Urgent Field Safety Notice

Affected Product	**Custom Procedure Packs manufactured by Pennine Healthcare**
Type of action	**Voluntary Recall**
Pennine Healthcare Ref:	**PHFSN0120**
Product Code	**COP-0101**
LOT Number	**04J17**

23rd January 2020

Dear Customer,

You are receiving this letter as our records indicate that you have received the above mentioned custom procedure packs manufactured by Pennine Healthcare.

Description of the issue:

Axiom Medical Inc. has initiated a recall of a number of its medical devices due to them being placed on the European market without a valid CE mark (See the attached Axiom Medical Inc. FSN for further details).

The above mentioned custom procedure pack is impacted as it contains one of the devices covered by the Axiom Medical Inc. FSN: – Item Number: 111132. Item Name: Thoracic Silicone Catheter, 32FR, Angle.

Actions to be taken by the distributor / user:

1. Identify and quarantine all affected stock immediately.
2. If you are a distributor you are required to confirm to Pennine that you have provided this FSN to all your customers and contained any returned stock.
3. Complete the attached Reply Form (Addendum A) to confirm that you have read and understood the contents of this Field Safety Notice. Return the completed form to your usual point of purchase (Distributor) and copy to:

   recalls@penninehealthcare.co.uk & exports@penninehealthcare.co.uk
4. Upon receipt of the completed reply form, your Distributor or Pennine Healthcare will arrange for the collection or confirm how destruction of the affected product should be organised (Proof of destruction and records of type and quantities involved will be needed).
5. For further clarification of quarantined or affected stock replacements or credits, please contact your local distributor or if supplied directly from Pennine our customer services using:
   - International Markets - exports@penninehealthcare.co.uk **tel.** +44 (0)1332 794 880
6. Maintain awareness of this Field Safety Notice until all stock of the affected LOT / batch has been destroyed or returned to Pennine Healthcare

Transmission of this Field Safety Notice:

This notice should be passed on to all those who need to be aware within your organisation or to any organisation where the affected devices have been transferred.

Please maintain awareness on this notice until all required actions have been performed within your organisation.

We confirm that this field safety corrective action has been communicated to the relevant competent authorities.

Pennine is committed to providing quality products to our customers and we sincerely apologise for any inconvenience this notice may cause.

For and on behalf of Pennine Healthcare:

Gareth Hazlewood
Regulatory Affairs Manager

Addendum A

Field Safety Notice Acknowledgement Form

Name	
Position	
Company/Institute	
Address	

We do not have any stock of the affected product. (✓ tick if this is your answer)	

Product Code and Quantity of Affected Product in Stock	
Product Code	Quantity
COP-0101	

Please do not arrange returns or destruction of affected stock until confirmed ok to do so by your usual point of purchase or Pennine Healthcare. Evidence will be required prior to and after destruction.

I hereby confirm that I have read and understood the contents of this Field Safety Notice.	
Sign	
Date	

Please return the completed form to your usual point of purchase and copy to:

recalls@penninehealthcare.co.uk & exports@penninehealthcare.co.uk