

Manager Quality Management  
and Product Development

Tel.: 0241 / 91 30 0  
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Aachen, 08.12.2022

### Urgent FSCA on guide wire used in the listed product – Recall 002

As the legal manufacturer of the affected articles, we would like to inform you that we have identified a batch-related manufacturing problem that makes placement of the catheter impossible.

The affected batch was supplied with a guide whose outer diameter was too large. The catheter cannot be placed over this guide wire and the placement time would be delayed. A catheter larger in internal diameter would have to be used or a new puncture with a correct set would have to be made.

The following product is involved:

Product Description	Code No.	Batch No.
multicath 2	157.114	310522GO

We therefore ask you to immediately withdraw this batch from services and to return the batch according to our instructions below.

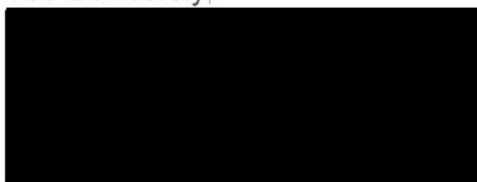
Please acknowledge receipt of this letter and complete and return the attached form by indicating the quantities withdrawn from your institution.

*Your National Competent Authority has been informed about this Recall.*

*If you should require further information, please contact your local Vygon distributor via telephone number detailed below.*

We apologize for any inconvenience this recall may cause.

Yours sincerely,



Manager Quality Management and Product Development

**Urgent FSCA on guide wire used in the listed product – Recall 002**

**ACKNOWLEDGMENT AND CUSTOMER RESPONSE FORM**

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**Please complete and return this form:  
by fax: +49(0)241 / 91 30 106 or e-mail to [vigilance@vygon.com](mailto:vigilance@vygon.com)**

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

**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 the above-mentioned product within our organization.**

**Please tick the appropriate box:**

**We have the following product available on stock :**

**Code 157.114, Batch 310522GO**  Yes  No      **If you have stock, number of units removed: \_\_\_\_\_**

**Signature and Date :** \_\_\_\_\_