ZIMMER BIOMET

03 August 2023

To: Hospitals and Surgeons

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

Affected Product: Zimmer® M/L Taper Hip Prosthesis

Material/Item Number	Material/Item Description	Batch/Lot Number	UDI Number
00-7711-004-40	Zimmer® M/L Taper Hip Prosthesis, **Size 4**, Extended Offset, Reduced Neck Length	65249215	(01)00889024131613(17)311109(10)65249215
00-7711-006-40	Zimmer® M/L Taper Hip Prosthesis, **Size 6**, Extended Offset, Reduced Neck Length	65236202	(01)00889024131699(17)311109(10)65236202

Zimmer Inc. is conducting a batch/lot specific medical device Field Safety Corrective Action (removal) for two lots of the Zimmer® M/L Taper Hip Prosthesis. The outer package labeling and product etch are for a Size 6, however, the implant is a Size 4, and vice versa. There has been one complaint received.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Clinically insignificant extension of surgery to find a replacement part.	Intraoperative bone fracture leading to significant extension of surgery (if actual size 6 stem attempted to be used in place of size 4 stem).
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.	Joint instability leading to surgical intervention.

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between January 2022 and March 2023. Local distribution may differ.

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Hospital Responsibilities:

1. Review this Field Safety Notice 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. If the product has been further distributed, provide your customers with the Field Safety Notice and ensure documentation.
4. Complete **Attachment 1 – Certificate of Acknowledgement Form** and send to fieldaction.gscc@zimmerbiomet.com. This form must be returned even if you do not have affected products at your facility.
5. Retain a copy of the **Attachment 1 – Certificate of Acknowledgement Form** with your records in the event of a compliance audit of your facility.
6. If you have further questions or concerns after reviewing this Field Safety Notice, please contact your Zimmer Biomet representative.

Surgeon Responsibilities:

1. Review this Field Safety Notice for awareness of the contents.
2. There are no specific patient monitoring instructions related to this Field Safety Corrective Action that are recommended beyond your existing follow-up schedule. It is anticipated that the fit of the stem would have been highly detectable, for example a physical size 4 stem sitting lower than expected in a bone prepared for size 6, or vice versa and the stem sitting proud. During surgery, the available offsets in femoral head implants may have provided the necessary flexibility to appropriately manage intraoperatively the desired joint kinematics. For your awareness, the resulting difference in head centers between the two stem sizes is approximately 3 mm.
3. If you have further questions or concerns after reviewing this Field Safety Notice, please contact your Zimmer Biomet representative.

Other Information

This Field Safety Corrective Action was reported to all relevant Competent Authorities and Notified Bodies as required under the applicable regulations for Medical Devices 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 ProductComplaintGSCC@zimmerbiomet.com.

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 Field Safety Notice has been delivered to the appropriate Regulatory Agencies.

We would like to thank you for your co-operation and regret any inconvenience caused by this Field Safety Corrective Action.

Sincerely,

ZIMMER BIOMET

ATTACHMENT 1 - Certificate of Acknowledgement Form

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Zimmer® M/L Taper Hip Prosthesis
Field Safety Corrective Action Reference Number: ZFA2023-00156

☐ A thorough search has been performed for the affected products and the below are available for return.

Please complete this table for all affected items returning. Do not return affected products with other returns.

Material/Item Number	Batch/Lot Number	Returning Quantity
00-7711-004-40	65249215	
00-7711-006-40	65236202	

All products that are not available for return have been implanted or used: ☐ Yes ☐ No ☐ Unknown

Note: All products that are not available for return will be considered as dispositioned on your location.

Certificate of Acknowledgement

By signing below, I acknowledge that I have received, read and understood the contents of Field Safety Notice communication. All required activities are complete or are being completed.

Printed Name: _____ **Signature:** _____

Title: _____ **Telephone:** _____ **Date:** _____

Hospital Name: _____

Hospital Address: _____

City: _____ **Country:** _____ **ZIP/Post Code:** _____