ZIMMER BIOMET

26 November 2020

To: Hospital and Surgeons

Subject: **FOLLOW-UP ZFA 2020-00041 -**
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	

In May 2020, as a precautionary measure Zimmer GmbH initiated a medical device Field Safety Corrective Action (Removal) for Anaverse Glenoid Polyethylene (PE) Liner following certain product complaints of intra-operative difficulties assembling the PE Liner with the Baseplate, and post-operative disassociation of the PE Liner. Following the Field Safety Notice (FSN), Zimmer GmbH completed the removal of these products and initiated a root cause investigation. This follow-up letter provides the current rate of post-operative disassociation, an update on our investigation, and additional information for you when treating your patients who received this product.

The current rate of post-operative disassociation of the PE-Liner is approximately 14.35%.

The investigation into the potential causes of the PE Liner disassociation has made significant progress since the initiation of the FSN, and Zimmer GmbH has decided to assess potential design updates pertaining to the locking feature(s) that are intended to enhance stability between the PE Liner and the Baseplate.

As a reminder, the PE Liners associated with this FSN are components used exclusively in the anatomical configuration of the Anaverse Glenoid System. There is currently not a PE Liner in the anatomical configuration available should a revision surgery be necessary, and an estimated availability date for new PE Liners has not been determined at this time. Given this, the following guidance is being provided regarding the follow-up and treatment of patients that have the anatomical configuration of the Anaverse Glenoid System.

Patient Follow Up and Treatment Guidance

While the decision on any medical treatment is at the discretion of the surgeon and patient, Zimmer GmbH is providing this guidance based on the information we have at this time and in consultation with surgeons familiar with this product.

It is recommended to ensure regular follow-up with all patients who have the Anaverse Glenoid PE Liner implanted. We recommend a protocol for consultation with the patient at 3 month intervals in the first year and then subsequently at 6 month intervals. Even if a patient reports no issues with their shoulder at follow-up, it is recommended to encourage them to contact their treating surgeon immediately should this change.

Based on the disassociations that have occurred, affected patients generally started out well and then experienced sudden onset of pain as well as reduced strength, limited range of motion, irregular noises in the shoulder joint, or a feeling of dislocation of the joint. In some cases, the pain went away before ultimately returning and it is suspected that this may have been due to the PE Liner subluxating and relocating before dissociating from the Baseplate.

If a patient reports current or past issues outside of typical recovery pain, it is recommended that they be further assessed radiographically to analyze the joint space and detect possible subluxation to confirm disassociation. A CT-arthrogram is another imaging option to potentially detect any change in the joint, as well as to support a potential revision strategy.

After confirmation of disassociation or instability of the liner, revision surgery and conversion to Anaverse reverse is recommended under the condition that the Baseplate is undamaged, well fixed, correctly positioned and aligned. The Anaverse system is designed for conversion from the anatomical to the reverse configuration and conversion can be completed by using the respective surgical technique. Approximately 75% of the reported revision surgeries involved conversion to the Anaverse reverse with positive outcomes reported. If a patient should refuse conversion to an Anaverse reverse, revision to a Hemi-arthroplasty is preferred to the use of a cemented glenoid prosthesis.

We recognize the challenges that this FSN poses to you and your patients. Please feel free to contact your Zimmer Biomet representative with any questions or concerns after reviewing this FSN.

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,

Francis Moloney, VP QA/RC EMEA

ATTACHMENT 1
Certificate of Acknowledgement

FOLLOW-UP ZFA 2020-00041 - 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

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:**_____

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	