Date

# URGENT FIELD SAFETY NOTICE: RA2013-091

Dear Customer

**Description:** **Neuroform 3™ Microdelivery Stent System**
**Catalogue #** **M003E3450200**
**Lot #** **15391019**

Dear Customer

Please find attached details of a Product Action that has been initiated by Stryker Neurovascular concerning the above referenced subject devices. This action has been taken to ensure that users are aware of important Information concerning the devices listed above.

*(NOTE: Stryker purchased the Boston Scientific Neurovascular business in early 2011. Today, Boston Scientific continues to manufacture and label Neuroform 3™ Microdelivery Stent Systems on behalf of Stryker.)*

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action. You are required only to read the attached Field Safety Notice and then sign and return the Customer Response Form confirming that you have completed the actions requested by the manufacturer. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore please complete even if you no longer have any of the subject devices in your physical inventory.

We request that you respond to this notice within seven calendar days from the date of receipt. The target date for completion of this action is 13th JULY 2013 and your timely response will enable us to ensure that we meet this target.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: XXX Position: XXX E-mail: XXX

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA 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 within date 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.

Yours....

**Date:**

# URGENT Field Safety Notice: RA2013-091

**Description:** **Neuroform 3™ Microdelivery Stent System**
**Catalogue #** **M003E3450200**
**Lot #** **15391019**

Stryker® Neurovascular *has initiated a product field action for the product referenced above. Upon investigation of a customer complaint it was found that during the reprinting of labels due to a cosmetic issue with the original print, the incorrect model information was entered. This resulted in the labels on the outer carton and inner pouch differing with regard to stent length. The stent diameter was not affected.

** (NOTE: Stryker purchased the Boston Scientific Neurovascular business in early 2011. Today, Boston Scientific continues to manufacture and label Neuroform 3™ Microdelivery Stent Systems on behalf of Stryker.)*

**Product Description**
The Neuroform™ product family consists of self-expanding nitinol stents and their delivery systems, intended for adjunctive-use with occlusive coils in the treatment of intracranial aneurysms. Principles of operation are such that a nitinol stent is deployed within an intracranial vessel across the neck of an aneurysm. Once the stent has been deployed, occlusive coils are delivered into the aneurysm via a microcatheter placed through the interstices of the stent. The stent is used to retain occlusive coils within the aneurysm.

**Potential Hazards**
Use of Product with pouch and carton labels that reference two different lengths may require additional intervention due to use of incorrect stent length.

**Rationale for not requiring patient follow up**
Use of the incorrect stent length, smaller than it is stated on the pouch, might result in additional intervention to place a second stent to cover aneurysm neck or to remove the stent from the patient. This would result in an increased prolongation of the procedure but there would be no clinical consequence to the patient as the physician would be able to place a second stent if required.

**Mitigating Factors**
The difference of device length on the label can be noticed if the treating physician will compare the device size on the package and on the pouch.

**Immediate actions**
We request that you read this notice carefully and complete the following actions:

Immediate actions

1. Immediately check your internal inventory and quarantine all subject devices pending return to Stryker.
2. Circulate this Field Safety Notice internally to all interested/affected parties.
3. Maintain awareness of this notice internally until all required actions have been completed within your facility.
4. 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.
5. Please inform Stryker of any adverse events.
    a. Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.
6. Complete the attached customer response form.
    a. Please complete this form even if you do not have any product to return. This will preclude the need for Stryker to send any unnecessary reminder notices.
7. Return the completed form to your nominated Stryker Representative.
    a. On receipt of the form a Stryker representative will contact you to arrange for the collection of any remaining inventory.

Stryker® Neurovascular maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients. We apologize for any inconvenience this Field Safety Action may create and appreciate your cooperation with our request.

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

Yours ……

# RA2013-091: FSN ACKNOWLEDGMENT FORM

**Description:** **Neuroform 3™ Microdelivery Stent System**
**Catalogue #** **M003E3450200**
**Lot #** **15391019**

I acknowledge receipt of the Field Safety Notice for RA2013-091 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:**

| Product description | Product Reference | Lot/Serial Number | Qty | Qty Quarantined |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

**We have further distributed subject devices to the following organizations:**

| | | |
|---|---|---|
| Facility Name | | |
| Facility Address | | |

**Form completed by:**

| | | | |
|---|---|---|---|
| **Contact Name** | | **Contact Facility** | |
| **Contact address** | | **Contact Position** | |
| | | **Contact Tel No** | |
| | | **Contact Fax No** | |
| | | **Contact e-mail** | |

**Please return the completed form to:**