

Imalux moves into commercial mode with OCT

CLEVELAND, OH—Following FDA clearance of the Niris Imaging System, Imalux Corporation has embarked on an intensive marketing and sales effort to make potential users more aware of the device's capabilities for real-time tissue diagnostics, surgical assistance, and post-treatment follow-up. Imalux is initially targeting the urology, gynecology, and gastroenterology markets; further out, the company anticipates also pursuing the dental, dermatology, and ENT markets.

The Niris system utilizes optical coherence tomography (OCT) technology originally developed in the 1990s at the Institute of Applied Physics of the Russian Academy of Sciences. Imalux received initial clearance from the FDA to market the Imalux OCT Imaging System in March, 2004. Since then, the company has received two additional FDA clearances, one for an accessory sheath for the Imaging System probe designed to provide a microbial barrier and aid in positioning the probe, the other clearing the Niris system for commercialization.

"The 510(k) clearance allows us to provide the sixth imaging modality, OCT, for a broad range of medical imaging applications," said J. Lloyd Breedlove, president and CEO of Imalux. "The (Niris) system fills a gap in current imaging modalities and has the potential to create a large new segment of the medical imaging industry."

The current Niris system is the result of several design improvements and customer-focused enhancements to the initial Imalux OCT Imaging System, including interchangeability of different probe lengths (2 to 5 meters) and an improved software interface. The Niris platform, which is the size of a desktop computer and weighs 35 lbs., comprises an imaging console and detachable, reusable, flexible probe that enables imaging at the point of use. The console contains a super luminescent diode that functions as a near-infrared light source. The NIR light is directed through the probe to the tissue; the probe then collects the backscattered light and combines it with a reference signal to produce a high resolution (10-25 μm) image of the superficial tissue microstructure.

To perform lateral scanning, the system incorporates a miniaturized electromagnetic mechanism coupled with an optical lens system that moves the probe's internal fiberoptic tip and enables the optical beam to scan laterally over a 2-mm range while maintaining a small (2.7 μm) outer diameter. The probe also contains a flexible optical fiber, enabling image acquisition at the tissue site and permitting use with various endoscopic procedures.

The system sells for about \$65,000 and is being manufactured through a partnership between Imalux and Optiphase (Van Nuys, CA). Optiphase develops and manufactures fiberoptic sensors using optical coherence domain reflectometry and is manufacturing the optoelectronic module being used in the Niris system.

— Kathy Kinkade

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