BIOTRONIK
excellence for life

BIOTRONIK AG
Ackerstrasse 6
CH-8180 Bülach
Switzerland

Bülach, May 2015

Urgent Field Safety Notice

Product:

Pulsar-18, Peripheral self-expanding Nitinol stent system, specific lots
Pulsar-35, 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 and Pulsar-35 peripheral self-expanding Nitinol stent systems from the market; stent length of **200 mm only**. Enclosed please find the list of the affected lot numbers.

Description of the problem:

We have received a higher than expected number of complaints regarding incomplete stent deployments with specific sizes and lots of our Pulsar-18 and Pulsar-35 peripheral self-expanding Nitinol stent systems. Potential health hazards resulting from this type of failure include increased procedure time, vessel wall injury or the need to remove the incompletely deployed stent.

Details on affected devices:

The Pulsar-18 and Pulsar-35 self-expanding stent system are indicated for use in patients with atherosclerotic disease of the femoral and infrapopliteal arteries (Pulsar-18) / femoral and proximal popliteal arteries (Pulsar-35) and for the treatment of insufficient results after percutaneous transluminal angioplasty, e.g. residual stenosis and dissection.

This Voluntary Field Safety Corrective Action affects **only** the lots and sizes of the Pulsar-18 and Pulsar-35 peripheral self-expanding stent systems listed **and not** any other Pulsar-18 and Pulsar-35 stent system lots. Stents that have already been implanted are not affected by this Voluntary Field Safety Corrective Action as the issue occurs during deployment of the stent.

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 Pulsar-18 and/or Pulsar-35 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 / Pulsar-35 lots listed on page 3. Identify and remove all the affected Pulsar-18 / Pulsar-35 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 / Pulsar-35. 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/ 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,

[redacted]
Director Regulatory Affairs & Post Market Surveillance

List of affected products:

This Voluntary Field Safety Corrective Action affects **only** Pulsar-18 and Pulsar-35 devices **with 200 mm stent length**, carrying the following REF **AND** LOT numbers:

Pulsar-18

REF number

366812	366832
366817	366837
366822	366842
366827	366847

LOT number

-	0113xxxx	0114xxxx
-	0213xxxx	0214xxxx
-	0313xxxx	0314xxxx
-	0413xxxx	0414xxxx
0512xxxx	0513xxxx	0514xxxx
0612xxxx	0613xxxx	0614xxxx
0712xxxx	0713xxxx	0714xxxx
0812xxxx	0813xxxx	-
0912xxxx	0913xxxx	-
1012xxxx	1013xxxx	-
1112xxxx	1113xxxx	-
1212xxxx	1213xxxx	-

Where xxxx can be any 4-digit number

Pulsar-35

REF number

379921	379941
379926	379946
379931	379951

LOT number

-	0113xxxx	0114xxxx
-	0213xxxx	0214xxxx
-	0313xxxx	0314xxxx
-	0413xxxx	0414xxxx
0512xxxx	0513xxxx	0514xxxx
0612xxxx	0613xxxx	0614xxxx
0712xxxx	0713xxxx	0714xxxx
0812xxxx	0813xxxx	-
0912xxxx	0913xxxx	-
1012xxxx	1013xxxx	-
1112xxxx	1113xxxx	-
1212xxxx	1213xxxx	-

Where xxxx can be any 4-digit number