

Urgent Field Safety Notice

Affected Product	Pennine Intro-Uri-Cath (Urethral catheter)
Type of action	Voluntary Recall / Product Disposal
Pennine Healthcare Ref:	PHFSN0319
Affected Product Code(s)	NC-1514 NC-1512 NC-1510
Lot Number	Various – All affected products manufactured between: 01 May 2014 and 01 May 2019 LOT Numbers between: 01E14 to 01E19 Any of the listed product with an Expiry date up to 2024-05

22 May 2019

Dear Customer,

Description of the problem:

This communication is to inform you that Pennine Healthcare has voluntarily initiated a recall to remove multiple LOTs of the products detailed within this Field Safety Notice (FSN).

Through internal monitoring activities we have identified that there is a small possibility that the products listed above may have reached the market in a nonsterile condition.

The use of a nonsterile product has the potential to cause harm to patients. For example, an increase risk of urinary tract infections.

Actions to be taken by the distributor / user:

1. Identify and quarantine all stock of the affected batch / LOT numbers 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.
4. Upon receipt of the completed reply form, Pennine Healthcare will arrange for the return 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:
 - UK markets – customer.services@penninehealthcare.co.uk tel. +44 (0)1332 794 880
 - 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.

Identification of affected products:

Use the Product Codes and LOT numbers or expiry dates as detailed above to identify the affected devices.

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 potentially 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 and distributors.

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:



Simon Motlib
Quality Assurance Manager

Addendum A

Field Safety Notice Acknowledgement Form

Name	
Position	
Company/Institute	
Address	

Confirmation of having none of the products referenced in this FSN.

We do not have any stock of the affected product. (✓ tick if this is your answer)	
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Product Code and Quantity of Affected Product in Stock		
Product Code	LOT Number(s)	Qty.

NB: Please contact your local distributor representative or Pennine directly to confirm quantity and type of quarantined stock before completing returns or plans for destruction. **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 reply form to: recalls@penninehealthcare.co.uk