HealthManagement
Promoting Management and Leadership

# St. Jude Medical Announces European Approval of 3D Vessel Reconstruction Technology


*3-D image of a stent inside a coronary artery taken using the ILUMIEN(TM) OPTIS(TM) (Photo: St. Jude Medical, Inc.)*

St. Jude Medical, Inc., a global medical device company, announced CE Mark approval of its ILUMIEN™ OPTIS™ PCI Optimization System™, a new technology designed to provide physicians with a comprehensive disease assessment tool for treating patients with coronary artery disease (CAD). The system will be on display for the first time in Europe during EuroPCR.

The ILUMIEN OPTIS system provides enhancements to the ILUMIEN™ system, including first-of-its-kind stent planning software tools to aid in the treatment of CAD. The ILUMIEN platform integrates both Fractional Flow Reserve (FFR) technology to measure pressure inside the coronary arteries and intravascular Optical Coherence Tomography (OCT) imaging technology, in one system.

Featuring a faster, high-powered laser, the ILUMIEN OPTIS system offers twice the resolution for microscopic examination of disease inside the artery to assist with stent placement. The real-time, three-dimensional (3-D) reconstruction offers a 360-degree panoramic view of the vessel, making it easier for physicians to visualize the area they are treating. St. Jude Medical is the only company to provide these tools together in an integrated platform.

“OCT technology has become increasingly important to help diagnose and treat patients with coronary artery disease. The ILUMIEN OPTIS system is a significant advancement in intravascular imaging technology allowing physicians to comprehensively assess more vessel in less time and more easily plan their PCI procedure. The three-dimensional format of the ILUMIEN OPTIS system provides a more true-to-life perspective of the arteries, which allows for individual decision making and precise guidance of stent placement to optimize coronary interventions, said Dr. Giulio Guagliumi, Cardiovascular Department of Ospedale Papa Giovanni XXIII, Bergamo, Italy.

Commonly known as coronary angioplasty, Percutaneous Coronary Intervention (PCI) is a non-surgical procedure used to treat narrowed coronary arteries of the heart found in patients with CAD.

The OCT technology in the new ILUMIEN OPTIS system uses the Dragonfly™ Duo Imaging Catheter to capture near-infrared light imaging and measure important vessel characteristics otherwise invisible or difficult to assess with older imaging technology. When used with the ILUMIEN OPTIS system, the Dragonfly Duo catheter offers faster, longer pull-backs, which allow the physician to assess more of the patient’s artery in less time.

The wireless PressureWire™ Aeris™ technology that is integrated into the platform measures pressure differences in blood flow within the coronary arteries leading to the heart, and determines the severity of any narrowings or blockages. The FFR pressure guidewire is directed along the vessel, taking measurements as the guidewire is pulled back through the artery. Knowing which specific blockages are causing the patient’s blood flow to be ineffective helps guide the interventional cardiologist in determining which lesions warrant stenting, resulting in improved patient outcomes and reduced health care costs.

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 (a restriction in blood flow), ultimately assisting in stent placement. The automated stent planning tools provide immediate information for assessment and real-time analysis, which is intended to streamline workflow, potentially helping physicians diagnose their patients more quickly.

“The advancements in the ILUMIEN OPTIS system reflect the commitment by St. Jude Medical to provide innovative products that reduce health care costs and improve outcomes for patients who suffer from coronary artery disease,” said Frank J. Callaghan, president of the St. Jude Medical Cardiovascular and Ablation Technologies Division. “This next-generation system delivers critical information to physicians about the location and severity of disease within the coronary arteries, potentially resulting in better medical decision-making and overall cost-effective treatment.”

According to the European Heart Network (EHN), the financial burden for EU health care systems related to cardiovascular diseases has been estimated to be just under € 110 billion (2006). This represents around 10 percent of the total health care expenditure in the EU. About one-fifth of that health care expenditure is due to coronary artery disease.

The benefits of St. Jude Medical’s PressureWire for 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 significantly reduced in patients whose treatment was guided by the company’s

PressureWire for FFR rather than by standard angiography alone. The FAME 2 study revealed that stenting to address significant blood flow blockages is better than medical treatment alone when the treatment is guided by St. Jude Medical's PressureWire. Specifically, instances of hospital re-admission because of an urgent revascularization were reduced by 86 percent when St. Jude Medical's PressureWire was used. These results add to the growing body of evidence demonstrating improved outcomes and cost-savings with the company's PressureWire-guided stenting.

Attendees can also visit St. Jude Medical at booth F16 of the exhibition hall during EuroPCR or visit us on the web for show-specific information at: http://www.sjmprofessional.com/europcr.

EuroPCR is the official congress of the European Association of Percutaneous Cardiovascular Interventions (EAPCI), a leading international course for interventional cardiovascular specialists.

Source: St. Jude Medical

Published on : Tue, 21 May 2013