ZIMMER BIOMET

December 18, 2017

To: Surgeons, Hospitals

Subject: **URGENT FIELD SAFETY NOTICE – REMOVAL**

Reference: **ZFA 2017-500**

Affected Products: **Optipac® 40 Refobacin® Revision and Optipac® 80 Refobacin® Revision**

Dear Madams, Dear Sirs,

Biomet Orthopedics Switzerland GmbH is conducting a voluntary medical device Field Safety Corrective Action (removal) for certain batches of Optipac® Refobacin® Revision (please see Appendix 1 for the list of potentially affected products).

Picture 1: Optipac product

Zimmer Biomet was informed through complaints of certain cement powder being too compact and/or showing an increase in the intended polymerization time involving certain batches of Optipac® Refobacin® Revision.
Investigation showed that the batches with an increase in the intended polymerization time had impaired mechanical cement properties.

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The potential risks associated to the issue are the following:

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Worst Case
	Compact powder: Slight delay during the surgery (< 30 min) after discovery of the issue and replacement of the product. **Polymerization time too long:** Slight delay during surgery.	**Compact powder:** None. The surgeon should pay attention that in some cases the alternative product must be adapted to the patient conditions. **Polymerization time too long:** Short time adverse reaction due to the anesthesia time prolongation. Surgical delay during the surgery > 30 min.
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Worst Case
	Compact powder: None. **Polymerization time too long:** None.	**Compact powder:** None. **Polymerization time too long:** Increase of infection risk and consequences of anesthesia due to the prolongation of the surgery. Revision of the prosthesis due to infection. Or revision due to potential loosening. Indeed, due to the reduced cement mechanical properties, if BPO level has declined too much and set-time is extended, potentially motion of the implant is applied within the cement that was placed into the prepared bone.

We believe it would be prudent to monitor closely those patients who have a prosthesis which has been cemented by means of the potentially affected Optipac® Refobacin® Revision batches as part of the patient's standard follow-up. As a manufacturer of medical devices Zimmer Biomet is not licensed to practice medicine. It is up to healthcare professionals to assess the risk and to decide on any patient monitoring.

As a precautionary measure Biomet Orthopedics Switzerland has decided to recall all potentially affected products. Our records indicate you may have received one or more of these products. To date no adverse health outcome has been reported.

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Surgeons and Hospitals Responsibilities:

1. Review this notification and ensure affected personnel are aware of the content.
2. Assist your Zimmer Biomet sales representative quarantine all affected products available in your inventory.
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 to fr.complaints@zimmerbiomet.com or to your local Zimmer Biomet contact.
    b. Retain a copy of the Certificate of Acknowledgement with your 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 contact your Zimmer Biomet sales 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 fr.complaints@zimmerbiomet.com or to your local Zimmer Biomet contact.

The undersigned confirms that this notice has been delivered to the relevant Competent Authorities.

We would like to thank you for your cooperation in advance and regret any inconveniences caused by this Field Safety Corrective Action.

Sincerely,

Matthias Bürger
Quality Assurance & Regulatory Affairs Vice President EMEA

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Appendix 1 : Affected Products

Product Name	Product reference	Batch number
OPTIPAC 40 REFOBACIN REVISION	4730501163-1	A648C04670
OPTIPAC 40 REFOBACIN REVISION	4730501163-1	A648C05100
OPTIPAC 40 REFOBACIN REVISION	4730501163-1	A705B05130
OPTIPAC 40 REFOBACIN REVISION	4730501163-1	A705B06130
OPTIPAC 40 REFOBACIN REVISION	4730501163-1	A722B00240
OPTIPAC 40 REFOBACIN REVISION	4730501163-1	A722B08910
OPTIPAC 40 REFOBACIN REVISION	4730501163-1	A722B08920
OPTIPAC 80 REFOBACIN REVISION	4732501165-1	A620A01788
OPTIPAC 80 REFOBACIN REVISION	4732501165-1	A620A0178A
OPTIPAC 80 REFOBACIN REVISION	4732501165-1	A705C05628
OPTIPAC 80 REFOBACIN REVISION	4732501165-1	B705B05128

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ATTACHMENT 1
Certificate of Acknowledgement ZFA 2017- 500

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

[ ] Hospital Facility **[ ] Surgeon** **(Please check one as applicable)**

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 can be considered closed for your account. It is important that you complete this form and email a copy to: fr.complaints@zimmerbiomet.com

Product reference	Lot	Number of products received	Number of products returned