

Medtronic announces regulatory approval and launch in Japan of Micra AV Transcatheter Pacing System

World's smallest pacemaker can now treat patients with AV block, bringing miniaturized, leadless pacing to more patients

DUBLIN, Jan. 10, 2022 /PRNewswire/ -- Medtronic plc (NYSE:MDT), a global leader in healthcare technology, today announced it has received approval from Japan's Ministry of Health, Labor and Welfare for the sale and reimbursement of the Micra™ AV Transcatheter Pacing System (TPS), and the company will launch the product this month.

This approval expands the number of patients in Japan – one of the largest markets in the world – who are eligible to receive the Micra TPS, the world's smallest pacemaker. The Micra AV is indicated for the treatment of patients with AV block, a condition in which the electrical signals between the chambers of the heart (the atria and the ventricle) are impaired. The Micra TPS is the first-ever leadless pacemaker; its first version (the Micra VR) was approved in Japan in 2017 for patients who only require single-chamber pacing.

"Pacemakers have made significant progress over their approximately 60-year history, including miniaturization, improvements in pacing technology, MRI compatibility, and remote monitoring," explained Kyoko Soejima, professor of cardiovascular internal medicine at Kyorin University Hospital and a member of the Micra TPS Global Clinical Trial steering committee. "The first Micra system transformed the concept of pacemakers by eliminating surgical pockets and leads, and Micra AV promises to deliver the benefits of leadless pacing to a larger number of patients because ventricular pacing can be performed synchronously with the atrium."

Historically, patients with AV block have been treated with traditional dual-chamber pacemakers which are implanted in the upper chest, under the skin below the collar bone, and connected to the heart using thin wires called "leads." Identical in size and shape to the original Micra TPS, Micra AV has several additional algorithms which detect cardiac movement, allowing the device to adjust pacing in the ventricle to coordinate with the atrium, providing "AV synchronous" pacing therapy to patients with AV block.

The Micra AV approval is based on data from the MARVEL 2 (Micra Atrial Tracking Using A Ventricular accelerometer) study, which evaluated the safety and effectiveness of accelerometer-based atrial sensing algorithms. The study evaluated the ability of the Micra's internal sensor to monitor and detect atrial contractions and enable coordinated pacing between the atrium and ventricle, thereby providing AV synchrony.

"Since introducing the first battery-powered external pacemaker in 1957 to the innovative Micra leadless pacemaker portfolio, Medtronic continues to pioneer pacing innovations for physicians and their patients," said Rob Kowal, M.D., Ph.D., chief medical officer of the Cardiac Rhythm Management business, which is part of the Cardiovascular Portfolio at Medtronic.

About the Micra Transcatheter Pacing Systems (TPS)

The Micra TPS received CE Mark in April 2015 and U.S. FDA approval in 2016. Comparable in size to a large vitamin, Micra is less than one-tenth the size of traditional pacemakers yet delivers advanced pacing technology to patients via a minimally invasive approach. During the implant procedure, the device 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, Micra does not require leads or a surgical "pocket" under the skin, so potential sources of complications related to leads and pockets are reduced, and there is no visible sign of the device.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, Ireland, is the leading global

healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 90,000+ passionate people across 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE:MDT), visit www.Medtronic.com and follow [@Medtronic](https://twitter.com/Medtronic) on Twitter and [LinkedIn](https://www.linkedin.com/company/medtronic).

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.

Contacts:

Tracy McNulty	Ryan Weispfenning
Public Relations	Investor Relations
+1-612-819-2190	+1-763-505-4626

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