Date: September 4, 2018

Urgent Field Safety Notice

Stryker Reference: RA 2018-1883171

Description: Instructions for: Cleaning, Sterilization, Inspection and Maintenance of Reusable Medical Devices - Instructions for Stryker Spine

Affected Product:

Product Name	Part Number (P/N)
XIA 3 Degen Tray	48230012
XIA 3 Rod and Cross Connector Tray	48230006
French Bender	48237010

Dear Customer,

Stryker Spine has issued a Field Safety Notice related to the reprocessing of the above reusable instrument and trays. The intent of this letter is to notify users of a correction in the Instructions for Cleaning, Sterilization, Inspection and Maintenance of Reusable Medical Devices – Instructions for Stryker Spine document, list potential hazards associated with the steam sterilisation of the devices and detail any risk mitigation factors.

Issue:

Stryker recently performed sterility validation testing in accordance with the HTM 01-01 standard commonly used within the UK (Health Technical Memorandum 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care).

The Xia 3 Degen Tray and the French Bender listed above did not successfully pass validation to the UK steam sterilisation cycle of 134°C for 3 minutes as the French Bender instrument contained within the tray did not meet the required sterility assurance level (SAL) of 10-6. Furthermore, since the Xia 3 Rod and Cross Connector Tray has the same device design and configuration with respect to the French Bender instrument, it has been determined that it would also not successfully pass validation.

In order for these two kits to meet the SAL, the French Bender instrument noted above must be removed from the tray and sterilised independently of the kit. Therefore, the newly released Instructions for: Cleaning, sterilization, inspection, and maintenance of reusable medical devices, includes the UK parameters (OUS parameters) for sterilisation of the French Bender outside of the instrument trays – see **Figure 1**

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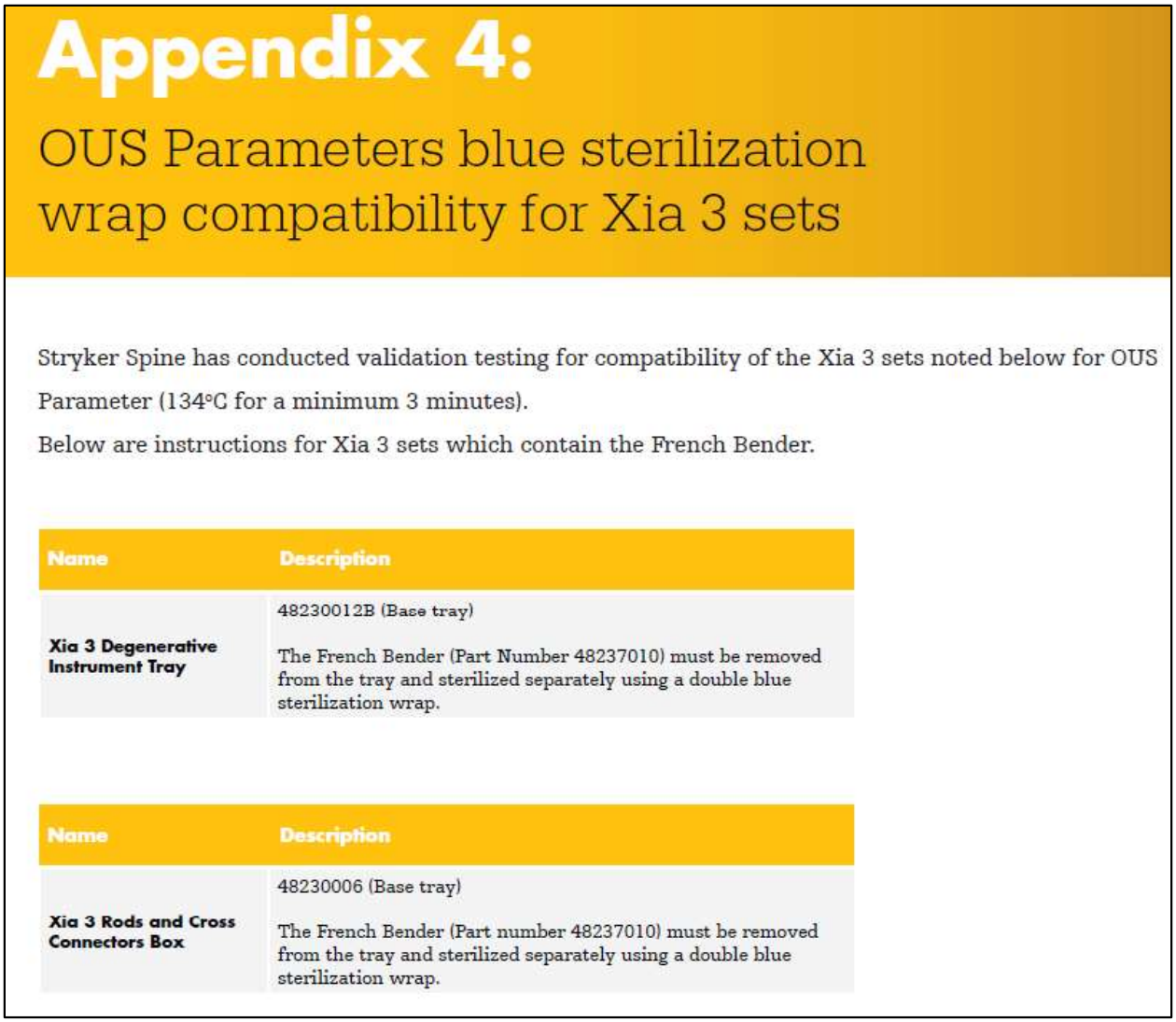

