ZIMMER BIOMET
Your progress. Our promise.

FIELD SAFETY CORRECTIVE ACTION

DATE: **29th March 2016**

SUBJECT: **Biolox Delta Ceramic Head 32mm Standard Neck type 1 taper**
REF **650-1162**
LOT **2015051327, 2015051328, 2015051329, 2015051214**

SUBJECT: **Biolox Delta Ceramic Head 36mm Standard Neck type 12/14 taper**
REF **650-0837**
LOT **2015051321**

Dear Customer,

Our records show that Biomet UK Ltd has supplied you with a **BIOLOX DELTA CERAMIC HEAD** of the above reference/lot number combination. We are requesting that you immediately locate and discontinue use of any implants with the above reference/lot number.

Biomet UK Ltd is issuing this FIELD SAFETY CORRECTIVE ACTION to make users aware of this issue and request them to immediately return the affected implants to their local Zimmer Biomet distributor. Further details are in the attached FIELD SAFETY NOTICE.

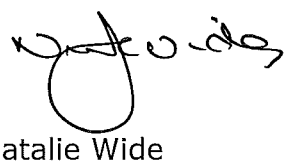
Please distribute this Field Safety Notice immediately to the appropriate people within your hospital.

Please complete and return without delay the attached "Fax-Back Response Form" acknowledging receipt of this letter and the attached FIELD SAFETY NOTICE and indicating the quantity of product you wish to return.

Phone:- 0044 1656 761678 Fax :- 0044 1656 645454

E-Mail:- uk.complaints@zimmerbiomet.com www.biomet.com

Yours sincerely,



Natalie Wide
QA/RC Director UK
Biomet UK Ltd

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FIELD SAFETY CORRECTIVE ACTION

DATE: 29th March 2016

SUBJECT: Biolox Delta Ceramic Head 32mm Standard Neck type 1 taper

REF 650-1162

LOT 2015051327, 2015051328, 2015051329, 2015051214

SUBJECT: Biolox Delta Ceramic Head 36mm Standard Neck type 12/14 taper

REF 650-0837

LOT 2015051321

FOR THE ATTENTION OF THE HEADS OF ORTHOPAEDIC DEPARTMENTS /OPERATING DEPARTMENTS / STERILE SERVICES DEPARTMENTS/ PROCUREMENT / SUPPLIES / RISK MANAGEMENT

This notice is to inform you of an URGENT FIELD SAFETY CORRECTIVE ACTION that has been initiated by Biomet UK Ltd which involves the BIOLOX DELTA CERAMIC HEAD implants referenced above. Our records show that the implants may have been distributed to your hospital. We are requesting that you immediately locate and discontinue use of any implants with the above listed reference/lot number combinations.

The ceramic heads are designed to be used with Biomet femoral stems in total hip joint replacement surgery procedures comprising of a ceramic femoral head component articulating against either a ceramic insert fitted into a cementless acetabular shell or against ultra-high molecular weight polyethylene (UHMWPE) cups.

Biomet UK Ltd has initiated this action following an investigation that has revealed that a product packaging labelled as Biolox Delta Ceramic Head 36mm Standard Neck type 12/14 taper (reference 650-0837/lot no. 2015051321) contained a Biolox Delta Ceramic Head 32mm Standard Neck type 1 taper, reference 650-1162 with serial number 5064122 engraved.

Review of internal records revealed that the Biolox Delta Ceramic Head 32mm Standard Neck type 1 taper with serial number 5064122 engraved, is used for the manufacturing of several lot numbers of reference 650-1162 Biolox Delta Ceramic Heads 32mm Standard Neck type 1 taper. The lot numbers 2015051327, 2015051328, 2015051329, 2015051214 were manufactured at at the same time as the Biolox Delta Ceramic Head 36mm Standard Neck type 12/14 taper (reference 650-0837/lot no. 2015051321).

As it cannot be determined based on current available data which of the above 4 listed lots of the Biolox Delta Ceramic Head 32mm Standard Neck type 1 taper, reference 650-1162 contains a Biolox Delta Ceramic Head 36mm Standard Neck type 12/14 taper (reference 650-0837/lot no. 2015051321) Biomet UK ltd decided to recall all above listed lots as a precautionary measure.

Due to the ceramic heads having different size/angle tapers as well different head diameters, it is highly likely that this issue would be detected by the surgeon and theatre staff upon opening the box and checking the Biolox Delta Ceramic head. In the unlikely event that it is not identified during the box opening process then the taper would not be compatible with the stem and the head would not fit to the liner correctly which would be very obvious to the surgeon. The most likely effect is therefore considered to be a delay to surgery whilst the surgeon sources another ceramic head.

PLEASE TAKE DUE NOTICE OF THE REMAINING INFORMATION FOR AN EXPLANATION OF THIS NOTICE:

What you need to do

1. To assist us with this action, please ensure that the operating staff are made aware of this matter without delay and that all the affected products are withdrawn from use at your facility as soon as possible.

2. Complete and return the attached "Response Form" to Biomet UK Ltd or to your local Zimmer Biomet Distributor. This confirms the fact that you have received and understand the attached FIELD SAFETY NOTICE, informed relevant theatre staff and have physically checked all inventory and hospital locations.

3. If you identify any item(s) from the affected products, you will need to indicate the quantity you have available for return, the affected products then need to be returned to Biomet UK Ltd or to your local Zimmer Biomet Distributor as soon as possible, you must ensure you complete the attached response form and return it to Biomet UK Ltd or to your local Biomet Distributor as soon as possible.

Please accept our sincere apologies for any inconvenience caused by this action.

If you have any questions please contact the Biomet U.K. complaints department.

Phone:- 0044(0) 1656 761678
Fax :- 0044(0) 1656 645454
E-Mail:- uk.complaints@zimmerbiomet.com www.biomet.com

Yours sincerely

Natalie Wide
QA/RC Director UK
Biomet UK Ltd

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RESPONSE FORM

We would appreciate it if you return this form within 3 business days to one of the following:

- **Address: Complaints Department, Biomet UK Ltd, Waterton Industrial Estate, Bridgend, CF31 3XA.**
- **Fax: to +44 (0)1656 645454**
- **Email:** uk.complaints@zimmerbiomet.com

Regulatory Action#:	HHE 2016-001
Description:	Biolox Delta Ceramic Head
Catalogue Number:	650-1162 650-0837
Lot Code:	2015051327, 2015051328, 2015051329, 2015051214 2015051321

PLEASE TICK APPROPRIATE SECTION

- o WE HAVE PHYSICALLY CHECKED ALL INVENTORY AND HOSPITAL LOCATIONS, AND WE DO NOT HAVE THE AFFECTED PRODUCT.

- o WE HAVE SOME OF THE ITEMS REFERENCED IN THE ENCLOSED LETTER. WE WILL BE RETURNING THE FOLLOWING ITEMS:

PRODUCT CODE	LOT CODE	QTY

If the product cannot be returned, please indicate below whether it was implanted, destroyed, not located, etc.

Please sign and return this form to acknowledge receipt of product notice.

Name of Hospital/ Organisation:		**Address:**
Contact Name:		
Contact Title:		
Contact Signature:		
Contact Phone No:		**Date:**