ZIMMER BIOMET

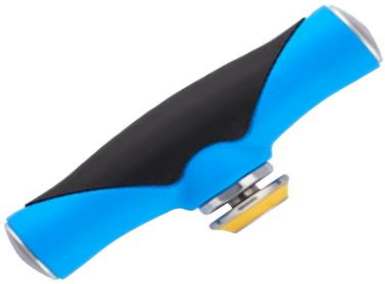
May 24, 2017

To: Risk Managers and Surgeons

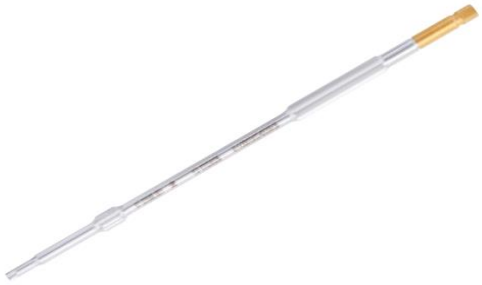
Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE- REMOVAL**

Affected Product: Vitality T27 Final Drivers and Vitality Torque Limiting Handle – 90 in-lbs

Item Number	Lot Number
07.02066.001	All
07.02053.001	All



Torque Limiting Handle – 90 in-lbs
07.02053.001



T27 Final Driver
07.02066.001

Zimmer Biomet Spine, Inc. is conducting a medical device field safety notice for Vitality T27 Final Drivers and Vitality Torque Limiting Handle – 90 in-lbs. When applying torque to tighten the closure top with the Vitality Torque Handle and Vitality T27 final driver, the Vitality T27 Final Driver shaft twists. This twist of the driver has the potential to create a torsional spring action on the mating parts of the T27 Final Driver and Torque Handle. The repeated spring action while applying torque can cause damage to the cam and cam lobe inside the Torque Handle. The damaged parts inside the Torque Handle have the potential to cause the values of torque to go out of specification. This can result in either over-torque, which has potential to cause driver tips to break, or under-torque, which has potential to result in inadequate tightening of closure tops.

The likelihood of failure is improbable; however, the issue could potentially lead to the risks as stated in the table below:

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	*Most Probable*	*Worst Case*
	Instrument breakage leading to delay in surgery 10 to 30 minutes	*Excess torsion during screw placement leading to bone fracture*
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	*Most Probable*	*Worst Case*
	None	*Inadequate tightening of construct leading to revision surgery*

Our records indicate you may have received one or more of the affected products. The affected units were distributed between the dates of December 2015 and April 2017.

Surgeon / Hospital Responsibilities:

1. Review this notification and ensure affected personnel are aware of the contents.
2. Assist your Zimmer Biomet sales representative quarantine all affected product.
3. There are no specific patient monitoring instructions related to this field action that are recommended beyond your existing follow up schedule.
4. Your Zimmer Biomet sales representative will remove the affected product from your facility.
5. Complete Attachment 1 – Certificate of Acknowledgement.
    a. Return a copy to fieldaction.emea@zimmerbiomet.com or to your local Zimmer Biomet contact.
    b. Retain a copy of the Acknowledgement Form with your recall records in the event of a compliance audit of your facilities documentation.
6. If after reviewing this notice you have further questions or concerns please contact your local Zimmer Biomet contact.

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.

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

The undersigned confirms that this notice has been delivered to the appropriate Competent Authorities, as per MEDDEV 2.12-1 revision 8.

We would like to thank you for your co-operation in advance.

Sincerely,

[redacted]

ATTACHMENT 1
Certificate of Acknowledgement- ZFA2017-159

By signing below, I acknowledge that the required actions have been taken in accordance with the Recall Notice.

[ ] **Hospital Facility** [ ] **Surgeon** (Please check one as applicable)

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 can be considered closed for your account. It is important that you complete this form and return a copy to fieldaction.emea@zimmerbiomet.com or to your local Zimmer Biomet contact.

Product Reference	Lot Reference	Number of returned products