HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Taperloc Lateralised PC Stem

Priority 2 – Warning

HPRA Safety Notice:
SN2016(19)

Issue Date: 05 July 2016

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Biomet UK Ltd. (Zimmer Biomet)	V28211

ISSUE
Biomet UK Ltd have found that the packaging for two lots of TAPERLOC HIP LATERALISED PC STEM is mismatched between the product label and the product identification, resulting in the actual size of the product being incorrectly identified by the packaging. As a previous distributor of this has entered into liquidation, Zimmer Biomet does not have full traceability for these devices.

ACTION OR RECOMMENDATIONS
The HPRA advises that users: 1 Be aware of the information in the attached field safety notice (FSN). 2 Please withdraw from use all affected products identified at your facility as soon as possible. 3 Complete the response form attached to the FSN and return to your local Zimmer Biomet distributor. 4 Please pass this notice on to all those who need to be aware within your organisation or to any organisation / persons where the potentially affected devices have been transferred.

5	Report any adverse events / incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS

Orthopaedic surgeons	Risk managers
Orthopaedic theatre staff	Hospital CEOs
Orthopaedic registrars	Public and Private Hospitals

BACKGROUND

A Biomet UK Ltd investigation 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 (Refer to attached FSN for images).

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.

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer / supplier** should be addressed to:

Biomet UK Ltd.
Waterton Industrial Estate
Bridgend
South Wales
CF31 3XA
United Kingdom

Telephone: +44(0) 1656 655221
Fax: +44 (0) 1656 645454
E-mail: grayham.burnell@zimmerbiomet.com
Website: www.zimmerbiomet.com

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie