# THE FUTURE IS HERE

## Meet Micra™ AV
**Now with AV Synchrony[1]**


## Micra™ VR
The World's Smallest Pacemaker[2]


## Now offering two leadless pacing options
Micra AV and Micra VR Transcatheter Pacing Systems

Medtronic

## UNMATCHED LEADLESS PACING EXPERIENCE

- World's smallest pacemaker[2]
  - 93% smaller than conventional pacemakers[3]
- 2,500+ patients studied in IDE & PAR trials[4-6]
  - 63% fewer major complications than traditional pacemakers[4]
- 5,000+ Micra VR* Medicare claims studied
  - 66% reduction in risk of complications at 6 months relative to transvenous devices[7]
- First and only FDA-approved leadless pacemaker portfolio

## AV SYNCHRONY REIMAGINED

- Accelerometer-based mechanical atrial sensing[8]
  - 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[1]
- New, integrated circuitry capable of sustaining new AV synchrony functionality[1]
- 11 new algorithms[1]
- Estimated average battery longevity of 8–13 years, dependent on the patient's degree of AV block[9,10]

## SAME, STREAMLINED PROCEDURE

- > 99% implant success in Micra VR clinical studies[4,5]
- Low dislodgement and infection rates[4,5]
- Same implant tools for delivery and deployment

# THE FUTURE IS HERE

## Meet Micra AV

Transcatheter Pacing System with AV Synchrony[1]


# UNMATCHED LEADLESS PACING EXPERIENCE

Micra AV and Micra VR*
Transcatheter Pacing Systems


**93%**
smaller than conventional pacemakers[3]

**2,500+**
patients studied in IDE & PAR trials[4-6]

Together, we can provide new opportunities to redefine the patient experience and reduce complications associated with traditional pacing technology.[11]

### Redefined Patient Experience

- No chest scar
- No bump
- No visible or physical reminder of a pacemaker under the skin
- Fewer post-implant activity restrictions

### Eliminated Pocket-related Complications[12]

- Infection
- Hematoma
- Erosion

### Eliminated Lead-related Complications[12]

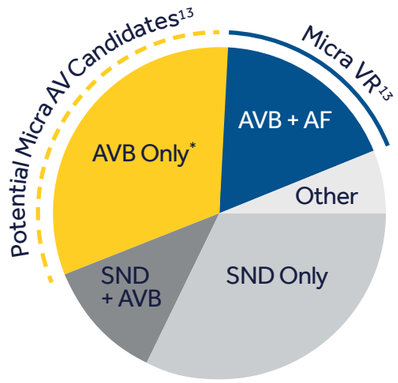
- Fractures
- Insulation breaches
- Venous thrombosis and obstruction
- Tricuspid regurgitation

*The single chamber Micra Transcatheter Pacing System is being described herein as Micra VR in order to distinguish it from the dual chamber (VDD) 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.

# UNMATCHED LEADLESS PACING EXPERIENCE

## Now offering two leadless pacing options

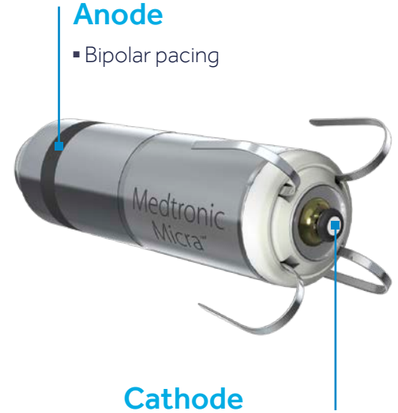
Micra AV provides AV synchrony,[1] allowing more of your patients to benefit from leadless pacing.




Pacing Capsule Technical Specifications

| Parameter | Micra AV[10] | Micra VR[14] |
|---|---|---|
| Pacing Mode | VVI, VVIR, VOO, OVO, VDD, VDI, ODO, OFF | VVI, VVIR, VOO, OVO, OFF |
| Mass | 1.75 g | 1.75 g |
| Volume | 0.8 cc | 0.8 cc |
| Electrode Spacing | 18 mm | 18 mm |
| Battery Longevity | 8–13 years†[9,10] | 12 years**[15] |
| Programmer | ▪ CareLink 2090<br>▪ Encore™ Programmer | ▪ CareLink 2090<br>▪ 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 | ✓ | ✓ |

