ZIMMER BIOMET

May 14, 2018

To: Clinicians

Subject: **MEDICAL DEVICE RECALL – INCORRECT CHART LABEL**

Affected Product: Tapered Screw-Vent Implants with 0.5 mm Machined Collar, MTX Surface and Microgrooves

Zimmer Biomet is conducting a medical device recall for a single lot of Tapered Screw-Vent Implants that were inadvertently packaged with patient chart labels, which incorrectly indicate TSVB10 lot 63773888. In order to maintain proper lot traceability, we are recalling the affected product with Part # TSVM4B10, Lot # 63781164, which will be replaced with product containing accurate patient chart labels.

Image 1: Incorrect Label

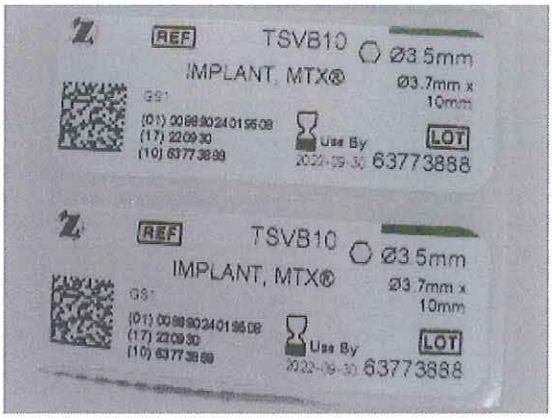

Table 1: Correct Part and Lot Number

Correct Item Number	Correct Lot Number
TSVM4B10	63781164

Because all outer and inner package labels were correct (except for the chart labels), there are minima safety or risk concerns. It is unlikely that an incorrect implant was placed because the implant would have been selected based on the outer package labelling (which is correct).

There is a minor risk that implantation may be delayed because the inconsistency with the chart label was detected prior to or at the time of the procedure.

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The primary risk is in the case of an adverse event involving one of the affected implants the incorrect number could be referenced, which could result in confusion during the troubleshooting, reporting and follow up for the adverse event.

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between October 5, 2017 and March 7, 2018.

Clinician Responsibilities:

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this recall that are recommended beyond your normal follow-up schedule.
3. Review your inventory: Complete Attachment 1 – Certificate of Acknowledgement and send to Vigilance.EU@zimmerbiomet.com.
4. For each return, send a copy of Attachment 1 – Certificate of Acknowledgement to Vigilance.EU@zimmerbiomet.com.
5. Customer Service will contact you to organize product recovery and will provide you with an RMA number.
6. Retain a copy of the acknowledgement form with your recall records in the event of a compliance audit of your facility's documentation.
7. If the product has already been implanted, please update the patient records with the correct part and lot number (see Table 1).
8. If you have further questions or concerns after reviewing this notice, please call EMEA Customer Service. Alternatively, your questions may be emailed to Vigilance.EU@zimmerbiomet.com.

Other Information

This medical device recall was reported to the U.S. Food and Drug Administration and will be reported to other Competent Authorities, Notified Bodies, and Regulatory Authorities as required.

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing 3iEUComplaints@zimmerbiomet.com.

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

Sincerely,

[redacted]

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ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Tapered Screw-Vent Implants TSVM4B10

Field Action Reference: ZFA 2018-00136

Do you have affected product in your facility?

☐ **Yes**, we currently have one or more affected items in our facility.

☐ **No**, we currently have no affected items in our facility.

By signing below, I acknowledge that the required actions have been taken in accordance with this recall notice.

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 is closed for your account. It is important that you complete this form and email a copy to Vigilance.EU@zimmerbiomet.com or fax to +34 93 193 42 79.