ZIMMER BIOMET

February 28, 2020

To: Hospitals and Surgeons

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

Affected Product: Anatomical Shoulder Trial Humeral PE-Insert 40-0

Item Number	Lot Number	UDI Number
01.04239.730	4502624503	(01) 00889024287808 (10)4502624503
	4503070153	(01) 00889024287808 (10)4503070153

Picture 1: Correct color coding (Yellow) for Item 01.04239.730

Picture 2: Incorrect color coding (Green) for Item 01.04239.730

As a precautionary measure Zimmer GmbH is conducting a medical device Field Safety Corrective Action (Removal) for two lots of Anatomical Shoulder Trial Humeral PE-insert 40-0. The two lots of the Anatomical Shoulder Trial Humeral PE-insert 40-0 were manufactured in the green color instead of the intended yellow color which can potentially lead to an incorrect size selection. To date no adverse outcome is reported.

The correct size can be identified through the laser marking on the product.

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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.	Non-clinical significant surgery time extension.
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.	Incorrect implant size for the patient will be used, resulting in joint overstuffing (trial head to large) or instability (trial head to small) leading to a potential revision.

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between February 2019 and December 2019 (Local deployment may differ).

Hospital Responsibilities:

1. Review this notification 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. Complete Attachment 1 – Certificate of Acknowledgement and send to fieldaction.emea@zimmerbiomet.com. This form must be returned even if you do not have any affected products at your facility.
4. Retain a copy of the acknowledgement form with your field 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 notice, please contact your Zimmer Biomet representative.

Surgeon Responsibilities:

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this field action that are recommended beyond your existing follow-up schedule.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.emea@zimmerbiomet.com. This form must be returned even if you do not have any affected products at your facility.
4. Retain a copy of the acknowledgement form with your field 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 notice, please contact your Zimmer Biomet representative.

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Other Information

This medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body 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 winterthur.per@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 notice has been delivered to the appropriate Regulatory Agencies. We would like to thank you for your co-operation in advance and regret any inconveniences caused by this field action.

Sincerely,

25. Feb 2020

Said Djaouat
VP EMEA QARC

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ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Anatomical Shoulder Trial Humeral PE-Insert 40-0

Field Action Reference: ZFA 2020-00007

Please return the completed form to your Zimmer Biomet contact person:
fieldaction.emea@zimmerbiomet.com

☐ I received and understood the Field Safety Notice.

Regarding the products:

☐ All inventories for the affected products have been checked and following products are to be returned:

Product Reference	Lot Reference	Number of products returned

OR

☐ The potentially affected products which are unavailable for return have been: ☐ discarded ☐ lost ☐ other:_____

By signing below, I acknowledge that the required actions have been taken in accordance with the Field Safety Notice.

[ ] **Hospital Facility** [ ] **Surgeon** *(Please check one as applicable)*

Printed Name: _____ **Signature:** _____ **Date:**____/____/____

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

Facility Name: _____ **Facility Address:** _____

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