



March 27, 2018

To: Risk Managers

Subject: **URGENT MEDICAL DEVICE RECALL**

Affected Product: ZNN & M/DN Guide Wires – See Attachment 2 – Affected Product List

Zimmer Biomet is conducting a lot specific medical device recall for ZNN and M/DN Trauma Guide Wires due to process monitoring failures related to the sterile seal on the packaging. A breach in the packaging seal could potentially lead to loss of sterility of the device.

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
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	Revision due to infection.

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between May 2017 and March 2018.

Risk Manager 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 CorporateQuality.PostMarket@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 recall 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 call customer service at 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of call center operating hours will receive a voicemail prompt or be transferred to an on-call representative in the event of an emergency. Alternatively, your questions may be emailed to CorporateQuality.PostMarket@zimmerbiomet.com.

Other Information

This medical device recall 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.

- Med Watch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's Med Watch 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 also 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.

Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes. This action is being taken with the knowledge of Health Canada and is in compliance with regulations set forth by Health Canada. Your urgent cooperation is needed.

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

Thank you for your assistance. We regret any inconvenience caused by this recall.

Sincerely,

A black rectangular box redacting the signature of Kevin W. Escapule.

Kevin W. Escapule
Post Market Surveillance & Regulatory Compliance Director



ATTACHMENT 1

Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: ZNN & M/DN Guide Wires Field Action Reference: ZFA 2017-00072

Do you have affected product in your facility?

(Hospital Facility Only: Please mark the appropriate response.)

- ☐ **Yes**, we currently have one or more affected items in our facility.
- ☐ **No**, we currently have no affected items in our facility.

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

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 is closed for your account. It is important that you complete this form and email a copy to CorporateQuality.PostMarket@zimmerbiomet.com or fax to 574-372-4265.

ATTACHMENT 2

Affected Product List

Item Number: 00-2228-024-00		Item Description: Pressure Sentinel Intramedullary Reaming System Guide Wire Bullet Tip 2.4 mm Diameter			
Lot Numbers	63655999	63715685	63731170	63733045	63812299

Item Number: 00-2255-025-00		Item Description: M/DN Intramedullary Fixation Humeral Guide Wire – Smooth 2.4 mm Diameter, 70 cm Length			
Lot Numbers	63733049	63738623	63748399	63753770	63758430
63849380	77006555	77006556	77006557		

Item Number: 00-2255-026-00		Item Description: M/DN Intramedullary Fixation Humeral Guide Wire – Bullet Tip 2.4 mm Diameter, 70 cm Length			
Lot Numbers	63733046	63758426	77006554		

Item Number: 47-2237-033-00		Item Description: ZMS Intramedullary Fixation Smooth Guide Wire 2.4 mm Diameter, 100 cm Length			
Lot Numbers	63715690	63780127	63787482		

Item Number: 47-2237-037-00		Item Description: ZMS Intramedullary Fixation Smooth Guide Wire 3.0 mm Diameter, 100 cm Length			
Lot Numbers	63662549	63668704	63696974	63709171	63721377
63731176	63764550	63771164	63781920	63803595	63812302
63817719	63826242				

Item Number: 47-2237-038-00		Item Description: ZMS Intramedullary Fixation Smooth Guide Wire – Bullet Tip 3.0 mm Diameter, 100 cm Length			
Lot Numbers	63645655	63650115	63650116	63655995	63655996
63655997	63655998				

Item Number: 47-2255-008-00		Item Description: Humeral Guide Wire Ball Tip 2.4 mm Diameter, 70 cm Length			
Lot Numbers	63738593	63738594	63738595	63738596	63748395
63748396	63748397	63748398	63753767	63753768	63758425
63758428	63771163	77006530	77006531	77006532	77006533
77006534	77006535	77006536	77006537	77006538	77006539
77006540	77006541	77006542	77006543	77006544	77006545

Item Number: 47-2255-008-01		Item Description: Smooth Guide Wire Bullet Tip 3.0 mm Diameter, 100 cm Length			
Lot Numbers	63619923	63625354	63625355	63625356	63631736
63631737	63638178	63638179	63638180	63638181	63639395
63639396	63639397	63639398	63639399	63639401	63645656
63645657	63645658	63645659	63648799	63648801	63648802
63648803	63650117	63650118	63651633	63651634	63651635
63656843	63662543	63662544	63662545	63662546	63662547
63668702	63668703	63668721	63675676	63675677	63681732
63681733	63681734	63681735	63690182	63690183	63690184
63690185	63696959	63696960	63696961	63705243	63705244
63705245	63705246	63709167	63709168	63709169	63709170
63715687	63715688	63721372	63721373	63721374	63721375
63731172	63731173	63731174	63731175	63733047	63733048
63764548	63771161	63771162	63780124	63780125	63781880
63803593	63812301	63796536	63796537		

Item Number: 47-2490-097-00		Item Description: Zimmer Natural Nail System Tear Drop Guide Wire 3.0 mm Diameter, 100 cm Length			
Lot Numbers	63609177	63631715	63638172	63638173	63638175
63638176	63645643	63645644	63655990	63655991	63655992
63655993	63655994	63662538	63662539	63662540	63662541
63668694	63668695	63668696	63668697	63675668	63675669
63675670	63675704	63675705	63681724	63681726	63681728
63690176	63690179	63690180	63705228	63705229	63709163
63709164	63709165	63709166	63715680	63715681	63715682
63715683	63721368	63721369	63721370	63721371	63731169
63748392	63753760	63753761	63753762	63753763	63758420
63758421	63758422	63758423	63771066	63771067	63780119
63780120	63780121	63780122	63781875	63781876	63781877
63781878	63787475	63787476	63787477	63796531	63796532
63796533	63796534	63796535	63803579	63803581	63803583

Item Number: 47-2490-097-00		Item Description: Zimmer Natural Nail System Tear Drop Guide Wire 3.0 mm Diameter, 100 cm Length			
63803591	63803592	63812281	63812283	63812284	63812285
63817702	63817704	63817705	63844026	63812282	63817701
63826234	63826235	63836285	63844028		

Item Number: 47-2490-097-01		Item Description: Zimmer Natural Nail System Tear Drop Guide Wire 2.4 mm Diameter, 100 cm Length			
Lot Numbers	63631719	63668698	63705230	63705231	63731168
63771071	63787479				

Item Number: 47-2490-098-00		Item Description: Zimmer Natural Nail System Tear Drop Guide Wire 3.0 mm Diameter, 70 cm Length			
Lot Numbers	63631729	63638177	63645647	63645648	63662542
63681727	63690177	63690178	63733040	63733041	63733042
63748389	63753764	63758424	63771141	63780123	63787478
63826236	77006549	77006550	77006551	77006553	77006558
63836288					

Item Number: 47-2490-098-01		Item Description: Zimmer Natural Nail System Tear Drop Guide Wire 2.4 mm Diameter, 70 cm Length			
Lot Numbers	63733044	63748390	63748391	77006546	77006547
77006548					