

August 19, 2019

To: Hospitals

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

Reference: **ZFA 2019-00185**

Affected Product: Calcar Trimmer Shaft

Item Number	Lot Number	UDI Number
110032331	784060	(01)00887868229541(11)190220(10)784060
	662870	(01)00887868229541(11)180329(10)662870



Zimmer Biomet is conducting a lot specific medical device field safety corrective action (Removal) for the Calcar Trimmer Shaft. The potential issue associated with the instrument is that the end of the shaft could fail to effectively mate with the broach.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None	<i>Extension of surgery less than 30 minutes to find a replacement or use another instrument.</i>
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 May 2019 (Local deployment may defer).

**Hospital Responsibilities:**

1. Review this notification 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.netherlands@zimmerbiomet.com](mailto:fieldaction.netherlands@zimmerbiomet.com). This form will 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 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 [per.nl@zimmerbiomet.com](mailto:per.nl@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,

.....  
.....  
.....

**ATTACHMENT 1**  
**Certificate of Acknowledgement**

**IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED**

**Affected Product:** Calcar Trimmer Shaft

**Field Action Reference:** ZFA 2019-00185

Please return the **completed** form to your Zimmer Biomet contact person or by e-mail [fieldaction.netherlands@zimmerbiomet.com](mailto:fieldaction.netherlands@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:

Reference	Lot Reference	Number of parts 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: \_\_\_\_\_