June 24, 2019

To: Hospitals and Surgeons

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

Reference: **ZFA 2019-00153**

Affected Product:

Comprehensive Reverse Shoulder Instrument Case –Total (Outer Case Vault Only)
Comprehensive Reverse Shoulder Instrument Case – Outer (Outer Case Vault Only)

Item Number	Lot Number	Description
595509	All Lots	Comprehensive Reverse Shoulder Instrument Case – Outer **(Outer Case Vault Only)**
595510	All Lots	Comprehensive Reverse Shoulder Instrument Case –Total **(Outer Case Vault Only)**

Zimmer Biomet is conducting a medical device field action for the Comprehensive Reverse Shoulder Instrument Case Outer and the Comprehensive Reverse Shoulder Instrument Case - Total due to a lack of an adequate sterilization validation.

This medical device field action is only for the black, outer instrument case vault. The internal sterilization trays and instrumentation are not affected by this field action.

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between May 2009 and May 2019 (local deployment may differ).

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 Surgical Intervention

Hospital Responsibilities:

1. Review this notification and ensure that affected personnel are aware of the contents.
2. If you have affected product at your facility, assist your Zimmer Biomet sales representative and quarantine all affected product. Your Zimmer Biomet sales representative will remove the affected product from your facility.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.emea@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 records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this notice, please contact your Zimmer Biomet sales representative.

Surgeon Responsibilities:

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this recall that are recommended beyond your existing follow-up schedule.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.emea@zimmerbiomet.com
4. Retain a copy of the acknowledgement form with your field actions records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this notice, please contact your Zimmer Biomet sales representative.

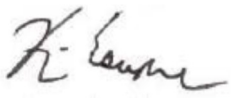
Other Information
This medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices as per MEDDEV 2.12-1 in Europe.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing winterthur.per@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 action.

Sincerely,



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Kevin W. Escapule
Post Market Surveillance & Regulatory Compliance Director

ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Comprehensive Reverse Shoulder Instrument Case –Total and Comprehensive Reverse Shoulder Instrument Case – Outer

Field Action Reference: ZFA 2019-00153

Please return the completed form to your Zimmer Biomet contact person:
fieldaction.emea@zimmerbiomet.com

☐ I received and understood the Field Safety Notice.

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

Product Reference	Lot Reference	Number of products 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: _____

NOTE: This form and affected product must be returned to Zimmer Biomet before this action is considered closed for your account. It is important that you complete this form and email a copy to fieldaction.emea@zimmerbiomet.com