May 20, 2020

To: **Hospitals and Surgeons**

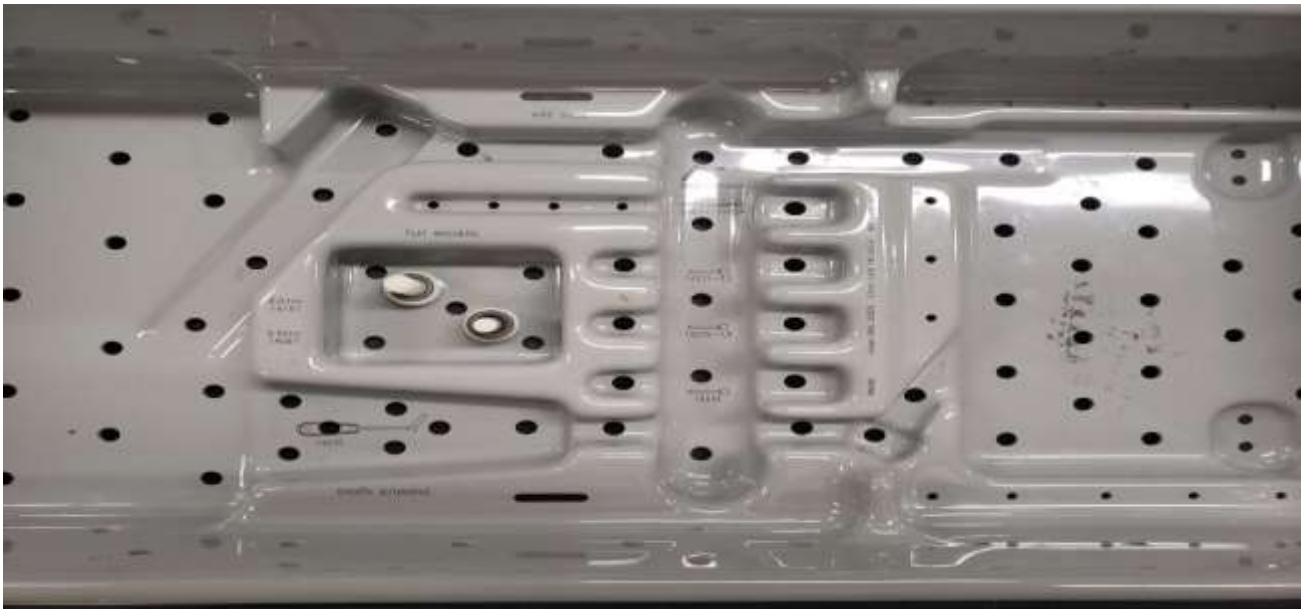
Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE - REMOVAL**

Reference: **ZFA 2020-00004 & 2020-00023**

Affected Product: Outer Sheath 4.5/5.0, 6.5 and Screw Instrument Tray 6.5/80MM

Item Number	Description	Lot Number
14235	Outer Sheath 4.5/5.0,6.5	All Lots
246111003	Screw Instrument Tray 6.5/80MM	All Lots

Item 14235 Outer Sheath 4.5/5.0,6.5



Item 24611103 Screw Instrument Tray 6.5/80MM

Biomet Orthopedics LLC is conducting a medical device Field Safety Corrective Action (removal) for all lots of the Outer Sheath and the 6.5/8.0MM Screw/Instrument Tray. The affected device and tray that houses the device did not pass steam sterilization process validation testing. To date there are no adverse events reported which could be linked to this issue. The affected device and tray are being obsoleted.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None	*None*
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None	*Infection leading to medical surgical intervention*

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between June 2012 and December 2019. (Local deployment may differ).

Hospital Responsibilities

1. Review this Field Safety Notice and ensure that affected personnel are aware of the contents.
2. If you have any affected products at your facility, assist your Zimmer Biomet sales representative and quarantine all affected products. Your Zimmer Biomet sales representative will remove the affected products from your facility.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.uk@zimmerbiomet.com. This form must be returned even if you do not have affected products at your facility.
4. Retain a copy of the acknowledgement form with your field action records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this Field Safety Notice, please contact your Zimmer Biomet representative.

Surgeon Responsibilities:

1. Review this Field Safety Notice for awareness of the contents.
2. There are no specific patient monitoring instructions related to this Field Safety Notice that are recommended beyond your existing follow-up schedule.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.uk@zimmerbiomet.com. This form must be returned even if you do not have affected products at your facility.
4. Retain a copy of the acknowledgement form with your field action records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this Field Safety Notice, please contact your Zimmer Biomet representative.

Other Information

This medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices as per MEDDEV 2.12-1 in Europe.

Please keep Zimmer Biomet informed of any adverse events associated with this units or any other Zimmer Biomet product by emailing per.uk@zimmerbiomet.com or to your local Zimmer Biomet contact.

Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes.

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

We would like to thank you for your co-operation in advance and regret any inconveniences caused by this Field Safety Corrective Action.

Sincerely,

Kevin Escapule
Director, Post Market Surveillance

ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

Affected Product: Outer Sheath 4.5/5.0, 6.5 and Screw Instrument Tray 6.5/80MM

Field Safety Corrective Action Reference: ZFA 2020-00004 & ZFA 2020-00023

Please return the completed form to your Zimmer Biomet contact person or by e-mail

fieldaction.uk@zimmerbiomet.com

☐ I received and understood the Field Safety Notice.

Regarding the parts:

☐ All inventories for the affected products have been checked and following parts are to be returned:

Item Reference	Lot Number	Number of parts returned

OR

☐ The affected products which are unavailable for return have been:

☐ discarded ☐lost ☐other: _____

By signing below, I acknowledge that the required actions have been taken in accordance with the Field Safety Notice.

[ ] **Hospital Facility** [ ] **Surgeon** *(Please check one as applicable)*

Printed Name: _____ **Signature:** _____ **Date:**____/____/____

Title: _____ **Telephone:** ( ) ____-_____

Facility Name: _____ **Facility Address:** _____

City:_____ **ZIP:**_____ **Country:**_____