

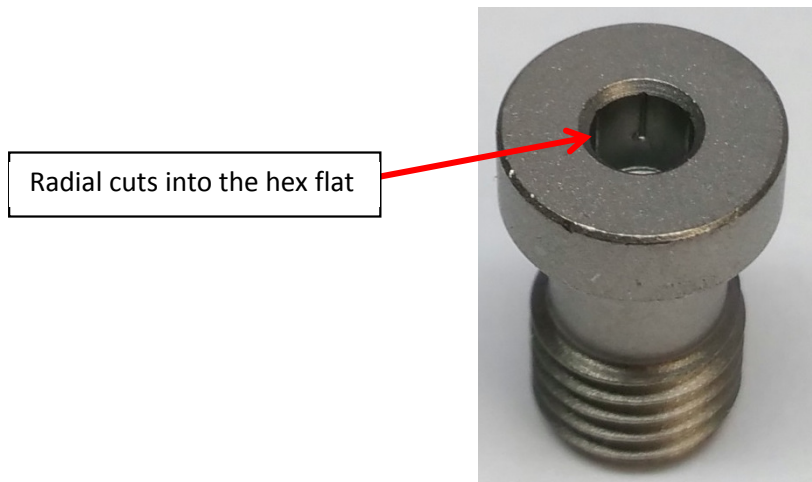
August 8, 2016

To: Risk Managers

Subject: **URGENT MEDICAL DEVICE RECALL REMOVAL**

Affected Product: Vanguard 360 Revision Knee System - Tibial Augment Bolts

Refer to **Attachment 2 – Affected Product List** for the affected item/lot combinations.



Zimmer Biomet is conducting a medical device recall for the Tibial Augment Bolts included in the Vanguard 360 Revision Knee System. The drill bit used to drill the hex pre-drilled hole in the screw head was larger than allowable per the process specification. As a result, the hex geometry can still be visible, but there are radial cuts into the hex flat which may prevent the bolt from being fully tightened into the augment.

The bolt stripping or the bolt not being fully tightened will be noticed by the surgeon intraoperatively when they are unable to screw the augment bolts into the augment. This possible event can result in an intraoperative delay resulting in increased time under anesthesia.

Our records indicate you may have received one or more of the affected products. The affected units were distributed between the dates of March 2016 and June 2016.

Risk Manager Responsibilities:

1. Review this notification and ensure affected personnel are aware of the contents.
2. Assist your Zimmer Biomet sales representative quarantine all affected product.
3. Your Zimmer Biomet sales representative will remove the affected product from your facility.
4. Complete Attachment 1 – Certificate of Acknowledgement.
 - a. Return a digital copy within three (3) days via email to CPWARFieldAction@zimmerbiomet.com or via fax to 574-372-1683.



- b. Retain a copy of the Acknowledgement Form with your recall records in the event of a compliance audit of your facilities documentation.
5. If after reviewing this notice you have further questions or concerns please call 1-800-348-9500 ext. 1251 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of business hours will receive a prompt to record a voicemail and will be returned upon receipt. Alternatively, your questions may be sent by email to CPWARFieldAction@zimmerbiomet.com.

Other Information

This voluntary 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.

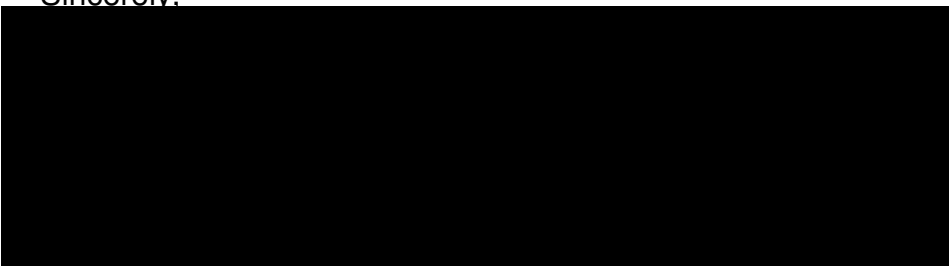
- MedWatch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by mail, or by fax.
- Online: www.fda.gov/medwatch/report.htm
- Mail: Use postage paid, pre-addressed form FDA 3500, 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 product.experience@zimmerbiomet.com.

