

August 28, 2018

To: Surgeons/ Hospitals

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

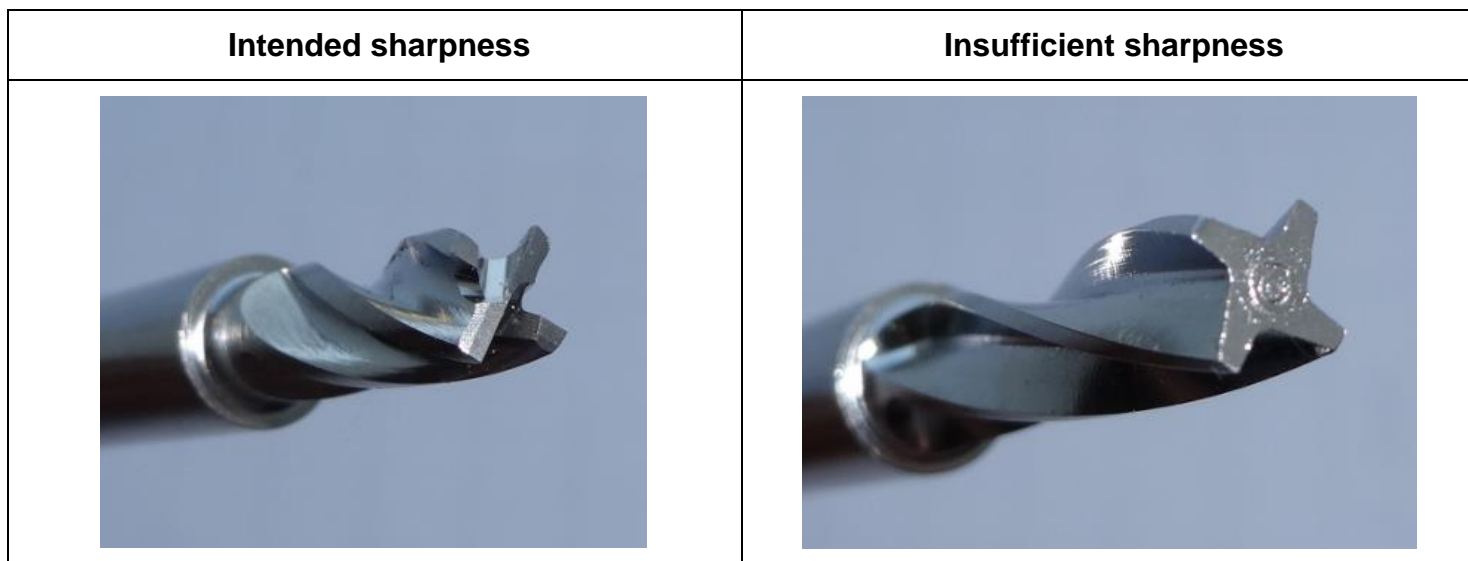
Reference: **ZFA2018-00304**

Affected Product: T.E.S.S Glenoid Drill 5mm

Reference #	Batch #
110029274	1477291060
	1618150010
	1639677010

Affected instruments

Biomet France SARL is conducting a medical device Field Safety Corrective Action (removal) for one specific T.E.S.S Glenoid 5mm drill with reference 110029274 and for the 3 lot numbers as indicated above. The removal is due to insufficient sharpness of the drill. No adverse events have been reported to date for this issue. The drill has correct dimension and form and could be used to make a hole in the subchondral bone but it is considered to be less efficient.



View of the issue

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 surgical time less than 30 min to get another instrument.	Extension of surgery time less than 30 min due to operation made with non-sharp (insufficient) drill.
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	None

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between May 2016 and April 2018 (local deployment dates might defer).

Please note that the TESS Glenoid 5mm drill with reference A1700244 is not affected by this removal.

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.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.

Surgeon Responsibilities:

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this field action that are recommended beyond your existing follow-up schedule. As a manufacturer of medical devices Zimmer Biomet is not licensed to practice medicine. It is up to healthcare professionals to assess the risk and decide on any patient monitoring.

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.

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.

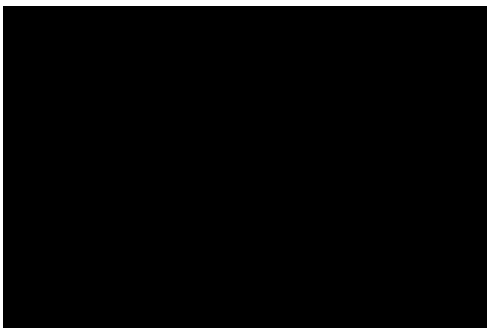
Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing fr.complaints@zimmerbiomet.com or to your local Zimmer Biomet contact.

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 Product: T.E.S.S Glenoid Drill 5mm Field Action Reference: ZFA2018-00304

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

Product Reference	Lot Reference	Number of products 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:** _____