

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

26/01/17

URGENT FIELD SAFETY CORRECTIVE ACTION

GTUBE 12FG 2L DEHP FREE

FSCA – Identifier: 1701/38676/00

Type of Action: RECALL DEVICE

Details of Affected Devices:

Product Code: VWJJC0100-12LVF

Lot Number: 081216UK

Description of Problem

Following an internal receipting error, 29 x product code: WJJC0100-12LVF, batch: 081216UK have mistakenly been sent to customers who have ordered and are expecting product code: VWJJC0110-12LVF. The difference between the two products are as follows:

- WJJC0100-12LVF is a gastrostomy feeding tube with a universal feeding port connector and incorporates a medication port.
- VWJJC0110-12LVF is a bolus gastrostomy feeding tube.

There is therefore a risk that if the incorrect product supplied is not identified by the receiver, the patient may be fitted with the incorrect tube and this will result in user unfamiliarity and the potential for medication to be administered via luer slip syringes via the medication port.

Field Safety Corrective Action Instructions:

Advice on action to be taken by Medical Staff

1. Identify and quarantine any remaining stock of **VWJJC0100-12LVF, 081216UK.**
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 replacements of code: WJKC0100-12LVF.

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 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 of code: WJKC0100-12LVF.

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

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 FSCA has been communicated to the MHRA.

A handwritten signature in black ink, appearing to read 'K. O'Connell', enclosed within a thin rectangular border.

Kate O'Connell
Technical Support Manager
Email: kate.oconnell@vygon.co.uk

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FSCA FAX BACK FORM

FIELD SAFETY CORRECTIVE ACTION REF. NO: 1701/38676/00

DATE: 26/01/17

CODE: VWJKC0100-12LVF - GTUBE 12FG 2L DEHP FREE

LOT: 081216UK

Please complete this form even if you do not have any affected product and Fax Back to Technical Support Services on **Fax Number 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: _____

 Telephone No: _____ Post code: _____
 Signature: _____ E-mail: _____
 _____ 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)
VWJKC0100-12LVF	081216UK		

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