Urgent Field Safety Notice

RECALL

Huber Needles POLYPERF

Date: April 23, 2026 **FSN Ref: CAPA IV-26-004 Rev00 EN** **FSCA Ref: CAPA IV-26-004 Rev00 EN**

For Attention of: Person responsible of Medical Devices Safety / vigilance – Passed on to all user departments and users.

Contact details of local representative
VYGON **5 Rue Adeline** **95440 ECOUEN France** **Email : VGLFSN@vygon.com**

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1. Information on Affected Devices

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.

2. Commercial name(s)

POLYPERF

3. Unique Device Identifier(s) (UDI-DI)

N/A

4. Primary clinical purpose of device(s)

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

5. Device Model / Lot number

Product	Catalogue number	Commercial name	Lot number
POLYPERF	VPE581509	POLYPERF Ø0,9X15MM, SANS SITE	25115124

6. Software version

N/A

7. Associated devices

NA

2. Reason for Field Safety Corrective Action (FSCA)

1. Description of the product problem

PEROUSE MEDICAL has identified that a carton of Huber Needles (POLYPERF), reference VPE581509, lot 25115124 was sent to our distributor in Romania even though this lot had not been released by PEROUSE MEDICAL.

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2.	**2. Hazard giving rise to the FSCA**	
	Use of products not yet released by the legal manufacturer.	
2.	**3. Probability of problem arising**	
	A carton of 300 units is affected by the problem. This is the first time in the last 5 years that products have been put on the market without being released.	
2.	**4. Predicted risk to patient/users**	
	Use of products not yet released by the legal manufacturer.	
2.	**5. Further information to help characterise the problem**	
	N/A	
2.	**6. Background on Issue**	
	PEROUSE MEDICAL has identified that a carton of Huber Needles (POLYPERF), reference VPE581509, lot 25115124 was sent to our distributor in Romania even though this lot had not been released by PEROUSE MEDICAL.	
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**	
	☑ Read carefully the urgent field safety notice (Recall notice) ☑ Identify, segregate and put in quarantine immediately the impacted devices, ☑ Complete the "Field Safety Notice Customer/Distributor Reply Form" attached to the field safety notice ☑ Destroy the recalled devices and document the destruction in the "Field Safety Notice Customer/Distributor Reply Form" ☑ Return the "Field Safety Notice Customer/Distributor Reply Form" to the identified contact	
	2. By when should the action be completed?	IMMEDIATELY
3.	**3. Particular considerations for, or Is follow-up of patients or review of patients' previous results recommended?**	
	N/A	
3.	**4. Customer Response Required**	**April 30, 2026**

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3.	**5. Action Being Taken by the Manufacturer**	
	Safety information: Recall of products	
3.	**6. Is the FSN required to be communicated to the patient /lay user?**	No

4. General Information

4.	**1. FSN Type**	New
4.	**2. Further advice or information already expected in follow-up FSN? ***	N/A
4.	The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4	**Manufacturer information**	
4	**Company Name**	PEROUSE MEDICAL
4	**Adress**	Route du Manoir 60173 IVRY LE TEMPLE France
4.	**Name/Signature**	Nathalie BAUDE Correspondant matériovigilance Responsable Qualité

5. Return acknowledgement to sender :

	Email	VGLFSN@vygon.com
	Adress	VYGON 5 rue Adeline 95440 ECOUEN FRANCE
	Deadline for returning the customer reply form	**April 30, 2026**
	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)	

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	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

URGENT Field Safety Notice

RECALL - Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	**FSN Ref: CAPA IV-26-004 Rev00 EN**
FSN Date	**April 23, 2026**
Manufacture	**PEROUSE MEDICAL**
Product/ Device name	**POLYPERF**
Reference code / Batch number	

Product	Catalogue number	Commercial name	Lot number
POLYPERF	VPE581509	POLYPERF Ø0,9X15MM, SANS SITE	25115124

2. Distributor/Importer Details	
Account Number	
Company Name	
Adress	
Contact Name	
Title or Function	
Telephone number	
Fax number	
Email	

3. Distributors/Importers	
☐	I confirm receipt of the Field Safety Notice (FSN) and that I read and understood its content
☐	I performed all actions requested by the FSN
☐	I have checked my stock and quarantined the affected devices
☐	I have products from this batch in stock and I confirm their destruction. (complete the quantity and destruction date)

Product	Catalogue number	Commercial name	Lot number	Quantity destroyed	Date of destruction
POLYPERF	VPE581509	POLYPERF Ø0,9X15MM, SANS SITE	25115124		

☐	I have identified customers that received or may have received this device **Product** | **Catalogue number** | **Commercial name** | **Lot number** | **Customer name** | **Quantity** POLYPERF | VPE581509 | POLYPERF Ø0,9X15MM, SANS SITE | 25115124 | |					
☐	I have attached customer list					
☐	I have informed the identified customers of this FSN	Date:				
☐	I have received confirmation of reply from all identified customers					
☐	None of my customers received the incriminated devices					
☐	Neither I nor any of my customers has any affected devices in inventory					

Name in capital character	
Signature	
Date	
4. Return acknowledgement to sender	
Email	**VGLFSN@vygon.com**
Adresse	VYGON 5 rue Adeline 95440 ECOUEN FRANCE
Deadline for returning this form	**April 30, 2026**

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.