

To: Hospitals and Surgeons

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

Affected Product: GTS Trunnion Rasp

See Attachment 2 – Instruments within scope of this field action



Figure 1: view of GTS Rasp

By means of this notice we notify you that Biomet France Sarl is conducting a medical device Field Safety Corrective action (recall) of all GTS Trunnion Rasps as per scope indicated in Attachment 2.

Some fractures of GTS Trunnion Rasps were identified through complaints, with no patient impact reported.

As a precautionary measure while appropriate corrective actions are identified Biomet France Sarl has decided to recall all GTS Trunnion Rasps from the market.



The potential health consequences were assessed as follows:

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product 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 another 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 product issue.	Most Probable	Highest Severity
	None.	Potential impact on the patient's rehabilitation due to longer anesthesia time

Our records indicate that you may have received one or more of the instruments within the scope of this field action.

Hospital Responsibilities:

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this Field Safety Corrective Action that are recommended beyond your existing follow-up schedule.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.france@zimmerbiomet.com.
4. Retain a copy of the acknowledgement form with your recall 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 or send your questions to fieldaction.france@zimmerbiomet.com



Other Information

This medical device Field Action will be reported to all relevant Competent Authorities, Notified Bodies, and Regulatory Authorities as required.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing fr.complaints@zimmerbiomet.com.

Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes. Your urgent cooperation is needed.

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

Thank you for your assistance. We regret any inconvenience caused by this Field Action.

Sincerely,

A handwritten signature in blue ink, appearing to be 'Yannick Bossert', written over a horizontal line.

Yannick BOSSERT
QARC Director EMEA West



**ATTACHMENT 1
Certificate of Acknowledgement**

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: GTS Trunnion Rasps Field Action Reference: ZFA 2019-00377

**Please return the completed form to your Zimmer Biomet contact person:
fieldaction.france@zimmerbiomet.com**

I received and understood the Field Action Safety Notice.

Regarding the products:

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

Item Number	Lot Number	Quantity 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 this recall notice.

Hospital Facility Surgeon (please check one as applicable)

Printed Name: _____ **Signature:** _____

Title: _____ **Telephone:** () _____ - _____ **Date:** ____ / ____ / ____

Facility Name: _____

Facility Address: _____

City: _____ **Country:** _____ **ZIP:** _____

Note: This form will be returned to Zimmer Biomet before this action is closed for your account. It is important that you complete this form and email a copy to fieldaction.france@zimmerbiomet.com.



ATTACHMENT 2

Instruments within scope of this field action

Item Number	Lot Number	Item Description
110025191	508860	GTS Trunnion Rasp S-7
110025191	429040	GTS Trunnion Rasp S-7
110025191	428880	GTS Trunnion Rasp S-7
110025191	427060	GTS Trunnion Rasp S-7
110025191	369580	GTS Trunnion Rasp S-7
110025191	368900	GTS Trunnion Rasp S-7
110025191	133900	GTS Trunnion Rasp S-7
110025192	897440	GTS Trunnion Rasp S-6
110025192	509170	GTS Trunnion Rasp S-6
110025192	452040	GTS Trunnion Rasp S-6
110025192	451290	GTS Trunnion Rasp S-6
110025192	429030	GTS Trunnion Rasp S-6
110025192	369710	GTS Trunnion Rasp S-6
110025192	134020	GTS Trunnion Rasp S-6
110025193	536720	GTS Trunnion Rasp S-5
110025193	509480	GTS Trunnion Rasp S-5
110025193	451300	GTS Trunnion Rasp S-5
110025193	426910	GTS Trunnion Rasp S-5
110025193	426900	GTS Trunnion Rasp S-5
110025193	426740	GTS Trunnion Rasp S-5
110025194	654920	GTS Trunnion Rasp S-4
110025194	451530	GTS Trunnion Rasp S-4
110025194	427040	GTS Trunnion Rasp S-4
110025194	426840	GTS Trunnion Rasp S-4
110025194	426540	GTS Trunnion Rasp S-4
110025194	369140	GTS Trunnion Rasp S-4
110025195	655020	GTS Trunnion Rasp S-3
110025195	428970	GTS Trunnion Rasp S-3
110025195	428920	GTS Trunnion Rasp S-3
110025195	428900	GTS Trunnion Rasp S-3
110025195	426880	GTS Trunnion Rasp S-3
110025195	349040	GTS Trunnion Rasp S-3
110025195	134090	GTS Trunnion Rasp S-3
110025196	655070	GTS Trunnion Rasp S-2



Item Number	Lot Number	Item Description
110025196	452120	GTS Trunnion Rasp S-2
110025196	428960	GTS Trunnion Rasp S-2
110025196	426780	GTS Trunnion Rasp S-2
110025197	655090	GTS Trunnion Rasp S-1
110025197	477050	GTS Trunnion Rasp S-1
110025197	426680	GTS Trunnion Rasp S-1
110025197	369010	GTS Trunnion Rasp S-1
110025198	655120	GTS Trunnion Rasp S 0
110025198	427070	GTS Trunnion Rasp S 0
110025198	426560	GTS Trunnion Rasp S 0
110025198	095590	GTS Trunnion Rasp S 0
110025199	655130	GTS Trunnion Rasp S+1
110025199	452290	GTS Trunnion Rasp S+1
110025199	429160	GTS Trunnion Rasp S+1
110025199	426920	GTS Trunnion Rasp S+1
110025199	426670	GTS Trunnion Rasp S+1
110025199	134120	GTS Trunnion Rasp S+1
110025200	892230	GTS Trunnion Rasp S+2
110025200	722280	GTS Trunnion Rasp S+2
110025200	699740	GTS Trunnion Rasp S+2
110025200	504010	GTS Trunnion Rasp S+2
110025200	437370	GTS Trunnion Rasp S+2
110025200	428950	GTS Trunnion Rasp S+2
110025200	401740	GTS Trunnion Rasp S+2
110025201	733320	GTS Trunnion Rasp S+3
110025201	722020	GTS Trunnion Rasp S+3
110025201	722010	GTS Trunnion Rasp S+3
110025201	368980	GTS Trunnion Rasp S+3
110025201	199220	GTS Trunnion Rasp S+3
110025201	134150	GTS Trunnion Rasp S+3
110025202	992700	GTS Trunnion Rasp S+4
110025202	509490	GTS Trunnion Rasp S+4
110025202	451430	GTS Trunnion Rasp S+4
110025202	426800	GTS Trunnion Rasp S+4
110025202	426630	GTS Trunnion Rasp S+4
110025203	722500	GTS Trunnion Rasp S+5
110025203	504020	GTS Trunnion Rasp S+5



Item Number	Lot Number	Item Description
110025203	498570	GTS Trunnion Rasp S+5
110025203	426520	GTS Trunnion Rasp S+5
110025203	368890	GTS Trunnion Rasp S+5
110025204	722300	GTS Trunnion Rasp S+6
110025204	398090	GTS Trunnion Rasp S+6
110025204	368880	GTS Trunnion Rasp S+6
110025204	292730	GTS Trunnion Rasp S+6
110025204	136070	GTS Trunnion Rasp S+6
110025205	641890	GTS Trunnion Rasp S+7
110025205	509510	GTS Trunnion Rasp S+7
110025205	398100	GTS Trunnion Rasp S+7
110025205	292740	GTS Trunnion Rasp S+7
110025206	429150	GTS Trunnion Rasp S+7
110025206	427100	GTS Trunnion Rasp S+7
110025206	427080	GTS Trunnion Rasp S+7
110025206	426580	GTS Trunnion Rasp S+7

