Medtronic News

Medtronic Receives FDA Approval for World's First Quadripolar Active Fixation Left Heart Lead

Attain Stability(TM) Quad MRI SureScan(TM) Lead Designed for Precise Placement and Stability

DUBLIN - May 1, 2019 - Medtronic plc (NYSE:MDT) announced it has received U.S. Food and Drug Administration (FDA) approval for the Attain Stability(TM) Quad MRI SureScan(TM) left heart lead. Paired with Medtronic quadripolar cardiac resynchronization therapy-defibrillators (CRT-D) and -pacemakers (CRT-P), the Attain Stability Quad lead is the only active-fixation left heart lead, and is designed for precise lead placement and stability. The lead will be commercially available in the U.S. in summer 2019.

"Appropriate placement of left heart leads during implantation of CRT devices is critical to achieve the clinical benefits of this therapy. Unfortunately, with present passive-fixation leads, we are not always able to position the lead in an ideal location due to variations in a patient's anatomy and size of the target vessel. We also continue to see lead dislodgements that require reprogramming or repeat surgery for lead repositioning. Having a new active fixation left heart lead allows us to target the ideal location in the patient's vessel with the confidence that the lead will remain in place to allow for continued effective delivery of CRT," said Steven Zweibel, M.D., F.A.C.C., F.H.R.S., C.C.D.S., director of Electrophysiology at the Hartford Healthcare Heart and Vascular Institute.

CRT is a treatment for heart failure in which an implantable device sends low levels of energy through thin wires, called leads, to stimulate the heart muscle and potentially improve the heart's pumping efficiency. With the introduction of quadripolar leads (leads with four electrodes), physicians can pace from different locations in the heart, but are limited in where they can place the lead. The Attain Stability Quad lead integrates the benefits of a quadripolar lead with a side-helix that allows physicians to fixate the lead precisely in veins of various sizes, including ones not typically amenable to positioning a passive lead. Additionally, patients with this lead and MR-conditional CRT devices are eligible for either 3 Tesla (T) and 1.5T magnetic resonance imaging (MRI) scans, if needed.

"Clinical trial evidence shows this lead is a safe and effective option for patients receiving CRT devices," said Kweli P. Thompson, M.D., M.P.H., vice president and general manager of the Cardiac Resynchronization Therapy business, which is part of the Cardiac Rhythm and Heart Failure division at Medtronic. "It offers the advantages of established quadripolar leads, while enabling secure placement across various patient anatomies. We are pleased to bring the latest advancement in left-heart lead technology to the U.S., adding to our diverse portfolio of solutions for patients with heart failure."

The Medtronic portfolio of therapies, diagnostic tools and services for patients suffering from heart failure includes MR-conditional CRT-Ds and CRT-Ps; mechanical circulatory support therapy for advanced heart failure patients; heart failure diagnostics; and meaningful expert analysis through Medtronic Care Management Services.

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 86,000 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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