Medtronic

Medicare Billing Instructions

for Micra™ leadless pacemakers

- Medicare has published coverage with evidence development (CED) claims instructions via Medicare Claims Processing Manual 100-04, Transmittal 3815, which instructs billing staff on how to properly submit claims under national coverage determination (NCD) 20.8.4. for leadless pacemakers.[1]
- These instructions apply for both traditional Medicare and Medicare Advantage claims.
- For non-Medicare payers, coverage and specific billing instructions may vary. We recommend contacting each individual plan for information.
- Additional coverage, coding, and payment information, along with frequently asked questions, is available in the Micra reimbursement guide found here.
- Example claims that follow contain appropriate additional billing information required by Medicare and are provided for your information only.

Coding for Micra ™ implants

Place of service	CPT®[2] code and description
Professional and outpatient hospital	33274 Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (e.g., interrogation or programming), when performed
Inpatient hospital	02HK3NZ Insertion of intracardiac pacemaker into right ventricle, percutaneous approach

Medicare leadless pacemaker billing requirements (**all** elements are required for claims submission)

Claim requirement	Identifying information required by leadless pacemaker NCD
Professional and facility claim requirements	
National clinical trial (NCT) number	**Micra VR devices :** 03039712 **Micra AV devices:** 04235491
Modifier to CPT® implant code (professional and outpatient facility claims only)	Q0 (zero) Investigational clinical service provided in a clinical research study that is in approved clinical research study
Secondary diagnosis code	Z00.6 Encounter for examination for normal comparison and control in clinical research program
Additional facility claim requirements	
Condition code	30[3] Qualifying clinical trial
Value code	D4 ("Code") and NCT number ("Amount")

