ZIMMER BIOMET

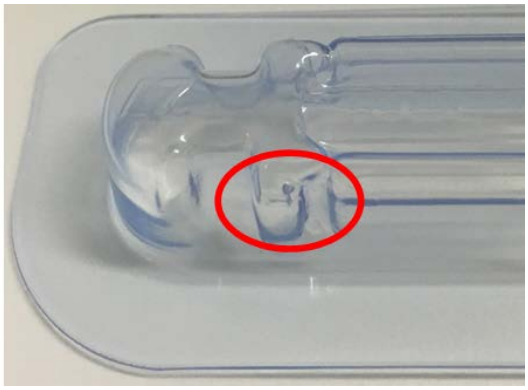
April 18, 2016

To: **Risk Managers and Surgeons**

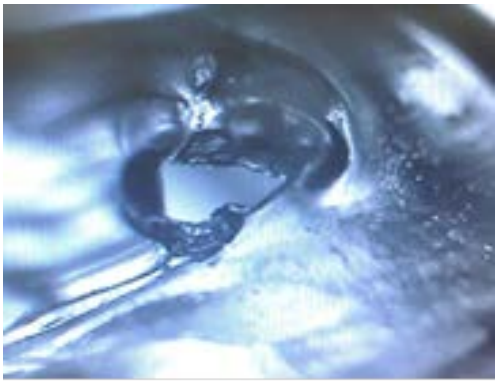
Subject: **URGENT MEDICAL DEVICE RECALL – LOT SPECIFIC**

Affected Product: **Various Sterile-Packaged Hip and Trauma Implant Screws (See Addendum A)**

Zimmer Inc. is initiating a recall of unconsumed devices from specific lots of sterile Hip and Trauma Implant Screws manufactured between February 2016 and March 2016. These screws are packaged with a double barrier system, two plastic trays and two Tyvek lids, to provide sterile integrity. Process monitoring conducted as part of the standard packaging process identified that in some instances, a small hole may be present in the inner tray. The photos below are examples of the holes observed during process monitoring, which were found to be caused by a single tool used by the tray supplier in the manufacturing process and estimated to be present in less than 10% of the affected devices. The outer tray is not affected and the device's sterile integrity remains until the outer tray is opened. No product complaints have been reported for this issue. Approximately 6,600 affected devices were distributed globally between March 2016 and April 2016.



Inner Tray Hole



Inner Tray Hole 6X magnification

Risks		
Immediate health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	The inner tray has a compromised sterility, but the product maintains sterility due to the outer tray. Product is implanted, but sterility of the product is maintained while handling the product during introduction to the sterile field. No Injury.	Product is utilized and sterility of the product was compromised during handling of the product prior to introduction to the sterile field. Lack of sterility leads to pain/infection and possible revision surgery.
Long range health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	The inner tray has a compromised sterility, but the product maintains sterility due to the outer tray. Product is implanted, but sterility of the product is maintained while handling the product during introduction to the sterile field. Injury is highly unlikely.	Product is utilized and sterility of the product was compromised during handling of the product prior to introduction to the sterile field. Lack of sterility leads to pain/infection and possible revision surgery.

Your Responsibilities

1. Review the notification and ensure affected personnel are aware of the contents.
2. Assist your Zimmer Biomet sales representative with the quarantine of any affected product from Addendum A.
3. Your Zimmer Biomet sales representative will remove the recalled product from your facility.
4. Complete the Certificate of Acknowledgement Form (Attachment 1) and return to corporatequality.postmarket@zimmerbiomet.com.
5. **If after reviewing this notification you have further questions or concerns please call the customer call center at 1-800-348-2759 between 8:00 am and 8:00 pm EST.**

Other Information

This voluntary recall was reported to the U.S. Food and Drug Administration.

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 regular mail or by fax.

