ZIMMER BIOMET

March 16, 2018

To: Surgeons/ Hospitals

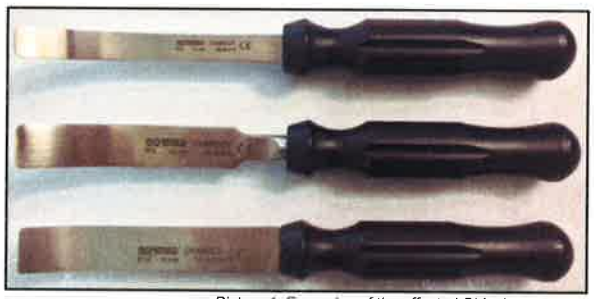
Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE (REMOVAL)**

Reference: **FA 2018-03 (ZFA2018-17)**

Affected Product: Charcot Osteotome Chisel (Trauma & Foot and Ankle instruments)

Item Number	Description
26.08.506	OSTEO 5MM AND W/HDL 20CM/8IN
26.08.507	OSTEO 8MM AND W/HDL 20CM/8IN
26.08.508	OSTEO 10MM AND W/HDL 20CM/8IN
26.08.509	OSTEO 12MM AND W/HDL 20CM/8IN
26.08.613	OSTEO 13MM CRVD R 10 23CM/9IN
26.08.619	OSTEO 19MM CRVD R 10 23CM/9IN
26.08.712	OSTEO 12MM CRVD R 6 23CM/9IN
26.08.715	OSTEO 15MM CRVD R 6 23CM/9IN
26.08.718	CHARC OSTE 18MM CRD R6 23CM/9
26.08.812	OSTEO 12MM CRVD R 8 23CM/9IN
26.08.815	OSTEO 15MM CRVD R 8 23CM/9IN
26.08.818	CHARC OSTE 18MM CRD R8 23CM/9
26.08.900	ARTHROPIC ARTH 18CM 45TUFF HDL
26.08.910	RUTREK CHIS 20CM/8 DBL CUT BLD

Table 1: Affected products



Picture 1: Examples of the affected Chisel

Zimmer GmbH is conducting a voluntary medical device field action (removal) for all lot numbers of the various chisels indicated in table 1. These chisels are used for removing, cutting, perforating or fenestrating specific cartilage, and fibroses of arthrodesis joint surfaces in the foot, ankle, hand, and wrist.

A recent complaint investigation revealed unexpected lumen in the interface of the handle with the metal chisel. As a precautionary measure, it was decided to remove all remaining product in the market. Alternative chisels are available for use in surgeries.

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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	Worst Case
	None, instrument fully processed during cleaning and sterilization process at the hospital.	Issues might be detected prior use intra-operatively (design issue) and a slight delay might occur (less then 30min) obtain/sterilize a new instrument.
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Worst Case
	None	Not fully decontaminated instrument might lead to local infection leading to potential revision surgery, in the worst case, a systemic infection conducting a circulatory collapse and organ failure.

These instruments have been deployed since 2007. Our records indicate that you may have received one or more of the affected products.

Surgeon/ Hospital Responsibilities:

1. Review this notification for awareness of the contents.
2. Assist your Zimmer Biomet sales representative to quarantine immediately all affected instruments.
3. Your Zimmer Biomet sales representative will remove the affected instruments from your facility.
4. Complete Attachment 1 – Certificate of Acknowledgement.
    a. Return a digital copy to fieldaction.emea@zimmerbiomet.com.
    b. Retain a copy of the Certificate of Acknowledgement with your field action records in the event of a compliance audit of your documentation.
5. If after reviewing the notice you have further questions or concerns please contact your Zimmer Biomet representative.

Other Information

This voluntary 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,

[redacted]

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ATTACHMENT 1
Certificate of Acknowledgement FA2018-03 (ZFA2018-17)

Affected Product: Charcot Osteotome Chisel

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:** _____

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

Facility Name: _____

Facility Address: _____

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

Note: This form must be returned to Zimmer Biomet before this action can be considered closed for your account. It is important that you complete this form and email a copy to: fieldaction.emea@zimmerbiomet.com.

Even if you have no product to return, this form must be completed, signed and returned.

Choose the following options:

☐ All received products were discarded or lost by the clinic/ hospital

Or complete the chart below for remaining products:

Product Reference	Lot Reference	Number of products returned

Comments (if needed): _____