



Press Release

FDA Clearance for Epithelial Thickness Mapping

ZEISS Receives FDA Clearance for Epithelial Thickness Mapping for CIRRUS HD-OCT, Enabling More Detailed Assessment of Refractive Surgery Patients

This new application will be unveiled at the Vision Expo East (VEE) Conference in New York from March 21-24

DUBLIN, CA, 8 March 2019

ZEISS Medical Technology Segment announced that it has received 510(k) clearance from the FDA for the CIRRUS HD-OCT platform, expanding the capabilities of its Anterior Segment Premier Module to include Epithelial Thickness Mapping (ETM).

According to refractive specialist Dr. John Doane of Discover Vision Center in Kansas City, the epithelium is the outermost layer of the cornea and is known to actively remodel itself in response to subtle changes in corneal shape due to pathologies such as early keratoconus that may be missed if using corneal topography alone. "With CIRRUS' Epithelial Thickness Mapping, I can now better identify eligible patients for refractive surgery, and I can also monitor the cornea's post-surgical healing response," Doane said.

ETM with CIRRUS provides a detailed nine-millimeter map of epithelial thickness that enables more thorough assessment of patients before refractive surgery, allows monitoring of the cornea's response to treatment, and aids in managing patients with ocular surface disorders such as dry eye and progressive corneal diseases such as keratoconus. With ETM, patients can expect a quick, comfortable non-contact exam that takes less than 1-second.

"The addition of this new software is another testament of our continued commitment to providing our customers innovative platforms, so they can provide their patients the highest level of care," said Jim Mazzo, Global President of Ophthalmic Devices at Carl Zeiss Meditec. "From early detection to post-operative evaluation, we're here to support to our customers, every step of the way," he added.

"ZEISS has been at the forefront of industry-defining advancements that have made CIRRUS HD-OCT the industry's standard of care for identifying retinal and glaucoma disease," said Dr. Ludwin Monz, President, and CEO of Carl Zeiss Meditec. "This milestone is yet another example to the strength and breadth of our portfolio, expanding CIRRUS' anterior segment capabilities to serve the needs of all eye care professionals."

ZEISS will showcase the new ETM feature in the latest CIRRUS Software release, along with other flagship products in Booth LP4003 at the Vision Expo East in New York from March 21-24.

For more information, visit <https://www.zeiss.com/meditec>.

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Brief profile

Carl Zeiss Meditec AG (ISIN: DE 0005313704), which is listed on MDAX and 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. 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 3,050 employees worldwide, the Group generated revenue of €1,280.9m in fiscal year 2017/18 (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