FSN Ref: PHFSN 2023-1
FSCA Ref: FSCA 2023-1

Date: 10th January 2023

Urgent Field Safety Notice

Suction Connecting Tubes and Link Yankauer Sets

For Attention of*: Risk Managers responsible for medical device vigilance, All Medical/Surgical department managers, Clinical Community Care Manager

Subject: Product Recall – Potential breach in sterile barrier packaging

Contact details of local representative (name, e-mail, telephone, address etc.)*
Ivor Shaw Ltd. t/a Pennine Healthcare Email: recalls@penninehealthcare.co.uk Telephone: 01332794880 Address: 300, City Gate, London Rd, Derby DE24 8WY

Device Type/Affected Products	Suction Connecting Tubes and Link Yankauer Sets See Appendix A for list of affected Product codes and LOT information
Type of action	Identify Device Quarantine Device Product Disposal Complete and return the applicable Response Form to Pennine
Pennine Healthcare Ref	PHFSN 2023-1
Clinical purpose of devices	Link Yankauer Sets: Surgical suction probe range of devices are hand operated, single use, and are used as a conduit to remove bodily fluids and secretions, surgical tissue debris, irrigation fluids and gasses. They are used in surgical sites and body cavities to facilitate observation and/or to clear an obstruction. To be used on all patient populations by clinicians and trained homecare users, in clinical setting, homecare and emergency settings. Suction Connecting Tubing Pennine's Sterile Suction Connecting Tubes are a length of flexible, single use, non-invasive PVC tubing, intended to interface between suction source and suction devices for use in a medical/ surgical procedure removing fluids, gasses, and debris. They are supplied and intended to be used sterile by clinicians or trained homecare users, in clinical, homecare and emergency settings.
Product Codes	Refer to Appendix A
LOT Number	Refer to Appendix A

Dear Customer,

The purpose of this letter is to advise you that Ivor Shaw Ltd. t/a Pennine Healthcare is voluntarily initiating a recall for specific batches of Link Yankauer Set and Suction Connecting Tubes products. You are receiving this letter as our record shows your facility may have received one or more of the potentially affected batches.

We are initiating this recall to prevent potential patient harm (risk of infection).

Description of product problem:

Pennine has received two customer complaints related to sterile barrier (pouch) breach. The pouches were found to be open before it was used compromising the product sterility. Our investigation has determined the affected products were manufactured using the same pouch batch that we received from our supplier.

Pennine has decided to recall the potential affected products from the market.

There is no patient harm reported. The issue was identified before the device was used.

Potential Hazard/Risk:

Using a non-sterile device may increase the risk of patients getting infections.

Action to be taken by the distributor / importer:

1. Confirm to Pennine Healthcare that you have provided this FSN to all your customers.

2. If you have products with batches listed in this FSN, please quarantine the devices, and contact Pennine Healthcare's customer service recalls@penninehealthcare.co.uk for replacement, credit note or disposal. Please provide detailed information on product code, batch numbers and quantity affected.

3. Please complete and return the attached form (**Appendix B**) to confirm that you have read and understood the contents of this Field safety Notice.

Action to be taken by the User/Hospital:

1. Identify and quarantine the affected batches listed in this FSN. **Do not use these devices.**

2. Please complete the User reply form (**Appendix C**) to confirm that you have read and understood the contents of this Field Safety Notice and send it to recalls@penninehealthcare.co.uk and to your local distributor representative.

3. If you have purchased these devices from a distributor, please contact your distributor to agree on disposal of affected products.

4. If you have purchased these devices directly from Pennine Healthcare, please dispose and contact Pennine customer services directly for refund or credit.

A copy of this FSN has been sent to the relevant Competent Authorities of the Member States.

Identification of affected products:

Use the Product Codes and LOT numbers as detailed in **Appendix A** of this document to identify the affected devices.

Only the identified products from the LOT listed in the FSN are affected.

Transmission of this Field Safety Notice:

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

Please transfer this notice to other organisations on which this action has an impact.

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

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

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

For and on behalf of Ivor Shaw Ltd t/a Pennine Healthcare:

M.Arun
Arun Mahendran
Head of Regulatory Affairs
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Appendix A – Affected Medical Devices and Batch Details

Product Code	Batch Numbers
Yankauer Link Set	
LYS-5530	06E22
LYS-5531	06E22
LYS-5620	04D22
LYS-5621	04D22
LYS-5630	31E22
LYS-5631	04D22; 31E22
LYS-5730	01F22; 05D22; 13G22
LYS-5731	01F22; 05D22
LYS-6620	06D22
Suction Connecting Tube	
CT-4372	22D22
CT-4624	29F22

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Appendix B
Distributor / Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	PHFSN 2023-1
FSN Date*	10/January/2023
Product/ Device name*	
Product Code(s)	
Batch/LOT Number (s)	

2. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Distributors/Importers (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	
☐	*I have informed the identified customers of this FSN	Date of communication:
☐	*I have received confirmation of reply from all identified customers/hospitals	
☐	*I have identified, quarantined, and destroyed the affected devices - enter number of devices destroyed and date completed.	Add quantity, Sales/Invoice number, Lot
☐	Neither I nor any of my customers has any affected devices in inventory	
Print Name*		
Signature*		
Date *		

Return the completed form to recalls@penninehealthcare.co.uk

Deadline for returning the Distributor/Importer reply form - 28th February 2023

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

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Appendix C

Appendix C: User (Healthcare organisation) Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	PHFSN 2023-1
FSN Date*	10/January/2023
Product/ Device name*	
Product Code(s)	
Batch/LOT number (s)	

2. Customer Details	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation		
☐	*I confirm receipt of the Field Safety Notice and that I read and understood its content.	
☐	*The information and required actions have been brought to the attention of all relevant users and executed.	
☐	*Affected devices have been quarantined and are available for return/ destruction	Please provide quantity and batch details
☐	Other Action (Define):	
☐	I do not have any affected devices.	
Print Name*		
Signature*		
Date*		

Mandatory fields are marked with *

Return the completed form to recalls@penninehealthcare.co.uk and to your local distributor representative. Please contact your local distributor representative or Pennine directly for replacement or credits for any defective products identified. Evidence will be required for any quarantined and/or destroyed items.

Deadline for returning the Distributor/Importer reply form - 28th February 2023