Medtronic France SAS
9, boulevard Romain Rolland
75014 Paris
RCS Paris B 722008232
www.medtronic.fr
Tel : 01 55 38 17 00

Information urgente de sécurité

Tubes endotrachéaux renforcés pour EMG NIM Contact™* et Tubes endotrachéaux renforcés standard pour EMG NIM™

Rappel

Juillet 2024

Référence Medtronic : FA1255

Numéro d'enregistrement unique du fabricant européen : US-MF-0000023264

Cher professionnel de santé, correspondants de matériovigilance,

L'objet de cette lettre est de vous informer que Medtronic procède à un rappel de tous les lots de tubes endotrachéaux renforcés pour EMG NIM CONTACT™* et de tubes endotrachéaux renforcés standard pour EMG NIM™.
Les données de Medtronic indiquent que votre établissement peut disposer d'au moins un des produits identifiés dans le tableau ci-dessous.
Ces dispositifs ne sont plus disponibles à la distribution ou à la vente. Veuillez suivre les actions du client indiquées ci-après.

Description du problème :

Ce rappel fait suite à des déclarations faisant état de problèmes de blocage du tube, correspondant à l'extension, une hernie ou la déformation du ballonnet en silicone à l'extrémité du tube et/ou de l'œil de Murphy,

Risques potentiels pour la santé :

Entre le 31 mars 2020 et le 20 mai 2024, Medtronic a reçu 77 déclarations indiquant des risques potentiels pour la santé liés à la dégradation ou à la perte de fonctionnalité du dispositif avec tous les modèles (voir le tableau des produits concernés), qui, selon les signalements, ont entraîné : obstruction des voies respiratoires, extubation non prévue, bronchospasme, hypoventilation, faible saturation en oxygène, hypoxie, détresse respiratoire, mesures anormales des gaz sanguins, cyanose, apnée, arrêt respiratoire, arrêt cardiaque, lésions cérébrales et décès.

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Les risques potentiels pour la santé liés à l'utilisation des produits concernés comprennent : obstruction des voies respiratoires, extubation non prévue, bronchospasme, hypoventilation, faible saturation en oxygène, hypoxie, détresse respiratoire, mesures anormales des gaz sanguins, cyanose, apnée, arrêt respiratoire, arrêt cardiaque, lésions cérébrales et décès.

Aperçu des précédents avis de sécurité de Medtronic :

En mai 2022, Medtronic a publié un avis de sécurité concernant l'utilisation du tube endotrachéal renforcé Standard pour EMG NIM™ et du tube endotrachéal renforcé pour EMG NIM CONTACT™* en raison de signalements d'événements liés à l'obstruction des voies respiratoires lors de l'utilisation de ces dispositifs. Cet avis comprenait également des informations sur l'importance d'examiner attentivement et de respecter le mode d'emploi, qui comprenait un avertissement sur le surgonflage ainsi que des mesures d'atténuation supplémentaires en cas d'obstruction des voies respiratoires.

En février 2024, lorsque les mises à jour de l'étiquetage des tubes endotrachéaux renforcés Standard pour EMG NIM™ ou NIM CONTACT™* ont été disponibles, Medtronic a publié une nouvelle information urgente de sécurité communiquant de nouveaux renseignements sur la sécurité fournis dans le mode d'emploi et réitérant l'importance d'examiner attentivement et de respecter les mises en garde, les précautions et les mesures d'atténuation dans la mise en pratique stricte du mode d'emploi. En outre, la formation sur le tube endotrachéal pour EMG NIM Standard et NIM Contact* a été déployée par Medtronic Academy.

Produits concernés :

Les données de Medtronic indiquent que votre établissement pourrait disposer d'au moins un des numéros de lot de dispositif identifiés dans le tableau ci-dessous.

Nom de marque	N° du modèle/N° à destination du client (CFN)	UDI
ENDOTRACHEAL TUBE 8229308 NIM EMG 8MM RE	8229308	00643169789548
		00763000745837
		00763000882402
ENDOTRACHEAL TUBE 8229307 NIM EMG 7MM RE	8229307	00643169789531
		00763000882396
		00763000745820
ENDOTRACHEAL TUBE 8229306 NIM EMG 6MM RE	8229306	00643169789524
		00763000882389
		00763000745813
ENDOTRACH TUBE 8229507 CONTACT* EMG 7MM	8229507	00643169789562
		00763000745851
		00763000882426
ENDOTRACH TUBE 8229506 CONTACT* EMG 6MM	8229506	00643169789555
		00763000745844

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Nom de marque	N° du modèle/N° à destination du client (CFN)	UDI
		00763000882419
ENDOTRACH TUBE 8229508 CONTACT* EMG 8MM	8229508	00643169789579
		00763000745868
		00763000882433

Actions du client :

- Au plus tôt, identifiez et placez en quarantaine les produits affectés de votre inventaire ou sous votre contrôle. N'utilisez pas les dispositifs concernés.
  Remarque : la liste des produits concernés est incluse dans le tableau ci-dessus. Tous les numéros de tubes endotrachéaux pour EMG NIM Standard et NIM Contact sont affectés.
- Retournez à Medtronic les produits concernés de votre inventaire. Veuillez contacter votre représentant Medtronic si vous avez besoin d'un dispositif de remplacement.
- Veuillez compléter et renvoyer le formulaire d'accusé de réception du client joint à ce courrier, même si vous n'avez pas de produit concerné à affaires.reglementaires@medtronic.com

La formation sur les tubes endotrachéaux pour EMG NIM Standard et NIM Contact* déployée avec la communication de février 2024 par Medtronic Academy n'est plus requise dans le cadre de ce rappel de lot.

