June 11, 2019

To: Hospitals

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

Reference: **ZFA2019-00103**

Affected Product: Biolox Hip Option Taper Adapter

Product Description	Item Number	Lot Number	UDI Number
Taper Adapter	650-1060	2958900	05019279354191
Taper Adapter	650-1064	2959032	00887868248658
Taper Adapter	650-1065	2959089	00887868248665
Taper Adapter	650-1066	2959122	00887868248672
Taper Adapter	650-1066	2959155	00887868248672
Taper Adapter	650-1068	2955132	00880304521902
Taper Adapter	650-1068	2961014	00887868248696

Table1: List of affected products

Biomet UK Ltd. is conducting a medical device Field Safety Corrective Action (removal) for specific lots of Biolox Hip Option Taper Adapters (indicated in table 1) due to non CE-certified and marked items shipped to countries with CE marking requirements. The lack of CE marking is readily detectable on the product's label and instructions 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
	None	*Delay or extension (<30 minutes) to surgery to locate a replacement implant.*
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	*None*

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between November 2018 and February 2019 (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.netherlands@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 per.nl@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
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Biolox Hip Option Taper Adapter

Field Action Reference: ZFA 2019-00103

Please return the completed form to your Zimmer Biomet contact person: fieldaction.netherlands@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

OR

○The affected products which are unavailable for return have been: ○used ○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.netherlands@zimmerbiomet.com