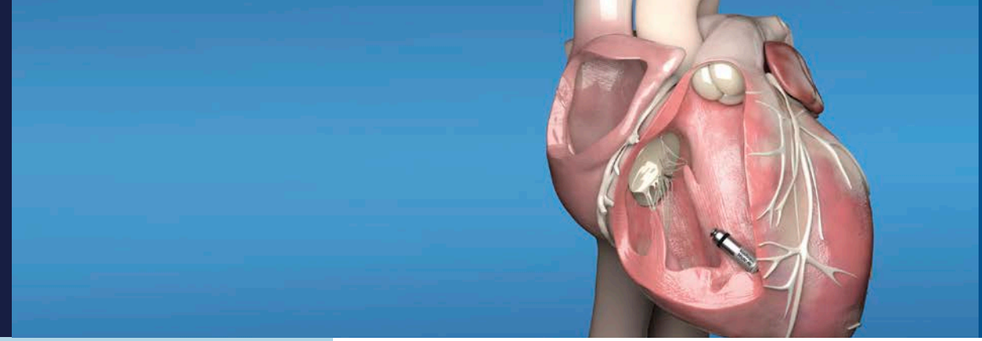
*AVB only patients who would benefit from leadless pacing per the indications for use.
†Use conditions include:
8 years = 100% VDD pacing, 60 bpm, pacing amplitude 1.5 V, impedance 500 Ω, pulse width 0.24 ms.
13 years = 15% VDD pacing, 70 bpm, pacing amplitude 1.5 V, impedance 600 Ω, pulse width 0.24 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.[16]


## FlexFix Nitinol Tines

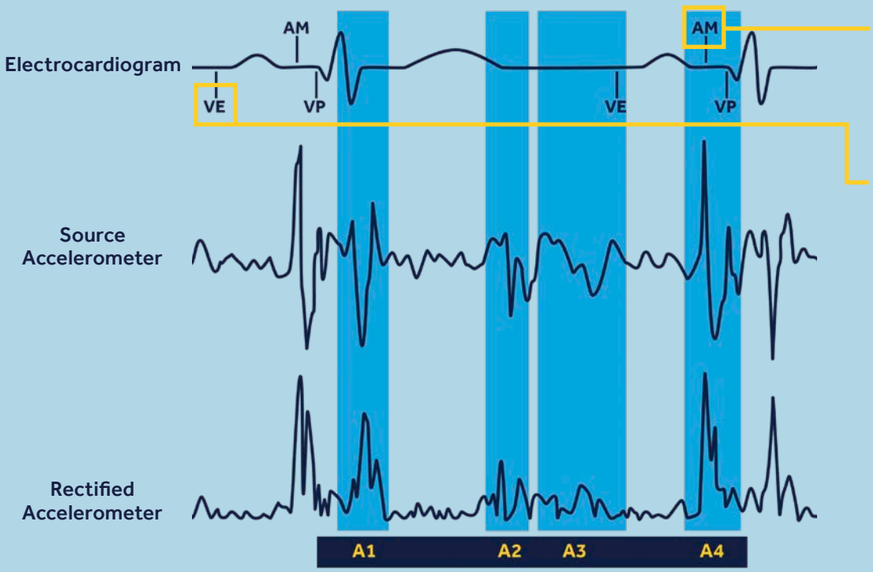
- Multidimensional redundancy: two tines have 15x the holding force necessary to hold the device in place[17]
- Designed to minimize tissue trauma during deployment, repositioning, and retrieval[18]
- Optimal electrode tissue interface allows for low and stable chronic thresholds[19]

# AV SYNCHRONY REIMAGINED



## The World's Smallest Pacemaker[2] Now with AV Synchrony[1]

- Micra AV's accelerometer detects mechanical atrial activity and uses this information to deliver AV synchronous ventricular pacing[1]
- Incorporates new, integrated circuitry capable of sustaining new AV synchrony functionality[1]
- Delivers estimated average battery longevity of 8–13 years, dependent on the patient's degree of AV block[9,10]




**Atrial mechanical (AM) marker**
Marker that indicates the device detected the atrial mechanical contraction or A4.

**Ventricular end (VE) marker**
The end of the A1–A3 ventricular-event signals.

**A1**
Start of ventricular systole, mitral and tricuspid valves close.

**A2**
End of ventricular systole, aortic and pulmonic valves close.

**A3**
Diastole, passive blood flow from A to V, corresponds to E-wave on Doppler echo.

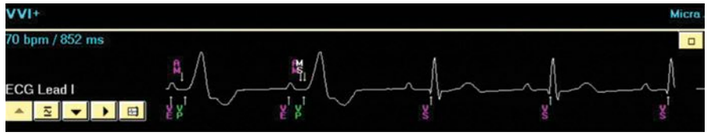
**A4**
Atrial systole, blood pushed into ventricles, 100 ms electromechanical delay, corresponds to A-wave on Doppler echo.