Informations complémentaires :
Medtronic a notifié l'ANSM cette action.
Nous vous présentons toutes nos excuses pour la gêne occasionnée. La sécurité du patient étant notre priorité, nous vous remercions par avance de votre intervention rapide. Pour toute question concernant cette communication, veuillez contacter votre représentant Medtronic ou les affaires réglementaires : affaires.reglementaires@medtronic.com.

Cordialement,

Eric Bonnet
Directeur Operating Unit ORL France

- **Pièces jointes :** Formulaire d'accusé de réception du client

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Executive Summary
This Issue Impact Assessment (IIA) is being updated to document the overinflation risk assessment of silicone-based EMG endotracheal tubes to include data received after the initiation of FA1255 Phase II, a Field Corrective Action (FCA) consisting of a Medical Device Safety Notice, modified IFU warnings and new precautions cleared under K230320, and video training emphasizing the need to carefully review and adhere to instructions for use and providing recommended actions when airway obstruction is encountered for the silicone-based tubes. More complaints after the distribution of FA1255 Phase II have been identified potentially related to overinflation of the cuff, leading to airway obstruction. This IIA will assess the effectiveness of the current mitigations including the additional mitigations from FA1255 Phase II. After reviewing the complaints post-FA1255 Phase II, it is concluded that a recall is necessary to further reduce risk in the field because complaint data indicates that the action taken did not effectively mitigate the risk and the risk-benefit analysis concludes that benefits of the device do not outweigh the risks related to overinflation of the cuff.

Assessment Information	
Location:	Medtronic, Inc. Jacksonville, FL ENT OU (Operating Unit)
Author:	Joseph Teixeira
Date:	• 15-Feb-2022 (initial) • 06-Oct-2023 (assess effectiveness of FA1255 Phase I) • 23-Apr-2024 (in response to Data Monitoring identifying additional complaints)
Issue Title:	EMG Tube Airway Blockage
Issue Source(s):	• Complaints (See Attachment A for full list) • Product Event (PE) 704727472, MDR 1045254-2021-00684 (initial) • Product Event (PE) 706355887, MDR 9612501-2024-00910 (triggered this revision due to Data Monitoring Plan)

Product Information	
Brand Name:	ENDOTRACHEAL TUBE 8229306 NIM® EMG 6MM RE ENDOTRACH TUBE 8229306J NIM® EMG 6MM ENDOTRACHEAL TUBE 8229307 NIM® EMG 7MM RE ENDOTRACH TUBE 8229307J NIM® EMG 7MM ENDOTRACHEAL TUBE 8229308 NIM® EMG 8MM RE ENDOTRACH TUBE 8229308J NIM® EMG 8MM ENDOTRACH TUBE 8229506 NIM CONTACT® EMG 6MM ENDOTRACH TUBE 8229507 NIM CONTACT® EMG 7MM ENDOTRACH TUBE 8229508 NIM CONTACT® EMG 8MM

Model Number(s)/ Catalog Number(s):	8229306; 8229306J; 8229307; 8229307J; 8229308; 8229308J; 8229506; 8229507; 8229508
Regulatory Classification	

CFN/Product Number	FDA Regulatory Status	MDD Regulatory Class	510k	FDA Product Code
8229306 8229307 8229308	Class II	Class IIa	K925640	ETN
8229506 8229507 8229508	Class II	Class IIa	K050162	ETN
8229306J 8229307J 8229308J	N/A – Japan Only	N/A – Japan Only	N/A – Japan Only	N/A – Japan Only

Product Description & Intended Use:

Intended use

The EMG Endotracheal tube is intended for use as a means of providing both an open airway for patient ventilation and for intraoperative monitoring of EMG activity of the intrinsic laryngeal musculature when connected to an appropriate EMG monitor.

Indications for use

The EMG tube is indicated for use where continuous monitoring of the nerves supplying the laryngeal musculature is required during surgical procedures. The EMG tube is not intended for postoperative use.

Device description

Medtronic's NIM Standard Reinforced EMG Endotracheal tube and the NIM CONTACT Reinforced EMG Endotracheal tube are flexible, reinforced silicone elastomer endotracheal tubes with inflatable cuffs. Each tube is fitted with four (two pairs) stainless steel wire electrodes. These are embedded in the silicone of the main shaft of the endotracheal tube and exposed only for a short distance, approximately 30 mm, slightly superior to the cuff, for contacting the vocal cords. The electrodes are designed to make contact with the laryngeal muscles around the patient's vocal cords to facilitate electromyographic (EMG) monitoring of the laryngeal musculature during surgery when connected to a multi-channel EMG monitoring device. Both the tube and cuff are manufactured from silicone elastomer that allows the tube to conform readily to the shape of the patient's trachea with minimal trauma to tissues.

