BIOTRONIK
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Bülach, October 2017

Urgent Field Safety Notice

Product: Passeo-18 Lux Paclitaxel-releasing PTA balloon catheter

Dear Customer,

BIOTRONIK AG Bülach Switzerland is initiating a Voluntary Field Safety Corrective Action to withdraw **one specific** lot of the Passeo-18 Lux Paclitaxel-releasing PTA balloon catheter.

Description of the problem:

It was determined that one Lot (21 units) of Passeo-18 Lux containing a single, possibly non-conforming product was unintentionally released to the market. As a cautionary measure Biotronik is withdrawing the concerned Lot from the market.
The non-conforming product could be in the worst, but unlikely case unsterile.

Details on affected products:

The Passeo-18 Lux catheter is indicated to dilate de novo or restenotic lesions in the infrainguinal arteries.

This Voluntary Field Safety Corrective Action applies only to the Passeo-18 Lux Lot listed below. Other Lots are NOT concerned.

Product name	Size	REF number	LOT
Passeo-18 Lux	4/120/130	370869	03171303

Advice on action to be taken by the customer:

Our records indicate that you have received Passeo-18 Lux products from the affected Lot and we are asking for your cooperation in our efforts to complete this Voluntary Field Safety Corrective Action. Therefore, please follow the instructions outlined below.

1. Please discontinue any further use of the affected Passeo-18 Lux lot. Identify and remove all the affected Passeo-18 Lux units from your inventory, store them at a safe place and mark them appropriately.
2. Please 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-18 Lux from the affected Lot. Please hand over all the affected products and the original signed Customer Acknowledgement Form.

3. Please 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, Ph.D
Director Regulatory Affairs and Post Market Surveillance