

FIELD SAFETY CORRECTIVE ACTION

DATE: 24th March 2015
SUBJECT: Exceed ABT Spring Loaded Impactor
Product Code: 31-601587
Product / Lot: Various - Please note, the above item number may also be in kit number 31-601120

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 Exceed ABT Spring Loaded Impactor referenced above. Our records show that the instrument may have been distributed to your hospital as a single instrument and/or as part of the instrument set contained in kit number 31-600120.

The Exceed ABT Spring loaded impactor handle is an impaction device used for insertion of the Exceed ABT acetabular shell during Total Hip Replacement.

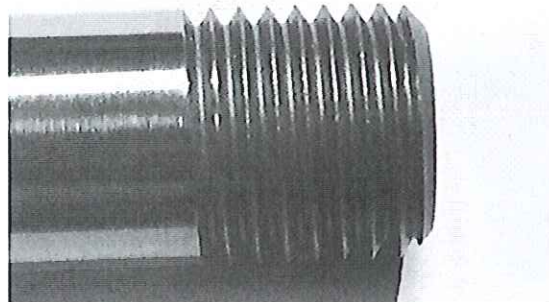
Biomet UK Ltd has initiated this action following certain complaints that the threaded central rod can break during acetabular shell insertion.

Biomet UK Ltd has been unable to replicate the reported breakage during investigation of these complaints; however Biomet UK Ltd is issuing this FIELD SAFETY NOTICE to make users aware of this potential issue and to highlight the importance of adhering to the relevant sections of the applicable surgical technique:

“Turn the strike plate clockwise to firmly tighten the spring loaded threaded tip in the shell apical hole. Hold the shell with the other hand whilst engaging the thread to prevent the shell from rotating.

IMPORTANT: It is advised to check that the threaded tip is always fully engaged in the cup apical hole when impacting. This helps minimise any risks of threaded tip damage.”

Biomet are initiating a full replacement programme to replace the threaded rods with a design enhancement. You will be contacted by your market representative to arrange this replacement in the coming weeks. **In the interim period, it is recommended that a visual inspection is performed to ensure thread is undamaged prior and post implantation of the cup.**



Undamaged thread condition

In the remote event of a thread fracture occurring during surgery, care should be taken to remove any debris from the surgical site and apical hole of the shell where it is most likely to be retained.

PLEASE TAKE DUE NOTICE OF THE REMAINING INFORMATION FOR AN EXPLANATION OF THIS NOTICE:

What you need to do

1. Ensure all relevant Hospital staff are given relevant awareness training relating to this matter to ensure they are fully informed.
2. 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 are identified. Any damaged instruments should be withdrawn from use and a replacement threaded rod will be made available.
3. 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 understood the attached FIELD SAFETY Notice, informed relevant theatre staff and have physically checked all inventory and hospital locations.
4. If you identify any item from the affected item/ lot combination, you will need to indicate the quantity you have available for return, the items 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 Fax-Back response form and return it to Biomet UK Ltd or to your local Biomet Distributor as soon as possible.

Please accept our apologies for any inconvenience caused by this action.

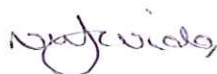
If you have any questions please contact the Biomet U.K. complaints department.

Phone:- 0044 1656 761678

Fax :- 0044 1656 645454

E-Mail:- uk.complaints@biomet.com www.biomet.com

Yours sincerely



Natalie Wide
QA/RC Director UK
Biomet UK Ltd

RESPONSE FORM

Biomet Reference Number:	HHE2015-004
Description:	Exceed ABT Spring Loaded Impactor
Product Code:	31-601587
Lot Codes:	Various - Please note, the above item number may also be in kit number 31-601120

PLEASE TICK APPROPRIATE SECTION:

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

<u>ITEM NUMBER and LOT NUMBERS</u>	<u>QTY</u>

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
- E-Mail:- uk.complaints@biomet.com
- Fax: +44 (0) 1656 645454