ZIMMER BIOMET

11 August 2017

To: Risk Managers
CC: Chairman Medical Board and relevant Head of Departments

Subject: **URGENT MEDICAL DEVICE RECALL REMOVAL**

Affected Product: Trauma, Guide Wires 70cm, Reference Attachment 2

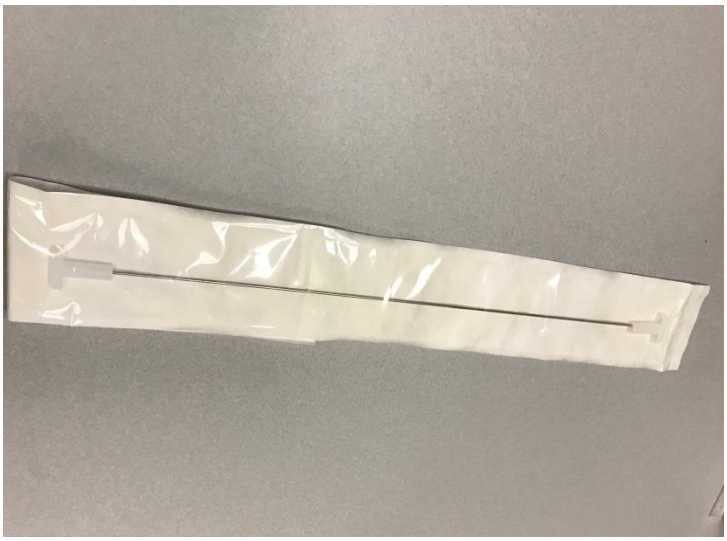

Image 1. Guide wire with protector

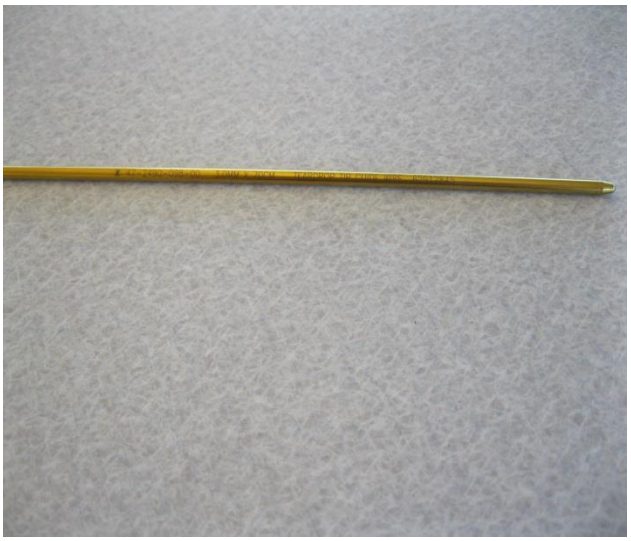

Image 2. 3mm*70cms Guide Wire

Zimmer is initiating a field action for 70cm Guide wire trauma products which assists in guiding the nail during implantation. The design verification for the previous packaging configuration does not cover the 70cm wires. While there has not been any complaints involving a breach in sterility, Zimmer has completed design verification to move the 70cm guide wires to a new packaging configuration. As a result, the products packaged in the previous packaging configuration are being removed.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Worst Case
	Extension of Surgery <30 min	Extension of Surgery <30 min
Describe long range health	Most Probable	Worst Case

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consequences (injuries or illness) that may result from use of or exposure to the product issue.	None	Infection

Our records indicate you may have received one or more of the affected products.

Hospital Responsibilities:

1. Review this notification and ensure affected team members are aware of the contents.
2. Complete the Certification of Acknowledgement portion of **Attachment 1**
    a. Return a digital copy to corporatequality.postmarket@zimmerbiomet.com within three (3) days.
3. Assist your Zimmer Biomet sales representative quarantine all affected product.
4. If after reviewing this notice you have further questions or concerns, please call 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of the call center operating hours will receive a prompt to record a voicemail or be transferred to an on-call representative in the case of an emergency. Alternatively, your questions may be sent by email to corporatequality.postmarket@zimmerbiomet.com.

Other Information

This field action 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.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA:

- MedWatch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch 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 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 zimmer.per@zimmerbiomet.com.

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

We thank you for your cooperation and regret any inconvenience caused by this field action.

Sincerely,

[redacted]

Kevin W. Escapule
Post Market Surveillance & Regulatory Compliance Director

ATTACHMENT 1
Certificate of Acknowledgement

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

[ ] **Hospital Facility**

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 email a copy to: corporatequality.postmarket@zimmerbiometcom.

ZIMMER BIOMET

Attachment 2
Affected Product List

Item Number	Lot Number Expiry Date Before	Description
00225502500	April 2022	M/DN HUM SMOOTH GUIDE WIRE
00225502600	March 2022	M/DN HUM BULLET TIP GUIDE WIRE
47225500800	April 2022	BALL TIP GUIDE WIRE 2.4MM
47249009800	April 2022	3MM X 70CM TEAR DROP GUIDE WIRE
47249009801	March 2022	2.4MM X 70CM TEAR DROP GUIDE WIRE