BIOTRONIK AG
Ackerstrasse 6
CH-8180 Bülach
Switzerland

Bülach, March 2019

Urgent Field Safety Notice

Product:

Cruiser, Coronary and peripheral artery guide wire, two specific lots

Dear Customer,

BIOTRONIK AG is initiating a Voluntary Field Safety Corrective Action to withdraw two specific lots of the Cruiser coronary and peripheral artery guide wire from the market.

Description of the problem:

It was determined that two lots of the Cruiser coronary and peripheral artery guide wire were mixed up. The labeled tip shape and guide wire flexibility do not reflect the actual shape and flexibility of the products inside the packaging. The risk of using a wrong product is low since the mismatch is promptly noticed by the user before insertion of the guide wire into the patient. A slight delay in the procedure time due to the selection of a new guide wire is possible.

Details on affected devices:

The Cruiser guide wires are indicated to facilitate the placement of interventional catheters with compatible guide wire lumen during an interventional procedure in coronary and peripheral arteries.

This Voluntary Field Safety Corrective Action affects **only** the two lots of the Cruiser guide wire listed below, **no other** Cruiser guide wire lots are affected.

Size	Ref Number	Lot Number
F	351461	06183710
ES-HF-J	351468	06182718

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

Advice on action to be taken by the customer:

Our records indicate that your facility received affected Cruiser coronary and peripheral artery guide wire 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 two affected Cruiser lots listed on page 1. Identify and remove all the affected Cruiser 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 sales representative will contact you to collect the affected Cruiser guide

wires. Please hand over all the affected products and the original signed Customer Acknowledgement Form.

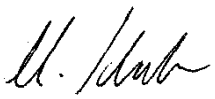
3. Please bring this Field Safety Notice to the attention of any health care professional in your organisation that needs to be aware.

Assistance

If you have questions or need any further information about 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/ -5526 or -7438.

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
Director Regulatory Affairs & Post Market Surveillance