ZIMMER BIOMET

May 16, 2018

To: Surgeon / Hospital

Subject: **UPDATE MEDICAL DEVICE MARKET REMOVAL**

Reference: ZFA2018-00073

Affected Product: Echo Instrument Case Shell - Outer Case Vault Only and
Comprehensive Reverse Shoulder Instrument - Outer Case Vault Only

Zimmer Biomet is conducting a medical device market removal for the Echo Instrument Case Shell Tall Outer Case Vault Only and the Comprehensive Primary Shoulder Instrument Outer Case Vault Only as they do not comply with the weight recommendation in the current ANSI/AAMI ST79 and ISO 17665-2006 standards. The outer case vaults allow for individual cases to be combined into a single larger case. The removal of the outer case vaults will eliminate the option to stack the cases, improving the ergonomics associated with handling the cases by allowing the weight recommendation to be met.

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between April 2007 and March 2018.

Item Number	Lot Number	Description
595608	All Lots	Echo Instrument Case Shell Tall – Outer Case Vault Only
595260	All Lots	Comprehensive Primary Shoulder Instrument – Outer Case Vault Only

Kit Number that includes Item Number 595260		
Kit Item Number	Lot Number	Description
595261	All Lots	Comprehensive Primary Shoulder Instrument Case - Total

Note: Only the empty Outer Case Vault (Item Number 595260) should be returned from the kit.

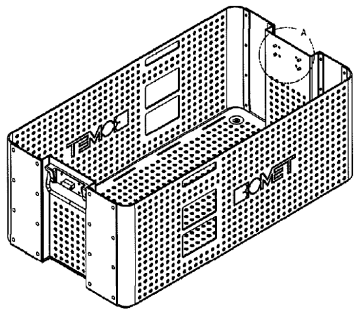


Figure 1: Echo Instrument Case Shell – Outer Case Vault Only

Figure 2: Comprehensive Primary Shoulder Instrument - Outer Case Vault Only

Special Note: Inner trays and all contents are to be kept and not returned.

Your Responsibilities:

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

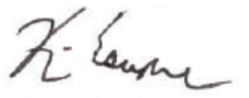
Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing winterthur.per@zimmerbiomet.com or to your local Zimmer Biomet contact.

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,



Kevin W. Escapule
Post Market Surveillance and Regulatory Compliance Director

ATTACHMENT 2
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Echo Instrument Case Shell - Outer Case Vault Only and Comprehensive Reverse Shoulder Instrument - Outer Case Vault Only

Field Action Reference: ZFA 2017-00073

Please return the completed form to your Zimmer Biomet contact person:
fieldaction.eire@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:** _____

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