ZIMMER BIOMET

August 9, 2017

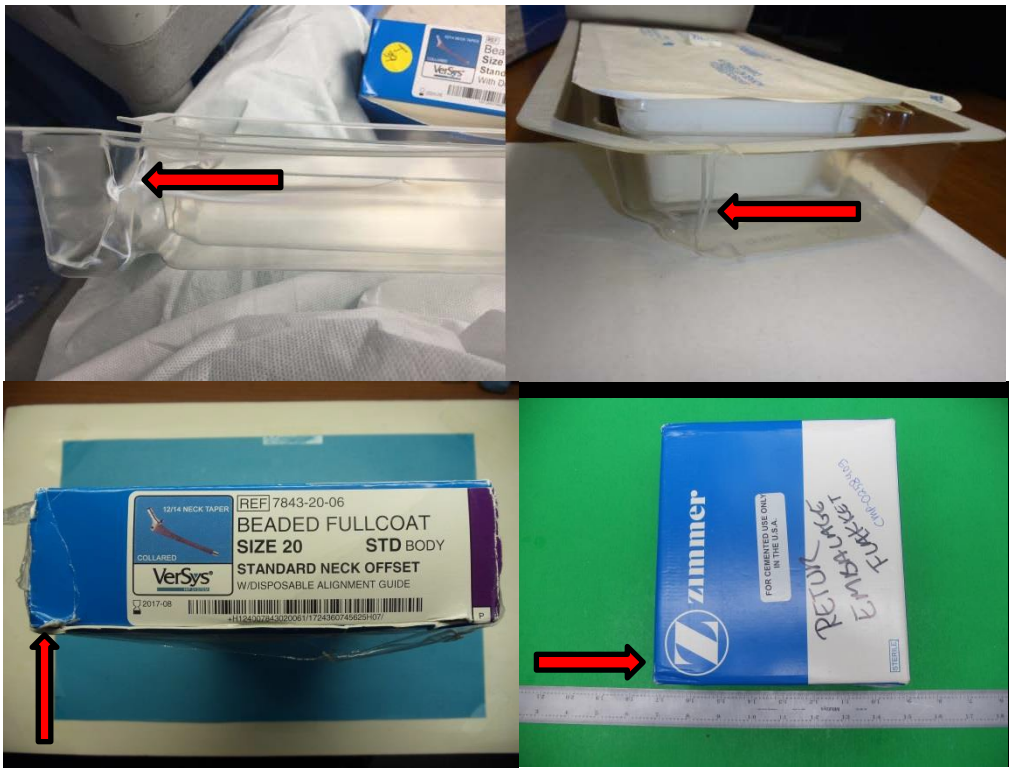
To: Surgeons/ Hospitals

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE - REMOVAL – Lot Specific**

Reference: **ZFA2017-300**

Affected Product: Versys Beaded Hip Stem and Segmental Knee Products Packaging Issue

See Attachment 2 – Affected Product List



Zimmer Biomet is conducting a medical device field safety notice related to packaging for selected lots of Versys Beaded Hip Stem and Segmental Knee products. The affected products were packaged in a previous configuration that was not tested for products weighing over 487 grams. If a product exceeds the weight tested, there is an increased likelihood of compromising the sterile barrier integrity. The products affected are only those that are packaged in the previous configuration. Products packaged in the current configuration are not affected by this issue.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Worst Case
	Delay in surgery <30 minutes	Delay in surgery > 30 minutes
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Worst Case
	None	Infection, requiring removal of the implant or implant loosening

Our records indicate you may have received one or more of the affected products. The affected units were distributed between the dates of December 2002 and October 2016.

Hospital Responsibilities:

1. Review this notification and ensure affected personnel are aware of the contents.
2. Assist your Zimmer Biomet sales representative quarantine all affected product.
3. Your Zimmer Biomet sales representative will remove the affected product from your facility.
4. Complete Attachment 1 – Certificate of Acknowledgement.
    a. Return a digital copy to fieldaction.netherlands@zimmerbiomet.com.
    b. Retain a copy of the Acknowledgement Form with your field action records in the event of a compliance audit of your facilities documentation.
5. If after reviewing this notice you have further questions or concerns please contact your Zimmer Biomet Representative.

Surgeon Responsibilities:

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this field action that are recommended beyond your existing follow up schedule.
3. Complete Attachment 1 – Certificate of Acknowledgement.
    a. Return a digital copy to fieldaction.netherlands@zimmerbiomet.com
    b. Retain a copy of the Acknowledgement Form with your field action records in the event of a compliance audit of your documentation.
4. If after reviewing the notice you have further questions or concerns please contact your Zimmer Biomet representative.

