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URGENT:
MEDICAL DEVICE SAFETY NOTICE: CUSTOMER NOTIFICATION
Number: RA2024 - 3612746

Synchro® Guidewire

Attn: Supply Chain Management/ Recall Coordinator/ Inventory Manager
Date: XX, 2024

Stryker Neurovascular has initiated a Voluntary Medical Device Recall - Customer Notification to alert customers of the potential for the optional introducer accessory packaged with the Synchro Guidewires to cause coating damage to the guidewire. This damage may increase the risk that coating particulates can be introduced into the patients' vasculature. Our records indicate that you have been supplied with the subject devices. We therefore request that you read this notice carefully and complete the actions requested.

Product Affected:

Catalog number	Product description	Lot Number
SSFT215PRE	SYNCHRO SELECT-14 SOFT PS 215 CM	See Appendix B
SSFT215STR	SYNCHRO SELECT-14 SOFT ST 215CM	
SSFT300STR	SYNCHRO SELECT-14 SOFT ST 300CM	
SSTD215PRE	SYNCHRO SELECT-14 STANDARD PS 215CM	
SSTD215STR	SYNCHRO SELECT-14 STANDARD ST 215CM	
SSTD300STR	SYNCHRO SELECT-14 STANDARD ST 300CM	
SSUP215PRE	SYNCHRO SELECT-14 SUPPORT PS 215CM	
SSUP300PRE	SYNCHRO SELECT-14 SUPPORT PS 300CM	
SSUP215STR	SYNCHRO SELECT-14 SUPPORT ST 215CM	
SSUP300STR	SYNCHRO SELECT-14 SUPPORT ST 300CM	
M00316310	SYNCHRO-10 STRAIGHT 200CM	
M00316330	SYNCHRO-10 STRAIGHT 300CM	
M00313010	SYNCHRO-14 STRAIGHT 200-35CM	
M00313020	SYNCHRO-14 STRAIGHT 200-45CM	
M00313310	SYNCHRO-14 STRAIGHT 300-35CM	
M00313410	SYNCHRO-14 SUPPORT STRAIGHT 200-35CM	
M00326110	SYNCHRO2-14 SOFT PRE-SHAPED 200CM	
M00326320	SYNCHRO2-14 SOFT PRE-SHAPED 300CM	
M00326010	SYNCHRO2-14 SOFT STRAIGHT 200CM	
M00326310	SYNCHRO2-14 SOFT STRAIGHT 300CM	
M00326420	SYNCHRO2-14 STANDARD PRE-SHAPED 200CM	
M00326520	SYNCHRO2-14 STANDARD PRE-SHAPED 300CM	
M00326410	SYNCHRO2-14 STANDARD STRAIGHT 200CM	
M00326510	SYNCHRO2-14 STANDARD STRAIGHT 300CM	

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Catalog number	Product description	Lot Number
S2SPP14215	SYNCHRO2-14 SUPPORT PRE-SHAPED 215CM	See Appendix B
S2SPP14300	SYNCHRO2-14 SUPPORT PRE-SHAPED 300CM	
S2SPS14215	SYNCHRO2-14 SUPPORT STRAIGHT 215CM	
S2SPS14300	SYNCHRO2-14 SUPPORT STRAIGHT 300CM	

Product Description

The Synchro Guidewires are a steerable guidewire family with a shapeable tip. The guidewires are compatible with existing microcatheters used in common procedures such as those used in endovascular diagnosis and therapy of neurovascular diseases. The Synchro, Synchro2 and Synchro SELECT Guidewire series is intended for general intravascular use, including neuro and peripheral vasculatures. For lubricity, the distal portion of the device is coated with a hydrophilic polymer, and the proximal portion of the guidewire is coated with polytetrafluoroethylene (PTFE).

The introducer included with the guidewire is intended to aid insertion of the guidewire into the catheter hub and/or hemostasis valve.

Product Issue

Stryker Neurovascular has observed an increased frequency of PTFE coating damage occurring on the Synchro Guidewires that may be caused by the practice of backloading the guidewire through the optional introducer accessory. This issue is limited to certain lots of the Synchro Guidewire listed in the "Product Affected" section above that contain an older version of the introducer accessory. Due to variation in the manufacturing process of the supplier of the introducer accessory, certain lots of introducers have sharper than intended edges that can peel off the PTFE coating when physicians use a technique known as backloading. Users with impacted product in their inventory are cautioned not to use this backloading technique. (Refer to Appendix A for more information on the backloading technique).

Stryker Neurovascular improved the optional introducer accessory packaged with the Synchro Guidewires. The improvement was made to reduce the likelihood of the introducer causing damage to the PTFE coating on the guidewire. This communication is for users who have product in their inventory which was manufactured prior to the improvement as listed in the "Product Affected" section above.

Potential Risks

The potential harms associated with particulate introduction into the patients' bloodstream can include, but not limited to, post procedural tissue necrosis, transient ischemic attack (TIA), stroke, or death. PTFE embolism may also induce chronic inflammation. There have been no reported patient harms to date.

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Required Actions

Please note that NO product is required to be returned; however, if you would like to replace your device, please contact your Stryker Neurovascular representative.