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 recall.

Sincerely,





ATTACHMENT 1 Certificate of Acknowledgement

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: _____ State: _____ ZIP: _____

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 send a copy via email to CPWARFieldAction@zimmerbiomet.com or via fax to 574-372-1683, in addition to including a copy with your product returns.



ATTACHMENT 2 Affected Product List

| ITEM | LOT | DESCRIPTION | UDI Number |
|--------|--------|-------------------------|--|
| 185220 | 262690 | BMT 360 TIB AUG 59X5MM | (01) 0 0880304 48156 5 (17) 260323 (10) 262690 |
| 185221 | 475560 | BMT 360 TIB AUG 63X5MM | (01) 0 0880304 48157 2 (17) 260401 (10) 475560 |
| 185222 | 262720 | BMT 360 TIB AUG 67X5MM | (01) 0 0880304 48158 9 (17) 260324 (10) 262720 |
| 185222 | 475570 | BMT 360 TIB AUG 67X5MM | (01) 0 0880304 48158 9 (17) 260330 (10) 475570 |
| 185222 | 524160 | BMT 360 TIB AUG 67X5MM | (01) 0 0880304 48158 9 (17) 260401 (10) 524160 |
| 185222 | 690770 | BMT 360 TIB AUG 67X5MM | (01) 0 0880304 48158 9 (17) 260406 (10) 690770 |
| 185223 | 421690 | BMT 360 TIB AUG 71X5MM | (01) 0 0880304 48159 6 (17) 260317 (10) 421690 |
| 185223 | 475580 | BMT 360 TIB AUG 71X5MM | (01) 0 0880304 48159 6 (17) 260401 (10) 475580 |
| 185223 | 475590 | BMT 360 TIB AUG 71X5MM | (01) 0 0880304 48159 6 (17) 260405 (10) 475590 |
| 185223 | 524170 | BMT 360 TIB AUG 71X5MM | (01) 0 0880304 48159 6 (17) 260330 (10) 524170 |
| 185224 | 475600 | BMT 360 TIB AUG 75X5MM | (01) 0 0880304 48160 2 (17) 260331 (10) 475600 |
| 185224 | 475610 | BMT 360 TIB AUG 75X5MM | (01) 0 0880304 48160 2 (17) 260404 (10) 475610 |
| 185224 | 524180 | BMT 360 TIB AUG 75X5MM | (01) 0 0880304 48160 2 (17) 260324 (10) 524180 |
| 185224 | 647840 | BMT 360 TIB AUG 75X5MM | (01) 0 0880304 48160 2 (17) 260405 (10) 647840 |
| 185224 | 690790 | BMT 360 TIB AUG 75X5MM | (01) 0 0880304 48160 2 (17) 260416 (10) 690790 |
| 185225 | 342740 | BMT 360 TIB AUG 79X5MM | (01) 0 0880304 48161 9 (17) 260317 (10) 342740 |
