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BIOTRONIK AG
Ackerstrasse 6
CH-8180 Bülach
Switzerland

Urgent Field Safety Notice

Document-Identification:

A11 REC 171955 EN 01

Product: **Passeo-35 Xeo Peripheral Dilatation Catheter**
Dynetic-35 Peripheral Balloon-Expandable Stent System

Bülach, November 2021

Dear Customer,

BIOTRONIK AG is initiating a Voluntary Field Safety Corrective Action to withdraw specific lots of its Passeo-35 Xeo Peripheral Dilatation Catheter and Dynetic-35 Peripheral Balloon-Expandable Stent System from the market.

Description of the problem:

During an in-house inspection, Biotronik discovered that a few sterilization pouches of the Passeo-35 Xeo and Dynetic-35 were incompletely sealed, which may compromise the sterility of the devices. Patients treated with non-sterile devices, may potentially suffer an infection.

So far Biotronik has not received complaints about incompletely sealed sterilization pouches, or any related patient harm. Nevertheless, Biotronik has voluntarily initiated this FSCA as a precautionary measure as part of its commitment to patient safety and product quality.

Details on affected devices:

The Passeo-35 Xeo is a balloon catheter indicated to dilate stenosis in the iliac, femoral, popliteal and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Passeo-35 Xeo is also recommended for post-dilation of balloon expandable and self-expanding stents in the peripheral vasculature.

The Dynetic-35 is a vascular stent system indicated for the treatment of de novo or restenotic atherosclerotic lesions in iliac arteries.

Affected products:

“Please refer to the attached the list of the affected products.”

This Voluntary Field Safety Corrective Action affects **only** the 17 lots of the Passeo-35 Xeo Peripheral Dilatation Catheter and 13 lots of the Dynetic-35 Peripheral Balloon-Expandable Stent System listed on page 3. Other lots are not affected.

BIOTRONIK AG will inform the appropriate Competent Authorities of this Voluntary Field Safety Corrective Action.

Advice on action to be taken by the customer:

According to our records you have received Passeo-35 Xeo Peripheral Dilatation Catheter and/or Dynetic-35 Peripheral Balloon-Expandable Stent System devices from the affected lots. We ask for your cooperation in our efforts to complete this Voluntary Field Safety Corrective Action. Therefore, please follow the instructions outlined below.

1. Discontinue any further use of the affected Passeo-35 Xeo Peripheral Dilatation Catheter and Dynetic-35 Peripheral Balloon-Expandable Stent System lots. Identify and remove all the affected Passeo-35 Xeo Peripheral Dilatation Catheter and Dynetic-35 Peripheral Balloon-Expandable Stent System units from your inventory, segregate them in a safe place and mark them appropriately.

2. Utilize standard hospital practice and policies to monitor patients who were treated with the affected devices.
3. Read, complete, sign and send the Customer Acknowledgement Form enclosed to this Field Safety Notice. A BIOTRONIK sales representative will contact you to collect all remaining Passeo-35 Xeo Peripheral Dilatation Catheter and/or Dynetic-35 Peripheral Balloon-Expandable Stent System from the affected lots. Please hand over all the affected products and the original signed Customer Acknowledgement Form.
4. Bring this Field Safety Notice to the attention of any health care professional in your organisation that needs to be aware.

Assistance

If you have further questions or need assistance with this Voluntary Field Safety Corrective Action, please do not hesitate to contact your local sales representative directly or BIOTRONIK AG on +41 44 864 5525/ or -5526.

We apologize for any inconvenience this Voluntary Field Safety Corrective Action may cause. We appreciate your cooperation in this matter and are committed to maintaining your confidence in the quality of our products.

Respectfully,

Marcel Schäfer
Senior Director Regulatory Affairs and Post Market Surveillance

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List of affected products and lots:

Passeo-35 Xeo

REF	Size	LOT
428786	3/40/90	08214473
428790	7/40/90	08212917
428799	7/60/90	08212918
428808	7/80/90	09214244
428815	5/100/90	08214901
428843	5/200/90	09213417
428863	6/40/130	08213996
428863	6/40/130	09214245
428864	7/40/130	07215172
428873	7/60/130	07214707
428873	7/60/130	08213964
428887	3/100/130	08215721
428890	6/100/130	08213965
428900	7/120/130	08212280
428909	7/150/130	08215748
428912	5/170/130	08215470
428916	4/200/130	09214288

Dynetic-35

REF	Size	LOT
428722	7/28/130	07214602
428738	7/78/130	07214603
448942	8/28/90	09211858
448943	9/28/90	10210645
448944	10/28/90	08210209
448945	8/38/90	09215818
448945	8/38/90	09216566
448946	9/38/90	08212385
448946	9/38/90	09216721
448946	9/38/90	09216966
448947	10/38/90	09210274
448960	8/38/130	08214477
448961	9/38/130	08213348