URGENT PRODUCT BULLETIN: RA2015-049EXT-2

Dear Customer

Subject Devices	**TARGET 360 SOFT 3.5MM X 10CM** **TARGET 360 NANO 1MM X 3CM** **TARGET 360 NANO 1.5MM X 4CM** **TARGET 360 ULTRA 3.5MM X 8CM** **TARGET 360 SOFT 6MM X15CM** **TARGET 360 ULTRA 2.5MM x 4CM**
Lot Numbers	**18281772, 18281806, 18310471, 18309730, 18310129, 18361396, 18316520, 18347752, 18311041**
Date range/scope	**Restricted by lot number**

Our manufacturer, Stryker Neurovascular has extended the initiated Product Field Action concerning the above referenced devices.

Our records indicate that you have been supplied with at least one of the subject devices. We therefore request that you read this notice carefully and complete the actions requested by the manufacturer.

Issue

The radiopaque (RO) marker may be missing from the coil delivery wire

Potential Hazards
Extended procedure after intervening in the patient
Aneurysm perforation
Aneurysm rupture
Hemorrhage: internal: cerebral

Scope of Action
Restricted by lot number

Patient/User Information

As provided in the Directions for Use (DFU)

Rationale for not requiring patient follow up

No need to follow up with patient as issue would occur during procedure

Mitigating Factors
In order to position the microcatheter markers and RO marker on the coil delivery wire correctly, physicians are specifically looking for the RO marker on the delivery wire under fluoroscopy, it is likely that the lack of RO marker will be noticed before pushing the coil delivery wire too far.

Corrective Actions
Recall all units from affected customers

Immediate actions required by your facility

1 Immediately locate subject devices referenced in this notice.

2 On location of each device:

* Quarantine devices

3 Ensure that copies of this FSN are circulated internally to all affected users.

4 Display the notice prominently until all required actions have been completed within the facility.

5 Immediately inform Stryker of any adverse events concerning use/attempted use of subject devices.

* Comply with any country vigilance regulations concerning notification of adverse events to National Regulatory Bodies.

6 Inform Stryker if any of the subject devices have been distributed to other organizations.

* Provide contact details so that Stryker can inform the recipients appropriately.

7 Complete the attached customer response form to confirm acknowledgement of this notice and disposition of subject devices.

* Please complete this form even if you no longer have any subject devices. This will negate the need to send any follow up notices.

8 Please respond to this notice before (insert date). The target date for closure of this action and upgrade of all subject devices is (insert date).

On receipt of the returned customer Response Form a Stryker Representative will contact you to arrange for credit of returned devices/ product replacement/ inspection upgrade of equipment/confirm updated records.

In line with the recommendations contained in the Meddev Vigilance Guidance document, Ref 2.12-1 we can confirm that this action has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market and appreciate your assistance in meeting this objective.

Should you have any queries concerning this matter please do not hesitate to contact the undersigned.

Yours …..