

Medical Surgical

Acute Care and Monitoring
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Urgent Medical Device Correction

Microstream™ Advance Neonatal-Infant and Adult-Pediatric Intubated CO₂ Filter Line, Microstream™ Luer Adult-Pediatric Intubated CO₂ Filter Line and Microstream™ Luer Adult-Pediatric Airway Adapter Sampling Line Update to the Instructions for Use (IFU)

17 February 2025

Dear Risk Manager, Director of Respiratory Care, Director of Anesthesiology:

The purpose of this letter is to advise you that Medtronic is issuing an update to the Instructions for Use (IFU) for Microstream™ Advance Neonatal-Infant and Adult-Pediatric Intubated CO₂ Filter Line, Microstream™ Luer Adult-Pediatric Intubated CO₂ Filter Line and Microstream™ Luer Adult-Pediatric Airway Adapter Sampling Line devices.

This labeling update follows receipt of ten (10) reports from customers stating that difficulty or inability in disconnecting the adapter from the patient's endotracheal tube to perform a procedure was encountered, resulting in a delay to treatment and/or unintended extubation. You are receiving this letter because Medtronic records indicate that these devices were shipped to your facility.

Issue Description:

Our investigation of the customer reports did not identify any anomaly or non-conformance with the product. All devices were manufactured to the specifications set for the product. The existing IFU includes a note instructing users to ensure that the airway adapter can be easily attached and detached from the breathing circuit/tubing during setup before proceeding.

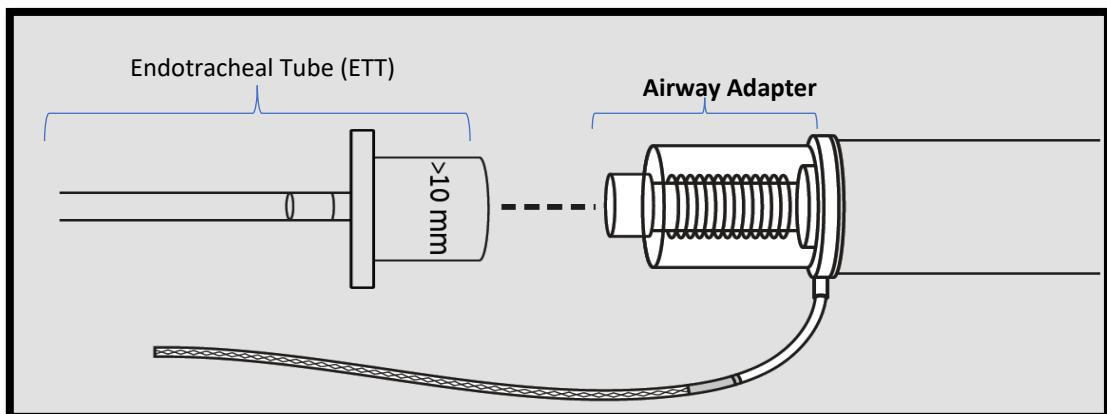


Diagram depicting airway adapter/endotracheal tube (ETT) attachment for Neonatal-Infant Intubated CO₂ Filter Line

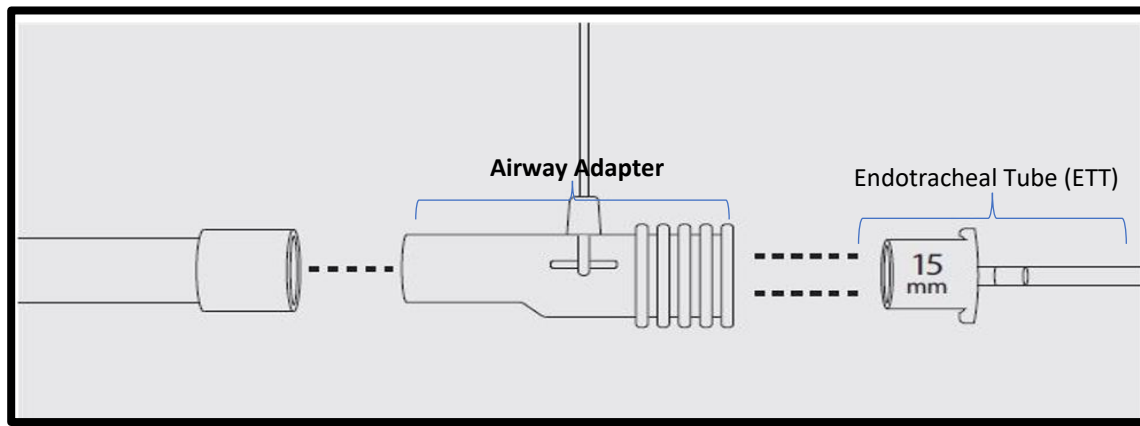


Diagram depicting airway adapter /endotracheal tube (ETT) attachment for Adult-Pediatric Intubated CO₂ Filter Line

Risk to Health:

The inability to, or difficulty in disconnecting the adapter from the endotracheal tube to perform a procedure such as suctioning or administration of airway medication such as surfactant can result in a delay to treatment and unintended extubation in order to perform the required procedures. The potential exists for respiratory failure, hypoxia, aspiration, and/or low oxygen saturation if a practitioner is unable to disconnect the adapter. The reported rate of occurrence for the inability to or difficulty in disconnecting the adapter is 0.00004%.

