



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

29th July 2015

URGENT FIELD SAFETY CORRECTIVE ACTION

ANTT ADULT CANNULATION PACK

FSCA – Identifier: **1507134598109**

Type of Action: **RECALL DEVICE**

Details of Affected Devices:

Product Code: **0P6193255PHA**

Lot Number(s): **13056**

Description of Problem

The expiry date stated on the label of batch: 13056 is incorrect.

The device label states an expiry date of **2015-08**; the correct expiry date is **2015-07**.

Field Safety Corrective Action Instructions:

Advice on action to be taken by Medical Staff

1. Identify and quarantine any remaining stock of Product Code: **0P6193255PHA**, batch: **13056**
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.
5. Please complete actions by **31st August 2015**

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 Wards	ITU Directors
MHRA Liaison Officer	A&E Directors
Risk Managers	Stores
Health and Safety Managers	Anaesthetics
Purchasing Managers	Theatres
Procurement Managers	ITU/HDU Units
Medical Directors	Maternity Units
Nursing Directors	Radiology
Critical Care Units	Oncology
IV Team	
OPAT Service	

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
Tel: 01793 748800

Vygon (UK) Ltd apologise for any inconvenience this FSCA may cause. This FSCA has been communicated to the MHRA.



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

FSCA FAX BACK FORM

FIELD SAFETY CORRECTIVE ACTION REF. NO: 1507/34598/09

DATE: 29/07/15

PRODUCT CODE: 0P6193255PHA – IPSWICH ANTT ADULT CANNULATION PACK

LOT: 13056

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: _____	
	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)
0P6193255PHA	13056		

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