MEET MICRA

Micra™ Transcatheter Pacing System

ACTUAL SIZE
The world’s smallest pacemaker

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
- Infection
- Hematoma
- Erosion

Eliminated Lead-related Complications
- Fractures
- Insulation breaches
- Venous thrombosis and obstruction
- Tricuspid regurgitation

Long-term Lead- and Pocket-related Complications with Traditional Systems
- Pocket-related complications 8% at five years
- Lead-related complications 11% at five years

Miniaturized.
93% smaller than modern-day pacemakers
- Completely self contained within the heart, no leads required
- New ultra-low power circuit design delivers a 12-year longevity

Sophisticated.
Engineered for a minimally invasive approach
- Atraumatic FlexFix™ nitinol tines provide secure capsule placement
- Integrated delivery system facilitates a streamlined implant procedure via a percutaneous, femoral approach

Complete.
The only transcatheter pacing system to offer a complete feature set
- 12-year battery longevity
- MRI SureScan™ Technology, which allows the patient to be safely scanned using either a 1.5T or 3T full body MRI
- Accelerometer-based rate response
- CareLink™ 2090 and Encore™ programmer compatible, no accessories required
- Capture Management™

Implant Success

63% Fewer Major Complications
Device life cycle 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 28 months in chronic animal models

63% fewer major complications than traditional pacemakers

Real-world experience reinforces safety and long-term performance of Micra (n = 1,817)
- 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%)

Primary prespecified safety, effectiveness, and long-term safety objectives were met (n = 726)
- 95% of patients experienced no major complications by 12 months follow-up
  - 0 dislodgements or systemic infections
  - Low (0.4%) revision rate
- Pacing thresholds remained low and stable through twelve months
  - Yielding an estimated battery longevity on average of 12.1 years

Device Specifications

- Pacing Mode: VVIR™
- Mass: 1.75 g
- Volume: 0.8 cc
- Electrode Spacing: 18 mm
- Programmable 3-axis Accelerometer

FlexFix Nitinol Tines
- Multidimensional redundancy: two tines have 15 times the holding force necessary to hold the device in place
- Designed to minimize tissue trauma during deployment, repositioning, and retrieval
- Optimal electrode tissue interface allows for low and stable chronic thresholds

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**Micra Delivery Catheter**

- 105 cm long catheter system with a handle that controls deflection and deployment of the Micra™ pacing capsule

- > 99% IMPLANT SUCCESS

**Streamlined Implant Procedure with Integrated Delivery System**

**Smooth Vessel Navigation with the Micra™ Introducer**

- Lubricious hydrophilic coating
- 23 Fr inner diameter (27 Fr outer diameter)
- Silicone oil-coated dilator tip

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

Linear one-step deployment facilitates consistent capsule placement, no torque required.

Tether Lock Button

Curve Deflection Button

Device Deployment Button

Tether Pin

Flush Port

Extended Distal Taper

Side Port with 3-way Stopcock

56 cm (22 in) working length
References

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), 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 Instructions for Use, or to heparin, or sensitivity to contrast media that cannot be adequately premedicated.

Steroid use — Do not use in patients for whom a single dose of 1.0 mg of dexamethasone acetate 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. 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.

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.

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.