FSN Ref: PHFSN 2021-2
FSCA Ref: FSCA 2021-2

Date: 11/11/2021

Urgent Field Safety Notice

Nasogastric devices (Ryles Tubes, Levins Tubes and Feeding Tubes), Suction Catheters, Rectal Tubes, Nelaton catheters.

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

Subject: Advisory Notification Only- Do not use the devices if side eyes are not present

This is not a Product recall.

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	Nasogastric devices (Ryles Tubes, Levins Tubes and Feeding Tubes), Suction Catheters, Rectal Tubes, Nelaton catheters. See Appendix A for list of affected Product codes and LOT information
Type of action	Advise users to visually inspect the device before it is used. **"Please inspect product for side eyes. Please do not use if side eyes are missing"** Reinforcement of IFU - supplied with Nasogastric devices.
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Clinical purpose of devices	Nasogastric devices: Intended for administration of enteral fluids or aspiration of gastric fluids or gas out of the stomach/duodenum. Nelaton catheters: Intermittent urinary bladder drainage for transient use. Suction Catheters: Intended to clear oral, tracheal and/or endobronchial secretions via suction. Rectal tubes: Tubing intended for instilling fluids into, and/or withdrawing fluids from rectum.
Product Codes	Refer to Appendix A
Lot Number	Refer to Appendix A

Dear Customer,

Description of product problem:

The manufacturer has been alerted to two reports stating that the manufactured Nasogastric tubing does not have side eyes (holes). The device is intended for administration and/or aspiration of gastric fluids or gas out of the stomach. Using a defective device (with no side eyes) may cause serious injury to the patient. While the defect rate is very low (as per our records), it is important that all users follow the Instructions for Use (supplied with Gastric Access devices- Ryles Tubes, Levins Tubes and Feeding Tubes) and check the product for defects prior to use.

"Please inspect product for side eyes. Please do not use if side eyes are missing"

Other products listed in the FSN are manufactured using the same machine. The manufacturer has not received any complaints related to missing side eyes on these products. However, we recommend following the same instructions as above before using them.

Potential Hazard/Risk:
Use of the defective product without the side eyes (holes) would mean the products would not perform as intended. There is a potential for serious harm to the patient should an alternative non-defective device not be available at the time.

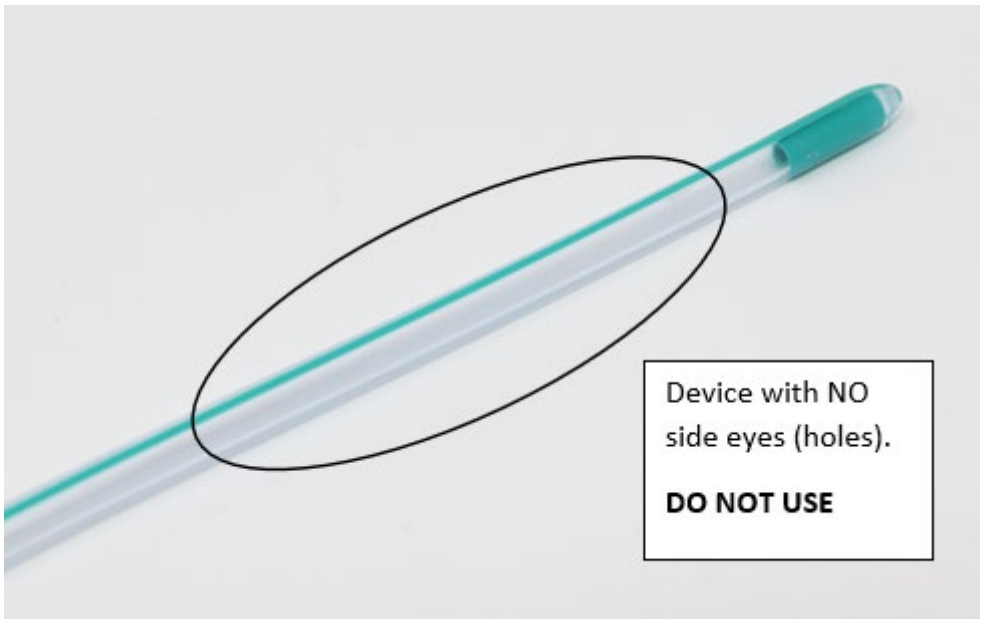
Action to be taken by the distributor/importer:

