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Bülach,13. February 2015

Urgent Field Safety Notice

Product: Passeo-18, Peripheral 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 peripheral balloon catheter.

Description of the problem:

It was determined that one lot of the Passeo-18 was wrongly labeled. The Passeo-18 3.5/40/135, LOT 11144151, was wrongly labelled as Passeo-18 4/200/90, LOT 12142151. To date, we have received one customer complaint relating to this error without any patient injury reported.

Details on affected devices:

The Passeo-18 peripheral dilatation catheter is indicated to dilate stenosis in the femoral, popliteal and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

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

Device name	Size	REF number	LOT
Passeo-18	4/200/90	376280	12142151

Advice on action to be taken by the customer:

Our records indicate that you have received Passeo-18 devices 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 lot. Identify and remove all the affected Passeo-18 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 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.

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.

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 5526/ -5673.

Respectfully,

Director Regulatory Affairs and Post Market Surveillance