

Valkenswaard, 17/08/2023

URGENT - FIELD SAFETY NOTICE – RECALL POLYFILM® – FSN 23-051

Dear Customer,

As the legal distributor of the affected article, we would like to inform you that our manufacturer PEROUSE MEDICAL has identified a batch-related manufacturing defect for the POLYFILM®, our reference VPEPF121401.

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

Following batch numbers are involved: A200006, A210007, A210008, A220009 and A220010.

We verified your purchase history and according to our records you received following products:

Code No.	Order number	Quantity	Batch No.	Date
VPEPF121401	[REDACTED]	2	A210008	25/03/2022
VPEPF121401	5000031602	300	A210008	29/04/2022

** For this order, [REDACTED] has received 2 non-sterile demo samples. These samples were not for use on patients.*

We kindly ask you to acknowledge receipt of this Field Safety Notice and to complete and return the attached Customer Reply Form as soon as possible so we can proceed with the withdrawal of the affected products.

Our National Competent Authority (IGZ) has been informed about this FSN.

If you should require further information, please contact our Sales Support department by telephone 040-2089380 or by e-mail salesupportnl@vygon.com.

We apologize for any inconvenience this FSN may cause.

Yours sincerely,

[REDACTED]

[REDACTED]

[REDACTED]



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ACKNOWLEDGMENT AND CUSTOMER RESPONSE FORM

Please complete, sign and return this form by e-mail to salesupportnl@vygon.com

Name and address of the hospital:	
Full name of the person to contact:	
Function :	
☎ Phone number:	
✉ E-mail:	

We acknowledge receipt of the above FSCA and that the information contained in this field safety notice has been shared with all recipients / end users of above-mentioned products within our organization.

We have the following products available on stock:

Code VPEPF121401, Batch A210008 Yes No

If you have stock, number of units removed and ready for withdrawal: _____

Signature and Date :

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 action.