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FDA approves world's smallest pacemaker

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Medtronic announced it has received US Food and Drug Administration (US 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).

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 said to be 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.

"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 Dr John Liddicoat, 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 US, 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."

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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.

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