

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

24th January 2017

URGENT FIELD SAFETY CORRECTIVE ACTION

SWITCH NEEDLE-PROTECTED SAFETY CATHETER

FSN – Identifier: **1701/38571/00**

Type of Action: **RECALL DEVICE**

Details of Affected Devices:

Product Code:	Lot Number
SW204501	P8096
SW204501	P8251
SW223501	P8098
SW224501	P8097

Description of Problem

FEP (Fluorinated Ethylene Propylene) catheter material in combination with beta-sterilization is more sensitive to repeated kinking than similar vascular catheters of other material and/or sterilization method. Repeated kinking of a beta-sterilized FEP catheter can, in rare cases, result in catheter breakage and may therefore need to be removed by surgical intervention.

Field Safety Corrective Action Instructions:

Advice on action to be taken by Medical Staff

1. Identify and quarantine any remaining stock of the product codes and batch numbers listed above.
2. If you do not have stock from the affected batch numbers, 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 numbers, 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

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 **24th February 2017**.

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/user of this product within your organisation, in particular, the following:

All Departments using I.V. access devices	Medical Directors
All Wards	Nursing Directors
Risk Managers	ITU Directors
Health and Safety Managers	A&E Directors
Purchasing Managers	Maternity Units

Please consider end users, clinicians and risk managers 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

Tara Pawley
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.



Tara Pawley
Technical Advisor
Email: tara.pawley@vygon.co.uk



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FSCA FAX/EMAIL BACK FORM

FIELD SAFETY NOTICE REF. NO: 1701/38571/00

DATE: 24th January 2017

Product Code:	Lot Number
SW20450I	P8096
SW20450I	P825I
SW22350I	P8098
SW22450I	P8097

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**, Email – technical@vygon.co.uk

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 Code:	Lot Number	Quantity
SW20450 I	P8096	
SW20450 I	P825 I	
SW22350 I	P8098	
SW22450 I	P8097	

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