



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

07/08/17

## URGENT FIELD SAFETY CORRECTIVE ACTION

### **XRO UMBILICAL CATHETER 37CM 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](mailto: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](mailto: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](mailto: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](mailto: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 grey ink, appearing to read 'Tara Pawley', is positioned above the printed name and title.

Tara Pawley  
Technical Advisor  
Email: [tara.pawley@vygon.co.uk](mailto: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 37CM 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](mailto: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)
<b>00027003 (FSY013)</b>	<b>151216FR</b>		
	<b>211216FR</b>		
	<b>060117FR</b>		
	<b>150217FR</b>		

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