1. Review the communication in Appendix A and ensure full understanding of the contents.
2. When using impacted Synchro Guidewires, please do not backload the guidewire, follow the Instructions for Use (IFU) provided with the device, and do not use the guidewire if you see any visible signs of coating damage.
3. Circulate this customer notification internally to all interested/affected parties.
4. Inform Stryker Neurovascular if any of the subject devices have been distributed to other organizations. If yes, provide contact details so that Stryker Neurovascular can inform the recipients appropriately.
5. Please inform Stryker Neurovascular of any adverse events concerning the use of the subject devices.
6. Complete the attached customer response form. 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 eliminate the need for us to send any further unnecessary communications on this matter.
7. Email the completed form to your local Stryker contact.
8. Contact your Stryker Neurovascular representative if you would like a replacement of the affected Synchro Guidewire with the improved Synchro Guidewire with a new optional introducer accessory from a different supplier.

We request that you respond to this notice within 10 calendar days from the date of receipt. The target date for completion of this action is September 30, 2024, 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: Position: email:

In line with the requirement of the Regulation (EU) 2017/745 on medical devices (MDR), we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker Neurovascular, we thank you sincerely for your help and support in completing this action by the target date and regret any inconvenience that may be caused.

Yours sincerely,

stryker

Business Reply Form

FSCA identifier: Number: RA2024 - 3612746

Account number:
Account name:
Account Address:

Product: Synchro Guidewires

Catalog number	Product description	Unique Device Identifier (UDI)	Lot Number	Qty Received	Qty on Hand
See Appendix B					

Replacement requested (circle option): Yes / No

- ☐ I have received the notification from Stryker Neurovascular 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 RECALL CUSTOMER COMMUNICATION.

Please return this signed and dated form to **your local Stryker representative.**

Note: Your signature indicates that you have received and understand the enclosed notification.

_____ _____
Printed name Title

_____ _____
Contact phone number Signature Date

_____ _____
Email address Phone Number

If you have loaned or sold any of the units listed, please, forward a copy of this notice to the new users and advise Stryker Neurovascular of their new location.

Appendix A Synchro® Guidewire

Backloading and How to Identify PTFE Coating Damage

1. The Synchro Guidewire package contains one torque device and one optional introducer accessory. For lubricity, the distal portion of the guidewire is coated with a hydrophilic polymer, and the proximal portion of the guidewire is coated with polytetrafluoroethylene (PTFE).

2. Backloading refers to the practice of loading the guidewire from the distal end of the introducer tool rather than through the hub at the proximal end of the tool. See Figure 1.

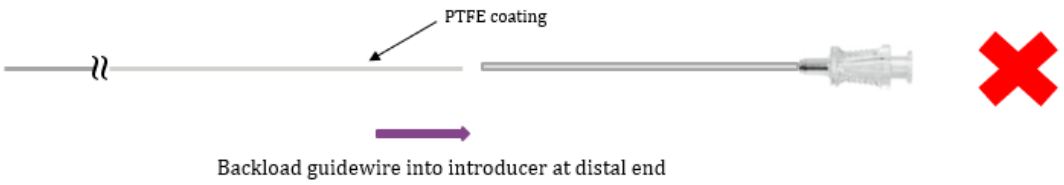

Figure 1: Improper backloading technique

3. The optional introducer accessory provided with the Synchro Guidewire may have sharp edges. These sharp introducer edges may cause peeling of the PTFE coating if users backload the guidewire into the introducer. See Figure 2. The PTFE coating is colored, and the peeled coating is visible to the naked eye when damage occurs. See Figure 3.

Figure 2: Peeling of the PTFE coating during backloading

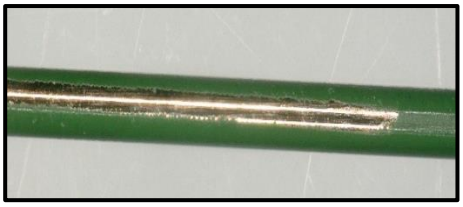

Figure 3: PTFE damage on the Synchro Guidewire

4. Users are cautioned NOT to backload the guidewire and instead load the distal end of the guidewire into the hub of the introducer accessory. See Figure 4.

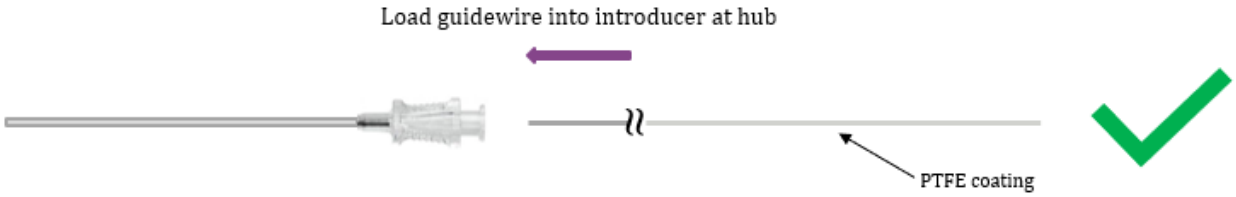

Figure 4: Proper guidewire loading technique using the introducer

5. If damage to the PTFE coating is observed, follow the Instructions for Use (IFU) precaution, and do not use the damaged guidewire. Contact your Stryker Neurovascular representative for a replacement product.

Appendix B Synchro® Guidewire

Catalog number	Product description	UDI number	Lot number	Qty on Hand	Replacement requested Yes/No
See excel file attached to this communication "***RA2024-3612746_Lots in scope_CNL.xlsx***"					