June 19, 2017

To: Surgeons/ Hospitals/ Clinics

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

Affected Product: Trauma, Guide Wires 70cm

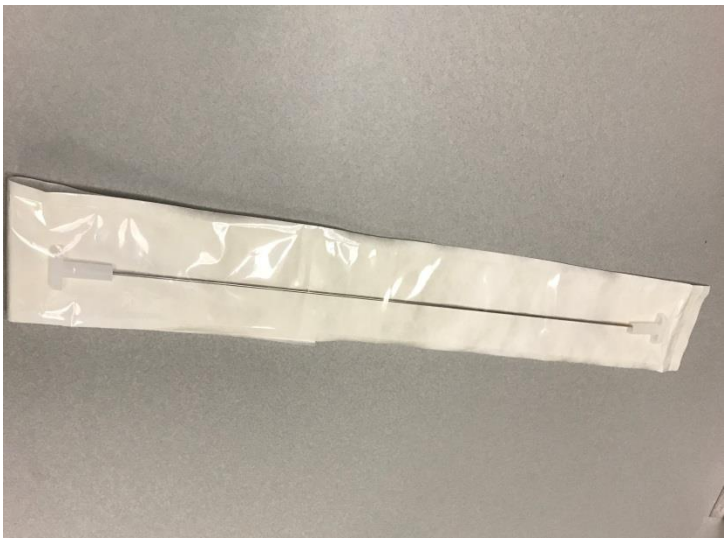


Image 1. Guide wire with protector

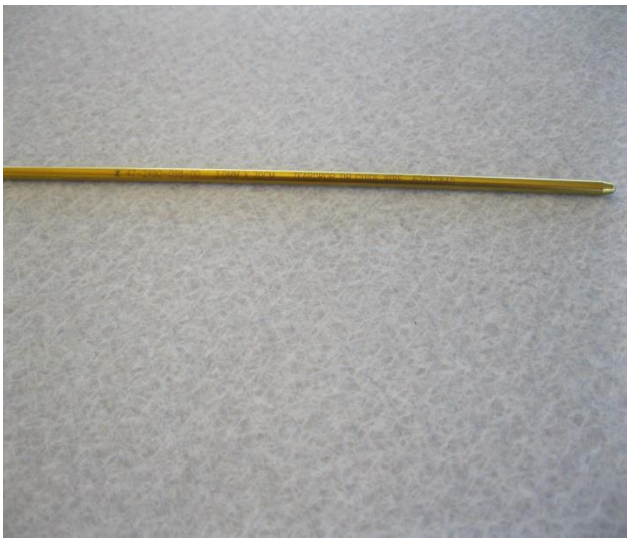


Image 2. 3mm*70cms Guide Wire

Zimmer is initiating a field safety notice/removal 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.

Affected Product List

Item Number	Lot Number Expiry Date Before	Description
00-2255-025-00	April 2022	M/DN HUM SMOOTH GUIDE WIRE
00-2255-026-00	March 2022	M/DN HUM BULLET TIP GUIDE WIRE
47-2255-008-00	April 2022	BALL TIP GUIDE WIRE 2.4MM
47-2490-098-00	April 2022	3MM X 70CM TEAR DROP GUIDE WIRE
47-2490-098-01	March 2022	2.4MM X 70CM TEAR DROP GUIDE WIRE

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

ZFA 2017-189

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

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 fieldaction.emea@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 contact your Zimmer Biomet representative.

Other Information

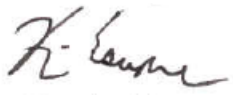
This voluntary medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices.

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 cooperation in advance and regret any inconveniences caused by this field action.

Sincerely,



_____

Kevin W. Escapule
Post Market Surveillance & Regulatory Compliance Director

ATTACHMENT 1
Certificate of Acknowledgement- ZFA 2017-189

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

[ ] **Hospital Facility**

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@zimmerbiometcom.

