

02/08/17

URGENT FIELD SAFETY CORRECTIVE ACTION

XRO UMBILICAL CATHETER 40CM 3.5FG

FSCA – Identifier: **1708/40032/00**

Type of Action: **RECALL DEVICE**

Details of Affected Devices:

Product Code: **00027003 (FSY013)**

Lot Number: **151216FR, 211216FR, 060117FR, 150217FR**

Description of Problem

A non-systemic manufacturing defect has been identified on the code and batch numbers listed above. The numbering on some catheters has been printed incorrectly. The first marking from the distal tip of the catheters may be at 5.5cm instead of 4cm.

Field Safety Corrective Action Instructions:

Advice on action to be taken by Medical Staff

1. Identify and quarantine any remaining stock of code: 00027003, batch: **151216FR, 211216FR, 060117FR, 150217FR**.
2. If you do not have stock from the affected batch number, stated above, mark the according checkbox on the enclosed FSCA Fax Back Form, complete the form and send it to the following fax number: 01793 748899 or email: technical@vygon.co.uk.
3. If you have stock of the affected batch numbers, stated above, mark the according checkbox on the enclosed FSCA Fax Back Form, provide the additional information requested and send the completed form to the following fax number: 01793 748899 or email: technical@vygon.co.uk.
4. On receipt of the completed FSCA Fax Back Form, a Vygon (UK) Ltd. representative will contact you to arrange return of the affected stock and replacements from an alternative batch number.

Instruction for Distributors of affected batch numbers

If you are a distributor, please provide this Field Safety Corrective Action (FSCA) to all your customers who have received products of the affected 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 Fax Back Form

The FSCA Fax 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 forward all completed FSCA Fax Back Forms to the following fax number: 01793 748899 or email: technical@vygon.co.uk.

Please also identify and quarantine any remaining stock of the affected batch number in your warehouse, complete the FSCA Fax Back Form and forward it to the following fax number: 01793 748899 or email: technical@vygon.co.uk.

On receipt of the completed FSCA Fax Back Form, a Vygon (UK) Ltd. representative will contact you to arrange return of the affected stock and replacements from an alternative batch number.

Transmission of this Field Safety Notice

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

MHRA Liaison Officer	Neonatal Units
Risk Managers	Maternity Units
Health and Safety Managers	Stores
Purchasing Managers	Anaesthetics
Procurement Managers	Theatres
Medical Directors	Special Care Baby Units
Nursing Directors	

Vygon (UK) Ltd.

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

Please consider end users, clinicians, risk managers, supply chain/distribution centres 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

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

Telephone: 01793 748800

Vygon (UK) Ltd apologise for any inconvenience this FSCA may cause.

This FSCA has been communicated to the MHRA.

A handwritten signature in black ink, appearing to read 'Tara Pawley', written in a cursive style.

Tara Pawley
Technical Advisor
Email: tara.pawley@vygon.co.uk

FSCA FAX BACK FORM

FIELD SAFETY CORRECTIVE ACTION REF. NO: 1708/40032/00

DATE: 01/08/17

PRODUCT: 00027003 (FSY013) - XRO UMBILICAL CATHETER 40CM 3.5FG

LOT: 151216FR, 211216FR, 060117FR, 150217FR

Please complete this form even if you do not have any affected product and Email/Fax the completed form back to Technical Support Services – **Email: technical@vygon.co.uk** or **Fax: 01793 748899**

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 Reference	Batch/Lot No.	Quantity	Name of Supplier (Direct/NHSSC/SSS/Other)
00027003 (FSY013)	151216FR		
	211216FR		
	060117FR		
	150217FR		

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