September 22, 2023

To: Distributors

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

Affected Product: Biomet Tibial Modular System

Item Number	Lot Number	UDI Number	Item Description
141256	2120000797	N/A	Polished Finned 1 Piece Tibial Tray 83 mm

Biomet Spain Orthopaedics, S.L. is conducting a Field Safety Correction Action for Biomet Tibial Modular System following the investigation on a product complaint. After investigation, it has been concluded that, the external labeling corresponds with a Polished Finned 1 Piece Tibial Tray 83 mm (Item Number 141256; Lot Number 2120000797) but the product inside the package, the patient labels and the inner label could correspond with a Polished Finned 1 Piece Tibial Tray 71 mm (Item Number 141253; Lot Number 2120000835).

The Biomet Tibial Modular System Trays are designed for use as a part of total knee arthroplasties in the following cases:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis, where one or more compartments are involved.
2. Correction of varus, valgus or post-traumatic deformity.
3. Replacement techniques when other treatments have failed.

If the event occurs, it could be recognized as per the following.

1. The Tibial Tray has an inner labeling and patient labeling which indicates the Item Number, Lot Number and Item Description including the size of the product which allow product identification.
2. The Tibial Tray is etched with the correct information (Item Number Lot Number and Size) to confirm identification. This etching mitigates harm by providing an opportunity for the issue to be identified and do not be used.
3. There is a size difference between both item numbers. Item Number 141253 is 71 mm length and 45,46 mm width and Item Number 141256 is 83 mm length and 53,06 mm width.
4. The Tibial Tray is implanted along with a Tibial Insert. Item Numbers 141253 and 141256 use different tibial inserts sizes which allow to identify the mismatch between tray and insert.
5. The surgical technique includes a specification regarding the Tibial Sizing in which is indicated that: "…Using the tibial template, select the tibial tray size that provides the appropriate coverage…" This tibial sizing step is used to check the correct size and could identify the issue.

Furthermore, as the health outcome for the patient, in the case the Tibial Tray is not identified as incorrect size before or during the surgery and, therefore, the incorrect tibial tray is implanted could lead to a revision surgery.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Minor Extension of surgery (generally <30 mins) to retrieve a secondary device	Major Extension of surgery (generally >30 mins) to retrieve a secondary device
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	No injury to any person (Minor Extension of surgery (generally <30mins) to retrieve a secondary device)	Patient subjected to additional surgical procedures, anesthetic and associated risks.

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between 03 August 2023 and 04 August 2023.

Your Responsibilities

1. Review this Field Safety Notice and ensure that affected team members are aware of the contents.
2. Immediately locate and quarantine affected product in your inventory.
3. Immediately return all affected product from your distributorship and from affected hospitals within your territory.
   a. Complete **Attachment 1 – Inventory Return Certification Form** for each return and send to xxxxxxxxxxxxx. This form must be returned even if you do not have affected products available to return in your territory.
   b. For International Returns, request an RGA by emailing xxxxxxxxxxxxx
   c. Include a hardcopy of **Attachment 1 – Inventory Return Certification Form** in each carton of your return shipment for immediate processing.
   d. Mark “RECALL” on the outside of the returned cartons.
4. Retain a copy of your **Attachment 1 – Inventory Return Certification Form** and product return forms for your records in the event of a compliance audit of your facility.
5. If you have further questions or concerns after reviewing this notice, please, email to xxxxxxxxxxxxx

Other Information

This medical device Field Safety Corrective Action was reported to all relevant Competent Authorities and related Notified Bodies as required under the applicable regulations for Medical Devices per MEDDEV 2.12-1 in Europe.

Please keep ZimVie informed of any adverse events associated with this product or any other ZimVie product by emailing xxxxxxxxxxxxx

The undersigned confirms that this 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,

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Regulatory Compliance Manager & BSO TR

ATTACHMENT 1 - Inventory Return Certification Form

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

Affected Product: Biomet Tibial Modular System **HHE Number: HHE-2023-00018**

Territory Number: _____ Account Number: _____

Account Name: _____

Account Address: _____

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

Biomet 3i Dental Iberica
Islas Baleares, 50 – 46988 Fuente del Jarro
Valencia (Spain)

	Check one of the following:	
This is the final return for the entire territory. **An exhaustive search has been performed for the affected products.**	**Yes** ☐	**No** ☐

Note: Any product not returned or found in your territory is considered consumed/lost and unavailable for use.

☐ **Credit My Account**

Item Number	Lot Number	Quantity Returned
141256	2120000797	

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

Certificate of Acknowledgement:

By signing below, I acknowledge that I have received, read, and understand the contents of this recall 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 ZimVie before this action is considered closed for your account. It is important that you complete this form and email a copy to xxxxxxxxxxxx

Please do not return affected product with other returns.