



FIELD SAFETY CORRECTIVE ACTION

DATE: 15 April 2014

SUBJECT: Biolox Delta Ceramic Head 36mm Standard

REF: 650-0837

Lot: 3262589

**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 implant 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 the implant.

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 the product packaging labelled as 650-0837 – Biolox Delta Ceramic Head 36mm Standard Neck Lot: 3262589 contains item 650-0836 - Biolox Delta Ceramic Head 36mm -4mm Neck.

The incorrectly packaged item would NOT be immediately recognizable by the surgeon/theatre staff. A delay could occur whilst an alternative item is sourced. If an alternative item was not available the surgeon would not be able to complete the procedure.



**650-0837 Correct item
marked 36-12/14 M**



**650-0836 Incorrect item
marked 36-12/14 S**

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

What you need to do

1. Ensure all relevant Hospital staff are given relevant awareness training relating to this possible packaging error and are fully informed of the matter.
2. To assist us with this action, please ensure that the operating staff are made aware of this issue without delay and that all the affected implants are identified and withdrawn from use at your facility as soon as possible.
3. Complete and return the attached "Response Form" to Biomet UK Ltd or to your local Biomet Distributor. This confirms the fact that you have received and understand the attached FIELD SAFETY CORRECTIVE ACTION Notice, informed relevant theatre staff and have physically checked all inventory and hospital locations.
4. If you identify any item from the suspect item/batch combination, you will need to indicate the quantity you have available for return, the items then need to be returned to Biomet UK Ltd or to your local Biomet Distributor as soon as possible, you must ensure you complete the attached Fax-Back response form and return it to Biomet UK Ltd or to your local Biomet Distributor as soon as possible.

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

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

Phone:- 0044 1656 761678

Fax :- 0044 1656 645454

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

Yours sincerely



Richard Young,
UK Director of RA/QA
Biomet UK Ltd



RESPONSE FORM

Biomet Reference Number:	HHE2014-007
Description:	Biolog Delta Ceramic Head 36mm Standard
Catalogue Numbers:	650-0837
Lot Codes:	3262589

PLEASE TICK APPROPRIATE SECTION:

- ☐ WE CONFIRM ALL RELAVENT STOCK HAS BEEN PHYSICALLY CHECKED
- ☐ WE HAVE IDENTIFIED THE RELAVENT ITEMS IN OUR STOCK AND WOULD LIKE TO RETURN THE BELOW PARTS FOR REPLACEMENT, DETAILS TO BE LISTED BELOW.
- ☐ WE CONFIRM THAT ALL RELAVENT STOCK HAS BEEN CHECKED AND THAT THEY DO NOT CONTAIN THE AFFECTED ITEMS.

<u>ITEM NUMBER and LOT NUMBER</u>	<u>QTY</u>

Please sign and return this form to acknowledge receipt of this Field Safety Notice.

Name and Address:	
Contact Name:	
Contact Title:	
Contact Signature:	
Contact Phone No:	
Date:	

We would appreciate it if you return this form within 3 business days to:

- **Biomet UK Ltd, Waterton Industrial Estate, Bridgend, CF31 3XA**
- **E-Mail:- uk.complaints@biomet.com**
- **Fax: +44 (0) 1656 645454**