THE FUTURE IS HERE

Meet Micra AV
Now with AV Synchrony¹

Micra VR
The World’s Smallest Pacemaker²

Now offering two leadless pacing options
Micra™ AV and Micra™ VR Transcatheter Pacing Systems
THE FUTURE IS HERE

Meet Micra™ AV
Transcatheter Pacing System with AV Synchrony

UNMATCHED LEADLESS PACING EXPERIENCE

- World’s smallest pacemaker
  - 93% smaller than conventional pacemakers
  - 63% fewer major complications than traditional pacemakers
- 4,000+ Micra VR patients studied in global clinical trials

AV SYNCHRONY REIMAGINED

- Accelerometer-based mechanical atrial sensing
  - Median AV synchrony at rest in complete AV block patients with normal sinus rhythm: 94.3%
  - Mean AV synchrony increased from 26.8% during VVI pacing to 89.2%
  - Stroke volume improvement: 8.8%
- Dynamic sensing that adjusts pacing based on the mechanical atrial contraction
- New, integrated circuitry capable of sustaining new AV synchrony functionality
- 11 new algorithms
- Estimated average battery longevity of 8-13 years, dependent on the patient’s degree of AV block

SAME, STREAMLINED PROCEDURE

- > 99% implant success in Micra VR clinical studies
- Low dislodgement and infection rates
- Same implant tools for delivery and deployment
Together, we can provide new opportunities to redefine the patient experience and reduce complications associated with traditional pacing technology.\textsuperscript{10}

Redefined Patient Experience\textsuperscript{11}
\begin{itemize}
  \item No chest scar
  \item No bump
  \item No visible or physical reminder of a pacemaker under the skin
  \item Fewer post-implant activity restrictions
\end{itemize}

Eliminated Pocket-related Complications\textsuperscript{11}
\begin{itemize}
  \item Infection
  \item Hematoma
  \item Erosion
\end{itemize}

Eliminated Lead-related Complications\textsuperscript{11}
\begin{itemize}
  \item Fractures
  \item Insulation breaches
  \item Venous thrombosis and obstruction
  \item Tricuspid regurgitation
\end{itemize}

Micra AV and Micra VR\textsuperscript{*} Transcatheter Pacing Systems

93\% smaller than conventional pacemakers\textsuperscript{3}

4,000+ Micra VR patients studied in global clinical trials\textsuperscript{4-6}

\textsuperscript{*} The single chamber Micra™ Transcatheter Pacing System is being described herein as Micra™ VR in order to distinguish it from the Micra™ AV product. When information in this document relates to both Micra AV and VR, “Micra™ Transcatheter Pacing Systems” is used to represent the portfolio of devices. Micra AV real world data not yet available.
**UNMATCHED LEADLESS PACING EXPERIENCE**

Now offering two leadless pacing options

Micra AV provides AV synchrony,¹ allowing more of your patients to benefit from leadless pacing.

Technical Specifications

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Micra AV⁹</th>
<th>Micra VR¹³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pacing Mode</td>
<td>VVI, VVIR, VOO, OVO, VDD, VDI, ODO, OFF</td>
<td>VVI, VVIR, VOO, OVO, OFF</td>
</tr>
<tr>
<td>Mass</td>
<td>1.75 g</td>
<td>1.75 g</td>
</tr>
<tr>
<td>Volume</td>
<td>0.8 cc</td>
<td>0.8 cc</td>
</tr>
<tr>
<td>Electrode Spacing</td>
<td>18 mm</td>
<td>18 mm</td>
</tr>
<tr>
<td>Battery Longevity</td>
<td>8-13 years¹⁸,¹⁹</td>
<td>12 years**¹⁴</td>
</tr>
</tbody>
</table>
| Programmer                             | • CareLink 2090  
• Encore™ Programmer | • CareLink 2090  
• Encore Programmer |
| Accelerometer-based Mechanical Atrial Sensing | ✔ | N/A |
| Accelerometer-based Rate Response      | ✔ | ✔ |
| MRI SureScan™                          | 1.5T & 3T | 1.5T & 3T |
| Capture Management™                    | ✔ | ✔ |
| FlexFix Nitinol Tines                  | ✔ | ✔ |
| CareLink™ Remote Monitoring            | ✔ | ✔ |

¹AVB only patients who would benefit from leadless pacing per the indications for use.

¹Use conditions include:

8 years = 100% VDD pacing, 60 bpm, pacing threshold 1.5 V, impedance 500 Ω, pulse width 0.24 ms.

13 years = 15% VDD pacing, 70 bpm, pacing threshold 1.5 V, impedance 600 Ω, pulse width 0.24 ms.

**Use conditions included: median pacing 53.5%, median pacing threshold 0.50 V, median impedance 543 Ω; 89% of patients with > 10-year projected longevity; 99% of patients with > 5-year longevity.¹⁵
Proximal Retrieval Feature

Anode
- Bipolar pacing

Cathode
- Steroid-eluting electrode
- Separated from FlexFix tines to ensure optimal contact with myocardium

FlexFix Nitinol Tines
- Multidimensional redundancy: two tines have 15x the holding force necessary to hold the device in place\textsuperscript{16}
- Designed to minimize tissue trauma during deployment, repositioning, and retrieval\textsuperscript{17}
- Optimal electrode tissue interface allows for low and stable chronic thresholds\textsuperscript{18}
The World’s Smallest Pacemaker² Now with AV Synchrony¹

