

February 28, 2018

**To:** Surgeons/ Hospitals

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

**Reference:** ZFA2017-00003

**Affected Product: AIM Tibial Nail**

See **Attachment 1 – Affected Product List**

Zimmer Biomet is conducting a medical device removal for AIM Tibial Nails after a Device Performance Review (DPR) failed clinical analysis for revision rate exceeding the acceptance criteria pursuant to the DPR protocol for the AIM/ART System.

| 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          | None   |
| 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          | Pain, screw fracture, or other failure modes resulting in revision surgery |

The affected units were previously distributed by Depuy. Zimmer Biomet acquired the trauma line in 2012, but did not manufacture or distribute the product. Any product you may have in your inventory would have been transferred during that acquisition and would be in Depuy packaging.

**Surgeon/ 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 2 – Certificate of Acknowledgement** and send to [fieldaction.emea@zimmerbiomet.com](mailto: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 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 as per MEDDEV 2.12-1 in Europe.



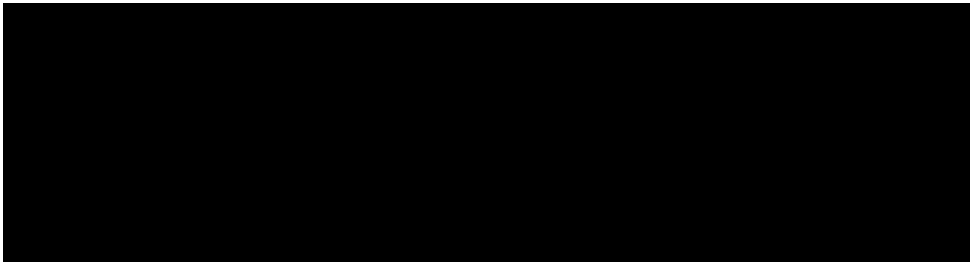
Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing [winterthur.per@zimmerbiomet.com](mailto:winterthur.per@zimmerbiomet.com) or to your local Zimmer Biomet contact.

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,





**ATTACHMENT 2**  
**Certificate of Acknowledgement**

**IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED**

**Affected Product: AIM Tibial Nails      Field Action Reference: ZFA 2017-00003**

**Choose the following option:**

All received products were used (implanted)

*Or complete the chart below for remaining products:*

| Product Reference | Lot Reference | Number of products returned |
|-------------------|---------------|-----------------------------|
|                   |               |                             |
|                   |               |                             |
|                   |               |                             |
|                   |               |                             |
|                   |               |                             |
|                   |               |                             |
|                   |               |                             |

Comments (if needed): \_\_\_\_\_

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:** \_\_\_\_\_ **ZIP:** \_\_\_\_\_ **Country:** \_\_\_\_\_

**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 [fieldaction.emea@zimmerbiomet.com](mailto:fieldaction.emea@zimmerbiomet.com).

