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FACT SHEET

MEDTRONIC MICRA™ AV2 and Micra™ VR2
The world's smallest, leadless cardiac pacemakers

The next generation of Micra™ AV2 and Micra™ VR2 leadless pacemakers are projected to last approximately **40% longer** than their predecessors,[1] which means that **more than 80%** of patients who receive a Micra are projected to need only one device for life.[2]

Disease Overview
Pacemakers like Micra are the most common way to treat bradycardia and atrioventricular block (AV block).

> ***Bradycardia:*** a condition characterized by a slow or irregular heart rhythm, usually fewer than 60 beats per minute (bpm) (normal heart rate is 60 – 100 bpm). At this rate, the heart is unable to pump enough oxygen-rich blood to the body during normal activity or exercise, causing dizziness, fatigue, shortness of breath or fainting spells.
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> ***AV block:*** a type of heart block in which the electrical signals between the chambers of the heart (the atria and the ventricles) are impaired. In patients with AV block, pacemakers restore AV synchrony so electrical activity of the atrium and ventricle are coordinated.

By sending electrical impulses to the heart, pacemakers help to restore the heart's normal rhythm and relieve symptoms.

Micra AV2 and Micra VR2 Technology Overview
Micra AV2 and Micra VR2 build on the legacy of the first generations of the Micra devices to provide patients and physicians with new benefits.

Micra AV2 and Micra VR2 have an extended battery life[1]:

- Micra AV2 is projected to have a battery life of nearly 16 years.[2]
- Micra VR2 is projected to have a battery life of nearly 17 years.[2]

Micra AV2 offers easier programming of AV synchrony that is customized to each patient:

- Advanced algorithms automatically customize AV synchrony (the coordination of the heart's upper and lower chambers) settings for each patient.
- Better tracking at heart rates between 80-100 beats per minute,[2] and for active patients, Micra AV2 device provides tracking capability at faster heart rates (upper tracking limit of 135 beats per minute).[3]
    - Better coordination between the heart's upper and lower chambers at higher heart rates may help to reduce potential future complications for patients related to cardiomyopathy, a heart muscle disease that makes it harder to pump blood to the rest of the body.
- Advanced algorithms reduce the need for clinicians to reprogram manually, compared to Micra AV.[4]

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Both Micra AV2 and Micra VR2 devices have the same shape, size, and implant procedure as previous generations:

The Micra AV2 and Micra VR2 leadless pacemakers shape and size remain unchanged, offering physicians the same implant procedure as the previous Micra devices but accompanied by an updated delivery system with a rounded catheter tip.[5]

The new devices retain the unique benefits of the original Micra device. Micra devices:

- Are 93% smaller than conventional pacemakers.[6]
- Are cosmetically invisible to the patient after implantation.
  - No chest scar or bump.
  - No visible or physical reminder of a pacemaker.
  - Fewer post-implant activity restrictions.
- Are comparable in size to a large vitamin.[6]
- Enable patients to benefit from remote monitoring capabilities, which can potentially reduce the number of times a patient needs to travel to their clinic for in-person device checks.
- Attach inside the heart via small tines and deliver electrical impulses that pace the heart through an electrode at the end of the device.
- Do not require the use of wires, known as "leads," to deliver pacing therapy.
- Are approved for full-body and low-field MRI scans for patients who might otherwise be unable to take a standard MRI scan.[3]
- Are implanted via a minimally invasive procedure:
  - Delivered directly into the heart through a catheter inserted in the femoral vein.
  - Do not require a surgical incision or creation of a "pocket" under the skin, which eliminates any visible sign of the device and potential sources of complications.
  - Have a more than 99% implant success rate, with low dislodgement and infection rates.[4,7]
  - Can be repositioned or retrieved, if needed, and another device can be added when the device battery is depleted.

Regulatory Status

Micra AV2 and Micra VR2 received U.S. Food and Drug Administration (FDA) approval in April 2023. The first Micra device pacemaker received Conformité Européenne (CE) Mark in 2015 to treat bradycardia, followed by FDA approval in 2016. In 2020 Micra AV received FDA approval and CE Mark to treat patients with AV block. These previous generation devices are approved in more than 75 countries, and nearly 200,000 patients globally have received Micra pacemakers.[8]

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References:

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

[2] 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.

[3] Device Manual. April, 2023.

[4] 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.

[5] Mattson AR and Raghupathy R. Reducing Cardiac Perforation in Leadless Pacing: An Update to the Micra Leadless Pacemaker Delivery System. January 2023. Medtronic Data on File.

[6] Leick A. Micra vs Leadless and Transvenous Pacemaker Size Comparison. March 2023. Medtronic data on file.

[7] Reynolds D, Duray GZ, Omar R, et al. A Leadless Intracardiac Transcatheter Pacing System. N Engl J Med. February 11, 2016;374(6):533-541

[8] Leick, A. Micra "Largest Reach" supporting data. March 2023. Medtronic Data on file.