Medtronic News

FDA Approves World's Smallest Pacemaker for U.S. Patients

The Medtronic Micra® TPS is the First Transcatheter Pacemaker Approved in the U.S.
Gives Patients Access to the Most Advanced Pacing Technology at One-Tenth the Size of Traditional Devices

DUBLIN - April 6, 2016 - Medtronic plc (NYSE:MDT) today announced it has received U.S. Food and Drug Administration (FDA) approval of the world's smallest pacemaker, the Medtronic Micra Transcatheter Pacing System (TPS). The Micra TPS is the first FDA-approved product with miniaturized pacing technology. It is cosmetically invisible and small enough to be delivered through a catheter and implanted directly into the heart -providing a safe alternative to conventional pacemakers without the complications associated with cardiac wires (leads).

"For many years we've been hopeful that a transcatheter pacing solution - with a safety and effectiveness profile on par with conventional devices - would become available, and today Micra has achieved this milestone," said Dwight Reynolds, M.D., regent's professor and chief of the Cardiovascular Section at the University of Oklahoma Health Sciences Center, and principal investigator in the Micra TPS Global Clinical Trial. "In the clinical trial, the Micra was successfully implanted in nearly all patients, and met its safety and effectiveness endpoints by wide margins. This gives us great confidence that this miniaturized device will bring patients the most advanced pacing technology, combined with the less-invasive nature of the new technology."

Comparable in size to a large vitamin, the Micra TPS is attached to the heart with small tines and delivers electrical impulses that pace the heart through an electrode at the end of the device. Unlike traditional pacemakers, the Micra TPS does not require leads or a surgical "pocket" under the skin, so potential sources of complications related to such leads and pocket are eliminated-as are any visible signs of the device. The device responds to patients' activity levels by automatically adjusting therapy.

Micra TPS is the first and only transcatheter pacing system to be approved for both 1.5 and 3 Tesla (T) full-body magnetic resonance imaging (MRI) scans, providing patients with access to the most advanced imaging diagnostic procedures available.

The Micra design incorporates a retrieval feature to enable retrieval when possible; however, the device is designed to be left in the body. For patients who need more than one device, the miniaturized Micra TPS was designed with a unique feature that enables it to be permanently turned off so it can remain in the body and a new device can be implanted without risk of electrical interaction.

In November 2015, data from the Medtronic Micra TPS Global Clinical Trial were published in the *New England Journal of Medicine* and presented during a late-breaking Special Report at the American Heart Association Scientific Sessions. Data showed the Micra TPS was successfully implanted in 99.2 percent of patients, there were no (0) dislodgements, and the system met its safety and effectiveness endpoints with wide margins.

In the Micra trial, 96 percent of patients (700 of 725; six-month Kaplan-Meier estimate) experienced no major complications, which is significantly fewer - 51 percent fewer - major complications than seen in patients with conventional pacing systems (hazard ratio: 0.49; 95 percent CI, 0.33 to 0.75; P=0.001). Major complications included cardiac injuries (1.6 percent), complications at the groin site (0.7 percent) and pacing issues (0.3 percent).

Almost all patients, 98.3 percent (292 of 297), had low and stable pacing thresholds at six months, yielding projected average longevity for the device of more than 12 years.

In addition, the low major complication rates experienced by Micra patients resulted in significant reductions in healthcare utilization compared to conventional pacing systems: Micra patients had 54 percent fewer hospitalizations (p=0.011) and 87

percent fewer system revisions (p<0.001) than observed in the historical control group.

The trial enrolled 744 patients; it evaluated the safety and efficacy of the device through a single-arm, multi-center study at 56 centers in 19 countries. Primary endpoints of the trial were freedom from device-related or procedure-related major complications with target performance of >90 percent (lower CI >83 percent) at six months, and low and stable pacing thresholds as demonstrated by <= 2V and no increase of >1.5V (relative to implant) and target performance of >89 percent (lower CI >80 percent) in the first 300 patients at six months.

"Dating back to the development of the first external battery operated pacemaker more than 60 years ago, Medtronic has a long history of collaborating with clinicians to better understand the needs of patients, and then innovating new products to meet those needs," said John Liddicoat, M.D., senior vice president, Medtronic, and president of the Cardiac Rhythm and Heart Failure division. "We are thrilled to be the first to introduce a transcatheter pacemaker to patients in the U.S., and we're looking forward to working with physicians and educating implanters to extend the positive results of our global clinical trial experience to even more patients."

The Micra TPS was awarded CE Mark in April 2015 based on early data from the Medtronic Micra TPS Global Clinical Trial. It is intended for use in patients who need a single-chamber pacemaker. The device was designed to allow patients to be followed by their physicians and send data remotely via the Medtronic CareLink® Network; remote monitoring of Micra devices is expected to be available later this year.

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 around the world.

Multimedia Release

A multimedia version of this release with a patient story, animation and downloadable graphics can be found at: https://medtronicmediacap.gcs-web.com/fda-approves-worlds-smallest-pacemaker-us-patients

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 85,000 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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