BIOTRONIK AG
Ackerstrasse 6
CH-8180 Bülach
Switzerland

Bülach, March 2018

Urgent Field Safety Notice

Product:

Pulsar-18, Peripheral self-expanding Nitinol stent system, specific lots

Dear Customer,

BIOTRONIK AG is initiating a Voluntary Field Safety Corrective Action to withdraw specific lots of its Pulsar-18 peripheral self-expanding Nitinol stent systems from the market.

Description of the problem:

It was determined that due to a manufacturing issue Pulsar-18 stent systems from the lots listed below did not meet the specifications for the tip tensile strength. No complaints or patient incidents related to this issue have been reported to BIOTRONIK so far. In the worst, but unlikely case the tip could come off the device during the procedure, embolize distally and lead to artery obstruction. As a cautionary measure BIOTRONIK is withdrawing the concerned lots from the market. This Voluntary Field Safety Corrective Action affects **only** the lots of the Pulsar-18 stent systems listed below and **no other** Pulsar-18 stent system lots.

Details on affected devices:

The Pulsar-18 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, e.g. residual stenosis and dissection.

Size	Ref Number	Lot Number
7/40/135	377493	12173610
4/20/135	377476	12174145
6/20/135	377486	12174146
6/150/90	366820	12174363
5/170/90	366816	01180140
6/100/90	366818	01180366
6/100/90	366818	01180381
6/100/90	366818	01180465
5/120/135	366834	01181147
7/100/135	366843	01181148
4/100/135	366828	01182456
6/20/135	377486	01182837

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 Pulsar-18 peripheral self-expanding stent systems 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 Pulsar-18 lots listed on page 1. Identify and remove all the affected Pulsar-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 sales representative will contact you to collect the affected Pulsar-18 devices. 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/ or -5526.

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