



### **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  $\leq 12.5$  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. 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 Medtronic's website at [www.medtronic.com](http://www.medtronic.com).

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