

April 28, 2017

To: Distributors, Sales Representatives, and Distributor Operation Managers

Subject: **URGENT MEDICAL DEVICE RECALL (REMOVAL) - LOT SPECIFIC**

Affected Product: Trauma Implants, Reference Attachment 2

Zimmer is initiating a field action for sterile-packaged implants packaged in a single package configuration due to packaging design verification test failures. Specifically, multiple test samples from the configuration failed simulated distribution and shipping testing. The devices impacted are generally the heaviest outlier sizes within the respective product family. Below are photos representative of failures seen during this testing.

Our records indicate that you may have received one or more of the affected products.

It is very likely that any damage to the carton box and/or to the outer tray would be detected prior to surgery. The package insert (instructions for use) provided with the device or device system contains a section on sterility. It instructs the user to inspect the package and not use the device if any seal or cavity is damaged.

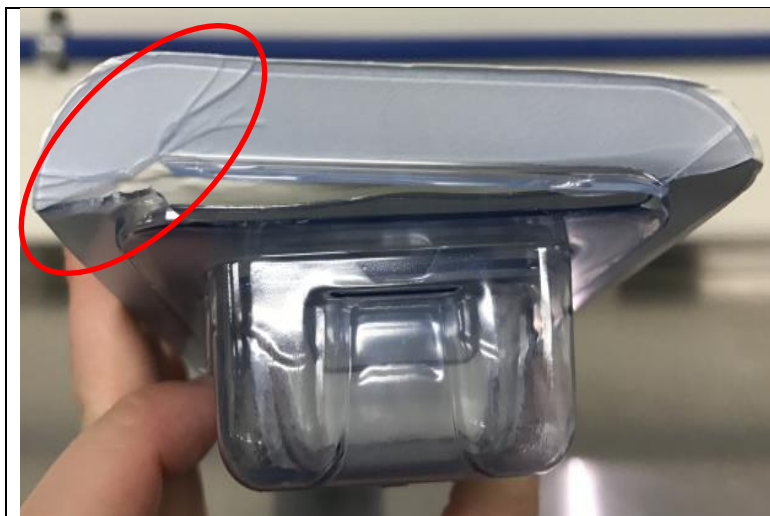


Fig 1. Outer Tray Flange Broken



Fig 2. Inner Tray cracks near the plug

Risks

Immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Extension of surgery 10-30 min	Infection
Long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None	Revision surgery due to Infection

- If compromised packaging is detected during surgery, it may result in a slight delay in surgery to obtain another implant.
- In the unlikely event that compromised packaging is not detected prior to or during surgery by the user, there is a risk of infection, which could result in revision surgery.

Your Responsibilities:

1. Review this notification and ensure affected personnel are aware of the contents.
2. Immediately locate and quarantine affected product in your inventory.
3. Complete the Certification of Acknowledgement portion of **Attachment 1 – Inventory Return Certification Form**
 - a. Return a digital copy to corporatequality.postmarket@zimmerbiomet.com within three (3) days.
4. Note that any hospitals and/or surgeons that received direct shipments of this product from Zimmer Biomet will be sent a copy of the Risk Manager and Surgeon Recall Notice directly. Additionally, Zimmer Biomet will also notify surgeon’s that have implanted the affected product within the past 12 months. It is important that you review the list of hospitals and/or surgeons included with the email notification sent to your facility to identify additional accounts Zimmer Biomet has not notified. Using the Additional Accounts Form provided with the email notice sent to your facility, return contact information for any additional hospitals and/or surgeons that may have received or used the affected product within the past 12 months. If there are no additional users to notify, please confirm this by annotating and returning the form provided indicating that no additional users have been identified.
5. Return all affected product from your distributorship and affected hospitals within your territory along with a completed Attachment 1 – Inventory Return Certification Form to Zimmer Biomet within 2 weeks.
 - a. For each return, send a copy of Attachment 1 to corporatequality.postmarket@zimmerbiomet.com.
 - b. Include a hardcopy of Attachment 1 with your shipment for immediate processing.
 - c. Clearly mark “RECALL” on the outside of return boxes.
6. Retain a copy of your field action acknowledgement and product return forms for your records in the event of a compliance audit of your facility.



7. If after reviewing this notice you have further questions or concerns, please call 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of the call center operating hours will receive a prompt to record a voicemail or be transferred to an on-call representative in the case of an emergency. Alternatively, your questions may be sent by email to corporatequality.postmarket@zimmerbiomet.com.

Other Information

This field action 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:

- 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 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.

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

We thank you for your cooperation and regret any inconvenience caused by this field action.

