10 November 2017

# URGENT Field Safety Notice

**Stryker Reference:** RA 2017-1481031

**Description:** Update to "Cleaning, Sterilisation, Inspection and Maintenance of Reusable Medical Devices – Instructions for Stryker Orthopaedics" (Document reference: LSTPI-B)

**Affected Products:**

| Product Code | Product Description | Product Type | Associated Orthopaedic Instrument Sets |
|---|---|---|---|
| 6541-4-803 | Slap Hammer | Knee Reusable Instrumentation | • Triathlon Misc. Revision Instruments<br>• Triathlon Primary Miscellaneous Instruments |
| 2101-0130 | Non Threaded Impactor | Hip Reusable Instrumentation | • Cutting Edge Acetabular Reamer Tray<br>• OMNIFIT Acetabular Instrument Tray<br>• Trident Acetabular Instrument Tray |
| 4842-2000 | Head Impactor | Hip Reusable Instrumentation | • ABG II Femoral Instrument Tray<br>• ABG II Femoral Instrument Tray<br>• Exeter Femoral V40 FE Tray |

Dear Customer,

Stryker Orthopaedics has issued a Field Safety Notice related to the reprocessing of the above reusable orthopaedic instruments. The intent of this letter is to notify users to a change in the LSTPI-B - Instructions for Cleaning, Sterilization, Inspection and Maintenance of Reusable Medical Devices, list potential hazards associated with the steam sterilization of the devices and detail any risk mitigation factors

**Issue:**

Stryker recently performed a sterility validation of all reusable instrument kits to standard UK sterility parameters (3 minutes at 134°C). It was determined that all reusable instruments kits would meet the sterility assurance level (SAL) of not less than $10^{-12}$, **with the exception** of kits which include any of the following instruments - Slap Hammer, Non Threaded Impactor, Head Impactor.

In order for these excepted kits to meet the SAL, the specific instruments noted above must be sterilised independently of their kit. Subsequently, Stryker's Instructions for Cleaning, Sterilization, Inspection and Maintenance of Reusable Medical Devices (LSTPI-B) documentation was updated to include the UK parameters and state that these instruments should be removed from their kits and sterilised separately – see **Figure 1**.

Stryker UK
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# Appendix 4: OUS Parameters Blue Sterilization Wrap Compatibility for Legacy Instruments Sets

Stryker Orthopaedics has conducted validation testing for compatibility of Hips and Knees Instrument Sets for OUS Parameters (134-137°C for minimum 3 minutes).

Below are instructions for Hip and Knee instrument sets which contain Slap Hammer, Non Threaded Impactor and Head Impactor.

| | |
|---|---|
| Knee Instrument | Triathlon Misc. Revision Instruments (Lower Tray) 6543-8-104<br>Triathlon Primary Miscellaneous Instruments (Lower Tray) 6541-8-104<br><br>The Slap Hammer (Part Number 6541-4-803) must be removed from the tray and sterilized separately using Double Blue Sterilization Wrap or Double Sterilization Pouch. |
| Hip Instrument | Cutting Edge Acetabular Reamer Tray 2402-0007<br>OMNIFIT Acetabular Instrument Tray<br>Trident Acetabular Instrument Tray<br>Non Threaded Impactor (Part Number 2101-0130) must be removed from the tray, disassembled and sterilized separately using Double Blue Sterilization Wrap or Double Sterilization Pouch. |
| | ABG II Femoral Instrument Tray 4849-6-300<br>ABG II Femoral Instrument Tray<br>Exeter Femoral V40 FET ray<br>Head Impactor (Part Number 4842-2000) must be removed from the tray, disassembled and sterilized separately using Double Blue Sterilization Wrap or Double Sterilization Pouch. |

**Fig. 1 – Excerpt from Instructions for Cleaning, Sterilization, Inspection and Maintenance of Reusable Medical Devices - – Instructions for Stryker Orthopaedics (LSTPI-B)**

A copy of the full cleaning and sterilisation document can be downloaded at the following link - www.stryker.com/en-us/products/Orthopaedics/IFU

**Potential Hazards:**

The potential hazard of not removing the 6541-4-803, 2101-0130, 4842-2000 from the instrument tray during the sterilisation process may include:

- Infectious agents remain on the device due to inadequate sterilisation

**Risk Mitigation:**

Instructions for Cleaning, Sterilization, Inspection and Maintenance, LSTPI-B, recommends inspecting reusable devices for trapped soil or instrument damage.

**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 30 November 2017 and your timely response will enable us to ensure that we meet this target.

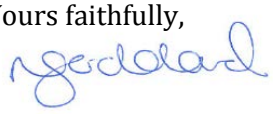
Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.


Name: Nina Goddard
Position: RAQA Specialist
Telephone: 01635 262 476
Fax: 01635 262 464
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

# RA 2017-1481031: Customer Acknowledgement Form

**FSCA Identifier:** RA 2017-1481031

**Description:** Update to "Cleaning, Sterilisation, Inspection and Maintenance of Reusable Medical Devices – Instructions for Stryker Orthopaedics" (Document reference: LSTPI-B)

I acknowledge receipt of the Field Safety Notice for RA 2017-1481031 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 sterilisation instructions

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

Facility Name _____

Facility Address _____

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

PLEASE COMPLETE AND FAX THIS FORM TO 01635 262 464
OR EMAIL TO nby_qara@stryker.com