

March 26, 2018

To: Distributors, Sales Representatives, and Distributor Operation 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 |
| | <i>None</i> | <i>Extension of surgery less than 30 minutes</i> |
| Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue. | Most Probable | Highest Severity |
| | <i>None</i> | <i>Revision due to infection.</i> |

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.

Your Responsibilities:

1. Review this notification and ensure that affected team members are aware of the contents.
2. Immediately locate and quarantine affected product in your inventory.
3. Immediately return all affected product from your distributorship and from affected hospitals within your territory.
 - a. Complete **Attachment 1 – Inventory Return Certification Form** and send to CorporateQuality.PostMarket@zimmerbiomet.com and FN-CN-EMEA-Americas@zimmerbiomet.com **within five (5) business days.**
 - b. **International returns, request an International Return Authorization** (IRA) Number by **completing the IRA form** (attached in the email) and emailing zimmerbiometintlirarequests@zimmerbiomet.com and FN-CN-EMEA-Americas@zimmerbiomet.com
 - c. **For each return, send a copy of Attachment 1 to** CorporateQuality.PostMarket@zimmerbiomet.com.
 - d. Include a hardcopy of Attachment 2 in each carton of your return shipment for immediate processing.
 - e. Mark “RECALL” on the outside of the returned cartons.
4. Retain a copy of your Inventory Return Certification and product return forms for your records in the event of a compliance audit of your facility.
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 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.

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

- 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 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 handwritten signature in black ink, appearing to read 'K. Escapule'.

Kevin W. Escapule
Post Market Surveillance & Regulatory Compliance Director



ATTACHMENT 1
Inventory Return Certification Form

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

Affected Product: ZNN & M/DN Guide Wires ZFA Number: ZFA 2017-00072

Territory Number: _____ 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:

Zimmer Biomet
 Product Service Department
 ATTN: RECALLS
 1777 West Center Street
 Warsaw, IN 46580

OR

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

| | | |
|--|------------------------------------|-----------------------------|
| This is the final return for the entire territory. An exhaustive search has been performed for the affected products. | Check one of the following: | |
| | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

Note: Any product not returned or found in your territory is considered consumed/lost and unavailable for use.

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 provide a spreadsheet and return it to CorporateQuality.PostMarket@zimmerbiomet.com and FN-CN-EMEA-Americas@zimmerbiomet.com with this form.

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:** () _____ **Ext.** _____ **Date:** _____

Note: This form and affected product must be returned to Zimmer Biomet before this action is considered closed for your account. It is important that you complete this form and email a copy to CorporateQuality.PostMarket@zimmerbiomet.com. Include a copy of this completed form with your product returns.

Please do not return affected product with other returns.

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 |
| 63803591 | 63803592 | 63812281 | 63812283 | 63812284 | 63812285 |

| Item Number: 47-2490-097-00 | | Item Description: Zimmer Natural Nail System Tear Drop Guide Wire 3.0 mm Diameter, 100 cm Length | | | |
|-----------------------------|----------|---|----------|----------|----------|
| 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 | 63733040 | 63733041 | 63733042 |
| | 63748389 | 63753764 | 63758424 | 63771141 | 63780123 |
| | 63826236 | 77006549 | 77006550 | 77006551 | 77006553 |
| | 63836288 | | | | 77006558 |

| 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 | | | | |