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FIELD SAFETY CORRECTIVE ACTION

DATE: 27TH January 2016

DESCRIPTION: Hiploc Plate/Lag Screw Introducer

REF 35-000263
LOT All Lots

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 HIPLOC PLATE/LAG SCREW INTRODUCER referenced above. Our records show that the instrument may have been distributed to your hospital. We are requesting that you immediately locate and discontinue use of any instruments with the above reference number

As a precautionary measure, Biomet UK Ltd has initiated this action following an investigation that indicated due to an undersized bore of the handle of a small number of the Hiploc Plate / Lag Screw Introducers (35-000263), the user will not be able to insert the Introducer Coupling Screw (470014).

These instruments are designed to hold a Hiploc Lag Screw and Hiploc Plate co-axially so when the Lag Screw is inserted into the femoral head, the plate is able to slide right over the Lag Screw for final placement of the plate. For the affected instruments, with the Introducer Coupling Screw not being able to pass through the Hiploc Plate/Lag Screw Introducer, the surgeon will not be able to perform the One-Step Plate and Lag Screw insertion technique.

If the instrument in question is used during surgery the surgeon can opt to use the alternative instrumentation for the Two-Step Plate and Lag Screw Insertion which is part of the applicable surgical technique. It is considered that the delay would be minimal in this instance.

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the operating staff are made aware of this matter without delay and that all the affected instruments identified are withdrawn from use at your facility as soon as possible.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 instruments, you will need to indicate the quantity you have available for return, the affected instruments 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 www.biomet.com

Yours sincerely

pp

Natalie Wide
QA/RC Director UK
Biomet UK Ltd

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RESPONSE FORM

Biomet Reference Number:	**HHE2015-014**
Description:	**Hiploc plate/lag screw introducer**
Ref	**35-000263**
Lot	**All Lots**

PLEASE TICK APPROPRIATE SECTION:

- ☐ WE CONFIRM ALL RELAVENT STOCK HAS BEEN PHYSICALLY CHECKED
- ☐ WE HAVE IDENTIFIED THE RELEVANT ITEMS IN OUR STOCK AND WOULD LIKE TO RETURN THE BELOW INSTRUMENTS FOR REPLACEMENT, DETAILS TO BE LISTED BELOW.
- ☐ WE CONFIRM THAT ALL RELAVENT STOCK HAS BEEN CHECKED AND THAT THEY DO NOT CONTAIN THE AFFECTED INSTRUMENTS.

REFERENCE NUMBER and LOT NUMBER	**QTY**

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:

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