

## Urgent Field Safety Notice

### Retrieval of the Vanta™ Implantable Neurostimulator (INS)

**Model 977006 PIN number 977006002H**

### Unable to be Interrogated

Recall

| Product Name                                                        | Model Number | UDI/ GTIN      |
|---------------------------------------------------------------------|--------------|----------------|
| Neurostimulator Model 977006 - Vanta™ with AdaptiveStim™ Technology | 977006       | 00763000478087 |

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

December 2025

Medtronic Reference: FA1240

Dear Customer/Distributor/Healthcare Provider/Risk Manager,

In March 2022, Medtronic began notifying customers of a potential issue with the Vanta™ Implantable Neurostimulator (INS) Model 977006. See the enclosed March 2022 Customer Letter for the previous communication. Medtronic has since developed and released updated firmware for the Vanta INS device to address the potential communication issue. Medtronic has identified your facility may have inventory of Vanta INS devices that contain the previous firmware version.

#### Issue Description:

The firmware update reduces the risk of therapy interruption and the need for a device reset or surgical intervention. At the time of the initial notification, no complaints were reported. Since then, Medtronic has received complaints with an occurrence rate of 0.052%.

Medtronic is recalling all unused Vanta INS devices with the previous firmware version. No action is required for Vanta INS devices that have already been implanted, and Medtronic does not recommend replacement of implanted Vanta INS devices with the previous firmware version. If this issue is encountered, Medtronic recommends following the mitigations in the attached March 2022 Customer Letter.

**Actions:**

Please review your facility's inventory of Vanta INS devices and take the following actions:

- Return unused devices with PIN number **977006002H** to Medtronic. Vanta INS devices manufactured with the previous firmware version can be identified by PIN number 977006002H on the device outer packaging. No other Vanta PIN numbers have the previous firmware version. The image below is what the PIN number looks like printed on the outer packaging. See Attachment A - Label Example, where the PIN number is located on the package label:

**PIN 977006002H**

- Return unused affected product to Medtronic per the return instructions.
- Complete the enclosed Customer Acknowledgement Form. When complete please return the form to Medtronic
- This notice should be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
- Please maintain a copy of this notice in your records.

**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 sales representative.

Sincerely,

Local / OU Manager

**Enclosures:**

- March 2022 Customer Letter
- Attachment A: Label Example
- Customer Acknowledgement Form

## Attachment A - Label Example

The following image is an example of what the Vanta INS device outer-packaging looks like and where to locate the PIN number. It does not reflect the specific data you will see on your device.