## 11 New Algorithms,[1] Including:

### AV CONDUCTION MODE SWITCH[1]

**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 SMOOTHING[1]

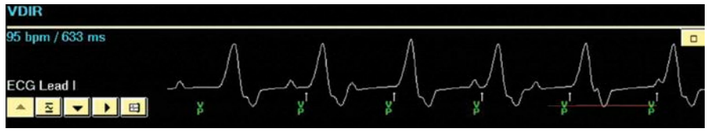
**Allows the device to preserve AV synchrony through short periods of atrial undersensing.**

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 SWITCH[1]

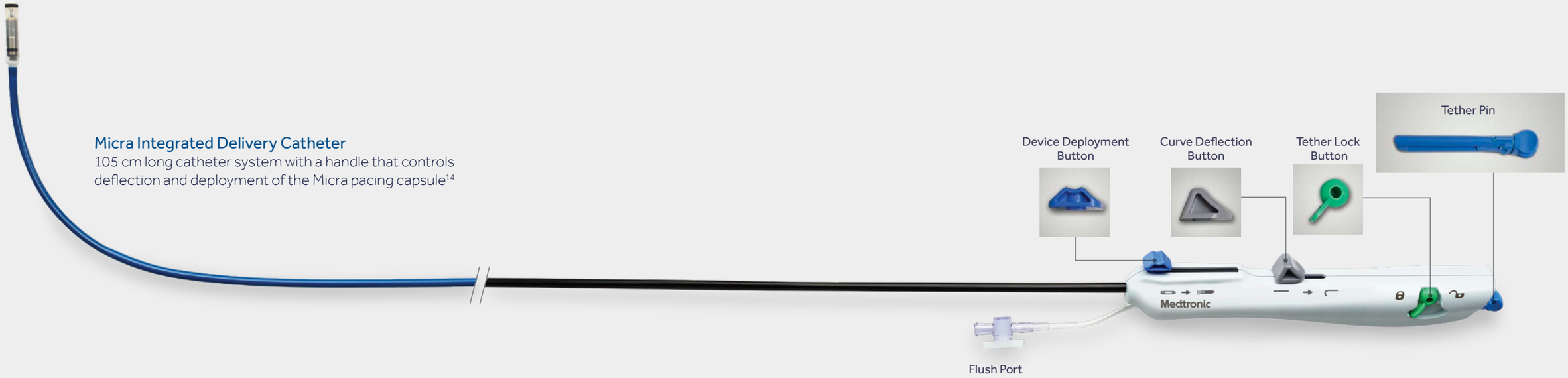
**Micra AV will mode switch to VDIR to provide ventricular rate support during patient activity.**

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.



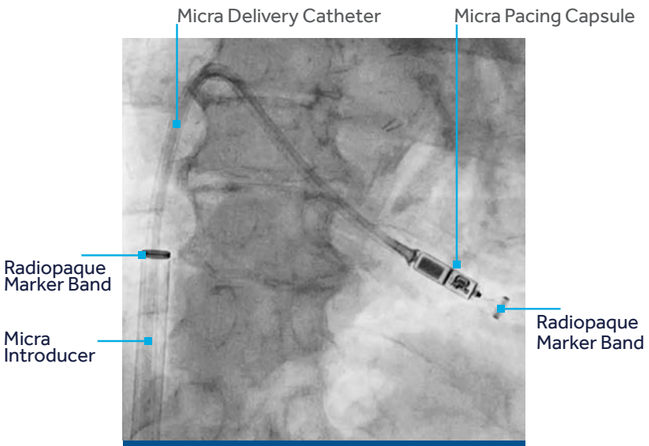
# SAME, STREAMLINED PROCEDURE

**> 99%** IMPLANT SUCCESS IN MICRA VR CLINICAL STUDIES[4,5]




### Micra Integrated Delivery Catheter

105 cm long catheter system with a handle that controls deflection and deployment of the Micra pacing capsule[14]

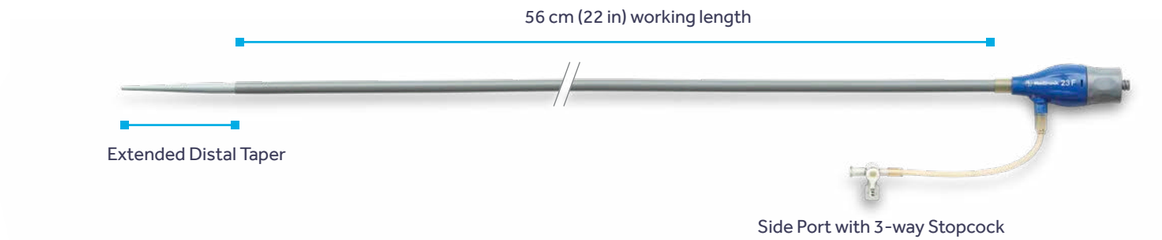



Delivery catheter provides visual feedback when adequate tip pressure has been achieved, and retracts during deployment.[14]

