ZIMMER BIOMET

07 November 2023

To: Hospitals

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

Affected Product: Biolox® Option Head

Material / Item Number	Material / Item Description	Batch / Lot Number	UDI Number
00-8777-040-01	Biolox Option, head, S, Ø 40/-3.0, taper 12/14	3145299	(01)00889024430556(17)330302(10)3145299
00-8777-040-02	Biolox Option, head, M, Ø 40/0, taper 12/14	3145300	(01)00889024430563(17)330302(10)3145300

Figure 1: Adapter with neck length S/-3.0

Figure 2: Adapter with neck length M/+0

As a precautionary measure, Zimmer GmbH is conducting a medical device Field Safety Corrective Action for two batches/lots of the Biolox Option Head due to a potential commingle. One product complaint was received reporting that there was an incorrect adapter in the packaging. An adapter with neck length M/+0 was inside the product packaging, which should have contained an adapter with neck length S/-3.0. The difference in neck length may be recognized by the size (S or M) indicator on the device.

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 insignificant extension of surgery.	Clinically insignificant extension of surgery, exposure to anesthesia.
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.	Potential minor pain or discomfort due to 3 mm. longer neck length, or potential minor instability due to 3 mm. shorter neck length, which may not necessarily require further surgical intervention.

Our records indicate that you may have received one or more of the affected products. The affected units were distributed in March 2023. Local distribution may differ.

ZIMMER BIOMET

Hospital Responsibilities

1. Review this Field Safety Notice and ensure that your affected personnel, including surgeons, are made aware of the contents.
   a. There are no specific patient monitoring instructions related to this Field Safety Corrective Action that are recommended beyond your existing follow-up schedule.
2. If you have affected product(s) at your facility, immediately locate and quarantine affected product(s) in your inventory and assist your Zimmer Biomet sales representative with amongst others the return of the affected product(s).
3. If you have distributed affected product(s) further, provide your customers with this Field Safety Notice and ensure documentation.
4. Complete **Attachment 1 – Certificate of Acknowledgement** and send it to fieldaction.gscc@zimmerbiomet.com. This form must be returned even if you do not have affected product(s) available to return from your facility.
5. Retain a copy of your **Attachment 1 – Certificate of Acknowledgement** and product return forms for your records in the event of a compliance audit of your facility.
6. If you have further questions or concerns after reviewing this Field Safety Notice, please contact your local Zimmer Biomet representative.

Other Information

This Field Safety Corrective Action was reported to all relevant Competent Authorities and Notified Bodies as required under the applicable regulations for Medical Devices per MEDDEV 2.12-1 in Europe. The undersigned confirms that this Field Safety Notice has been delivered to the appropriate Regulatory Agencies.

Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing ProductComplaintGSCC@zimmerbiomet.com.

We would like to thank you for your co-operation in advance and regret any inconvenience caused by this Field Safety Corrective Action.

Sincerely,

Persoonsgegevens

ZIMMER BIOMET

ATTACHMENT 1 - Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Biolox® Option Head
Field Safety Corrective Action Reference Number: ZFA2023-00237

Do you have affected product in your facility? Please mark the appropriate response.

☐ Yes, we currently have one or more affected items in our facility.

☐ No, we currently have no affected items in our facility.

Note: Any product not available for return is considered dispositioned at your location and unavailable for use.

All products that are not available for return have been implanted or used:

☐ Yes ☐ No ☐ Unknown

Complete the table below for all affected products returned. If additional space is needed, please provide a spreadsheet and return it to fieldaction.gscc@zimmerbiomet.com with this form. **Do not return products with other returns.**

Material/Item Number	Batch/Lot Number	Returning Quantity
00-8777-040-01	3145299	
00-8777-040-02	3145300	

Hospital acknowledgement

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

Printed Name: _____ **Signature:** _____

Title: _____ **Tel. No.:** _____ **Date:** _____

Hospital Name: _____

Hospital Address: _____

City: _____ **Country:** _____ **ZIP/Post Code:** _____