Urgent Field Safety Notice - FSCA
RECALL POLYFILM®

FSN Ref: CAPA23-051 Rev01 EN

Date: August 16th 2023

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

Contact details of local representative (name, e-mail, telephone, address etc.)
VYGON **5 Rue Adeline** **95440 ECOUEN France** **Email : VGLFSN@vygon.com** **Tel : + 33 (0)1.39.92.63.81**

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1. Information on Affected Devices

1 — 1. Device Type(s)

POLYFILM® is a sterile adhesive dressing dedicated to secure percutaneous medical devices, in particularly, Huber needles.

1 — 2. Commercial name(s)

Synthetic polymer semi-permeable film dressing

1 — 3. Primary clinical purpose of device(s)

Fixation of percutaneous medical devices particularly Huber needles.

1 — 4. Device Model/Catalogue/part number(s)

Product Code(s) / Vygon code	Batches number
PF121401 / VPEPF121401	**A200006** **A210007** **A210008** **A220009** **A220010**

2 Reason for Field Safety Corrective Action (FSCA)

2 — **1. Description of the product problem**

PEROUSE MEDICAL became aware about a sealing problem on the packaging of POLYFILM batches number **A200006, A210007, A210008, A220009 and A220010.**
Some units of these batches may have been manufactured with a potential defective sealing.

2 . — **2. Hazard giving rise to the FSCA**

If the packaging of POLYFILM has a defective sealing, it can potentially lead to a loss of sterility of the medical device.
As a preventive measure, PEROUSE MEDICAL has decided to recall all the batches present on the market.

3. Type of Action to mitigate the risk

3. — **1. Action To Be Taken by the User**

x Identify Device
x Send a photo of some devices
x Destroy the Device
x Send the destruction certificate
x Communicated the FSN to the customer (As appropriate)

3. — **2. By when should the action be completed?** — August 31st 2023

3. — **3. Action Being Taken by the Manufacturer**

Recall product

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4. General Information		
4.	The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	Manufacturer information	
	a. Company Name	**PEROUSE MEDICAL**
	b. Address	**Route du Manoir 60173 IVRY LE TEMPLE - FRANCE**
	c. Website address	N/A
4.	10. Name/Signature	[redacted] **Matériovigilance Correspondent** **Quality Manager**

5. Return acknowledgement to sender		
	Email	**VGLFSN@vygon.com**
	Customer Helpline	(+33) 01.39.92.63.81
	Postal Adress	VYGON 5 rue Adeline 95440 ECOUEN FRANCE
	Fax	(+33) 01 39 92 64 82
	Deadline for returning the customer reply form	**August 31st 2023**
	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	

Template for a Field Safety Notice
Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	**FSN Ref: CAPA23-051 Rev01**
FSN Date*	**August 16th 2023**
Product/ Device name*	**POLYFILM®**
Product Code(s) / Vygon code	**PF121401 / VPEPF121401**
Batch/Serial Number (s)	☐ **A200006** ☐ **A210007** ☐ **A210008** ☐ **A220009** ☐ **A220010**

2. 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*	

☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.
☐	I performed all actions requested by the FSN.
☐	I have received products from these batches and I confirm that I have used them ☐ **A200006** Quantity : ☐ **A210007** Quantity : ☐ **A210008** Quantity : ☐ **A220009** Quantity : ☐ **A220010** Quantity :
☐	I have affected devices in stock and I confirm their destruction to VYGON. (complete quantity and date of destruction) ☐ **A200006** Quantity : Destruction date : ☐ **A210007** Quantity : Destruction date : ☐ **A210008** Quantity : Destruction date : ☐ **A220009** Quantity : Destruction date : ☐ **A220010** Quantity : Destruction date :
☐	For each batch, send a photo of some devices before destruction
☐	I do not have any affected devices.

Name*
Signature*
Date*

4. Return acknowledgement to sender	
Email	**VGLFSN@vygon.com**
Customer Helpline	(+33) 01.39.92.63.81
Postal Address	VYGON 5 rue Adeline 95440 ECOUEN FRANCE
Web Portal	N/A
Fax	(+33) 01 39 92 64 82
Deadline for returning the customer reply form*	**August 31st 2023**

Mandatory fields are marked with *

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