PRODUCT SPECIFICATIONS

**Introducer sheath with Hydrophilic Coating**

<table>
<thead>
<tr>
<th>Specification</th>
<th>Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sheath ID</td>
<td>7.8 mm (23 F)</td>
</tr>
<tr>
<td>Working Length</td>
<td>55.7 cm (21.9 in)</td>
</tr>
<tr>
<td>H x W x D</td>
<td>73 mm x 51 mm x 13 mm</td>
</tr>
</tbody>
</table>

**Dilator**

<table>
<thead>
<tr>
<th>Specification</th>
<th>Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Working Length</td>
<td>69.9 cm (27.5 in)</td>
</tr>
<tr>
<td>Guidewire compatibility</td>
<td>0.89 mm (0.035 in)</td>
</tr>
</tbody>
</table>

**Additional Features**

- Stopcock for aspirating and flushing
- Radiopaque marker on end of Introducer for location identification

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Micra™ Introducer Sheath MI2355A with hydrophilic coating
Brief Statement
Micra™ Transcatheter Pacing System VVIR Single Chamber with SureScan™ MRI

Indications
Micra Model MC1VR01 is indicated for patients with:
- symptomatic paroxysmal or permanent high grade AV block in the presence of AF
- symptomatic paroxysmal or permanent high grade AV block in the absence of AF, as an alternative to dual chamber pacing when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy
- symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia/sinus pauses), as an alternative to atrial or dual chamber pacing when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy
- Rate-responsive pacing is indicated to provide increased heart rate appropriate to increasing levels of activity.

Contraindications
Micra Model MC1VR01 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), morbidity 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 prevents the implanted device from obtaining telemetry communication.

Potential Complications
Potential complications include, but are not limited to, toxic/allergic reaction, oversensing, acceleration of tachycardia, myocardial infarction, and surgical complications such as cardiac perforation, pericardial effusion, cardiac tamponade, death, device embolization, access site hematoma and AV fistulae, vessel spasm, infection, inflammation, and thrombosis.

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

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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.

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