ZIMMER BIOMET

March 12, 2019

To: Surgeon / Hospital

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE**

REMOVAL EXPANSION – LOT NUMBER SPECIFIC

Reference: ZFA 2019-00009

Affected Product: LactoSorb System 14mm Rapid Flap Item # 915-0020

Please note that this notice is for an expansion of lots for a previous notice you received for Field Action 2018-00172 dated May 14th, 2018.

Item #	Description	Lots #s	Lot #s	Lot #s
915-0020	LactoSorb Rapid Flap	538220	593400	331850
		538510	593410	379800
		538880	593430	691290
		538900	615370	054070
		538940	615380	110860
		662300	615390	110900
		699490	615400	110940
		699600	615410	111030
		991750	615420	173290
		379730	615630	218330
		379910	662320	218340
		538120	662330	331750
		538180	662370	331820
		538250	662380	331840
		538310	699470	331880
		538370	699500	379760
		538480	699520	379810
		538520	699540	379870
		538610	699560	379920
		538630	699570	444380
		538660	699580	676830
		538680	699590	835110
		538920	110910	997260

Zimmer Biomet CMF and Thoracic, LLC ("Zimmer Biomet") is conducting an expansion of a medical device removal for certain serial numbers of the LactoSorb Rapid Flap, part 915-0020. The Zimmer Biomet team has initiated this action upon confirmation that the Outer Plate component, part 915-0020-03, exhibits an excessive chamfer on the threading after deburring operations. This excessive chamfer results in non-conforming product where the threads of the outer plate component have limited to no engagement with the post component, part 915-0020-01. Review of impacted inventory and received complaints indicates that this issue is highly detectible and identifiable prior to implantation of the device and an adverse patient health outcome is not anticipated.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Minor delay in surgery.	Major delay in surgery
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 anticipated	None anticipated

Hospital Responsibilities:

1. Review this 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. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.emea@zimmerbiomet.com. This form must be returned even if you do not have affected products at your facility.
4. Retain a copy of the acknowledgement form with your field 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 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 winterthur.per@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 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 action.

Sincerely,

Sincerely,

[redacted]

ZIMMER BIOMET

ATTACHMENT 1

Certificate of Acknowledgement

ZFA Number: ZFA-2019-00009

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

Affected Product: LactoSorb Rapid Flap

Please return the completed form to your Zimmer Biomet contact person:
fieldaction.emea@zimmerbiomet.com

I received and understood the Field Safety Notice.

Regarding the products:
All inventories for the affected products have been checked and following products are to be returned:

Product Reference	Lot Reference	Number of products returned

OR

All received products were used (implanted)

OR

The affected products which are unavailable for return have been: discarded lost
other: _____

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:**_____ **Date:**____/___/____

Title: _____ **Telephone:** ( )_____-_____

Facility Name: _____ _ **Facility Address:** _____

NOTE: This form and affected product must be returned to Zimmer Biomet before this action is considered closed for your account. It is important that you complete this form and email a copy to fieldaction.emea@zimmerbiomet.com.