Per IFU M040175C001 C

Section 1: Issue Identification

Issue Description:

The event description of the complaint triggering the initial IIA (Product Event (PE) 704727472, MDR 1045254-2021-00684) is as follows:

> "A physician reported that during a parathyroid revision procedure the EMG tube and inflation assembly were checked for functionality prior to intubation, after which the patient was intubated, and the cuff was inflated with 10cc's of air. About 15-20 minutes into the procedure the patient was then turned 180, at which time the cuff of the EMG tube was deflated and then re-inflated after the positioning was complete; when re-inflating another 5cc's of air were added to the cuff, amounting to 15cc's, total. After the cuff was re-inflated with the 15cc's of air, the patient's oxygen diminished. It is believed that the cuff of the tube herniated over the tip and murphy eye of the tube, blocking oxygen flow; the inflated cuff was not able to move air through bronch. The patient coded. After 20 minutes of CPR the patient was transferred to the ICU and passed away 3-4 days later after another coding episode."

The above reported event indicates that the cuff of the endotracheal EMG tube was inflated beyond minimum sealing pressure as recommended by the IFU and the overinflation of the cuff caused blockage of the Murphy Eye and consequently caused the patient to experience airway obstruction.

Additional action was taken to reduce risk through FA1255 Phase I, which consisted of a safety notice emphasizing the need to carefully review and adhere to instructions for use and providing recommended actions when airway obstruction is encountered for the silicone-based tubes. Upon evaluation of the effectiveness of FA1255 Phase I, additional action was required as identified in D00644849 Rev C, and FA1255 Phase II was initiated.

FA1255 Phase II consisted of a new customer letter with modified IFU warnings and new precautions cleared under K230320 with a link to video training and IFU as a subsequent phase to the existing 806 correction and began distribution on 23-Jan-2024. However, after distribution complaints have been identified as potentially related to overinflation of the cuff leading to airway obstruction and per the requirements of Data Monitoring Plan D00637893 Rev E, escalation to Field Issue Risk Evaluation (FIRE) Triage was required and the IIA was reopened to further assess current mitigations and FCA effectiveness.

Issue Scope and Rationale:

Products considered in-scope of this IIA were the NIM Standard and Contact EMG Endotracheal Tubes as listed in Table 1, as they share the same basic construction, materials, instructions for use, and potential for overinflation of the cuff.

*Table 1: Models Utilizing IFU M040175C001, Rev B**

Brand	CFN
ENDOTRACH TUBE 8229306 NIM EMG 6MM ROHS	8229306
ENDOTRACH TUBE 8229306J NIM EMG 6MM ROHS	8229306J*
ENDOTRACH TUBE 8229307 NIM EMG 7MM ROHS	8229307
ENDOTRACH TUBE 8229307J NIM EMG 7MM ROHS	8229307J*
ENDOTRACH TUBE 8229308 NIM EMG 8MM ROHS	8229308
ENDOTRACH TUBE 8229308J NIM EMG 8MM ROHS	8229308J*
ENDOTRACH TUBE 8229506 CONT EMG 6MM ROHS	8229506
ENDOTRACH TUBE 8229507 CONT EMG 7MM ROHS	8229507

ENDOTRACH TUBE 8229508 CONT EMG 8MM ROHS	8229508

**Note: Medtronic Japan uses IFUs translated to Japanese for products 8229306J, 8229307J, and 8229308J, which are only distributed in Japan, but the products are consistent with products 8229306, 8229307, and 8229308, respectively. The 'J' versions of the tubes have a blue pigment whereas the non-'J' versions have a white pigment. Additionally, the 'J' versions are only sold/distributed in Japan.*

Distribution reports for the devices in scope from 31-Mar-2020 to 20-May-2024 can be found in Attachments B and C. The total distributed devices are as follows:

Table 2: Distribution for products listed in Table, from 31-Mar-2020 to 22-Jan-2024 and 23-Jan-2024 to 20-May-2024.

Region	Distributed from 31-Mar-2020 to 22-Jan-2024	Distributed from 23-Jan-2024 to 20-May-2024
United States (US)	120,929	4,052
Latin America	6,299	362
Canada	13,162	470
Europe/Middle East/Africa (EMEA)	108,762	7,870
Asia Pacific (APAC)	40,619	3,422
Greater China	567,102	16,447
Total	856,873	32,623

Was a Sales Database Query Used?

☒ Yes:

Table 3: Sales Database Query Details

Query Used	ENT World Wide Sales Sourced from SAP R3 : 366187497
Date of Query	21-May-2024
Date Range Queried	31-Mar-2020 to 22-Jan-2024; 23-Jan-2024 to 20-May-2024
Data Source	Business Objects
Fields Pulled	N/A
Filters Used	Filtered for CFNs 8229306; 8229306J; 8229307; 8229307J; 8229308; 8229308J; 8229506; 8229507; 8229508

☐ Not applicable, Rationale: [Explain why the issue did not require a sales query.]

Are any device subsets at higher risk?

☐ Yes. Subsets:

☒ No

Rationale: This issue is related to overinflation of the cuff, and all the devices considered in-scope share the same basic construction, materials, instructions for use, and potential for overinflation of cuff. While some distributed devices may contain different labeling from the different revisions of IFU over time, there were no notable design or manufacturing changes that would indicate a subpopulation of devices would be at higher risk.

Depending on the event date of complaints, additional information for safety mitigations through the safety notice associated with FA1255 Phase I or Phase II may have been available to the user. However, D00644849 Rev D concluded that FA1255 Phase I was not effective at mitigating risk and therefore will not be analyzed separately in this IIA. Since FA1255 Phase II has not been assessed for effectiveness separately, event dates after 23-Jan-2024 will be analyzed separately from the overall complaint rate prior to 23-Jan-2024.

