Field Safety Notice

ViaCath NG 4/S/5mm - ViaCath 20/XL/2-8-2mm

Reference: FCMVC **May 2026**

Subject: Field Safety Corrective Action for
ViaCath NG 4/S/5mm **Lot Number 12250386 and**
ViaCath 20/XL/2-8-2mm **Lot Number 01260302**

Dear Customer,
VascoMed is voluntarily implementing a Field Safety Correction Action (FSCA) by a product removal of unused inventory associated with one lot of ViaCath NG 4/S/5mm and one lot ViaCath 20/XL/2-8-2mm. This action applies to two specific product lots with 19 products in total. A potentially affected product has been supplied to your organization.

1. Description of the Issue

VascoMed has identified a labelling non-conformity affecting two specific lots of the products ViaCath NG 4/S/5mm and ViaCath 20/XL/2-8-2mm.
For the affected products, the manufacturing date printed on the product label is incorrectly stated as 2027-07 instead of 2025-07. Accordingly, the use-by date is also incorrect, shown as 2029-07 instead of the correct date of 2027-07.
All other information on the product label is correct. The devices themselves are not defective. They have been 100% tested and comply with all applicable technical and regulatory requirements. The quality, safety, and performance of the devices are not impaired when used within their correct validated shelf life. However, the incorrect labelling may lead to a use of a product with an expired use-by date.

2. Potential Risk to Patients

There have been no patient injuries reported in connection with this issue.
However, if a catheter were to be used after its correct use-by date 2027-07, there is a potential risk for the patient including infection, toxic or allergic reactions, or loss of mechanical or electrical device functionality.
Therefore, Vascomed has initiated a Corrective and Preventive Action.

3. Affected Products

This Field Safety Notice applies only to the following specific lots:

- Device Name: ViaCath NG 4/S/5mm
- Catalogue / Reference Number: 351197
- Affected Lot Number (as shown on the outer box): 12250386
- Affected Products: 10

and

- Device Name: ViaCath 20/XL/2-8-2mm
- Catalogue / Reference Number: 351201
- Affected Lot Number (as shown on the outer box): 01260302
- Affected Products: 9

No other ViaCath products or lot numbers are affected.

4. Actions to Be Taken by the Customer

1. Identify affected products
   - Check all available stock of ViaCath NG 4/S/5mm and ViaCath 20/XL/2-8-2mm
   - Compare lot numbers with the affected lots above
2. Verify the use-by date
   - Be aware that the use-by date printed on the label of affected products is incorrect
3. Remove these products from stock
   - Segregate and quarantine these products
   - Return these products via the local sales representative to BIOTRONIK SE & Co. KG
4. Inform relevant personnel and confirm receipt
   - Please ensure that this information is communicated to all relevant staff within the corresponding organization, including clinical users and personnel responsible for inventory management
   - Please complete and return the attached Customer Acknowledgement Form to confirm receipt and implementation of this Field Safety Corrective Action

The relevant Competent Authorities have been or will be informed in accordance with Regulation (EU) 2017/745 (MDR) and applicable national requirements.

Thank you for your assistance in helping us to manage this market action.

If you have further questions or need assistance with this Corrective Action, please do not hesitate to contact local sales organisation, BIOTRONIK SE & Co. KG or VascoMed GmbH.

VascoMed GmbH
Hertzallee 1
79589 Binzen, Germany
Email: prrc@vascomed.com

BIOTRONIK SE & Co. KG is the distributor of the affected devices and partner for this FSCA.

We apologize for any inconvenience this Field Safety Corrective Action may have caused to

you, your patients, or your team. We appreciate your cooperation in this matter and are committed to maintaining your confidence in the quality of our products.

Yours sincerely,

Dr. Janosch Lichtenberger
Person Responsible for Regulatory Compliance