04 Oct 2022 Version 02 Coleraine, Northern Ireland
FSN Ref: SI22-113
NCA Ref: 2022/009/021/601/003
FSCA Ref: 2022/010/004/601/002

Urgent Field Safety Notice – risk of patient harm due to the non-function of a resuscitation set with an APL valve.

Resuscitation Set - Mapleson C System with APL Valve

Product codes AMBS1604-062 and AMBSN1604-5-2

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 the non-function of a resuscitation set with an APL valve.
Device:	Resuscitation Set with APL Valve
Manufacturer:	Armstrong Medical Limited (Coleraine, Northern Ireland)
Date of Issue:	04 Oct 2022
For Attention of:	Healthcare professionals working in 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:	Resuscitation Set, APL Valve, Mapleson C

Summary
Armstrong Medical is aware of reports indicating that there are a small number of devices in the field associated with Resuscitation Sets that may contain APL valves that do not function as intended, which could lead to indirect patient harm such as a delay in treatment or could possibly lead to a serious deterioration in the health of a patient.

Each device is expected to be subjected to a "Before use, verify flow patency" test before clinical use. This is to ensure that the APL valve performs as intended in the closed cap and open cap positions of the valve, ensuring that the reservoir bag inflates (cap position closed) and collapses (cap position open). Such a pre-use test is mandated in the Instructions for Use supplied with the device.

In instances where the device is to be made available to use in emergency situations, Armstrong Medical suggest that all devices are subjected to pre-use tests prior to being made available for use in critical care situations or emergency service vehicles.

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 device that fails the pre-use tests documented in the Instruction for Use.

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 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 230320 means that the devices were manufactured on 23rd March 2020.

[2]For the thirteen-digit A000000000000 LOT Number, the final six digits are in DDMMYY format. For example: LOT number A117832020320 means that the devices were manufactured on 2nd March 2020.

Product Code: AMBS1604-062		Product Code: AMBSN1604-5-2		
LOT[1] Number	LOT[2] Number	LOT[1] Number	LOT[1] Number	LOT[2] Number
230320	A117832020320	210320	150420	A119223260320
010420	A117958040320	220320	220420	A120169090420
020420	A119435310320	230320	240420	A122881030620
070420	A125953290620	240320	250420	A123735260620
110420	A125998300620	250320	260420	A123738290620
120420	A125458080720	260320	270420	A128007011020
270620	A125925090720	270320	280420	A128398141020
280620		280320	290420	A130760011220
040720		290320	030620	
		010420	040620	
		020420	050620	
		030420	060620	
		040420	070620	
		050420	080620	
		060420	250620	
		100420	280620	
		110420	300620	
		120420	010720	
		130420	020720	
		140420	030720	

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: SI22-113 Date: 04 Oct 2022

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: _____