

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Oridion Medical 1987 Ltd. Microstream Sets

Recall Date	Product Description	Recalling Firm	Recall Reason
03/17/2025	FilterLine H Set & VitaLine H Set Infant/Neonatal Part Number: 006147 MICROSTREAM FilterLine H Set Infant/Neonatal CO2 Sampling Line and Airway Adapter for Humid Environments REF: 006324 MICROSTREAM FilterLine H Set Long Infant/Neonatal CO2 Sampling Line and Airway Adapter for Humid Environments REF: 007738 MICROSTREAM VitaLine H Set Infant/Neonatal CO2 Sampling Line and Airway Adapter for Humid Environments REF: 010807 FilterLine Sets & VitaLine Sets Adult/Pediatric Part Number: MQ04616 MICROSTREAM FilterLine H Set Long Adult-Pediatric CO2 Sampling Line and Airway Adapter for Humid Environments REF: 007737 MICROSTREAM FilterLine Set	Oridion Medical 1987 Ltd.	Neonatal-Infant and Adult-Pediatric CO2 Sampling Line/Airway Adapter/CO2 Oral-Nasal Filter Line/Intubated Filter (CO2) Line device users may experience difficulty/inability to disconnect adapter from endotracheal tube for procedures (e.g. suctioning), may cause treatment delay and/or unintended extubation, which could lead to respiratory failure, hypoxia, aspiration, and/or low oxygen saturation.

	Long Adult-Pediatric CO2 Sampling Line and Airway Adapter REF: 007768 MICROSTREAM FilterLine Set Adult-Pediatric CO2 Sampling Line and Airway Adapter REF: 010579 MICROSTREAM FilterLine H Set Adult-Pediatric CO2 Sampling Line and Airway Adapter for Humid Environments REF: 010580 MICROSTREAM VitaLine H Set Adult-Pediatric CO2 Sampling Line and Airway Adapter for High Ambient Humidity X25 REF: 010787 MICROSTREAM FilterLine Set Adult-Pediatric CO2 Sampling Line and Airway Adapter for Humid Environments REF: 015016 MICROSTREAM FilterLine Set Adult-Pediatric CO2 Sampling Line and Airway Adapter REF: 015021, XS04620 MICROSTREAM FilterLine H Set Adult-Pediatric CO2 Sampling Line and Airway Adapter for Humid Environments REF: XS04624 Filter Line Sets Adult/Pediatric & Infant/Neonatal Part Number: 10129497 CapnoLine Neonatal-Infant Intubated Filter Line with Microstream Technology H, Length 7 (2.0 m) REF: 006324COV CapnoLine Adult-Pediatric Intubated Filter Line with Microstream Technology Length 7 (2.0 m)		
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	REF: XS04620COV CapnoLine Adult-Pediatric Intubated Filter Line with Microstream Technology H, Length 7 (2.0 m) REF: XS04624COV Airway Adapter and CO2 Sampling Line Part Number: 01158 Microstream Luer Adult- Pediatric Airway Adapter REF: 010989 Omnistream CO2 Sampling Line X25 REF: 010991 OmniVentLine Set Part Number: 012808 OmniVentLine Set Adult- Pediatric CO2 Sampling Line and Airway Adapter REF: 012495 Microstream Adv. Adult- Pediatric Intubated Part Number: PT00134333 Microstream Advance Adult- Pediatric Intubated CO2 Filter Line 2m/6.5ft Short-term use: Procedural/Emergency REF: QMVAI Microstream Advance Adult- Pediatric Intubated CO2 Filter Line 2m/6.5ft Extended Duration REF: QMVAIH Microstream Adv. Infant Intubated Part Number: PT00134354 Microstream Advance Neonatal-Infant Intubated CO2 Filter Line 2m/6.5ft Extended Duration REF: QMVIIH Microstream Instructions for		
