

Radiofrequency (RF) or Microwave Ablation

CRM Technical Services Standard Letter

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The guidance provided in this letter is for healthcare providers and Medtronic representatives and applies to the following Medtronic device models:

<u>MRI Conditional Device Model Number, Model Name, Description</u>
MC1AVR1 Micra™ AV MR Conditional dual chamber transcatheter pacing system with SureScan™ technology (VDD)
MC1VR01 Micra™ MR Conditional single chamber transcatheter pacing system with SureScan™ technology (VVIR)
MC2AVR1 Micra™ AV2 MR Conditional dual chamber transcatheter pacing system with SureScan™ technology (VDD)
MC2VR01 Micra™ VR2 MR Conditional single chamber transcatheter pacing system with SureScan™ technology (VVIR)

This Standard Letter addresses Radiofrequency (RF) or microwave ablation:

Ablation is a surgical technique in which radio frequency (RF) or microwave energy is used to destroy cells by creating heat. Common types of ablation include, but are not limited to, intracardiac ablation and endometrial ablation.

RF or microwave ablation used for cardiac device patients can result in, but is not limited to, ventricular tachyarrhythmias, oversensing, unintended tissue damage, or unintended device function.

Observe the following precautions when you administer RF or microwave ablation to a patient with a transcatheter pacemaker:

- Make sure that temporary pacing and defibrillation equipment is available.
- Avoid direct contact between the ablation catheter and the implanted system.
- Consider using at least 2 methods to monitor the patient during ablation. These methods can include arterial pressure display, ECG, manual monitoring of patient rhythm (taking pulse), ear or finger pulse oximetry, or Doppler pulse detection.

Note: An asynchronous mode will avoid or mitigate the effects of oversensing.

Labeling

Micra™ AV MC1AVR1 MR Conditional Device Manual. Manual Document Number: M042501C001 REV. A, www.medtronic.com/manuals

Micra™ MC1VR01 MR Conditional Clinician Manual. Manual Document Number: M042502C001 REV. A, www.medtronic.com/manuals

Micra™ AV2 MC2AVR1 MR Conditional Device Manual. Manual Document Number: M019277C001 REV. E, www.medtronic.com/manuals

Micra™ VR2 MC2VR01 MR Conditional Device Manual. Manual Document Number: M019292C001 REV. E, www.medtronic.com/manuals

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PATIENT MANAGEMENT GUIDANCE

This document is useful to health care professionals who perform medical procedures on patients with Medtronic implanted cardiac device systems and who consult with the patients' cardiologists.

Additional comments

For further information please contact the following:

Technical questions: Medtronic Technical Services can answer additional questions regarding these device operations.

Device labeling: For additional device-specific guidance, consult the labeling associated with the device available on the Medtronic Manual Library website at www.medtronic.com/manuals

How to contact U.S. CRM Technical Services: Email: tshelp@medtronic.com

Pacemakers: (800) 505-4636, ICDs: (800) 723-4636, Programmer Support: (800) 638-1991

This information is verified for devices approved in the U.S. and may differ by country. For product-specific information on device operation and indications for use, reference the appropriate product labeling.