XXX XX, 2017

To: Risk Managers & Surgeons
CC: Chairman Medical Board and relevant Head of Departments

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

Affected Product: Specific Knee, Hip and Nail Implants, Reference Attachment 2

Zimmer is initiating a field action for sterile-packaged implants packaged in two different package configurations due to packaging design verification test failures. Specifically, multiple test samples from each of the two configurations 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.

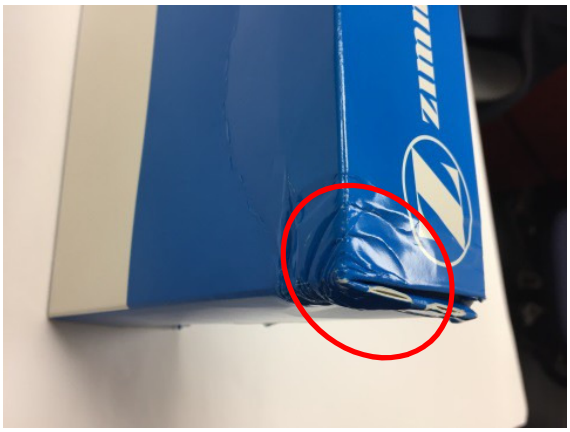
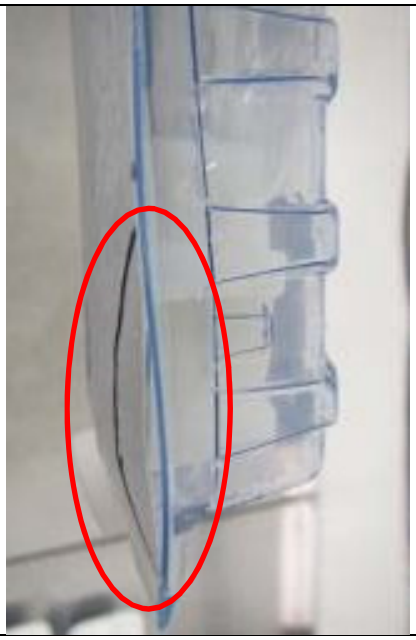


Fig 1. Carton Box Damage Corner

Fig 2. Cracked Corner

		
Fig 1. Cracked Inner tray near peel tab	Fig 2. Outer Seal Channel/Void	Fig 3. Outer Carton Damage

Risks:

- 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 periprosthetic infection, which could result in revision or multi-stage revision to treat the infection.

Hospital Responsibilities:

1. Review this notification and ensure affected team members are aware of the contents.
2. Complete the Certification of Acknowledgement portion of **Attachment 1**
   a. Return a digital copy to corporatequality.postmarket@zimmerbiomet.com within three (3) days.
3. Assist your Zimmer Biomet sales representative quarantine all affected product.
4. 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.

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Surgeon Responsibilities:

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this recall that are recommended beyond your existing surgical follow up protocol.
3. Complete Attachment 1 – Certificate of Acknowledgement.
    a. Return a digital copy 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: Certificate of Acknowledgement

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

[ ] **Hospital Facility** [ ] **Surgeon** (Please select)

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 email a copy to: corporatequality.postmarket@zimmerbiomet.com.

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Attachment 2
Affected Product List

Item Number	Lot Number Expiry Date Before	Description
00225236016	March 2027	FEM IM NAIL 16MMDX36CM
00225238016	March 2027	FEM IM NAIL 16MMDX38CM
00225240016	March 2027	FEM IM NAIL 16MMDX40CM
00225242016	March 2027	FEM IM NAIL 16MMDX42CM
00225244015	March 2027	FEM IM NAIL 15MMDX44CM
00225244016	March 2027	FEM IM NAIL 16MMDX44CM
00225246015	March 2027	FEM IM NAIL 15MMDX46CM
00225246016	March 2027	FEM IM NAIL 16MMDX46CM
00225248015	March 2027	FEM IM NAIL 15MMDX48CM
00225248016	March 2027	FEM IM NAIL 16MMDX48CM
00225250015	March 2027	FEM IM NAIL 15MMDX50CM
00225250016	March 2027	FEM IM NAIL 16MMDX50CM
00225344015	March 2027	TIBIAL I/M NAIL 15MMDX44CM
00225748004	March 2027	FEM IM NAIL 14MMDX48CM LEFT
00225748014	March 2027	FEM IM NAIL 14MMDX48CM RIGHT
00225750004	March 2027	FEM IM NAIL 14MMDX50CM LEFT
00225750014	March 2027	FEM IM NAIL 14MMDX50CM RIGHT
00585004620	March 2027	SEG MALE-FEMALE TAPER, 200MM
00585004622	March 2027	SEG MALE-FEMALE TAPER, 220MM
00585205217	March 2027	SEG FLUTED STEM, 17X190MM STR
00585205218	March 2027	SEG FLUTED STEM, 18X190MM STR

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Item Number	Lot Number Expiry Date Before	Description
00585205219	March 2027	SEG FLUTED STEM, 19X190MM STR
00585205415	March 2027	SEG FLUTED STEM, 15X250MM BWD
00585205416	July 2026	SEG FLUTED STEM, 16X250MM BWD
00585205417	September 2026	SEG FLUTED STEM, 17X250MM BWD
00585205418	July 2026	SEG FLUTED STEM, 18X250MM BWD
00585205419	July 2026	SEG FLUTED STEM, 19X250MM BWD
00585207419	March 2027	SEGMENTAL VSS BOWED 19X190MM
00784301508	March 2027	POR FULL-CT FEM ST 15X200MM
00784301608	July 2026	POR FULL-CT FEM ST 16X200MM
00784301708	July 2026	POR FULL-CT FEM ST 17X200MM
00784301808	July 2026	POR FULL-CT FEM ST 18X200MM
00784302008	July 2026	POR FULL-CT FEM ST 20X200MM
00992124033	March 2027	XL POR ST 24.0X220MM, BOWED
00992125533	March 2027	XL POR ST 25.5X220MM BOWED