Product specifications

Device delivery catheter system —
The Micra delivery system consists of the following parts:

- A delivery catheter designed to deliver and position the device for implant in the right ventricle by accessing this chamber through the femoral vein. The delivery catheter has a steerable, flexible shaft with a distal end that contains a device cup to hold the device and a recapture cone to retrieve it. It is compatible with the Medtronic Micra Introducer that is 23 French (7.8 mm). Additionally, it can function as a retrieval catheter post tether removal.

- A handle with controls to navigate the delivery catheter and deploy the device. The handle also provides a tether designed as an aid to test the device fixation and to recapture and reposition the device for proper fixation during the implant procedure.

Catheter specifications

### Physical characteristics of the delivery catheter

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outer diameter</td>
<td>7.8 mm (23 Fr)</td>
</tr>
<tr>
<td>Effective length</td>
<td>105 cm (± 2 cm)</td>
</tr>
<tr>
<td>Maximum system profile</td>
<td>0.308”</td>
</tr>
<tr>
<td>In-plane distal shaft articulation angle (min)</td>
<td>120°</td>
</tr>
<tr>
<td>In-plane distal shaft articulation length (max)</td>
<td>5.8 cm</td>
</tr>
<tr>
<td>Stability member</td>
<td>59 cm</td>
</tr>
<tr>
<td>Articulation cyclic fatigue (min)</td>
<td>30 cycles</td>
</tr>
<tr>
<td>Radiopacity Tungsten Polyurethane</td>
<td>(80% Tungsten)</td>
</tr>
<tr>
<td>Tether management</td>
<td>polyester (PET) coated with polytetrafluoroethylene (PTFE)</td>
</tr>
</tbody>
</table>

*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.*
### Contraindications

Micra AV Model MC1AVR1 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 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 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

### 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:

- 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
- Paroxysmal or permanent high-grade AV block in the presence of AF

### 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.

### 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.