August 2013

RA2013-100: URGENT FIELD SAFETY NOTICE

Description: **Wingspan Stent System**
Catalog #: **Please refer to Page 5 for list of subject devices**
Lot/Serial #: **Please refer to Page 5 for list of subject devices**

Dear Customer

Please find attached details of a Product Field Action that has been initiated by Stryker Neurovascular* *(*On Behalf of Boston Scientific)* concerning the above referenced devices. Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action. It may be that you no longer have any physical inventory on site. In this case you are receiving the notice because you have potentially received non-conforming devices in the past and as a responsible manufacturer we feel that it is our duty to ensure that you are aware of the information contained within the manufacturer's Field Safety Notice.

This action requires that you read the attached Field Safety Notice and complete the actions requested by the manufacturer that are detailed within this notice. We request that you then complete and return the attached customer response form to your local Stryker Distributor to confirm that you have received this notice.

Completing the Customer Response 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 (insert date) and your timely response will enable us to ensure that we meet this target and ensure that the information has been shared with the appropriate parties.

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:	Position:	E-mail:
Tel:	Fax:	

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 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....

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Stryker purchased the Boston Scientific Neurovascular business in early 2011. Today Boston Scientific continues to manufacture and label these devices on behalf of Stryker. The purpose of this letter is to inform you of a Product Field Action concerning one of these devices, the Wingspan® Stent System.

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
Stryker distribution center attached a version of the local language IFU that was not consistent with the global IFU enclosed in the box.

Summary of Difference between local language IFU and global IFU

Wingspan IFU – The only difference between the two versions is the intended use section:

- Attached to all part numbers involved:
  The Wingspan Stent System with Gateway PTA Balloon Catheter is indicated for use in patients with TIA or stroke.

- What should have been attached:
  The Wingspan Stent System with Gateway PTA Balloon Catheter is indicated for use in improving cerebral artery lumen diameter in patients 22 to 80 years old with recurrent (2 or more) strokes refractory to a comprehensive regimen of medical therapy and due to atherosclerotic disease of intracranial vessels with 70-99% stenosis that are accessible to the system. The most recent stroke must have occurred more than 7 days prior to treatment with the Wingspan Stent System. Patients are eligible for treatment with the Wingspan Stent System if their Modified Rankin Score (mRS) is 3 or less at the time of treatment.

Potential Hazards
No adverse health consequence is anticipated due to the inconsistent local language DFU attached to the box. The product is performing as intended and the customers are aware of the indications of use.

Summary of Differences between the local language IFU and the global IFU

Patient Follow Up
There is no requirement to perform any additional patient monitoring or follow up.

Rationale for not requiring patient follow-up
The indication for use for the countries in EMEA was aligned with US indication twice in the past year. The global DFU with multi-languages (English, French, Dutch, Portuguese, German, Spanish and Italian) was always included inside the box and can be used as a reference. The

inconsistent local language DFU attached to outside of the box will not affect safety of the patients as many physicians have already changed their practice to restrict the use of the device due to well publicized SAMMPRIS study results. The device is performing as intended.

Mitigating Factors
Non conformity is easily visible

Immediate actions

Please complete the following actions for all subject devices in your possession.

1. Immediately check your internal inventory and locate all subject devices:
    a. *Ensure that a copy of the new Instructions for Use for your Wingspan Stent System is attached to any documentation files for reprocessing.*
    b. *Find attached a copy of the correct IFU, version 90776914, in local language.*
    c. *Ensure that current users are made aware of the information contained within the IFU*
    d. *Ensure that any obsolete IFUs are discarded*.
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 associated with the use of the subject devices.
    a. *Comply with any local regulations concerning the reporting of adverse events to local Competent Authorities.*
6. Complete the attached customer response form and return to the address indicated.
    a. *(Please complete this form even if you do not have any product to return. This will preclude the need to Stryker to send any reminder notice).*

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 Corrective Action may create and appreciate your cooperation with our request.

If you have any further enquiries regarding this Field Safety Notice please do not hesitate to contact your designated Stryker Representative as indicated on the covering letter.

Yours Sincerely,

RA2013-100: CUSTOMER RESPONSE FORM

Description: **Wingspan Stent System**
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I acknowledge receipt of the Field Safety Notice for the above referenced action 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 and replaced the IFU:				
Product description	**Product Reference**	**Lot Number**	**Qty**	**Comments**

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	

RA2013-100 Wingspan Stent System

UPN	Lot Number	Date of Manufacture	Expiration Date
M003WE0250090, 2.5 X 9mm	15248505	05/07/2012	05/15/2015
M003WE0250150, 2.5 X 15mm	15130566	03/29/2012	03/26/2015
	15162868	04/12/2012	04/10/2015
	15227842	05/10/2012	05/07/2015
	15046982	02/23/2012	02/20/2015
M003WE0250200, 2.5 x 20mm	15939487	03/12/2013	03/10/2016
M003WE0300090, 3.0 x 9mm	15464622	08/21/2012	04/25/2015
M003WE0300150, 3 x 15mm	15133156	03/29/2012	03/27/2015
	15133158	03/29/2012	03/27/2015
	15163268	04/12/2012	04/10/2015
	15227706	05/10/2012	05/07/2015
	15506665	09/06/2012	09/04/2015
	15523639	09/13/2012	09/11/2015
	15555714	09/25/2012	09/24/2015
	15591267	10/11/2012	10/08/2015
M003WE0350150, 3.5 x 15mm	15177229	04/19/2012	04/16/2015
	15180389	04/19/2012	04/17/2015
	15280935	05/31/2012	05/29/2015
	15427727	08/02/2012	07/31/2015
	15524060	09/13/2012	09/11/2015
	15663724	11/08/2012	11/07/2015
M003WE0300200, 3.0 x 20mm	15027904	02/17/2012	02/12/2015
	15163270	04/12/1012	04/10/2015
M003WE0350200, 3.5 x 20mm	15640313	11/01/2012	10/29/2015
	15027906	02/16/2012	02/12/2015
	15591263	10/10/2012	10/08/2015
	15593659	10/10/2012	10/09/2015
M003WE0400090, 4 x 9mm	14946922	01/12/2012	01/09/2015
	15139419	04/05/2012	03/29/2015
M003WE0400150, 4 x 15mm	15014388	02/10/2012	02/06/2015
	15904034	02/27/2013	02/25/2016
M003WE0400200, 4.0 x 20mm	15506927	09/06/2012	09/04/2015
	15524061	09/13/2012	09/11/2015
M003WE0450090, 4.5 x 9mm	15180393	04/19/2013	04/17/2015
M003WE0450150, 4.5 x 15mm	15265073	05/24/2012	05/22/2015
	15292489	06/05/2012	06/04/2015
M003WE0450200, 4.5 x 20mm	15676468	11/14/2012	11/12/2015
	15904027	02/27/2013	02/25/2016
M003WE0450200, 4.5 x 20mm	15078171	03/08/2012	03/05/2015
	15260788	05/24/2012	05/21/2015