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Bülach, September 2011

Urgent Field Safety Notice

Product: Cruiser Hydro Coronary and Peripheral Artery Guide Wire

Dear Customer,

BIOTRONIK AG is initiating a Voluntary Field Safety Corrective Action to withdraw specific lots of its Cruiser Hydro coronary and peripheral artery guide wire from the market. Enclosed please find the list of the affected lot numbers.

Description of the problem:

Routine three year shelf life testing of Cruiser Hydro guide wires has shown that the tensile strength of the flexible distal tip of some of the tested articles did not meet the specifications. This may increase the likelihood of tip fracture during the procedure. As a cautionary measure BIOTRONIK AG has decided to remove the potentially affected products from the market. No complaint related to a low tensile strength of the distal tip has been received so far.

Details on affected devices:

The Cruiser Hydro guide wire is 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 lots of the Cruiser Hydro guide wire listed **and not** any other Cruiser Hydro guide wire lots.

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 you have received affected Cruiser Hydro guide wires 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.

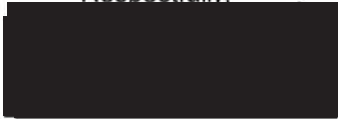
1. Please discontinue any further use of the affected Cruiser Hydro lots listed on page 3. Identify and remove all the affected Cruiser Hydro units from your inventory, store them at a safe place and mark them appropriately.

2. Please read, complete and sign the Customer Acknowledgement Form enclosed to this Field Safety Notice. A BIOTRONIK sales representative will contact you to collect the affected Cruiser Hydro. 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 5525/ -5526.

Respectfully,



Director Regulatory Affairs

List of affected products:

Product	REF Nr.	Lot Nr.
Cruiser Hydro HF	351455	06099011
Cruiser Hydro HF	351455	07099001
Cruiser Hydro HF	351455	07099006
Cruiser Hydro HF	351455	08099002
Cruiser Hydro HF	351455	10099002
Cruiser Hydro HF	351455	10099005
Cruiser Hydro HF	351455	11099002
Cruiser Hydro HF	351455	11099003
Cruiser Hydro HF	351455	02109002
Cruiser Hydro HF	351455	03109002
Cruiser Hydro HF	351455	03109005
Cruiser Hydro HF	351455	03109007
Cruiser Hydro F	351456	07099002
Cruiser Hydro F	351456	07099004
Cruiser Hydro F	351456	07099005
Cruiser Hydro F	351456	08099008
Cruiser Hydro F	351456	08099009
Cruiser Hydro F	351456	08099010
Cruiser Hydro F	351456	09099002
Cruiser Hydro F	351456	09099003
Cruiser Hydro F	351456	09099004
Cruiser Hydro F	351456	09099005
Cruiser Hydro F	351456	11099004
Cruiser Hydro F	351456	02109001
Cruiser Hydro M	351457	08099006
Cruiser Hydro M	351457	10099007
Cruiser Hydro M	351457	10099008
Cruiser Hydro M	351457	01109001
Cruiser Hydro M	351457	01109002
Cruiser Hydro ES-HF	351458	07099003
Cruiser Hydro ES-HF	351458	08099001
Cruiser Hydro ES-HF	351458	08099003
Cruiser Hydro ES-HF	351458	08099004
Cruiser Hydro ES-HF	351458	08099005
Cruiser Hydro ES-HF	351458	08099007
Cruiser Hydro ES-HF	351458	10099004
Cruiser Hydro ES-HF	351458	10099006
Cruiser Hydro ES-HF	351458	11099001
Cruiser Hydro ES-HF	351458	01109003
Cruiser Hydro ES-HF	351458	01109004
Cruiser Hydro ES-HF	351458	03109006
Cruiser Hydro ES-F	351459	09099001
Cruiser Hydro ES-F	351459	10099001
Cruiser Hydro ES-F	351459	10099003
Cruiser Hydro ES-F	351459	02109003