



January 15, 2018

**To:** Surgeons / Hospitals

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

**Reference:** ZFA2017-00006

**Affected Product:** ACE Trochanteric Nail (ATN) System

**See Attachment 2 – Affected Product List**

Zimmer Biomet is conducting a medical device field safety notice (removal) for the ACE Trochanteric Nail (ATN) system after a Device Performance Review (DPR) failed clinical analysis for survivorship pursuant to the acceptance criteria for the DPR protocol for the ATN 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	Secondary reduction loss or lateral sliding of the screw resulting in a revision surgery. Screw cut-out resulting in a total hip arthroplasty or revision surgery.

Our records indicate that you may have received one or more of the affected products. The affected units were distributed by Zimmer Biomet between July 2012 and December 2017. These products were previously distributed by the company Depuy.

**Surgeons/ Hospitals 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 [fielddaction.emea@zimmerbiomet.com](mailto:fielddaction.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 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 contact your Zimmer Biomet representative.

### **Other Information**

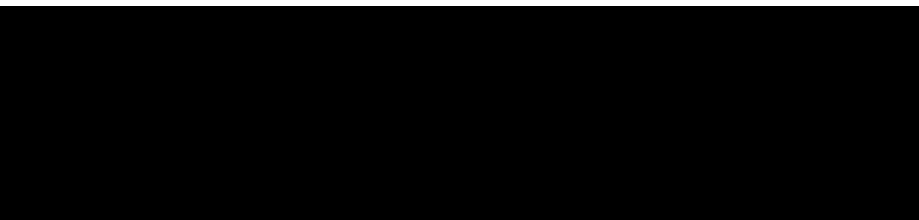
This voluntary medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing [product.experience@zimmerbiomet.com](mailto:product.experience@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 co-operation in advance.

Sincerely,





**ATTACHMENT 1**  
**Certificate of Acknowledgement**

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

**Affected Product: ACE Trochanteric Nail (ATN) System**

**Field Action Reference: ZFA 2017-00006**

**Please check one as applicable:**

Hospital Facility

**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 field safety 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 2

### Affected Product List

Item Number	Lot Number	Item Description
903011225	All	ACE TROCH NAIL 125 DEG. X 11MM
903011230	All	ACE TROCH NAIL 130 DEG. X 11MM
903011235	All	ACE TROCH NAIL 135 DEG. X 11MM
903013225	All	ACE TROCH NAIL 125 DEG. X 13MM
903013230	All	ACE TROCH NAIL 130 DEG. X 13MM
903013235	All	ACE TROCH NAIL 135 DEG. X 13MM
903208000	All	STER TROC END CAP
903208005	All	STER TROC END CAP 5 MM
903208010	All	STER TROC END CAP 10MM
903208015	All	STER TROC END CAP 15 MM
903208020	All	STER TROC END CAP 20 MM
903208025	All	STER TROC END CAP 25 MM
903209125	All	STER TROC NAIL 125 DEG X 9MM
903209130	All	STER TROC NAIL 130 DEG X 9MM
903209135	All	STER TROC NAIL 135 DEG X 9MM
903211070	All	STER TROC LAG SCR 70 MM
903211125	All	TROCH NAIL ST 11X180 125DG STRL
903211130	All	TROCH NAIL ST 11X180 130DG STRL
903211135	All	TROCH NAIL ST 11X180 135DG STRL
903211140	All	STER TROC NAIL 180X11X140
903211225	All	STER TROC NAIL 125 DEG X 11MM
903211230	All	STER TROC NAIL 130 DEG X 11MM
903211235	All	STER TROC NAIL 135 DEG X 11MM
903213125	All	TROCH NAIL ST 13X180 125DG STRL
903213130	All	TROCH NAIL ST 13X180 130DG STRL
903213135	All	TROCH NAIL ST 13X180 135DG STRL
903213140	All	STER TROC NAIL 180X13X140
903213225	All	STER TROC NAIL 125 DEG X 13MM
903213230	All	STER TROC NAIL 130 DEG X 13MM
903213235	All	STER TROC NAIL 135 DEG X 13MM
903305060	All	ATN AR SCREW 60MM STERILE
903305065	All	ATN AR SCREW 65MM STERILE
903311060	All	ATN LAG SCREW 60MM STERILE
903311065	All	ATN LAG SCREW 65MM STERILE
903311070	All	ATN LAG SCREW 70MM STERILE
903311075	All	ATN LAG SCREW 75MM STERILE