| 185225 | 421700 | BMT 360 TIB AUG 79X5MM | (01) 0 0880304 48161 9 (17) 260323 (10) 421700 |
| 185225 | 524190 | BMT 360 TIB AUG 79X5MM | (01) 0 0880304 48161 9 (17) 260401 (10) 524190 |
| 185225 | 524200 | BMT 360 TIB AUG 79X5MM | (01) 0 0880304 48161 9 (17) 260404 (10) 524200 |
| 185225 | 690800 | BMT 360 TIB AUG 79X5MM | (01) 0 0880304 48161 9 (17) 260416 (10) 690800 |
| 185226 | 647850 | BMT 360 TIB AUG 83X5MM | (01) 0 0880304 48162 6 (17) 260405 (10) 647850 |
| 185226 | 751570 | BMT 360 TIB AUG 83X5MM | (01) 0 0880304 48162 6 (17) 260416 (10) 751570 |
| 185228 | 647910 | BMT 360 TIB AUG 91X5MM | (01) 0 0880304 48164 0 (17) 260404 (10) 647910 |
| 185228 | 751420 | BMT 360 TIB AUG 91X5MM | (01) 0 0880304 48164 0 (17) 260414 (10) 751420 |
| 185230 | 524210 | BMT 360 TIB AUG 59X10MM | (01) 0 0880304 48165 7 (17) 260407 (10) 524210 |
| 185231 | 421730 | BMT 360 TIB AUG 63X10MM | (01) 0 0880304 48166 4 (17) 260317 (10) 421730 |
| 185231 | 475620 | BMT 360 TIB AUG 63X10MM | (01) 0 0880304 48166 4 (17) 260404 (10) 475620 |
| 185231 | 524220 | BMT 360 TIB AUG 63X10MM | (01) 0 0880304 48166 4 (17) 260324 (10) 524220 |
| 185232 | 377450 | BMT 360 TIB AUG 67X10MM | (01) 0 0880304 48167 1 (17) 260321 (10) 377450 |
| 185232 | 377460 | BMT 360 TIB AUG 67X10MM | (01) 0 0880304 48167 1 (17) 260315 (10) 377460 |
| 185232 | 421750 | BMT 360 TIB AUG 67X10MM | (01) 0 0880304 48167 1 (17) 260321 (10) 421750 |
| 185232 | 475630 | BMT 360 TIB AUG 67X10MM | (01) 0 0880304 48167 1 (17) 260404 (10) 475630 |
| 185232 | 524230 | BMT 360 TIB AUG 67X10MM | (01) 0 0880304 48167 1 (17) 260404 (10) 524230 |
| 185233 | 342750 | BMT 360 TIB AUG 71X10MM | (01) 0 0880304 48168 8 (17) 260314 (10) 342750 |
| 185233 | 377470 | BMT 360 TIB AUG 71X10MM | (01) 0 0880304 48168 8 (17) 260319 (10) 377470 |
| 185233 | 475640 | BMT 360 TIB AUG 71X10MM | (01) 0 0880304 48168 8 (17) 260319 (10) 475640 |
| 185233 | 524240 | BMT 360 TIB AUG 71X10MM | (01) 0 0880304 48168 8 (17) 260404 (10) 524240 |

