

## FDA Approves STAR S4 IR(TM) Excimer Laser System for Treatment of High Myopia With Astigmatism



Advanced Medical Optics is a global leader in the discovery and delivery of ophthalmic surgical and eye care products. (PRNewsFoto)

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### CustomVue(TM) Wavefront-Guided LASIK Procedure Treats Highest Range of Nearsightedness and Astigmatism

SANTA ANA, Calif., Sept. 7 /PRNewswire-FirstCall/ -- Advanced Medical Optics, Inc. (AMO) (NYSE: [EYE](#)), today announced that it has received approval from the U.S. Food and Drug Administration (FDA) to treat high myopia, also known as nearsightedness, and myopic astigmatism with the STAR S4 IR(TM) Excimer Laser System with the CustomVue(TM) procedure. The indications include the reduction or elimination of myopia and myopic astigmatism from -6.00 to -11.00 diopters with up to -3.00 diopters of cylinder.

The CustomVue(TM) procedure now has the highest range of myopia and astigmatism treatment as well as approval for treatment of hyperopia (farsightedness) and mixed astigmatism available on the market. This gives AMO the broadest range of wavefront-guided approvals in the U.S.

"This approval by the FDA further demonstrates the importance of our May 2005 acquisition of VISX, Incorporated and reinforces the value we have placed on our laser vision correction business," said AMO President and CEO Jim Mazzo. "The CustomVue(TM) procedure is one of the fundamental platforms in our refractive portfolio that includes such technologies as the Amadeus(TM) microkeratome, Tecnis(R) and ReZoom(TM) multifocal IOLs and Verisyse(TM) phakic IOL."

Clinical studies found that 98.3 percent of those receiving the CustomVue(TM) high myopia treatment were corrected at six months to 20/40 or better and 84.3 percent were corrected to 20/20 or better without spectacles or contact lenses.

The CustomVue(TM) procedure employs the WaveScan WaveFront(R) System, a diagnostic system that captures a comprehensive "fingerprint" of each eye and generates an individualized treatment for each CustomVue(TM) procedure. As shown in several clinical studies, CustomVue(TM) treatments have the potential to deliver better vision than is possible with contacts or glasses.

"The expansion of the CustomVue(TM) procedure for highly nearsighted and/or astigmatic individuals adds yet another level of safety, precision and personalization to the laser vision correction procedure," said Sandy T. Feldman, M.D., who was a contributor to the clinical trials study. "In this group of individuals, the improved quality of vision is particularly significant. Almost all individuals who are eligible for LASIK surgery can now be treated with the truly personalized approach of the CustomVue(TM) procedure."

CustomVue(TM) procedures for High Myopia will be released to certified VISX(R) Technology doctors over the next several weeks after they have completed the training and certification process.

"I'm very excited about having this option for my high myopic patients," said Colman R. Kraff, M.D., a clinical trials contributor. "The results from the clinical trial are outstanding. No high myopic results on any other laser

platform, past or present, come close to the results that were achieved in this clinical trial. My patients will greatly benefit from this technology."

#### About the Laser Vision Correction Market:

Laser vision correction is one of the most popular forms of elective surgery in the U.S. today, where more than 3 million people have undergone the procedure. According to industry research, there are 50 to 60 million people in the U.S. that are good candidates for laser vision correction.

#### About Advanced Medical Optics (AMO)

AMO is a global medical device leader focused on the discovery and delivery of innovative vision technologies that optimize the quality of life for people of all ages. Products in the ophthalmic surgical line include intraocular lenses, laser vision correction systems, phacoemulsification systems, viscoelastics, microkeratomes and related products used in cataract and refractive surgery. AMO owns or has the rights to such ophthalmic surgical product brands as ReZoom(TM), Phacoflex(R), Clariflex(R), Array(R), Sensar(R), CeeOn(R), Tecnis(R) and Verisyse(TM) intraocular lenses, STAR S4 IR(TM) laser vision correction system, WaveScan Wavefront(R) System, CustomVue(TM) procedure, Sovereign(R) and Sovereign(R) Compact(TM) phacoemulsification systems with WhiteStar(TM) technology, Amadeus(TM) and Amadeus(TM) II microkeratomes, Healon(R) and Vitrax(R) viscoelastics, and the Baerveldt(R) glaucoma shunt. Products in the contact lens care line include disinfecting solutions, daily cleaners, enzymatic cleaners and lens rewetting drops. Among the contact lens care product brands the company possesses are COMPLETE(R) Moisture PLUS(TM), COMPLETE(R) Blink-N-Clean(R), Consept(R)F, Consept(R) 1 Step, Oxysept(R) 1 Step, UltraCare(R), Ultrazyme(R), Total Care(R) and blink(TM) branded products. Amadeus is a licensed product of, and a trademark of, SIS, Ltd. AMO is based in Santa Ana, California, and employs approximately 3,500 worldwide. The company has operations in 24 countries and markets products in approximately 60 countries. For more information, visit the company's Web site at <http://www.amo-inc.com>.

#### Forward-Looking Statements

Mr. Mazzo's statements, statements by Dr.'s Feldman and Kraff and statements in this press release regarding new product benefits and expected release timing, and any other statements that refer to AMO's estimated or anticipated future results are forward-looking statements. All forward-looking statements in this press release reflect AMO's current analysis of existing trends and information and represent AMO's judgment only as of the date of this press release. Actual results may differ from current expectations based on a number of factors affecting AMO's businesses, including but not limited to unexpected changes in competitive, regulatory and market conditions, AMO's ability to obtain adequate product supply, unexpected litigation or intellectual property issues, and the uncertainties associated with market acceptance of new products. Therefore, the reader is cautioned not to rely on these forward-looking statements. AMO disclaims any intent or obligation to update these forward-looking statements.

Additional information concerning these and other risk factors may be found in previous financial press releases issued by AMO. AMO's public periodic filings with the Securities and Exchange Commission, including the discussion under the heading "Certain Factors and Trends Affecting AMO and its Businesses" in AMO's 2004 Form 10-K filed in March 2005, and the supplemental information related to the laser vision correction business filed with a Form

8-K on July 13, 2005, include information concerning these and other risk factors. Copies of press releases and additional information about AMO are available at <http://www.amo-inc.com>, or you can contact the AMO Investor Relations Department by calling 714-247-8348.

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