ZIMMER BIOMET

August 19, 2019

To: Hospital

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

Reference: ZFA2019-00213

Affected Product: Sidus Stem-Free Shoulder Humeral Head, 50-18

Item Number	Lot Number	UDI Number
01.04555.500	2941696	(01)00889024415973(17)280299(10)2941696

Zimmer GmbH is conducting a medical device Field Safety Corrective Action (Removal) for one specific lot of Sidus Stem-Free Shoulder Humeral Head 50-18 due to incorrect labeling on the product's package. The label on the package shows size 50-18 whereas the implant inside is a Sidus Stem-Free Shoulder Humeral Head size 40-14.

The issue can be detected by the user through the size difference and the laser marking on the product during surgery prior to implantation. In the case of unavailable replacement product, the surgery can be completed by the usage of a smaller or bigger size.

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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
	The issue will be detected during surgery. A replacement device will be made available, the surgery will be completed with replacement device (<30min surgery time extension).	*If a replacement device is not available in the planned size the surgeon will complete the surgery by usage of a smaller or bigger size, surgery time extension would be < 30min.*
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 affected products. The affected units were distributed between April 2018 and March 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 affected products at your facility, assist your Zimmer Biomet sales representative and quarantine all affected products. Your Zimmer Biomet sales representative will remove the affected products 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 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 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 product or any other Zimmer Biomet product by emailing winterthur.per@zimmerbiomet.com or to your local Zimmer Biomet contact.

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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,

Said Djaouat
VP EMEA QARC

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ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Sidus Stem-Free Shoulder Humeral Head 50-18

Field Action Reference: ZFA 2019-00213

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

☐ I received and understood the Field Safety Notice.

Regarding the parts:

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

Item Reference	Lot Number	Number of parts returned

OR

☐ The affected products 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:**_____