

FIELD SAFETY CORRECTIVE ACTION

DATE: 12th February 2015
SUBJECT: Mallory Shell
REF /LOT 11-104048 :- 3419528
REF: /LOT 11-104054 :- 3417749

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 **MALLORY SHELL** 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 number

The Mallory-Head porous acetabular shell is made from titanium alloy and is hemispherical in shape, allowing a uniform transfer of forces to the bone throughout the acetabular vault.

The shell design has a threaded apical hole to allow attachment to a handle during fixation, after implantation an apical plug is used to close the threaded hole this reduces the potential for debris migration.

Biomet UK Ltd has initiated this action following an investigation that indicated certain products were supplied without an apical plug.

As a result there is potential for implantation of the Mallory shell without the apical plug or for a minimal delay in surgery whilst a replacement plug is sourced from another Mallory shell or as an individual product. Without an apical plug the Mallory shell will no longer provide a complete solid barrier to any wear particle migration.



Mallory shell without the apical plug

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that the operating staff are made aware of this matter without delay and that all the affected products identified are withdrawn from use at your facility as soon as possible.
2. Complete and return the attached "Fax-Back 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 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 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 sincere apologies for any inconvenience caused by this action.

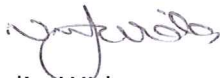
If you have any questions please contact the Biomet U.K. complaints department.

Phone:- 0044(0) 1656 761678

Fax :- 0044(0) 1656 645454

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

Yours sincerely



Natalie Wide
QA/RC Director UK
Biomet UK Ltd



FAX BACK RESPONSE FORM

Biomet Reference Number:	HHE2015-002
Description:	Mallory Shells
Ref / Lot(s)	11- 104048 :- 3419528
Ref / Lot(s)	11-104054 :- 3417749

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 PRODUCTS FOR REPLACEMENT, DETAILS TO BE LISTED BELOW.
- WE CONFIRM THAT ALL RELEVANT STOCK HAS BEEN CHECKED AND THAT THEY DO NOT CONTAIN THE AFFECTED PRODUCTS.

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