



FIELD SAFETY CORRECTIVE ACTION

DATE: 23rd March 2015
SUBJECT: Oxford Tibial Tray
REF 166578
LOT 3468125

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 **OXFORD TIBIAL TRAY** 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 any implants with the above reference and lot number.

The Oxford Partial Knee System - is intended for use in primary reconstructive knee joint surgery, in patients with osteoarthritis or avascular necrosis limited to the medial compartment, where the anterior and posterior cruciate ligaments are intact. The Hydroxyapatite (HA) coating is intended to enhance the bone growth into the Porous Plasma Spray (PPS) coat layer of the tibia component. Hydroxyapatite is applied to provide an osteoconductive surface that has been shown through various studies to 'promote' gap filling between bone and implant.

Biomet UK Ltd has initiated this action following an investigation that has revealed the product referenced above was manufactured without the pre-defined HA coating processes being completed.

Although no adverse health outcome is expected as a result of the missing HA coating as the tibia trays have the required PPS coating applied for fixation, there is potentially an increased risk of biological reactions and compromised bone attachment as the components have not been through the required HA preparation processes. However, please note that the involved components have been through a passivation stage and subsequently undergone a gamma sterilization process.

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that the operating staff are made aware of this matter without delay and that all the affected products identified are withdrawn from use at your facility as soon as possible.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

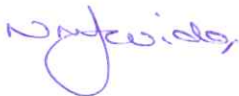
If you have any questions please contact the Biomet U.K. complaints department.

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:	HHE2015-006
Description:	Oxford Tibial Tray
Ref	166578
Lot	3468125

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**