



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

04/05/18

## URGENT FIELD SAFETY CORRECTIVE ACTION

### **MICRO SELDINGER KIT**

**FSCA – Identifier:** **1805/41782/00**

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

#### **Details of Affected Device:**

**Product Code:** **G1146-057**  
**NHS Supply Chain Code:** **FSY242**  
**Lot Number:** **S18025037**

#### **Description of Problem**

It has been identified by the manufacturer that the product listed above may contain unsafe levels of bacterial endotoxins (Pyrogens) introduced during the manufacturing process. Bacterial endotoxins (also called pyrogenic bacteria) can activate the inflammatory process and produce fever, chills and hypotension in patients. The manufacturer has investigated the problem and has taken steps to assure this problem does not re-occur.

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

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

1. Identify and quarantine any stock of product code: G1146-057, lot number: **S18025037**.
2. If you do not have stock from the affected lot 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 lot 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](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.
5. Please complete actions by **4<sup>th</sup> June 2018**

## **Instruction for Distributors of the Affected Lot Number**

Please provide this FSCA to all your customers who have received the affected lot number of the product code listed above. Please send your customers the following documents:

- A copy of this FSCA
- A copy of the FSCA fax-back form

The FSCA fax-back form should be completed by your customers and returned to you.

As a distributor you are required to confirm to Vygon (UK) Ltd. that you have received this FSCA by completion and return of the attached fax back form. 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 lot 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.

Please complete actions by **4<sup>th</sup> June 2018**

## **Transmission of this Field Safety Notice**

This notice needs to be passed on to all recipients/users of this product within your organisation, in particular, the following:

- MHRA Liaison Officer
- Risk Managers
- Medical Device Safety Officer
- Medical Directors
- Nursing Directors
- Infection Prevention & Control
- Procurement
- Purchasing
- Main Stores
- Theatres
- A&E
- Cardiac Unit
- Radiology
- Oncology
- ITU/HDU
- Maternity
- Anaesthetics
- Fluoroscopy
- Critical Care
- IV Team
- Nutrition Team
- OPAT Service

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

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

**Vygon (UK) Ltd.**

Vygon (UK) Ltd. has informed all customers, employees of Vygon (UK) Ltd. and distributors of this Field Safety Corrective Action.

**Contact Person**

Tara Pawley  
Technical 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.



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: 1805/41782/00**

**DATE: 04/05/18**

**Details of Affected Device:**

**Product Code:** **G1146-057**  
**NHS Supply Chain Code:** **FSY242**  
**Lot Number:** **S18025037**

Please complete this form even if you do not have any affected product listed above 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 Code	Lot Number	Quantity	Name of Supplier (Direct/NHSSC/SSS/Other)
<b>G1146-057</b>	<b>S18025037</b>		

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