

FIELD SAFETY CORRECTIVE ACTION

DATE: 21st June 2016

SUBJECT: TAPERLOC HIP LATERALISED PC STEM 15.0mm 12/14 Taper

REF: 650-0352

LOT: 1466692

SUBJECT: TAPERLOC HIP LATERALISED PC STEM 17.5mm 12/14 Taper

REF: 650-0353

LOT: 1463373

**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 TAPERLOC HIP LATERALISED PC HIP STEMS listed above. Our records show that these implants may have been distributed to your hospital. We are requesting that you immediately locate and return to Biomet UK Ltd ANY implants that you have with the above listed reference/lot number combinations.

The TAPERLOC HIP LATERALISED PC STEM is designed after the European philosophy of a flat tapered wedge design. The Flat Tapered Wedge Geometry Enhances proximal offloading and bone preservation and provides for rotational stability.

Biomet UK Ltd has initiated this action following an investigation that found that the packaging for a TAPERLOC LAT PC 17.5mm 12/14 stem, product code 650-0353, lot 1463373, contained an item with the product code 650-0352, lot 1466692 which is a TAPERLOC LAT PC 15.0mm 12/14.

The hip stem's lot number and size are etched on the top of the stem taper trunion, which would be checked by the theatre staff on opening the box and reviewing the component. This would identify a mismatch between label and product identification. An example can be seen in the pictures over the page.



If the condition was not identified upon opening the box and if the surgeon had planned for a 17.5mm stem but used a 15mm stem, the stem would be undersized and sit obviously lower in the prepared femur. It is likely that the surgeon would identify the mismatch in size, because the smaller hip stem implanted would not achieve sufficient press-fit and would likely move.

If the surgeon had planned for a 15mm stem but used a 17.5mm stem, given the wedge shaped design of the stem, it would sit obviously proud of the resection level in the prepared femur.

A delay of less than 30 minutes in surgery is expected whilst the correct sized hip stem is sourced.

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 Zimmer 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 Zimmer 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

www.biomet.com

Yours sincerely


Natalie Wide
QA/RC Director UK
Biomet UK Ltd