ZIMMER BIOMET

July 5, 2019

To: Hospitals

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

Reference: **ZFA2019-00056**

Affected Product: GTS Trunnion Rasp

Item #	Lot #	Item name
110025196	426960	GTS Trunnion Rasp S-2
110025197	426860	GTS Trunnion Rasp S-1
110025198	426950	GTS Trunnion Rasp S 0
110025196	369650	GTS Trunnion Rasp S-2
110025197	426660	GTS Trunnion Rasp S-1
110025198	368990	GTS Trunnion Rasp S 0
110025199	451450	GTS Trunnion Rasp S+1
110025200	459970	GTS Trunnion Rasp S+2
110025201	534290	GTS Trunnion Rasp S+3
110025202	427090	GTS Trunnion Rasp S+4
110025203	292520	GTS Trunnion Rasp S+5
110025204	203990	GTS Trunnion Rasp S+6
110025204	129280	GTS Trunnion Rasp S+6
110025204	134170	GTS Trunnion Rasp S+6

Affected instruments

View of the GTS Rasp

As a precautionary measure Biomet France Sarl is conducting a medical device Field Safety Corrective Action (removal) for specific lots of the GTS Rasps as per scope indicated above.

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Certain fractures of GTS Trunnion Rasp were identified through complaints, with no patient impact associated. Investigations demonstrated that the issue might be linked with a specific raw material. Therefore, GTS rasps that are not included in the scope of this Field Safety Corrective Action are not impacted by this issue and can be used.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Highest Severity
	Extension of the surgical time less than 30 minutes to replace the rasp with a bigger size.	Extension of the surgical time more than 30 minutes to get the rasp out and rasp with a bigger size or to modify the surgical approach.
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	Potential impact on the patient's rehabilitation due to longer anaesthesia time.

Our records indicate that you may have received one or more of the affected instruments. The affected units were distributed between January 2018 and December 2018 (local deployment may differ).

Hospital Responsibilities:

1. Review this notification and ensure that affected personnel are aware of the contents.
2. If you have affected instruments at your facility, assist your Zimmer Biomet sales representative and quarantine all affected instruments. Your Zimmer Biomet sales representative will remove the affected instruments 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 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.

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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 instrument or any other Zimmer Biomet product by emailing fr.complaints@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,

Yannick BOSSERT
QARC Director EMEA West

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ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Instrument: GTS Rasps **Field Action Reference: ZFA2019-00056**

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 instruments have been checked and following instruments are to be returned:

Product Reference	Lot Reference	Number of instruments returned

OR

☐ The affected instruments 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:**_____