ZIMMER BIOMET

17 January 2023

To: Hospitals and Surgeons

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE (REMOVAL)**

Affected Product: Vanguard® Knee System, Posterior Stabilized Open Box Femoral

Item Number	Lot Number	Item Description	UDI Number
183104	J7209534	Vanguard Knee System PS Open Box Femoral; Right; 60 mm	(01)00880304270770(17)320408(10)J7209534
183122	J7186089	Vanguard Knee System PS Open Box Femoral; Left; 57.5 mm	(01)00880304270862(17)320504(10)J7186089

Picture on the left

Label Item Number: 183122
Label Lot Number: J7186089
Label Size: 57,5 mm (in yellow box)
Label Side: Left (in red box)

Actual Size: 60 mm
Actual Side: Right
On item identifiable as: "60R" (in blue box)

Biomet Orthopedics LLC is conducting a medical device Field Safety Corrective Action (removal) for two lots of Vanguard Posterior Stabilized Open Box Femoral components due to a commingle. Two complaints were received with no patient impact for packaging that was incorrectly labeled as either smaller or larger and as the incorrect side (right/left). Please see above example. The incorrectly labeled products could have the potential risks as described in the table below.

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 retrieve a readily available replacement	Bone fracture due to interference condition or acute revision due to implanting incorrect size or side
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	Abnormal joint kinematics due to incorrect size or side leading to surgical intervention

Our records indicate that you may have received one or more of the affected products. The affected units were distributed in June and July 2022. Local deployment may differ.

ZFA2022-00278

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 for hospitals 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 Field Safety Corrective Action records in the event of a compliance audit of your facility's documentation.
6. If you have further questions or concerns after reviewing this Field Safety Notice, please contact your local 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.
3. Complete **Attachment 1 – Certificate of Acknowledgement Form** and send to fieldaction.gscc@zimmerbiomet.com.
4. Retain a copy of the **Attachment 1 – Certificate of Acknowledgement Form** with your Field Safety Corrective Action records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this Field Safety Notice, please contact your local Zimmer Biomet representative.

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 Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing ProductComplaintsGSCC@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 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,

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ZIMMER BIOMET

ATTACHMENT 1 - Certificate of Acknowledgement Form

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Vanguard® Knee System, Posterior Stabilized Open Box Femoral
Field Safety Corrective Action Reference: ZFA2022-00278

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

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

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

Item Number	Lot Number	Quantity returned

Complete this table for all affected items returned or provide a spreadsheet with the return of this form if the table above has not enough space to list all products. **Do not return affected products with other returns.**

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:**_____

Facility Name:_____

Facility Address:_____

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

Please return the completed form to your Zimmer Biomet contact or by e-mail to fieldaction.gscc@zimmerbiomet.com.