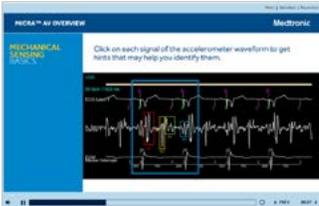
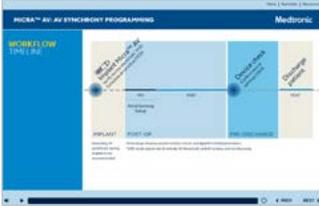
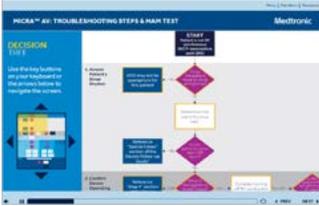
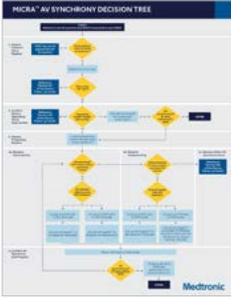
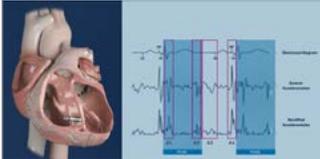
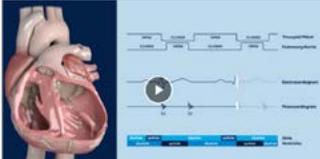


MICRA AV CUSTOMER TRAINING MATERIALS

THUMBNAIL IMAGE	ITEM TITLE	LOCATION	UC#
	<p>Micra™ AV eLearning Module 1: Device Overview</p> <p>This eLearning module describes what Micra AV is, the indications, and how the device's 3D accelerometer is used for mechanical sensing. This module would be relevant for any physician, nurse, or allied health professional who needs background on Micra AV.</p>	<p>Academy</p>	<p>N/A</p>
	<p>Micra™ AV eLearning Module 2: Features and Diagnostics</p> <p>This eLearning module describes the features and diagnostics unique to Micra AV. This also includes a new manual atrial mechanical test. This module would be relevant to those who will conduct device follow-ups.</p>	<p>Academy</p>	<p>N/A</p>
	<p>Micra™ AV eLearning Module 3: Programming: Implant through Follow-up</p> <p>This eLearning module describes what occurs with the Micra AV device during the implant, postop, predischarge, and ongoing follow-up stages. It highlights the device follow-up steps that are unique to AV synchrony.</p>	<p>Academy</p>	<p>N/A</p>
	<p>Micra™ AV eLearning Module 4: AV Synchrony Programming: Troubleshooting Steps</p> <p>This eLearning module utilizes the Micra AV synchrony decision tree and elaborates on each decision point in this tree. This module would be relevant to those who will conduct device follow-ups.</p>	<p>Academy</p>	<p>N/A</p>

THUMBNAIL IMAGE	ITEM TITLE	LOCATION	UC#
	<p>Micra™ AV Technical Training Series: Basic Concepts and Device Follow-up Program Recording</p> <p>This program recording provides a review of basic technical concepts related to the Micra AV device as well as practical device follow-up information.</p>	<p>Academy (Video View)</p> <p>Academy (PDF View)</p>	N/A
	<p>Micra™ AV Technical Training Series: Intermediate Course I Case Scenarios Program Recording</p> <p>This program recording provides an overview of Micra AV concepts and case scenarios to adjust AV synchrony programming settings including a review of device follow-up steps, AV Conduction Mode Switch, and Optimizing the A3 Threshold and A3 Window end.</p>	<p>Academy (Video View)</p> <p>Academy (PDF View)</p>	N/A
	<p>Micra™ AV Technical Training Series: Intermediate Course II Case Scenarios Program Recording</p> <p>This program recording provides an overview of Micra AV concepts and case scenarios to adjust AV synchrony programming settings including a review of accelerometer signals and AV Conduction Mode Switch, A4 amplitude and diagnostics, and managing patients with atrial arrhythmias.</p>	<p>Academy (Video View)</p> <p>Academy (PDF View)</p>	N/A
	<p>Micra™ AV Technical Training Series: Advanced Troubleshooting — Features Review and Case Scenarios</p> <p>This program recording provides an overview of Micra AV concepts and case scenarios to adjust AV synchrony programming settings including accelerometer vectors and programming options, Activity Mode Switch and Rate Response optimization, and managing Micra AV patients with sinus rates > 85 BPM.</p>	<p>Academy (Video View)</p> <p>Academy (PDF View)</p>	N/A
	<p>Micra™ AV Device Checklist</p> <p>The Micra AV Device Checklist provides an overview of how to conduct a Micra AV follow-up and assess AV synchrony. It also includes key troubleshooting steps from the Micra AV Reference Guide for AV Synchrony.</p>	<p>Academy</p>	202117090 EN

THUMBNAIL IMAGE	ITEM TITLE	LOCATION	UC#
	<p>Micra™ AV Synchrony Decision Tree</p> <p>When a patient is not AV synchronous, use this decision tree to guide you through steps to optimize synchrony.</p>	<p>Academy (Flow Chart View)</p> <p>Academy (Interactive View)</p>	<p>202005000a EN</p>
	<p>Micra™ AV Device Follow-up for AV Synchrony Reference Guide</p> <p>A guide of technical details to reference when conducting a device follow-up that impacts AV synchrony.</p>	<p>Academy</p>	<p>202006410 EN</p>
	<p>Micra™ AV: AV Synchrony Practice Scenarios</p> <p>Practice the troubleshooting steps for AV synchrony through interacting with several AV synchrony patient scenarios. Each scenario is around five to eight minutes long.</p>	<p>Academy</p>	<p>N/A</p>
	<p>Micra™ AV Accelerometer Signals Animation</p> <p>Learn how the Micra AV device uses its three-axis accelerometer to sense the atrial mechanical contraction that aids in AV synchrony. This animation describes each part of the accelerometer waveform and its timing in relation to the cardiac cycle.</p>	<p>Academy</p>	
	<p>Cardiac Cycle Primer</p> <p>This brief animation reviews the components and timing that make up cardiac motion (such as the mechanical contraction, the opening and closing of valves, and blood flow) which are fundamental to understanding the way the Micra AV accelerometer uses cardiac motion to identify atrial mechanical contraction to facilitate atrial tracking.</p>	<p>Academy</p>	

THUMBNAIL IMAGE	ITEM TITLE	LOCATION	UC#
	<p>Micra Implanter Summit 2020 Video</p> <p>The November 2020 Implanter Summit included an algorithm overview and multiple case study presentations on troubleshooting and patient selection.</p>	<p>Academy</p>	
	<p>Global Grand Rounds June 2020 Recording</p> <p>This June 2020 recording provides an overview of Micra AV and case studies.</p>	<p>Academy</p>	
	<p>Micra Patient Selection Decision Tree</p> <p>Use this decision tree to determine the patient's indication for pacing.</p>	<p>Academy</p>	

Brief Statement

MR Conditional dual chamber transcatheter pacing system with SureScan™ technology (VDD)

Indications

Micra™ AV Model MC1AVR1 is 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

The device 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 AV Model MC1AVR1 is 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.

Medtronic

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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. 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 explantation of the Micra device, which should be turned off.

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 Complications

Potential complications include, but are not limited to, toxic/allergic reaction, oversensing, pacemaker syndrome, cardiac arrest, necrosis, 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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