Medtronic
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URGENT MEDICAL DEVICE RECALL

For a Subset of Medtronic
Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and
Implantable Cardioverter Defibrillators (ICDs)
Device Model and Serial Numbers in Appendix A

January 2018,

Dear Physician or Healthcare Professional,

Medtronic is writing to inform you of a potential issue that may occur in an identified set of 48 Medtronic Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) and Implantable Cardioverter Defibrillators (ICDs). These devices underwent a specific sequence of manufacturing processes that could result in an unexpected loss of device functionality, including high-voltage therapy. Refer to Appendix A for a complete list of model and serial numbers for this identified sub-population of devices. No other Medtronic devices are included in this advisory.

These 48 devices were sent through a manufacturing sequence that introduced the potential for internal arcing during high-voltage charging, leading to the immediate and permanent loss of device functionality. Through 12 January 2018, Medtronic has confirmed one (1) implanted device failure resulting in loss of high-voltage therapy related to this issue, where the patient was rescued with external defibrillation.

Due to the nature of this issue, it is not possible to identify which of these 48 devices may fail or when they may fail. Further, we cannot predict how many high-voltage charges can occur prior to a potential failure. Based on testing of a limited number of available devices that underwent this manufacturing sequence, this failure was observed during high-voltage cycle testing to battery depletion in 23% of these devices, with failure observed within the first two (2) high-voltage charges in 7.7% of the tested devices. Successful delivery of previous high-voltage therapy does not guarantee future performance.

Medtronic records indicate you are following one or more patients implanted with an affected device as noted in the enclosed Physician / Patient Detail Report.

Patient Management Recommendations
We realize that each patient requires unique clinical considerations. In consultation with Medtronic's Independent Physician Quality Panel (IPQP), Medtronic provides the following recommendation:

- Prophylactic device replacement should be strongly considered for patients who have been implanted with one of the devices listed in Appendix A.

Medtronic will offer a supplemental device warranty for this affected population. Contact your Medtronic sales representative for terms and conditions. Medtronic will notify all applicable regulatory agencies about this matter. Please share this notification with others in your organization as appropriate.

We sincerely regret any difficulties this may cause you and your patients. Medtronic remains dedicated to patient safety and will continue to monitor device performance to ensure we meet your needs and those of your patients. Medtronic Patient Services is available to assist patients at 800-551-5544 (Monday-Friday, 8am-5pm Central Time). If you have any questions, please contact your local Medtronic Representative or Medtronic Technical Services at 800-723-4636.

Sincerely,

Tim Samsel
Vice President, Quality and Regulatory
Medtronic Cardiac Rhythm Heart Failure

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Appendix A: Device Model and Serial Number Information

Cardiac Resynchronization Therapy with Defibrillation (CRT-Ds)		
Device Name	**Device Model**	**Device Serial Number**
Amplia MRI™ CRT-D DF4	DTMB1D4	RPJ201956H
Amplia MRI™ Quad CRT-D DF4	DTMB1QQ	RPE201417H
		RPE204789H
		RPE206207H
		RPE207850H
		RPE209095H
		RPE212027H
Claria MRI™ Quad CRT-D DF4	DTMA1QQ	RPA204495H
Compia MRI™ Quad CRT-D DF4	DTMC1QQ	RPL201034H
Viva® Quad S CRT-D DF4	DTBB1QQ	BLK204122H
Viva® Quad XT CRT-D DF4	DTBA1QQ	BLC224272H
		BLC227175H
		BLC227641H
Viva® S CRT-D DF1	DTBB1D1	BLO204984H
Viva® XT CRT-D DF1	DTBA1D1	BLF216780H
		BLF231229H
		BLF250740H
		BLF251155H
		BLF255165H
Viva® XT CRT-D DF4	DTBA1D4	BLE220200H

Implantable Cardioverter-Defibrillators (ICDs)		
Device Name	**Device Model**	**Device Serial Number**
Evera MRI® XT DR DF1	DDMB1D1	CWA200012H
		CWA202259H
		CWA203498H
Evera MRI® XT DR DF4	DDMB1D4	PFZ214605H
		PFZ228504H
		PFZ228590H
		PFZ228836H
		PFZ228838H
		PFZ229236H
Evera MRI® XT VR DF4	DVMB1D4	PKZ203327H
		PKZ210673H
Evera MRI™ S DR ICD DF1	DDMC3D1	CWC200055H
Evera® S DR ICD DF1	DDBC3D1	BWG204574H
Evera® S VR DF1	DVBC3D1	BWM204635H
Evera® XT DR DF1	DDBB1D1	BWC223253H
		BWC233374H
		BWC234767H
		BWC234772H
Evera® XT VR DF1	DVBB1D1	BWI208876H
Evera® XT VR ICD DF4	DVBB1D4	BWH201158H
		BWH214640H
Visia AF MRI™ VR SureScan DF1	DVFB1D1	CWG200402H
Visia AF MRI™ VR SureScan DF4	DVFB1D4	PKX202448H
		PKX205417H
		PKX205779H
		PKX209277H
		PKX212710H
Visia AF™ VR DF1	DVAB1D1	BWN201126H