August 23, 2018

To: Surgeon/ Hospitals

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

Reference: **ZFA2018-00326**

Affected Product: Vitality® Shear-off Set Screw

See **Attachment 2 – Affected Product List** for affected product information.

Zimmer Biomet is conducting a medical device field action (removal) for the Vitality® Shear-off Set Screw because it was determined that the Shear-off Set Screw is not threading properly with the mating tulip head of the Vitality screws, hooks and connectors due to a manufacturing issue.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Delay less than 30 minutes to locate another closure top (Standard or shear-off)	*Delay less than 30 minutes to locate another closure top (Standard or shear-off)*
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	*None*

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between December 2015 and July 2018 (from legal manufacturer. Local deployment might show different dates).

Hospital/ surgeon 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.

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 winterthur.per@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,

[redacted]

ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Vitality® Shear-off Set Screw Field Action Reference: ZFA 2018-00326

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

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 email a copy to: fieldaction.emea@zimmerbiomet.com.

Even if you have no product to return, this form must be completed, signed and returned.

Choose the following options:

☐ All received products were used (implanted)

Or complete the chart below for remaining products:

Product Reference	Lot Reference	Number of products returned

Comments (if needed): _____

ATTACHMENT 2
Affected Product List

Item Number	07.02011.001		
Item Description	Vitality® Shear-off Set Screw		
Lot Number	**UDI Number**	**Lot Number**	**UDI Number**
P141352 (Z00176603)	(01)00889024003187 (10)P141352	P141353	(01)00889024003187 (10)P141353
P141354 (Z00468651)	(01)00889024003187 (10)P141354	P141358 (Z00420148)	(01)00889024003187 (10)P141358
P141359 (Z00274115)	(01)00889024003187 (10)P141359	P141360	(01)00889024003187 (10)P141360
P142510	(01)00889024003187 (10)P142510	W508041	(01)00889024003187 (10)W508041
W505611	(01)00889024003187 (10)W505611	W509661	(01)00889024003187 (10)W509661
W509651	(01)00889024003187 (10)W509651	W526991	(01)00889024003187 (10)W526991
W5096619	(01)00889024003187 (10)W5096619	W530301	(01)00889024003187 (10)W530301
W529371	(01)00889024003187 (10)W529371	W554821	(01)00889024003187 (10)W554821
W546001	(01)00889024003187 (10)W546001	W573501	(01)00889024003187 (10)W573501
W559871	(01)00889024003187 (10)W559871	W577991	(01)00889024003187 (10)W577991
W573511	(01)00889024003187 (10)W573511		