Complaints:

Table 4: Airway obstruction complaints potentially related to silicone cuff overinflation, from 31-Mar-2020 to 22-Jan-2024 and 23-Jan-2024 to 20-May-2024

As of Date:	**Total Number of Complaints Related to Issue**:		
Complaint Event Date	**Number of Complaints**	**Number of Complaint Products**	**Number of Complaints with Regulatory Reports**
31-Mar-2020 to 22-Jan-2024	73	80	65
23-Jan-2024 to 20-May-2024	4	4	4
31-Mar-2020 to 20-May-2024	77	84	69

Was a Complaint Handling System Query Used?

☒ Yes:

Query Used	All complaints report
Date of Query	22-May-2024
Date Range Queried	31-Mar-2020 to 20-May-2024
Data Source	Global Complaint Handling (GCH)
Fields Pulled	GCH Family: XOM215 - NIM EMG Tube-Non-Specified-Type

	XOM215-03-01 - NIM Contact Endotracheal Tube XOM215-03-01 - NIM Standard Endotracheal Tube
Filters Used	Filtered for applicable RFR Codes: ALLEGED ADVERSE EVENT/NO MALFUNCTION, BLOCKED, CUFF BALLOON ISSUE, LEAK, MALFORMED, NOT WORKING PROPERLY, TEXTURE TOO HARD/RIGID/ROUGH, TEXTURE TOO SOFT/SMOOTH, VENTILATION ISSUE, WON'T INFLATE/DEFLATE; CUFF BALLOON OVER-INFLATED Performed Key Word Search in Event Description: Blocked, Ventilate/Ventilation, Herniated, Covered

After the above report was generated, resulting complaints were read by Quality and Medical Safety and the following inclusion/exclusion criteria was used to identify complaints related the hazardous situation of "Patient exposed to compromised airway/airway obstruction."

Inclusion Criteria:

- Excess intracuff pressure, including greater than 25 cmH2O pressure.
- Airway blockage/inability to ventilate without being linked to a different cause.
- Excess volume of air added in description (greater than 5 cc at a minimum.)
- Excess ventilator pressure, including if situation is improved by replacing tube/deflating cuff.
- Any detail in complaint description suggesting cuff was overinflated during intubation.
- Any detail in complaint description suggesting cuff was herniating over the murphy eye.

Exclusion Criteria:

- Leaky valves.
- Event unrelated to ventilation/blocked airway.
- Ventilation problems where event points to an unrelated cause.
- Overinflation of cuff prior to use, during testing of cuff.

☐ Not applicable:

Section 2: Health Hazard Analysis (HHA) Section

Section 2.1: Hazard / Harm / Other Factors

Hazard and Hazardous Situation:

- Risk ID PRA_NIM_12540 from PRA D00847575 Rev. G
  - Hazard: Functionality / Loss of Functionality
  - Hazardous Situation: Patient exposed to compromised airway/airway obstruction (Silicone)
- This hazardous situation is readily detectable in that the patient experiencing airway obstruction would exhibit signs including:
  - Decreased oxygen saturation in the blood and increased ventilation pressure due to extra force being required to "push" the air into the lungs, both which would be displayed on the patient monitor in real time. Monitors keeping track of patient vital signs (oxygen saturation (O2), heart rate, respiratory rate, etc.) are standard practice in healthcare facilities and are always used with patients under general anesthesia so that healthcare professionals can react quickly if something were to alert them of an issue.

Harm(s):
A blocked endotracheal EMG Tube has the potential to result in a cascade of events to occur that range in severity from negligible to catastrophic if the issue is not resolved in a timely manner. If a blocked airway is observed, the most reasonably foreseeable action would be for the user to identify the issue immediately and most commonly remove some of the air from the tube cuff, reposition the tube or replace the EMG tube with a backup device. If the airway is blocked for an extended period, the patient may experience hypoxia, cyanosis, respiratory arrest, cardiac arrest, cardiopulmonary resuscitation, and ultimately brain injury or death. A delay to the resolution of a blocked airway by correcting the patient's symptoms would directly exacerbate the outcome.

The device PRA, D00847575 Rev. D, lists the following potential harms as related to the issue of an overinflated cuff extending beyond the end of the endotracheal tube and blocking the patient's airway:

- Airway Obstruction
- Unintended Extubation
- Bronchospasm
- Hypoventilation
- Oxygen Saturation, Low
- Hypoxia
- Respiratory Distress
- Abnormal Blood Gas Measurements
- Cyanosis
- Apnea
- Respiratory Arrest
- Cardiac Arrest
- Brain Injury

Are any subpopulations of patients at higher risk?

☐ Yes. Subpopulations:

☒ No

Rationale: The potential hazardous situations described in this IIA occur within the operative setting in which patients are administered anesthesia (e.g., general, monitored anesthesia care [MAC]) commensurate with the needs of the procedure they are undergoing. In the context of any surgical procedure, there may be individual characteristics and comorbidities that makes some patients more susceptible to the impacts of a blocked EMG tube; however, these patients are incorporated in the overall distribution of patients undergoing procedures and assessed in totality of the overall risk assessment below.

Exacerbating Factors:

- If the healthcare provider does not anticipate a patient's unique anatomy or overinflates the cuff contradictory to the IFU, comorbidities such as heart disease, kidney failure, obesity, and increased intracranial pressure may exacerbate the effects of airway blockage.
- Over-inflation is the cause of the cuff herniation, and a delay to react to the occluded airway exacerbates the issue and may result in a cascade of events that has the potential to result in a higher severity of harm to the patient.

