URGENT FIELD NOTICE: RA2012-018

Dear xxxx

Description: **Wingspan® Stent System and Gateway® PTA Balloon Catheter**
Catalog No.: **Refer to the attached table for product reference numbers.**
Lot Code: **All lots**

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 and Gateway® PTA Balloon Catheter device.

Issue
In September 2011 interim results from the Stenting and Aggressive Medical Management for Preventing Recurrent stroke in Intracranial Stenosis (SAMMPRIS) trial were published in the New England Journal of Medicine. The interim results of the SAMMPRIS trial demonstrated that use of aggressive medical therapy plus angioplasty and stenting (PTAS) to prevent stroke in high risk ICAD patients was not better than aggressive medical therapy alone. Though it is the standard of care to initially treat ICAD patients with medical therapy, we had not stated in the directions for use of the Wingspan® Stent System and Gateway® PTA Balloon Catheter that patients should be refractory to medical therapy prior to the use the Wingspan stent. We have revised the Intended Use/Indications for Use of the Wingspan Stent as follows:

> **Intended Use/Indications for Use**
> The Wingspan® Stent System and Gateway® PTA Balloon Catheter indicated for use in improving cerebral artery lumen diameter in patients with intracranial atherosclerotic disease, refractory to medical therapy, in intracranial vessels $\geq$ 50% stenosis that are accessible by the system.

Potential Hazards
There are no hazards associated with this issue.

Risk Mitigation
Medical therapy prior to intervention is the standard of care, so no adverse health consequence is reasonably expected to occur from this issue. These devices have been on the market since 2005 and the manufacturer has not received any complaints associated with the issue noted.

Patient Follow up
There are no hazards identified and therefore no patient follow up is required.

Usage
There are no hazards associated with the device and they may continue to be used.

Product identifiers
These devices continue to be manufactured and labelled by Boston Scientific on behalf of Stryker. The Authorised Representative for these devices is based in France. Please refer to a copy of the device label on the attachment below.

LEGAL MANUFACTURER:

Boston Scientific Corporation,
One Boston Scientific Place,
Natick,
MA 01760, USA

AUTHORISED REP:

Boston Scientific International S.A.,
55 avenue des Champs Pierreux,
TSA 51101,
92729 NANTERRE CEDEX,
FRANCE

Immediate Actions Required

1. Circulate this Field Notice internally to all interested/affected parties.
2. Inform Stryker if any of the subject devices have been distributed to other organisations. *(Please provide contact details so that Stryker can inform the recipients appropriately.)*
3. Complete the attached customer response form.
    - (Please complete this form even if you do not have any product to return. This will preclude the need for Stryker to send any reminder notice.)
4. Inform the legal manufacturer/Authorised representative of any adverse events associated with the use of the subject devices.
    - Comply with any local regulations concerning the reporting of adverse events to the National Competent Authority for your country.

We apologize sincerely for any inconvenience this Field Safety Corrective Action may create. If you have any further enquiries, please contact the undersigned in the first instance.

Yours faithfully,

Bob Ware
Field Action Team Leader

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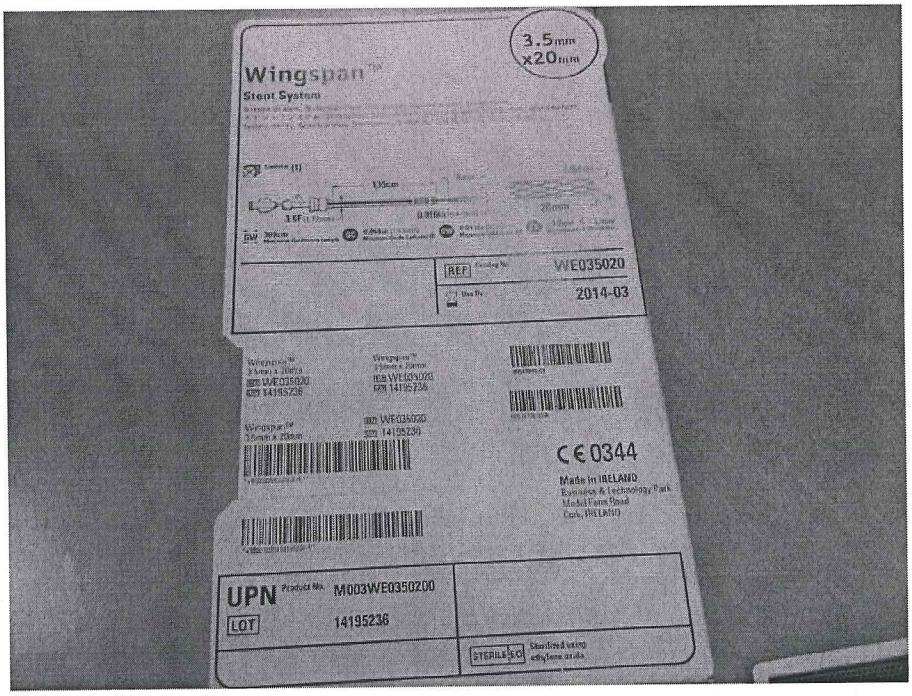
Lot Code: All lots

AFFECTED PRODUCT LISTING: REF 90741728-FA

PRODUCT NUMBER	CATALOGUE NUMBER	LOT/BATCH
M003WE0250090	WE025009	ALL
M003WE0250150	WE025015	ALL
M003WE0250200	WE025020	ALL
M003WE0300090	WE030009	ALL
M003WE0300150	WE030015	ALL
M003WE0300200	WE030020	ALL
M003WE0350090	WE035009	ALL
M003WE0350150	WE035015	ALL
M003WE0350200	WE035020	ALL
M003WE0400090	WE040009	ALL
M003WE0400150	WE040015	ALL
M003WE0400200	WE040020	ALL
M003WE0450090	WE045009	ALL
M003WE0450150	WE045015	ALL
M003WE0450200	WE045020	ALL



CUSTOMER RESPONSE FORM: RA2012-018

Customer name
Customer account number
Customer address
Customer address
Customer address

Description:
Catalogue No:
Lot No:

I acknowledge receipt of the Field Notice for this action and can confirm that I have read and understood the contents.

I am aware of the revised IFU for the above referenced device

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:
(all customer response forms to be returned to Stryker offices – QARS)