November 6, 2018

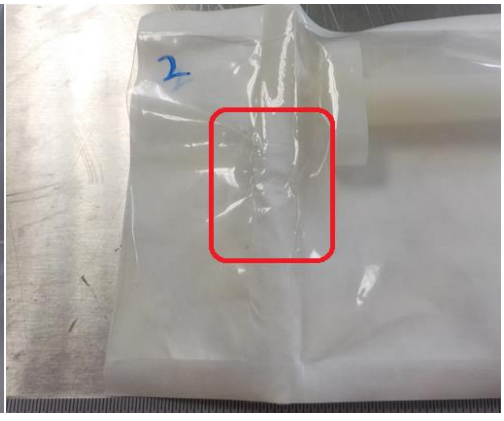
To: Hospitals

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

Reference: **ZFA2018-00391**

Affected Product: Various Trauma Guide Wires

Item Number	Item Description	Lot Number
00-2228-024-00	Pressure Sentinel® Intramedullary Reaming System, Guide Wire, Bullet Tip, 2.4 mm Diameter	All lots expiring prior to September 30, 2023
00-2255-025-00	M/DN® Intramedullary Fixation Humeral Guide Wire - Smooth, 2.4 mm Diameter, 70 cm Length	
00-2255-026-00	M/DN® Intramedullary Fixation Humeral Guide Wire - Bullet Tip, 2.4 mm Diameter, 70 cm Length	
47-2237-033-00	ZMS® Intramedullary Fixation Smooth Guide Wire, 2.4 mm Diameter, 100 cm Length	
47-2237-037-00	ZMS® Intramedullary Fixation Smooth Guide Wire, 3.0 mm Diameter, 100 cm Length	
47-2237-038-00	ZMS® Intramedullary Fixation Smooth Guide Wire - Bullet Tip, 3.0 mm Diameter, 100 cm Length	
47-2255-008-00	Humeral Guide Wire - Ball Tip, 2.4 mm Diameter, 70 cm Length	
47-2255-008-01	Smooth Guide Wire - Bullet Tip, 3.0 mm Diameter, 100 cm Length	
47-2490-097-00	Zimmer® Natural Nail® System - Tear Drop Guide Wire, 3.0 mm Diameter, 100 cm Length	
47-2490-097-01	Zimmer® Natural Nail® System - Tear Drop Guide Wire, 2.4 mm Diameter, 100 cm Length	
47-2490-098-00	Zimmer® Natural Nail® System - Tear Drop Guide Wire, 3.0 mm Diameter, 70 cm Length	
47-2490-098-01	Zimmer® Natural Nail® System - Tear Drop Guide Wire, 2.4 mm Diameter, 70 cm Length	
00-2228-024-00	Pressure Sentinel® Intramedullary Reaming System, Guide Wire, Bullet Tip, 2.4 mm Diameter	



Zimmer Biomet is conducting a medical device field safety corrective action (removal) for Various Trauma Guide Wires due to potential creases in the sealing area on the end opposite of the product's chevron opening.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None	*Extension of surgery less than 30 minutes to find replacement parts*
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	*Infection, leading to surgical intervention*

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between October 2013 and September 2018 (local deployments might differ).

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.

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: Various Trauma Guide Wires

Field Action Reference: ZFA2018-00391

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 parts:

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

Reference	Lot Reference	Number of parts returned

OR

☐ The affected parts 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:**_____