FSN Ref: FSN 2022-1
FSCA Ref: FSCA 2022-1

Urgent Field Safety Notice
Cannulation Pack

Device Type/Affected Product	**Custom Procedure Packs manufactured by Pennine Healthcare**	
Type of action	**Voluntary Recall**	
Pennine Healthcare Ref:	**FSCA 2022-1**	
Procedure Pack Product code and LOT Number (Device Model)	**Product Code**	**LOT**
	BRA17400	**17C20; 29D20, 23F20, 16G20, 25H20, 30L20, 17B21**
	RMT552106	**30L20; 29D20**
Clinical Purpose of the device	**Custom Procedure Pack – Cannulation pack**	
FSN Type	**New**	

10th March 2022

Dear Customer,

You are receiving this letter as our records indicate that you have received the above mentioned custom procedure packs (with Vasofix® Safety device) manufactured by Pennine Healthcare.

The B.Braun Melsungen AG has decided to proactively recall some of its batches of Vasofix® Safety, Vasofix® Certo and VasoVet® G24 devices in the context of a Field Safety Corrective Action (FSCA) from the market.

Description of the product problem:

Through post market surveillance activities, B.Braun has identified that the injection port of the affected batches might be leaky.

Hazard giving rise to the FSCA:

The defect might result in potentially critical clinical consequences for the patient such as blood loss, underdosage or delay of therapy. The user or third parties are at risk due to contact with incompatible substances or foreign blood. Based on the identified risks and the consideration that the concerned products are mainly used for infants or in general for patients with difficult veins, B.Braun has decided to recall the affected devices from the market.

The above mentioned **custom procedure packs** are impacted as they contain the affected batches of “VASOFIX SFTY PUR 24G” product. We decided to proactively recall all affected procedure packs from the market.

No additional follow-up activities are required for patients already treated with the devices.

(See the attached B.Braun FSN for further details).

Actions to be taken by the distributor:

1. Please forward the FSN to the affected customers.
2. Identify and quarantine all affected batches.
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. Identify, quarantine, and return affected packs to your distributor (B.Braun).
3. Do not use affected packs anymore.
4. 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 distributor (B.Braun).

Contact details of local representative:

For Technical Issues
Rachel Kent
Marketing Manager – IV Therapy
Rachel.kent@bbraun.com
Tel 07772 115 887

For Stock/Returns Issues
Catherine Clulow
Team Leader Product Complaints
productcomplaints.bbmuk@bbraun.com
Tel: 0114 2259 155

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:

M.Arun

Arun Mahendran
Head of Regulatory Affairs

FSN Ref: FSN 2022-1
FSCA Ref: FSCA 2022-1

Appendix A
Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN 2022-1
FSN Date*	FSCA 2022-1
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*	

3. 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 quarantined inventory	
☐	*I have identified customers that received or may have received this device	
☐	*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: FSN 2022-1
FSCA Ref: FSCA 2022-1

Appendix B
Customer Reply Form

Please complete this form and return to
Catherine Clulow
Fax: 0114 2259 141
Email: productcomplaints.bbmuk@bbraun.com

4. Field Safety Notice (FSN) information	
FSN Reference number*	FSN 2022-1
FSN Date*	FSCA 2022-2
Product/ Device name*	Procedure pack – Cannulation pack
Product Code(s)	
Batch/Serial Number (s)	

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

☐	We have received the Field Safety Notice and confirm that we have no remaining products in stock.
☐	We have received the Field Safety Notice and confirm that we have quarantined the stock and wish to return the following:

Product code	Quantity to be returned	Lot/Batch Number

☐	We have not shipped any products affected by this Field Safety Notice to third parties.
☐	We have notified our customer who are affected by this recall notice, and we will contact our customers to arrange collection of any affected products for onward return to B Braun Medical Limited.

Print Name*
Position:
Company name:
Telephone number
Date*

Mandatory fields are marked with *