Medicare leadless pacemaker required fields

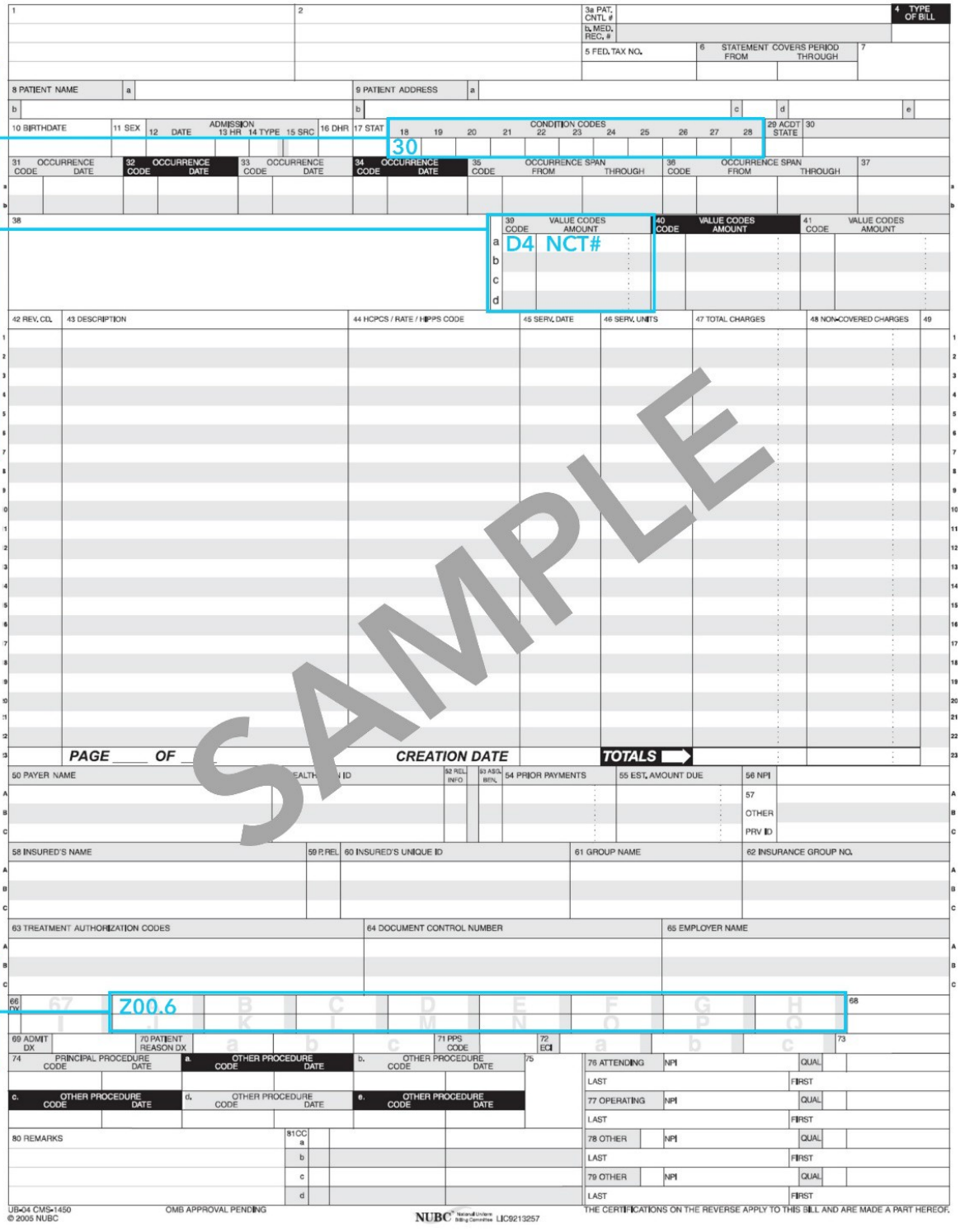
Inpatient hospital claim form

Form Locator 18: Condition code **30** is required on leadless pacemaker claims for Medicare

Form Locator 39: Value code **D4** and the NCT number in the amount section are required on Medicare claims. The NCT number for:

- Micra VR is **03039712**
- Micra AV is **04235491**

Form Locator 67: Diagnosis code **Z00.6** is required as a secondary diagnosis



Medicare leadless pacemaker required fields

Outpatient hospital claim form

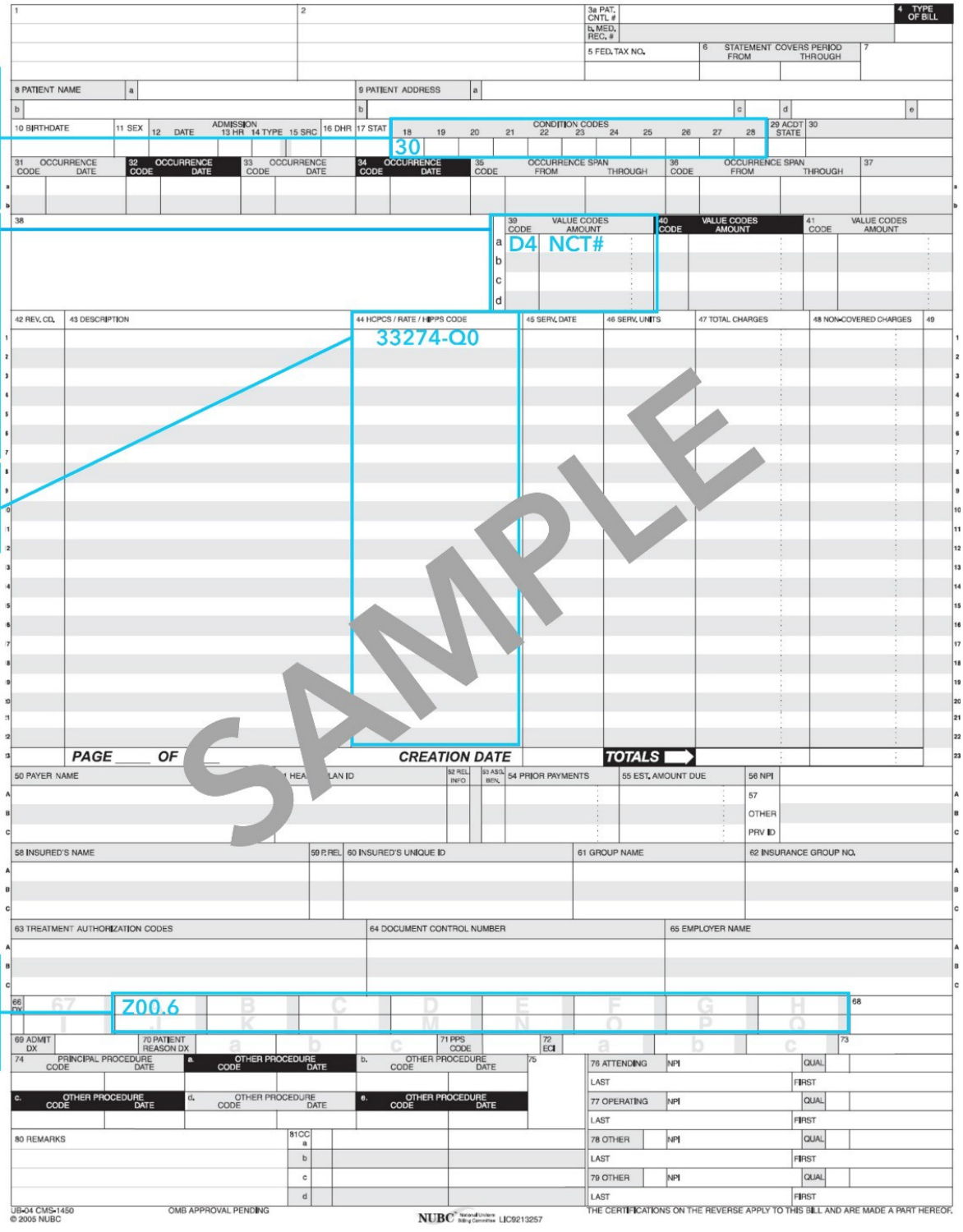
Form Locator 18: Condition code **30** is required on leadless pacemaker claims for Medicare

