Medtronic

Medtronic Ireland Limited
Block 3090-3094
Lake Drive
Citywest Business Campus
Dublin
DN24 XN47
www.medtronic.ie
Tel: 01 511 1400
Fax: 01 807 7220

Urgent Field Safety Notice

Vectris™ SureScan™ MRI Lead Kits

Part Numbers 977A260, 977A275, 977A290

Incorrect Lead Spacing on Labeling

Recall

July 2021,

Medtronic Reference: FA984

Dear Healthcare Professional,

The purpose of this letter is to advise you that Medtronic is voluntarily recalling specific Product Identification Numbers (PINs) of the Vectris SureScan MRI Lead Kits due to incorrect lead electrode spacing information printed on the shelf box and sterile pack labeling. Please review the information contained in this letter, quarantine any unused affected product in your inventory for return to Medtronic.

Issue Description:

Medtronic has identified that specific PINs of the Vectris SureScan MRI Lead Kits contain the incorrect lead electrode spacing information printed on the shelf box and sterile pack labeling. The labeling shows 1.5 mm spacing between electrodes, when it should actually show 4.0 mm. The 4.0 mm lead catalog numbers of 977A260, 977A275, and 977A290 are accurate, but the image is incorrect. Through June 7, 2021, Medtronic has received two complaints on this issue, neither of which reported any patient harm. The incorrect labelling spacing information could lead to inconvenience for the user, a situation that requires additional troubleshooting, or a potential delay in surgery.

Image 1: Label with incorrect spacing information

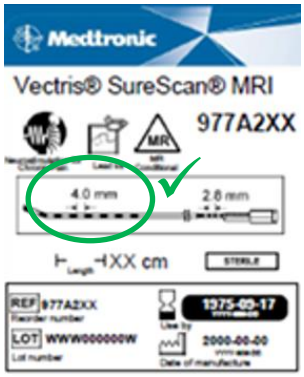

Image 2: Label with correct spacing information

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Product Scope:

The following product is impacted by this issue:

Unique Device Identifier	Catalog Number	Product Identification Number
00763000324353	977A260	977A20024V
00763000324360	977A275	977A20025V
00763000324377	977A290	977A20028V

Image 3: Label showing placement of PIN number

Required Actions:

1) Identify, segregate, and quarantine any impacted product (listed above) within your inventory.

2) Contact your Medtronic Representative at 01 511 1400 to return impacted product and receive replacement(s).

3) Please share this communication within your organization and with others who may have inventory of affected products or may be impacted by this issue.

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

We regret any inconvenience and difficulty this issue may have caused. We are committed to patient safety and appreciate your prompt attention to this matter.

If you have questions related to this issue, please contact your local Medtronic representative at 01 511 1400.

Sincerely,

Keith Taverner
Regulatory Affairs Manager UK & Ireland