Sincerely,



Kevin W. Escapule
Post Market Surveillance & Regulatory Compliance Director



**ATTACHMENT 1
Inventory Return Certification Form**

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

Affected Product: Trauma Implants

Territory: _____ **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:

**ATTN: Return Goods
Zimmer Biomet
1777 W. Center St.
Warsaw, IN 46580**

OR

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

An exhaustive search for the affected lots has been performed and all available affected product is being returned to Zimmer Biomet; any product not returned or found in inventory are considered consumed and unavailable for use.	Check one of the following:		
	Yes		No

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, list the information on a separate spreadsheet and return with this form to corporatequality.postmarket@zimmerbiomet.com.

Certificate of Acknowledgement:

By signing below, I acknowledge that received, read, and understand the contents of this recall communication. All required activities are complete or are being completed.

Printed Name: _____ **Signature:** _____

Title: _____ **Tel:** () _____ - _____ x _____ **Date:** ___/___/___

Note: This form and affected product 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 email a copy to: corporatequality.postmarket@zimmerbiomet.com, in addition to including a copy with your product returns.

Please do not return recalled product with other returns.

Attachment 2

All lot numbers expiring before May 2027 are affected

Item Number	Description
00119309016	VERSA-FXII SC TUBE PLT 90DX16H
00119309516	VERSA-FXII SC TUBE PLT 95DX16H
00119309518	VERSA-FXII SC TUBE PLT 95DX18H
00119309520	VERSA-FXII SC TUBE PLT 95DX20H
00119309522	VERSA-FXII SC TUBE PLT 95DX22H
00119313016	VERSA-FX II STD TUBE 130DX16H
00119313018	VERSA-FX II STD TUBE 130DX18H
00119313020	VERSA-FX II STD TUBE 130DX20H
00119313516	VERSA-FX II STD TUBE 135DX16H
00119313518	VERSA-FX II STD TUBE 135DX18H
00119313520	VERSA-FX II STD TUBE 135DX20H
00119314016	VERSA-FX II STD TUBE 140DX16H
00119314018	VERSA-FX II STD TUBE 140DX18H
00119314020	VERSA-FX II STD TUBE 140DX20H
00119314516	VERSA-FX II STD TUBE 145DX16H
00119314518	VERSA-FX II STD TUBE 145DX18H
00119314520	VERSA-FX II STD TUBE 145DX20H
00119315016	VERSA-FX II STD TUBE 150DX16H
00119315018	VERSA-FX II STD TUBE 150DX18H
00119315020	VERSA-FX II STD TUBE 150DX20H
00224001048	R-F IM NAIL 10MMDX48CM LG
00224001142	R-F IM NAIL 11MMDX42CM
00224001144	R-F IM NAIL 11MMDX44CM
00224001146	R-F IM NAIL 11MMDX46CM LG
00224001148	R-F IM NAIL 11MMDX48CM LG
00224001246	R-F IM NAIL 12MMDX46CM LG
00224001248	R-F IM NAIL 12MMDX48CM LG
00224001340	R-F IM NAIL 13MMDX40CM
00224001342	R-F IM NAIL 13MMDX42CM
00224001344	R-F IM NAIL 13MMDX44CM
00224001346	R-F IM NAIL 13MMDX46CM LG
00224001348	R-F IM NAIL 13MMDX48CM LG
00224001434	R-F IM NAIL 14MMDX34CM
00224001436	R-F IM NAIL 14MMDX36CM
00224001438	R-F IM NAIL 14MMDX38CM
00224001440	R-F IM NAIL 14MMDX40CM

Item Number	Description
00224001442	R-F IM NAIL 14MMDX42CM
00224001444	R-F IM NAIL 14MMDX44CM
00224001446	R-F IM NAIL 14MMDX46CM LG
00224001448	R-F IM NAIL 14MMDX48CM LG
00225230015	FEM IM NAIL 15MMDX30CM
00225230016	FEM IM NAIL 16MMDX30CM
00225232014	FEM IM NAIL 14MMDX32CM
00225232015	FEM IM NAIL 15MMDX32CM
00225232016	FEM IM NAIL 16MMDX32CM
00225234014	FEM IM NAIL 14MMDX34CM
00225234015	FEM IM NAIL 15MMDX34CM
00225234016	FEM IM NAIL 16MMDX34CM
00225236014	FEM IM NAIL 14MMDX36CM
00225236015	FEM IM NAIL 15MMDX36CM
00225238014	FEM IM NAIL 14MMDX38CM
00225238015	FEM IM NAIL 15MMDX38CM
00225240011	FEM IM NAIL 11MMDX40CM
00225240013	FEM IM NAIL 13MMDX40CM
00225240014	FEM IM NAIL 14MMDX40CM
00225240015	FEM IM NAIL 15MMDX40CM
00225242011	FEM IM NAIL 11MMDX42CM
00225242012	FEM IM NAIL 12MMDX42CM
00225242013	FEM IM NAIL 13MMDX42CM
00225242014	FEM IM NAIL 14MMDX42CM
00225242015	FEM IM NAIL 15MMDX42CM
00225244011	FEM IM NAIL 11MMDX44CM
00225244012	FEM IM NAIL 12MMDX44CM
00225244013	FEM IM NAIL 13MMDX44CM
00225244014	FEM IM NAIL 14MMDX44CM
00225246010	FEM IM NAIL 10MMDX46CM
00225246011	FEM IM NAIL 11MMDX46CM
00225246012	FEM IM NAIL 12MMDX46CM
00225246013	FEM IM NAIL 13MMDX46CM
00225246014	FEM IM NAIL 14MMDX46CM
00225248010	FEM IM NAIL 10MMDX48CM
00225248011	FEM IM NAIL 11MMDX48CM