Form Locator 39: Value code **D4** and the NCT number in the amount section are required on Medicare claims. The NCT number for:

- Micra VR is **03039712**
- Micra AV is **04235491**

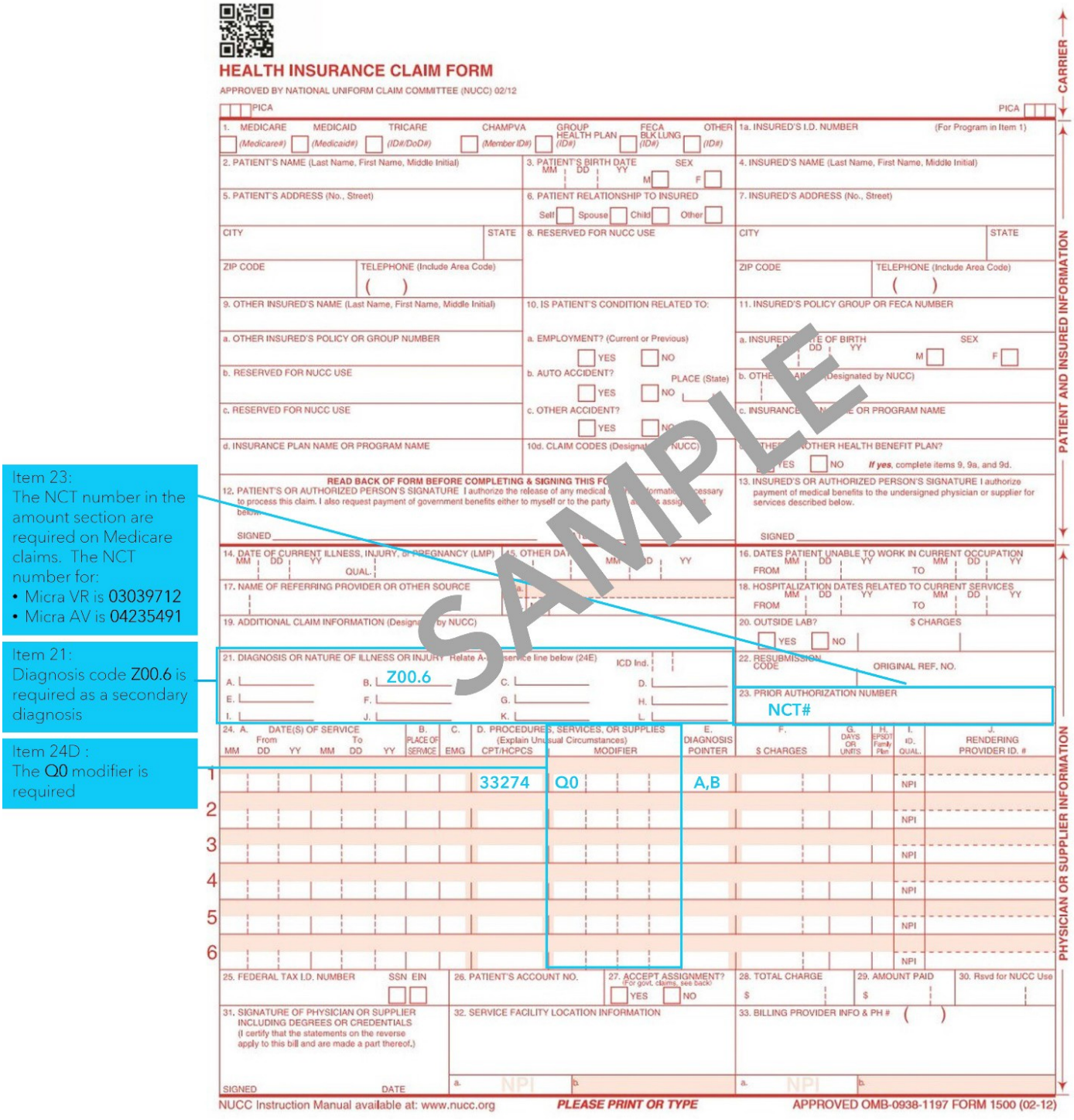
Form Locator 44: The **Q0** modifier is required

