ZIMMER BIOMET

February 25, 2020

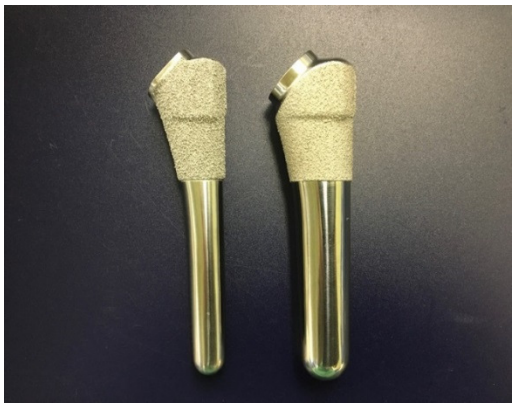
To: Hospital

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

Reference: ZFA2020-00024

Affected Product: **Comprehensive Shoulder Mini Humeral Stem**

Item Number	Description	Lot Number
113629	Comprehensive Shoulder Mini Humeral Stem 9MM	659260



Representative Size Difference

Biomet Orthopedics is conducting a medical device Field Safety Corrective Action (removal) for one single lot of the Comprehensive Shoulder Mini Humeral Stem 9MM. A Comprehensive Shoulder Mini Humeral Stem 15mm was misidentified as a Comprehensive Shoulder Mini Humeral Stem 9mm. The issue can be recognized easily by the surgeon due to the large size difference.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Non-clinically significant extension of surgery to find another readily available product	*Intra-operative humeral fracture*
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	*Tissue damage necessitating medical intervention*

Our records indicate that you may have received one or more of the potentially affected implants. The potentially affected implants were distributed between Dec 17, 2019 and Dec 20, 2019 (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 any potentially affected implants at your facility, assist your Zimmer Biomet sales representative and quarantine all potentially affected implants. Your Zimmer Biomet sales representative will remove the potentially affected implants from your facility.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.italy@zimmerbiomet.com. This form must be returned even if you do not have potentially affected implants 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 Field Safety Notice, please contact your Zimmer Biomet representative.

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 units or any other Zimmer Biomet product by emailing per.it@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,

Kevin W. Escapule
Post Market Surveillance & Regulatory Compliance Director

ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Comprehensive Shoulder Mini Humeral Stem

Field Action Reference: ZFA 2020-00024

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

☐ I received and understood the Field Safety Notice.

Regarding the parts:

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

Item Reference	Lot Number	Number of parts returned

OR

☐ The potentially affected units which are unavailable for return have been used

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:**_____