

Urgent Field Safety Notice

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

Recall

November 2023

Medtronic Reference: FA1369

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

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. 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.

Medtronic

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,
Medtronic GmbH

Enclosure:
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	0226299303	0226227428	0226276006	0225750658
EMG TUBE 8229707 NIM TRIVANTAGE™ 7.0MM ID	8229707	0226352807	0225848738	0225846916	0225809612
		0225784383	0226086011	0226012345	0226406353
		0226086014	0225915542	0226057748	0226398929
		0226376135	0226246722	0226232540	0226232159
		0226144162	0226119539	0226030095	0226004326
		0226177145	0226352808	0226144161	0225932768
		0225849141			
EMG TUBE 8229737 3PK NIM TRIVANTAGE™ 7MM	8229737	0225908334	0225908334	0226103711	0225908332
		0225908183	0226177141	0225908330	0225908328
		0225908326			