Rev 1: January 2025

FSN Ref: 2507/51830/00 - CAPA25-037 Rev00 EN: FSCA Ref 2507/51830/00 - CAPA25-037 Rev00 EN:

Date: 09/07/2025

Urgent Field Safety Notice
Device Commercial Name

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

Contact details of local representative (name, e-mail, telephone, address etc.)*
Technical Department - technical-uk@vygon.com, Tel: 01794 748800 - Vygon (UK) Ltd, The Pierre Simonet Building, V Park, Gateway North, Latham Road, Swindon, SN25 4DL

Urgent Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

1. Information on Affected Devices*

1.1. Device Type(s)*

POLYPERF needles are curved Huber needles with a connecting line (tubing). They are available in various lengths and diameters and with or without a side injection site.

1.2. Commercial name(s)

POLYPERF

1.3. Unique Device Identifier(s) (UDI-DI)*

N/A

1.4. Primary clinical purpose of device(s)*

Needles indicated for the administration or withdrawal of fluids through implantable catheter ports.

1.5. Device Model/Catalogue/part number(s)*

Product	Product code	Commercial Name	LOT number
POLYPERF	VPE581709	POLYPERF W/O Y 0.9D X 17MM 20G	24075013
	VPE581709	POLYPERF W/O Y 0.9D X 17MM 20G	24085061
	VPE582009	POLYPERF W/O Y 0.9D X 20MM 20G	24065182
	VPE582009	POLYPERF W/O Y 0.9D X 20MM 20G	24075215
	VPE582009	POLYPERF W/O Y 0.9D X 20MM 20G	24105076
	VPE582009	POLYPERF W/O Y 0.9D X 20MM 20G	24105111
	VPE582009	POLYPERF W/O Y 0.9D X 20MM 20G	24105167
	VPE582009	POLYPERF W/O Y 0.9D X 20MM 20G	24105185
	VPE582009	POLYPERF W/O Y 0.9D X 20MM 20G	24105254
	VPE582509	POLYPERF W/O Y 0.9D X 25MM 20G	24055165
	VPE582509	POLYPERF W/O Y 0.9D X 25MM 20G	24065177

1.6. Software version

N/A

1.7. Affected serial or lot number range

Product	Product code	Commercial Name	LOT number
POLYPERF	VPE581709	POLYPERF W/O Y 0.9D X 17MM 20G	24075013
	VPE581709	POLYPERF W/O Y 0.9D X 17MM 20G	24085061
	VPE582009	POLYPERF W/O Y 0.9D X 20MM 20G	24065182
	VPE582009	POLYPERF W/O Y 0.9D X 20MM 20G	24075215
	VPE582009	POLYPERF W/O Y 0.9D X 20MM 20G	24105076
	VPE582009	POLYPERF W/O Y 0.9D X 20MM 20G	24105111
	VPE582009	POLYPERF W/O Y 0.9D X 20MM 20G	24105167
	VPE582009	POLYPERF W/O Y 0.9D X 20MM 20G	24105185
	VPE582009	POLYPERF W/O Y 0.9D X 20MM 20G	24105254
	VPE582509	POLYPERF W/O Y 0.9D X 25MM 20G	24055165
	VPE582509	POLYPERF W/O Y 0.9D X 25MM 20G	24065177

1.8. Associated devices

N/A

2 Reason for Field Safety Corrective Action (FSCA)*

2.1. Description of the product problem*

The legal manufacturer (PEROUSE MEDICAL) has identified a potential defect on some rigid blisters of POLYPERF products after sterilization. A very small number of blister packs may have localised cracks on the corners. This could result in a breach of the products' sterile barrier system.

2.2. Hazard giving rise to the FSCA*

Breakage of the sterile barrier system may result in contamination of the medical device and lead to an infectious risk for the patient.

2.3. Probability of problem arising

Batches involved have a blister crack/leak rate between 0.06% and 1.17%.

2.4. Predicted risk to patient/users

Breakage/rupture of the sterile barrier system may result in contamination of the medical device and lead to an infectious risk for the patient.

2.5. Further information to help characterise the problem

N/A

2.6. Background on Issue

The legal manufacturer (PEROUSE MEDICAL) has identified a potential defect on some rigid blisters of POLYPERF products after sterilization. A very small number of blister packs may have localised cracks on the corners. This could result in a breach of the products' sterile barrier system.

2.	7. Other information relevant to FSCA
	N/A

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User***	
	☒ Identify Device ☒ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	6th August 2025
3.	3. Particular considerations for: Choose an item. N/A	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Provide further details of the action(s) identified.	
3	6. By when should the action be completed?	Specify where critical to patient/end user safety
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	N/A	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Vygon (UK) Ltd (on behalf of PEROUSE MEDICAL)
	b. Address	The Pierre Simonet Building, V Park, Gateway North, Latham Road, Swindon, Wiltshire, SN25 4DL
	c. Website address	www.vygon.co.uk
4.	8. The Regulatory Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Appendix 1 -
4.	10. Name/Signature	Kate O'Connell, Technical Support Manager(On behalf of Jules Peacemaker Harelimana, Quality PMS Manager)

	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. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. 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..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

FSCA EMAIL BACK FORM

FIELD SAFETY CORRECTIVE ACTION REF. NO: *2507/51830/00*

DATE: 9 July 2025

DETAILS OF AFFECTED DEVICES:

Product Code:	Batch/Lot	NHSSC Code
VPE581709	24075013	FTR3039
VPE581709	24085061	FTR3039
VPE582009	24065182	FTR3027
VPE582009	24075215	FTR3027
VPE582009	24105076	FTR3027
VPE582009	24105111	FTR3027
VPE582009	24105167	FTR3027
VPE582009	24105185	FTR3027
VPE582009	24105254	FTR3027
VPE582509	24055165	FTR3047
VPE582509	24065177	FTR3047

Please complete this form even if you do not have any affected product listed above and email the completed form back to Technical Support Services – **Email:** technical-uk@vygon.com

I/we acknowledge receipt of the above FSCA, and that the information contained in this FSCA has been shared with all recipients/users of the above products within our organisation.

Name: _____ Mr/Mrs/Miss/Other: _____

Designation: _____

Organisation: _____

Department: _____

Address: _____

_____

Post code: _____

Telephone No: _____ E-mail: _____

Signature: _____ Date: _____

☐ We do not have any of the affected stock listed above

☐ We have the following stock remaining

Product Code	Batch/Lot Number	Quantity	Name of Supplier Direct/NHSSC/SSS/Other)
VPE581709	24075013		
VPE581709	24085061		
VPE582009	24065182		
VPE582009	24075215		
VPE582009	24105076		
VPE582009	24105111		
VPE582009	24105167		
VPE582009	24105185		
VPE582009	24105254		
VPE582509	24055165		
VPE582509	24065177		

On receipt of this completed form, a representative of Vygon (UK) Ltd will contact you to arrange the return and replacement of affected stock.