ZIMMER BIOMET

March 11, 2019

To: Distributors

Subject: URGENT MEDICAL DEVICE FIELD SAFETY NOTICE
REMOVAL –LOT NUMBER SPECIFIC

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

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 a medical device removal for certain lot 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

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between August 2017 and November of 2018.

Distributors Responsibilities

1. Review this notification and ensure that affected team members are aware of the contents.
2. Immediately locate and quarantine affected parts in your inventory.
3. Immediately return all affected product from your distributorship and from affected hospitals within your country. You have to provide your customers with the field safety notice for surgeons/ hospitals and ensure documentation.
   a. Complete Attachment 1 – Inventory Return Certification Form and send to fieldaction.netherlands@zimmerbiomet.com within three (3) days.
   b. Include a hardcopy of Attachment 1 in each carton of your return shipment for immediate processing.
   c. Mark "RECALL" on the outside of the returned cartons.
4. Retain a copy of your Inventory Return Certification and product return forms for your records in the event of a compliance audit of your facility.
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,

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ATTACHMENT 1

Inventory Return Certification Form

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: LactoSorb RapidFlap

Field Action Reference: ZFA2019-00009

Please return the affected product to the appropriate address below with a spreadsheet containing item number, lot number, and quantity:

Biomet Global Supply Chain Center B.V.
Hazeldonk 6530
Dock 20 Breda
4836 LD, Netherlands

This is the final return for the entire territory. An exhaustive search has been performed for the affected products.	Check one of the following:	
	Yes ☐	No ☐

Note: Any product not returned or found in your territory is considered consumed/lost and unavailable for use.

☐ **Credit My Account** ☐ **Send a Replacement**

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.netherlands@zimmerbiomet.com.

Certificate of Acknowledgement:

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

Printed Name:_____ **Signature:** _____

Title:_____ **Tel:** ( )_____ **Ext.**_____ **Date:** _____

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.netherlands@zimmerbiomet.com. Include a copy of this completed form with your product returns.

Please do not return affected product with other returns.