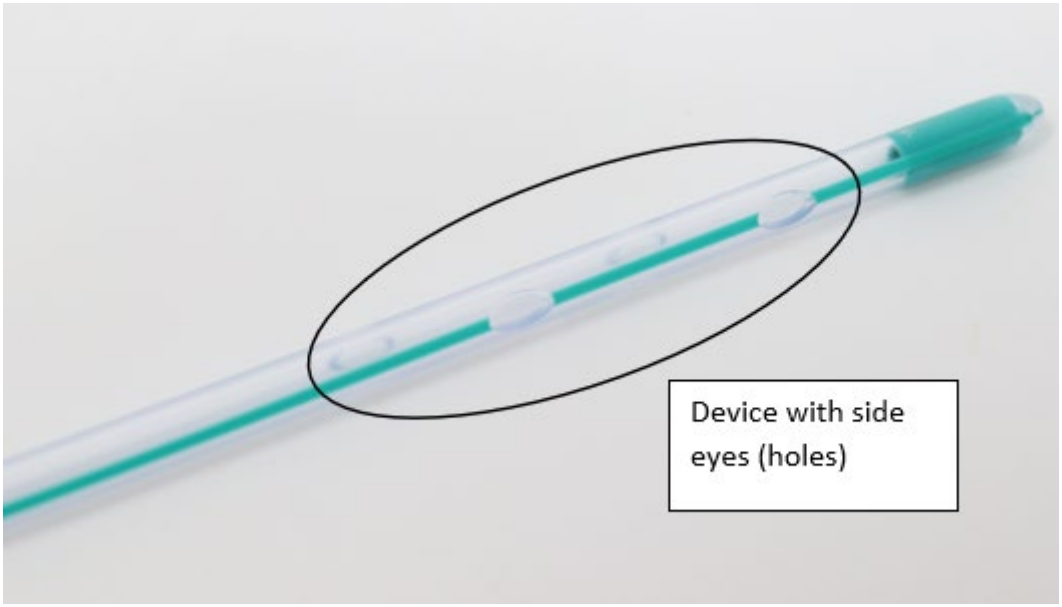
1. Confirm to Pennine that you have provided this FSN to all your customers.
2. Please complete and return the attached form (**Appendix B**) to confirm that you have read and understood the contents of this Field safety Notice.
3. If you or your end user identify any product with missing side eyes, please contact Pennine customer service for clarification for next steps.

Action to be taken by the User:

1. All impacted devices must be inspected prior to the removal from their primary packaging.
2. Identify if side eyes (holes) are present. Please see below for pictures showing with and without side eyes.
3. Where side eyes are present, continue to use the device as normal.
4. Where no side eyes are present, quarantine and do not use the device.
5. For further clarification of quarantined or affected stock replacements or credits, please either contact your local distributor or if supplied directly from Pennine our customer services.
6. Please complete the customer 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.

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.

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 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

