

Urgent Field Safety Notice

NIM Trivantage EMG Endotracheal Tube Multiple Product Models Impacted

Recall

December 2021

Medtronic reference: FA1218

Dear Risk Manager:

The purpose of this letter is to advise you that Medtronic is voluntarily recalling specific production lots of EMG Tube NIM Trivantage. The scope of this action includes only specific lot numbers of the products listed below (reference Table A and Attachment 1 for additional impacted product information).

Table A: Affected Product Information

Product Name	Model#/CFN	Material#	Batch/Lot#
EMG TUBE 8229705 NIM TRIVANTAGE 5.0MM ID	8229705	00763000033934	See Attachment 1 for Impacted Lot Information
EMG TUBE 8229706 NIM TRIVANTAGE 6.0MM ID	8229706	00763000033941	
EMG TUBE 8229707 NIM TRIVANTAGE 7.0MM ID	8229707	00763000033958	
EMG TUBE 8229708 NIM TRIVANTAGE 8.0MM ID	8229708	00763000033965	
EMG TUBE 8229709 NIM TRIVANTAGE 9.0MM ID	8229709	00763000033972	
EMG TUBE 8229735 3PK NIM TRIVANTAGE 5MM	8229735	20763000041506	
EMG TUBE 8229736 3PK NIM TRIVANTAGE 6MM	8229736	20763000041513	
EMG TUBE 8229737 3PK NIM TRIVANTAGE 7MM	8229737	20763000041520	
EMG TUBE 8229738 3PK NIM TRIVANTAGE 8MM	8229738	20763000041537	
EMG TUBE 8229739 3PK NIM TRIVANTAGE 9MM	8229739	20763000041544	

Issue Description:

Medtronic has received complaint reports from customers experiencing issues with the Trivantage EMG Tubes during use. Reported issues include users:

- Experiencing difficulty passing the Electrode Check on the NIM Mainframe immediately after intubating the patient
- Losing the connection between the EMG Tube and the Mainframe during a procedure, resulting in an “Electrode Off,” “Lead Off,” or “Channel Not Reading” error message on the NIM console screen and the inability to proceed with nerve monitoring
- Receiving excess signal noise from the NIM console due to lead-off issues

Through investigation, the root cause of the non-conforming product was determined to be in the adhesive application step of the manufacturing process. This issue impacts specific production lots (See Attachment 1) manufactured between 28-Aug-2019 and 25-Oct-2021. Corrective actions have been implemented to address the underlying issue and new products will not be impacted by this issue.

Risk to Health:

From 1-Nov-2019 to 31-Oct-2021, Medtronic received 163 complaints worldwide. Of these complaints, there were four (4) cases of aborted procedures and one (1) case of nerve damage. The remaining complaints did not result in serious patient injury.

If any of these issues are identified during surgery, the risks associated with a non-conforming Trivantage EMG Tube could potentially result in:

- A case being canceled after the patient is anesthetized
- Possible nerve damage

Required Actions:

Our records show that your facility has received one or more lots of the impacted products. Lot Numbers of the impacted product are listed in Attachment 1. Consequently, Medtronic requires that you immediately take the following actions:

1. Do NOT use any impacted product. Remove and quarantine all unused impacted product(s) in your inventory
2. Return the impacted product(s) to Medtronic. Your Medtronic representative can assist in facilitating the return of the product as necessary. If an alternative product is needed, your Medtronic representative can assist you with identifying a suitable replacement product

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

Transmission of this Communication:

Please share this communication within your organization, with other organizations where impacted devices have been transferred, and any other associated organizations that may be impacted by this action. Please maintain a copy of this letter for your records.

We are committed to patient safety and appreciate your prompt attention to this matter. We regret any inconvenience this may cause. If you have any questions regarding this communication, please contact your Medtronic representative <XXXXX>.

Sincerely,

Local / BU manager

Enclosures:

Attachment 1: Affected Lot Information

Attachment 2: Example of Labeling

Attachment 1: Affected Lot Information

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Table 1: EMG TUBE 8229705 NIM TRIVANTAGE 5.0MM ID (8229705)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Model Number	Lot/Serial Number
EMG TUBE 8229705 NIM TRIVANTAGE 5.0MM ID	00763000033934	8229705	0218663943, 0218762694, 0219904500, 0220293429, 0220584798, 0220756285, 0220774358, 0221736070, 0221805033, 0222186741, 0222495993, 0222591367, 0222832233