**ATTACHMENT 1**  
**Affected Product List**

| Item Number | Lot Number | Item Description               |
|-------------|------------|--------------------------------|
| 800508255   | All        | NAIL TIB DYN 08X255<br>STERILE |
| 800508270   | All        | NAIL TIB DYN 08X270<br>STERILE |
| 800508285   | All        | NAIL TIB DYN 08X285<br>STERILE |
| 800508300   | All        | NAIL TIB DYN 08X300<br>STERILE |
| 800508315   | All        | NAIL TIB DYN 08X315<br>STERILE |
| 800508330   | All        | NAIL TIB DYN 08X330<br>STERILE |
| 800508345   | All        | NAIL TIB DYN 08X345<br>STERILE |
| 800508360   | All        | NAIL TIB DYN 08X360<br>STERILE |
| 800508375   | All        | NAIL TIB DYN 08X375<br>STERILE |
| 800508390   | All        | NAIL TIB DYN 08X390<br>STERILE |
| 800508405   | All        | NAIL TIB DYN 08X405<br>STERILE |
| 800508420   | All        | NAIL TIB DYN 08X420<br>STERILE |
| 800509255   | All        | NAIL TIB DYN 09X255<br>STERILE |
| 800509270   | All        | NAIL TIB DYN 09X270<br>STERILE |
| 800509285   | All        | NAIL TIB DYN 09X285<br>STERILE |
| 800509300   | All        | NAIL TIB DYN 09X300<br>STERILE |
| 800509315   | All        | NAIL TIB DYN 09X315<br>STERILE |
| 800509330   | All        | NAIL TIB DYN 09X330<br>STERILE |
| 800509345   | All        | NAIL TIB DYN 09X345<br>STERILE |
| 800509360   | All        | NAIL TIB DYN 09X360<br>STERILE |
| 800509375   | All        | NAIL TIB DYN 09X375<br>STERILE |
| 800509390   | All        | NAIL TIB DYN 09X390<br>STERILE |
| 800509405   | All        | NAIL TIB DYN 09X405<br>STERILE |
| 800509420   | All        | NAIL TIB DYN 09X420<br>STERILE |

| Item Number | Lot Number | Item Description               |
|-------------|------------|--------------------------------|
| 800510255   | All        | NAIL TIB DYN 10X255<br>STERILE |
| 800510270   | All        | NAIL TIB DYN 10X270<br>STERILE |
| 800510285   | All        | NAIL TIB DYN 10X285<br>STERILE |
| 800510300   | All        | NAIL TIB DYN 10X300<br>STERILE |
| 800510315   | All        | NAIL TIB DYN 10X315<br>STERILE |
| 800510330   | All        | NAIL TIB DYN 10X330<br>STERILE |
| 800510345   | All        | NAIL TIB DYN 10X345<br>STERILE |
| 800510360   | All        | NAIL TIB DYN 10X360<br>STERILE |
| 800510375   | All        | NAIL TIB DYN 10X375<br>STERILE |
| 800510390   | All        | NAIL TIB DYN 10X390<br>STERILE |
| 800510405   | All        | NAIL TIB DYN 10X405<br>STERILE |
| 800510420   | All        | NAIL TIB DYN 10X420<br>STERILE |
| 800511270   | All        | NAIL TIB DYN 11X270<br>STERILE |
| 800511285   | All        | NAIL TIB DYN 11X285<br>STERILE |
| 800511300   | All        | NAIL TIB DYN 11X300<br>STERILE |
| 800511315   | All        | NAIL TIB DYN 11X315<br>STERILE |
| 800511330   | All        | NAIL TIB DYN 11X330<br>STERILE |
| 800511345   | All        | NAIL TIB DYN 11X345<br>STERILE |
| 800511360   | All        | NAIL TIB DYN 11X360<br>STERILE |
| 800511375   | All        | NAIL TIB DYN 11X375<br>STERILE |
| 800511390   | All        | NAIL TIB DYN 11X390<br>STERILE |
| 800511405   | All        | NAIL TIB DYN 11X405<br>STERILE |
| 800511420   | All        | NAIL TIB DYN 11X420<br>STERILE |
| 800512270   | All        | NAIL TIB DYN 12X270<br>STERILE |

