BIOTRONIK
excellence for life

BIOTRONIK AG
Ackerstrasse 6
CH-8180 Bülach
Switzerland

Tel. +41 44 864 51 11
Fax +41 44 864 51 81

Urgent Field Safety Notice

Document-Identifcation:

REC_000-043-928 Rev.A

Product: Pulsar-35, Peripheral Self-expanding Nitinol Stent System

Bülach, January 2025

Dear Customer,

BIOTRONIK AG is initiating a Voluntary Field Safety Corrective Action to withdraw **one specific lot** of the Pulsar-35 Peripheral Self-expanding Nitinol Stent System from the market.

Description of the problem:

It was determined that one lot of the Pulsar-35 consisting of 10 units was wrongly labeled. The Pulsar-35 7/30/90, LOT 11244543, was wrongly labelled as Pulsar-35 6/100/90. To date, we have received one customer complaint relating to this error without any patient injury reported. The wrong size of the device is easily be noticed prior to use and therefore no harm for the patient is expected due to this wrong labelling.

Details on affected devices:

The Pulsar-35 Peripheral Self-expanding Nitinol Stent is indicated for use in patients with atherosclerotic disease of the femoral and proximal popliteal arteries, in particular for the treatment of insufficient results after percutaneous transluminal angioplasty (PTA), e.g. residual stenosis and dissection.

This Voluntary Field Safety Corrective Action affects **only** the lots of the Pulsar-35 listed **and not** any other Pulsar-35 lots.

Device name	Size	REF number	LOT
Pulsar-35	7/30/90 Wrongly labelled as 6/100/90	379888	11244543

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

BIOTRONIK
excellence for life

Advice on action to be taken by the customer:

According to our records you have received Pulsar-35 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 Pulsar-35 lots. Identify and remove all the affected Pulsar-35 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 Pulsar-35 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 79 799 1069 +41 79 799 1052.

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
Senior Director Regulatory Affairs and Post Market Surveillance

Holger Ritzmann
Person Responsible for Regulatory Compliance