November 13, 2017

To: Surgeons/ Hospitals

Subject: **URGENT FIELD SAFETY NOTICE - CORRECTION**

Reference: **ZFA 2017-425**

Affected Products: Bone Cement and Optipac

Dear Madams, Dear Sirs,

Biomet Orthopedics Switzerland GmbH and Biomet France Sarl are conducting jointly a voluntary medical device field safety corrective action (correction) for the Bone Cement and Optipac (please see Appendix 1 for the list of affected products).

Picture 1: Optipac product

Picture 2: Refobacin Bone Cement powder and monomer ampoule

Zimmer Biomet was informed of an increase in histamine levels in the gentamicin contained in specific batches of Bone Cement and Optipac. Histamine is a normal impurity in the gentamicin manufacturing process.

Investigation showed that the increase in histamine levels in the gentamicin is due to a change in at our gentamicin producer and affects only specific references and batches, listed in Appendix 1. These references and batches were manufactured from 13th June 2017 to 29th September 2017 and distributed from 1st August 2017 to 18th October 2017.

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
	Sudden skin redness (flush symptoms), itching and redness on the body gastrointestinal symptoms such as nausea and / or vomiting or diarrhea and abdominal pain.	Respiratory and cardiovascular symptoms such as blood pressure drop, asthma attacks, dizziness or tachycardia (transient circulatory dysregulations).
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Worst Case
	Symptomatic treatment (Antihistamines) reduces the transient symptoms.	None.

As a precautionary measure it has been decided to issue this Field Safety Notice to inform healthcare professionals and distributors who received one or more affected products.
Patients being administrated these identified products should be monitored closely for potential reactions associated with increased levels of histamine. The likelihood of the potential risk was estimated as less than remote as per investigation.

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

Surgeons Responsibilities:

1. Review this notification and ensure affected personnel are aware of the contents.
2. Complete Attachment 1 – Certificate of Acknowledgement.
    a. Return a digital copy to fieldaction.ch@zimmerbiomet.com .
    b. Retain a copy of the Certificate of Acknowledgement with your field action records in the event of a compliance audit of your facilities documentation.
3. If after reviewing this notice you have further questions or concerns please contact your Zimmer Biomet representative.

Other Information

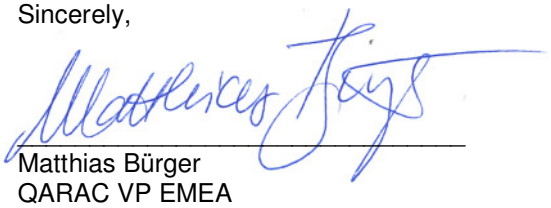
This voluntary medical device Field Safety Corrective Action was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing winterthur.per@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
QARAC VP EMEA

Appendix 1: Affected Products

Bone cement

Product Name	Product reference	Batch number
REFOBACIN BONE CEMENT R 1X40	3003940001-3	714CAB1601
REFOBACIN BONE CEMENT R 1X40	3003940001-3	714CAD0505
REFOBACIN BONE CEMENT R 1X40	3003940001-3	714CAA3103
REFOBACIN PLUS BONE CEMENT 1X20	3020820401-3	718AAD0505
REFOBACIN PLUS BONE CEMENT 1X40	3020830401-3	718ABA3103
REFOBACIN PLUS BONE CEMENT 2X40	3021170001-3	718ABD2003
REFOBACIN BONE CEMENT R 2X40	3003940002-3	717BAA3103
REFOBACIN BONE CEMENT R 1X40	3003940001-3	717BAA3103
REFOBACIN BONE CEMENT R 2X40	4003940002	A711CB0707
REFOBACIN BONE CEMENT R 1X40	4003940001	A711CB0706
REFOBACIN BONE CEMENT R 1X40	4003940001	B711BB0706
REFOBACIN BONE CEMENT R 2X20	4003920002	A711BA2303
REFOBACIN PLUS BONE CEMENT 2X20	4021180001	A711AA2303
REFOBACIN PLUS BONE CEMENT 1X20	4020820401	A711AA2303
REFOBACIN PLUS BONE CEMENT 2X20	4021180001SA	A711AA2303
REFOBACIN PLUS BONE CEMENT 1X40	4020830401	A713BB0706
REFOBACIN BONE CEMENT R 2X40	4003940002	A715BA2303
REFOBACIN BONE CEMENT R 1X40	4003940001	A715BA2303
REFOBACIN BONE CEMENT R 2X20	4003920002	B720BD2002
REFOBACIN BONE CEMENT R 1X20	4003920001	B720BD2002
REFOBACIN BONE CEMENT R 1X40	4003940001	A716CA2303