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	Use and Part Number used with - Product Description, REF: Microstream Luer Intubated Adult Pediatric Part Number: PT00156355 Microstream Luer Adult-Pediatric Intubated CO2 Sampling Line 2m/6.5ft Short-term use: Procedural/Emergency REF: MLAI Microstream Instructions for Use and Part Number used with - Product Description, REF: Microstream Advance Intubated Adult-Pediatric Part Number: PT00156254 Microstream Advance Adult-Pediatric Intubated CO2 Filter Line 2m/6.5ft Short-term use: Procedural/Emergency REF: MVAI Microstream Advance Adult-Pediatric Intubated CO2 Filter Line 2m/6.5ft Short-term use: Procedural/Emergency REF: MVAI100U Microstream Advance Adult-Pediatric Intubated CO2 Filter Line 2m/6.5ft Extended Duration REF: MVAIH Microstream Advance Adult-Pediatric Intubated CO2 Filter Line 2m/6.5ft Extended Duration REF: MVAIH100U Microstream Advance Adult-Pediatric Intubated CO2 Filter Line 2m/6.5ft High Humidity REF: MVAIHH Microstream Advance Adult-Pediatric Intubated CO2 Filter Line 4m/13ft Extended Duration REF: MVAIHL		
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	Microstream Advance Adult-Pediatric Intubated CO2 Filter Line 4m/13ft Short-term use: Procedural/Emergency REF: MVAIL Microstream Advance Air Military Sample Kit CO2 Oral-Nasal Filter Line with O2 Tubing (MVAO) and Adult-Pediatric Intubated Filter Line, High Humidity (MVAIHH) 2m/6.5ft REF: MVAMSK Microstream Advance Adult Sample Kit CO2 Intubated Filter Line (MVAI) and CO2 Oral-Nasal Filter Line with O2 Connector (MVA) 2m/6.5ft REF: MVASK Microstream Advance Adult-Pediatric IntubatedCO2 Filter Line 2m/6.5ft Extended Duration REF: ZMVAIH Microstream Advance Adult-Pediatric IntubatedCO2 Filter Line 2m/6.5ft High Humidity REF: ZMVAIHH Microstream Advance Adult-Pediatric IntubatedCO2 Filter Line 2m/6.5ft Short-term use: Procedural/Emergency REF: ZMVAI Microstream Instructions for Use and Part Number used with - Product Description, REF: Microstream Advance Intubated Infant Part Number: PT00156250 Microstream Advance Neonatal-Infant Intubated CO2 Filter Line 2m/6.5ft Extended Duration REF: MVIIH Microstream Advance Neonatal-Infant Intubated CO2		
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	Filter Line 2m/6.5ft High Humidity REF: MVIIHH Microstream Advance Neonatal-Infant Intubated CO2 Filter Line 4m/13ft Extended Duration REF: MVIIHL Microstream Advance Neonatal-Infant Intubated CO2 Filter Line 2m/6.5ft Extended Duration REF: ZMVIIH		
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Recall Class	Product Identification	Distribution	Affected Dates
II	Part Number: 006147 Revision: Rev N REF: 006324 UDI-DI: 20884521551692 Lot: C210417257 - D220211210 UDI-DI: 10884521551695 Lot: D191171644 - D210103472 REF: 007738 UDI-DI: 20884521216010 Lot: D191069375 - D211155459 REF: 010807 UDI-DI: 20884521551920 Lot: D200101284 - D210837166 UDI-DI: 10884521551923 Lot: D200101284, D200745037 Part Number: MQ04616 Revision: Rev N REF: 007737 UDI-DI: 20884521551784 Lot: C210417261 - D210729258 REF: 007768 UDI-DI: 10884521554023 Lot: C210417263 - D211046826 REF: 010579 UDI-DI: 10884521551985	186,500 units in California	February and prior

