Medtronic

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Urgent Field Safety Notice

Vectris™ Lead Kits

Recall of specific lots of and model numbers

July 2018

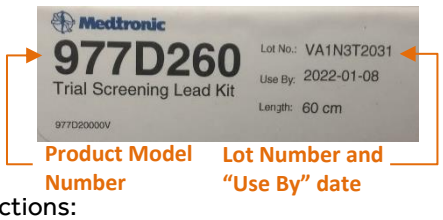
Medtronic reference: FA822

Dear Risk Manager, Healthcare Professional,

Medtronic is voluntarily recalling specific production lots of the Vectris™ Trial Screening Lead Kits (Models 977D160 and 977D260) and the Vectris™ SureScan® Lead Kits (Models 977A160, 977A175, 977A190, 977A260, 977A275 and 977A290). These lead kits are used in Spinal Cord Stimulation (SCS) Pain Therapy surgical procedures. The issue affects a subset of lots with a "Use By" date beginning 31-Oct-2021 through 8-Mar-2022.

Issue Description
This voluntary recall is being conducted due to the curved tip introducer needle which is included in the kit, to have a potential manufacturing defect. This could result in difficulty advancing or withdrawing the Vectris lead through the curved tip introducer needle. If this occurs, it may result in the inability to complete the procedure with the initial kit, associated surgical delays, and the potential for an additional epidural puncture to place the lead. There is no impact to reliability or performance for a lead that has been implanted with an affected curved tip introducer needle. There are no special recommendations for patients who had a lead implanted from an affected curved tip introducer needle.

Product Scope
This issue affects a subset of Vectris Lead Kit lots with a "Use By" date beginning 31-Oct-2021 through 8-Mar-2022. For your convenience, Medtronic has established a website (http://CurvedNeedleInVectrisKits.medtronic.com) where you may enter the lot number of a Lead Kit to determine if it is in the scope of this recall.



Customer Actions: Medtronic is asking that you immediately take the following actions:

1. Identify and quarantine all unused affected product in your inventory.
2. Return all affected products in your inventory to Medtronic. Your Medtronic Representative can assist you in the return and replacement of this product as necessary.

The Competent Authority of your country has been notified of this action.

Please share this notification with others in your organization as appropriate or to any organization where the potentially affected product may have been transferred. In case of any questions related to this Urgent Field Safety Notice contact your Medtronic Representative Directly or via Tel. No: 01 511 1400.

We are committed to acting responsibly in the best interest of patient safety. We sincerely appreciate your patience as it relates to this matter.

Sincerely,

Keith Taverner
Regulatory Affairs Manager UK & Ireland