March 31, 2020

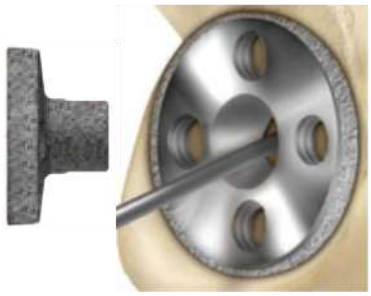
To: Hospital

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

Reference: **ZFA2020-00012**

Affected Product: **Comprehensive Reverse Shoulder Glenosphere Mini Baseplate with Taper Adapter**

Item Number	Lot Number	UDI Number
010000589	410420	(01) 0 0880304 53246 5 (17) 290825 (10) 410420



Biomet Orthopedics is conducting a medical device field safety corrective action (removal) for one single lot of the Comprehensive Reverse Shoulder Glenosphere Mini Baseplate with Taper Adapter, due to the product potentially being packaged without a taper adapter. The package is intended to contain one (1) baseplate and one (1) taper adapter; however, devices within the scope of this Field Safety Corrective Action may be packaged with two (2) baseplates and no (0) adapters.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	A non-clinically significant extension of surgery to find another product that is readily available or to switch to an alternate technique.	*A clinically significant extension of surgery to find another product that is not readily available or to switch to an alternate technique.*
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	*None*

Our records indicate that you may have received one or more of the potentially affected implants. The potentially affected implants were distributed between Sep 04, 2019 and Sep 25, 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.netherlands@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.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 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 Safety Corrective Action.

Sincerely,

_____

xxx

ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Potentially Affected Product: Comprehensive Reverse Shoulder Glenosphere Mini Baseplate with Taper Adapter

Field Safety Corrective Action Reference: ZFA 2020-00012

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

☐ I received and understood the Field Safety Notice.

Regarding the parts:

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

Item Reference	Lot Number	Number of parts returned

OR

☐ The potentially affected implants 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:**_____