

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.



Certain fractures of GTS Trunion 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 [fielddaction.emea@zimmerbiomet.com](mailto:fielddaction.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.



ZIMMER BIOMET

### 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](mailto: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,





# 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](mailto: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: \_\_\_\_\_