Form Locator 67: Diagnosis code **Z00.6** is required as a secondary diagnosis



Medicare leadless pacemaker required fields

Professional claim form



Item 23:
The NCT number in the amount section are required on Medicare claims. The NCT number for:
- Micra VR is 03039712
- Micra AV is 04235491

Item 21:
Diagnosis code Z00.6 is required as a secondary diagnosis

Item 24D :
The Q0 modifier is required

Coding, coverage, and reimbursement information is available at: medtronic.com/crhfreimbursement.

For questions or for more information, please contact Medtronic Reimbursement Customer Support at 1-866-877-4102 (8:00 a.m. to 5:00 p.m. CT, Monday-Friday) or rs.healthcareeconomics@medtronic.com.

References

[1]Center for Medicare and Medicaid Services. Medicare Claims Processing Manual 100-04, Transmittal 3815. National Coverage Determination (NCD 20.8.4): Leadless Pacemakers. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3815CP.pdf. Accessed April 6, 2022.

[2]CPT codes and descriptions only are copyright © 2021 American Medical Association. All rights reserved. No fee schedules are included in CPT. The American Medical Association assumes no liability for data contained or not contained herein.

[3]Centers for Medicare and Medicaid Services. Change Request #MM8401 Revised. Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2955CP.pdf. Accessed April 6, 2022.

Brief Statement
Micra™ VR2 and Micra™ AV2
Indications

Micra Model MC1VR01, Micra VR2 Model MC2VR01, and Micra AV Model MC1AVR1, are 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

Micra AV Model MC1AVR1 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.

Micra AV2 Model MC2AVR1 is indicated for VDD pacing in patients when a dual chamber transvenous pacing system is considered a poor option or not deemed necessary for effective therapy, and when a right ventricular transcatheter pacing system promoting AV synchrony at rest is acceptable. Conditions when a patient is considered a poor candidate for transvenous pacing may include, but are not limited to, tortuous anatomy, a need to preserve venous access, or increased risk of infection. The device provides AV synchrony at rest and rate responsive (VVIR) pacing during periods of high patient activity.

Device-mediated AV synchrony can vary depending on patient condition and activity levels, and it can be limited at high sinus rates. During periods of intermittent AV synchrony, the device will provide ventricular pacing support with an increased potential for pacing rate variability. Micra AV2 is indicated for use in patients who have experienced one of the following:

- Paroxysmal or permanent high-grade AV block in the absence of AF
- Paroxysmal or permanent high-grade AV block in the presence of paroxysmal AF
- Paroxysmal or permanent high-grade AV block in the presence of persistent AF when attempts at restoring sinus rhythm are still planned

The device is designed to be used only in the right ventricle.

Contraindications

Micra Model MC1VR01, Micra AV Model MC1AVR1, Micra VR2 Model MC2VR01 and Micra AV2 Model MC2AVR1 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 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.

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

For Micra AV Model MC1AVR1 and Micra AV2 Model MC2AVR1, 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, 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 800-328-2518 and/or consult Medtronic's 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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