Patient Management:

For Microstream™ Advance Neonatal-Infant and Adult Pediatric Intubated CO₂ Filter Line, Microstream™ Luer Adult-Pediatric Intubated CO₂ Filter Line and Microstream™ Luer Adult-Pediatric Airway Adapter Sampling Line devices that are currently in use on patients, continue to use these devices following the instructions provided in the IFU.

As noted in the IFU, during setup, ensure that the airway adapter can be easily attached and detached from the breathing circuit/tubing before proceeding. The airway adapter can be connected to the breathing circuit/tubing in a variety of configurations. These include a direct connection to the endotracheal tube.

Actions Medtronic is taking:

In September 2025, Medtronic will issue an update to the Instructions for Use (IFUs) for the devices listed on Attachment A, to include an Adverse Events section stating:

Adverse events associated with attaching and detaching the airway adapter from the breathing circuit are listed in descending order of severity: unintended extubation, respiratory failure, hypoxia, low oxygen saturation, aspiration/inhalation and delay to treatment. Any serious incident related to device use that may occur should be reported immediately to the manufacturer, the local competent authority, and any other regulators as required.

Actions you should take:

- Continue using the Microstream™ Advance Neonatal-Infant and Adult Pediatric Intubated CO₂ Filter Line, Microstream™ Luer Adult-Pediatric Intubated CO₂ Filter Line and Microstream™ Luer Adult-Pediatric Airway Adapter Sampling Line devices.
- Pass on and post this notice for all those who need to be aware within your organization and to any organization where the affected product has been transferred or distributed.
- Please complete and return the enclosed Customer Confirmation Form to rs.gmbmitgfca@medtronic.com even if you **do not** have unused inventory.

Additional Information:

Medtronic is communicating this information to the U.S Food and Drug Administration.

Local contact details (US):

Adverse reactions or quality problems experienced with this product should be reported to FDA and Medtronic:

- Online at <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm> (form available to fax or mail), or
- Call FDA (800) FDA-1088
- Call Medtronic Quality Assurance at 800-255-6774 option 1, then option 1

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 Representative or Customer Service at 800-962-9888, Option 2.

Sincerely,



Dan Howk

Vice President, Quality

Acute Care and Monitoring

Enclosures:

Attachment A: List of affected product codes

Customer Confirmation Form

**Attachment A:
List of Affected Products**

CFN	GTIN	Product Description	Instructions For Use	Note
006324	20884521551692 10884521551695	MICROSTREAM FilterLine® H Set Infant/Neonatal CO ₂ Sampling Line and Airway Adapter for Humid Environments	006147 Rev N FilterLine H Set & VitaLine H Set Infant/Neonatal	*
007738	20884521216010	MICROSTREAM FilterLine® H Set Long Infant/Neonatal CO ₂ Sampling Line and Airway Adapter for Humid Environments		
010807	20884521551920 10884521551923	MICROSTREAM VitaLine™ H Set Infant/Neonatal CO ₂ Sampling Line and Airway Adapter for Humid Environments		
007737	20884521551784	MICROSTREAM FilterLine® H Set Long Adult- Pediatric CO ₂ Sampling Line and Airway Adapter for Humid Environments	MQ04616 Rev N FilterLine Sets & VitaLine Sets Adult/Pediatric	*
007768	10884521554023	MICROSTREAM FilterLine® Set Long Adult- Pediatric CO ₂ Sampling Line and Airway Adapter		
010579	10884521551985	MICROSTREAM FilterLine® Set Adult-Pediatric CO ₂ Sampling Line and Airway Adapter		
010580	10884521551992 10884521184770	MICROSTREAM FilterLine® H Set Adult-Pediatric CO ₂ Sampling Line and Airway Adapter for Humid Environments		
010787	10884521554085 10884521552029	MICROSTREAM VitaLine™ H Set Adult-Pediatric CO ₂ Sampling Line and Airway Adapter for High Ambient Humidity X25		
015016	10884521552296	MICROSTREAM FilterLine® Set Adult-Pediatric CO ₂ Sampling Line and Airway Adapter for Humid Environments		
015021	10884521552340	MICROSTREAM FilterLine® Set Adult-Pediatric CO ₂ Sampling Line and Airway Adapter		
XS04620	30884521551989 20884521551982	MICROSTREAM FilterLine® Set Adult-Pediatric CO ₂ Sampling Line and Airway Adapter		
XS04624	30884521551996 20884521551999	MICROSTREAM FilterLine® H Set Adult-Pediatric CO ₂ Sampling Line and Airway Adapter for Humid Environments		

