

## **FIELD SAFETY CORRECTIVE ACTION**

**DATE:** 4<sup>th</sup> March 2016

**SUBJECT:** RHK™ Knee 16mm Bearing for 71mm, 75mm & 79mm RHK Tibial Tray

**REF** 159437

**LOT** 3339725, 3498140, 3511855, 3521016, 3527208, 3545393, 3553638, 3580815, 3586003, 3593513, 3598555.

**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 **RHK KNEE BEARING** 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 listed reference/lot number combinations.

The RHK knee system is a fully constrained hinged knee, suitable for diseased knees with absent cruciate and collateral ligaments. The weight bearing meniscal bearing has a bi-helical design which articulates on the highly polished cobalt chrome tibial tray.

Biomet UK Ltd has initiated this action following an investigation that indicated certain bearings were discovered to be etched with the incorrect end numerical suffix. The implant was etched 71-75-95 instead of the correct etching 71-75-79.



The etching above is designed to be an indicator to the surgeon of which sized tibial tray implant is compatible with that bearing.

The items in question are dimensionally conforming to predefined specification. If the surgeon notices that the etching of the RHK bearing does not match with the label on the box, he/she may decide to source another bearing which may lead to a delay to surgery. However, the involved risk is considered to be remote due to the following points. No customer complaints have been received to date for this matter.

- The applicable surgical technique confirms sizes of available RHK bearings for implantation with the available RHK tibial trays and these are referenced by part number.
- The surgeon will be aware there is no sized RHK Tibial Tray to match the etch -95.
- Tibial trialling will have confirmed which size RHK bearing to be used
- The surgeon will be aware that the incorrectly etched bearing properly matches up with the tibial at the time of implantation.

**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 "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 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.

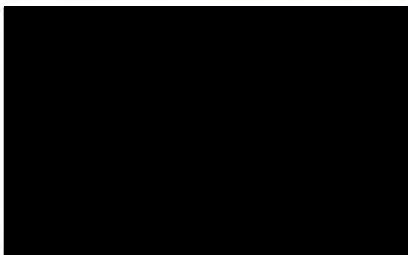
If you have any questions please contact the Biomet U.K. complaints department.

Phone:- 0044(0) 1656 761678

Fax :- 0044(0) 1656 645454

E-Mail:- [uk.complaints@zimmerbiomet.com](mailto:uk.complaints@zimmerbiomet.com)

[www.biomet.com](http://www.biomet.com)



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