Medtronic News

Medtronic Gains U.S. FDA Clearance for New Catheter System for HIS Bundle Pacing

DUBLIN - May 29, 2019 - Medtronic plc (NYSE:MDT) today announced U.S. Food and Drug Administration (FDA) clearance and commercial launch for the SelectSite(TM) C304-HIS deflectable catheter system for use in procedures involving His-bundle pacing (HBP).

The SelectSite C304-HIS deflectable catheter system features a deflectable, out-of-plane curve to reach the bundle of His and is designed to enable enhanced range maneuverability, fixation and implant success for a wider range of patient anatomies. Its adjustable form helps accommodate and secure the pacing lead in more challenging anatomies, including patients with a large right atrium.

"Pacing at the bundle of His is a promising procedure with a growing body of clinical evidence," said Pugazhendhi Vijayaraman, M.D., director of electrophysiology at Geisinger Heart Institute in Wilkes-Barre, Pa. "The C304-HIS catheter's adjustable curve design should help implanters reach the His bundle fibers more easily and accommodate a variety of patient anatomies."

The new catheter system facilitates placement of the Medtronic SelectSecure(TM) MRI SureScan(TM) Model 3830 cardiac pacing lead, the only pacing lead on the U.S. market approved for HBP. His-bundle pacing is a physiologic alternative to right ventricular pacing, in which a pacing lead is placed at or near the bundle of His, using the heart's native His-Purkinje conduction system to restore the heart's normal rhythm.

"There is a growing trend of physicians interested in His-bundle pacing for certain patients as it leverages the native conduction system," said Rob Kowal, M.D., Ph.D., chief medical officer, vice president of medical affairs in the Cardiac Rhythm and Heart Failure division, which is part of the Cardiac and Vascular Group at Medtronic. "Medtronic is pleased to continue to lead the industry with product innovations and training to support this emerging therapy technique."

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.

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 90,000 people worldwide, serving physicians, hospitals and patients in more than 150 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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