CFN	GTIN	Product Description	Instructions For Use	Note
006324COV	10884521531574	CapnoLine™ Neonatal-Infant Intubated Filter Line with Microstream™ Technology H, Length 7' (2.0 m)	10129497 Rev B Filter Line Sets Adult/Pediatric & Infant/Neonatal	*
XS04620COV	10884521531529	CapnoLine™ Adult-Pediatric Intubated Filter Line with Microstream™ Technology Length 7' (2.0 m)		
XS04624COV	10884521531536	CapnoLine™ Adult-Pediatric Intubated Filter Line with Microstream™ Technology H, Length 7' (2.0 m)		
010989	20884521762159 20884521552033 10884521762152	Microstream™ Luer Adult-Pediatric Airway Adapter	PT00156356 Rev A Microstream™ Luer Adult-Pediatric Airway Adapter Sampling Line	**
010991	10884521554092	Omnistream™ CO ₂ Sampling Line X25	011582 Rev E Omnistream™ Airway Adapter and CO ₂ Sampling Line	*
012495	10884521554122	OmniVentLine™ Set Adult-Pediatric CO ₂ Sampling Line and Airway Adapter	012808 Rev E OmniVentLine Set	*
QMVAI	10884521762329	Microstream™ Advance Adult-Pediatric Intubated CO ₂ Filter Line 2m/6.5ft Short-term use: Procedural/Emergency	PT00134333 Rev A Microstream Adv. Adult-Pediatric Intubated	*
QMVAIH	10884521762336	Microstream™ Advance Adult-Pediatric Intubated CO ₂ Filter Line 2m/6.5ft Extended Duration		
QMVIH	10884521762374	Microstream™ Advance Neonatal-Infant Intubated CO ₂ Filter Line 2m/6.5ft Extended Duration	PT00134354 Rev A Microstream Adv. Infant Intubated	*
MLAI	10884521762145	Microstream™ Luer Adult-Pediatric Intubated CO ₂ Sampling Line 2m/6.5ft Short-term use: Procedural/Emergency	PT00156355 Rev A Microstream Luer Intubated Adult Pediatric	**

MVAI	20884521761886 10884521761889	Microstream™ Advance Adult-Pediatric Intubated CO ₂ Filter Line 2m/6.5ft Short-term use: Procedural/Emergency	PT00156254 Rev A Microstream Advance Intubated Adult-Pediatric	**
MVAI100U	20884521761893 10884521761896	Microstream™ Advance Adult-Pediatric Intubated CO ₂ Filter Line 2m/6.5ft Short-term use: Procedural/Emergency		
MVAIH	10884521761919	Microstream™ Advance Adult-Pediatric Intubated CO ₂ Filter Line 2m/6.5ft Extended Duration		
MVAIH100U	10884521761926	Microstream™ Advance Adult-Pediatric Intubated CO ₂ Filter Line 2m/6.5ft Extended Duration		
MVAIHH	10884521762008	Microstream™ Advance Adult-Pediatric Intubated CO ₂ Filter Line 2m/6.5ft High Humidity		
MVAIHL	10884521761933	Microstream™ Advance Adult-Pediatric Intubated CO ₂ Filter Line 4m/13ft Extended Duration		
MVAIL	20884521761909 10884521761902	Microstream™ Advance Adult-Pediatric Intubated CO ₂ Filter Line 4m/13ft Short-term use: Procedural/Emergency		
MVAMSK	10884521783997	Microstream™ Advance Air Military Sample Kit CO ₂ Oral-Nasal Filter Line with O ₂ Tubing (MVAO) and Adult-Pediatric Intubated Filter Line, High Humidity (MVAIHH) 2m/6.5ft		
MVASK	10884521783980	Microstream™ Advance Adult Sample Kit CO ₂ Intubated Filter Line (MVAI) and CO ₂ Oral-Nasal Filter Line with O ₂ Connector (MVA) 2m/6.5ft		
ZMVAIH	20884521762258	Microstream™ Advance Adult-Pediatric Intubated CO ₂ Filter Line 2m/6.5ft Extended Duration		
ZMVAIHH	20884521762265	Microstream™ Advance Adult-Pediatric Intubated CO ₂ Filter Line 2m/6.5ft High Humidity		
ZMVAI	20884521771762	Microstream™ Advance Adult-Pediatric Intubated CO ₂ Filter Line 2m/6.5ft Short-term use: Procedural/Emergency		

MVIIH	20884521761985 10884521761988	Microstream™ Advance Neonatal-Infant Intubated CO ₂ Filter Line 2m/6.5ft Extended Duration	PT00156250 Rev A Microstream Advance Intubated Infant	**
MVIIHH	10884521762015 20884521762012	Microstream™ Advance Neonatal-Infant Intubated CO ₂ Filter Line 2m/6.5ft High Humidity		
MVIIHL	10884521761995	Microstream™ Advance Neonatal-Infant Intubated CO ₂ Filter Line 4m/13ft Extended Duration		
ZMVIIH	10884521762275	Microstream™ Advance Neonatal-Infant Intubated CO ₂ Filter Line 2m/6.5ft Extended Duration		

Notes:

* These products are no longer being manufactured. The IFU will not be updated.

** These IFUs are being updated to add the Adverse Events Section.