Item Number	Description
00225248012	FEM IM NAIL 12MMDX48CM
00225248013	FEM IM NAIL 13MMDX48CM
00225248014	FEM IM NAIL 14MMDX48CM
00225250013	FEM IM NAIL 13MMDX50CM
00225250014	FEM IM NAIL 14MMDX50CM
00225326015	TIBIAL I/M NAIL 15MMDX26CM
00225328015	TIBIAL I/M NAIL 15MMDX28CM
00225330015	TIBIAL I/M NAIL 15MMDX30CM
00225332014	TIBIAL I/M NAIL 14MMDX32CM
00225332015	TIBIAL I/M NAIL 15MMDX32CM
00225334014	TIBIAL I/M NAIL 14MMDX34CM
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00225336014	TIBIAL I/M NAIL 14MMDX36CM
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00225338014	TIBIAL I/M NAIL 14MMDX38CM
00225338015	TIBIAL I/M NAIL 15MMDX38CM
00225340013	TIBIAL I/M NAIL 13MMDX40CM
00225340014	TIBIAL I/M NAIL 14MMDX40CM
00225340015	TIBIAL I/M NAIL 15MMDX40CM
00225342013	TIBIAL I/M NAIL 13MMDX42CM
00225342014	TIBIAL I/M NAIL 14MMDX42CM
00225342015	TIBIAL I/M NAIL 15MMDX42CM
00225344011	TIBIAL I/M NAIL 11MMDX44CM
00225344013	TIBIAL I/M NAIL 13MMDX44CM
00225344014	TIBIAL I/M NAIL 14MMDX44CM
00225346011	TIBIAL I/M NAIL 11MMDX46CM
00225346012	TIBIAL I/M NAIL 12MMDX46CM
00225346013	TIBIAL I/M NAIL 13MMDX46CM
00225730004	FEM IM NAIL 14MMDX30CM LEFT
00225730014	FEM IM NAIL 14MMDX30CM RIGHT
00225732003	FEM IM NAIL 13MMDX32CM LEFT
00225732004	FEM IM NAIL 14MMDX32CM LEFT
00225732013	FEM IM NAIL 13MMDX32CM RIGHT
00225732014	FEM IM NAIL 14MMDX32CM RIGHT
00225734001	FEM IM NAIL 11MMDX34CM LEFT

Item Number	Description
00225734003	FEM IM NAIL 13MMDX34CM LEFT
00225734004	FEM IM NAIL 14MMDX34CM LEFT
00225734011	FEM IM NAIL 11MMDX34CM RIGHT
00225734013	FEM IM NAIL 13MMDX34CM RIGHT
00225734014	FEM IM NAIL 14MMDX34CM RIGHT
00225736001	FEM IM NAIL 11MMDX36CM LEFT
00225736002	FEM IM NAIL 12MMDX36CM LEFT
00225736003	FEM IM NAIL 13MMDX36CM LEFT
00225736004	FEM IM NAIL 14MMDX36CM LEFT
00225736011	FEM IM NAIL 11MMDX36CM RIGHT
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00225736013	FEM IM NAIL 13MMDX36CM RIGHT
00225736014	FEM IM NAIL 14MMDX36CM RIGHT
00225738000	FEM IM NAIL 10MMDX38CM LEFT
00225738001	FEM IM NAIL 11MMDX38CM LEFT
00225738002	FEM IM NAIL 12MMDX38CM LEFT
00225738003	FEM IM NAIL 13MMDX38CM LEFT
00225738004	FEM IM NAIL 14MMDX38CM LEFT
00225738010	FEM IM NAIL 10MMDX38CM RIGHT
00225738011	FEM IM NAIL 11MMDX38CM RIGHT
00225738012	FEM IM NAIL 12MMDX38CM RIGHT
00225738013	FEM IM NAIL 13MMDX38CM RIGHT

