Medtronic News

Medtronic receives CE Mark for its next generation Micra leadless pacing systems

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

DUBLIN, Jan. 5, 2024 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, today announced it has received CE (Conformité Européenne) Mark for its Micra™ AV2 and Micra™ VR2, the next generation of its industry-leading miniature, 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] Medtronic projects the 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 may only require one device for life.[3]

This CE Mark milestone follows U.S. Food and Drug Administration approval for the Micra AV2 and VR2 devices in 2023.

In addition to size and longevity benefits, Micra devices are also the only leadless pacemakers with remote monitoring capabilities, which allow a doctor or clinic to check on a patient's heart device without the need for a patient to travel to their clinic for an in-person appointment. Other patient benefits of remote monitoring may include a reduction in hospitalizations and increase in sense of security.[4,5]

"For more than eight years, our Micra leadless pacemakers have provided meaningful benefits to people in Europe who require a pacemaker. Now, these patients have access to the latest leadless pacing technology that, for most of them, may be the only device they will ever need," 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.

"The first generation of leadless Micra pacemakers demonstrated a significant reduction in major complications, and this next generation of Micra brings several additional benefits including greater longevity, and specifically for the Micra AV2, new algorithms to optimize AV synchrony at faster heart rates while requiring less in-office programming," said Prof. Dr. Christophe Garweg, Cardiologist at University Hospitals of Leuven, Belgium. "These advantages likely will expand the use of the leadless pacemaker to more patients."

Globally, more than 200,000 patients have received Micra pacemakers.[6] Comparable in size to a large vitamin, 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

Receiving CE Mark for Micra AV2 and VR2 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).
6. Receiving U.S. approval for Micra AV2 and VR2 in 2023.

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 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:

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