



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

12/04/2022

URGENT FIELD SAFETY CORRECTIVE ACTION

SOL-M Blunt Fill Needle 18G 40mm No Filter

FSCA – Identifier: 2204/46897/00

Type of Action: RECALL DEVICE

Details of Affected Devices:

| Product Code: | Batch/Lot | NHSSC Code |
|---------------|-----------|------------|
| VSM110022 | 05006007 | FTR1922 |
| VSM110022 | 05009065 | FTR1922 |
| VSM110022 | 05012041 | FTR1922 |
| VSM110022 | 05012043 | FTR1922 |
| VSM110022 | 05012045 | FTR1922 |
| VSM110022 | 05012046 | FTR1922 |
| VSM110022 | 05012057 | FTR1922 |
| VSM110022 | 05105009 | FTR1922 |
| VSM110022 | 05108034 | FTR1922 |
| VSM110022 | 08106075 | FTR1922 |
| VSM110022 | 08106076 | FTR1922 |

Description of Problem

The Legal Manufacturer, Sol-Millennium, with this FSN is initiating a voluntary removal of the product codes and batch numbers listed above from the market with immediate effect. Sol-Millennium has determined an increase in coring of the vial rubber stoppers of medication, when reconstituting diluent and accessing vials. Once the medication is reconstituted, visible pieces of rubber were found floating in the medication, in the barrel of the syringe used to aspirate the medication, and in the IV bag used to administer the medication.

The affected product was supplied by Vygon (UK) Ltd between November 2020 and February 2022.

Field Safety Corrective Action Instructions:

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 of the affected batch numbers, 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 numbers, 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 16th May 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 16th May 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
- MHRA Liaison Officer
- Risk Managers
- Medical Device Safety Officer
- Medical Directors
- Nursing Directors
- Procurement
- Pharmacy

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.



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: **2204/46897/00**

DATE: **12/04/2022**

Details of Affected Devices:

| Product Code: | Batch/Lot | NHSSC Code |
|---------------|-----------|------------|
| VSM110022 | 05006007 | FTR1922 |
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| VSM110022 | 05105009 | FTR1922 |
| VSM110022 | 05108034 | FTR1922 |
| VSM110022 | 08106075 | FTR1922 |
| VSM110022 | 08106076 | FTR1922 |

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 | Batch/Lot Number | Quantity | Name of Supplier (Vygon Direct/NHSSC/SSS/Other) |
|---------------------|-------------------------|-----------------|--|
| VSMI I0022 | 05006007 | | |
| VSMI I0022 | 05009065 | | |
| VSMI I0022 | 05012041 | | |
| VSMI I0022 | 05012043 | | |
| VSMI I0022 | 05012045 | | |
| VSMI I0022 | 05012046 | | |
| VSMI I0022 | 05012057 | | |
| VSMI I0022 | 05105009 | | |
| VSMI I0022 | 05108034 | | |
| VSMI I0022 | 08106075 | | |
| VSMI I0022 | 08106075 | | |

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