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Urgent Field Safety Notice

Induction of ventricular arrythmia during Sphere-9™ catheter radiofrequency ablation in patients with Biotronik ICDs

Notification

Product Name	Model Number	Basic UDI Number	GTIN
Sphere-9™ Catheter	AFR-00001	0763000B000262284	00763000811341; 00763000871734; 00763000911515; 00763000973384; 00763000973513.

EU Manufacturer Single Registrations Number (SRN): US-MF-000019977

March 2026

Medtronic Reference: FA1546

Dear Healthcare Professional/Risk Manager:

Medtronic has observed an unanticipated device interaction inducing ventricular tachycardia (VT) or ventricular fibrillation (VF) during radiofrequency (RF) therapy with the Medtronic Sphere-9™ catheter in patients who have a Biotronik Implantable Cardioverter Defibrillator (ICD) or Biotronik Cardiac Resynchronization Therapy-Defibrillator (CRT-D) implanted. The observation is caused by an interaction between the Sphere-9 catheter current flow and a safety feature built into Biotronik ICDs and CRT-Ds; refer to Appendix A for further detail. Medtronic recommends physicians use increased caution when using the Sphere-9 catheter for RF ablation therapy in patients implanted with a Biotronik ICD/CRT-D system, and to ensure external defibrillation systems are readily available.

ISSUE DESCRIPTION

Up until 20 February 2026, a total of 33 incidents of VT or VF induction have occurred during RF therapy delivery with the Medtronic Sphere-9 catheter in patients with a Biotronik ICD or CRT-D. The induced ventricular arrhythmias have either self-terminated or required external defibrillation, and there have been no reported deaths or serious injuries associated with this device interaction. While there have been an estimated 60,000 worldwide uses of the Medtronic Sphere-9 catheter to date, the number of uses of the Sphere-9 catheter in patients with a Biotronik ICD/CRT-D is unknown.

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INVESTIGATION DETAILS

- Medtronic and Biotronik have collaborated on the interaction investigation.
- Reported events have occurred during the application of RF therapy from the Medtronic Sphere-9 catheter in patients with a Biotronik ICD or CRT-D.
- Of the 33 reported incidents of VT/VF induction, 22 occurred during RF ablation on the cavotricuspid isthmus (CTI) line / tricuspid annulus, 10 occurred during ventricular RF ablation, and 1 occurred during RF ablation near a repaired mitral valve. Note that ventricular ablation is not an approved indication for use.
- Medtronic has not observed this phenomenon with pulsed field ablation (PFA) therapy using the Sphere-9 catheter in conjunction with any manufacturer's ICDs/CRT-Ds (including Biotronik).
- Medtronic has not observed this phenomenon with RF therapy using the Sphere-9 catheter in conjunction with ICDs/CRT-Ds from Medtronic, Abbott, or Boston Scientific.
- This interaction is observed during the ablation procedure and does not impact patients who have already had the procedure.

There are no Medtronic manufacturing or design non-conformances that may contribute to this issue. See Appendix A for findings from a joint Medtronic/Biotronik evaluation.

PROCEDURE RECOMMENDATIONS

Arrhythmia and or VT/ VF is a known potential adverse event during a cardiac ablation procedure, as indicated within the Sphere-9 IFU. Medtronic recommends physicians use increased caution when using the Sphere-9 catheter for RF ablation therapy in patients implanted with a Biotronik ICD/CRT-D system, and to ensure external defibrillation systems are readily available.

As described in the Medtronic Sphere-9 IFU, defibrillation equipment must be available for immediate use in the case of a life-threatening arrhythmia. Further, the IFU recommends to not deliver energy when in contact with pacing and defibrillation leads.

LABELING UPDATE

Medtronic will update the Sphere-9 IFU regarding the use of RF therapy in patients with a Biotronik ICD/CRT-D. Medtronic will obtain approvals for updated IFUs as required. Until then, physicians should continue to adhere to the recommendations in this communication.

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CUSTOMER ACTIONS

- Follow the procedure recommendations listed in this letter in addition to the Instructions for Use (IFU) when using a Sphere-9 catheter with a concomitant Biotronik ICD/CRT-D.
- Please forward this notice to all those who need to be aware within your organization, including, but not limited to, physicians using the Sphere-9 catheter, and maintain a copy for your records.

ADDITIONAL INFORMATION

Medtronic has notified the Competent Authority of your country of this action.

Patient safety is our top priority, and we are committed to delivering safe and effective therapies that undergo rigorous clinical, quality, manufacturing and regulatory controls for our customers. We regret any inconvenience this may cause. If you have any questions regarding this communication, please contact your local Medtronic Cardiac Ablation Solutions representative.

Sincerely,

Local / OU Manager

Enclosures:

- Appendix A: Medtronic/Biotronik joint evaluation details

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APPENDIX A

Medtronic/Biotronik joint evaluation details

Medtronic collaborated with representatives from Biotronik to understand the specific relationship between the Sphere-9 RF energy delivery and the VT/VF induction interaction with Biotronik devices. Biotronik has informed Medtronic that they have not observed this phenomenon with any other manufacturers' RF ablation or PF ablation systems and a Biotronik ICD/CRT-D. Biotronik has informed Medtronic that their analysis of complaint data did not reveal any signs of non-conformance with the manufacturing or design of the ICD/CRT-D devices included in the complaints. During Medtronic simulated use testing, Sphere-9 RF energy did not reproduce the VT/VF inducing energy in other manufacturers' ICD devices (Medtronic, Abbott, and Boston Scientific).

The evaluation concluded that the issue is caused by an interaction between the Sphere-9 catheter current flow and a safety feature built into Biotronik ICDs and CRT-Ds. Biotronik describes this safety feature as being designed in accordance with applicable state-of-the-art standards to protect the device from high coupled currents even when ICD therapy is disabled, which may otherwise damage the ICD or CRT-D device. Because of how this safety feature is implemented in Biotronik ICDs and CRT-Ds, the specific characteristics of the current of the Sphere-9 catheter during RF application may lead to an unfavorable modulation of the coupled current that can be conducted via the implanted leads and result in possible VT or VF induction.

Biotronik and Medtronic will continue to collaborate as additional clinical information becomes available.

If you have any questions regarding this communication in relation to Biotronik devices, please contact your local Biotronik representative.