

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

3rd October 2016

URGENT FIELD SAFETY CORRECTIVE ACTION

LECTROGAURD

FSCA – Identifier: 1609/37717/00

Type of Action: RECALL DEVICE

Details of Affected Devices:

Product Code: 1188.15 (FSB393)

Lot Number: 230115EE, 010615EE, 071015EE

Description of Problem

The manufacturer has identified a white deposit on the outer surface of some devices. The white deposit is an excess quantity of an anti-UV additive.

The extension tubing of the device is manufactured from two layers of polyethylene. The outer layer contains an anti-UV additive to protect light sensitive drugs during infusions. The inner layer of the extension tubing does not contain the additive and will act as a barrier, preventing contact between the anti-UV additive and the fluid pathway. As patient safety is of paramount importance to Vygon and, as a precaution, we are recalling the affected batch numbers.

Field Safety Corrective Action Instructions:

Advice on action to be taken by Medical Staff

1. Identify and quarantine any remaining stock of 1188.15, batch: 230115EE, 010615EE & 071015EE
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 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 discuss 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/users 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
Critical Care Units
Chemotherapy Suites
Pulmonary Hypertension Units
Nutrition & Dietetic Units

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.

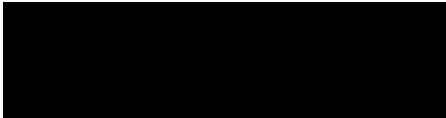
Contact Person

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.



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: 1609/37717/00

DATE: 28/09/16

CODE: 1188.15 (FSB393) - AMBER LECTROCATH ANTI-UV 150CMS BX50

LOT/BATCH: 230115EE, 010615EE & 071015EE

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)
1188.15	230115EE		
1188.15	010615EE		
1188.15	071015EE		

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