HealthManagement
Promoting Management and Leadership

Volume 4 - Issue 1, 2010 - Exhibitors @ RSNA 2010

Update From Healthcare Industry

European Approval Given to ST. Jude Medical ICD and CRT-D Devices

St. Jude Medical implantable cardio verter defibrillators (ICD) and cardiac resynchronisation therapy defibrillators (CRTD) have been given the European CE Mark approval.

The products, including the Fortify(TM) and Fortify ST ICDs as well as the Unify(TM) CRT-D, will be fully launched in Europe this spring. Their reduced size, the smallest available device footprint in the industry, allows the products to be implanted through a smaller incision, as well as limits the number of connections from the defibrillation lead and the device, improving patient comfort.

ICDs and CRT-Ds help ensure effective therapy and provide additional disease management monitors for heart failure patients or patients at risk for sudden cardiac arrest.

The devices feature the highest energy level available in the industry. Energy capability of the device is especially important for patients with an enlarged heart, low ejection-fraction, advanced heart failure or have previously demonstrated a high defibrillation threshold.

The Unify CRT-D and Fortify ICD include the Corvue(TM) pulmonary congestion monitoring algorithm which alerts physicians when a patient's heart failure may be worsening through changes in electrical signals.

Edwards Initiates Study of Aortic Valve Surgery System

Edwards Life sciences has completed the first in-man procedures of minimally invasive aortic valve surgery system and has initiated a feasibility study that is now actively enrolling in Europe.

Known as Project Odyssey, the system uses the Carpentier-Edwards PERIMOUNT Magna Ease tissue heart valve design to create a new valve platform. The system enables a faster procedure, shorter patient time on cardiopulmonary bypass and a smaller incision.

The feasibility study for Project Odyssey, TRITON, is part of Edwards' corporate strategy to couple its expertise in heart valves with innovation in delivery. Ideally, TRITON will improve the valve surgery experience for both surgeons and patients.

Meditronic to Acquire Invatec and Affiliated Companies

Meditronic, Inc. has signed an agreement to acquire Invatec, a developer of technologies for the interventional treatment of cardiovascular disease, and two affiliated companies.

Expanding its product offering and adding franchise and pipeline, the agreement could be worth 500 million dollars, 350 million initially and up to 150 million with further Invatec achievement.

Invatec will add products such as stents and angioplasty balloons, while the affiliate companies, Fogazzi and Krauth Cardiovascular, will provide polymer technology and distribution services respectively.

Medtronic Non-Surgical Valve Replacement Receives FDA Approval

The Melody® Transcatheter Pulmonary Valve manufactured by Medtronic Inc. Has received U.S. Food and Drug Administration (FDA) Approval, the first transcatheter heart valve to do so.

The device is designed for patients with a malformation of their pulmonary valve. While these patients often require open-heart surgery, the Melody valve is delivered through a catheter requiring only a small incision.

Since receiving European CE approval in 2006, the Melody valve has been used in more than 1,100 cases.

Biosensors Biomatrix Flex (TM) Receives CE Mark Approval

BioMatrix Flex(TM), a new version of the Biosensors BioMatrix drug-eluting stent system, will be made available over the coming months upon European CE Mark approval.

The BioMatrix Flex combines the abluminal biodegradable polymer and proprietary limus drug, Biolimus A9(TM). The BioMatrix stents first received approval in 2008 and also include a smaller-diameter version that was approved last year.

Also recently, the BioMatrix stent system received approval for reimbursement in France through addition to the Liste des Produits et Pestations Remboursables (LPPR).

Already the BioMatrix stent system has been helping patients with coronary artery disease in other parts of the world including Latin America and Asia.

GE Healthcare Appoints New Chief Medical Officer

William (Pepper) Denman has been appointed Chief Medical Officer (CMO) at GE Healthcare, the most senior physician in the company.

The former CMO and Vice President of Medical Affairs for Covidien, Denman will provide clinical direction to GE Healthcare as the new CMO. Working primarily with the Global Quality, Regulatory and Medical organisation, Denman will focus on improving process rigor in clinical trial design, strengthening academic research partnerships and improving medical risk assessments. Denman also will lead all clinical and evidence generation strategies, driving technology and scientific synergies across all of GE Healthcare.

Denman is currently involved in multiple clinical and basic science research projects at Massachusetts General Hospital and Harvard Medical School. He received his Doctor of Medicine at the University of Aberdeen (United Kingdom).

