



## Press Release

### **Innovative SMILE procedure from ZEISS successfully performed on more than 80,000 eyes**

*Micro-invasive refractive surgery becomes an established laser vision procedure for the correction of myopia. Clinical trial in the USA expanded.*

Two years after its international launch, the SMILE procedure developed by ZEISS has become the third generation of laser vision correction. More than 80,000 eyes worldwide have now been successfully treated using the micro-invasive method which offers improved predictability of the vision correction outcome without the need to create a corneal flap. The US FDA has approved expansion of the US clinical trial.

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The SMILE procedure developed by ZEISS for refractive surgery stands for Small Incision Lenticule Extraction and combines state-of-the-art femtosecond laser technology and precise lenticule extraction providing a micro-invasive laser vision correction method. Unlike LASIK (Laser-Assisted in situ Keratomileusis), in which an excimer laser ablates tissue inside the cornea after opening the corneal surface by cutting a corneal flap, the SMILE procedure is performed without a flap. The ZEISS femtosecond laser VisuMax® is used to create a very thin disc of tissue (lenticule) inside the intact cornea, which can then be extracted through a small incision. An excimer laser is not required.

"With SMILE ophthalmic surgeons now for the first time have a refractive surgery procedure that provides great benefits for their patients with the least possible intervention: the cornea of the eye remains intact as much as possible; the predictability of the correction is very good. The results are convincing more and more physicians and patients around the world," says Dr. Ludwin Monz, President and CEO of Carl Zeiss Meditec AG.

One of those physicians is Detlev R.H. Breyer, MD from the eye surgery clinic "Breyer & Kaymak" located in Düsseldorf. "SMILE is a very valuable addition to our clinic's portfolio of procedures, as we can now treat patients on an even more individual basis, and less invasively. Our practice is happy about the increasing demand we are receiving for this procedure, thanks to many recommendations from satisfied SMILE patients."

The SMILE procedure has also been documented in scientific publications as "predictable, effective and safe", regardless of the patient's age. Jesper Hjortdal, MD, DrMedSci, PhD from Aarhus University Hospital in Denmark concludes in one of his studies, on 670 eyes of 335 patients with myopia, that SMILE



is not inferior in any way to the LASIK procedure in these three aspects,<sup>1</sup> and was awarded the Waring Medal for outstanding contributions by the *Journal of Refractive Surgery*.

In the period after the surgery SMILE proves to be superior to the LASIK method: According to recent studies, inflammation was less common after SMILE procedures, and healing of the cornea was better<sup>2</sup>. The problem of dry eye syndrome often described following laser vision correction has also shown to be reduced after a SMILE procedure, as reported by Prof. Dan Z. Reinstein, MD from the London Vision Clinic, in several publications<sup>3</sup>: "As the nerve tracts of the cornea remain largely intact, the SMILE procedure is the least invasive of all refractive procedures. Various studies show that dry eye syndrome is a much rarer side-effect compared with LASIK."

The refractive correction of vision defects using laser technology has established itself as a method to enable eligible patients to have a life without glasses. Over the past few years development has focused on making the treatment less risky. The micro-invasive SMILE can now be considered a third-generation procedure, after methods such as PRK (Photorefractive Keratectomy) and LASIK – it involves the least possible intervention with the cornea remaining as intact as possible.

The procedure was launched internationally in September 2011 and is established in key markets such as Europe, China and India. A clinical trial is currently underway in the USA. The first results were presented in April 2013 by Jon Dishler, MD, US Medical Monitor for the VisuMax IDE Study and the FDA approved expansion of the clinical trial in July 2013. "Based on the excellent safety and effectiveness data submitted to the FDA on the first 79 subjects treated with the SMILE procedure and followed for at least three months, the FDA granted approval to expand the study to the full cohort of 360 subjects. This is an important milestone for the study," said Dr. Dishler at the Annual Meeting of the American Academy of Ophthalmology (AAO) in New Orleans at the beginning of November. In December 2013 the FDA granted approval to extend the trial further to include myopia of up to -10.00 diopters. The clinical trial in the USA began in June 2012; Dr. Dishler presented the first results in April 2013. To date, a total of 255 patients have been treated within the scope of the trial, at five centers in the USA. Outside the USA there are more than 150 centers in 38 countries with more than 300 surgeons performing the SMILE procedure.

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<sup>1</sup> Predictors for the outcome of small-incision lenticule extraction for myopia. Hjortdal JØ, Vestergaard AH, Ivarsen A, Ragunathan S, Asp S.; *J Refract Surg*. 2012 Dec;28(12):865-71. doi: 10.3928/1081597X-20121115-01.

<sup>2</sup> Small incision lenticule extraction (SMILE) and femtosecond laser LASIK: comparison of corneal wound healing and inflammation. Dong Z, Zhou X, Wu J, Zhang Z, Li T, Zhou Z, Zhang S, Li G.; *Br J Ophthalmol*. 2013 Nov 13. doi: 10.1136/bjophthalmol-2013-303415. [Epub ahead of print]

<sup>3</sup> Kumano Y, Matsui H, Zushi I, Mawatari A, Matsui T, Nishida T, Miyazaki M. Recovery of corneal sensation after myopic correction by laser in situ keratomileusis with a nasal or superior hinge. *J Cataract Refract Surg*. 2003.29(4): 757-761  
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**Contact for the press:**

Jann Gerrit Ohlendorf, Group Communications, Carl Zeiss Meditec AG  
Phone +49 (0) 3641 220-331, Email: [press.meditec@zeiss.com](mailto:press.meditec@zeiss.com)

**For investors:**

Sebastian Frericks, Investor Relations, Carl Zeiss Meditec AG  
Phone +49 (0) 3641 220-116, Email: [investors.meditec@zeiss.com](mailto:investors.meditec@zeiss.com)

**[www.meditec.zeiss.de/presse](http://www.meditec.zeiss.de/presse)**

**Carl Zeiss Meditec AG**

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 Carl Zeiss Meditec is rounded off by promising, future-oriented technologies such as intraoperative radiotherapy. In financial year 2012/2013 (ended 30 September) the Group's more than 2,500 employees generated revenue of € 906 million. The head office of Carl Zeiss Meditec is in Jena, Germany.

The company 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 Research and Development (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 shares are in free float. The remaining approx. 65 percent are held by Carl Zeiss AG, one of the world's leading groups in the optical and optoelectronic industries. For more than 160 years Carl Zeiss has been contributing to the progress of technology on the markets for Industrial Solutions, Research Solutions, Medical Technology and Consumer Optics, improving the quality of life for many people. Carl Zeiss AG, Oberkochen, is wholly owned by the Carl Zeiss Foundation.

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