FSN Ref: PHFSN2024-1
FSCA Ref: PHFSCA2024-1

Urgent Field Safety Notice

Device Type/Affected Product	**Intermittent Standard Nelaton Catheter manufactured by Pennine Healthcare**
Type of action	**Identify all affected stock and organise return to Pennine Healthcare**
Pennine Healthcare Ref:	**PHFSCA2024-1**
Product code and LOT Number (Device Model)	**See Appendix C**
Clinical Purpose of the device	**Intermittent passive evacuation of urine**
Manufacturer SRN	**GB-MF-000004160**
UDI-DI	**5033241CATHETERSVY**
FSN Type	**New**

06th August 2024

Dear Customer,

You are receiving this letter because our records show that you have received the above mentioned intermittent standard nelaton catheter, manufactured by Pennine Healthcare.

Pennine Healthcare are recalling certain batches of intermittent standard nelaton catheters as part of a Field Safety Corrective Action (FSCA). The affected codes are listed in Appendix C. Your records may only show that you have received NC-1218/SW (25A23) however the individual units may be labelled as NC-1212/SW (30A23).

Please follow the instructions as detailed on page 2.

Description of the product problem:

Pennine Healthcare have identified a packaging error where NC-1218/SW (lot: 25A23) devices have been packed into pouches labelled with the product code NC-1212/SW (lot: 30A23). The box labels present the correct product code, NC-1218/SW (lot: 25A23).

The diameter/CH of the device (18 CH) is larger than identified by the NC-1212/SW code (12 CH). We believe only a small quantity of the above batches were affected however Pennine Healthcare are recalling the entire batch as a precautionary measure.

Hazard giving rise to the FSCA:

If a size 12 diameter catheter is required, but a size 18 CH is used, it may cause patient discomfort. This has been assessed as low risk by Pennine Healthcare.

Actions to be taken by the distributor:

1. Please forward the FSN to the affected customers.
2. Identify and quarantine all affected batches and contact Pennine Healthcare at recalls@penninehealthcare.co.uk to organise the return of affected devices.
3. Complete and return the attached form **(Appendix A)** to confirm that you have read and understood the contents of this FSN.

Actions to be taken by the User:

1. Review this Field Safety Notice in its entirety and ensure all users of the affected devices in your organisation and other concerned persons are informed about this Field Safety Notice.
2. Please use the attached list to identify all affected, unused devices in your stock.
3. **Identify and quarantine all affected devices.**
4. **Contact your supplier to organise the return of the affected devices.**
5. Please complete the customer response form **(Appendix B)** to confirm that you have read and understood the contents of this Field Safety Notice and send it to your supplier of the device and email a copy to recalls@penninehealthcare.co.uk

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 organization or user where the affected devices have been transferred.

Please maintain awareness of 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 Ivor Shaw Ltd. t/a Pennine Healthcare:

Jessie Nurse

Quality Manager – Projects and Complaints

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Appendix A
Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	PHFSN2024-1
Product/ Device name	Intermittent Standard Nelaton Catheter
Product Code(s)	**Batch/Serial Number (s)**

2. Distributor Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

Distributors/Importers (Tick all that apply)	
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.
☐	I have checked my stock and identified if any affected codes/batches are present.
☐	*I have identified customers that received or may have received this device.
☐	I have quarantined the stock and organised the return of all affected devices.
☐	*I have informed the identified customers of this FSN.
☐	I have received confirmation of reply from all identified customers.
☐	Neither I nor any of my customers have any affected devices in inventory.
*Print Name	
*Signature	
*Date	

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

Mandatory fields are marked with *

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Appendix B
End User (Hospital/Clinic) Reply Form

Please complete this form and return to your supplier and email a copy to Pennine Healthcare
Email: recalls@penninehealthcare.co.uk

3. Field Safety Notice (FSN) information	
FSN Reference number*	PHFSN2024-1
Product/ Device name*	Intermittent Standard Nelaton Catheter
Product Code(s)*	**Batch/Serial Number(s)***

4. Customer Details	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

5. End User (Tick all that apply)	
☐	*We confirm the receipt, the reading and understanding of the Field Safety Notice.
☐	*We confirm that we have checked stock and identified all affected devices if present.
☐	We have received the Field Safety Notice and confirm that we have no remaining devices in stock.
☐	We have received the Field Safety Notice and confirm that we quarantined all impacted stock and organised return of devices to the supplier.
*Print Name	
Signature	
Position	
Telephone number	
*Date	

Mandatory fields are marked with *

FSN Ref: PHFSN2024-1
FSCA Ref: PHFSCA2024-1

Appendix C
Affected Product codes and Lot numbers

Product Code	Lot Number
NC-1218/SW	25A23
NC-1212/SW	30A23

End of list