

May 16, 2018

To: Distributors

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.

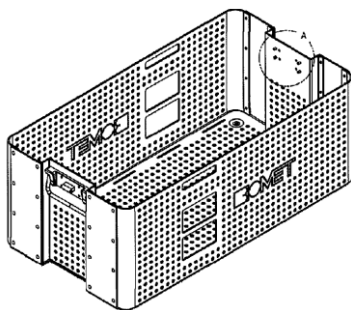


Figure 1: Echo Instrument Case Shell – Outer Case Vault Only



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. Contact your customers using the surgeon/ hospital Field Safety Notice and execute the removal as indicated. Ensure documentation of removal with the customers.
3. Complete **Attachment 1 – Inventory Return Certification Form**
4. Return a digital copy to fielddaction.export@zimmerbiomet.com. This form must be returned **even if you do not have affected products at your facility**.
5. Include a copy of **Attachment 2 – Certificate of Sterilization** with returned instruments
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 1
Inventory Return Certification Form

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

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

Field Action Reference: ZFA 2018-00073

Please return the affected product to the appropriate address below with a spreadsheet containing item number, lot number, and quantity:

Biomet Global Supply Chain Center B.V.
 Hazeldonk 6530
 Dock 20
 Breda 4836 LD, Netherlands

This is the final return for the country. An exhaustive search has been performed for the affected products.	Check one of the following:	
	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Credit My Account **Send a Replacement**

Item Number	Lot Number	Quantity Returned

Complete this table for all affected items returned. If additional space is needed, please provide a spreadsheet and return it to fieldaction.export@zimmerbiomet.com with this form.

Certificate of Acknowledgement:

By signing below, I acknowledge that I have received, read, and understand the contents of this field action communication. All required activities are complete or are being completed.

Printed Name: _____ **Signature:** _____

Title: _____ **Tel:** () _____ **Ext.** _____ **Date:** _____

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.export@zimmerbiomet.com Include a copy of this completed form with your product returns.

Please do not return affected product with other returns.



ATTACHMENT 2
Certificate of Decontamination

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

Field Action Reference: ZFA 2018-00073

By signing below, I acknowledge that the instrumentation being quarantined has been cleaned and sterilized prior to being returned to Zimmer Biomet.

Describe method of disinfecting: _____

Printed Name: _____ Signature: _____

Title: _____ Phone: () _____ - _____ Date: ____/____/____

Attachment 2, Certificate of Sterilization, is only required when returning used instruments from the field or when returning product that has been removed from its sterile packaging and held in a clinical environment where there is a potential for exposure to biological contamination.