

3<sup>rd</sup> January 2013

## **URGENT FIELD SAFETY CORRECTIVE ACTION**

### ***RYLES TUBE (WEIGHTED TIP) 12FG 125CM***

**FSCA – Identifier:** ***1212/29183/16***

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

#### **Details of Affected Devices:**

**Product Code:** ***0392.12***

**Lot Number:** ***160412FG***

#### **Description of Problem**

It has been identified that, due to a production error, the depth markings have been incorrectly applied to a number of tubes of this batch number.

During use, the inserted length of tube indicated by the markings would be incorrect and this could result in misplacement of the feeding tube.

#### **Field Safety Corrective Action Instructions:**

##### **Advice on action to be taken by Medical Staff**

1. Identify and quarantine any remaining stock of product 0392.12, batch number: 160412FG.
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 from the affected batch number, 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 replacement products 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 number, 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 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 replacement products from an alternative batch number.

### **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 of this product within your organisation, in particular, the following:

All Wards  
Risk Managers  
Health and Safety Managers  
Purchasing Managers  
Medical Directors  
Nursing Directors  
ITU Directors  
A&E Directors  
Maternity Units  
Critical Care Units  
Nutrition & Dietetics  
Radiology

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

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

**Contact Person**

Should you require any further information or support concerning this issue, please contact:

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

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

This Field Safety Notice has been communicated to the MHRA



Kate O'Connell  
Laboratory Supervisor  
Email: [kate.oconnell@vygon.co.uk](mailto:kate.oconnell@vygon.co.uk)

## **FSCA FAX BACK FORM**

**FIELD SAFETY CORRECTIVE ACTION REF. NO:** *1212/29183/16*

**DATE:** *03/01/2013*

**CODE:** *0392.12 - RYLES TUBE (WEIGHTED TIP) 12FG 125CM*

**LOT:** *160412FG*

Please complete this form even if you do not have any affected product and Fax Back to Technical Support Services on Fax Number 01285 650293 or Email: [technical@vygon.co.uk](mailto: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 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

<b>Product Reference</b>	<b>Batch/Lot No.</b>	<b>Quantity</b>	<b>Name of Supplier</b> (Direct/NHSSC/SSS/Other)
<i>0392.12</i>	<i>160412FG</i>		

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