Medtronic News

Medtronic receives FDA approval for its next generation Micra leadless pacing systems

New pacemakers offer 40% more battery life,[1] extend Medtronic legacy of pacing leadership

DUBLIN, May 1, 2023 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, today announced it has received U.S. Food and Drug Administration (FDA) approval of its Micra™ AV2 and Micra™ VR2, the next generation of its industry-leading miniaturized, leadless pacemakers.

Micra AV2 and Micra VR2, the world's smallest pacemakers, provide longer battery life and easier programming than prior Micra pacemakers, while still delivering the many benefits of leadless pacing such as reduced complications compared to traditional pacemakers.[2]

With approximately 40% more battery life compared to previous generations,[1] the median projected battery life of Micra AV2 and Micra VR2 is nearly 16 and 17 years, respectively.[3] This means more than 80% of patients who receive a Micra are projected to only need one device for life.[3]

The new Micra AV2 also includes advanced algorithms that automatically program AV synchrony, thereby coordinating the heart's upper and lower chambers. Also, for patients who are active, Micra AV2 has a higher available tracking capability for faster heart rates (increased from 115 to 135 beats per minute for upper limits).[4]

"Improved AV synchrony – requiring less in-office reprogramming thanks to algorithm optimization – and longer battery life are major wins for patients," said Camille Frazier-Mills, M.D., MHS, an electrophysiologist at Duke University Health System. "I'm excited to offer my patients the new Micra devices. This best-in-class technology transforms the patient experience by eliminating pocket-related complications, and now reduces the chance that patients will need their device changed in the future."

"Our goal is to improve the patient experience by continuously reinventing our ground-breaking leadless pacemaker," said Robert C. Kowal, M.D., Ph.D., general manager, Cardiac Pacing Therapies within the Cardiac Rhythm Management business, which is part of the Cardiovascular Portfolio at Medtronic. "Since inventing the first battery-operated cardiac pacemakers 65 years ago, Medtronic has transformed pacing technologies to benefit patients, including the nearly 200,000 patients globally who have received a Micra device so far."

Comparable in size to a multivitamin, Micra pacemakers are less than one-tenth the size of traditional pacemakers. Unlike traditional pacemakers, Micra pacemakers do not require leads or a surgical "pocket" under the skin, so potential sources of complications related to leads and pockets are eliminated, and there is no visible sign of the device.

Leaders in Cardiac Pacing This FDA approval builds on the Medtronic legacy in cardiac pacing, which includes:

1. Inventing the first wearable pacemaker in 1957.
2. Launching the first pacemaker for use in MRIs in 2011.
3. Creating and launching the first leadless pacemaker in 2015.
4. Launching the first leadless pacemaker to coordinate the heart's electrical signals by sensing atrial activity, without a lead or device in the atria, in 2020.
5. Gaining regulatory approval for the first pacing system to activate the heart's natural electrical system, conduction system pacing (approval via the His-bundle in 2018 and via the left bundle branch area in 2022).

About Medtronic Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered inDublin, 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 more than 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 on Twitter and LinkedIn.

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.

References:

[1] Escalante K. Micra AV2 and Micra VR2 longevity comparison. 2023. Medtronic Data on File.

[2] El-Chami MF, Al-Samadi F, Clementy N, et al. Updated performance of the Micra transcatheter pacemaker in the real-world setting: A comparison to the investigational study and a transvenous historical control. Heart Rhythm. December 2018;15(12):1800-1807.

[3] Sheldon T, Escalante K, and Fagan D. Device Longevity and AV Synchrony Algorithm Modeling of a Leadless Pacemaker Family: A Virtual Patient Analysis. January 2023. Medtronic Data on File.

[4] Device Manual. April 2023.

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