

Medtronic Ireland Limited

T Block 3090-3094
Lake Drive
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DN24 XN47
Ireland
Tel: 01 511 1400
Fax: 01 807 7220
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Urgent Field Safety Notice

**NIM TriVantage™ EMG Endotracheal Tube Model Numbers 8229706, 8229707, 8229708,
8229736, 8229737, and 8229738**

Recall

November 2023

EU Manufacturer Single Registration Number (SRN): US-MF-000023264

Medtronic Reference: FA1369

Dear Risk Manager/ Customer:

The purpose of this letter is to advise you that Medtronic is recalling specific lots of the NIM TriVantage™ EMG Endotracheal Tubes. This recall was initiated because of reports received in which customers reported experiencing noise from the NIM system, lead-off or high impedance issues, or loss of/intermittent nerve monitoring.

Potential Health Hazard:

As of 05-Oct-2023, Medtronic has received 87 complaints indicating potential health hazards of degraded or loss of functionality of the device with specific lots (see Attachment A). The potential hazards can cause unintended extubation, a delay or a cancellation of the case or dysphonia, dysphagia, dyspnea, or possible nerve damage. Medtronic records indicate your facility may have at least one of the device lot numbers identified in Attachment A.

Actions:

- Identify, segregate, and quarantine affected products within your inventory. The list of affected lot numbers is included in Attachment A. Return affected product in your inventory to Medtronic. Instructions on how to return this form and any impacted products to Medtronic can be found on the Customer Acknowledgment Form. Your local Medtronic Representative can assist you with the initiation of the return.
- Please complete and return the Customer Acknowledgment Form even if you do not have the affected product.

Regulatory notification:

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

Local contact details:

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 ENT Representative or via Tel. No: 01 511 1400.

Sincerely,



Heidar Hussain
Associate Regulatory Affairs Specialist

Enclosure(s): Attachment A – Impacted Product List

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Attachment A: Impacted Product List

Product Scope:

Product Names	Product Number	Lot Number
EMG TUBE 8229706 NIM TRIVANTAGE™ 6.0MM ID	8229706	0225750658 0225785080 0225785081 0225785083 0225785085 0225785587 0225787473 0225892912 0225894523 0225904858 0225974682 0225998102 0225998104 0226099513 0226121951 0226130941 0226227428 0226246448 0226246716 0226253848 0226258673 0226276006 0226294121 0226299303 0226299304 0226321727 0226350207 0226604403 0226628515 0226648757 0226684520 0226718176 0226745452
EMG TUBE 8229707 NIM TRIVANTAGE™ 7.0MM ID	8229707	0225784378 0225784379 0225784380 0225784381 0225784382 0225784383 0225784384 0225784385 0225785406 0225785407 0225785408 0225785410 0225787474 0225798573 0225803180 0225805468 0225805470 0225809609 0225809610 0225809612 0225824531 0225825616 0225828951 0225832074 0225832077 0225841439 0225841440 0225846915 0225846916 0225848733 0225848733 0225848736 0225848738 0225849141 0225869998 0225870000 0225877834 0225877835 0225886691 0225915233 0225915542 0225921185 0225929260 0225929261 0225932768 0225934163 0225952300 0225952301 0225956683 0225962826 0225965501 0225965502 0225965503 0225972240 0225980517 0225983909 0225983910 0225994033 0225994034 0226003805 0226004326 0226012343 0226012345 0226020502 0226020503 0226020788 0226030091 0226030095 0226030100 0226043357 0226057364 0226057365 0226057748 0226057749 0226079291 0226084995 0226086007 0226086011 0226086014 0226086015 0226097641 0226102998 0226112818 0226115170 0226119539 0226121428 0226124551 0226124551 0226130050 0226130051 0226130055 0226139423 0226144158 0226144159 0226144160 0226144161 0226144162 0226149512 0226150740 0226157390 0226157394 0226166003 0226166004 0226166728 0226166730 0226177144 0226177145 0226177545 0226177687 0226177688 0226177689 0226185843 0226186007 0226194910 0226201784 0226203121 0226209733 0226232159 0226232540 0226246722 0226252324 0226276007 0226278505 0226279176 0226300072 0226300073 0226321734 0226321735 0226337995 0226337996 0226350218 0226352415 0226352807 0226352808 0226376135 0226385562 0226389384 0226389651 0226397416 0226398799 0226398929 0226406353 0226406354 0226406370 0226406372 0226429408 0226429410 0226441448 0226452151 0226455033

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		0226455044 0226490525 0226490808 0226512177 0226520885 0226522308 0226537201 0226537203 0226549613 0226553472 0226564997 0226564998 0226564999 0226579984 0226591832 0226601698 0226618838
EMG TUBE 8229708 NIM TRIVANTAGE™ 8.0MM ID	8229708	0225785421 0225785422 0225785423 0225785424 0225785425 0225785466 0225785467 0225785468 0225787472 0225809611 0225975149 0225998251 0225998253 0226004208 0226004209 0226086712 0226121950 0226130937 0226130938 0226130939
EMG TUBE 8229736 3PK NIM TRIVANTAGE™ 6MM	8229736	0225998248
EMG TUBE 8229737 3PK NIM TRIVANTAGE™ 7MM	8229737	0225908183 0225908184 0225908185 0225908326 0225908327 0225908328 0225908329 0225908330 0225908332 0225908334 0226103711 0226177141
EMG TUBE 8229738 3PK NIM TRIVANTAGE™ 8MM	8229738	0225785470