

10/01/2025

URGENT FIELD SAFETY CORRECTIVE ACTION

LIFECATH PICC+MST DOUBLE 4.5FG B10

FSCA – Identifier: **2501/51058/00**

Type of Action: **RECALL DEVICE**

Details of Affected Devices:

Product Code:	Batch/Lot	NHSSC Code
001294345	101024GT	FSU373

Description of Problem

Due to an injection moulding fault a partial quantity of the grey hub of the affected batches might be damaged and the hub may not withstand the mechanical stresses which could be applied to it. Furthermore, a leakage at the hub might have a subsequential effect.

Field Safety Corrective Action Instructions: Advice on action to be taken by Medical Staff

1. Identify and quarantine any remaining stock of the affected product codes and batch/lot numbers.
2. If you do not have stock from the affected batch number, stated above, mark the according checkbox on the enclosed FSCA Email Back Form, complete the form, and send it to the email address: technical-uk@vygon.com.
3. If you have stock from the affected batch number, stated above, mark the according checkbox on the enclosed FSCA Email Back Form, provide the additional information requested, and send the completed form to the email address: technical-uk@vygon.com.
4. On receipt of the completed FSCA Email Back Form, a Vygon (UK) Ltd. representative will contact you to arrange return of the affected stock and replacements.
5. **Please complete these actions by 03-02-2025.**

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 stock of the affected product codes and batch numbers, as stated above. Please send your customers the following documents:

- A copy of this Field Safety Corrective Action
- A copy of the FSCA Email Back Form

The FSCA Email 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 Email Back Forms to the email address: technical-uk@vygon.com.

Please also identify and quarantine any remaining stock of the affected batch number in your warehouse, complete the FSCA Email Back Form, and forward it to the email address: technical-uk@vygon.com.

On receipt of the completed FSCA Email Back Form, a Vygon (UK) Ltd. representative will contact you to arrange return of the affected stock and replacements.

Please complete these actions by 03-02-2025.

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** departments/wards
- MHRA Liaison Officer
- Risk Managers
- Medical Device Safety Officer
- Medical Directors
- Nursing Directors
- Procurement

Please consider end users, clinicians, risk managers, supply chain/distribution centers 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
Email: technical-uk@vygon.com

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

FSCA EMAIL BACK FORM

FIELD SAFETY CORRECTIVE ACTION REF. NO: 2501/51058/00

DATE: 13 January 2025

DETAILS OF AFFECTED DEVICES:

Product Code:	Batch/Lot	NHSSC Code
001294345	101024GT	FSU373

Please complete this form even if you do not have any affected product listed above and email the completed form back to Technical Support Services – Email: technical-uk@vygon.com

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	Batch/Lot Number	Quantity	Name of Supplier Direct/NHSSC/SSS/Other)
001294345	101024GT		

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