



Press Release

FDA Approval for SMILE Astigmatism

ZEISS Receives FDA Approval for ReLEx SMILE, Expanding Myopia Treatment to Patients with Astigmatism

Small Incision Lenticule Extraction, better known as ReLEx SMILE from ZEISS is a minimally-invasive corneal refractive procedure performed on the ZEISS VisuMax femtosecond laser.

DUBLIN, CA, October 5, 2018

Today, the ZEISS Medical Technology Segment announced the FDA Premarket Approval (PMA) for ReLEx[®] SMILE[®] PMA expanding myopia treatment to patients with astigmatism. The PMA also provides for a small entry incision to be made, allowing the SMILE[®] procedure to be potentially less disruptive to the corneal surface tissue.

"The expansion of Myopia treatment to patients with Astigmatism will enable current and future SMILE[®] surgeons to expand their patient base, paving the way for a new generation of refractive surgery patients," said Jim Mazzo, Global President Ophthalmic Devices at Carl Zeiss Meditec.

ZEISS ReLEx SMILE utilizes the high-precision femtosecond laser VisuMax[®] to create a lenticule inside the cornea and access incision in a single treatment step. Its outstanding cutting precision, exceptional speed and gentle treatment make it an ideal platform for advanced corneal surgery such as SMILE[®]. Incisions are made through microscopic-photodisruptions of tissue, created by ultrashort pulses.

Many patients are patiently awaiting this approval, reported John F. Doane, M.D., F.A.C.S. of Discover Vision Centers. "We and our patients are excited to say the least. Refractive surgery just keeps getting better with Carl Zeiss Meditec's FDA approval of SMILE[®] for compound myopic astigmatism," Doane added.

VisuMax laser is the first femtosecond laser to receive FDA PMA approval for the treatment of a refractive indication in addition to 510k clearances for LASIK flap, keratoplasty, and ICR. With the approval of ReLEx[®] SMILE[®], patients can now benefit from a minimally invasive surgery, performed on one laser versus two.

Refractive surgeons benefit from SMILE[®]'s versatility, offering patients a more comfortable treatment option. With the approved new indication range the surgeon has also the option to benefit from extended technical parameters.

"Thanks to our continued collaboration with partner surgeons worldwide, we are able to pave the way for new developments and technologies in the refractive space," said Dr. Ludwin Monz, President, and CEO of Carl Zeiss Meditec. "Now with the FDA approval for US SMILE[®] Astigmatism, we can now extend this great treatment option to US Astigmatism patients as well."

ReLEx[®] SMILE[®] from ZEISS made its U.S. debut in 2016. In the last 10 years, over 1.5 million SMILE[®] treatments have been performed worldwide constituting over 10% of global laser vision correction procedures. To date, there are over 1700 surgeons using SMILE[®] in over 70 countries. The technology behind SMILE was recently featured in the Scientific Background on the Nobel Prize in Physics 2018. Dr. Gérard Mourou and Dr. Donna Strickland were awarded the Nobel Prize for his method to generate high-intensity ultrashort optical pulses. Their invention of so-called chirped pulse amplification is essential to generate the ultrashort laser pulses of the ZEISS VisuMax femtosecond laser system. ReLEx[®] SMILE[®] is a registered trademark of Carl Zeiss Meditec. For more information about ReLEx[®] SMILE[®], visit <https://www.zeiss.com>.



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Brief profile

Carl Zeiss Meditec AG (ISIN: DE 0005313704), the Medical Technology Business Group of ZEISS, is listed on SDAX and TecDAX of the German stock exchange and 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. The Company offers complete solutions, including implants and consumables, to diagnose and treat eye diseases. The Company creates innovative visualization solutions in the field of microsurgery. With approximately 3,000 employees worldwide, the Group generated revenue of € 1,189.9 million in fiscal year 2016/17 (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 41 percent of Carl Zeiss Meditec AG's shares are in free float. The remaining approx. 59 percent are held by Carl Zeiss AG, one of the world's leading groups in the optical and optoelectronic industries.

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

