19 May, 2020

To: Hospital and Surgeons

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

Affected Product: Anaverse Glenoid Liner

Field Action Reference: ZFA 2020-00041

Item Number	Description	Lot Number
01.04440.011	Anaverse Glenoid Liner XS	All lots; Please refer to **Attachment 2** for the full list of lot numbers.
01.04440.012	Anaverse Glenoid Liner S	
01.04440.013	Anaverse Glenoid Liner M	
01.04440.014	Anaverse Glenoid Liner L	

Zimmer GmbH is conducting a medical device Field Safety Corrective Action (Removal) for Anaverse Glenoid Polyethylene (PE) Liner following certain product complaints on intra-operative difficulties of assembling the PE Liner with the base plate and post-operative disassociation of the PE Liner. Zimmer GmbH is investigating the root cause of the reported events. Preliminary data suggest the cause is multi-factorial. As a precautionary measure Zimmer GmbH decided to remove the product from the market.

The Anaverse Glenoid System is intended for long-term uncemented implantation into the human shoulder joint in primary (anatomical or reverse), or conversion total shoulder arthroplasty. The Polyethylene Liner is a component used exclusively in the anatomical configuration of Anaverse Glenoid System. The Anaverse Glenoid System is indicated for conversion from an anatomical to a

reverse configuration upon fulfilment of each of the requirements as emphasized in the applicable Surgical Technique and Instruction for Use.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Clinically significant extension of surgery	*Clinically significant extension of 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	*Revision Surgery*

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between January 2019 and March 2020 (Local deployment may differ).

Hospital 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 fieldaction.emea@zimmerbiomet.com. This form must be returned even if you do not have any 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.

Surgeon Responsibilities:

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this field action that are recommended beyond your existing follow-up schedule.
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 any 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.

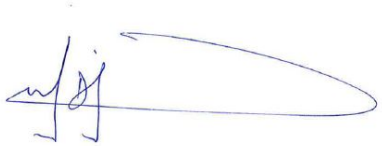
Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing winterthur.per@zimmerbiomet.com or to your local Zimmer Biomet contact.

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,



Said Djaouat
VP EMEA QARC

ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Anaverse Glenoid Liner

Field Action Reference: ZFA 2020-00041

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

☐ The potentially affected products which are unavailable for return have been:

☐ implanted ☐ 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:** _____

City:_____ **ZIP:**_____ **Country:**_____

ZIMMER BIOMET

ATTACHMENT 2

Affected Product List

Item Number	Description	Lot number		Item number	Description	Lot Number	
01.04440.011	Anaverse Glenoid Liner XS	2977478	3014540	01.04440.012	Anaverse Glenoid Liner S	2977479	3002133
		2980442	3016217			2980090	3008927
		2984902	3016218			2984779	3010265
		2990755	3017817			2986237	3012187
		2992346	3016212			2990603	3012977
		2993144	3019293			2991234	3015903
		2993477				2991840	3016214
		3001051				2993143	3016219
		3007009				2993054	3016222
		3009654				2993170	3019294
		3011261				3000373	
01.04440.013	Anaverse Glenoid Liner M	2977500	3009184	01.04440.014	Anaverse Glenoid Liner L	2977501	3004794
		2980089	3011088			2979705	3009186
		2984901	3012186			2982185	3011260
		2986238	3015912			2985836	3014542
		2989189	3016213			2986916	3016215
		2992347	3016220			2990754	3016221
		2991495	3017816			2992215	3019863
		2993142	3016216			2993141	3020729
		2993171	3019292			2993172	
		3000372	3023275			2999118	
		3004793				3003519	