Medtronic News

CardioGuide System Enables Real-Time Navigation of Left Ventricular Leads During Medtronic CRT Implants

System Available in U.S. and Canada

MINNEAPOLIS - April 9, 2013 - Medtronic, Inc. (NYSE:MDT) today announced market release of the CardioGuide(TM) Implant System, a novel real-time navigation system for cardiac resynchronization therapy pacemakers and defibrillators (CRT-P and CRT-D), in the United States and Canada. The system helps physicians determine the most appropriate location for left-ventricular lead placement by generating 3-D images of the cardiac veins; enhanced software for the system will be commercially available later this year that also analyzes the motion of select cardiac vessels on the left side of the heart. Clinical studies have shown that appropriate left-ventricular lead placement may improve CRT response in heart failure patients1,2,3.

Paieon Inc. is the developer of the CardioGuide(TM) system. Based on its unique expertise in the field of real-time cardiac fluoroscopy-based image navigation, Paieon has invested considerable engineering efforts in the development of the CardioGuide system. Medtronic has an exclusive licensing agreement with Paieon to market the CardioGuide System worldwide.

"The future of LV lead implantation requires an individual-patient-tailored approach. We know from studies that the best location for one patient can be the least effective for another," said Raymond Yee, M.D., director, Arrhythmia Service, London Health Sciences Centre, Ontario, Canada. "This system provides clinical and physiologic data acquired during the CRT case to ensure that the optimal lead and tools are used to implant the lead at the targeted location, potentially helping improve patient response to the therapy."

CRT is a safe and effective treatment4 for indicated heart failure patients, proven to significantly reduce mortality and heart failure hospitalization rates4. However, approximately one-third of patients who receive a CRT device do not fully benefit from this therapy5; appropriate lead placement may improve patient outcomes. The CardioGuide System's 3-D imaging software projects a roadmap and the targeted lead placement onto an overlay of the patient's heart, and tracks the real-time location of the electrodes within the body using fluoroscopy. This enables the implanting physician to confirm that the lead is placed in the targeted location.

In addition, left-ventricular lead positioning is known to be time-consuming for physicians. In approximately 43 percent of cases, patient procedure times extend to two hours or more6. Given its ability to guide lead placement in real-time, the CardioGuide System may help reduce overall implant procedure times.

"The CardioGuide Implant System offers the medical community a viable, cost-effective solution for targeting left-ventricular lead placement, the cornerstone of successful CRT therapy," said David Steinhaus, M.D., Vice President and General Manager, Heart Failure, and Medical Director for the Cardiac Rhythm Disease Management business. "This is yet another example of our commitment to offering physicians the most advanced medical technology to help improve CRT response and ensure the best quality of care for all heart failure patients."

The CardioGuide System is part of a comprehensive approach Medtronic has undertaken to deliver solutions to optimize CRT response and manage heart failure patients at every stage of care. The system is compatible with all Medtronic CRT devices, including the Viva®/Brava® portfolio available in Europe. The system received a Cardiostim Innovation Award from the European Society of Cardiology in 2012, and is available in the United States and Canada.

About the CardioGuide(TM) Implant System

The CardioGuide Implant System is designed to analyze fluoroscopy images and create 3-D imaging of the heart for transvenous left-ventricular lead implants. The components currently offered in the system include:

- CardioGuide software and work station, which includes a dedicated computer and monitor that are used to calculate anatomical measurements and provide lead navigation support.
- Physician monitor, which displays the implant system inside the procedure room or cath lab.
- Tablet computer, which includes a touch screen and stylus and is used as a tableside console in the procedure room.
- Markers that are placed on the patient's chest to automatically calibrate the system.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers worldwide.

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health, and extending life for millions of people around the world.

About Paieon Inc.

Paieon Inc., based in New York and its R&D center in Israel, is a medical imaging company pioneering in the field of real-time imaging for cardiac navigation. Paieon's mission is to develop progressive cardiac navigation imaging solutions that bridge between the imaging world and implantable devices, adding its valuable decision tools to support physicians and their patients throughout interventional cardiac procedures.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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