Appendix A – Affected Medical Devices and Batch Details

Product Code	Batch Numbers
Nasogastric (Ryles/Levins and Feeding Tubes)	
FT-1608/105	22F20, 06H21, 27G20
FT-1610/105	23F20
FT-1908/105	01E20, 11E20, 04F21, 04H20, 06H21, 21D21, 21G21, 22A21, 28E20, 28G20, 08D21
FT-1908/60	15J20, 21E21, 30C21
FT-1910/60	29A21
LT-2214	11K19, 14K19, 17J19
LT-2414	26J19, 27J19
RT-2014	01K19
RT-2308	01G20, 12B21, 20L19, 12K20, 18L19, 19L19, 02J20, 13G20, 02L20
RT-2308/EF	21A21
RT-2310	08G20, 13G20, 17C20, 27A21, 24F20, 29G20, 10J20, 22E19, 17F20, 18L19, 04H21, 02L20, 11L20, 01E20, 19L19, 20L19, 12K20
RT-2310/EF	27A21
RT-2312	10G20, 16M20, 19B20, 25C20, 04H21, 12M19, 09A20, 30J20, 06G20, 19F20, 28A20, 03L20, 10L20, 11L20
RT-2312/EF	12M19, 06G20, 30J20, 03B21
RT-2314	02D20, 11C20, 16M20, 22G20, 16L20, 25L20, 27H20, 06B20, 10G20, 06G20, 01K19, 19K20, 10J19, 11H21, 12K20, 15D20, 30G20, 21D21, 29A20, 17F20, 19B20, 04H21, 06H21, 13G21, 21G21, 30J20
RT-2314/EF	03G20, 30J20, 03B21, 21D21
RT-2316	21G21, 11C20, 16M20, 17C20, 25B21, 30G20, 31G20, 04C20, 13L20, 22F20, 03B20, 14H20, 02A20, 19K20, 21K19, 02D20, 10H21, 01E20, 08G20
RT-2316/EF	07G20, 11A21, 21D21, 30J20
RT-2318	11A21, 24G20, 03B20, 04C20, 09G20, 11L20, 15D20, 26F20, 12M19, 25B21, 01E20, 02D20
RT-2318/EF	02F20, 12M19, 21D21
RT-2320	31K19, 21L19, 22L19, 11C21, 20D21, 09D20, 18H21
RT-2320/EF	27G20, 11J20, 27A21
XLT-2208	03M19, 06M19, 12B21, 15C21, 09M19, 27A21
XLT-2208/EF	22A21
XLT-2210	02J20, 02L20, 03C21, 03M19, 06M19, 08D21, 09M19, 10J20, 12B21, 13G20, 13G21, 16C21, 16M20, 17C20, 19B20, 26F20, 27A21
XLT-2210/EF	27A21
XLT-2212	02L20, 03M19, 08D21, 10H21, 12B21, 13G20, 13G21, 15C21, 16M20, 17H20, 19K20, 22A21, 26L19, 27L19, 30J20
XLT-2212/EF	03B21, 12M19
XLT-2214	01K19, 02G20, 02J20, 03B21, 03C21, 03K19, 03L20, 04H21, 08D21, 09G20, 10H21, 12K20, 13G21, 13L20, 15C21, 16M20, 17J19, 19K20, 20G20, 30D21, 30G20, 30J20
XLT-2214/EF	03B21, 12M19
XLT-2216	01E20, 02A20, 02J20, 04F21, 05C21, 06G20, 08A21, 08D21, 08F21, 10L20, 11C20, 12M19, 15D20, 16C21, 17F20, 19K20, 19M19, 25B21, 27A21, 29G20, 30D21

XLT-2216/EF	12M19, 27A21
XLT-2218	02A20, 02L20, 03B20, 03C21, 03M19, 06H21, 06M19, 08A21, 08D21, 09A20, 09G20, 10H21, 12B21, 13G21, 16C21, 19K20, 23G20, 24F20, 25C20, 26L19, 27L19
XLT-2218/EF	03B21, 06M19
XLT-2220	15A20, 18M19, 29A21
XLT-2220/EF	27A21
XST-2408	01G20
XST-2410	11E20
XST-2412	11E20
XST-2414	01E20
XST-2416	11E20
XST-2418	07E20
XST-2418/BULK	16F20
XST-2420	02F20
Suction Catheter	
SC-1020	08L19, 11L19, 02B21, 12L19, 18L20, 27L20, 29A21,
Nelaton Catheter (Intermittent urethral catheter)	
NC-1220/SW	06C20, 16G20, 16M19, 21D20, 21M20, 25F21
NC-1220/SW/1	14M20, 16G20, 21H20, 26L20, 30K20
Rectal Tubes	
RC-1820	16M19, 06C20, 14M20, 16G20, 21D20, 26L20
RC-1820/1	06C20, 16G20, 21H20, 21K20, 22A20, 27A20, 30K20

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FSCA Ref: FSCA 2021-2

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Appendix B
Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	PHFSN 2021-2
FSN Date*	11/October/2021
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	
☐	I have identified affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number/Date Returned
☐	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 - 30th November 2021

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.

Pennine

Appendix C
Customer (Healthcare organisation) Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	PHFSN 2021-2
FSN Date*	11/October/2021
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 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 - 30th November 2021