

## **St. Jude Medical Announces Launch of 3D Vessel Reconstruction Technology in Japan**

The Associated Press

ST. PAUL, Minn.--(BUSINESS WIRE)--Mar 11, 2013--St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced the launch of its ILUMIEN™ OPTIS™ System, a next-generation technology designed to help physicians make personalized stenting decisions based on each patient's unique anatomy and disease state. The new ILUMIEN OPTIS system remains the only combined Fractional Flow Reserve (FFR) and intravascular Optical Coherence Tomography (OCT) imaging technology platform. Together, FFR and OCT offer physicians a physiological and anatomical view of the coronary vessels to help diagnose and treat coronary artery disease. The ILUMIEN OPTIS system provides enhancements to the ILUMIEN™ System, including a first-of-its-kind stent planning software tool.

"The ILUMIEN OPTIS system enables a higher image resolution, and thus makes it possible for us to analyze difficult anatomical structures, allowing me to focus on diagnostic and treatment strategies. Also, this new analytical tool will be helpful for sizing and placing the stent. This technology has become increasingly important to help efficiently diagnose and treat patients," says Dr. Takashi Akasaka of Wakayama Medical University.

The PressureWire™ Aeris™ Wireless FFR Measurement System collects detailed analyses of blood flow blockages in the coronary vessels to help determine which specific blockages are causing the patient's blood flow to be ineffective. The FFR pressure guidewire is directed through the coronary arteries and across the narrowed vessel, taking measurements as the guidewire is pulled back through the narrowed part of the artery.

The OCT technology in the new ILUMIEN OPTIS system uses the Dragonfly™ JP Imaging Catheter to capture near-infrared light imaging and measure important vessel characteristics otherwise invisible or difficult to assess with older intracoronary imaging tools. New high resolution setting and real-time, three-dimensional (3-D) reconstruction with the ILUMIEN OPTIS provide a 360-degree panoramic view of the vessel, which makes it easier for physicians to visualize the anatomy they are treating.

The FFR and OCT measurements captured by the ILUMIEN OPTIS system allow physicians to more easily differentiate plaque build-up and determine if the narrowed arteries are causing ischemia, or a restriction in blood flow, ultimately assisting in stent placement. Three-Dimensional representation enables better visualization in preparation for stenting and evaluation of the stent's position once placed. These advanced functionalities have previously only been available off-line. Three-Dimensional vessel reconstruction offers a better picture, and real-time analysis streamlines workflow, potentially helping physicians diagnose their patients

more quickly.

“We are very pleased to offer the ILUMIEN OPTIS system in Japan, which is a world leader in imaging technology utilization,” said William Phillips, president of St. Jude Medical Japan. “The new system is the latest in PCI optimization technology, and helps physicians understand the needs of each patient, ultimately resulting in better medical decision making and overall cost-effective treatment.” The benefits of FFR have been supported in a number of clinical trials, including FAME and FAME 2. The trials effectively demonstrate the important role FFR plays in improving patient care. Results from the original FAME trial found that instances of major adverse cardiovascular events (MACE) were reduced in patients whose treatment was guided by FFR rather than by standard angiography alone. The FAME 2 study revealed the number of patients returning to the hospital for urgent care was 86 percent lower for patients with stable coronary artery disease whose stenting procedure was guided by FFR than for those who received medical therapy alone.

Each year in Japan about 245,000 Percutaneous Coronary Intervention (PCI) procedures are performed to treat cardiovascular disease, and of those, nearly 80 percent are estimated to use imaging technology. ILUMIEN OPTIS comes with both English and Japanese language options.

#### About St. Jude Medical

St. Jude Medical develops medical technology and services that focus on putting more control into the hands of those who treat cardiac, neurological and chronic pain patients worldwide. The company is dedicated to advancing the practice of medicine by reducing risk wherever possible and contributing to successful outcomes for every patient. St. Jude Medical is headquartered in St. Paul, Minn. and has four major focus areas that include: cardiac rhythm management, atrial fibrillation, cardiovascular and neuromodulation. For more information, please visit [sjm.com](http://sjm.com).

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