

May 9, 2018

To: Surgeons/ Hospitals

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

Reference: **FA 2018-05 (ZFA2018-00135)**

Affected Product: Werber Countersink Cannulated instrument for micro CBS Screws, AO

Part Number	Description	Lot Number
503004352	CBS CSK15MM AO CAN1.4MM DPCBS4	14935
503004352	CBS CSK15MM AO CAN1.4MM DPCBS4	15039
503004352	CBS CSK15MM AO CAN1.4MM DPCBS4	15393

Table 1: Affected instruments



Picture 1: View of the Countersink instrument with AO

Dear Madam / Sir,

Zimmer GmbH is conducting a medical device Field Safety Notice (Removal) for specific lots of Werber Countersink Cannulated instrument as specified in table 1.

The Werber Countersink Cannulated instrument 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. An investigation identified that an incorrect raw material was used to manufacture these specific lots. The material used for these specific lots is a softer grade material, which has different mechanical properties like a reduced tensile strength which could lead to a potential breakage of the instrument.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Highest Severity
	Surgery is finalized with another instrument. Any debris from the broken instrument is removed from the wound. Surgical extension time < 30min.	No replacement instrument is available. The screw cannot be fully set into the bone
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Highest Severity
	None	Foreign body (from the instrument) not fully removed from the wound and remains as an encapsulated foreign body. Encapsulated foreign body could lead to tissue reaction. Pressure on cortical due to the not fully set screw head could lead to micro fractures.

Our records indicate that you may have received one or more of the affected units. The affected units were distributed from 2014.

Surgeon/ Hospital Responsibilities:

1. Review this Field Safety Notice and ensure that affected personnel are aware of the contents.
2. If you have affected product at your facility, assist your Zimmer Biomet sales representative and quarantine all affected product. Your Zimmer Biomet sales representative will remove the affected product 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 Certificate of 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 in Europe.

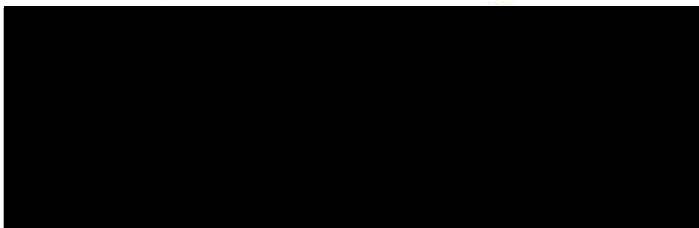
Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing winterthur.per@zimmerbiomet.com or to your local Zimmer Biomet contact.

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 Field Safety 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,





ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

**Affected Product: Werber Countersink Cannulated instrument for micro CBS Screws, AO Field
Action Reference: FA2018-05 (ZFA2018-00135)**

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 products:

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

Product Reference	Lot Reference	Number of products returned

OR

The affected products which are unavailable for return have been: discarded lost other: _____

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:** _____