

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 cancelation 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. Your local Medtronic Representative can assist you with the initiation of the return.

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.

Sincerely,

Local / OU Manager

Enclosure(s): Attachment A – Impacted Product List

Attachment A: Impacted Product List

Product Scope:

Product Names	Product Number	Lot Number
EMG TUBE 8229706 NIM TRIVANTAGE™ 6.0MM ID	8229706	0225750658 0226321727 0226350207 0226604403
EMG TUBE 8229707 NIM TRIVANTAGE™ 7.0MM ID	8229707	0225846915 0225846916 0225848738 0225849141 0225915542 0225932768 0225983910 0226086014 0226119539 0226144161 0226177145 0226232159