BIOMET

One Surgeon. One Patient.

FIELD SAFETY CORRECTIVE ACTION

DATE: 1st August 2014

SUBJECT: M-H 6 HOLE SHELL HA/PC DIA54MM LN24

REF: 103854

Lot: 3072321

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 **FIELD SAFETY CORRECTIVE ACTION** that has been initiated by Biomet UK Ltd which involves the M-H 6 Hole Shell HA/PC implant referenced above. Our records show that the above implants may have been distributed to your hospital. We are requesting that you locate and discontinue use of the implant referenced above.

The Mallory Head HA/PC acetabular shell is intended to be used as an uncemented acetabular component used as part of a total hip replacement. The HA coating is intended to enhance the bone growth into the porous coat layer of the acetabular implant.

Following a complaint, Biomet UK Ltd. has initiated an investigation that has revealed the certain M-H 6 Hole Shell HA/PC Shells have been manufactured without the pre-defined HA coating.

A customer that is not familiar with the HA Coated Mallory-Head Shell would not easily recognise that the implant has been manufactured without the required HA coating. No adverse health outcome is expected as the shells have the required porous coating for fixation.

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 matter and are fully informed.

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the operating staff are made aware of this issue without delay and that all the affected implants are identified and withdrawn from use at your facility as soon as possible.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 Castaneda
UK Quality and Regulatory Compliance Director
Biomet UK Ltd