29th July 2015

URGENT FIELD SAFETY CORRECTIVE ACTION

ANTT ADULT CANNULATION PACK

FSCA – Identifier: 1507/34598/09
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:

<table>
<thead>
<tr>
<th>All Wards</th>
<th>ITU Directors</th>
</tr>
</thead>
<tbody>
<tr>
<td>MHRA Liaison Officer</td>
<td>A&amp;E Directors</td>
</tr>
<tr>
<td>Risk Managers</td>
<td>Stores</td>
</tr>
<tr>
<td>Health and Safety Managers</td>
<td>Anaesthetics</td>
</tr>
<tr>
<td>Purchasing Managers</td>
<td>Theatres</td>
</tr>
<tr>
<td>Procurement Managers</td>
<td>ITU/HDU Units</td>
</tr>
<tr>
<td>Medical Directors</td>
<td>Maternity Units</td>
</tr>
<tr>
<td>Nursing Directors</td>
<td>Radiology</td>
</tr>
<tr>
<td>Critical Care Units</td>
<td>Oncology</td>
</tr>
<tr>
<td>IV Team</td>
<td></td>
</tr>
<tr>
<td>OPAT Service</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Product Reference</th>
<th>Batch/Lot No.</th>
<th>Quantity</th>
<th>Name of Supplier (Direct/NHSSC/SSS/Other)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0P6193255PHA</td>
<td>13056</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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