Optipac

Product Name	Product reference	Batch number
OPTIPAC 40 REFOBACIN PLUS BONE CEMENT	4720502083-3	714AA07260
OPTIPAC HIPSET REFOBACIN BONE CEMENT R	4740500394-3	0001226500
OPTIPAC 60 REFOBACIN BONE CEMENT R	4711500396-3	712AA07275
OPTIPAC 40 REFOBACIN BONE CEMENT R	4710500394-3	711AA07260
OPTIPAC 60 REFOBACIN PLUS BONE CEMENT	4721502084-3	714BA06955
OPTIPAC 80 REFOBACIN PLUS BONE CEMENT	4722502117-3	714BB07288
OPTIPAC 60 REFOBACIN BONE CEMENT R	4711500396-3	712AA06375
OPTIPAC 60 REFOBACIN BONE CEMENT R	4711500396-3	712AA07255
OPTIPAC 40 REFOBACIN BONE CEMENT R	4710500394-3	711AA07290
OPTIPAC 80 REFOBACIN BONE CEMENT R	4712500398-3	712BA07300
OPTIPAC 60 REFOBACIN PLUS BONE CEMENT	4721502084-3	714BA07305

Product Name	Product reference	Batch number
OPTIPAC 40 REFOBACIN PLUS BONE CEMENT	4720502083-3	714AA08910
OPTIPAC 40 REFOBACIN BONE CEMENT R	4710500394-3	711AA08920
OPTIPAC 80 REFOBACIN BONE CEMENT R	4712500398-3	712BA08920
OPTIPAC 40 REFOBACIN PLUS BONE CEMENT	4720502083-3	714AA00220
OPTIPAC 40 REFOBACIN PLUS BONE CEMENT	4720502083-3	714AA00230
OPTIPAC 80 REFOBACIN BONE CEMENT R	4712500398-1	A710D06370
OPTIPAC 40 REFOBACIN PLUS BONE CEMENT	4720502083-1	B712A06130
OPTIPAC 80 REFOBACIN BONE CEMENT R	4712500398-1	A710E06120
OPTIPAC 80 REFOBACIN BONE CEMENT R	4712500398-1	A713C06130
OPTIPAC 40 REFOBACIN PLUS BONE CEMENT	4720502083-1	B712A06120
OPTIPAC HIPSET (40&80) REFOBACIN BONE CEMENT R	4740500394-1	0001218400
OPTIPAC 40 REFOBACIN PLUS BONE CEMENT	4720502083-1	B712A06350
OPTIPAC 40 REFOBACIN BONE CEMENT R	4710500394-1	A714D07270
OPTIPAC 80 REFOBACIN BONE CEMENT R	4712500398-1	A710D05600
OPTIPAC 40 REFOBACIN BONE CEMENT R	4710500394-1	A714D06130
OPTIPAC 40 REFOBACIN PLUS BONE CEMENT	4720502083-1	A717D07260
OPTIPAC KNEE REFOBACIN PLUS BONE CEMENT	4719502082-1	A712A07263
OPTIPAC 80 REFOBACIN PLUS BONE CEMENT	4722502117-1	A719A07288
OPTIPAC 60 REFOBACIN BONE CEMENT R	4711500396-1	A713D07285
OPTIPAC 40 REFOBACIN REVISION	4730501163-1	A722B08910
OPTIPAC 60 REFOBACIN BONE CEMENT R	4711500396-1	A713D07305
OPTIPAC 60 REFOBACIN BONE CEMENT R	4711500396-1	A715A08915
OPTIPAC 60 REFOBACIN PLUS BONE CEMENT	4721502084-1	A720C08915
OPTIPAC 40 REFOBACIN REVISION	4730501163-1	A722B08920
OPTIPAC 40 REFOBACIN PLUS BONE CEMENT	4720502083-1	A717D08920
OPTIPAC HIPSET (40&80) REFOBACIN BONE CEMENT R	4740500394-1	0001240600
OPTIPAC 60 REFOBACIN BONE CEMENT R	4711500396-1	A713D06365
OPTIPAC 60 REFOBACIN PLUS BONE CEMENT	4721502084-1	A720C06365
OPTIPAC HIPSET (40&80) REFOBACIN BONE CEMENT R	4740500394-1	0001241312
OPTIPAC 80 REFOBACIN BONE CEMENT R	4712500398-1	A713C00230
OPTIPAC 40 REFOBACIN BONE CEMENT R	4710500394-1	A716D00230
OPTIPAC 60 REFOBACIN PLUS BONE CEMENT	4721502084-1	A720C00235
OPTIPAC 40 REFOBACIN REVISION	4730501163-1	A722B00240
OPTIPAC HIPSET (40&80) REFOBACIN BONE CEMENT R	4740500394-1	0001243555
OPTIPAC 60 REFOBACIN BONE CEMENT R	4711500396-1	A717C00225
OPTIPAC 80 REFOBACIN BONE CEMENT R	4712500398-1	A717B08930
OPTIPAC 40 REFOBACIN BONE CEMENT R	4710500394-1	A714D02310
OPTIPAC 40 REFOBACIN BONE CEMENT R	4710500394-1	A720A02310
OPTIPAC 40 REFOBACIN PLUS BONE CEMENT	4720502083-1	A717D02310
OPTIPAC 60 REFOBACIN BONE CEMENT R	4711500396-1	A715A02315

Note: products references ending with "-3" are under the legal manufacturer Biomet Sarl and other products references are under Biomet Orthopedics Switzerland GmbH

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ATTACHMENT 1
Certificate of Acknowledgement ZFA 2017- 425

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

[ ] 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: fieldaction.ch@zimmerbiomet.com