

1st April 2022

URGENT FIELD SAFETY NOTICE

PEELABLE CANNULA

FSN – Identifier: 2203/46851/00

Type of Action: AWARENESS

Details of Affected Devices:

Product Code	Description	Batch Number
00114702	MICROSITE 2FR MST KIT	060122GG
00114702	MICROSITE 2FR MST KIT	091221GG
001252030	NUTRILINE STYLETTED 24G 30CM	240122GP
001261208	PREMICATH+STYLET+MICROFLSH INTRO B10	050122GS

Description of Problem

The legal manufacturer, Vygon GmbH, has identified a possible malfunction of the peelable introducer cannula included with the product codes and batch numbers listed above. After catheter placement and withdrawal of the peelable cannula, in a few cases the cannula may not peel completely, causing one half of the cannula to break off. As a result, a section of the cannula will remain on the catheter.

Action

If this occurs, the legal manufacturer recommends that the catheter remains in situ and the non-removable section of the cannula is gently pulled along with catheter towards the hub as far as possible and secured. To improve securment, the yellow cannula wing and the peeled section of cannula may be cut off with a pair of scissors, leaving the distal part of the cannula on the catheter.

Please ensure that there is sufficient distance between the catheter and scissors to prevent accidental damage to the catheter (figure 1).

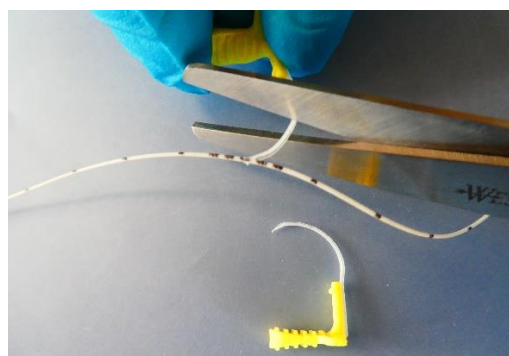


Figure 1

Medical Staff

Please confirm receipt of this FSN by completing the attached fax back form and returning it to Vygon (UK) Ltd using the following fax number: 01793 748899 or email: technical@vygon.co.uk

Distributors

Please provide this Field Safety Notice (FSN) to all of your customers who have received the affected products and batch numbers, as stated above. Please send your customers the following documents:

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

The FSN 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 FSN by completion and return of the attached fax back form.

As a distributor you are also required to confirm to Vygon (UK) Ltd that you have completed the instructed activity for all of your customers affected by this FSN. Please send all completed FSN fax back forms to the following fax number: 01793 748899 or email: technical@vygon.co.uk

Transmission of this Field Safety Notice

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

Neonatal Units
Maternity Units
Risk Managers
Health and Safety Managers
Purchasing Managers
Medical Directors
Nursing Directors
ITU Directors
A&E Directors
All departments using the affected product codes

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

For further information please contact our Technical Support Department by e-mail - technical@vygon.co.uk or by telephone - 01793 748800.

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
Email: technical@vygon.co.uk

Vygon (UK) Ltd apologise for any inconvenience this FSN may cause.

This FSN has been communicated to the MHRA.



Kate O'Connell
Technical Support Manager
Email: kate.oconnell@vygon.co.uk ; technical@vygon.co.uk

FSN FAX/EMAIL BACK FORM

FIELD SAFETY NOTICE REF. NO: 2203/46851/00

DATE: 01/04/2022

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Please complete this form and return it to Vygon (UK) LTD, Technical Support Department using **Fax Number 01793 748899** or email: technical@vygon.co.uk

I/we acknowledge receipt of the above FSN and that the information contained in this FSN has been shared with all recipients/user of the above products within our organisation.

Name: _____	Mr/Mrs/Miss/Other: _____
Designation: _____	
Organisation: _____	
Department: _____	
Address: _____	
	Post code: _____
Telephone No: _____	E-mail: _____
Signature: _____	Date: _____