FSN Ref: PHFSN 2023-2
FSCA Ref: PHFSCA 2023-2

Urgent Field Safety Notice

Device Type/Affected Product	**Custom Procedure Packs manufactured by Pennine Healthcare**
Type of action	**Identify all affected packs in stock and organise return to Pennine Healthcare**
Pennine Healthcare Ref:	**PHFSCA 2023-2**
Procedure Pack Product code and LOT Number (Device Model)	**See Appendix C**
Clinical Purpose of the device	**Custom Procedure Pack**
Manufacturer SRN	**GB-PR-000023775**
FSN Type	**New**

01st November 2023

Dear Customer,

You are receiving this letter because our records show that you have received above mentioned custom procedure packs (with Klinion Kliniray X-Ray Gauze) manufactured by Pennine Healthcare.

MEDECO BV, the manufacturer of Klinion Kliniray gauze, has decided to recall certain batches of Klinion Kliniray Compress X-Ray Gauze and Klinion Kliniray Abdominal Compress X-Ray Gauze as part of a Field Safety Corrective Action (FSCA). As a result of the FSCA we are therefore notifying you of this issue highlighted by our supplier and recalling all procedure packs containing the above items. The affected procedure packs containing the gauze are outlined in **Appendix C.** Please follow the instructions as detailed on page 2.

Description of the product problem:

The supplier (MEDECO BV) has issued an FSN stating that X-ray threads in gauze compresses can disintegrate, and the products do not meet the required criteria. Small pieces of thread could be left behind if the X-ray thread breaks or frays. This, for example, may lead to inflammation and/or granuloma formation when they remain in the body.

Hazard giving rise to the FSCA:

May lead to inflammation and/or granuloma formation.

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 custom procedure packs.
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 above-mentioned procedure packs 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 procedure packs in your stock.
3. **Identify and quarantine all affected custom procedure packs.**
4. **Contact your supplier to organise the return of the affected custom procedure packs.**
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 Procedure Pack 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 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 Ivor Shaw Ltd. t/a Pennine Healthcare:

[redacted]

[redacted]

[redacted]

FSN Ref: PHFSN 2023-2
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Appendix A
Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	PHFSN 2023-2
Product/ Device name	
Product Code(s)	**Batch/Serial Number (s)**

2. Distributor/Importer 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 custom procedure packs.
☐	*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 has any affected devices in inventory.
*Print Name	
*Signature	
*Date	

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

Mandatory fields are marked with *

FSN Ref: PHFSN 2023-2
FSCA Ref: PHFSCA 2023-2

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*	PHFSN 2023-2
Product/ Device name*	
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 procedure packs if present.
☐	We have received the Field Safety Notice and confirm that we have no remaining procedure packs in stock.
☐	We have received the Field Safety Notice and confirm that we quarantined all impacted stock and organised return of custom procedure packs to the supplier.
*Print Name	
Signature	
Position	
Telephone number	
*Date	

Mandatory fields are marked with *

FSN Ref: PHFSN 2023-2
FSCA Ref: PHFSCA 2023-2

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Appendix C
Affected Product codes and Lot numbers

Pack Code	Lot Number
MCG-79400	16M19
MMN-05301	17K19
MMN-05301	19M19
MMN-05301	07B20
MMN-05301	18F20
MMN-05301	05K20
MMN-05301	17M20
MMN-05301	25A21
MMN-05301	10C21
MMN-05301	04C20
MMN-05401	24A20
MMN-05401	23F20
MMN-05401	15J20
MMN-05401	10M20
MMN-05401	22A21
MMN-05401	25A21
MMN-05401	25B20
MMN-05401	27B20
MMN-05401	02C21
MMN-05501	08A20
MMN-05501	05B20
MMN-05501	22F20
MMN-05501	14J20
MMN-05501	15K20
MMN-05501	15C21
MMN-05501	16C21
MMN-05501	19B20
MMN-05701	11F20
MMN-05701	02M19
MMN-05701	18M19
MMN-05701	17B20
MMN-05701	17H20
MMN-05701	25A21
MMN-05801	20L19
MMN-05801	25B20
MMN-05801	27B20
MMN-05801	11F20
MMN-05801	15J20
MMN-05801	15C21
MMN-05801	19C21

Appendix C (Continued)
Affected Product codes and Lot numbers

Pack Code	Lot Number
MMN-05902	08AXX
MMN-05902	17BXX
MMN-05902	21AXX
MMN-05902	01GXX
MMN-05902	02GXX
MMN-05902	07HXX
MMN-05902	03LXX
MMN-05902	15CXX
MMN-06102	20LXX
MMN-06102	20BXX
MMN-06102	13AXX
MMN-06102	30FXX
MMN-06102	17HXX
MMN-06102	03JXX
MMN-06102	16KXX
MMN-06102	09MXX
MMN-06102	17CXX
MMN-06102	12CXX
MMN-06102	14DXX
MMN-06202	02MXX
MMN-06202	19BXX
MMN-06202	19MXX
MMN-06202	13GXX
MMN-06202	10HXX
MMN-06202	11FXX
MMN-06202	04LXX
MMN-06202	16CXX
MMN-06202	15CXX
MMN-06301	17B20
MMN-06301	29A20
MMN-06301	11F20
MMN-06301	16F20
MMN-06301	10H20
MMN-06301	25A21
MMN-06301	22K20
MMN-06301	04L20
MMN-06301	12C21

Appendix C (Continued)
Affected Product codes and Lot numbers

Pack Code	Lot Number
MMN-06402	19MXX
MMN-06402	21LXX
MMN-06402	03JXX
MMN-06402	05BXX
MMN-06402	15AXX
MMN-06402	01GXX
MMN-06402	19BXX
MMN-06402	15JXX
MMN-06402	16CXX
MMN-06402	22CXX
MMN-06501	19MXX
MMN-06501	21AXX
MMN-06501	07HXX
MMN-06501	01GXX
MMN-06501	15CXX
OMS-36900	05C20
OMS-37000	20CXX

End of list