

January 27, 2020

To: Hospital

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

Reference: ZFA2019-00322

Affected Product: Calcar Trimmer Shaft

Item Number	Description	Lot Number	UDI Number
110032332	Calcar Trimmer Shaft for use with Zimmer Rasps	203240	(01) 00887868 229558 (10) 203240
		711160	(01) 00887868 229558 (10) 711160
		827310	(01) 00887868 229558 (10) 827310



Biomet Orthopedics is conducting a medical device Field Safety Corrective Action (removal) for certain lots of 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.

The issue can be recognized easily by the surgeon due to inability / difficulty to mate the broach. In case of an unavailable replacement product, the surgery can be completed by using another instrument.

NOTE: This is a scope expansion which is adding three lots of a sister part to the Field Safety Corrective Action initiated on August 19, 2019 for the Calcar Trimmer Shaft (ZFA 2019-00185).

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	<i>None</i>	<i>Non clinically significant extension of surgery 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
	<i>None</i>	<i>None</i>

Our records indicate that you may have received one or more of the potentially affected instruments. The potentially affected units were distributed between April 2018 and March 2019 (Local deployment may differ).

Hospital Responsibilities:

1. Review this Field Safety Notice and ensure that affected personnel are aware of the contents.
2. If you have any potentially affected instruments at your facility, assist your Zimmer Biomet sales representative and quarantine all potentially affected instruments. Your Zimmer Biomet sales representative will remove the potentially affected instruments from your facility.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.netherlands@zimmerbiomet.com This form must be returned even if you do not have potentially affected instruments 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 Field Safety 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 instrument or any other Zimmer Biomet product by emailing 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,

XXX

ATTACHMENT 1

Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Calcar Trimmer Shaft **Field Action Reference:** ZFA 2019-00322

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

I received and understood the Field Safety Notice.

Regarding the parts:

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

Item Reference	Lot Number	Number of parts returned

OR

The affected products which are unavailable for return have been used

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:** _____