Table 2: EMG TUBE 8229706 NIM TRIVANTAGE 6.0MM ID (8229706)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Model Number	Lot/Serial Number
EMG TUBE 8229706 NIM TRIVANTAGE 6.0MM ID	00763000033941	8229706	0218663944, 0218664146, 0218762695, 0218762697, 0218762698, 0218762699, 0219010138, 0219010139, 0219010140, 0219010141, 0219010142, 0219272545, 0219278186, 0219278187, 0219278188, 0219278189, 0219278190, 0219444156, 0219444157, 0219444158, 0219444159, 0219444160, 0219444161, 0219836614, 0219836616, 0219969085, 0219972526, 0219972527, 0219972528, 0220087596, 0220087597, 0220087598, 0220293430, 0220293431, 0220293432, 0220293433, 0220293434, 0220293435, 0220371534, 0220371535, 0220371536, 0220371537, 0220517618, 0220517619, 0220584803, 0220584804, 0220734720, 0220769468, 0220769469, 0220769470, 0220878556, 0220878557, 0220934885, 0221123594, 0221123639, 0221248867, 0221248868, 0221248869, 0221493241, 0221543452, 0221543453, 0221637121, 0221637122, 0221710524, 0221805030, 0221805031, 0221805039, 0221805041, 0222024594, 0222048142, 0222057391, 0222140123, 0222200982, 0222200983, 0222200984, 0222239874, 0222239875, 0222352848, 0222396630, 0222428754, 0222465659, 0222495994, 0222495995, 0222495996, 0222542347, 0222542348, 0222563000, 0222563288, 0222684388, 0222719941, 0222738659

Table 3: EMG TUBE 8229707 NIM TRIVANTAGE 7.0MM ID (8229707)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Model Number	Lot/Serial Number
EMG TUBE 8229707 NIM TRIVANTAGE 7.0MM ID	00763000033958	8229707	0218664148, 0218664149, 0218664150, 0218664151, 0218664152, 0218664153, 0218664154, 0218664155, 0218664156, 0218664157, 0218664158, 0218762700, 0218762701, 0218762702, 0218762703, 0218762704, 0218762705, 0218762806, 0218762807, 0218762809, 0218762811, 0218762812, 0218762814, 0218762815, 0219010143, 0219010144, 0219010145, 0219010806, 0219010807, 0219010808, 0219010809, 0219010810, 0219010811, 0219010812, 0219010813, 0219010814, 0219010815, 0219010816, 0219010817, 0219010818, 0219010819, 0219010820, 0219010821, 0219010822, 0219278191, 0219278192, 0219278193, 0219278194, 0219278195, 0219278196, 0219278197, 0219278198, 0219444369, 0219444370, 0219444371, 0219444372, 0219444373, 0219444374, 0219444375, 0219444376, 0219723502, 0219952958, 0219952959, 0219985176, 0219985177, 0220008823, 0220008824, 0220008825, 0220010546, 0220010547, 0220010548, 0220033883, 0220033885, 0220037915, 0220047459, 0220047460, 0220057008, 0220057009, 0220057010, 0220057011, 0220076607, 0220081032, 0220081037, 0220087591, 0220087599, 0220087600, 0220087601, 0220087602, 0220087603, 0220087886, 0220142052, 0220142053, 0220142054, 0220142055, 0220142057, 0220142058, 0220142059, 0220142060, 0220142062, 0220142063, 0220142064, 0220142065, 0220149776, 0220149778, 0220149779, 0220230467, 0220230468, 0220230469, 0220230472, 0220370784, 0220370785, 0220371526, 0220371527, 0220371528, 0220371529, 0220371530, 0220371531, 0220371532, 0220371533, 0220517189, 0220517190, 0220517191, 0220517192, 0220517193, 0220517194, 0220517195, 0220517196, 0220517197, 0220517198, 0220517199, 0220517200, 0220517201, 0220517202, 0220517620, 0220517621, 0220622252, 0220622253, 0220637407, 0220637408, 0220637409, 0220637410, 0220688264, 0220688265, 0220691509, 0220691510, 0220734718, 0220756281, 0220756282, 0220756283, 0220756284, 0220769471, 0220769472, 0220798476, 0220804919, 0220813969,

