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Aachen, 09.01.2025

Urgent FSCA on lifecath PICC pur, Code 1294.245, Batch 081024GQ and Code 1294.345, Batch 101024GT – Recall 008

As legal manufacturer of the affected article, we would like to inform you that we have identified a batch-related manufacturing problem at the grey Luer Lock hub.

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 be a subsequential effect.

Product Description	Code No.	Batch No.
<i>lifecath PICC pur</i>	<i>1294.245</i>	<i>081024GQ</i>
<i>lifecath PICC pur</i>	<i>1294.345</i>	<i>101024GT</i>

We therefore ask you to immediately withdraw these batches from services and to return them according to our instructions below.

Please acknowledge receipt of this letter and complete and return the attached form by indicating the quantities withdrawn from your institution.

Your national Competent Authority has been informed about this Recall.

If you should require further information, please contact your local Vygon distributor.

We apology for any inconvenience this recall may cause.

Yours sincerely,

Ralf Quentin

Department Manager Quality Assurance & Medical Device Surveillance

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ACKNOWLEDGMENT AND CUSTOMER RESPONSE FORM

Please complete and return this form:
by e-mail to vigilance@vygon.com or fax: 0241 / 91 30 106 or

Name and address of the institution :	
Full name of the person to contact:	
Function :	
☎ Phone number:	
✉ E-mail:	

We acknowledge receipt of the above FSCA and that the information contained in this field safety notice has been shared with all recipients / end users of above-mentioned products within our organization.

Please tick the appropriate box:

We have the following products available on stock :

Code 1294.245, Batch 081024GQ Yes No If you have stock, number of units removed: _____

Code 1294.345, Batch 101024GT Yes No If you have stock, number of units removed: _____

Signature and Date : _____

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