- Online:www.fda.gov/medwatch/report.htm
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

Under 21 CFR Part 803, manufacturers are also required to report any serious injuries where a device has contributed to or may have contributed to the event. Please keep Zimmer Biomet informed of any adverse events associated with this device or any other Zimmer Biomet product. Adverse events may be reported to Zimmer Biomet at zimmer.per@zimmerbiomet.com.

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ATTACHMENT 1

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

Certificate of Acknowledgement:

Affected Product: Various Sterile-Packaged Hip and Trauma Implant Screws

By signing below, I acknowledge that the required actions have been taken in accordance with the Recall Notice.

Printed Name: _____ Signature: _____

Title _____ Telephone: ( ) _____-_____ Date: ____/____/____

Facility Name: _____

Facility Address: _____

City: _____ State: _____ ZIP: _____

Note: This form and affected product must be returned to Zimmer Biomet before this action can be considered closed for your account. It is your responsibility to complete this form and email a copy to: CorporateQuality.PostMarket@ZimmerBiomet.com, in addition to including a copy with your product returns. Clearly mark the outside carton of each product return shipment made as "Recall." Please keep a copy of your completed form for your records.

Please do not return recalled product with other returns.

ZFA 2016-104

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ADDENDUM A

Part Number	Description	Lot Number
00114205012	MINI MAGNA-FX CANN SCREW	63295341
00114205020	MINI MAGNA-FX CANN SCREW	63290148
00114205036	MINI MAGNA-FX CANN SCREW	63295349
00114205124	MINI MAGNA-FX CANN SCREW	63290143
00114205128	MINI MAGNA-FX CANN SCREW	63295363
00114205130	MINI MAGNA-FX CANN SCREW	63290146
00114205138	MINI MAGNA-FX CANN SCREW	63296605
00114205148	MINI MAGNA-FX CANN SCREW	63295371
00114205165	MINI MAGNA-FX CANN SCREW	63295372
00114605599	MAGNA-FX CANN SCREW 7.0MM	63308565
00114606099	MAGNA-FX CANN SCREW 7.0MM	63308562
00114606532	MAGNA-FX CANN SCREW 7.0MM	63303825
00114606599	MAGNA-FX CANN SCREW 7.0MM	63259852
00225304542	INTERLOCKING IM SCREW MED	63295051
00225305745	INTERLOCKING IM SCREW 4.5	63275969
00225307042	INTERLOCKING IM SCREW MED	63293672
00625004525	BONE SCREW 4.5X25 SELF-TA	63284572
00625004525	BONE SCREW 4.5X25 SELF-TA	63284570
00625004550	BONE SCREW 4.5X50 SELF-TA	63284573
00625006515	BONE SCREW 6.5X15 SELF-TA	63187350
00625006520	BONE SCREW 6.5X20 SELF-TA	63272712
00625006520	BONE SCREW 6.5X20 SELF-TA	63296123
00625006520	BONE SCREW 6.5X20 SELF-TA	63301504
00625006520	BONE SCREW 6.5X20 SELF-TA	63225662
00625006525	BONE SCREW 6.5X25 SELF-TA	63259476
00625006525	BONE SCREW 6.5X25 SELF-TA	63209528
00625006525	BONE SCREW 6.5X25 SELF-TA	63204283
00625006530	BONE SCREW 6.5X30 SELF-TA	63257719
00662406515	HGP II ACETABULAR CUP BON	63276979
00662406520	HGP II ACETABULAR CUP BON	63276976
00662406525	HGP II ACETABULAR CUP BON	63276975
00662406525	HGP II ACETABULAR CUP BON	63245682
00662406535	HGP II ACETABULAR CUP BON	63276977
00662406550	HGP II ACETABULAR CUP BON	63301523
00662406560	HGP II ACETABULAR CUP BON	63303436
00662406560	HGP II ACETABULAR CUP BON	63276980
47115504507	HERBERT CANNULATED BONE S	63303808
47115507507	HERBERT CANNULATED BONE S	63292589
47115509007	HERBERT CANNULATED BONE S	63292588
47116202400	COMPRESSION SCREW 1-3/4IN	63290189
47234702116	PERI. SCR 4.0MM X16MM	63146423
47482701401	2.7MM CORT. SCREW 14MM, S	63292596
47483501001	3.5MM CORT. SCREW 10MM LN	63252354
47483501401	3.5MM CORT. SCREW 14MM LN	63283819
47483501601	3.5MM CORT. SCREW 16MM LN	63308551
47483502401	3.5MM CORT. SCREW 24MM LN	63252355
47483502401	3.5MM CORT. SCREW 24MM LN	63312340
47483503001	3.5MM CORT. SCREW 30MM LN	63252350
47483504001	3.5MM CORT. SCREW 40MM LN	63283820
47483507501	3.5MM CORT. SCREW 75MM LN	63243831