	Lot: D191171913 - D200744634 REF: 010580 UDI-DI: 10884521551992 Lot: D191171665 - D200434507 UDI-DI: 10884521184770 Lot: D200314310 REF: 010787 UDI-DI: 10884521554085 Lot: C210417265 - D220318806 UDI-DI: 10884521552029 Lot: D200101678 REF: 015016 UDI-DI: 10884521552296 Lot: S2003151 REF: 015021 UDI-DI: 10884521552340 Lot: S1911041 - S2104131 REF: XS04620 UDI-DI: 30884521551989 Lot: D191067442 - D211266886 UDI-DI: 20884521551982 Lot: D191067442 - D200640404 REF: XS04624 UDI-DI: 30884521551996 Lot: D191064978 - D220946384 UDI-DI: 20884521551999 Lot: D191064978 - D210307270 Part Number: 10129497 Revision: Rev B REF: 006324COV UDI-DI: 10884521531574 Lot: D200320382, D201260758 REF: XS04620COV UDI-DI: 10884521531529 Lot: D200322148, D200742380 REF: XS04624COV UDI-DI: 10884521531536 Lot: D200320376 Part Number: 01158 Revision: Rev E PT00156356 REF: 010989 UDI-DI: 20884521762159 Lot: C220975945 UDI-DI: 20884521552033		
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	Lot: D200320259 UDI-DI: 10884521762152 Lot: C210845590 - C221193754 REF: 010991 UDI-DI: 10884521554092 Lot: D200638964 - D210204584 Part Number: 012808 Revision: Rev E REF: 012495 UDI-DI: 10884521554122 Lot: D210725620, D211155495 Part Number: PT00134333 Revision: Rev A REF: QMVAI UDI-DI: 10884521762329 Lot: C201200644 REF: QMVAIH UDI-DI: 10884521762336 Lot: C210314314 Part Number: PT00134354 Revision: Rev A REF: QMVIIH UDI-DI: 10884521762374 Lot: C210314316, C211085494 Part Number: PT00156355 Revision: Rev A REF: MLAI UDI-DI: 10884521762145 Lot: C210103390 - D210206012 Part Number: PT00156254 Revision: Rev A REF: MVAI UDI-DI: 20884521761886 Lot: C220756034 - D211154042 UDI-DI: 10884521761889 Lot: C201200384 - D220104966 REF: MVAI100U UDI-DI: 20884521761893		
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	Lot: D201262882 UDI-DI: 10884521761896 Lot: C201200394 - D210206032 REF: MVAIH UDI-DI: 10884521761919 Lot: C210314324 - D211046881 REF: MVAIH100U UDI-DI: 10884521761926 Lot: C210415654 - D210725654 REF: MVAIHH UDI-DI: 10884521762008 Lot: C210415652 - D220944770 REF: MVAIHL UDI-DI: 10884521761933 Lot: C210314318 - D220317742 REF: MVAIL UDI-DI: 20884521761909 Lot: C230211736 - D210104124 UDI-DI: 10884521761902 Lot: C201100339 - D220635679 REF: MVAMSK UDI-DI: 10884521783997 Lot: C211085718 - C230624523 REF: MVASK UDI-DI: 10884521783980 Lot: C210525106 - D220104894 REF: ZMVAIH UDI-DI: 20884521762258 Lot: M230500059 REF: ZMVAIHH UDI-DI: 20884521762265 Lot: M240100079 REF: ZMVAI UDI-DI: 20884521771762 Lot: M221200053, M230500056 Part Number: PT00156250 Revision: Rev A REF: MVIIH UDI-DI: 20884521761985 Lot: C220646817 - D201159585 UDI-DI: 10884521761988 Lot: C210415594 - D220632267 REF: MVIIHH UDI-DI: 10884521762015 Lot: C210415656 - D220102672 UDI-DI: 20884521762012		
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	Lot: C220108515 - C230519983 REF: MVIIHL UDI-DI: 10884521761995 Lot: C210415658 - D210837945 REF: ZMVIIH UDI-DI: 10884521762275 Lot: M221200054, M230700062		
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For additional information, please visit the [FDA Website \(1\)](#), [FDA Website \(2\)](#), [FDA Website \(3\)](#), [FDA Website \(4\)](#), [FDA Website \(5\)](#), [FDA Website \(6\)](#), [FDA Website \(7\)](#), [FDA Website \(8\)](#), [FDA Website \(9\)](#), and [FDA Website \(10\)](#).