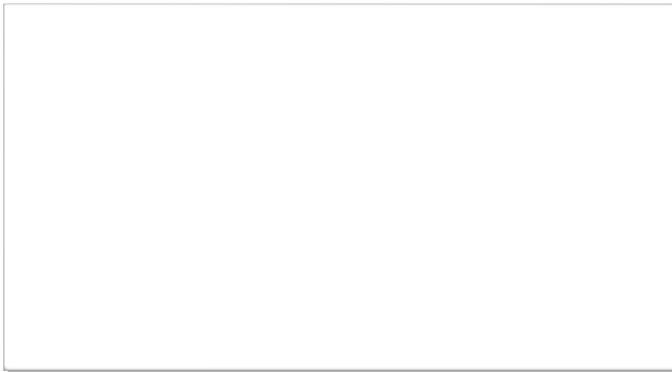


Medtronic announces CE Mark approval for Micra pacemaker

15 April 2015 | News | By BioSpectrum Bureau

Medtronic announces CE Mark approval for Micra pacemaker



Medtronic has announced that it has received the CE (Conformit   Europ  enne) Mark for the Micra Transcatheter Pacing System (TPS), the world's smallest pacemaker.

At less than one-tenth the size of a traditional pacemaker, the Micra pacing system provides the most advanced pacing technology available while being cosmetically invisible and small enough to be delivered with minimally invasive techniques through a catheter, and implanted directly into the heart.

Comparable in size to a large vitamin, the Micra TPS does not require the use of wires, known as "leads," to deliver pacing therapy; rather, it is attached to the heart via small tines and delivers electrical impulses that pace the heart through an electrode at the end of the device.

Once positioned, the Micra TPS is attached to the heart wall and can be repositioned or retrieved, if needed. The device responds to patients' activity levels by automatically adjusting therapy. Despite its miniaturized size, the Micra TPS has an estimated 10-year battery life and is approved for full body MRI scans, providing patients with access to the most advanced imaging diagnostic procedures.

The device was awarded CE Mark based on results from the first 60 patients (at three months) in the Medtronic Micra TPS Global Clinical Trial. The trial is ongoing and will continue to evaluate the safety and efficacy of the device through a single-arm, multi-center study that will enroll up to 780 patients at approximately 50 centers in 20 countries. Initial results from the Micra TPS Global Clinical Trial will be revealed for the first time at a late-breaking clinical trials session at the Heart Rhythm Society's 2015 Annual Scientific Sessions in May.

In the US, the Micra TPS is an investigational device and not yet approved for commercial use.

"Our cross-functional teams have been working for years to redefine engineering limits and production capabilities by radically reducing the size of medical devices by more than 90 percent while continuing to innovate upon the existing technology. We believe our investment in this research is transforming cardiac care and will provide more and better therapy

options to patients," said Dr Brian Urke, vice-president and general manager of the Cardiac Rhythm and Heart Failure's Brady business, which is part of the Cardiac and Vascular Group at Medtronic.