**ATTACHMENT 1**  
**Affected Product List**

| Item Number | Lot Number | Item Description               |
|-------------|------------|--------------------------------|
| 800512285   | All        | NAIL TIB DYN 12X285<br>STERILE |
| 800512300   | All        | NAIL TIB DYN 12X300<br>STERILE |
| 800512315   | All        | NAIL TIB DYN 12X315<br>STERILE |
| 800512330   | All        | NAIL TIB DYN 12X330<br>STERILE |
| 800512345   | All        | NAIL TIB DYN 12X345<br>STERILE |
| 800512360   | All        | NAIL TIB DYN 12X360<br>STERILE |
| 800512375   | All        | NAIL TIB DYN 12X375<br>STERILE |
| 800512390   | All        | NAIL TIB DYN 12X390<br>STERILE |
| 800512405   | All        | NAIL TIB DYN 12X405<br>STERILE |
| 800512420   | All        | NAIL TIB DYN 12X420<br>STERILE |
| 800513285   | All        | NAIL TIB DYN 13X285<br>STERILE |
| 800513300   | All        | NAIL TIB DYN 13X300<br>STERILE |
| 800513315   | All        | NAIL TIB DYN 13X315<br>STERILE |
| 800513330   | All        | NAIL TIB DYN 13X330<br>STERILE |
| 800513345   | All        | NAIL TIB DYN 13X345<br>STERILE |
| 800513360   | All        | NAIL TIB DYN 13X360<br>STERILE |
| 800513375   | All        | NAIL TIB DYN 13X375<br>STERILE |
| 800513390   | All        | NAIL TIB DYN 13X390<br>STERILE |
| 800513405   | All        | NAIL TIB DYN 13X405<br>STERILE |
| 800513420   | All        | NAIL TIB DYN 13X420<br>STERILE |
| 810508255   | All        | NAIL TIB DYN 08 X 255          |
| 810508270   | All        | NAIL TIB DYN 08 X 270          |
| 810508285   | All        | NAIL TIB DYN 08 X 285          |
| 810508300   | All        | NAIL TIB DYN 08 X 300          |
| 810508315   | All        | NAIL TIB DYN 08 X 315          |
| 810508330   | All        | NAIL TIB DYN 08 X 330          |

| Item Number | Lot Number | Item Description      |
|-------------|------------|-----------------------|
| 810508345   | All        | NAIL TIB DYN 08 X 345 |
| 810508360   | All        | NAIL TIB DYN 08 X 360 |
| 810508375   | All        | NAIL TIB DYN 08 X 375 |
| 810508390   | All        | NAIL TIB DYN 08 X 390 |
| 810508405   | All        | NAIL TIB DYN 08 X 405 |
| 810508420   | All        | NAIL TIB DYN 08 X 420 |
| 810509255   | All        | NAIL TIB DYN 09 X 255 |
| 810509270   | All        | NAIL TIB DYN 09 X 270 |
| 810509285   | All        | NAIL TIB DYN 09 X 285 |
| 810509300   | All        | NAIL TIB DYN 09 X 300 |
| 810509315   | All        | NAIL TIB DYN 09 X 315 |
| 810509330   | All        | NAIL TIB DYN 09 X 330 |
| 810509345   | All        | NAIL TIB DYN 09 X 345 |
| 810509360   | All        | NAIL TIB DYN 09 X 360 |
| 810509375   | All        | NAIL TIB DYN 09 X 375 |
| 810509390   | All        | NAIL TIB DYN 09 X 390 |
| 810509405   | All        | NAIL TIB DYN 09 X 405 |
| 810509420   | All        | NAIL TIB DYN 09 X 420 |
| 810510255   | All        | NAIL TIB DYN 10 X 255 |
| 810510270   | All        | NAIL TIB DYN 10 X 270 |
| 810510285   | All        | NAIL TIB DYN 10 X 285 |
| 810510300   | All        | NAIL TIB DYN 10 X 300 |
| 810510315   | All        | NAIL TIB DYN 10 X 315 |
| 810510330   | All        | NAIL TIB DYN 10 X 330 |
| 810510345   | All        | NAIL TIB DYN 10 X 345 |
| 810510360   | All        | NAIL TIB DYN 10 X 360 |
| 810510375   | All        | NAIL TIB DYN 10 X 375 |
| 810510390   | All        | NAIL TIB DYN 10 X 390 |
| 810510405   | All        | NAIL TIB DYN 10 X 405 |
| 810510420   | All        | NAIL TIB DYN 10 X 420 |