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Model Number	Lot/Serial Number
			0220813970, 0220817686, 0220817687, 0220826216, 0220826217, 0220845825, 0220846126, 0220857889, 0220878558, 0220878559, 0220878560, 0220878561, 0220878562, 0220878563, 0220913062, 0220935486, 0220935487, 0220935488, 0220935489, 0220974382, 0221040035, 0221040036, 0221056071, 0221056072, 0221069155, 0221073627, 0221082044, 0221082126, 0221090327, 0221090328, 0221097604, 0221097605, 0221098066, 0221098067, 0221118571, 0221118572, 0221123591, 0221123638, 0221146333, 0221146457, 0221146458, 0221146459, 0221146460, 0221146461, 0221146462, 0221146463, 0221146879, 0221146889, 0221146901, 0221248875, 0221248876, 0221248877, 0221248878, 0221248879, 0221248880, 0221248881, 0221248882, 0221248883, 0221248884, 0221248885, 0221378722, 0221378724, 0221378725, 0221379386, 0221379387, 0221379388, 0221493665, 0221493866, 0221514981, 0221526915, 0221526917, 0221526918, 0221526919, 0221526920, 0221571421, 0221599117, 0221599118, 0221599119, 0221599181, 0221637118, 0221651974, 0221656118, 0221656119, 0221659143, 0221659144, 0221736003, 0221736005, 0221736786, 0221766208, 0221766209, 0221766211, 0221772984, 0221805043, 0221805044, 0221886337, 0221893433, 0221893434, 0221893435, 0221897719, 0221897720, 0221924396, 0221931540, 0221938901, 0221938902, 0221962166, 0221967955, 0222024589, 0222057392, 0222069692, 0222069693, 0222069694, 0222093329, 0222093330, 0222101075, 0222106107, 0222110921, 0222110922, 0222136940, 0222139599, 0222139600, 0222140118, 0222140119, 0222140120, 0222140125, 0222140446, 0222163047, 0222168488, 0222168489, 0222168491, 0222168492, 0222168493, 0222202226, 0222202227, 0222202228, 0222202229, 0222202230, 0222202231, 0222202232, 0222239878, 0222239881, 0222239882, 0222239883, 0222239884, 0222239885, 0222240046, 0222240047, 0222312293, 0222312878, 0222334220, 0222334221, 0222334222, 0222334223, 0222334224, 0222358414, 0222358415, 0222358416, 0222358417, 0222358418, 0222396631, 0222396632, 0222396633, 0222396634, 0222396635, 0222456848, 0222456849, 0222456850, 0222456851, 0222456852, 0222476127, 0222476128, 0222476129, 0222476130, 0222476131, 0222495997, 0222495998, 0222495999, 0222496000, 0222496001, 0222496002, 0222496003, 0222542349, 0222542350, 0222542351, 0222542352, 0222542353, 0222563001, 0222563002, 0222563003, 0222563004, 0222563005, 0222563286, 0222563287, 0222684391, 0222684392, 0222684393, 0222684394, 0222684395, 0222719938, 0222719943, 0222719944, 0222719945, 0222720028, 0222720029, 0222738660, 0222738661, 0222738662, 0222738663, 0222738664, 0222738665, 0222857891, 0222857892, 0222857893, 0222857894, 0222857895, 0222857896, 0222857897, 0222857898, 0222857900

Table 4: EMG TUBE 8229708 NIM TRIVANTAGE 8.0MM ID (8229708)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Model Number	Lot/Serial Number
EMG TUBE 8229708 NIM TRIVANTAGE 8.0MM ID	00763000033965	8229708	0218664159, 0218664160, 0218664161, 0218664162, 0218664163, 0218762816, 0218762818, 0218762819, 0218762820, 0218762821, 0218762822, 0219278199, 0219278200, 0219278201, 0219278202, 0219444162, 0219444163, 0219444164, 0219444165, 0220087592, 0220087593, 0220087594, 0220087595, 0220142106, 0220142108, 0220142109, 0220142110, 0220142111, 0220228325, 0220293438, 0220293439, 0220293440, 0220370781, 0220370782, 0220370783, 0220517614, 0220517615, 0220517616, 0220517617, 0220658898, 0220730554, 0220855164, 0220855447, 0220855448, 0220855449, 0220873204, 0220935503, 0220935505, 0220935648, 0220935651, 0220935654, 0221056080, 0221056081, 0221097602, 0221097603, 0221146343, 0221146446, 0221146448, 0221146936, 0221146951, 0221248874, 0221378720, 0221588082, 0221588083, 0221637123, 0221710525, 0221710926, 0221851580, 0221851581, 0221893436, 0221931647, 0221931648, 0222031317, 0222081991, 0222101073, 0222140121, 0222140122, 0222217071, 0222240048, 0222302776, 0222358419, 0222358421, 0222396636, 0222396637, 0222456853, 0222456854, 0222476133, 0222542354, 0222563290, 0222720030, 0222739006

Table 5: EMG TUBE 8229709 NIM TRIVANTAGE 9.0MM ID (8229709)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Model Number	Lot/Serial Number
EMG TUBE 8229709 NIM TRIVANTAGE 9.0MM ID	00763000033972	8229709	0218275305, 0218275886, 0218452814, 0218452815, 0218496850, 0218515807, 0218540733, 0218540734, 0218540735, 0219906760, 0220586086, 0220973095, 0221248873, 0221517237, 0221805028, 0222187092, 022248291, 0222336506

