

Urgent Field Safety Notice

RECALL

Huber Needles POLYPERF

Date: July 09, 2025

FSN Ref: CAPA25-037 Rev00 EN

FSCA Ref: CAPA25-037 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
<p>VYGON 5 Rue Adeline 95440 ECOUEN France</p> <p>Email : VGLFSN@vygon.com</p>

Urgent Field Safety Notice

RECALL

Huber Needles POLYPERF

Date: July 09, 2025

FSN Ref: CAPA25-037 Rev00 EN

FSCA Ref: CAPA25-037 Rev00 EN

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 / Lot number	<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr style="background-color: #0070c0; color: white;"> <th style="width: 25%;">Product</th> <th style="width: 25%;">Catalogue number</th> <th style="width: 40%;">Commercial name</th> <th style="width: 10%;">Lot number</th> </tr> </thead> <tbody> <tr><td rowspan="23">POLYPERF</td><td>VPE581511</td><td>POLYPERF Ø1,1X15MM, SANS SITE</td><td>24045089</td></tr> <tr><td>VPE581511</td><td>POLYPERF Ø1,1X15MM, SANS SITE</td><td>24085161</td></tr> <tr><td>VPE581707</td><td>POLYPERF Ø0,7X17MM, SANS SITE</td><td>24055164</td></tr> <tr><td>VPE581709</td><td>POLYPERF Ø0,9X17MM, SANS SITE</td><td>24075013</td></tr> <tr><td>VPE581709</td><td>POLYPERF Ø0,9X17MM, SANS SITE</td><td>24085061</td></tr> <tr><td>VPE581711</td><td>POLYPERF Ø1,1X17MM, SANS SITE</td><td>24065169</td></tr> <tr><td>VPE582007</td><td>POLYPERF Ø0,7X20MM, SANS SITE</td><td>24115030</td></tr> <tr><td>VPE582009</td><td>POLYPERF Ø0,9X20MM, SANS SITE</td><td>24065182</td></tr> <tr><td>VPE582009</td><td>POLYPERF Ø0,9X20MM, SANS SITE</td><td>24075215</td></tr> <tr><td>VPE582009</td><td>POLYPERF Ø0,9X20MM, SANS SITE</td><td>24105076</td></tr> <tr><td>VPE582009</td><td>POLYPERF Ø0,9X20MM, SANS SITE</td><td>24105111</td></tr> <tr><td>VPE582009</td><td>POLYPERF Ø0,9X20MM, SANS SITE</td><td>24105167</td></tr> <tr><td>VPE582009</td><td>POLYPERF Ø0,9X20MM, SANS SITE</td><td>24105185</td></tr> <tr><td>VPE582009</td><td>POLYPERF Ø0,9X20MM, SANS SITE</td><td>24105254</td></tr> <tr><td>VPE582011</td><td>POLYPERF Ø1,1X20MM, SANS SITE</td><td>24095192</td></tr> <tr><td>VPE582509</td><td>POLYPERF Ø0,9X25MM, SANS SITE</td><td>24055165</td></tr> <tr><td>VPE582509</td><td>POLYPERF Ø0,9X25MM, SANS SITE</td><td>24065177</td></tr> <tr><td>VPE582511</td><td>POLYPERF Ø1,1X25MM, SANS SITE</td><td>24045085</td></tr> <tr><td>VPE582511</td><td>POLYPERF Ø1,1X25MM, SANS SITE</td><td>24045092</td></tr> <tr><td>VPE582511</td><td>POLYPERF Ø1,1X25MM, SANS SITE</td><td>24055110</td></tr> <tr><td>VPE583009</td><td>POLYPERF Ø0,9X30MM, SANS SITE</td><td>24105169</td></tr> <tr><td>VPE592509</td><td>POLYPERF Ø0,9X25MM, AVEC SITE</td><td>24055156</td></tr> <tr><td>VPE593509</td><td>POLYPERF Ø0,9X35MM, AVEC SITE</td><td>24045088</td></tr> </tbody> </table>		Product	Catalogue number	Commercial name	Lot number	POLYPERF	VPE581511	POLYPERF Ø1,1X15MM, SANS SITE	24045089	VPE581511	POLYPERF Ø1,1X15MM, SANS SITE	24085161	VPE581707	POLYPERF Ø0,7X17MM, SANS SITE	24055164	VPE581709	POLYPERF Ø0,9X17MM, SANS SITE	24075013	VPE581709	POLYPERF Ø0,9X17MM, SANS SITE	24085061	VPE581711	POLYPERF Ø1,1X17MM, SANS SITE	24065169	VPE582007	POLYPERF Ø0,7X20MM, SANS SITE	24115030	VPE582009	POLYPERF Ø0,9X20MM, SANS SITE	24065182	VPE582009	POLYPERF Ø0,9X20MM, SANS SITE	24075215	VPE582009	POLYPERF Ø0,9X20MM, SANS SITE	24105076	VPE582009	POLYPERF Ø0,9X20MM, SANS SITE	24105111	VPE582009	POLYPERF Ø0,9X20MM, SANS SITE	24105167	VPE582009	POLYPERF Ø0,9X20MM, SANS SITE	24105185	VPE582009	POLYPERF Ø0,9X20MM, SANS SITE	24105254	VPE582011	POLYPERF Ø1,1X20MM, SANS SITE	24095192	VPE582509	POLYPERF Ø0,9X25MM, SANS SITE	24055165	VPE582509	POLYPERF Ø0,9X25MM, SANS SITE	24065177	VPE582511	POLYPERF Ø1,1X25MM, SANS SITE	24045085	VPE582511	POLYPERF Ø1,1X25MM, SANS SITE	24045092	VPE582511	POLYPERF Ø1,1X25MM, SANS SITE	24055110	VPE583009	POLYPERF Ø0,9X30MM, SANS SITE	24105169	VPE592509	POLYPERF Ø0,9X25MM, AVEC SITE	24055156	VPE593509	POLYPERF Ø0,9X35MM, AVEC SITE	24045088
Product	Catalogue number	Commercial name	Lot number																																																																										
POLYPERF	VPE581511	POLYPERF Ø1,1X15MM, SANS SITE	24045089																																																																										
	VPE581511	POLYPERF Ø1,1X15MM, SANS SITE	24085161																																																																										
	VPE581707	POLYPERF Ø0,7X17MM, SANS SITE	24055164																																																																										
	VPE581709	POLYPERF Ø0,9X17MM, SANS SITE	24075013																																																																										
	VPE581709	POLYPERF Ø0,9X17MM, SANS SITE	24085061																																																																										
	VPE581711	POLYPERF Ø1,1X17MM, SANS SITE	24065169																																																																										
	VPE582007	POLYPERF Ø0,7X20MM, SANS SITE	24115030																																																																										
	VPE582009	POLYPERF Ø0,9X20MM, SANS SITE	24065182																																																																										
	VPE582009	POLYPERF Ø0,9X20MM, SANS SITE	24075215																																																																										
	VPE582009	POLYPERF Ø0,9X20MM, SANS SITE	24105076																																																																										
	VPE582009	POLYPERF Ø0,9X20MM, SANS SITE	24105111																																																																										
	VPE582009	POLYPERF Ø0,9X20MM, SANS SITE	24105167																																																																										
	VPE582009	POLYPERF Ø0,9X20MM, SANS SITE	24105185																																																																										
	VPE582009	POLYPERF Ø0,9X20MM, SANS SITE	24105254																																																																										
	VPE582011	POLYPERF Ø1,1X20MM, SANS SITE	24095192																																																																										
	VPE582509	POLYPERF Ø0,9X25MM, SANS SITE	24055165																																																																										
	VPE582509	POLYPERF Ø0,9X25MM, SANS SITE	24065177																																																																										
	VPE582511	POLYPERF Ø1,1X25MM, SANS SITE	24045085																																																																										
	VPE582511	POLYPERF Ø1,1X25MM, SANS SITE	24045092																																																																										
	VPE582511	POLYPERF Ø1,1X25MM, SANS SITE	24055110																																																																										
	VPE583009	POLYPERF Ø0,9X30MM, SANS SITE	24105169																																																																										
	VPE592509	POLYPERF Ø0,9X25MM, AVEC SITE	24055156																																																																										
	VPE593509	POLYPERF Ø0,9X35MM, AVEC SITE	24045088																																																																										

