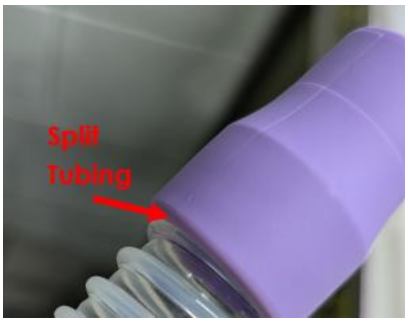
19 Dec 2025 (Version 04, 28 Jan 2026)
Ref: CF-1573

Urgent Field Safety Notice



Smoothbore Tubing Recall – risk of patient harm as a result of the tubing separating from the purple cuff connector.

Type of Action:	To communicate an identified risk of patient harm as a result of the tubing separating from the purple cuff connector.
Devices:	Anaesthetic Circuit, AquaVENT® CPAP System, Ventilator Circuit for Non-invasive Ventilation.
Manufacturer:	Armstrong Medical Limited, Wattstown Business Park, Newbridge Road, Coleraine, BT52 1BS, Northern Irelan.
Date of Issue:	19 Dec 2025
For Attention of:	Healthcare professionals working in anaesthesia and critical care areas of hospitals and all others to whom potentially affected devices have been transferred, including distributors.
Scope of Action:	**Manufacturing LOT specific Field Safety Notice.**
Keywords:	Anaesthetic Circuit, AquaVENT® CPAP System, Ventilator Circuit for Non-invasive Ventilation.

Summary
Armstrong Medical Limited is issuing this Field Safety Notice (FSN) to inform users of a manufacturing defect identified in specific Anaesthetic Circuits, AquaVENT® CPAP Systems and Ventilator Circuits for Non-invasive Ventilation devices.

During routine post-market surveillance, Armstrong received eight (8) customer reports describing holes and tears between the tubing and the purple cuff connector. These defects have resulted in delays to treatment and required replacement of the breathing circuit. Following internal investigation, Armstrong Medical has determined that the issue is linked to a manufacturing defect, and therefore the affected products must be recalled.

Armstrong Medical records indicate that affected devices listed in Table 1 were shipped to your facility. Please review the information below and take the required actions.

Issue Description
A manufacturing defect has been identified that may cause holes or tearing at the junction between the tubing and the purple cuff connector. This can occur during handling, including when replacing a filter.

Risk to Health
Separation or tearing of the tubing may interrupt respiratory support. Replacement of the circuit can result in treatment delays, creating a potential risk of respiratory distress, hypoxia, and low oxygen saturation.

Actions Armstrong is taking
Armstrong Medical is conducting a formal recall of the affected product codes. Corrective actions are being implemented to resolve the manufacturing issue and strengthen inspection processes. Updated Instructions for Use (IFU) will also be issued after these corrective actions have been fully implemented.

Actions for the User

Notify all relevant departments, users, and any organisations to whom affected product may have been supplied.

Where a suitable alternative product is available, users should:

1. Identify and quarantine all affected products listed in Table 1.
2. Cease use immediately.
3. Return or dispose all affected units following the instructions provided by your Armstrong representative.

Where a suitable alternative product cannot be sourced, continued use of the product is permitted in adherence with the following controls:

1. Please ensure particular attention is paid to pre-use leak testing. Always perform a leak test on the circuit before clinical use and review pre-use test results.
2. When changing the breathing filter, hold the purple cuff connector securely whilst gently pulling on the filter to remove. Do not pull on the tubing.
3. When adding a new filter, push the filter into position gently until reaching the point of resistance. Do not push the purple cuff connector excessively onto the breathing filter.
4. Throughout use, please remain vigilant for any source of leakage outside of a clinically acceptable level by monitoring the circuit for unintended leaks during therapy.

If any device currently in use shows signs of tubing-hole formation or separation from the purple cuff connector, discontinue use immediately and report the issue to Armstrong Medical.

Table 1. Affected Devices

Product Codes and Lot Numbers Affected			
AMAC1401-001	200421	060922	201123
	220721	181022	211123
	040821	251022	211223
	151021	151122	221223
	031121	161122	290324
	211221	291122	300324
	080222	200323	110424
	110222	170523	110724
	030322	110723	190824
	260422	120723	180725
	180722	080823	080925
	090822	090823	090925
AMAC1784-039	160523		
AMCPUK01209	220921	030322	
AMCPUK01265	110621	280622	

AMVC1790-006	240122	140322	280223
AMVC1792-013	180521	050423	201224
	200721	070423	211224
	020821	120423	020125
	120821	090523	060125
	260821	120523	070125
	281021	220523	080125
	091121	060623	090125
	161221	070623	150125
	040122	150623	030225
	110122	170723	060225
	180122	190723	250225
	020222	260723	030425
	150222	290823	240425
	030322	140224	030725
	310522	150224	010825
	290622	160224	180825
	070722	120424	190825
	030822	250624	200825
	260822	300824	210825
	060922	020924	221025
	121022	060924	231025
	281122	130924	291025
	301122	140924	311025
	071222	170924	021225
	060123	181024	091225
	160123	251024	101225
	060223	071124	111225
	060323	281124	050126
	080323	121224	070126
	150323	181224	140126
	040423	191224	230126
AMVC1792-070	090621	220823	040225
	110621	290823	110225
	160621	040923	120225
	230721	050923	030425
	280721	140923	090425
	300721	250923	100425
	220921	021023	140525
	280921	011123	200525
	261021	271123	220525
	171121	221223	260525
	231121	090124	270525
	011221	090424	280525
	081221	090524	290525
	101221	030624	300525
	010222	060624	060625
	020222	190624	070625
	160222	080724	110625
	280222	110724	180625
	260422	220724	190625
	290422	050824	120725
	130522	270824	210725

