

# Urgent Field Safety Notice

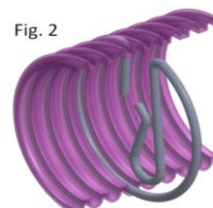
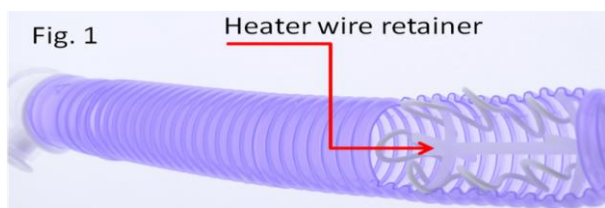
## Voluntary Recall of Heated Ventilator and CPAP Breathing Circuits Manufactured Using Corrugated Tubing

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

### Summary

Armstrong Medical Limited is investigating a component used in its heated ventilator and CPAP breathing circuits manufactured using corrugated tubing. *This notice does not apply to any Armstrong Medical heated breathing circuit manufactured using smooth bore tubing.*

The component is referred to as a *heater wire retainer* and is located in the heated limbs of adult (22mmØ) corrugated heated ventilator and CPAP breathing circuits as a means to locate the heater wire in a fixed position. Fig. 1 shows the heater wire retainer in position. The retainer is white or off-white in colour and made from polymeric (plastics) material. If breakage of this component were to occur there could be a possible inhalation risk to the patient.



### Field Safety Corrective Action

As a voluntary, precautionary measure and in advance of full details of an incident being made available, Armstrong Medical Limited has decided to recall potentially affected breathing circuits and replace these with circuits which use an alternative form of retainer made from metal (as shown in Fig. 2).

A representative from Armstrong Medical or our authorised distributor will make contact with each delivery point where affected products have been receipted, aim to establish if affected products exist and arrange replacement of these.

### Advice for Continued Use of Affected Products

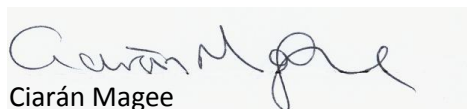
As a precaution until affected stock can be replaced, confirm the absence of loose fragments of heater wire retainer inside the heated limb(s), referring to Fig. 1 for guidance.

### Immediate Steps to be Taken

Establish whether your facility is in possession of Armstrong Medical adult heated breathing circuits made with corrugated tubing and having the code format starting AMCP- or AMHO- or AMVC17- or AMVC18-. Further check whether the LOT number/s is in the range 080310 to 310812 (DDMMYY) or expiry date in the range 2015-02 to 2017-07 (see Fig. 3 showing a specimen package insert).

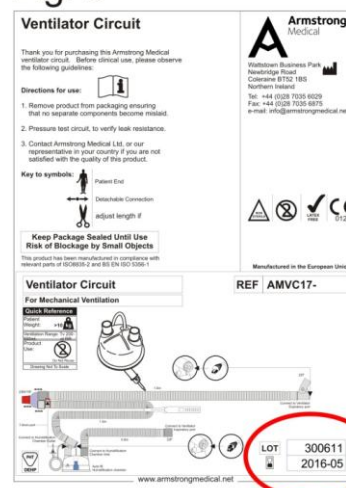
Segregate affected stock not immediately required for clinical use and complete the attached Stock Reconciliation Form and return this by email to [info@armstrongmedical.net](mailto:info@armstrongmedical.net) or by fax to 00 44 28 70356875 or to your local representative. If you purchased product from an authorised distributor, contact them to arrange return of the affected circuits.

Relevant National Competent Authorities have been advised of this FSN.



Ciarán Magee

Fig. 3



# Urgent Field Safety Notice

## Armstrong Medical Heated Ventilator and CPAP Breathing Circuits Manufactured Using Corrugated Tubing

### Stock Reconciliation Form

Facility Name: \_\_\_\_\_

Address: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Contact telephone number: \_\_\_\_\_

After reviewing inventory of product codes starting with AMCP-, AMVC17- and AMVC18- of LOT numbers after 080310 and before 310812 (format DDMMYY), please 'tick' one box on the table below.

<input type="checkbox"/>	<p>A thorough search for all affected products has been completed and none remain in inventory. <b>No products will be returned.</b></p>
<input type="checkbox"/>	<p>We are in possession of affected products and these will be returned to Armstrong Medical or its authorised distributor or made available for collection from the address above.</p> <p>Product code: _____ LOT Number: _____ Quantity: _____ (pcs)</p> <p>Product code: _____ LOT Number: _____ Quantity: _____ (pcs)</p> <p>Product code: _____ LOT Number: _____ Quantity: _____ (pcs)</p> <p>Product code: _____ LOT Number: _____ Quantity: _____ (pcs)</p>

Contact Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Return this form by email or fax to Armstrong Medical Limited at:

[info@armstrongmedical.net](mailto:info@armstrongmedical.net) or by fax to 00 44 28 70356875