Item Number	Description
00225738014	FEM IM NAIL 14MMDX38CM RIGHT
00225740000	FEM IM NAIL 10MMDX40CM LEFT
00225740001	FEM IM NAIL 11MMDX40CM LEFT
00225740002	FEM IM NAIL 12MMDX40CM LEFT
00225740003	FEM IM NAIL 13MMDX40CM LEFT
00225740004	FEM IM NAIL 14MMDX40CM LEFT
00225740010	FEM IM NAIL 10MMDX40CM RIGHT
00225740011	FEM IM NAIL 11MMDX40CM RIGHT
00225740012	FEM IM NAIL 12MMDX40CM RIGHT
00225740013	FEM IM NAIL 13MMDX40CM RIGHT
00225740014	FEM IM NAIL 14MMDX40CM RIGHT
00225742000	FEM IM NAIL 10MMDX42CM LEFT
00225742001	FEM IM NAIL 11MMDX42CM LEFT
00225742002	FEM IM NAIL 12MMDX42CM LEFT
00225742003	FEM IM NAIL 13MMDX42CM LEFT
00225742004	FEM IM NAIL 14MMDX42CM LEFT
00225742010	FEM IM NAIL 10MMDX42CM RIGHT
00225742011	FEM IM NAIL 11MMDX42CM RIGHT
00225742012	FEM IM NAIL 12MMDX42CM RIGHT
00225742013	FEM IM NAIL 13MMDX42CM RIGHT
00225742014	FEM IM NAIL 14MMDX42CM RIGHT
00225744000	FEM IM NAIL 10MMDX44CM LEFT

Item Number	Description
00225744001	FEM IM NAIL 11MMDX44CM LEFT
00225744002	FEM IM NAIL 12MMDX44CM LEFT
00225744003	FEM IM NAIL 13MMDX44CM LEFT
00225744004	FEM IM NAIL 14MMDX44CM LEFT
00225744010	FEM IM NAIL 10MMDX44CM RIGHT
00225744011	FEM IM NAIL 11MMDX44CM RIGHT
00225744012	FEM IM NAIL 12MMDX44CM RIGHT
00225744013	FEM IM NAIL 13MMDX44CM RIGHT
00225744014	FEM IM NAIL 14MMDX44CM RIGHT
00225746000	FEM IM NAIL 10MMDX46CM LEFT
00225746001	FEM IM NAIL 11MMDX46CM LEFT
00225746002	FEM IM NAIL 12MMDX46CM LEFT
00225746003	FEM IM NAIL 13MMDX46CM LEFT
00225746004	FEM IM NAIL 14MMDX46CM LEFT
00225746010	FEM IM NAIL 10MMDX46CM RIGHT
00225746011	FEM IM NAIL 11MMDX46CM RIGHT
00225746012	FEM IM NAIL 12MMDX46CM RIGHT
00225746013	FEM IM NAIL 13MMDX46CM RIGHT
00225746014	FEM IM NAIL 14MMDX46CM RIGHT
00225748000	FEM IM NAIL 10MMDX48CM LEFT
00225748001	FEM IM NAIL 11MMDX48CM LEFT
00225748002	FEM IM NAIL 12MMDX48CM LEFT

Item Number	Description
00225748003	FEM IM NAIL 13MMDX48CM LEFT
00225748010	FEM IM NAIL 10MMDX48CM RIGHT
00225748011	FEM IM NAIL 11MMDX48CM RIGHT
00225748012	FEM IM NAIL 12MMDX48CM RIGHT
00225748013	FEM IM NAIL 13MMDX48CM RIGHT
00225750000	FEM IM NAIL 10MMDX50CM LEFT
00225750001	FEM IM NAIL 11MMDX50CM LEFT
00225750002	FEM IM NAIL 12MMDX50CM LEFT
00225750003	FEM IM NAIL 13MMDX50CM LEFT

Item Number	Description
00225750010	FEM IM NAIL 10MMDX50CM RIGHT
00225750011	FEM IM NAIL 11MMDX50CM RIGHT
00225750012	FEM IM NAIL 12MMDX50CM RIGHT
00225750013	FEM IM NAIL 13MMDX50CM RIGHT
47249146014	Z NAIL PF 14MM X 46CM UNIV
47249246014	Z NAIL GT 14MM X 46CM R
47249246114	Z NAIL GT 14MM X 46CM L
47249538014	Z NAIL TIBIA 14MM X 38CM UNIV
47249540014	Z NAIL TIBIA 14MM X 40CM UNIV
47249542014	Z NAIL TIBIA 14MM X 42CM UNIV
47249544014	Z NAIL TIBIA 14MM X 44CM UNIV
47494502601	4.5 BROAD SCP PLT 26-H STER