



## Press Release

### **ZEISS receives the first US FDA Clearance for Swept-Source OCT posterior ocular imaging with PLEX Elite 9000**

**ZEISS continues to set the pace in OCT innovation with Swept-Source OCT imaging that expands the potential for clinical researchers to open new frontiers of discovery in diseases affecting the retina. ZEISS PLEX Elite 9000 allows the potential to see deeper, wider and in more detail from vitreous to sclera than previously possible with other technologies.**

DUBLIN, California, USA, November 16, 2016

Having received the first US FDA Clearance for OCT Angiography technology in September 2015, the Medical Technology business group of ZEISS now announces receiving the first US FDA Clearance for Swept-Source OCT imaging technology for posterior ocular structures with ZEISS PLEX® Elite 9000. This powerful, cutting-edge Swept-Source OCT and OCT Angiography platform was designed for advanced retina research and is at the core of the Advanced Retina Imaging (A R I) Network<sup>1</sup>.

The A R I Network, led by Philip J. Rosenfeld, MD, PhD, is a unique global consortium of clinicians and scientists from around the world working at the forefront of retinal disease research. The A R I Network is focused on exploring new clinical applications for the diagnosis and treatment of eye disease and advancing OCT innovation to benefit patients today and in the future. The US FDA clearance will help US members of the A R I Network to more easily enroll patients and may facilitate faster Institutional Review Board (IRB) review for protocol approval of research.

The wide-field high-resolution visualization provided by the Swept-Source OCT and OCT Angiography imaging of the PLEX Elite platform from ZEISS expands clinicians' ability to examine the critical microstructures and microvasculature of the posterior segment at any depth of interest from vitreous to sclera.

"ZEISS' Swept-Source OCT and OCT Angiography platform is truly a remarkable breakthrough in our quest to achieve better, wider, deeper, and faster imaging of the retina and choroid. This instrument opens up a new world of structural and microvascular clarity. By imaging deeper and in greater detail than ever before, we will further our understanding of the retina and choroid, and greatly facilitate clinical trial investigations into different diseases," says Dr. Rosenfeld, Chairman of the A R I Network. "This collaboration between the retina experts in the A R I Network and the engineers and scientists at ZEISS is vital to the advancement of retinal and choroidal imaging and scientific discovery."

"The A R I Network is unique in that it promotes innovation through collaboration," says Jim Mazzo, Global President Ophthalmic Devices for Carl Zeiss Meditec. "Through the active exchange of ideas and findings, the A R I Network is driving not only the development of new clinical applications but is helping to accelerate innovation development to advance clinical practice and patient care."

ZEISS PLEX Elite 9000 offers researchers the potential to assess early mechanisms for micro- and neovascularization, to explore the progression of retinal and choroidal pathology, to deepen the understanding of choroid physiopathology, and to evaluate mechanisms of retina and choroid response to therapy.



ZEISS PLEX Elite 9000 Swept-Source OCT and OCT Angiography platform has a limited release as a research tool for clinicians conducting retina research. The latest technology for daily comprehensive care, ZEISS AngioPlex™ OCT Angiography is available on the CIRRUS™ HD-OCT 5000 platform allowing ophthalmic practices to easily integrate advanced vascular imaging into their routine OCT diagnostic exams. The full complement of capabilities for CIRRUS OCT gives practices a broad spectrum of clinical analysis for patients with various chronic eye diseases.

<sup>1</sup> ZEISS PLEX Elite 9000 and the Advanced Retina Imaging Network limited to select markets.

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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.

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