- Anesthesia providers do not typically expect cuff overinflation to cause an airway obstruction and may look for other sources of obstruction as part of their diagnostic algorithm to restore ventilation. Mucous plugs in the tube, a leak in the airway circuit, or bronchospasm are suspected first.

Mitigating Factors:

- Physicians and anesthesiologists are trained in correctly intubating patients with standard endotracheal tubes. The difference between a standard tube and an EMG tube is that EMG tubes have electrodes included for nerve monitoring; the first indication for both design of tube being to maintain a patent airway. It is anticipated that training for intubations with any type of endotracheal tube would be the same; the minimum amount of air required to create an adequate seal between the trachea and cuff should be used. If standard intubation practice is adhered to, the reported issue of a herniated cuff would not likely be experienced.

Mitigation Priority	Existing Mitigations	Evidence (e.g., document sources) or Rationale when not applicable
Design	The tubes are tested to ISO 5361. Specifically, testing for cuff herniation as described in Annex E of ISO 5361:2023 is conducted during design verification (DVe.)	An example of such testing is documented in 12-08-30, NIM EMG Tube 6mm 8229306J 100% Ethylene Oxide Endotracheal J-Tube Design.
Information for Safety	• From the 'Warnings – EMG tubes' section, bullet 6: 'Inflation of the cuff by "feel" alone is not recommended since resistance is an unreliable guide during inflation. Use less than 5mL of air to inflate and verify intracuff pressure using a pressure monitoring device. • From the 'Warnings – EMG tubes' section, bullet 7: 'Do not overinflate the cuff. Overinflation can result in tracheal damage, rupture of the cuff with subsequent deflation, or in cuff distortion which may lead to airway blockage.' • From the 'Warnings – EMG tubes' section, bullet 8: 'Minimal Occluding Volume or Minimum Leak techniques, using a 5mL syringe, should be used in conjunction with an intracuff pressure measuring device in selecting the sealing pressure. Cuff pressure should continue to be monitored thereafter, and any deviation from the selected seal pressure should be investigated and corrected immediately.' • From the 'Warnings – EMG tubes' section, bullet 20: 'If airway obstruction is encountered immediately deflate the cuff and attempt to recover ventilation. If ventilation cannot be re-established: ○ 1. Extubate the EMG endotracheal tube from the patient.	IFU M040175C001 Rev. C

	○ 2. Re-establish ventilation with Bag Valve Mask (BVM) or Laryngeal Mask Airway (LMA). ○ 3. Re-intubate with a new non-silicone (PVC) endotracheal tube and establish airway or alternatively, if surgically needed, re-intubate with a new EMG endotracheal tube. If reintubating with a new EMG endotracheal tube, it is imperative to: ▪ i. use less than 5mL of air to inflate the cuff and verify intracuff pressure using a pressure monitoring device; or ▪ ii. use Minimal Occluding Volume or Minimum Leak techniques using a 5mL syringe.' • From the 'Precautions' section, bullet 3: 'It is strongly recommended that the surgeon consult with the attending licensed medical practitioner who will be administering anesthesia prior to the use of EMG monitoring to review EMG monitoring techniques, goals and the effects of the administration of anesthesia on neuromuscular activity.' • From the 'Precautions' section, bullet 10 'The use of Nitrous Oxide as an anesthetic agent should be avoided as this gas can diffuse into the EMG ET Tube (silicone) cuff resulting in significant increase in cuff pressures which may increase cuff herniation. If Nitrous Oxide must be used, it should only be used with continuous pressure monitoring and careful attention to keep the cuff pressure under 25cm of H2 O pressure.'	

Detectability:

- This hazardous situation is readily detectable in that the patient experiencing airway obstruction would exhibit signs including:
  - Decreased oxygen saturation in the blood and increased ventilation pressure due to extra force being required to "push" the air into the lungs, both which would be displayed on the patient monitor in real time. Monitors keeping track of patient vital signs (oxygen saturation (O2), heart rate, respiratory rate, etc.) are standard practice in healthcare facilities and are always used with patients under general anesthesia so that healthcare professionals can react quickly if something were to alert them of an issue.

Severity of Harm:

☒ Harm Severity 5 (Catastrophic) scenario: A blocked airway, if not addressed and resolved in a timely manner, has the potential to result in a catastrophic injury such as cardiac or respiratory arrest or a brain injury resulting in cessation of life.

☒ Harm Severity 4 (Critical) scenario: If not resolved in a timely manner a blocked airway may result in hypoxia, respiratory distress, cyanosis, cardiac arrest, or an irreversible brain injury, all of which are life-threatening, may be permanent and would require medical intervention to preclude a catastrophic event.

☒ Harm Severity 3 (Major) scenario: There is the potential for hypoxia, hypoventilation, or abnormal blood gas measurements to require major intervention to resolve if the airway of the EMG tube is blocked; this impact would be considered temporary in nature or a reversable patient impact.

☒ Harm Severity 2 (Minor) scenario: An unintended extubation or minor medical intervention, such deflating and repositioning the cuff of the endotracheal tube, may be required if the cuff of the tube has been over-inflated, resulting in clinical symptoms such as low oxygen saturation.

