

Biomet Danmark ApS  
Hattingvej 7  
DK 8700 Horsens  
Denmark

19<sup>th</sup> December 2012

## **FIELD SAFETY CORRECTIVE ACTION**

**SUBJECT:** RHK Axle, RHK Short Hinge and RHK Long Hinge Assembly

**REF:** 154998 All items with a use by date prior to 2023-01  
161583 All items with a use by date prior to 2018-01  
161584 All items with a use by date prior to 2018-01

Dear Customer,

Our records show that Biomet UK Ltd has supplied you with a RHK Axle or RHK Hinge Assembly of above reference. We are requesting that you immediately locate and discontinue use of the product.

Biomet UK Ltd has initiated this action following a customer complaint that an Axle will not enter the Yoke of a RHK SHORT HING ASSEMBLY. An investigation has revealed that the items in question have possibly been manufactured with an oversized diameter axle.

Biomet UK Ltd is issuing this FIELD SAFETY CORRECTIVE ACTION to make users aware of this issue and request them to immediately return the affected product to their local Biomet distributor. Further details are in the attached FIELD SAFETY CORRECTIVE ACTION NOTICE.

Please distribute this field safety corrective action notice immediately to the appropriate people within your hospital.

Please complete and return without delay the attached "Fax-Back Response Form" acknowledging receipt of this letter and the attached FIELD SAFETY CORRECTIVE ACTION NOTICE and indicating the quantity of product you wish to return.

Biomet will be supplying replacement parts to allow the use of remaining modular components as soon as possible. The use by dates of these items will be later than the date ranges covered by this notice.

Phone:- 0044 1656 761678

Fax :- 0044 1656 645454

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

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

Yours sincerely,

  
**Richard Young**  
**QA/RA Director UK**  
**Biomet UK Healthcare Ltd**