



FIELD SAFETY CORRECTIVE ACTION

DATE: 5th January 2015

SUBJECT: **Bilox Delta Ceramic Head 28mm -3.5mm Neck (Catalogue No. 650-0830/Lot no. 3256398) mixed with Bilox Delta Ceramic Head 28mm Standard Neck (Catalogue No. 650-0831/Lot 3243206).**

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 referenced lot numbers.

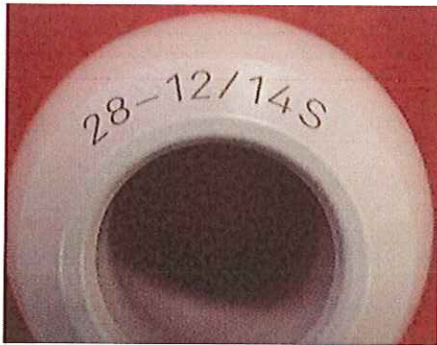
The Ceramic heads are designed to be used with Biomet femoral stems in total hip joint replacement surgery procedures comprising of a ceramic femoral head component articulating against either a ceramic insert fitted into a cementless acetabular shell or against ultra-high molecular weight polyethylene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

Biomet UK Ltd has initiated this action following an investigation that has revealed a product packaging labelled as **650-0830 Bilox Delta Ceramic Head 28mm - 3.5mm Neck Lot: 3256398** contains item **650-0831 Bilox Delta Ceramic Head 28mm Standard Neck Lot 3243206.**

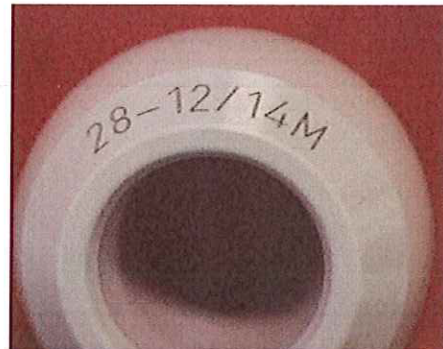
The incorrectly packaged item would NOT be immediately recognizable by the surgeon/theatre staff. A delay could occur whilst an alternative item is sourced. If an alternative item was not available the surgeon would not be able to complete the procedure.

While the reported difference in neck length is 3.5mm the actual discrepancy in offset for a typical hip stem would be in the order of 2.5mm due to the neck angle of the stem. In addition any insufficiency in joint stability would likely be assessed by the surgeon at the time of surgery as it is a routine surgical procedure for each hip surgery.

The overall risk is therefore deemed negligible if the incorrectly packaged item would be implanted.



**650-0830 item
is marked 28 -12/14 S**



**650-0831 item
is marked 28 - 12/14 M**

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/ lot combinations, 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



QA/RC Director UK
Biomet UK Ltd



RESPONSE FORM

Biomet Reference Number:	HHE2014-012
Description:	BioloX Delta Ceramic Head
Catalogue Numbers:	650-0830 and 650-0831
Lot Codes:	3256398 and 3243206

PLEASE TICK APPROPRIATE SECTION:

- WE CONFIRM ALL RELEVANT STOCK HAS BEEN PHYSICALLY CHECKED
- WE HAVE IDENTIFIED THE RELEVANT ITEMS IN OUR STOCK AND WOULD LIKE TO RETURN THE BELOW PARTS FOR REPLACEMENT, DETAILS TO BE LISTED BELOW.
- WE CONFIRM THAT ALL RELEVANT 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**