- Micra AV’s accelerometer detects mechanical atrial activity and uses this information to deliver AV synchronous ventricular pacing¹
- Incorporates new, integrated circuitry capable of sustaining new AV synchrony functionality¹
- Delivers estimated average battery longevity of 8-13 years, dependent on the patient’s degree of AV block⁸,⁹

<table>
<thead>
<tr>
<th>Event</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A1</strong></td>
<td>Start of ventricular systole, mitral and tricuspid valves close.</td>
</tr>
<tr>
<td><strong>A2</strong></td>
<td>End of ventricular systole, aortic and pulmonic valves close.</td>
</tr>
<tr>
<td><strong>A3</strong></td>
<td>Diastole, passive blood flow from A to V, corresponds to E-wave on Doppler echo.</td>
</tr>
<tr>
<td><strong>A4</strong></td>
<td>Atrial systole, blood pushed into ventricles, 100 ms electromechanical delay, corresponds to A-wave on Doppler echo.</td>
</tr>
</tbody>
</table>
New Algorithms,¹ Including:

**AV CONDUCTION MODE SWITCH¹**

Micra AV will mode switch to VVI 40 during periods of intact AV conduction to promote intrinsic rhythm in patients with episodic AV block.

1. Designed to limit amount of RV pacing and maximize device longevity by disabling atrial sensing during mode switch.
2. Aims to detect intact AV conduction by periodically dropping into VVI 40 (VVI + mode).
3. Switches back to VDD mode when device paces at 40 bpm.
4. AV conduction mode switch can be programmed to ON or OFF.

**RATE SMOOTHING¹**

Allows the device to preserve AV synchrony through short periods of atrial undersensing.

1. Appropriate atrial sensing with AV synchronous pacing.
2. Atrial undersense. Ventricular pace occurs at Rate Smoothing interval instead of Lower Rate (1,200 ms).
3. Recovery of appropriate atrial sensing with AV synchronous pacing.

**ACTIVITY MODE SWITCH¹**

Micra AV will mode switch to VDIR to provide ventricular rate support during patient activity.

1. Designed to provide appropriate rate support during activity.
2. Switches to a rate-responsive mode (e.g., VDIR) when it detects high activity and a low ventricular rate.
3. Switches back to VDD when high activity stops.
4. Activity mode switch can be programmed to ON or OFF.
Micra Integrated Delivery Catheter
105 cm long catheter system with a handle that controls deflection and deployment of the Micra device

Delivery catheter provides visual feedback when adequate tip pressure has been achieved, and retracts during deployment.

Linear, one-step deployment facilitates consistent device placement; no torque required.

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Smooth Vessel Navigation with the Micra Introducer
- Lubricious hydrophilic coating
- 23 Fr inner diameter (27 Fr outer diameter)
- Silicone oil-coated dilator tip

Device Lifecycle Management Options
- Micra is designed to offer options
  - Micra can be programmed Off at the end of service and can be differentiated from additional Micra devices, if subsequent devices are implanted
- The Micra design incorporates a proximal retrieval feature to enable acute retrieval
  - Successful retrieval demonstrated after 4 years
Micra AV Algorithm Performance
MARVEL 2 Trial (n = 75)*

- The MARVEL 2 trial is a multicenter, pivotal IDE study in which the MARVEL 2 algorithm was downloaded into existing Micra VR devices in order to provide AV synchronous pacing.

- The target patient population included patients with an existing Micra VR implant who had AV block without persistent atrial arrhythmia.

- The primary efficacy objective was to characterize the rate of AV synchrony at rest for 20 minutes in complete AV block patients with normal sinus rhythm using a Holter monitor for confirmation.

- The primary safety objective was to demonstrate freedom from pauses and inappropriate tracking > 100 bpm.

- Algorithm download was limited to no more than 5 hours during feasibility trial to preserve battery impact on the existing Micra VR device.

*Number of enrolled patients that received the software download.

94.3% median AV synchrony at rest in complete AV block patients with normal sinus rhythm (n = 40)

89.2% mean AV synchrony increased from 26.8% during VVI pacing to 89.2%

95% of patients (38 of 40) with complete AV block and normal sinus rhythm had ≥ 70% AV synchrony

8.8% improvement in stroke volume as measured by LVOT VTI (n = 39)
**Micra VR Procedural Performance**

Data from Micra VR IDE and Post-approval Registry

- Primary prespecified safety, effectiveness, and long-term safety objectives were met (n = 726)$^{5,14}$
  - 96% of patients experienced no major complications by 12-month follow-up$^{14}$
    - 0 dislodgements or systemic infections
    - Low (0.4%) revision rate
  - Pacing thresholds remained low and stable through 12 months$^{14}$
    - Yielding an estimated battery longevity on average of 12.1 years

- Real-world experience reinforces safety and long-term performance of Micra VR (n = 1,817)$^4$
  - High implant success rate (99.1%)
  - Low major complication rate through 12 months (2.7%)
    - Low dislodgement rate (0.06%)
    - Low procedure-related infection rate (0.17%)

- 63% fewer major complications than traditional pacemakers$^4$

*Historical cohort comprised of 2,667 patients from six trials of commercially available technology (HR: 0.46, 95% CI: 0.30–0.72; P-value < 0.001). To adjust for difference in patient populations, propensity matching to a subset of the historical control confirmed a reduction in major complications with Micra VR.
References


See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. If using an MRI SureScan® device, see the MRI SureScan® technical manual before performing an MRI. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu.

For applicable products, consult instructions for use on www.medtronic.com/manuals. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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