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Urgent Field Safety Notice

Vanta™ Implantable Neurostimulator (INS)

Failure After Cardioversion

Notification

June 2023

Medtronic Reference: FA1340

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

Dear Healthcare Professional,

The purpose of this letter is to communicate mitigations to reduce the risk for damage to the Model 977006 Vanta™ Implantable Neurostimulator (INS) from a cardioversion procedure. Please review the information contained in this letter and share it with your implanted patients or patients planning on receiving an implant as appropriate.

Issue Description:

As reflected in the original Information for Prescribers (IFP) manual, a cardioversion procedure may damage the electronics in the Vanta™ INS device, making the INS unresponsive and non-functional. As of April 19, 2023, Medtronic has received a total of two (2) complaints concerning this issue from patients implanted with a Vanta™ INS, both of which have resulted in explant procedures. Medtronic has identified programming mitigations that reduce the risk for damage. In the event of damage to the device, surgical replacement of the INS is required to restore stimulation therapy. Cessation of therapy will likely cause a return of pain symptoms. The potential for electrical damage to the Vanta™ INS can be minimized by temporarily reprogramming the patient's Vanta™ INS for cardioversion procedures as recommended in the IFP manual.

Medtronic updated the IFP manual and applicable labeling to add specific recommended neurostimulator settings and programming considerations for cardioversion procedures. Additionally, the Patient Therapy Guide (PTG) was updated, instructing patients to inform their treating and managing clinicians of any upcoming cardioversion

procedures to determine proper programming of their Vanta™ INS as indicated in the IFP. The updated IFP and PTG are available at the Medtronic website

www.medtronic.com/patientimplantinfo for (PTG)

https://manuals.medtronic.com/manuals/main/region for (IFP)

Product Scope:

Product Name	Manufacturer's Model Number	GTIN/UDI/Material#
Vanta™ INS	977006	00763000478087 00763000411923 00763000518615

Required Actions:

- Please communicate to your patients the above Instruction for Prescriber (IFP) and Patient Therapy Guide (PTG) updates regarding programming considerations for cardioversion procedures with patients implanted with Vanta™ INS devices.
- If a patient will be undergoing a cardioversion procedure (e.g., nonemergent scenario) refer to the recommended neurostimulator settings and programming considerations in the Information for Prescribers (IFP) manual which include not turning off your patient's Vanta™ INS device and reprogramming the settings.
- After a cardioversion procedure, confirm that the neurostimulator is functioning and programmed as intended. Contact Medtronic if you have any questions.
- For patients who are considering a new or replacement implant, and who have concomitant conditions such that they may require future cardioversion, please talk to these patients about the relative benefits and risks associated with proceeding with a Vanta™ INS device.
- Share this notice with all those who need to be aware of this issue within your organization or to any organization where the potentially affected devices have been transferred and maintain a copy of this notice in your records.
- Please complete and return the customer confirmation form enclosed with this letter, acknowledging that you have received this information.

Additional Information:

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

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic Representative directly or via Tel No: 01 511 1400

Sincerely,  Keith Taverner: Principal Regulatory Affairs Specialist

Medtronic

FA1340: Customer Acknowledgement Form - Response is required.

Vanta™ INS Failure After Cardioversion

Please complete this Form in its entirety.

Date: _____

Name of Person Completing this Form: _____

Title:_____

Direct Phone #:_____

Email:_____

Hospital / Account Name:_____

Account Number:_____

Country:_____

I have read and understand the instructions provided and acknowledge receipt of the notification regarding the use of the **Vanta™ INS** by signing below. I also agree to further distribute and communicate this important information within my facility and to anyone whom I have further distributed **Vanta™ INS** as required.

_____	_____	_____
Name: (print)	Signature:	Date:

If you have any questions regarding this notification, please contact your Medtronic sales representative.

PLEASE EMAIL THIS ACKNOWLEDGEMENT TO:

rs.regulatoryuk-ire@medtronic.com