



Vygon (UK) Ltd
 The Pierre Simonet Building
 V Park, Gateway North
 Latham Road
 Swindon
 Wiltshire SN25 4DL

24/10/22

URGENT FIELD SAFETY CORRECTIVE ACTION

FILTER-A-LINE; 96 HOUR IV FILTER

FSCA – Identifier: ***2210/47526/00***

Type of Action: ***RECALL DEVICE***

Details of Affected Devices:

Product Code	Batch/Lot	NHSSC Code
00080701	101221AH	FTC037
00080701	110222AH	FTC037
00080701	120222AH	FTC037
00080701	220121AH	FTC037

Product Code	Batch/Lot	NHSSC Code
00080702	050321AE	FTC065
00080702	051121AE	FTC065
00080702	070122AE	FTC065
00080702	130522AE	FTC065
00080702	170921AE	FTC065
00080702	181220AE	FTC065
00080702	210122AE	FTC065
00080702	261121AE	FTC065
00080702	300421AE	FTC065

Description of Problem

Field Safety Corrective Action Instructions:

This recall has been initiated by the Legal Manufacturer of the filter component of product codes: 00080701 and 00080702. The Legal Manufacturer, PALL Corporation, has identified a defect on the outlet port of the filter. Use of this product may lead to clinical consequences, e.g., embolism. The root cause of the defect is currently under investigation.

Advice on action to be taken by Medical Staff

1. Identify and **quarantine** any remaining stock of the affected product codes and batch/lot numbers.
2. If you do not have stock from the affected batch number, stated above, mark the according checkbox on the enclosed FSCA Email Back Form, complete the form and send it to the following email address: technical@vygon.co.uk
3. If you have stock from the affected batch number, stated above, mark the according checkbox on the enclosed FSCA Email Back Form, provide the additional information requested and send the completed form to the following email address: technical@vygon.co.uk
4. On receipt of the completed FSCA Email Back Form, a Vygon (UK) Ltd. representative will contact you to arrange return of the affected stock and replacements.
5. Please complete these actions by **30th November 2022**.

Instruction for Distributors of affected batch numbers

Please identify and **quarantine** any remaining stock of the affected product codes and batch/lot numbers in your warehouse(s), complete the FSCA Email Back Form and send the completed form to technical@vygon.co.uk. On receipt of the completed FSCA Email Back Form, a Vygon (UK) Ltd. representative will contact you to arrange return of the affected stock and replacements.

As a distributor, please provide this Field Safety Corrective Action (FSCA) to all your customers who have received stock of the affected product codes and batch numbers, as stated above. Please send your customers the following documents:

- A copy of this Field Safety Corrective Action
- A copy of the FSCA Email Back Form

The FSCA Email Back Form should be completed by your customer and returned to you.

As a distributor you are required to confirm to Vygon (UK) Ltd that you have completed the instructed activity for all of your customers affected by this Field Safety Corrective Action. Please provide confirmation via email to technical@vygon.co.uk.

Please complete these actions by 30th November 2022.

Vygon (UK) Ltd

Vygon (UK) Ltd has informed all customers, employees of Vygon (UK) Ltd and distributors of this Field Safety Corrective Action.

Transmission of this Field Safety Corrective Action

This notice needs to be passed on to all recipients/users of this product within your organisation, in particular, the following:

- **All** departments/wards
- Pharmacy Departments
- MHRA Liaison Officer
- Risk Managers
- Medical Device Safety Officer
- Medical Directors
- Nursing Directors
- Procurement

Please consider end users, clinicians, risk managers, supply chain/distribution centers etc. in the circulation of this FSCA.

Please maintain awareness of this FSCA and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact Person

Kate O'Connell
Technical Support Department
Vygon (UK) Ltd
The Pierre Simonet Building
V Park, Gateway North
Latham Road
Swindon
Wiltshire
SN25 4DL

Telephone: 01793 748800

Email: technical@vygon.co.uk

Vygon (UK) Ltd apologise for any inconvenience this FSCA may cause. This FSCA has been communicated to the MHRA.

A rectangular box containing a handwritten signature in black ink that reads "K. O'Connell".

Kate O'Connell
Technical Support Manager
E-mail: kate.oconnell@vygon.co.uk ; technical@vygon.co.uk

FSCA EMAIL BACK FORM

FIELD SAFETY CORRECTIVE ACTION REF. NO: **2210/47526/00**

DATE: **24/10/22**

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00080702	261121AE	FTC065
00080702	300421AE	FTC065

Please complete this form even if you do not have any affected product listed above and email the completed form to technical@vygon.co.uk

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	NHSSC Code	Batch/Lot Number	Quantity (Pieces)	Stock Purchased From (NHSSC, Vygon, Bunzl, etc.)
00080701	FTC037	101221AH		
00080701	FTC037	110222AH		
00080701	FTC037	120222AH		
00080701	FTC037	220121AH		
00080702	FTC065	050321AE		
00080702	FTC065	051121AE		
00080702	FTC065	070122AE		
00080702	FTC065	130522AE		
00080702	FTC065	170921AE		
00080702	FTC065	181220AE		
00080702	FTC065	210122AE		
00080702	FTC065	261121AE		
00080702	FTC065	300421AE		

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