Table 6: EMG TUBE 8229735 3PK NIM TRIVANTAGE 5MM (8229735)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Model Number	Lot/Serial Number
EMG TUBE 8229735 3PK NIM TRIVANTAGE 5MM	20763000041506	8229735	0218275302, 0218452816, 0220584797, 0220883592, 0221996821, 0222146974

Table 7: EMG TUBE 8229736 3PK NIM TRIVANTAGE 6MM (8229736)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Model Number	Lot/Serial Number
EMG TUBE 8229736 3PK NIM TRIVANTAGE 6MM	20763000041513	8229736	0218762829, 0218762830, 0219010516, 0219010517, 0219010518, 0219904499, 0219985174, 0220293436, 0220293437, 0220584799, 0220880266, 0220998690, 0221038763, 0221246105, 0221248866, 0221378719, 0221543451, 0221805267, 0222024592, 0222140124, 0222240053, 0222527962, 0222684399

Table 8: EMG TUBE 8229737 3PK NIM TRIVANTAGE 7MM (8229737)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
EMG TUBE 8229737 3PK NIM TRIVANTAGE 7MM	20763000041520	8229737	0010791039, 0218762831, 0218762832, 0218762833, 0218762834, 0218762835, 0219010519, 0219733959, 0219744709, 0219785665, 0219788607, 0219788608, 0219795296, 0219795301, 0219795302, 0219795303, 0219802958, 0219802959, 0219802960, 0219836612, 0219836613, 0219904496, 0219904497, 0219972534, 0219972535, 0219972536, 0219972537, 0219972538, 0219985178, 0220010550, 0220010551, 0220010552, 0220010554, 0220010555, 0220087604, 0220087605, 0220142112, 0220142113, 0220142114, 0220142116, 0220228945, 0220230426, 0220230427, 0220230428, 0220230429, 0220230430, 0220230480, 0220230481, 0220293442, 0220293443, 0220293444, 0220713083, 0220734719, 0220734721, 0220769474, 0220769475, 0220769476, 0220785122, 0220790899, 0220826214, 0220826215, 0220847263, 0220857890, 0220998691, 0221010990, 0221034442, 0221035008, 0221038764, 0221056079, 0221248870, 0221248871, 0221248872, 0221378718, 0221463272, 0221463273, 0221493238, 0221493240, 0221493867, 0221493869, 0221543449, 0221637119, 0221637120, 0221718467, 0221766210, 0221805034, 0221805035, 0221805037, 0221805038, 0221910040, 0221924395, 0221931646, 0221967715, 0222024590, 0222024595, 0222024596, 0222034109, 0222034111, 0222065770, 0222119577, 0222123196, 0222187098, 0222334225, 0222358420, 0222396638, 0222456855, 0222496004, 0222496005, 0222542355, 0222562999, 0222563291, 0222684396, 0222719939, 0222720026, 0222739007, 0222739008, 0222908102

Table 9: EMG TUBE 8229738 3PK NIM TRIVANTAGE 8MM (8229738)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
EMG TUBE 8229738 3PK NIM TRIVANTAGE 8MM	20763000041537	8229738	0218762837, 0218762838, 0218762840, 0218762841, 0218762842, 0219011550, 0219011551, 0219011552, 0219861136, 0219861141, 0219878782, 0219878783, 0219878784, 0219879026, 0219952951, 0219952952, 0220142117, 0220142118, 0220142119, 0220142120, 0220142121, 0220855453, 0220966544, 0221038762, 0221146339, 0221247365, 0221463276, 0221514982, 0221543448, 0221765700, 0221898348, 0222007804, 0222031318, 0222187101, 0222476134, 0222542356, 0222684398, 0222739009

Table 10: EMG TUBE 8229739 3PK NIM TRIVANTAGE 9MM (8229739)

Product Names, Unique Device Identifier (if applicable)	Global Trade Item Number (GTIN)	Customer Facing Number (CFN)	Lot/Serial Number
EMG TUBE 8229739 3PK NIM TRIVANTAGE 9MM	20763000041544	8229739	0218762824, 0220584805, 0222024591, 0222272928, 0222476135

Attachment 2: Example of Labeling

Model #

REF 8229707 **x1**

NIM TriVantage® EMG Endotracheal Tube
7.0 mm I.D. x 9.5 mm O.D.

Medtronic Xomed, Inc.,
6743 Southpoint Drive North
Jacksonville, FL 32216-0980 USA

~~PHT~~ ~~DEHP~~ ~~LATEX~~ ~~2~~

CE 0123 i ! 27 mm **ORAL**

9999-09-09 **STERILE EO R Only** **LOT 0999999999**
M986379A001 A 0001

Made in Dominican Republic

REF 8229707 **LOT 0999999999** **9999-09-09**
REF 8229707 **LOT 0999999999** **9999-09-09**

Medtronic Xomed, Inc.

Lot #