Item Number	Lot Number	Item Description
903311080	All	ATN LAG SCREW 80MM STERILE
903311085	All	ATN LAG SCREW 85MM STERILE
903311090	All	ATN LAG SCREW 90MM STERILE
903311095	All	ATN LAG SCREW 95MM STERILE
903311100	All	ATN LAG SCREW 100MM STERILE
903311105	All	ATN LAG SCREW 105MM STERILE
903311110	All	ATN LAG SCREW 110MM STERILE
903311115	All	ATN LAG SCREW 115MM STERILE
903311120	All	ATN LAG SCREW 120MM STERILE
903311125	All	ATN LAG SCREW 125MM STERILE
903311130	All	ATN LAG SCREW 130MM STERILE
915209320	All	STER L H TROC NAIL 320X9X125
915209340	All	STER L H TROC NAIL 340X9X125
915209360	All	STER L H TROC NAIL 360X9X125
915209380	All	STER L H TROC NAIL 380X9X125
915209400	All	STER L H TROC NAIL 400X9X125
915209420	All	STER L H TROC NAIL 420X9X125
915209440	All	STER L H TROC NAIL 440X9X125
915209460	All	STER L H TROC NAIL 460X9X125
915211320	All	STER L H TROC NAIL 320X11X125
915211340	All	STER L H TROC NAIL 340X11X125
915211360	All	STER L H TROC NAIL 360X11X125
915211380	All	STER L H TROC NAIL 380X11X125
915211400	All	STER L H TROC NAIL 400X11X125
915211420	All	STER L H TROC NAIL 420X11X125
915211440	All	STER L H TROC NAIL 440X11X125
915211460	All	STER L H TROC NAIL 460X11X125
915213320	All	STER L H TROC NAIL 320X13X125
915213340	All	STER L H TROC NAIL 340X13X125
915213360	All	STER L H TROC NAIL 360X13X125
915213380	All	STER L H TROC NAIL 380X13X125
915213400	All	STER L H TROC NAIL 400X13X125
915213420	All	STER L H TROC NAIL 420X13X125
915213440	All	STER L H TROC NAIL 440X13X125
915213460	All	STER L H TROC NAIL 460X13X125
916209320	All	STER R H TROC NAIL 320X9X125
916209340	All	STER R H TROC NAIL 340X9X125
916209360	All	STER R H TROC NAIL 360X9X125
916209380	All	STER R H TROC NAIL 380X9X125

Item Number	Lot Number	Item Description
916209400	All	STER R H TROC NAIL 400X9X125
916209420	All	STER R H TROC NAIL 420X9X125
916209440	All	STER R H TROC NAIL 440X9X125
916209460	All	STER R H TROC NAIL 460X9X125
916211320	All	STER R H TROC NAIL 320X11X125
916211340	All	STER R H TROC NAIL 340X11X125
916211360	All	STER R H TROC NAIL 360X11X125
916211380	All	STER R H TROC NAIL 380X11X125
916211400	All	STER R H TROC NAIL 400X11X125
916211420	All	STER R H TROC NAIL 420X11X125
916211440	All	STER R H TROC NAIL 440X11X125
916211460	All	STER R H TROC NAIL 460X11X125
916213320	All	STER R H TROC NAIL 320X13X125
916213340	All	STER R H TROC NAIL 340X13X125
916213360	All	STER R H TROC NAIL 360X13X125
916213380	All	STER R H TROC NAIL 380X13X125
916213400	All	STER R H TROC NAIL 400X13X125
916213420	All	STER R H TROC NAIL 420X13X125
916213440	All	STER R H TROC NAIL 440X13X125
916213460	All	STER R H TROC NAIL 460X13X125
925200320	All	STER L H TROC NAIL 320X11X130
925209320	All	STER L H TROC NAIL 320X9X130
925209340	All	STER L H TROC NAIL 340X9X130
925209360	All	STER L H TROC NAIL 360X9X130
925209380	All	STER L H TROC NAIL 380X9X130
925209400	All	STER L H TROC NAIL 400X9X130
925209420	All	STER L H TROC NAIL 420X9X130
925209440	All	STER L H TROC NAIL 440X9X130
925209460	All	STER L H TROC NAIL 460X9X130
925211340	All	STER L H TROC NAIL 340X11X130
925211360	All	STER L H TROC NAIL 360X11X130
925211380	All	STER L H TROC NAIL 380X11X130
925211400	All	STER L H TROC NAIL 400X11X130
925211420	All	STER L H TROC NAIL 420X11X130
925211440	All	STER L H TROC NAIL 440X11X130
925211460	All	STER L H TROC NAIL 460X11X130
925213320	All	STER L H TROC NAIL 320X13X130
925213340	All	STER L H TROC NAIL 340X13X130
925213360	All	STER L H TROC NAIL 360X13X130

