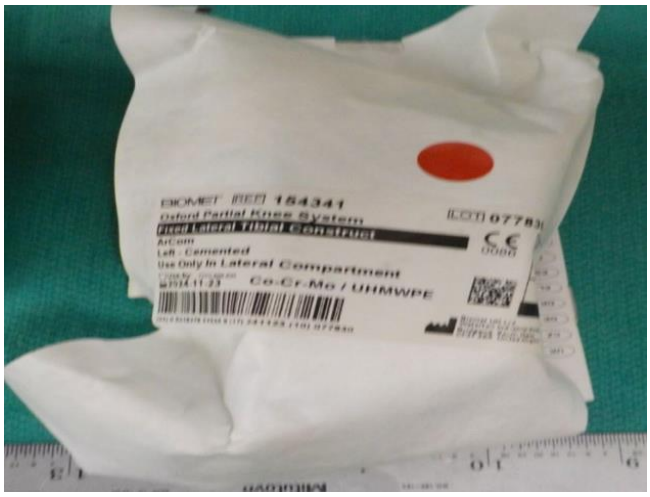
29 December 2022

To: Hospitals and Surgeons

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

Affected Product: Oxford® Partial Knee System, Fixed Lateral Tibial Construct

Item Number	Lot Number	UDI Number
154341	077830	(01) 05019279515349(17)241123(10)077830



Biomet Orthopedics LLC is conducting a lot specific medical device Field Safety Corrective Action (removal) for certain Oxford Partial Knee System, Fixed Lateral Tibial Constructs. A field complaint investigation confirmed the item and lot number combination in scope was packaged in the incorrect shelf carton. While the incorrect shelf carton was used during manufacturing, there is a potential for this issue to compromise the sterile barrier through distribution. There have been two complaints received for the affected scope.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None	Clinically signification extension of surgery to find a non-readily available replacement.
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	Infection 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 September 2020 and December 2021. Local deployment may differ.

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.netherlands@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.netherlands@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 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 as 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 per.nl@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 in advance 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: Oxford® Partial Knee System, Fixed Lateral Tibial Construct
Field Safety Corrective Action Reference: ZFA2022-00204

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

☐ A thorough search has been performed for the affected products and the below are available for return.
Please provide a spreadsheet with the return of this form if the table below has not enough space to list all products.

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

Item Number	Lot Number	Quantity Returned

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 this Field Safety Notice communication. All required activities are complete or are being completed.

☐ **Hospital Facility** ☐ **Surgeon** *(Please check one as applicable)*

Printed Name: _____ **Signature:** _____

Title: _____ **Telephone:** ( ) _____-_____ **Date:** ____/____/____

Facility Name: _____

Facility Address: _____

City: _____ **Country:** _____ **ZIP:** _____