ZIMMER BIOMET

11th March 2020

To: Hospitals

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE – REMOVAL - LOT SPECIFIC**

Affected Product: Biolox® Delta Modular Ceramic Heads

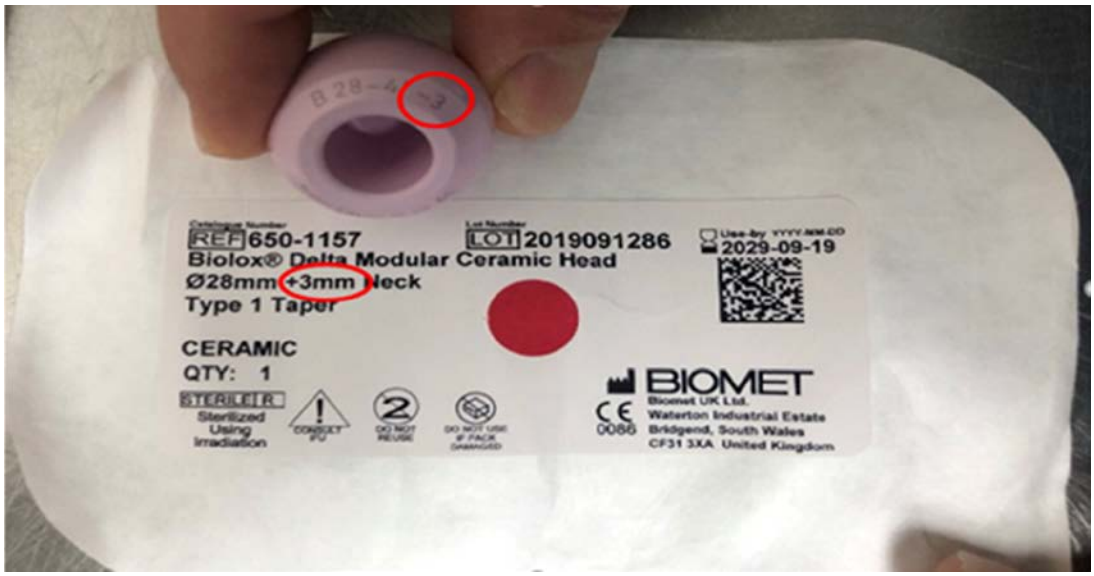
Item Number	Lot Number	Description
650-1157	2019091286	DELTA CER FEM HD 28/+3MM T1
650-1159	2019091306	DELTA CER FEM HD 28/-3MM T1
650-1159	2019091307	DELTA CER FEM HD 28/-3MM T1

Reference: **ZFA 2020-00040**

Item Number	Lot Number	UDI
650-1157	2019091286	(1)05019279456932(17)290919(10)2019091286
650-1159	2019091306	(1)05019279466956(17)290919(10)2019091306
650-1159	2019091307	(1)05019279456956(17)290919(10)2019091307

Biomet UK Ltd is conducting a medical device Field Safety Corrective Action (removal) for the above three lots of Biolox® Delta Modular Ceramic Heads.

A product complaint investigation revealed that the above batches may contain items of which the neck length on the product label does not match with the engraving on the device.



It is expected that the most probable outcome is that prior to the surgery the surgeon will notice the difference in the engraving denoting the neck length to that on the labelling of the device causing delay to surgery whilst an alternative device is obtained.

There is also a less likely possibility that the difference in the engraving to that on the labelling of the device is not be noticed by the surgeon and the item is implanted leading to a leg length discrepancy.

It would be expected that a check of leg length is conducted before the completion of surgery, which offers an opportunity for the surgical staff to identify the issue and mitigate the risk of the highest severity event.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Extension to surgery <30 mins to obtain replacement device	*Extension to surgery >30 mins to obtain replacement device*
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 to rectify leg length discrepancy*

Our records indicate that you may have received one or more of the affected products. The units were distributed from October 2019 (local deployment may be different).

Hospital Responsibilities:

1. Review this notification and ensure that affected personnel are aware of the contents.
2. If you have affected products at your facility, assist your Zimmer Biomet sales representative and quarantine all affected products. Your Zimmer Biomet sales representative will remove the affected products 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.

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.netherlands@zimmerbiomet.com.
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 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. Your urgent cooperation is needed.

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

Thank you for your assistance. We regret any inconvenience 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® Delta Modular Ceramic Heads

Field Action Reference: ZFA 2020-00040

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

Reference	Lot Reference	Number of parts returned

OR

The affected products which are unavailable for return have been: implanted discarded lost other:

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

Printed Name:_____ **Signature:** _____

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

Facility Name: _____

Facility Address: _____

City:_____ **Postcode:**_____

Country: _____

Note: This form will be returned to Zimmer Biomet before this action is closed for your account. It is important that you complete this form and email a copy to fieldaction.nl@zimmerbiomet.com.