Urgent Field Safety Notice

RECALL

Huber Needles POLYPERF

Date: July 09, 2025

FSN Ref: CAPA25-037 Rev00 EN

FSCA Ref: CAPA25-037 Rev00 EN

1.	6. Software version
	N/A
1.	7. Associated devices
	NA
2. Reason for Field Safety Corrective Action (FSCA)	
	1. Description of the product problem
2.	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. Hazard giving rise to the FSCA
2.	Breakage of the sterile barrier system may result in contamination of the medical device and lead to an infectious risk for the patient.
	3. Probability of problem arising
2.	Batches involved have a blister crack/leak rate between 0.06% and 1.17%.
	4. Predicted risk to patient/users
2.	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
	6. Background on Issue
2.	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.
	7. Other information relevant to FSCA
2.	N/A
3. Type of Action to mitigate the risk	

Urgent Field Safety Notice

RECALL

Huber Needles POLYPERF

Date: July 09, 2025

FSN Ref: CAPA25-037 Rev00 EN

FSCA Ref: CAPA25-037 Rev00 EN

	1. Action To Be Taken by the User	
3.	<input checked="" type="checkbox"/> Read carefully the urgent field safety notice (Recall notice) <input checked="" type="checkbox"/> Identify, segregate and put in quarantine immediately the impacted batches available <input checked="" type="checkbox"/> Complete the "Field Safety Notice Customer/Distributor Reply Form" attached to the field safety notice <input checked="" type="checkbox"/> Destroy the recalled devices and document the destruction in the "Field Safety Notice Customer/Distributor Reply Form" <input checked="" type="checkbox"/> 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	July 31, 2025
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

Urgent Field Safety Notice

RECALL

Huber Needles POLYPERF

Date: July 09, 2025

FSN Ref: CAPA25-037 Rev00 EN

FSCA Ref: CAPA25-037 Rev00 EN

5. Return acknowledgement to sender :		
	Email	VGLFSN@vygon.com
	Adress	VYGON 5 rue Adeline 95440 ECOUEN FRANCE
	Deadline for returning the customer reply form	July 31, 2025
Transmission of this Field Safety Notice		
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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</p>	