Medtronic News

Medtronic CardioInsight Mapping Solution Cleared by FDA

System First Used Commercially in U.S. This Week

DUBLIN - Feb. 1, 2017 - Medtronic plc (NYSE: MDT) has received U.S. Food and Drug Administration (FDA) 510(k) clearance for the CardioInsight(TM) Noninvasive 3D Mapping System. The CardioInsight system is used to map a wide range of irregular heart rhythms in the upper and lower chambers of the heart, and provides electroanatomic 3D maps of the heart. The system was first used commercially in the U.S. by Vivek Reddy, M.D., director of cardiac arrhythmia services at the Mount Sinai Hospital and the Mount Sinai Health System, New York.

Cardiac mapping - typically accomplished by inserting a catheter into the heart via an artery or vein - allows physicians to locate the origin of a patient's irregular heart rhythms (arrhythmias). In contrast, the CardioInsight system is the first commercially released, noninvasive, cardiac electrical mapping system in the world, eliminating the invasive steps of this clinical procedure.

The CardioInsight system uses a 252-electrode sensor vest that is worn by the patient to pair body surface electrical data with heart-torso anatomy. The noninvasive technology creates 3D electroanatomic maps of the heart by collecting electrocardiogram (ECG) signals from the chest, and combining these signals with data from a computed tomography (CT) scan of the heart. The vest technology contours to the patient's body and allows for continuous and simultaneous panoramic mapping of both atria or both ventricles, which cannot be achieved with current invasive methods. The 3D cardiac maps can be created by capturing a single heartbeat, and enable rapid mapping of these heart rhythms. The predecessor system has been used with more than 1,600 patients and is featured in more than 120 peer-reviewed journals and presentations.

"By offering this noninvasive approach, we are effectively streamlining the clinical procedure planning process for clinicians, and making it easy for patients to receive precise mapping results from their providers right at their bedside," said Dr. Reddy. "This system shifts mapping away from the EP lab, potentially saving time and enhancing the patient experience." Dr. Reddy receives financial compensation as a consultant to Medtronic, as well as research grant support from Medtronic.

Medtronic will employ a strategic rollout of the technology in the geographies where it is cleared. Medtronic acquired CardioInsight in 2015, now part of the Medtronic AF Solutions business in the Cardiac Rhythm and Heart Failure division.

"The CardioInsight system further expands the portfolio of solutions available for common and complex arrhythmias," said Colleen Fowler, vice president and general manager of the AF Solutions business. "This technology - which has been in development for decades - is now poised to drive greater physician insights and new advancements in the study and treatment of infrequent, unstable cardiac rhythms in a noninvasive, patient-friendly manner."

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 of the highest quality that deliver clinical and economic value to healthcare consumers and providers around the world.

To view animation of the CardioInsight System in use, click here http://oak.ctx.ly/r/5ea9h.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 88,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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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Contacts:
Tracy McNulty
Public Relations
+1-763-526-2492

Ryan Weispfenning
Investor Relations
+1-763-505-4626
