

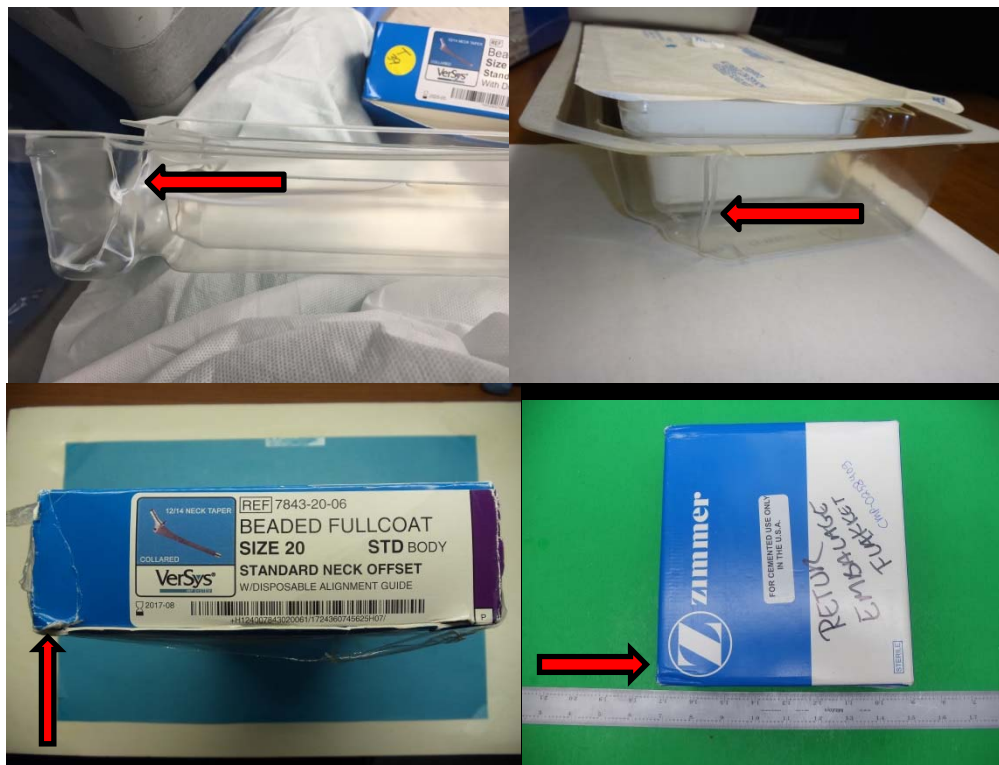
24 August 2017

cc: Chairman Medical Board and relevant Head of Departments

Subject: **URGENT MEDICAL DEVICE RECALL REMOVAL – Lot Specific**

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

See Attachment 2 – Affected Product List



Zimmer Biomet, in consultation with Health Sciences Authority (HSA), is issuing this letter to inform you of a medical device recall related to packaging for selected lots of Versys 6" Beaded Full Coat Plus Hip Prosthesis* and Segmental System Distal Femoral Prosthesis** 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.

****Intended for total hip replacement and hemi-hip replacement;***

*****Intended to replace the distal femur, mid-shaft femur, proximal femur, and/or total knee in cases that require extensive resection and restoration. Indicated for: -moderate to severe knee instability - significant bone loss and/or ligament deficiencies caused by neoplasma, trauma, rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthrtitis, collagen disorders, and/or avascular necrosis of the***



femoral condyle -valgus, varus or flexion deformities -the salvage of previously failed surgical attempts

| 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 February 2017.

Risk Manager / 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 your local distributor.
 - 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 this Dear Healthcare Professional Letter and you have further questions or concerns, please contact your local Zimmer Biomet representative.

Reporting of Adverse Event:

Healthcare professionals are advised to report any adverse events and/or suspected adverse reactions associated with these devices to Jennifer Concepcion at Tel: 6854 7222, Email: Jennifer.concepcion@zimmerbiomet.com, Fax: 6472 6657. Alternatively, healthcare professionals may report the adverse events to the Vigilance and Compliance Branch, Health Products Regulation Group, HSA at Tel: 6866 3538, Fax: 6478 9069, or report online at www.hsa.gov.sg/ae_online. Events that are reported to Zimmer Pte Ltd will be investigated and subsequently reported to HSA.

Sincerely,



Kevin W. Escapule
Product Surveillance & Regulatory Compliance Director



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: _____

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: corporatequality.postmarket@zimmerbiomet.com.

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 |