☒ Harm Severity 1 (Negligible) scenario: If the EMG Tube is found to be occluded during the intubation process prior to an airway being established, replacing the tube with a back-up or adjusting the volume of the cuff would be considered a negligible impact.

☒ No Harm scenario: If the EMG tubes are used per standard intubation protocol and the IFU warnings are followed, there would be no anticipated patient impact.

Predicted/Observed rate of occurrence of this issue and number of occurrences

- Risk ID PRA_NIM_12540 from PRA D00847575 Rev. G
  - Hazard: Functionality / Loss of Functionality
  - Hazardous Situation: Patient exposed to compromised airway/airway obstruction (Silicone)

Predicted P1: 1.45E-4

Observed P1 Pre-FA1255 Phase II (31-Mar-2020 to 22-Jan-2024): 9.34E-5

Observed P1 Post-FA1255 Phase II (23-Jan-2024 to 20-May-2024): 1.2E-4

Observed P1 Overall (31-Mar-2020 to 20-May-2024): 9.44E-5

P2 Calculations:

Description of P2 data range	P2 Sev 1	P2 Sev 2	P2 Sev 3	P2 Sev 4	P2 Sev 5
Observed from 31-Mar-2020 to 22-Jan-2024	0.013	0.488	0.413	0.05	0.038
Observed from 23-Jan-2024 to 20-May-2024	0.25	0.25	0.5	0	0

Observed from 31-Mar-2020 to 20-May-2024	0.024	0.476	0.417	0.048	0.036
Predicted	0.012	0.512	0.391	0.084	0.001

Ph Calculations:

Description of Ph data range	Ph Sev 1	Ph Sev 2	Ph Sev 3	Ph Sev 4	Ph Sev 5
Observed from 31-Mar-2020 to 22-Jan-2024	1.17E-6	4.55E-5	3.85E-5	4.67E-6	3.50E-6
Observed from 23-Jan-2024 to 20-May-2024	3.07E-5	3.07E-5	6.13E-5	0	0
Observed from 31-Mar-2020 to 20-May-2024	2.25E-6	4.50E-5	3.93E-5	4.50E-6	3.37E-6
Predicted	1.74E-6	7.42E-5	5.67E-5	1.22E-5	1.45E-7

Rationale for method of occurrence probability calculation:

- The method used for occurrence probability calculation was quantitative using guidance from D00811701, P1 and P2 Calculation Guidance. Details of calculations can be found in Attachment D.
- The denominator used is the raw sales data that corresponds with the same timeframe ranges of the event dates of complaints. A modifier was not used on the raw sales data because these products are known to be in high demand, with generally limited time between sale and usage. Additionally, products sold prior to this timeframe may have been involved in the complaints during the timeframe.
- Four years was the timeframe selected as many devices were distributed/used (856,873) ensuring statistical significance and reliability in the analysis, and there was no data indicating a more specific timeframe would be more relevant as no special cause for this issue was identified.
- A specific timeframe of interest was identified to calculate risk, during the post-FA1255 Phase II timeframe to analyze its effectiveness.

Summary of risk(s) considering all harms and occurrences in above sections:

Patient Populations	**Hazard**	**Probability of Hazardous Situation** (p1)	**Harm**	**Probability of Hazardous Situation Leading**	**Probability of Harm** (p1xp2)	**Harm Occurrence Category** *(As defined by the OU)*	**Severity Rank of Harm** *(per 034)*	**Risk Zone** *(per OU risk matrix)*

				to Harm (p2)				
General, Severity 1	Loss of Functionality	9.44E-5	Airway Obstruction	0.024	2.25E-6	1	1	1
General, Severity 2	Loss of Functionality	9.44E-5	Airway Obstruction	0.476	4.50E-5	2	2	1
General, Severity 3	Loss of Functionality	9.44E-5	Airway Obstruction	0.417	3.93E-5	2	3	1
General, Severity 4	Loss of Functionality	9.44E-5	Airway Obstruction	0.048	4.50E-6	1	4	2
General, Severity 5	Loss of Functionality	9.44E-5	Airway Obstruction	0.036	3.37E-6	1	5	2

Other Factors:

- While the initiating complaint (PE 704727472, MDR 1045254-2021-00684) associated with patient death included death in the event description, the incident occurred in the operating room while the patient was intubated with the EMG tube, after which they were resuscitated and were moved to the ICU. A severity of 4 was assigned to that event; the death was not directly attributable to use of the device as the coding episode leading to death was several days later in an unrelated incident.
- Complaints involving brain death or a vegetative state (PE 0705835537, MDR 1045254-2023-00860 and PE 0705363422, MDR 1045254-2023-00033) patient outcome were assigned a severity of 5. Patients who are pronounced brain dead or in a vegetative state are clinically dead, their brain is not functioning and is not able to sustain life.

