ZIMMER BIOMET

December 22, 2021

To: Hospitals and Surgeons

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE (REMOVAL)**

Affected Product: Various LactoSorb System Implants

Item	Lot	UDI Number	Descrption
915-2430	937010	(01)00841036055707(17)260201(10)937010	1.5mm Lactosorb 100x100mm Pnl
915-2430	653540	(01)00841036055707(17)260202(10)653540	1.5mm Lactosorb 100x100mm Pnl
915-2430	639050	(01)00841036055707(17)260505(10)639050	1.5mm Lactosorb 100x100mm Pnl
915-2430	286130	(01)00841036055707(17)251102(10)286130	1.5mm Lactosorb 100x100mm Pnl
915-2430	280540	(01)00841036055707(17)260318(10)280540	1.5mm Lactosorb 100x100mm Pnl
915-2430	088500	(01)00841036055707(17)251022(10)088500	1.5mm Lactosorb 100x100mm Pnl
915-2817	855000	(01)00841036055943(17)260608(10)855000	100mmx100mmx.25mm Sht W/ Holes
915-2817	854990	(01)00841036055943(17)260524(10)854990	100mmx100mmx.25mm Sht W/ Holes
915-2817	341170	(01)00841036055943(17)260412(10)341170	100mmx100mmx.25mm Sht W/ Holes
915-2817	341150	(01)00841036055943(17)260416(10)341150	100mmx100mmx.25mm Sht W/ Holes

As a precautionary measure, Biomet Microfixation LLC is conducting a lot specific medical device Field Safety Corrective Action (removal) for several lots of the LactoSorb System implants due to potential presence of elevated bacterial endotoxin levels that exceed the specification limit. The issue was identified through process monitoring sample failures, and there have been no complaints received for the affected product.

Endotoxins (pyrogens) are substances found in certain bacteria. The FDA-adopted standard for endotoxin levels is 2.15 EU/device for cerebrospinal fluid contacting materials. There were three implant samples that were found to exceed this level. As a result, the implants cleaned between Nov 2, 2020 and Oct 22, 2021 are being removed. Affected products that have the potential to exceed process limits for endotoxins could present the potential risks described below:

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	*None*
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	*Surgical or medical intervention due to Adverse Local Tissue Reaction, Pain or ache (critical), Reaction to allergen or toxin (severe systemic)*

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between February and September 2021.

Hospital Responsibilities:

1. Review this Field Safety Notice 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. If the product has been further distributed, provide your customers with the Field Safety Notice for hospitals and ensure documentation.
4. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.gscc@zimmerbiomet.com. This form must be returned even if you do not have affected products at your facility.
5. Retain a copy of the **Certificate of Acknowledgement** with your Field Safety Corrective Action records in the event of a compliance audit of your facility's documentation.
6. If you have further questions or concerns after reviewing this Field Safety Notice, please contact your Zimmer Biomet representative.

Surgeon Responsibilities:

1. Review this Field Safety Notice for awareness of the contents.
2. There are no specific patient monitoring instructions related to this Field Safety Corrective Action that are recommended beyond your existing follow-up schedule.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.gscc@zimmerbiomet.com.
4. Retain a copy of the **Certificate of Acknowledgement** with your Field Safety Corrective Action records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this Field Safety Notice, please contact your Zimmer Biomet representative.

Other Information

This 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 as per MEDDEV 2.12-1 in Europe.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing GSCC.Supplier.Quality@zimmerbiomet.com or to your local Zimmer Biomet contact.

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

The undersigned confirms that this Field Safety Notice has been delivered to the appropriate Regulatory Agencies.

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

Sincerely,

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ZIMMER BIOMET

ATTACHMENT 1- Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Various LactoSorb System Implants
Field Safety Corrective Action Reference: ZFA 2021-00204

Please return the completed form to your Zimmer Biomet contact person or by e-mail to:

fieldaction.gscc@zimmerbiomet.com

☐ I received and understood the Field Safety Notice.

Regarding the parts:

☐ A thorough search has been performed for the affected products and the below are available for return.
All products that are not available (for return) have been implanted or used: ☐ Yes ☐ No

Note: All products that are not available (for return) will be considered as dispositioned on location and therefore physical unavailable unless otherwise specified.

Item Number	Lot Number	UDI Number	Quantity Returned

Complete this table for all affected items returned. If additional space is needed, please provide a spreadsheet and return it to fieldaction.gscc@zimmerbiomet.com with this form.

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

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

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 fieldaction.gscc@zimmerbiomet.com.