Urgent Medical Device Voluntary Customer Communication

Immediate Action Required

08 June 2018

Field Action identifier: RA2018-1812665

Type of Action: CUSTOMER COMMUNICATION

Description: Incorrect diameter listed in mm on Synchro 2 Label

Catalog #:

UPN CODE	DESCRIPTION	UPN CODE	DESCRIPTION
M00326010	SYNCHRO 2/14 200 CM SOFT	M00326410	SYNCHRO 2/14 200 CM STANDARD
M00326110	SYNCHRO 2/14 200 CM SOFT PRESHAPED	M00326420	SYNCHRO 2/14 200 CM STANDARD PRESHAPED
M00326310	SYNCHRO 2/14 300 CM SOFT	M00326510	SYNCHRO 2/14 300 CM STANDARD
M00326320	SYNCHRO 2/14 300 CM SOFT PRESHAPED	M00326520	SYNCHRO 2/14 300 CM STANDARD PRESHAPED

Lot Codes:
All Lots manufactured from 02 October 2017 to 01 June 2018. All lots manufactured after this date have the correct dimension listed.

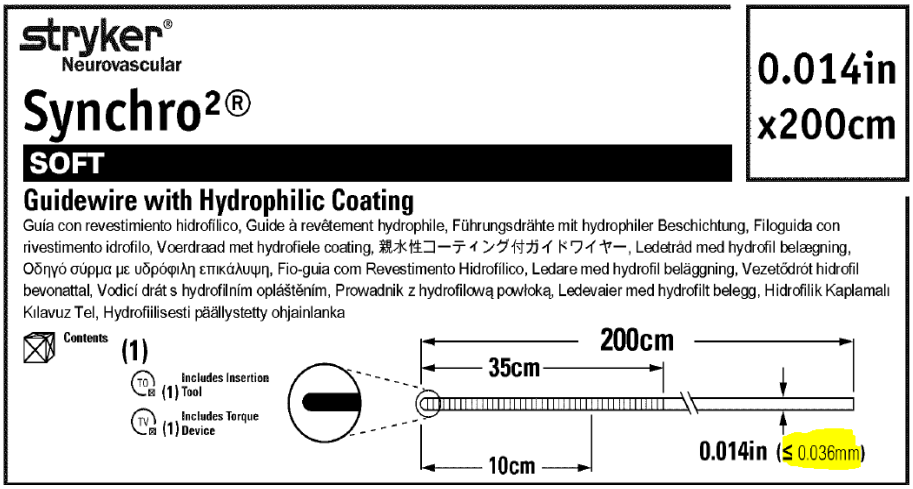
Dear Customer:

Cc: Chairman Medical Board and relevant Head of Departments

Stryker Neurovascular has initiated a voluntary customer communication regarding the devices identified above. 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 acknowledge receipt and understanding of it.

The intent of this letter is to list all known potential hazards associated with the below noted issue and list the risk mitigation factors associated with the use of the product. All whole lots in Stryker control will be corrected.

Issue:
Stryker Neurovascular has become aware that the product labels (pouch and carton) for Synchro 2 products contain an incorrect value in millimeters (0.036mm) for the Guidewire Outer Diameter dimension. The inches dimension (0.014in) on the label is correct. The correct values are 0.014in (0.36mm). 0.036mm represents a typographical error.



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Potential Risk
No adverse health consequences are anticipated.
There is no risk to patients associated with previous use of affected devices.

Please note that NO product will be returned as a result of this action.

Risk Mitigation:
We request that you read this communication carefully and complete the following actions:

1. Immediately check your internal inventory.
2. Review the Communication and ensure full understanding of the contents.
3. Circulate this Customer Communication internally to all interested/affected parties.
4. Inform Stryker if any of the subject devices have been distributed to other organizations.
5. Please provide contact details so that Stryker can inform the recipients appropriately.
6. Please inform Stryker of any adverse events concerning the use of the subject devices.
7. Return the completed form to your nominated Sales Representative or to NVFieldActions@stryker.com.

We request that you respond to this notice within 7 calendar days from the date of receipt. The target date for completion of this action is 30 Jun 2018 and your timely response will enable us to ensure that we meet this target.

On behalf of Stryker we thank you sincerely for your help and support in completing this action by the target date.

Yours Sincerely,

[redacted]

Geraldine Ahern
Quality Manager

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STRYKER® NEUROVASCULAR

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I have received the notification from Stryker stating that they have initiated a product field action for the above referenced product and I acknowledge receipt and review of this **URGENT MEDICAL DEVICE CUSTOMER COMMUNICATION**

Comments: _____

Form completed by:			
Contact Name		**Facility**	
Contact address		**Signature**	
		Phone	
Date		**Email**	

Please email this signed and dated form to NVFieldActions@stryker.com