Siemens Presents Interventional Neuradiology Imaging

Siemens has developed new functional imaging that displays cerebral blood flow during interventional procedures.

Labeled syngo Neuro PBV IR (Parenchymal Blood Volume, Interventional Suite), the technology allows review of parenchymal blood flow during minimally invasive interventions in the brain for the first time. Neuroradiologists will now be able to see the condition of the cerebral tissue directly in the angio suite of stoke patients.

Unlike traditional CT acquisition, clinicians will have blood volume data for the entire brain, and be able to review the information from any orientation, axial, coronal, sagittal, etc. The advantages will be seen in stroke treatments, as well as tumor biopsy and treatment, tissue embolisation and vasospasm therapy.

Biotronik Signs Exclusive Distribution Agreement with Endosense

Biotronik has announced it will be the exclusive distributor of Endosense's Tacti- Cath® in all major markets outside the United States, Japan and Asia.

The TactiCath® is a force-sensing ablation catheter that was granted CE mark approval for atrial fibrillation and supraventricular tachycardia indications in 2009. Supported by acute and chronic evidence, the catheter gives physicians a real-time, objective measure of contact force for cardiac ablation procedures. The partnership brings together Biotronik, a manufacturer of implantable cardiac devices and wireless remote monitoring technologies, and Endosense, a Geneva-based company that specialises in catheter ablation technology.

Maquet Cardiovascular Initiates Option Sstudy

Maquet Cardiovascular LLC initiates OPTION study designed to address conduit quality of endoscopically-harvested grafts.

OPTION, or the Optimal Improvement of Vein Graft Patency Long Term by the Implementation of Novel Endoscopic Harvesting Techniques Study, will evaluate the equivalence of endoscopic vessel harvesting (EVH) in coronary artery bypass graft (CABG) compared with historical data for open vein harvesting.

The 100-patient, single-centre study will evaluate the vein graft patency at one month and one year after CABG surgery. In the U.S., EVH is used in around 80 percent of CABG procedures.

Sorin Group Joins "Bambini Cardiopatici Nel Mondo" in Providing Cardiac Care to Disadvantaged Children

Sorin Group will work with the non-profit organisation Bambini Cardiopatici nel Mondo in order to serve disadvantaged children with congenital heart disease. Sorin Group has guaranteed financial contributions, not less than 600,000 euros over three years, as well as donation of medical devices and volunteer participation by its employees. These humanitarian activities are a part of Sorin Group's first Global Cause.

Volcano Receives CE Mark for Optical Coherence Tomography Imaging System

Volcano Corporation has received the CE mark approval for their Optical Coherence Tomography (OCT) imaging system and catheter. The OCT line is used in coronary imaging and lesion assessment, complimenting Volcano's existing products such as its IVUS imaging catheters and pressure guide wires.

UK Reviews Dronedarone for Atrial Fibrillation

UK cardiologists among others are petitioning the UK National Institute for Health and Clinical Excellence (NICE) to support dronedarone for treatment of recurrent atrial fibrillation (AF).

The use of the antiarrhythmic drug, Multaq, produced by Sanofi-Aventis was discouraged by NICE in December on the grounds that it was more expensive and not as effective as others in the market. UK cardiologists, nurses, patients and industry are now encouraging it to be made available for prescription by the National Health Service (NHS). Multaq® was approved by the European Union in September 2009.

Already discussed in Parliament, comments from interested parties are being reviewed and a stakeholder inquiry is underway. Efforts have been coordinated by the Atrial Fibrillation Association and Heart Rhythm UK receiving more than 100 doctors' signatures on the petition. Sanofiaventis has taken part of the activities, but has not contributed financially. A final guidance to the NHS will be issued by NICE in the weeks following their second panel meeting that took place 24 February.

Merge Introduces Patient-Focused IT Solution

Merge has announced the launch of a full-service kiosk focused on the patient in healthcare facilities.The automated technology guides patients through the checkin process with the ability of an avatar based agent. The deployment of the kiosk came from the success of similar technologies in other industries.

The system sets the appropriate alerts, updates a patients' status and scans required documents, all within the normal workflow of the clinic. The kiosks have seen positive results and through their use healthcare facilities hope to establish loyalties with their customers with the improvements in operational efficiency.

Published on : Mon, 4 Jan 2010