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Bülach, June 2015

Urgent Field Safety Notice

Product: Orsiro, Sirolimus Eluting Coronary Stent System

Dear Customer,

BIOTRONIK AG Bülach Switzerland is initiating a Voluntary Field Safety Corrective Action to withdraw **4 specific** lots (total 165 devices) of the Orsiro Coronary Stent System.

Description of the problem:

It was determined that 4 lots of the Orsiro stent system were wrongly labeled. The labeled diameter does not reflect the actual diameter of the packed product. The use of a product from the affected lots may result in vessel injury and/or increased procedure time.

Details on affected devices:

The Orsiro Sirolimus Eluting Coronary Stent System is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete de-novo stenotic lesions and in-stent restenotic lesions (length ≤ 40 mm) in native coronary arteries with a reference vessel diameter of 2.25 mm to 4.0 mm.

This Voluntary Field Safety Corrective Action applies only to the 4 Orsiro lots listed below. Other lots are NOT concerned.

Device name	Size	REF number	LOT
Orsiro	2.75/40	391240	02152670
Orsiro	2.75/40	391240	02152671
Orsiro	3.0/40	391241	02152672
Orsiro	3.0/40	391241	02152673

Advice on action to be taken by the customer:

According to our records you have received Orsiro 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 Orsiro lots. Identify and remove all the affected Orsiro units from your inventory, segregate them in a safe place and mark them appropriately.
2. 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 Orsiro from the affected lots. Please hand over all the affected products and the original signed Customer Acknowledgement Form.
3. 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/ or -5673.

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,

Director Regulatory Affairs and Post Market Surveillance