	220622	020924	010825
	240622	040924	060825
	040722	090924	110825
	190722	170924	020925
	260722	031024	240925
	100822	101024	250925
	300822	181024	260925
	160922	231024	021025
	220922	241024	201025
	280922	251024	221025
	290922	261024	291025
	261022	271024	301025
	011122	281024	311025
	021122	301024	101225
	091122	111124	111225
	101122	131124	121225
	121222	191124	151225
	131222	201124	161225
	161222	271124	171225
	100123	281124	191225
	110123	291124	201225
	160123	301124	221225
	140323	011224	231225
	210323	021224	050126
	290323	041224	070126
	120423	131224	080126
	150523	070125	090126
	220523	080125	120126
	270623	100125	130126
	180723	160125	150126
	240723	030225	160126
AMVC1792-078	020221	080923	071124
	180521	051023	201124
	240522	171023	251124
	270522	311023	031224
	240622	090124	210125
	290622	050424	100225
	080822	170624	110225
	310822	180624	120525
	210922	250624	230625
	260922	280624	101125
	121222	060824	111125
	130223	140824	080126
AMVC1792-092	120523	170723	
AMVC1792-126	310719	111022	020125
	170725		
AMVC1792-127	220621	200524	170725
	051121	110325	050125
	240222	240325	
AMVC1792-128	070521		
AMVC1792-137	251021	290623	140225
	090622	170823	150525
	150822	101023	210725

	141122	041223	050925
	021222	110124	170925
	060123	240624	070126
	200123	170924	
	160223	160125	
AMVC1792-138	281021		
AMVC1792-143	070324		
AMVC1792-155	250521		
AMVC1792-156	220221	220223	020924
	100321	030423	120924
	160321	040423	160924
	260321	070423	141024
	280421	120423	181024
	080621	130423	241024
	240621	090523	111124
	030821	120623	131124
	080921	200623	031224
	271021	280623	200125
	110122	040723	100325
	270122	070723	030425
	310122	250723	300425
	150622	260723	150525
	210622	080823	120625
	050722	110823	090725
	260722	290823	230725
	270922	110923	290725
	011122	120923	180825
	091122	130923	100925
	211122	231023	021025
	221122	021123	051125
	251122	071123	121125
	191222	101123	131125
	040123	011223	161125
	200123	051223	201125
	170223	061223	
	200223	210224	
AMVC1792-168	070521	111022	290925
	110521	121223	210126
	041022	140225	
	101122	170625	
AMVC1792-177	190722		
AMVC1792-178	071122	210224	
AMVC1792-234	041121		
AMVC1871-136	160621	141221	171221
	140222		
AMVC1871-157	100221	050723	230524
	140222	070723	060924
	200522	250723	291024
	260522	080823	121124
	230622	100823	131224
	290622	110823	181224
	260722	210823	130325
	031122	101123	060625

	230223	221123	240725
	280323	020124	030925
	020623	160224	101125
	220623	120424	200126

Armstrong Medical Limited confirms that this Field Safety Notice has been submitted to the UK Competent Authority, the Medicines and Healthcare Products Regulatory Agency (MHRA), and has also been communicated to all relevant Competent Authorities in jurisdictions where the device has been placed on the market.

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 Armstrong representative by telephone at +44 (0)28 7035 6029 and request the Sales Department.

Field Safety Notice Response Form

FSN Reference: CF-1573 Date: 19 Dec 2025 (Version 04, 28 Jan 2026)

Hospital or Delivery Location Name: _____

Hospital or Delivery Location Address: _____

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Please complete the information below and return to respiratory.regulatoryaffairs@eakinhealthcare.com. Alternatively, you may contact Armstrong Medical by telephone at +44 (0)28 7035 6029 and request the Sales Department.

Please also tick one of the following options:

☐ We confirm that we have received this FSN and have distributed it to relevant individuals or departments within our organisation.

Please also tick one of the following options:

☐ We do not have remaining stock of the affected products.

☐ We have stock of affected products and confirm that we wish to retain some of the devices until replacements can be provided and are committed to following the advice for continued safe use of these devices as detailed in the FSN. Quantity of replacements required _____.

☐ We have stock of affected products and confirm they have been quarantined for return to Armstrong. Quantity of stock returned _____. Quantity of replacements required _____.

☐ **Armstrong Medical Distributors Only:** We confirm that we have received this FSN and have distributed it to all customers that have been supplied with the products listed in Table 1.

Form Completed by:

Name: _____

Department or Position: _____

E-mail Address: _____

Date: _____