3rd August 2021 Coleraine, Northern Ireland
FSN Ref: SI21-33
FSCA Ref: 2021/007/026/487/007

Urgent Field Safety Notice – risk of device high gas flow resistance

Carbon dioxide absorbent canister AMSORB® PLUS PREFILLED G-CAN® 1.0L

Product codes AMAB3801 and AMAB3801GE

Please pass this Field Safety Notice (FSN) to all persons in your organisation who need to be aware of it.

Type of Action:	To communicate an identified issue which may result in high and unexpected resistance to gas flow during clinical use
Device:	AMSORB® PLUS PREFILLED G-CAN® 1.0L
Manufacturer:	Armstrong Medical Limited (Coleraine, Northern Ireland)
Date of Issue:	3rd August 2021
For Attention of:	Nursing and medical staff (caregivers) 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 recall**
Keywords:	Carbon Dioxide Absorbent, Anaesthesia, Breathing System, Resistance, Gas Flow

Summary
Armstrong Medical is aware of reports indicating that a small number of devices are associated with high and unexpected resistance to gas flow during clinical use. Such resistance could impact or prevent adequate ventilation of an anaesthetised patient, should a defective device go into clinical use. Assessment of available data and results from product testing suggest that these devices account for 0.25% of devices manufactured from June 2020 until 11th June 2021. The defect could present as failure to pass the pre-use test on the anaesthesia machine. This test is also known as **«CHECK-OUT»** test. The defect could also cause alarm **«Unable to drive bellows»** when used in mechanical ventilation modes. This will cause the anaesthesia machine to prematurely cycle to the expiratory phase, which could lead to hypoventilation of the patient. During spontaneous breathing while in *bag* mode, the patient's inspiratory work-of-breathing could be increased.

As the device is expected to be subjected to a pre-use test before clinical use, a canister exhibiting high flow resistance could be identified during set-up of the anaesthesia workstation. However, not all canisters, which could cause alarm **«Unable to drive bellows»** will be identified by the pre-use test. We recognise that this defect could give rise to a delay in treatment, whilst a defective G-CAN® is replaced. Further, we are aware that it is sometimes necessary to replace a CO_2 absorbent canister intraoperatively when the installed canister no longer adequately absorbs CO_2. If such a practice is employed, a pre-use test will not be performed. We suggest that, in the event of a device with high gas flow resistance being put into use in this manner, the consequent alarms from the anaesthesia machine must be investigated for a link to increased gas flow resistance in the canister.

Action to be taken by Users
Users are requested to review the list of potentially affected devices and return the completed FSN response form to Armstrong Medical or to an appointed distributor to receive replacement units. Where users have opted to temporarily retain their stock of potentially-affected devices, those users are asked to ensure that the revised pre-use test below is always completed.

To supplement the **«CHECK-OUT»** test before every patient as specified in the User Reference Manual, please also perform the following test:

- **To check that the ventilator functions correctly:**
  - Connect a 3L reservoir bag as a test lung to the patient breathing circuit connection.
  - Set the ventilator to VCV mode and the settings to TV to 500mL; RR to 60; I:E to 1:2; Tpause to Off; and Pmax to the highest setting.
  - Set the MV High alarm to Off.
  - Set the Fresh Gas flow to the minimum setting, then:
    - Start a case.
    - Set the Bag/Vent switch to Vent.
    - Fill the bellows using O_2 flush.
    - Check that mechanical ventilation starts.
    - Check that the bellows inflate and deflate.
    - Check that the display shows the correct ventilator data.
    - Check that there are no inappropriate alarms.
      - If inappropriate alarms occur, which may stem from canisters with high flow resistance, replace the CO_2 absorbent canister and repeat this pre-use test.
    - Proceed to clinical use

Where unexpected, elevated gas flow resistance in clinical use is observed or suspected - with or without associated anaesthesia machine alarms - the canister should be replaced intraoperatively.

Where an installed canister no longer adequately absorbs CO_2 (due to absorbent exhaustion) during an anaesthesia procedure, we advise that fresh gas flow rate is increased above the required minute ventilation volume for the period until the end of the anaesthesia procedure – whereafter a new canister can be put through the revised pre-use tests specified above.

Field Safety Corrective Action
This Field Safety Notice is published to facilitate a manufacturing LOT specific device recall. See Table 1 for detail of all LOTs of finished medical devices that are subject to recall under this FSN.

