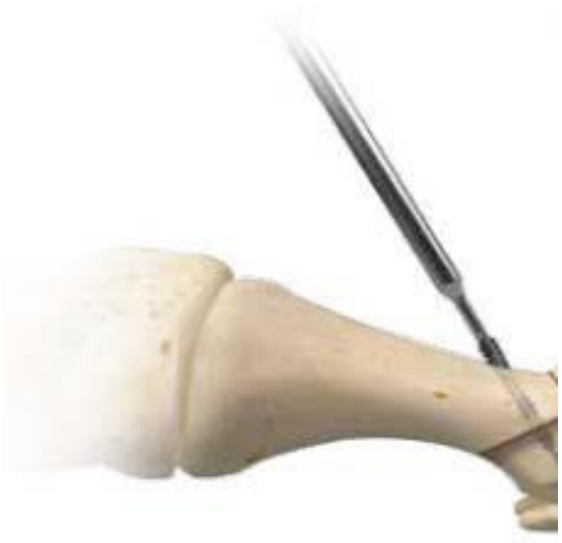
April 5, 2019

Dear Healthcare Professional,
cc: Chairman Medical Board and relevant Head of Departments

Subject: **URGENT MEDICAL DEVICE REMOVAL AND NOTICE OF DISCONTINUATION**

Affected Product: T7 Cannulated Driver AO and T7 Driver Solid AO

Item Number	Description	Lot Numbers
110018541	T7 Driver Solid AO	All Lots
110018531	T7 Cannulated Driver AO	All Lots



Zimmer Biomet is conducting a removal of the T7 Cannulated Driver AO and T7 Driver Solid AO due to the potential of fracture, bending or shearing of the T7 Driver. The T7 Driver is being redesigned. All distributed product remaining in the field is being removed. The T7 Driver will be replaced with a new design with new part numbers. This letter also serves as a notice for the discontinuation of the current design product.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Minor extension of surgery generally <30 minutes to find replacement	*Major extension of surgery generally >30 minutes to find replacement and to remove foreign particles.*
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	*Retention of foreign particle leading to adverse tissue reaction*

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between May 2015 and March 2019.

Risk Manager 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 CorporateQuality.PostMarket@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 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 call customer service at 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of call center operating hours will receive a voicemail prompt or be transferred to an on-call representative in the event of an emergency. Alternatively, your questions may be emailed to CorporateQuality.PostMarket@zimmerbiomet.com.

Other Information

This medical device recall was reported to the U.S. Food and Drug Administration and will be reported to other Competent Authorities, Notified Bodies, and Regulatory Authorities as required.

- Med Watch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's Med Watch Adverse Event Reporting program either online, by mail, or by fax.
- Online: www.fda.gov/medwatch/report.htm
- Mail: Use postage paid, pre-addressed form FDA 3500, available at: www.fda.gov/MedWatch/getforms.htm
- Fax: 1-800-FDA-0178

Under 21 CFR 803, manufacturers are also required to report any serious injuries where a product has contributed or may have contributed to the event. Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing product.experience@zimmerbiomet.com.

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.

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

Sincerely,

[redacted]

Kevin W. Escapule
Post Market Surveillance & Regulatory Compliance Director

ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: T7 Cannulated Driver AO and T7 Driver Solid AO

Field Action Reference: ZFA 2019-00046

Do you have affected product in your facility?
(Hospital Facility Only: Please mark the appropriate response.)

☐ **Yes**, we currently have one or more affected items in our facility.

☐ **No**, we currently have no affected items in our facility.

By signing below, I acknowledge that the required actions have been taken in accordance with this recall notice.

Printed Name: _____ **Signature:** _____

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

Facility Name: _____

Facility Address: _____

City:_____ **State:**_____ **ZIP:**_____

Note: This form must 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 CorporateQuality.PostMarket@zimmerbiomet.com or fax to 574-373-3589.