Appendix 4:

OUS Parameters blue sterilization wrap compatibility for Xia 3 sets

Stryker Spine has conducted validation testing for compatibility of the Xia 3 sets noted below for OUS Parameter (134°C for a minimum 3 minutes).

Below are instructions for Xia 3 sets which contain the French Bender.

Name	Description
Xia 3 Degenerative Instrument Tray	48230012B (Base tray) The French Bender (Part Number 48237010) must be removed from the tray and sterilized separately using a double blue sterilization wrap.

Name	Description
Xia 3 Rods and Cross Connectors Box	48230006 (Base tray) The French Bender (Part number 48237010) must be removed from the tray and sterilized separately using a double blue sterilization wrap.

Figure 1 – Excerpt from Appendix 4 Instructions for: Cleaning, sterilization, inspection and maintenance of reusable medical devices.

A copy of the full cleaning and sterilisation document can be downloaded at the following link.
https://www.stryker.com/us/en/spine.html

Potential Hazard:

The potential hazard of not removing the French Bender instrument (P/N: 48237010) from the instrument tray during the sterilisation process is that a non-sterile instrument could be used during surgery.

Immediate Actions:

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action.

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

1. Immediately check your internal inventory.

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.
   b) If you are a Distributor, note that you are responsible for notifying your affected customers.

5. Please inform Stryker of any adverse events concerning the use of the subject devices.

6. Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

7. Complete the attached customer response form. It may be that you no longer have any affected devices 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.

8. Return the completed form to your nominated Stryker Representative (indicated below)

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 **26th October 2018** 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: Nina Goddard
Position: RAQA Specialist
Telephone: 01635 262 476
Fax: 01635 580 300
E-mail: nina.goddard@stryker.com

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA has been notified 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 the target 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 faithfully,

Nina Goddard
Regulatory Affairs and Quality Assurance

Customer Acknowledgement Form

FSCA Identifier: RA 2018-1883171

Description: Update to "Cleaning, Sterilization, Inspection and Maintenance of Reusable Medical Devices- Instructions for Stryker Spine"

I acknowledge receipt of the Field Safety Notice for RA 2018-1883171 and confirm that:
(please tick all that apply)

☐ We do not have any affected devices in our inventory

☐ We have affected devices in our inventory and have read and understood the updated cleaning and sterilization instructions

☐ We have further distributed subject devices to the following organization(s)

Facility Name _____

Facility Address _____

Please sign and return this form to acknowledge receipt of this Field Safety Notice.			
Name of Hospital /Organization		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail	
Contact Phone No.		Date	

PLEASE COMPLETE AND FAX THIS FORM TO 01635 580 300
OR EMAIL TO nby_qara@stryker.com