Linear, one-step deployment facilitates consistent capsule placement; no torque required.[17]

### 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[20]

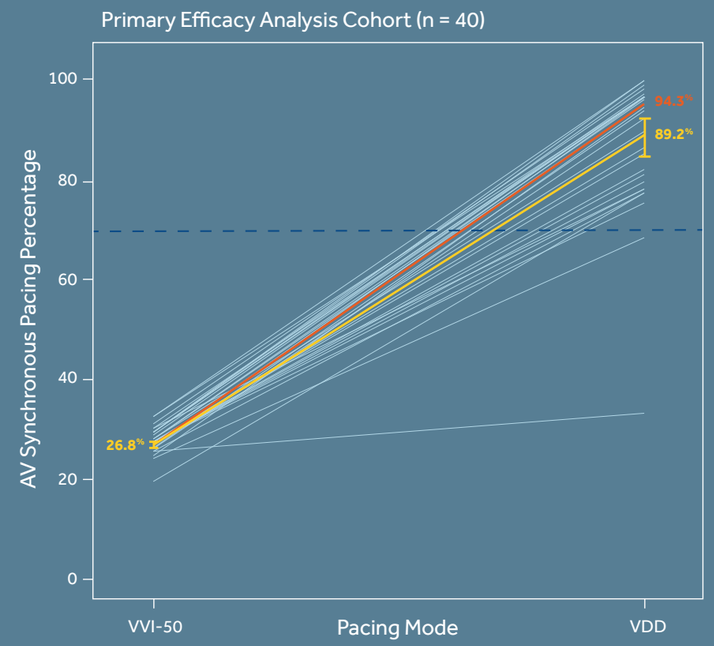
# CLINICAL **EVIDENCE**

## Micra AV Algorithm Performance[8]

### 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, Post-approval Registry, and Coverage with Evidence Development

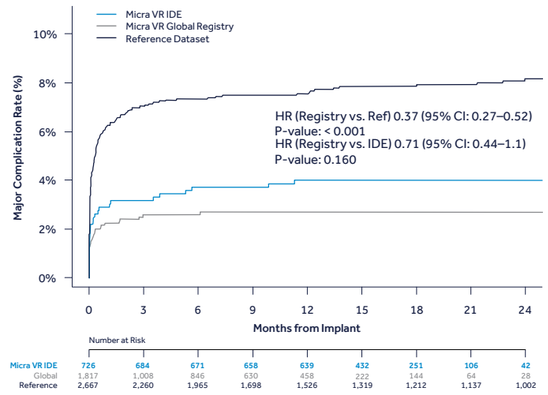
#### Primary prespecified safety, effectiveness, and long-term safety objectives were met (n = 726)[5,15]

- 96% of patients experienced no major complications by 12-month follow-up[15]
  - 0 dislodgements or systemic infections
  - Low (0.4%) revision rate
- Pacing thresholds remained low and stable through 12 months[15]
  - 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.

#### Contemporaneous Comparison of Outcomes among Patients Implanted with a Leadless versus Transvenous VVI pacemaker using Medicare claim data[7]

- 66% reduction in risk for complications through 6 months relative to transvenous-VVI pacemakers
- No difference in adjusted overall acute complications between Micra and transvenous-VVI patients

**References**

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[14] Medtronic Micra™ MC1VR01 Clinician Manual. October 2016.

[15] Duray GZ, Ritter P, El-Chami M, et al. Long-term performance of a transcatheter pacing system: 12-Month results from the Micra Transcatheter Pacing Study. *Heart Rhythm*. May 2017;14(5):702-709.

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[17] Eggen MD, Grubac V, Bonner MD. Design and Evaluation of a Novel Fixation Mechanism for a Transcatheter Pacemaker. *IEEE Trans Biomed Eng*. September 2015;62(9):2316-2323.

[18] Eggen M. FlexFix Tine Design. April 2015. Medtronic data on file.

[19] Bonner M, Eggen M, Haddad T, Sheldon T, Williams E. Early Performance and Safety of the Micra Transcatheter Pacemaker in Pigs. *Pacing Clin Electrophysiol*. November 2015;38(11):1248-1259.

[20] Kiani S, Merchant FM, El-Chami MF. Extraction of a 4-year-old leadless pacemaker with a tine-based fixation. *Heart Rhythm Case Rep*. August 2019;5(8):424-425.