Section 2.2: HHA Summary Section

Safety Risk:

Occurrence		Severity Rating				
		Negligible	Minor	Major	Critical	Catastrophic
Occurrence Rate	Rating	1	2	3	4	5
1 to >0.01 Rate > 1 in 100	5					
0.01 to >0.001 1 in 100 ≥ Rate > 1 in 1000	4					
0.001 to >0.0001 1 in 1000 ≥ Rate > 1 in 10,000	3					
0.0001 to >0.00001 1 in 10,000 ≥ Rate > 1 in 100,000	2	Post-Phase II	Pre-Phase II Overall Post-Phase II [Obstruction]	Pre-Phase II Overall Post-Phase II [Obstruction]	[Obstruction]	
0.00001 ≥ P 1 in 100,000 ≥ Rate	1	Overall Pre-Phase II [Obstruction]			Pre-Phase II Overall	Pre-Phase II Overall [Obstruction]

"Pre-Phase II": *Observed* value during the pre-FA1255 Phase II Timeframe (from 31-Mar-2020 to 22-Jan-2024)
"Post-Phase II": *Observed* value during the post-FA1255 Phase II Timeframe (from 23-Jan-2024 to 20-May-2024)
"Overall": *Observed* value including both the Pre-Phase II and Post-Phase II Timeframes (from 31-Mar-2020 to 20-May-2024)
"[Obstruction]": *Predicted* value from the risk management file

No Risk ☐ | **Low/Risk Zone 1** ☒ | **Medium/Risk Zone 2** ☒ | **High/Risk Zone 3** ☐

Risk Summary and Acceptability

If the EMG tube is used in accordance with the IFU, including not overinflating the cuff, cuff herniation would not be anticipated. If the user makes a use error that causes the cuff to herniate over the Murphy eye or end and obstructs the patient's airway, there is potential for a cascade of events which without timely health care provider response, may ultimately result in death due to a lack of oxygen.

Based on this assessment and thorough review of reported events and calculate Ph, FA1255 Phase II was determined to not be effective at mitigating the risk and additional action to mitigate risk is required.

The risk of the issue is determined to be UNACCEPTABLE based on the rationale below:

Characterization	Impact on Acceptability
• Does the issue and risk assessment indicate immediate actions required to reduce the risks of imminent safety or regulatory concerns?	• Yes, in spite of the additional action taken through FA1255 Phase II, additional action is required to reduce risks of imminent safety.
• Is the product conforming to applicable regulatory	• Yes

Section 2.2: HHA Summary Section

requirements, safety standards, intended use and design specifications?	
• Are there meaningful and reasonable risk reduction actions (including field safety notification pending a design change, product removal or corrections), or an interim control that can be or needs to be implemented to mitigate the risk of product under investigation?	• Yes, a product recall will meaningfully reduce risk
• Depending on the complexity of the issue, are the risk acceptance and controls different in the subgroups (e.g., patient sub-groups, devices in the use, device in distribution, device in production) of the impacted products?	• There are no patient subgroups identified at higher risk. Different devices in the field may have different revision of IFU, but given both FA1255 Phase I and Phase II were ineffective at mitigate risk all devices regardless of IFU are considered in scope.
• Does risk from this issue affect overall safety such that the benefits no longer outweigh the risk?	• Yes, product recall is recommended as the risk of patient death outweighs the benefits the silicone-cuff design provides.
• Other potential considerations: ○ Risks from equivalent or similar devices ○ State of the Art	• Risks from similar devices such as PVC-based tubes are lower due to the cuff not having the tendency to overinflate in the same manner as tubes with silicone-based cuffs.

Section 3: Actions

Safety Risk

- Mitigations included in IFU M040175C001 Rev. C, video training, testing the tubes per ISO 5361, and standard of care when intubating patients both contribute to this issue being a low patient safety risk in the field.
- The risk is determined to be unacceptable based on an inability to demonstrate that the risks for overinflation has been reduced as far as possible and the ineffectiveness of FA1255. Additional action is required.
- Current risk is UNACCEPTABLE, additional action to remove product from the field is recommended.

Clinical Benefits/Loss of Patient Benefits – with consultation from Medical Safety

- Polyvinyl chloride (PVC) tubes tendency to kink during surgery is well documented in clinical literature.[3-6] This can also be exacerbated by increased temperatures that the tube is exposed to when in the patient's anatomy over time.[7] The Standard and Contact EMG tubes are more resistant to kinking due to its 302-grade steel coil in between the inner and outer silicon cannulas.[8] This gives the tube the ability to bend in acute angles without kinking.[9]
- Silicone tubes have a reduced frictional force against mucosa during intubation and the silicone cuff conforms better to the trachea as compared to PVC.[10,11]
- Loss of the benefit in cases where the reinforced Standard and Contact EMG tube may need to be used eliminates the ability to monitor for recurrent laryngeal nerve injury during various neck procedures. The incidence of post operative dysphonia (hoarse voice) is nearly 4%, the incidence of post operative dysphagia (difficulty in swallowing) is as high as 21%, and the incidence of surgeon related recurrent laryngeal nerve injury can occur in over 14% of cases where visual identification of the nerve alone is used.[12,13]

Compliance Impact

- The mitigations implemented through 510k K230320 were found to be ineffective in reducing the risk-benefit analysis, leading to an indefinite voluntary recall. This decision has moderate compliance risk since current product in the field does not comply with safety requirements set forth in 21 CFR and other potential regional regulations. The recall will cease distribution globally, affecting regulatory submissions (i.e. license deactivation).

