April 12, 2019

To: Surgeon/ Hospital

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

Reference: **ZFA 2019-00074**

Affected Product: **Alpha Durasul Inlay GG/32 (Hip)**

Item Number	Lot Number
01.00013.407	2975251

Picture 1: View of the deformed blister

Zimmer GmbH is conducting a medical device Field Safety Notice (Removal) for one lot of Alpha Durasul Inlay due to a potentially deformed blister. Zimmer Biomet received one complaint with this issue. An investigation identified that the deformation was due to excessive heat during the shrinking packaging process. Any product demonstrating this deformed packaging should not be used.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	The deformed blister is detected prior use. A replacement device is made available and surgery is completed with a replacement device (< 30min).	*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	*An insertion of a potentially deformed PE implant from a deformed packaging where the integrity of the sterile packaging due to deformation might be impacted can lead to further surgical intervention due to potential infection / loosening.*

Our records indicate that you may have received one or more of the possible affected products. The pieces were manufactured in December 2018 and deployed from December 2018 till Beginning of March 2019 (local deployments might differ).

Surgeon/ 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.

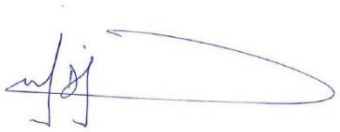
Other Information
This medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices as per MEDDEV 2.12-1 in Europe.

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,



Said Djaouat
VP EMEA QARC

ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: **Alpha Durasul Inlay GG/32 (Hip)**

Field Action Reference: **ZFA 2019-00074**

Please return the completed form to your Zimmer Biomet contact person or by e-mail
fieldaction.emea@zimmerbiomet.com

☐ I received and understood the Field Safety Notice.

Regarding the parts:

☐ All inventories for the affected parts have been checked and following parts are to be returned:

Item Reference	Lot Number	Number of parts returned

OR

☐ The affected products which are unavailable for return have been used

By signing below, I acknowledge that the required actions have been taken in accordance with the Field Safety Notice.

Hospital Facility

Printed Name: _____ **Signature:** _____ **Date:**____/____/____

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

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

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