Other Information

This voluntary 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.

Thank you for your assistance. We regret any inconvenience caused by this Field Action.

Sincerely,

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ATTACHMENT 1
Certificate of Acknowledgement

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

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

Printed Name:_____ **Signature:**_____

Title:_____ **Telephone:** ( )____-_____ **Date:**___/___/____

Facility Name: _____

Facility Address: _____

City:_____ **State:**_____ **ZIP:**_____

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

Product Reference	Lot Reference	Number of products returned

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ATTACHMENT 2
Affected Product List

Item Number	Lot Expiry Date Before	Item Description
00585001201	July 31, 2026	SEGMENTAL DISTAL FEMUR, SIZE B-LT
00585001202	July 31, 2026	SEGMENTAL DISTAL FEMUR, SIZE B-RT
00585001301	August 31, 2026	SEGMENTAL DISTAL FEMUR, SIZE C-LT
00585001302	July 31, 2026	SEGMENTAL DISTAL FEMUR, SIZE C-RT
00784301606	June 30, 2026	VERSYS 6 INCH BEADED FC 16X160MM STD BODY STD NECK
00784301506	June 30, 2026	VERSYS 6 INCH BEADED FC 15X160MM STD BODY STD NECK
00784301406	July 31, 2026	VERSYS 6 INCH BEADED FC 14X160MM STD BODY STD NECK
00784301706	June 30, 2026	VERSYS 6 INCH BEADED FC 17X160MM STD BODY STD NECK
00784301836	July 31, 2026	VERSYS 6 INCH BEADED FC STEM 18X160MM LM
00784301806	March 31, 2026	VERSYS 6 INCH BEADED FC 18X160MM STD BODY STD NECK
00784301856	June 30, 2026	VERSYS 6 INCH BEADED FC 18X160MM LM BODY EXT NECK
00784301826	April 30, 2026	VERSYS 6 INCH BEADED FC 18X160MM STD BODY EXT NECK
00784301756	July 31, 2025	VERSYS 6 INCH BEADED FC 17X160MM LM BODY EXT NECK
00784302256	July 31, 2026	VERSYS 6 INCH BEADED FC 22X160MM LM BODY EXT NECK
00784302136	February 28, 2025	VERSYS 6 INCH BEADED FC STEM 21X160MM LM
00784301926	November 30, 2025	VERSYS 6 INCH BEADED FC 19X160MM STD BODY EXT NECK
00784301956	September 30, 2025	VERSYS 6 INCH BEADED FC 19X160MM LM BODY EXT NECK
00784302206	January 31, 2026	VERSYS 6 INCH BEADED FC 22X160MM STD BODY STD NECK
00784302006	November 30, 2025	VERSYS 6 INCH BEADED FC 20X160MM STD BODY STD NECK
00784302036	January 31, 2026	VERSYS 6 INCH BEADED FC STEM 20X160MM LM
00784302156	July 31, 2026	VERSYS 6 INCH BEADED FC 21X160MM LM BODY EXT NECK
00784301936	June 30, 2026	VERSYS 6 INCH BEADED FC STEM 19X160MM LM
00784302056	July 31, 2026	VERSYS 6 INCH BEADED FC 20X160MM LM BODY EXT NECK
00784302026	July 31, 2026	VERSYS 6 INCH BEADED FC 20X160MM STD BODY EXT NECK
00784302126	July 31, 2026	VERSYS 6 INCH BEADED FC 21X160MM STD BODY EXT NECK
00784302226	September 30, 2025	VERSYS 6 INCH BEADED FC 22X160MM STD BODY EXT NECK
00784301906	May 31, 2025	VERSYS 6 INCH BEADED FC 19X160MM STD BODY STD NECK
00784301746	July 31, 2026	VERSYS 6 INCH BEADED FC 17X160MM LM BODY XEXT NECK
00784301846	July 31, 2026	VERSYS 6 INCH BEADED FC 18X160MM LM BODY XEXT NECK
00784301946	July 31, 2026	VERSYS 6 INCH BEADED FC 19X160MM LM BODY XEXT NECK
00784302046	July 31, 2026	VERSYS 6 INCH BEADED FC 20X160MM LM BODY XEXT NECK
00784302146	July 31, 2026	VERSYS 6 INCH BEADED FC 21X160MM LM BODY XEXT NECK
00784302246	July 31, 2026	VERSYS 6 INCH BEADED FC 22X160MM LM BODY XEXT NECK
00784302106	June 30, 2025	VERSYS 6 INCH BEADED FC 21X160MM STD BODY STD NECK
00784302236	July 31, 2026	VERSYS 6 INCH BEADED FC STEM 22X160MM LM