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Bülach, 02. April 2014

Urgent Field Safety Notice

Product: Astron Pulsar Self-Expanding Nitinol Stent System

Dear Customer,

BIOTRONIK AG Bülach Switzerland is initiating a Voluntary Field Safety Corrective Action to withdraw **three specific** Lots of the Astron Pulsar Self-Expanding Nitinol Stent System.

Description of the problem:

Five complaints about stent release were reported out of two specific Astron Pulsar Lots. In these complaints either the stent could not be released or could only be released with difficulties. No patient harm was reported.

There is a non-negligible likelihood that the remaining products from these Lots will experience similar problems. Therefore BIOTRONIK AG decided to remove the two affected Lots and a third potentially affected Lot from the market.

Details on affected devices:

The Astron Pulsar self-expanding stent system is indicated for use in patients with atherosclerotic disease of the femoral and infrapopliteal arteries and for the treatment of insufficient results after percutaneous transluminal angioplasty (PTA), e.g. residual stenosis and dissection.

This Voluntary Field Safety Corrective Action applies only to the Astron Pulsar Lots listed below. Other Lots are NOT concerned.

Device name	Size	REF number	LOT
Astron Pulsar	6/40/70	349277	10133584; 10132726; 11131915

Advice on action to be taken by the customer:

Our records indicate that you have received Astron Pulsar device/s from the affected Lots 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.

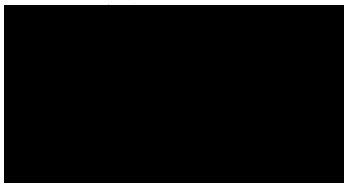
1. Please discontinue any further use of the affected Lots of Astron Pulsar. Identify and remove all the affected Astron Pulsar units from your inventory, store them at a safe place and mark them appropriately.

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 all remaining Astron Pulsar from the affected Lots. 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/ -5673.

Respectfully,



Director Regulatory Affairs and Post Market Surveillance