Stryker House, Hambridge Road
Newbury, Berkshire RG14 5AW
t: +44(0)1635 262400 f: +44(0)1635 580300
www.stryker.co.uk

stryker®
UK

URGENT Field Safety Notice: RA 2015-049

7th July 2015

Product Description	Product Code	Lot Number(s)
TARGET 360 SOFT 3.5MM X 10CM	M0035473510	18281772, 18281806
TARGET 360 NANO 1.0MM X 3CM	M0035421030	18310471
TARGET 360 NANO 1.5MM X 4CM	M0035421540	18309730, 18310129, 18347752
TARGET 360 ULTRA 3.5MM X 8CM	M0035423580	18361396
TARGET 360 SOFT 6.0MM X 15CM	M0035476150	18316520
TARGET 360 ULTRA 2.5MM X 4CM	M0035422540	18311041

Dear Customer,

Stryker Neurovascular has initiated a voluntary Field Safety Corrective Action for Target Detachable Coils. This letter lists the known hazards potentially associated with the use of these products along with the risk mitigation factors.

Issue

Stryker Neurovascular has received complaints reporting that the radiopaque (RO) marker is missing from the coil delivery marker. The absence of this RO platinum marker would result in the physician being unable to line up the coil marker with the catheter marker to facilitate positioning and detaching of the coil. Potential hazards relating to the reported issue are listed below:

- Extended procedure after intervening in the patient
- Aneurysm perforation
- Aneurysm rupture
- Haemorrhage, internal, cerebral

Risk Mitigation

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 an RO marker would be noticed before pushing the delivery wire too far.

bsi.
RS11877

Actions Required

1. Immediately check your internal inventory to locate subject devices referenced in this notice.

2. Immediately quarantine any subject devices that are located to ensure that they are withdrawn from service.

3. Circulate this Field Safety Notice internally to all interested / affected parties.

4. Maintain awareness of this notice internally until all required actions have been completed within your facility.

5. Inform Stryker if any of the subject devices have been distributed to other organisations.

    a) Please provide contact details so that Stryker can inform the recipients appropriately.

6. Complete the attached customer response form and return to Mark Fielding by fax (01635 262 464) or by e-mail (mark.fielding@stryker.com).

    a) Please complete this form even if you do not have any products to return. This will preclude the need for Stryker to send any reminder notice.

7. Please inform Stryker of any adverse events concerning the use of the subject devices.

    a) Comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

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.

If you have any further enquiries, please do not hesitate to contact the undersigned.

Yours faithfully,

Mark Fielding
Quality Assurance and Regulatory Affairs

RA 2015-049: PFA Acknowledgement Form

Product Description	Product Code	Lot Number(s)
TARGET 360 SOFT 3.5MM X 10CM	M0035473510	18281772, 18281806
TARGET 360 NANO 1.0MM X 3CM	M0035421030	18310471
TARGET 360 NANO 1.5MM X 4CM	M0035421540	18309730, 18310129, 18347752
TARGET 360 ULTRA 3.5MM X 8CM	M0035423580	18361396
TARGET 360 SOFT 6.0MM X 15CM	M0035476150	18316520
TARGET 360 ULTRA 2.5MM X 4CM	M0035422540	18311041

I acknowledge receipt of the Field Safety Notice for RA 2015-049 and can confirm that:

We have not located any of these devices in our inventory: ***(please delete if not applicable)***	

We have located the following devices which require replacement:			
Product Description	**Product Reference**	**Lot Number**	**Qty**

We have further distributed subject devices to the following organisations:	
Facility Name	
Facility Address	

Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organisation		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

PLEASE COMPLETE AND FAX THIS FORM TO 01635 262 464
OR EMAIL TO MARK.FIELDING@STRYKER.COM.