ZIMMER BIOMET

May 23, 2017

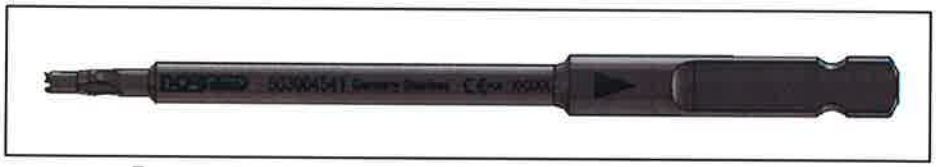
To: Surgeons

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

Affected Product: Werber Countersink Cannulated for micro CBS Screws, AO and round-shaft

Product Description	Item Number	Lot Number	UDI Number
Werber Countersink Cannulated for micro CBS Screws, round-shaft	503004341	13015	GTIN: 00889024111851
		13016	GTIN: 00889024111851
		13571	GTIN: 00889024111851
		14341	GTIN: 00889024111851
		14482	GTIN: 00889024111851
		14570	GTIN: 00889024111851
Werber Countersink Cannulated for micro CBS Screws, AO	503004541	13065	GTIN: 00889024111967
		13569	GTIN: 00889024111967
		15350	GTIN: 00889024111967

Table 1: Affected products



Picture 1: View of the Countersink instrument with AO

Dear Madam / Sir,

Zimmer Biomet is conducting a medical device Field Safety Notice for specific lots of two Countersink Cannulated instruments as specified in table 1.

The Countersink is an instrument which is used over the guide wire to prepare for adequate space in the cortical bone rim to sink the screw head in to bones/tissues for different Foot, Ankle and Hand implant systems.

Zimmer Biomet received a total of 3 complaints claiming the tip breakages of the instrument regarding the same lot number. An investigation was initiated and it was identified that an incorrect raw material was used to manufacture these specific lots. The material used for these specific lots is a harder grade material, which has different mechanical properties like a reduced elastic limit which could lead to a potential breakage of the instrument.

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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
	If the fragments of the broken instrument fall into the wound of the patient, surgeon would try to remove the fragments. The wound would be washed (common procedure) to ensure that the foreign material is being removed. A slight delay in surgery time (< 30min) would occur due to washing of the wound and also to obtain a new instrument to complete the surgery. As the incorrect raw material is biocompatible, fragments remaining in patient body do not pose an increased risk to the patient. The fragments would remain as an encapsulated foreign body and could lead to tissue irritation.	None
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Worst Case
	If a replacement device for the countersink instrument is not available, the screw cannot be fully set, and the screw head is not fully plane with the bone a potential irritation of the tissues might happen due a screw not fully set.	If the screw cannot be fully set into the bone this can lead to pressure of the corticalis by the screw head which could lead to micro fractures of the bone. If the micro fractures occur, an early revision surgery might occur.

Our records indicate you may have received one or more of the affected products. The affected units were distributed between June 2013 and April 2017.

Hospital / Surgeon Responsibilities:

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this recall that are recommended beyond your existing follow up schedule.
3. Assist your Zimmer Biomet sales representative quarantine all affected product.
4. Your Zimmer Biomet sales representative will remove the affected product from your facility.
5. Complete Attachment 1 – Certificate of Acknowledgement.
    a. Return a digital copy to fieldaction.emea@zimmerbiomet.com.

   b. Retain a copy of the Acknowledgement Form with your recall records in the event of a compliance audit of your documentation.
6. If after reviewing the notice you have further questions or concerns please contact your local Zimmer Biomet representative. Alternatively, your questions may be sent by email to fieldaction.emea@zimmerbiomet.com.

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.

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.

The undersigned confirms that this notice has been delivered to the appropriate Competent Authorities, as per MEDDEV 2.12-1 revision 8.

We would like to thank you for your co-operation in advance.

Sincerely,

[redacted]

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ATTACHMENT 1
Certificate of Acknowledgement- FA 2017-02 (ZFA 2017-95)

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:_____ **State:**_____ **ZIP:**_____

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 **or to your local Zimmer Biomet contact.**

Product Reference	Lot Reference	Number of returned instruments