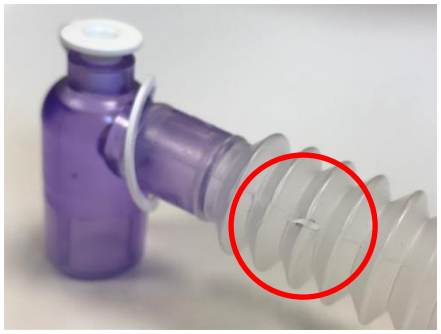
Urgent Field Safety Notice

15mmØ Collapsible/Extendible Tubing - present in Armstrong Medical Catheter Mounts, Face Mask Kits and some Breathing Circuits

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

Type of Action:	Recall
Device:	Catheter Mounts (GMDN 42476)
Manufacturer:	Armstrong Medical Limited (Coleraine, N. Ireland)
Date of Issue:	16th August 2019
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
Scope of Action:	**Recall of certain LOTs of devices containing 15mmØ Collapsible/Extendible Tubing**
Keywords:	Breathing System, Catheter Mount, Face Mask Kit, Collapsible Tubing, Extendible Tubing

Summary
Certain LOTs are suspected of having a manufacturing defect, resulting in holes found in the tubing, during clinical use. The potential hazard associated with use of a defective device is a delay to treatment with an associated risk of patient desaturation. Root causes analysis is currently ongoing. As a precautionary measure, the decision has been taken to recall all devices manufactured using affected tubing. A photograph showing an example of the defect is provided for user reference.



Action to be taken by Users
Refer to Table 1 on page 2 for the list of affected devices. Users are requested to check their stocks and return any unused affected devices. Replacement product will be provided.

Field Safety Corrective Action
Description of Action
This FSN relates to a single LOT of tubing, extruded in February 2019 and used in finished product dispatches from 10th May 2019. Interim measures, to maintain supply to customers, involves pressure testing the tubing prior to its use in a finished device. In response to a small number of reports from a single user, the decision has been taken to recall all devices containing this LOT of suspected defective tubing.

Advice for Continued Use of Affected Devices
Armstrong Medical recognises that, due to demand within healthcare facilities, it may not be practicable for some users to return their stocks for replacement. In such circumstances, Armstrong Medical advises that, for continued

Cont'd

safe use of the device, the catheter mount should be expanded and included in the pre-use pressure test along with the breathing circuit. A successful 'pass' confirms that the catheter mount is absent the reported defect. A documented risk assessment should be conducted by healthcare facilities intending to use affected devices. This should be completed prior to use of those devices.

Armstrong Medical Limited confirms that this notice has been notified to UK Competent Authority - Medicines and Healthcare Products Regulatory Agency.

Table 1. Affected Devices

Product Family	Product Code	LOT Number	Product Family	Product Code	LOT Number
Catheter Mount	AMCM5141	210519	Face Mask Kit	AMK1625100	290519
	AMCM5141/MBP	120619, 040719		AMKU14T14100-19	140519, 050619, 170619, 210619
	AMCM5141/MFP	150519		AMKU14T15100-19	140519, 280619, 230719
	AMCM5142	230519		AMKU14T23200	170519, 280519
	AMCM5143	260419, 280519		AMKU14T24100/66	250619
	AMCM5144	200419, 210419, 220419, 230419, 240419, 260419, 270419, 280419, 290419, 030619		AMKU14T24200	090519, 100519, 230719, 290719
	AMCM5144/001	200319, 210319, 230319, 310519, 060619, 070619, 240719		AMKU14T24200/19	040719
	AMCM5144/002	240419, 290519		AMKU14T24700	140619
	AMCM5144/003	150519		AMKU14T25100	240519, 120619
	AMCM5144/008	160719, 170719		AMKU14T25100/66	220519, 250619
	AMCM5144/HHP	030619		AMKU14T25200	240419, 210519, 050619
	AMCM5144/MFP1	100619		AMKU14T25200/19	040719
	AMCM5144/V1	160519, 020719		AMKU14T25700	210519, 280519, 050619, 120619, 140619, 180619, 160719
	AMCM5146	270619		AMKU14T26100	240519, 120619, 240719
	AMCM5146/2	230519, 170619, 190619, 250619, 040719, 160719, 230719		AMKU14T26700	120619, 180619, 160719
	AMCM5147	300519, 050619, 240619		AMKU16T15100/83	200519, 170619
	AMCM5148	010419, 020419, 030419, 260419, 150519, 230519, 250519, 030619, 100619		AMMA2045466120	290419, 260619
	AMCM5148/1	290519, 310519		AMMA2055466120	290419
	AMCM5148/HH	030619		AMMA2055477030	140519, 150519
	AMCM5149	220519		AMMAU3065486120	130519
	AMCM5174/010	130519, 270619		AMK14T24700	190619
	AMCM5178	240119		AMK14T25700	220519
Combi-Flex	AMUF1910/003	140519, 020719		AMK1624100	100419, 150519, 190619
	AMUF1910/050	130519, 020719	Ventilator Circuit	AMVC1812/002	210519
	AMUF1920/015	150519, 230519, 310519, 200619, 030719, 090719, 100719		AMVC1871/086	290519, 050619

[1]The LOT number is the date of manufacture and follows the format - DDMMYY (example: 210519 is 21st May 2019)

Field Safety Notice Response Form

FSCA Reference: SI19-38 Date: 16th August 2019

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 are happy to pressure test these as part of the breathing circuit pre-use pressure test

☐ We have stock of affected products and wish to return these for *replacement or *credit (*delete as appropriate)

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: _____