measure unique imperfections in a person's eyes and design an individualized treatment. Iris registration technology increases accuracy and precision by centering the treatment correctly, regardless of changes in the pupil center from measurement to treatment.

How does the Advanced CustomVue procedure work?

First, the WaveScan technology precisely measures each eye's unique imperfections and creates an individualized treatment plan. This information is then digitally transferred to the VISX STAR S4 IR Excimer Laser System, where it is used to deliver the treatment to your eyes.

How does Advanced CustomVue individualized laser vision correction differ from standard LASIK?

Advanced CustomVue uses WaveScan WaveFront technology with VISX-exclusive algorithms (mathematical guidelines) to measure the unique imperfections in your eyes *25 times more precisely* than the methods used for glasses or contact lenses. The VISX STAR S4 IR Excimer Laser with Iris Registration (IR) also includes a number of technology advancements that improve treatment accuracy and precision.

What is Iris Registration Technology?

It's normal for a patient's pupil to shift positions from the time their eye is measured to the time of treatment. Iris registration technology centers the treatment correctly, independent of changes in the pupil center from measurement to treatment.

Is the Advanced CustomVue™ procedure approved by the FDA?

Yes, the Advanced CustomVue procedure is FDA-approved to potentially treat more than 94 percent* of the eligible population, including patients with nearsightedness, farsightedness (hyperopia) and astigmatism. Advanced CustomVue™ is the first FDA-approved wavefront-guided treatment for high myopia (from -6 to -11 diopters).

*Market Scope Data, U.S. Vision Population, 21 Years of Age or Older, 2005

How can the Advanced CustomVue procedure treat nearsightedness, farsightedness and astigmatism?

All three vision problems are most often caused by imperfections in the cornea. Advanced CustomVue uses the WaveScan WaveFront™ System to measure those distinct imperfections, creating a map of each eye. The WaveScan™ System translates these detailed digital measurements into a set of treatment instructions, which it transmits to the laser. The laser reshapes the cornea to improve vision.

How accurate is WaveScan technology?

WaveScan technology measures imperfections in an individual's eyes *25 times more precisely* than standard methods used for glasses and contact lenses. Before WaveScan technology was available, LASIK surgery was performed using the same measurement methods doctors use when prescribing glasses and contact lenses.

What makes the Advanced CustomVue procedure different than other procedures?

The combination of WaveScan WaveFront System measurement technology and the sophisticated capabilities of the VISX STAR S4 IR™ Excimer Laser System enable doctors to calculate a more precise and individualized treatment.

How is the Advanced CustomVue procedure able to treat conditions like mixed astigmatism and high myopia where other systems can't?

The precision enabled by the WaveFront WaveScan System's measurements is made possible by the STAR S4 IR™ Excimer Laser System. The laser system includes Variable Spot Scanning (VSS™) technology, along with Variable Repetition Rate (VRR™) technology, and Iris Registration, ensuring the laser can perform the treatments indicated by the WaveScan System's measurements.

What can the Advanced CustomVue procedure do for me?

As shown in clinical studies, the Advanced CustomVue procedure can produce better vision than possible with glasses or contact lenses. Though statistical results vary by the type of condition being treated, more than 95 percent of all study participants – regardless of condition treated – could see well enough to pass a driving test. More detailed information on outcomes can be found in the *Patient Information Booklet* for your condition and the *Patient Information Sheet*.

Who is a candidate for the Advanced CustomVue procedure?

If you are 21 years of age or older and wear glasses or contact lenses to correct nearsightedness, farsightedness, astigmatism, or mixed astigmatism, you may benefit from the Advanced CustomVue procedure. See your ophthalmologist for more information and to determine if you are a candidate for the Advanced CustomVue procedure.

How does the Advanced CustomVue procedure affect night vision?

FDA clinical studies showed the vast majority of participants were very satisfied with their night vision after treatment compared to their night vision with glasses or contact lenses before treatment. See your eye doctor for more information.

Will I need glasses or contact lenses after the Advanced CustomVue™ procedure?

Probably not. Individual results may vary, but one year after a clinical study for treatment of myopia (nearsightedness), all participants saw well enough to drive a car without glasses or contact lenses. Most participants achieved 20/20 vision or better.

How can I get more information about Advanced CustomVue?

Discuss the procedure with your doctor and be sure to review the *Advanced CustomVue Patient Information Booklet* for your condition. You can also find out more information by visiting **www.personalbestvision.com**.

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