04th March 2025

# URGENT FIELD SAFETY NOTICE

## *LIFECATH BIFLUX DOUBLE LUMEN CATHETER*

**FSN – Identifier:** **2503/51349/00**

**Type of Action:** ***ADVISORY***

**Details of Affected Devices:**

| Product Code: | Batch/Lot | NHSSC Code |
|---|---|---|
| 00229370 | ALL | FSU129 |

**Description of Problem**

The legal manufacturer, VYGON Germany GmbH, is releasing an Advisory Field Safety Notice (FSN), to inform customers of an increase of customer reports in the UK relating to catheter fractures and malfunction of the pinch clamps on the catheter, specifically product code: 00229370.

After excessive use of the clamps and when closed for long periods (as described within clinical guidelines), in a few cases the clamps may open spontaneously. Lifecath catheters are made from Silicone. Silicone is also a delicate material, and even minor damage can lead to a catheter fracture.

We are communicating this information to raise awareness that the recommended handling of Lifecath catheters differs in some respects from common clinical practice.

We can confirm that no root cause has been identified and there have been no changes to the materials nor the manufacturing process within the last three years.

Please follow the information and actions described within this FSN.

**Action**

VYGON Germany GmbH recommends applying the pinch clamps only temporarily and closing the catheter hubs with a needle-free device (e.g. Bionector) as stated in the device IFU:

- *"when the catheter is not in use, close the hub with an injectable membrane […] or a Bionector […]"*

This is sufficient to close the hub and avoid strain on the clamps when the catheter is not in use. The clamps should only be closed when dis-/connecting a medical device to the catheter hubs.

Furthermore, the catheter is made of silicone, which is known to be bioinert and therefore it will not react with chemicals or other substances – except for iodine-based solutions as stated in the IFU:

- *"CAUTION: Do not expose this catheter to contact with iodine-based solutions!".*

Silicone is also a delicate material, and even minor damage can lead to a catheter fracture/lumen fracture. We recommend handling the catheter with particular care and preventing any mechanical damage as stated in the IFU:

- *"WARNING: Silicone is a delicate material. Pay particular attention when manipulating a sharp or pointed instruments (scissors, scalpel, needles, etc.) near the catheter."*
- *"CAUTION: Do not bend the catheter or the extension line permanently to avoid damage to the catheter.".*

For the paediatric patient population, it is important to ensure adequate fixation of the catheter lumens and to avoid additional movement resulting in twisting or kinking of the catheter, which can lead to damage/catheter fractures.

**We can also confirm that the use of the product does not need to change if none of the possible handling problems stated above have occurred.**

**There is no requirement for customers to return any devices to VYGON. Lifecath catheters can continue to be used in accordance with the IFU and this advisory FSN.**

VYGON will continue investigating reports of catheter fractures and clamp malfunction and will follow up with any additional actions if needed.

If you require further information, or experience an issue with the product, please contact Vygon (UK) Ltd using the email address: technical-uk@vygon.com.

We also encourage the reporting of incidents to the MHRA via the Yellow Card reporting site - https://yellowcard.mhra.gov.uk/.

**Medical Staff**

Please confirm receipt of this FSN by completing the attached email back form and returning it to Vygon (UK) Ltd using the email address: technical-uk@vygon.com.

**Distributors**

Please provide this Field Safety Notice (FSN) to all your customers who have received product as stated above. Please send your customers the following documents:

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

The FSN email 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 email 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 email back forms to technical-uk@vygon.com.

**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:

All departments using Lifecath Tunnelled Catheters, including:

- Vascular Access Services
- Children's Nutrition Departments
- Paediatric Oncology Departments
- Theatres
- Haematology/Oncology Departments
- Interventional Radiology
- Paediatric Oncology Shared Care Units
- Community Outpatient Services
- Clinical Procurement
- Risk Managers
- Health and Safety Managers
- Medical Directors
- Nursing Directors

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 email (technical-uk@vygon.com) 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

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.com

# FSN EMAIL BACK FORM

**FIELD SAFETY NOTICE REF. NO: 2503/51349/00**
**DATE: 10/03/2025**

## DETAILS OF AFFECTED DEVICES:

| Product Code: | Batch/Lot | NHSSC Code |
|---|---|---|
| 00229370 | ALL | FSU129 |

Please complete this form and return it to Vygon (UK) LTD, Technical Support Department using the email address: technical-uk@vygon.com

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: _____