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ADDENDUM A Continued

Part Number	Description	Lot Number
47484001200	4.0 X 12 CANCELL. SCREW	63303573
47484001400	4.0 X 14 CANCELL. SCREW	63282072
47484001600	4.0 X 16 CANCELL. SCREW	63303577
47484001800	4.0 X 18 CANCELL. SCREW	63303574
47484002000	4.0 X 20 CANCELL. SCREW	63296633
47484002200	4.0 X 22 CANCELL. SCREW	63295456
47484002600	4.0 X 26 CANCELL. SCREW	63296634
47484003001	4.0 X 30 PART THD CANC SC	63198636
47484003200	4.0 X 32 CANCELL. SCREW	63295464
47484003600	4.0 X 36 CANCELL. SCREW	63296636
47484004000	4.0 X 40 CANCELL. SCREW	63296638
47484004500	4.0 X 45 CANCELL. SCREW	63301486
47484005000	4.0 X 50 CANCELL. SCREW	63301487
47484005500	4.0 X 55 CANCELL. SCREW	63301489
47484006000	4.0 X 60 CANCELL. SCREW	63296639
47484501601	4.5 X 16 CORT SCREW SELF	63248519
47484501801	4.5 X 18 CORT SCREW SELF	63298802
47484502001	4.5 X 20 CORT SCREW SELF	63298803
47484502201	4.5 X 22 CORT SCREW SELF	63287869
47484502401	4.5 X 24 CORT SCREW SELF	63248522
47484502401	4.5 X 24 CORT SCREW SELF	63317364
47484502601	4.5 X 26 CORT SCREW SELF	63317363
47484502801	4.5 X 28 CORT SCREW SELF	63248525
47484503401	4.5 X 34 CORT SCREW SELF	63298795
47484503801	4.5 X 38 CORT SCREW SELF	63320881
47484504001	4.5 X 40 CORT SCREW SELF	63287871
47484504201	4.5 X 42 CORT SCREW SELF	63317168
47484505401	4.5 X 54 CORT SCREW SELF	63248527
47484505401	4.5 X 54 CORT SCREW SELF	63317167
47484505801	4.5 X 58 CORT SCREW SELF	63287874
47484506401	4.5 X 64 CORT SCREW SELF	63248531
47484506601	4.5 X 66 CORT SCREW SELF	63248532
47484506801	4.5 X 68 CORT SCREW SELF	63248535
47484507001	4.5 X 70 CORT SCREW SELF	63248537
47486504500	6.5 X 45 CANC SCREW, FULL	63293690
47486505500	6.5 X 55 CANC SCREW, FULL	63293693
47486506000	6.5 X 60 CANC SCREW, FULL	63293694
47486506002	6.5 X 60 CANC SCREW, 32MM	63305250
47486506500	6.5 X 65 CANC SCREW, FULL	63298784
47486506502	6.5 X 65 CANC SCREW, 32MM	63284871
47486507000	6.5 X 70 CANC SCREW, FULL	63298783
47486508001	6.5 X 80 CANC SCREW, 16MM	63249226
47486508002	6.5 X 80 CANC SCREW, 32MM	63305251
47486508502	6.5 X 85 CANC SCREW, 32MM	63312141
47493501801	3.5 X 18 CORT SCREW SELFT	63297474