Product Reference	Lot Reference	Number of returned instruments

ZIMMER BIOMET

June 19, 2017

To: Distributors

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

Affected Product: Trauma, Guide Wires 70cm

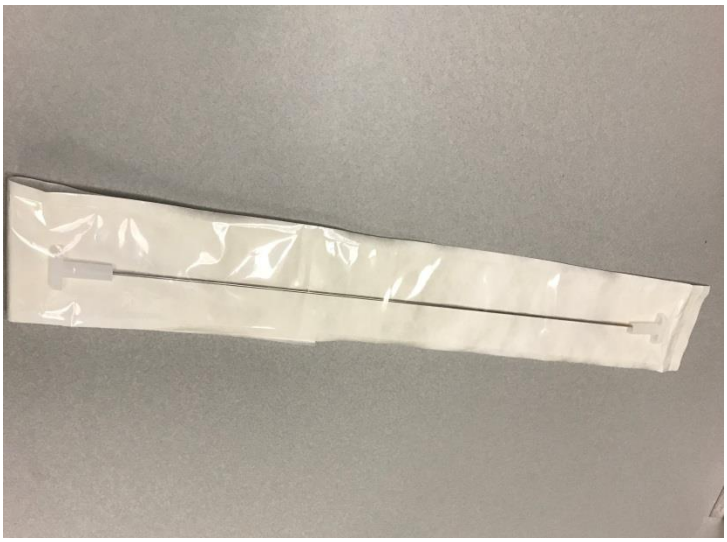
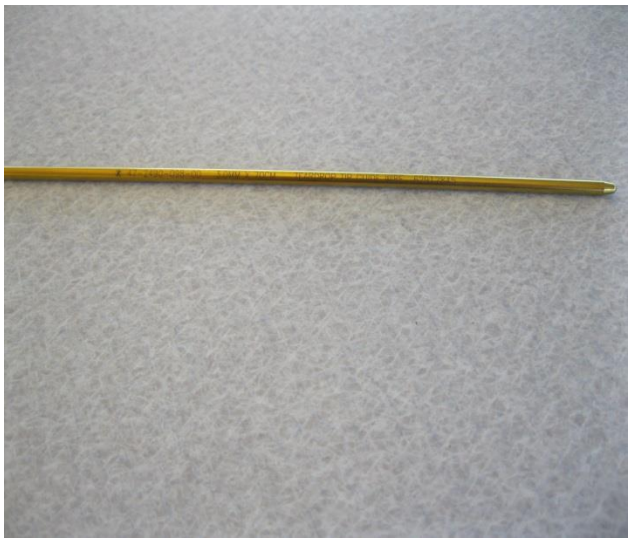


Image 1. Guide wire with protector



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47-2490-098-01	March 2022	2.4MM X 70CM TEAR DROP GUIDE WIRE

ZFA 2017-189

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

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

Your Responsibilities:

1. Review this notification and ensure affected personnel are aware of the contents.
2. Immediately locate and quarantine affected product in your inventory.
3. Complete the Certification of Acknowledgement portion of **Attachment 1 – Inventory Return Certification Form**
   a. Return a digital copy to fieldaction.emea@zimmerbiomet.com within three (3) days.
4. Inform the identified clinics/ hospitals with the Field Safety Notice for Surgeons/ clinics/ hospitals.
5. Return all affected product from your distributorship and affected hospitals within your territory/ country along with a completed Attachment 1 – Inventory Return Certification Form to Zimmer Biomet within 2 weeks.
   a. For each return, send a copy of Attachment 1 to fieldaction.emea@zimmerbiomet.com.
   b. Include a hardcopy of Attachment 1 with your shipment for immediate processing.
   c. Clearly mark “RECALL” on the outside of return boxes.
6. Retain a copy of your acknowledgement and product return forms for your records in the event of a compliance audit of your facility.
7. If after reviewing this notice you have further questions or concerns, please contact your local Zimmer Biomet representative.

Other Information

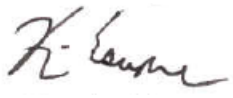
This voluntary medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices.

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 cooperation in advance and regret any inconveniences caused by this field action.

Sincerely,



_____

Kevin W. Escapule
Post Market Surveillance & Regulatory Compliance Director

ZIMMER BIOMET

ATTACHMENT 1
Inventory Return Certification Form

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

Affected Product: _____

Country: _____ **Account Number:** _____

Account Name: _____

Account Address: _____

Please return the affected product to the appropriate address below with a spreadsheet containing item number, lot number, and quantity:

Return Department /Zimmer GmbH
Biomet Global Supply Chain Center B.V.
Hazeldonk 6530 - Dock 20
Breda 4836 LD, Netherlands

An exhaustive search for the affected lots has been performed and all available affected product is being returned to Zimmer Biomet; any product not returned or found in inventory are considered consumed/lost and unavailable for use.	**Check one of the following:**			
	Yes		**No**	

☐ **Credit My Account** ☐ **Send a Replacement**

Item Number	Lot Number	UDI Number	Quantity Returned

Complete this table for all affected items returned. If additional space is needed, please enter the above information on a spreadsheet and return with this form to fieldaction.emea@zimmerbiomet.com.

Certificate of Acknowledgement:

By signing below, I acknowledge that I have received, read, and understand the contents of this recall communication. All required activities are complete or are being completed.

Printed Name: _____ **Signature:** _____

Title: _____ **Tel:** ( ) ____-_____ x _____ **Date:** ___/___/_____

Note: This form and affected product 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, in addition to including a copy with your product returns.

Please do not return affected product with other returns.