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|-----------|--------|-------------------------------|--|
| 185234 | 262780 | BMT 360 TIB AUG 75X10MM | (01) 0 0880304 48169 5 (17) 260305 (10) 262780 |
| 185234 | 262790 | BMT 360 TIB AUG 75X10MM | (01) 0 0880304 48169 5 (17) 260307 (10) 262790 |
| 185234 | 524250 | BMT 360 TIB AUG 75X10MM | (01) 0 0880304 48169 5 (17) 260331 (10) 524250 |
| 185235 | 421770 | BMT 360 TIB AUG 79X10MM | (01) 0 0880304 48170 1 (17) 260323 (10) 421770 |
| 185235 | 421780 | BMT 360 TIB AUG 79X10MM | (01) 0 0880304 48170 1 (17) 260404 (10) 421780 |
| 185237 | 229750 | BMT 360 TIB AUG 87X10MM | (01) 0 0880304 48172 5 (17) 260310 (10) 299750 |
| 185238 | 229760 | BMT 360 TIB AUG 91X10MM | (01) 0 0880304 48173 2 (17) 260309 (10) 299760 |
| 185238 | 262820 | BMT 360 TIB AUG 91X10MM | (01) 0 0880304 48173 2 (17) 260310 (10) 262820 |
| 185239 | 511390 | BMT 360 TIB AUG BOLT 10MM | (01) 0 0880304 48175 6 (17) 260317 (10) 511390 |
| 185241 | 148190 | BMT 360 TIB AUG 63X15MM RL/LM | (01) 0 0880304 48177 0 (17) 260310 (10) 148190 |
| 185242 | 969710 | BMT 360 TIB AUG 67X15MM RL/LM | (01) 0 0880304 48178 7 (17) 260311 (10) 969710 |
| 185243 | 377480 | BMT 360 TIB AUG 71X15MM RL/LM | (01) 0 0880304 48179 4 (17) 260325 (10) 377480 |
| 185247 | 262750 | BMT 360 TIB AUG 87X15 RL/LM | (01) 0 0880304 48183 1 (17) 260314 (10) 262750 |
| 185250 | 421790 | BMT 360 TIB AUG 59X15MM LL/RM | (01) 0 0880304 48185 5 (17) 260404 (10) 421790 |
| 185251 | 262770 | BMT 360 TIB AUG 63X15MM LL/RM | (01) 0 0880304 48186 2 (17) 260313 (10) 262770 |
| 185253 | 421800 | BMT 360 TIB AUG 71X15MM LL/RM | (01) 0 0880304 48188 6 (17) 260404 (10) 421800 |
| 185254 | 229770 | BMT 360 TIB AUG 75X15MM LL/RM | (01) 0 0880304 48189 3 (17) 260304 (10) 299770 |
| 185255 | 229780 | BMT 360 TIB AUG 79X15MM LL/RM | (01) 0 0880304 48190 9 (17) 260310 (10) 229780 |
| 185256 | 988680 | BMT 360 TIB AUG 83X15MM LL/RM | (01) 0 0880304 48191 6 (17) 260309 (10) 988680 |
| 185257 | 148210 | BMT 360 TIB AUG 87X15 LL/RM | (01) 0 0880304 48192 3 (17) 260304 (10) 148210 |
| 185229-00 | 493640 | BMT TIB AUG BOLT 5MM | (01) 0 0880304 48174 9 (17) 260406 (10) 493640 |
| 185229-00 | 582090 | BMT TIB AUG BOLT 5MM | (01) 0 0880304 48174 9 (17) 260330 (10) 582090 |
| 185229-00 | 582100 | BMT TIB AUG BOLT 5MM | (01) 0 0880304 48174 9 (17) 260406 (10) 582100 |
| 185229-00 | 582110 | BMT TIB AUG BOLT 5MM | (01) 0 0880304 48174 9 (17) 260331 (10) 582110 |
| 185229-00 | 590570 | BMT TIB AUG BOLT 5MM | (01) 0 0880304 48174 9 (17) 260328 (10) 590570 |
| 185229-00 | 789260 | BMT TIB AUG BOLT 5MM | (01) 0 0880304 48174 9 (17) 260413 (10) 789260 |
| 185239-00 | 493690 | BMT 360 TIB AUG BOLT 10MM | (01) 0 0880304 48175 6 (17) 260331 (10) 493690 |
| 185239-00 | 590580 | BMT 360 TIB AUG BOLT 10MM | (01) 0 0880304 48175 6 (17) 260401 (10) 590580 |
| 185239-00 | 590590 | BMT 360 TIB AUG BOLT 10MM | (01) 0 0880304 48175 6 (17) 260404 (10) 590590 |
| 185239-00 | 590600 | BMT 360 TIB AUG BOLT 10MM | (01) 0 0880304 48175 6 (17) 260401 (10) 590600 |
| 185239-00 | 590610 | BMT 360 TIB AUG BOLT 10MM | (01) 0 0880304 48175 6 (17) 260404 (10) 590610 |
| 185239-00 | 590620 | BMT 360 TIB AUG BOLT 10MM | (01) 0 0880304 48175 6 (17) 260401 (10) 590620 |
| 185239-00 | 590630 | BMT 360 TIB AUG BOLT 10MM | (01) 0 0880304 48175 6 (17) 260405 (10) 590630 |
| 185239-00 | 666760 | BMT 360 TIB AUG BOLT 10MM | (01) 0 0880304 48175 6 (17) 260405 (10) 666760 |
| 185239-00 | 666780 | BMT 360 TIB AUG BOLT 10MM | (01) 0 0880304 48175 6 (17) 260406 (10) 666780 |