



Press Release

U.S. FDA Approval for the innovative VisuMax® SMILE laser eye correction procedure

The Medical Technology Business Group of ZEISS announces receiving U.S. FDA approval for the VisuMax small incision lenticule extraction (SMILE) procedure. The approval of this novel, minimally invasive corneal refractive treatment of myopia is supported by extensive study results demonstrating its safety and effectiveness. SMILE - performed on the VisuMax femtosecond laser - is already available in about 500 clinics across 61 countries. With more than half a million SMILE procedures performed internationally since its introduction in 2011 so far, ZEISS is excited to now offer this innovative technology also to the US market.

JENA, Germany/DUBLIN, California, USA, September 13, 2016

Pivotal study results submitted to the FDA in Zeiss' Premarket Approval (PMA) application demonstrated excellent visual acuity and refractive predictability outcomes for the 336 eyes treated at 5 investigational sites in the US. The SMILE procedure, carried out on the VisuMax® femtosecond laser, has already established itself in global markets such as Europe, China and India. The positive decision of the FDA was welcomed by study investigators, who have performed the procedure over the last few years, as well as the community of refractive surgeons who excitedly look forward to offering SMILE to their patients.

Dr. Jon D. Dishler, refractive surgery specialist of Dishler Laser Institute in Denver, Colorado, and US Medical Monitor for the VisuMax IDE Study, said: "We are thrilled that this exciting new technology is finally available to surgeons and patients in the US. It is a new and appealing option for many who have concerns about the existing choices for surgical vision correction. I was very impressed with the excellent refractive outcomes in our clinical study, especially in those patients who were most dependent on their spectacles for daily life."

James V. Mazzo, President and CEO of Carl Zeiss Meditec, Inc. and Global President of Ophthalmic Devices at ZEISS said: "Launching SMILE in the U.S. marks the beginning of a new era of ophthalmology for ZEISS. The commercialization of SMILE will significantly strengthen our presence in the cataract and refractive space. We are convinced that the VisuMax SMILE procedure has the potential to grow the entire US market. There are lots of patients who have never decided for laser based refractive surgery but who might decide now for this minimally invasive approach."

ZEISS is also conducting an IDE trial in the US on astigmatic myopia to further broaden the spectrum of SMILE for more patients.

Dirk Muehlhoff, Head of the Global Refractive Business of ZEISS, commented on the collaboration with clinical investigators and the way forward: "It has been an honor working with such an esteemed team of clinical investigators. Now that we paved the way for this innovation in the US, we will build upon the



foundation of the early work with our study investigators for the commercialization of SMILE in the refractive practices throughout the U.S. to offer the benefits of SMILE to their patients.”

Great benefits, small incisions

SMILE is the first femtosecond laser-based vision correction procedure to treat myopia in a minimally invasive way. A small incision of just a few millimeters is needed to extract a lenticular-shaped laser-incised stromal lens from the cornea in order to induce the intended refractive change. The strong stromal tissue anterior to the extracted lenticule provide good biomechanical and refractive stability and fast visual recovery.

Indication for use:

For use in the reduction or elimination of myopia -1.00 D to -8.00D, with $\leq -0.50D$ cylinder and MRSE - 8.25D in the eye to be treated in patients who are 22 years of age or older with documentation of stable manifest refraction over the past year.

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Brief profile

Carl Zeiss Meditec AG (ISIN: DE 0005313704), which is listed on TecDAX of the German stock exchange, is one of the world's leading medical technology companies. The Company supplies innovative technologies and application-oriented solutions designed to help doctors improve the quality of life of their patients. It provides complete packages of solutions for the diagnosis and treatment of eye diseases, including implants and consumable materials. The Company creates innovative visualization solutions in the field of microsurgery. The medical technology portfolio of ZEISS is rounded off by promising future technologies such as intraoperative radiation therapy. With approximately 2,900 employees worldwide, the Group generated revenue of € 1,040 million in financial year 2014/2015 (to 30 September).

The Group's head office is located in Jena, Germany, and it has subsidiaries in Germany and abroad; more than 50 percent of its employees are based in the USA, Japan, Spain and France. The Center for Application and Research (CARIn) in Bangalore, India and the Carl Zeiss Innovations Center for Research and Development in Shanghai, China, strengthen the Company's presence in these rapidly developing economies. Around 35 percent of Carl Zeiss Meditec AG's shares are in free float. The remaining approx. 65 percent are held by Carl Zeiss AG, one of the world's leading companies in the optical and optoelectronic industries.

For more information visit our website at: www.zeiss.com/med