Description of Action
All devices identified in Table 1 can be used safely, provided that the devices are subjected to the revised machine pre-use tests above. Any device which fails the revised pre-use tests or generates system alarms should be disposed of or returned to Armstrong Medical or to an appointed distributor.

Table 1. Affected Devices

[1]The first six digits of the LOT number is the date of manufacture and follows the format – DDMMYY (meaning Day Day Month Month Year Year). For example: LOT number 120820F123 means that the devices were manufactured on 12th August 2020).

Product Code: AMAB3801GE (GE part number 2105489-003)					
LOT[1] Number					
090920F311	210121F211	090321F113	280421F51	260521F111	200621F41
090920F312	210121F212	100321F211	280421F511	270521F21	210621F11
090920F313	250121F31	100321F212	290421F41	270521F211	210621F111
160920F41	250121F311	110321F31	290421F411	280521F31	210621F51
160920F411	260121F41	110321F311	290421F11	280521F311	210621F511
160920F412	260121F411	120321F41	300421F11	310521F51	290621F211
160920F413	290121F21	120321F411	300421F111	310521F511	290621F212
210920F51	290121F211	150321F51	050521F41	010621F11	290621F31
210920F511	020221F21	150321F511	050521F411	010621F111	290621F311
210920F512	080221F11	160321F11	050521F51	040621F411	010721F212
210920F513	090220F21	160321F111	050521F511	070621F31	060721F413
240920F61	090221F211	170321F21	050521F512	080621F11	060721F414
240920F611	110221F11	170321F211	060521F21	080621F111	070721F11
290920F11	110221F111	180321F31	060521F211	090621F21	070721F111
290920F111	150221F21	180321F311	070521F41	100621F41	070721F112
290920F112	150221F211	220321F41	070521F411	100621F411	070721F51
011020F21	160221F31	220321F411	100521F21	110621F51	070721F511
011020F211	160221F311	230321F51	100521F211	110621F511	070721F512
091220F512	180221F51	230321F511	100521F212	160621F11	080721F31
141220F11	180221F511	240321F11	110521F31	160621F111	080721F311
141220F111	250221F311	120421F211	110521F311	180621F21	
141220F112	250221F312	120421F212	180521F111	180621F211	
190121F512	250221F411	130421F31	250521F511	190621F31	
210121F21	010321F51	270421F312	260521F11	190621F311	

Product Code: AMAB3801					
LOT[1] Number					
030820F51	010920F611	040121F413	250221F31	010421F11	120521F411
030820F511	020920F11	080121F31	090321F112	010421F111	120521F412
030820F512	020920F111	080121F312	090321F111	120421F21	130521F51
030820F513	020920F112	080121F311	100321F21	160421F511	130521F511
210820F31	020920F113	130121F11	240321F111	190421F11	130521F512
210820F313	040920F212	130121F112	250321F21	200421F41	180521F11
210820F311	040920F213	130121F111	250321F211	200421F411	020621F21
210820F312	040920F21	190121F51	250321F212	200421F412	020621F211
250820F41	040920F211	190121F511	290321F312	210421F111	030621F411
250820F411	090920F31	190221F11	290321F31	210421F11	030621F41
250820F412	011220F414	190221F111	290321F311	220421F21	040621F11
270820F51	091220F51	220221F21	300321F41	230421F41	040621F111
270820F511	091220F511	220221F211	300321F411	230421F51	
270820F512	040121F411	240221F11	310321F51	230421F411	
010920F61	040121F412	240221F111	310321F511	230421F511	

Armstrong Medical Limited confirms that this Field Safety Notice has been notified to the UK Competent Authority - Medicines and Healthcare Products Regulatory Agency (MHRA).

Armstrong Medical Limited confirms that this Field Safety Notice has been notified to all Competent Authorities, in jurisdictions where the device is made available on the market. Including, but not limited to, Canada, Japan, USA and Australia.

Field Safety Notice Response Form

FSN Reference: SI21-33 Date: 3rd August 2021

Hospital or Delivery Location Name: _____

Hospital or Delivery Location Address: _____

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Please complete the information below and return to quality@armstrongmedical.net. Alternatively, please telephone Armstrong Medical on 00 44 (0)28 70356029 and ask for the Sales Department.

☐ 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 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 _____

☐ **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: _____