BIOMET

FIELD SAFETY CORRECTIVE ACTION

DATE: 17 February 2014

SUBJECT: Exceed Shell

REF: 131358

Lot: 3194397

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 EXCEED SHELL 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 Exceed acetabular shells are compatible with a range of Biomet's polyethylene liners and are secured into the acetabular shell via a locking ring which is pre-assembled in the shell for use in hip replacement surgery.

An investigation has revealed that the affected lot has possibly been manufactured without the required locking ring.

It is very likely that the surgeon will notice that the locking ring is missing prior to surgery as he / she will be listening for an audible click as evidence that the poly liner engages with the locking ring / shell. If the locking ring is missing, the surgeon would either have to remove a ring from another shell (if available), or undertake surgical intervention by removing the implanted shell (if implanted) and re-reaming the acetabulum to fit a larger sized shell.

Shell and locking ring

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 missing locking ring 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the operating staff are made aware of this issue without delay and that all the affected implants are identified and withdrawn from use at your facility as soon as possible.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 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 761658
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

BIOMET

RESPONSE FORM

Biomet Reference Number:	**HHE2014-003**
Description:	**Exceed Shell**
Catalogue Numbers:	**131358**
Lot Codes:	**3194397**

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.

IIEM NUMBER and LOT NUMBER	**QTY**

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**
- **Fax: +44 (0) 1656 645454**
- E-Mail:- uk.complaints@biomet.com