CAPA assessment/request recommended?	☐ Yes: ☒ No, Rationale: CAPA related to this issue is already open, 653773 EMG Tube Cuff Overinflated
PHO Initiated?	☒ Yes: D01115601 ☐ No, Rationale:
Initiate actions to manage issue/mitigate risk in the field?	☒ Yes • Type of recommended action: -- Product removal ☐ No, Rationale: ☐ No, a follow up revision will be required to finalize this document, based on limited information available at this time. **System that will contain evidence of completion:** FA1255 **OU review board decision** FCA Action Required – Decision made on 23 May 2024. Board Members Contributing to Decision: Jason Busch – Vice President Quality & Regulatory ENT Gabriela Moreira – Regulatory Affairs Director Scott Carpenter – Medical Safety Director

	Danyel Racenet – Vice President R&D ENT Ricardo Bedoya – Senior Legal Director Amy Van Sach – OU President
IIA Reassess Threshold	• Per Data Monitoring Plan D00637893 Rev E, escalation to Field Issue Risk Evaluation (FIRE) Triage is required for complaints coded with RFR Code NSCE006 Cuff Balloon Over-Inflated and NSCE005 Ventilation that have been confirmed to be potentially related to overinflated cuff. **System that will contain evidence of completion**: FIRE Triage PR in TrackWise
Risk Management Files Update (if applicable)	☐ Yes ☒ No, Rationale: • The risk of this issue was identified in the risk management file, Risk ID PRA_NIM_12540 from PRA D00847575 Rev. G **System that will contain evidence of completion**: N/A
Update of Instructions for Use (if applicable) recommended?	• The risk for this issue was disclosed in the IFU and labeling, no update to instructions for use is recommended. **System that will contain evidence of completion:** N/A
EU MDR Article 88 Trend Report Decision	Check appropriate boxes and assess the impact to the benefit-risk profile for this issue to determine if EU MDR Article 88 Trend Reporting is required. This section must be updated with each IIA revision. Criteria: ☐ The issue is related to a statistically significant increase in the frequency or severity of fielded product complaints ☒ The issue includes Conformité Européene (CE) marked devices ☐ This assessment did not recommend action in the field ☐ Complaints for this issue are typically not EEA+CH+TR vigilance reportable Impact to Risk Benefit assessment indicates (e.g., consider a significant change in occurrence or a risk zone shift): ☐ Significant adverse impact to benefit risk. ☐ No significant adverse impact to benefit risk. Rationale: If ALL items are checked, then submit a trend report. If any items are unchecked and the benefit-risk profile is not significantly and adversely impacted, then trend reporting is not required. **System that will contain evidence of completion**: N/A, trend reporting is not required.
Notifications as required by actions above	**<u>Complaint Handling:</u>**

	☒ Yes. Notification to Complaint Handling is required upon initial IIA release and all subsequent revisions. **System that will contain evidence of notification:** Agile MAP, RCH00444643 **Patient Safety Risk Management Oversight Board's (PSRB) Notification Required?** ☐ Yes. Notification to the Head of Risk Management COE for PSRB review. **System that will contain evidence of notification to PSRB:** N/A: Escalation conditions are not met, FCA recommended. ☒ No. Rationale: The IIA does not meet the escalation criteria per 034 Product Risk Management. **FCA Team:** ☒ Yes. Field Corrective Action is recommended. Notify Field Corrective Action team responsible for FCA planning per 004, Govern Field Corrective Actions ☐ No. Not applicable as FCA is not recommended. **System that will contain evidence of notification to FCA Team:** FA1255

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Section 4: Approval Requirements

Required IIA Approvers
Function/Roles **At minimum, the following functions are required: Engineering, Quality, Regulatory Affairs, Medical Safety Clinician.** **Note**: one individual may potentially fulfill multiple approver functions.
Author *Joseph Teixeira, Post-Market Surveillance Engineering Manager*
OU Quality Leader *Jason Busch, Vice President Quality and Regulatory ENT*
Regulatory Management Representative *Gabriela Moreira, Regulatory Affairs Director*
Medical Safety Clinician *Michelle Alford, Senior Medical Safety Clinician*
Additional Subject Matter Expert(s) (If different from Author) *Jennifer Raines, Product Development Director* *Monika Budhabhatti, Senior Quality Systems Director*
Medical Safety Director* *Scott Carpenter, Medical Safety Director* *Approval Signature not required for IIAs that do not require actions to manage issue/mitigate risk in the field and have No Patient Harm * If the "Medical Safety Clinician" is already represented by a Medical Safety Director, there is no requirement for a second Medical Safety Director's approval

Medtronic

Medtronic Reference Number: FA1255

Date: 15-July-2024

[SENT VIA EMAIL ONLY]

To:

ANSM

RE: ANSM reference number R2213861

Medtronic reference number FA1255, 808428436

Dear Sir/Madam,

Thank you for your request on July 12, 2024, with respect to the reference number stated above. Please find answers to your questions below. Questions are in **bold text** and responses are in plain text.

1. Causes of the identified problem

The cause of the identified problem is that the silicone-based cuff design of the Standard and Contact EMG Endotracheal tube allows continued cuff expansion when overinflated beyond recommended sealing pressure, which can lead to the overinflated cuff covering the open end of the tube and/or Murphy Eye, leading to airway blockage. This tendency for overinflation is unique to the silicone-based cuff design, as the silicone elastomer is a very compliant material and does not resist continued air injection in the same manner that alternative designs, such as PVC-based cuffs can.

2. Why is the recall limited to these batches?

The recall applies to all non-expired distributed product.

3. Does this recall risk creating a supply disruption?

There are currently alternative products available.

We appreciate the opportunity to address your concerns. Please let us know if you have any additional questions.

With kind regards,

Winston Fredericks
MDR/Vigilance Specialist
Medtronic Neurosciences