

Urgent Field Safety Notice – risk of breathing system leakage

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 canister gas leakage during clinical use.
Device:	AMSORB® PLUS PREFILLED G-CAN® 1.0L
Manufacturer:	Armstrong Medical Limited (Coleraine, Northern Ireland)
Date of Issue:	07 Jun 2022
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:	CO ₂ , Absorbent, Anaesthesia, Leakage, Breathing System, Fresh Gas Flow

Summary

Armstrong Medical is aware of reports indicating that a small number of devices in the field are associated with gas leakage originating from an interface within the G-CAN®, where the purple-coloured lid interfaces with the canister body.

Each device is expected to be subjected to a pre-use test before clinical use. A canister exhibiting gas leakage, beyond levels tolerated by the controlling firmware on the connected device (models Aisys, Avance and Aespire series anaesthesia workstations (GE Healthcare, Helsinki, Finland)) will be identified during pre-use test of the anaesthesia workstation prior to clinical use. Such a pre-use test is mandated in the User Manual of the connected device.

However, we are aware that it is sometimes necessary to replace a CO₂ absorbent canister intraoperatively when the installed canister no longer adequately absorbs CO₂. If such a practice is employed, a pre-use test will not be performed. We suggest that, in the event of a canister with a gas leakage going into clinical use in this manner, consequent alarms from the anaesthesia machine during clinical use must be investigated for a link to unexpected loss of gas volume from the breathing circuit, originating from the G-CAN®.

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 reminded to conduct the pre-use test and to exclude from clinical use, any canister that fails the pre-use test.

Where unexpected loss of gas volume from the breathing circuit in clinical use is observed or suspected - with or without associated anaesthesia machine alarms - the canister should be replaced intraoperatively. Where such a replacement canister is then suspected to be the cause of unexpected loss of gas volume from the breathing

system, the fresh gas flow rate (FGFR) should be temporarily increased sufficiently to overcome the gas loss and the canister replaced as soon as practicable thereafter.

Where an installed canister no longer adequately absorbs CO₂ (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 a new canister can be connected to the anaesthesia workstation.

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 pre-use test. Any device which fails the pre-use test or generates system alarms should be disposed of or returned to Armstrong Medical or to an appointed distributor.

Table 1. Affected Devices

¹The 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: AMAB3801	Product Code: AMAB3801GE
LOT ¹ Number	LOT ¹ Number
040122F21	110122F31
040122F213	110122F312
	280122F51

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: SI22-12 Date: 07 Jun 2022

Hospital or Delivery Location Name: _____

Hospital or Delivery Location Address: _____

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 _____(units)

We have stock of affected products and confirm we will discard these devices, and we request replacements from the manufacturer sent to the address above.

Quantity of device(s) Discarded _____ (units)

Quantity of replacements required _____ (units)

Form Completed by:

Name: _____

Department or Position: _____

e-mail Address: _____

Date: _____