ZIMMER BIOMET

August 21, 2019

Dear Healthcare Professional,
cc: Chairman Medical Board and relevant Head of Departments

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

Affected Product: MOBI-C/MOBI-C Plug & Fit

Item Number	Lot Number	UDI Number
MB2355	L081448C102	(01)03662663018333(17)210901(10)L081448C102
MB2374	L081436C102	(01)03662663018371(17)210801(10)L081436C102
MB2556	L081531C111	(01)03662663018548(17)211201(10)L081531C111
MB2556	L081572C112	(01)03662663018548(17)220201(10)L081572C112
MB2575	L081418C102	(01)03662663018586(17)210801(10)L081418C102
MB2775	L081444C102	(01)03662663018784(17)210801(10)L081444C102
MB2776	L081403C100	(01)03662663018791(17)210701(10)L081403C100
MB2776	L081544C111	(01)03662663018791(17)220101(10)L081544C111
MB2796	L081376C100	(01)03662663018845(17)210501(10)L081376C100
MB2574	L081637C122	(01)03662663018579(17)220401(10)L081637C122

Zimmer Biomet is conducting a medical device recall for MOBI-C/MOBI-C Plug & Fit due to the inadvertent use of certain outdated versions of labels, within the above-referenced product lots. For example, labels within the scope of this recall may be missing some material information, such as branding information for “Plug & Fit”, a mention of “lordosis” on superior plate, and Traditional Chinese on “MOBI-C P&F” labels.

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Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None	*Delay with patient harm, rescheduling of surgery or patient is fused.*
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None	*None*

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between January of 2017 and June of 2019.

Risk Manager Responsibilities:

1. Review this notification and ensure that affected personnel are aware of the contents.
2. If you have affected product at your facility, assist your Zimmer Biomet sales representative and quarantine all affected product. Your Zimmer Biomet sales representative will remove the affected product from your facility.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to CorporateQuality.PostMarket@zimmerbiomet.com or Complaint-LDR@zimmerbiomet.com. This form will be returned even if you do not have affected products at your facility.
4. Retain a copy of the acknowledgement form with your recall records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this notice, please call customer service at 1-800-447-3625 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of call center operating hours will receive a voicemail prompt or be transferred to an on-call representative in the event of an emergency. Alternatively, your questions may be emailed to CorporateQuality.PostMarket@zimmerbiomet.com or Complaint-LDR@zimmerbiomet.com .

Other Information

This medical device recall will be reported to Competent Authorities, Notified Bodies, and Regulatory Authorities as required.

- Med Watch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's Med Watch 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 also 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 Complaint-LDR@zimmerbiomet.com .

Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes. Your urgent cooperation is needed.

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

Thank you for your assistance. We regret any inconvenience caused by this recall.

Sincerely,

[redacted]

Kevin Escapule, Post Market Surveillance & Regulatory Compliance Director

ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: MOBI-C/MOBI-C Plug & Fit ZFA Field Action Reference: ZFA 2019-00209

Please check as applicable:

Do you have affected product in your facility?

☐ **Yes**, we currently have one or more affected items in our facility.

☐ **No**, we currently have no affected items in our facility.

By signing below, I acknowledge that the required actions have been taken in accordance with this recall notice.

Printed Name: _____ **Signature:** _____

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

Facility Name: _____

Facility Address: _____

City:_____ **State:**_____ **ZIP:**_____

Note: This form will be returned to Zimmer Biomet before this action is closed for your account. It is important that you complete this form and email a copy to CorporateQuality.PostMarket@zimmerbiomet.com or fax to 574-373-3589.

ATTACHMENT 2
Affected Product List

Item Number	Lot Number	Item Description
MB2355	L081448C102	MOBIC IMPLANT M « STANDARD » 13X15 H5
MB2374	L081436C102	MOBI-C IMPLANT M « STANDARD » 13X17 H4.5
MB2556	L081531C111	MOBIC IMPLANT M « STANDARD » 15X15 H6
MB2556	L081572C112	MOBIC IMPLANT M « STANDARD » 15X15 H6
MB2575	L081418C102	MOBIC IMPLANT M « STANDARD » 15X17 H5
MB2775	L081444C102	MOBIC IMPLANT M « STANDARD » 17X17 H5
MB2776	L081403C100	MOBIC IMPLANT M « STANDARD » 17X17 H6
MB2776	L081544C111	MOBIC IMPLANT M « STANDARD » 17X17 H6
MB2796	L081376C100	MOBIC IMPLANT M « STANDARD » 17X19 H6
MB2574	L081637C122	MOBI-C IMPLANT M « STANDARD » 15X17 H4.5