



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



**FDA ADVISORY**  
No: **2022-1016**

04 MAY 2022

**TO: ALL HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

**SUBJECT: Voluntary Recall of NIM Trivantage EMG Endotracheal Tube**

The Food and Drug Administration (FDA) warns all healthcare professionals and establishments on the voluntary recall of affected specific lot numbers of NIM Trivantage EMG Endotracheal Tube imported and distributed by Medtronic Philippines, Inc.

Product Name	Customer Facing Number	Lot / Serial Number
EMG Tube 8229705 NIM Trivantage 5.0MM ID	8229705	0218663943, 0218762694, 0219904500, 0220293429, 0220584798, 0220756285, 0220774358, 0221736070, 0221805033, 0222186741, 0222495993, 0222591367, 0222832233
EMG Tube 8229706 NIM Trivantage 6.0MM ID	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,



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EMG Tube 8229735 3PK NIM Trivantage 5MM	8229735	0218275302, 0218452816, 0220584797, 0220883592, 0221996821, 0222146974
EMG Tube 8229736 3PK NIM Trivantage 6MM	8229736	0218762829, 0218762830, 0219010516, 0219010517, 0219010518, 0219904499, 0219985174, 0220293436, 0220293437, 0220584799, 0220880266, 0220998690, 0221038763, 0221246105, 0221248866, 0221378719, 0221543451, 0221805267, 0222024592, 0222140124, 0222240053, 0222527962, 0222684399
EMG Tube 8229737 3PK NIM Trivantage 7MM	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,

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EMG Tube 8229738 3PK NIM Trivantage 8MM	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
EMG Tube 8229739 3PK NIM Trivantage 9MM	8229739	0218762824, 0220584805, 0222024591, 0222272928, 0222476135

Table 1. Affected Lot Numbers of NIM Trivantage EMG Endotracheal Tube



Figure 1. Photo of the Affected EMG Tube 8229705 NIM Trivantage 5.0MM ID

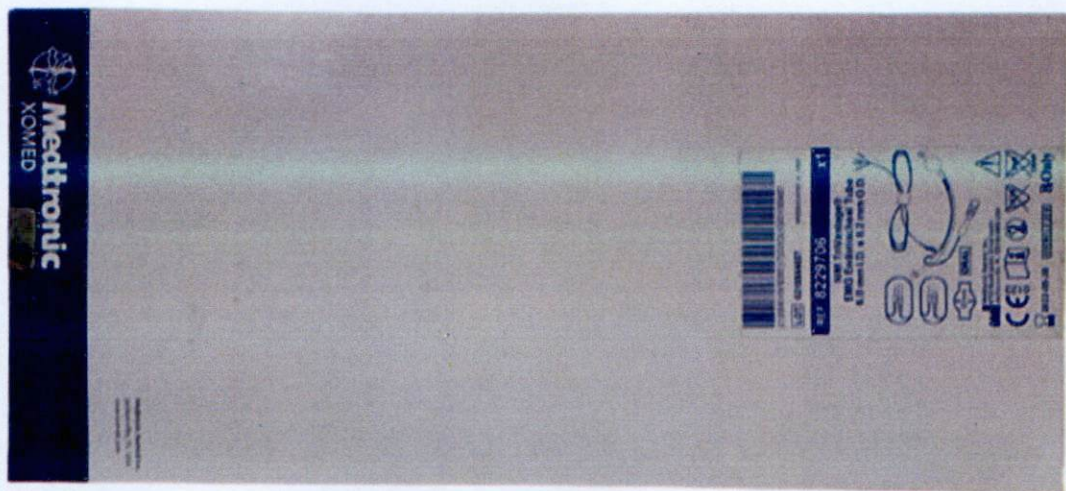


Figure 2. Photo of the Affected EMG Tube 8229706 NIM Trivantage 5.0MM ID



Figure 3. Photo of the Affected EMG Tube 8229707 NIM Trivantage 7.0MM ID

Medtronic has received complaint reports from customers experiencing issues with the use of the abovementioned medical device. 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 inability to proceed with nerve monitoring. Lastly, 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 manufactured between 28 August 2019 and 25 October 2021. Corrective actions have been implemented to address the underlying issue and new products will not be impacted by this issue.

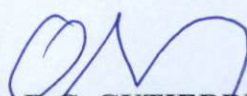
In light of the foregoing, all concerned healthcare professional, establishments, and the general public are warned to discontinue further use, sale, and distribution of the said affected lot numbers of NIM Trivantage EMG Endotracheal Tube.

All FDA Regional Field Offices and Regulatory Enforcement Units, in coordination with law enforcement agencies and Local Government Units, are requested to ensure that product is not sold or made available in the market or areas of jurisdiction.

Any suspected adverse reaction experienced from the use of the medical device but not limited to the lot numbers stated above should be reported immediately to FDA.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through e-mail at [cdrhr@fda.gov.ph](mailto:cdrhr@fda.gov.ph), or call (02) 8857-1900 loc. 8301.

Dissemination of this advisory to all concerned is hereby requested.

  
**DR. OSCAR G. GUTIERREZ, JR.**  
Officer-in-Charge, Director General

DTN 20220407075301