Item Number	Lot Number	Item Description
925213380	All	STER L H TROC NAIL 380X13X130
925213400	All	STER L H TROC NAIL 400X13X130
925213420	All	STER L H TROC NAIL 420X13X130
925213440	All	STER L H TROC NAIL 440X13X130
925213460	All	STER L H TROC NAIL 460X13X130
926209320	All	STER R H TROC NAIL 320X9X130
926209340	All	STER R H TROC NAIL 340X9X130
926209360	All	STER R H TROC NAIL 360X9X130
926209380	All	STER R H TROC NAIL 380X9X130
926209400	All	STER R H TROC NAIL 400X9X130
926209420	All	STER R H TROC NAIL 420X9X130
926209440	All	STER R H TROC NAIL 440X9X130
926209460	All	STER R H TROC NAIL 460X9X130
926211320	All	STER R H TROC NAIL 320X11X130
926211340	All	STER R H TROC NAIL 340X11X130
926211360	All	STER R H TROC NAIL 360X11X130
926211380	All	STER R H TROC NAIL 380X11X130
926211400	All	STER R H TROC NAIL 400X11X130
926211420	All	STER R H TROC NAIL 420X11X130
926211440	All	STER R H TROC NAIL 440X11X130
926213320	All	STER R H TROC NAIL 320X13X130
926213340	All	STER R H TROC NAIL 340X13X130
926213360	All	STER R H TROC NAIL 360X13X130
926213380	All	STER R H TROC NAIL 380X13X130
926213400	All	STER R H TROC NAIL 400X13X130
926213420	All	STER R H TROC NAIL 420X13X130
926213440	All	STER R H TROC NAIL 440X13X130
926213460	All	STER R H TROC NAIL 460X13X130
935209320	All	STER L H TROC NAIL 320X9X135
935209340	All	STER L H TROC NAIL 340X9X135
935209360	All	STER L H TROC NAIL 360X9X135
935209380	All	STER L H TROC NAIL 380X9X135
935209400	All	STER L H TROC NAIL 400X9X135
935209420	All	STER L H TROC NAIL 420X9X135
935209440	All	STER L H TROC NAIL 440X9X135
935209460	All	STER L H TROC NAIL 460X9X135
935211320	All	STER L H TROC NAIL 320X11X135
935211340	All	STER L H TROC NAIL 340X11X135
935211360	All	STER L H TROC NAIL 360X11X135



Item Number	Lot Number	Item Description
935211380	All	STER L H TROC NAIL 380X11X135
935211400	All	STER L H TROC NAIL 400X11X135
935211420	All	STER L H TROC NAIL 420X11X135
935211440	All	STER L H TROC NAIL 440X11X135
935211460	All	STER L H TROC NAIL 460X11X135
935213320	All	STER L H TROC NAIL 320X13X135
935213340	All	STER L H TROC NAIL 340X13X135
935213360	All	STER L H TROC NAIL 360X13X135
935213380	All	STER L H TROC NAIL 380X13X135
935213400	All	STER L H TROC NAIL 400X13X135
935213420	All	STER L H TROC NAIL 420X13X135
935213440	All	STER L H TROC NAIL 440X13X135
935213460	All	STER L H TROC NAIL 460X13X135
936213320	All	STER R H TROC NAIL 320X13X135
936213340	All	STER R H TROC NAIL 340X13X135
936213360	All	STER R H TROC NAIL 360X13X135
936213380	All	STER R H TROC NAIL 380X13X135
936213400	All	STER R H TROC NAIL 400X13X135
936213420	All	STER R H TROC NAIL 420X13X135
936213440	All	STER R H TROC NAIL 440X13X135
936213460	All	STER R H TROC NAIL 460X13X135
936309320	All	STER R H TROC NAIL 320X9X135
936309340	All	STER R H TROC NAIL 340X9X135
936309360	All	STER R H TROC NAIL 360X9X135
936309380	All	STER R H TROC NAIL 380X9X135
936309400	All	STER R H TROC NAIL 400X9X135
936309420	All	STER R H TROC NAIL 420X9X135
936309440	All	STER R H TROC NAIL 440X9X135
936309460	All	STER R H TROC NAIL 460X9X135
936311320	All	STER R H TROC NAIL 320X11X135
936311340	All	STER R H TROC NAIL 340X11X135
936311360	All	STER R H TROC NAIL 360X11X135
936311380	All	STER R H TROC NAIL 380X11X135
936311400	All	STER R H TROC NAIL 400X11X135
936311420	All	STER R H TROC NAIL 420X11X135
936311440	All	STER R H TROC NAIL 440X11X135
936311460	All	STER R H TROC NAIL 460X11X135