**Brief Statement**
**Micra™ and Micra™ AV**

**Indications**

Micra devices, Micra Model MC1VR01 and Micra AV Model MC1AVR1, are indicated for use in patients who have experienced one or more of the following conditions:

- Paroxysmal or permanent high-grade AV block in the presence of AF
- Paroxysmal or permanent high-grade AV block in the absence of AF, as an alternative to dual chamber pacing, when a dual-chamber transvenous pacing system is considered difficult, high risk, or not deemed necessary for effective therapy
- Symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses), as an alternative to atrial or dual chamber pacing, when a dual-chamber transvenous pacing system is considered difficult, high risk, or not deemed necessary for effective therapy

Micra AV Model MC1AVR1 is also indicated for VDD pacing in patients with adequate sinus rates who may benefit from maintenance of AV synchrony. The Micra AV device provides AV synchronous ventricular pacing similar to a transvenous VDD system.

The implanted device depends on the appropriate sensing of atrial mechanical signals to achieve AV synchrony. The level of AV synchrony may vary in individual patients and may not be predictable prior to implant.

Rate-responsive pacing is indicated to provide increased heart rate appropriate to increasing levels of activity.

The device is designed to be used only in the right ventricle.

**Contraindications**

Micra Model MC1VR01 and Micra AV Model MC1AVR1 are contraindicated for patients who have the following types of medical devices implanted: an implanted device that would interfere with the implant of the Micra device in the judgment of the implanting physician, an implanted inferior vena cava filter, a mechanical tricuspid valve, or an implanted cardiac device providing active cardiac therapy that may interfere with the sensing performance of the Micra device.

The device is contraindicated for patients who have the following conditions: femoral venous anatomy unable to accommodate a 7.8 mm (23 French) introducer sheath or implant on the right side of the heart (for example, due to obstructions or severe tortuosity), morbid obesity that prevents the implanted device from obtaining telemetry communication within ≤ 12.5 cm (4.9 in), or known intolerance to the materials listed in the Instruction for Use, or to heparin, or sensitivity to contrast media that cannot be adequately premedicated, or if the steroid dose from this device cannot be tolerated.

**Warnings and Precautions**

End of Service (EOS) — When the EOS condition is met, the clinician has the option of permanently programming the device to Off and leaving it in the heart, or retrieving the device, provided the device has not yet become encapsulated. Removal of the Micra device after it has become encapsulated may be difficult because of the development of fibrotic tissue. If removal of the device is required, it is recommended that the removal be performed by a clinician who has expertise in the removal of implanted leads.

MRI conditions for use — Before an MRI scan is performed on a patient implanted with the Micra device, the cardiology and radiology professionals involved in this procedure must understand the requirements specific to their tasks as defined in the device manuals.

Rate-responsive mode may not be appropriate for patients who cannot tolerate pacing rates above the programmed Lower Rate. For Micra Model MC1VR01, asynchronous VVIR pacing with sinus rhythm may not be appropriate when competitive pacing is considered undesirable or causes symptoms of pacemaker syndrome. The patient's age and medical condition should be considered by physicians and patients as they select the pacing system, mode of operation, and implant technique best suited to the individual.

Precautions should be taken before administering anticoagulant agents, antiplatelet agents, or contrast media in patients with known hypersensitivity to these agents.

The use of deactivated Micra devices in situ and an active Micra device, or an active transvenous pacemaker or defibrillator, has not been clinically tested to determine whether EMI or physical interaction is clinically significant. Bench testing supports that implantation of an active Micra device, or an active transvenous pacemaker or defibrillator, next to an inactivated Micra device is unlikely to cause EMI or physical interaction. Post-approval studies are planned to characterize risks of co-implanted, deactivated Micra devices. Currently recommended end of device life care for a Micra device may include the addition of a replacement device with or without explanation of the Micra device, which should be turned off.

For Micra AV Model MC1AVR1, patient activities and environments which present mechanical vibrations to the patient can interfere with the mechanical sensing of atrial contractions. This can result in a loss of AV synchrony.

**Potential Adverse Events or Potential Complications**

Potential complications include, but are not limited to, toxic/allergic reaction, oversensing, pacemaker syndrome, cardiac arrest, acceleration of tachycardia, necrosis, myocardial infarction and surgical complications such as cardiac perforation, pericardial effusion, cardiac tamponade, device embolization, hematoma, AV fistula, vessel dissection, infection, cardiac inflammation, and thrombosis.

*See the device manuals for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, MRI conditions for use, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at* medtronic.com.

**Caution:** Federal law (USA) restricts these devices to sale by or on the order of a physician.


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