



FIELD SAFETY CORRECTIVE ACTION

DATE: 3 February 2014

SUBJECT: RHK Femoral Components

REF: 154975, 154976, 154978 & 154979

Lot: See attached list

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 ("FSCA")** that has been initiated by Biomet UK Ltd which involves the RHK femoral components referenced above. Our records show that the implants involved may have been distributed to your hospital. We are requesting that you immediately locate and discontinue use of the implant.

The RHK is a rotating hinge knee system that addresses most revision or oncological indications for knee reconstruction where hinge constraint is required. The femur is linked to the tibial component by means of a hinge mechanism.

An investigation has revealed that some of above referenced RHK femoral components have not been manufactured in accordance with its pre-defined manufacturing specifications. A detailed investigation is on-going to assess its (clinical) implications. Further information will be provided to you in a separate letter after this assessment has been completed.

This FSCA affects solely the RHK femoral components with the reference/lot numbers listed above.

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 issue 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the operating staff are made aware of this issue without delay and that all the affected implants are identified and withdrawn from use at your facility as soon as possible.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 affected reference/ 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, and 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

A handwritten signature in black ink, appearing to read "P.P. Rogers". The signature is written in a cursive style with a large initial "P" and "R".

Richard Young,
UK Director of RA/QA
Biomet UK Ltd



RESPONSE FORM

Biomet Reference Number:	HHE2014-002
Description:	RHK Femoral Components
Catalogue Numbers:	154975,154976,154978, 154979
Lot Codes:	Various (see attached list)

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

<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:

- E-Mail:- uk.complaints@biomet.com
- Biomet UK Ltd, Waterton Industrial Estate, Bridgend, CF31 3XA
- Fax: +44 (0) 1656 645454

HHE2014-002

RHK Femoral Components

Ref: 154975

Lot: 2829414, 2829415, 2829417, 2829418, 2829420, 2829421, 2829425, 2885573, 2885575, R2983762C, 2983763, 2983769, R2983770C, 3100777, 3100778, 3100779, 3100780, 3112728, 3112729, 3185068, 3221486, 3221487.

Ref: 154976

Lot: 3038677, 3044152, 3044153, 3100781, 3100782, 3100783, 3100784, 3100785, 3100786, 3100787, 3112731, 3112732, 3120955, 3148682, 3148683, 3182450, 3182451, 3194561.

Ref: 154978

Lot: 3033120, 3033121, 3033122, 3100788, 3100789, 3100790, 3100791, 3100792, 3100793, 3100794, 3112733, 3112735, 3112736, 3112738, 3115226, 3148685, 3194562, 3194563, 3194564, 3200810, 3200812, 3200813.

Ref: 154979

Lot: 3033129, 3033130, 3033131, 3100795, 3100796, 3100797, 3100798, 3103923, 3148689, 3200817, 3210453, 3210454.