Medtronic

7000 Central Ave NE
Minneapolis, MN 55432
www.medtronic.com

URGENT: MEDICAL DEVICE RECALL NOTIFICATION
Curved Tip Introducer Needle for Spinal Cord Stimulation Leads
Specific Lots of Vectris™ Lead Kits

May 2018

Dear Customer,

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 2021-10-31 through 2022-03-08.

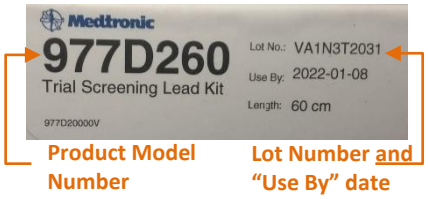
Issue Description

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 2021-10-31 through 2022-03-08. Refer to the "*Affected Product Lot Numbers*" attachment for a list of recalled products by lot number, specific to your facility. Also, 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.



Actions

Please use the enclosed customer confirmation form to complete the following steps:

- Identify, locate, and segregate any affected product listed on the "*Affected Product Lot Number*" attachment
- Complete the Customer Confirmation Form and return to Medtronic **even if you do not have unused inventory**
- Call Customer Service, referencing "FA19-02", for return authorization and credit information (1-888-854-0978)
- Return affected product per instructions located on the Customer Confirmation Form

Additional Information

Medtronic is communicating this recall to Customers who, based on our records, may have unused Vectris Lead Kits with the affected curved tip needle. Please share this letter with those in your organization who require this information.

Medtronic is also communicating to regulatory agencies including the US Food and Drug Administration. Customers with device related questions can contact Technical Services at 1-800-707-0933 weekdays 7am-6pm CT. Please report any malfunction or adverse event related to a device to Medtronic Neuromodulation Technical Services and to FDA's MedWatch Program (www.fda.gov/medwatch). We apologize for the disruption or inconvenience resulting from this action.

Sincerely,

Mike Ronningen
Vice President, Quality & Regulatory Affairs

enclosures: Customer Confirmation Form

Customer Confirmation Form – FA19-02

Medtronic
7000 Central Ave NE RCC150
Minneapolis, MN 55432
Neuro.Quality@medtronic.com

URGENT: MEDICAL DEVICE RECALL

Curved Tip Introducer Needle for Spinal Cord Stimulation Leads
Specific Lots of Vectris™ Lead Kits

Account Name:
Account Number:
Address:
City, State, Zip:
Consignee Id:

Return this completed form to Medtronic Quality (even if you do not have any product to return) using the enclosed return envelope. You may also return via email neuro.quality@medtronic.com or fax to 800-897-3899.

The Customer listed above has received the Medtronic *Curved Tip Introducer Needle for Spinal Cord Stimulation Leads - Specific lots of Vectris Lead Kits device* recall notification dated May 2018 and taken appropriate actions.

Name (Print): _____ Date: _____
(First Name & Last Name)

Title (Print): _____

Signature (ink): _____

Email & Telephone: _____

Please fill-in below the affected lot number(s) in your existing stock that you will be returning.

Product Model Number	Lot Number		Product Model Number	Lot Number

RETURN AFFECTED INVENTORY TO:
Medtronic Returns Center
ATTN: RGR # XXXXXX *(enter the RGR # obtained from Medtronic customer service 1-888-638-7627)*
4340 Swinnea Rd Bldg A Returns
Memphis TN 38118-6603

The addressee may continue to receive reminders of this notice until a response is received.