C+TBA gGmbH | Magnesitstraße 1 | 3500 Krems | Austria

Krems, 15.04.2021

To: Hospital
Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE-REMOVAL**
Reference: AWB21-163 Allograft
Affected Product: ASP310 Cancellous Granules 30cc (5-8mm)

Item Number	Lot Number
ASP310	310X21013S

As a precautionary measure C+TBA gGmbH is conducting a medical device Field Safety Corrective Action (Removal) for the above listed lot (Item Number: ASP310; Lot number 310X21013S) of ASP310 Cancellous Granules 30cc (5-8mm) which was shipped on 19.02.2021 and had the wrong grain size. Instead of the ordered 5-8 mm grain size, the products with the Batch Nr. 310X21013S were wrongly packaged and contain the same product, but with a smaller grain size of 2-5 mm. The grain size 2-5mm of the product can be recognized from the label on the primary packaging.

Since both products were produced at the same time, with the same procedure and the same quality protocolls, there is no risk to the health of your patients with exception of the risk listed in the instruction for use.
As it isnot the ordered grain size, there is a possibility that the product does not meet the expected characteristics for the planned treatment.

Our records indicate that you may have received one or more of the potentially affected products.

Hospital Responsibilities

1. Review this notification and ensure that affected personnel are aware of the contents.
2. Identify and quarantine the product in scope.
   Please contact your local Zimmer Biomet representative to have these products returned and replaced.
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 potentially 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.

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 rev. 8 in Europe.

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 apologize for any inconvenience occurred due to this field action.

Sincerely,

Alexandra Hartmann
Head Regulatory & Quality

ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: ASP310 Cancellous Granules 30cc (5-8mm)

Field Action Reference: AWB21-163 Allograft

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 parts:

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

Reference	Lot Reference	Number of products returned

OR

☐ The potentially affected products which are unavailable for return have been implanted

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:**_____