



FIELD SAFETY CORRECTIVE ACTION

DATE: 20th January 2015
SUBJECT: Biolox Delta Ceramic Head 36mm -4mm Neck
REF: 650-0836
Lot: 3262574 & 3262576

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 the implants with the above lot numbers.

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 one **DELTA CERAMIC HEAD** may not be in a sterile condition as the inner pouch and blister seals have been broken.

It is likely that the theatre staff would notice that the device was not properly packaged and as a consequence discard the device and use another head. The instructions for use Ref: 5401000257 packaged with the item indicate :- The packages should be inspected for damage or flaws in the sterile barrier before opening. Product should be assumed to be non- sterile if the packaging is damaged. Do not use if packaging is damaged. Surgery could be delayed as the surgeon would need to source another head or, if the issue was not identified then there would be an increased risk to the patient of infection.



Item shown with opened inner pouch

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the operating staff are made aware of this issue without delay and that all the affected implants are identified and withdrawn from use at your facility as soon as possible.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



Natalie Wide
QA/RC Director UK
Biomet UK Ltd



RESPONSE FORM

Biomet Reference Number:	HHE2014-014
Description:	Bilox Delta Ceramic Head 36mm
Catalogue Numbers:	650-0836
Lot Codes:	3262574, 3262576

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 NUMBERS</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**