



## **FIELD SAFETY CORRECTIVE ACTION**

**DATE:** 20<sup>th</sup> March 2013

**SUBJECT:** Oxford Uni Toffee Hammer

**REF:** 32-422760 ( sold as part of instrument set 32-422763 )

**Lots** ZB100901, ZB110201, ZB110301, ZB110302, ZB110303,  
ZB110304, ZB110601, ZB110602, ZB110701, ZB111201,  
ZB111202, ZB120201, ZB120202, ZB120701, ZB120801,  
ZB120802, ZB121102, ZB121103

**FOR THE ATTENTION OF THE HEADS OF ORTHOPAEDIC DEPARTMENTS  
/OPERATING DEPARTMENTS / STERILE SERVICES DEPARTMENTS/  
PROCUREMENT / SUPPLIES / RISK MANAGEMENT**

This FIELD SAFETY CORRECTIVE ACTION Notice is to inform you of an URGENT FIELD SAFETY CORRECTIVE ACTION that has been initiated by Biomet UK Ltd which involves the Oxford Uni Toffee Hammers which have the above listed lot numbers. Our records show that these instruments may have been distributed to your hospital.

We are requesting that you immediately locate and discontinue use of the affected instruments.

The Oxford Uni Toffee Hammer should be returned to Biomet UK Ltd or to your local Biomet distributor, at the address on the covering letter.

Please read the remaining information for an explanation of this request:

This device is a small surgical hammer supplied with the Oxford Partial Knee Microplasty Instrument set which is used for impacting implants.

For ease of reference please find below a picture of the instrument involved.

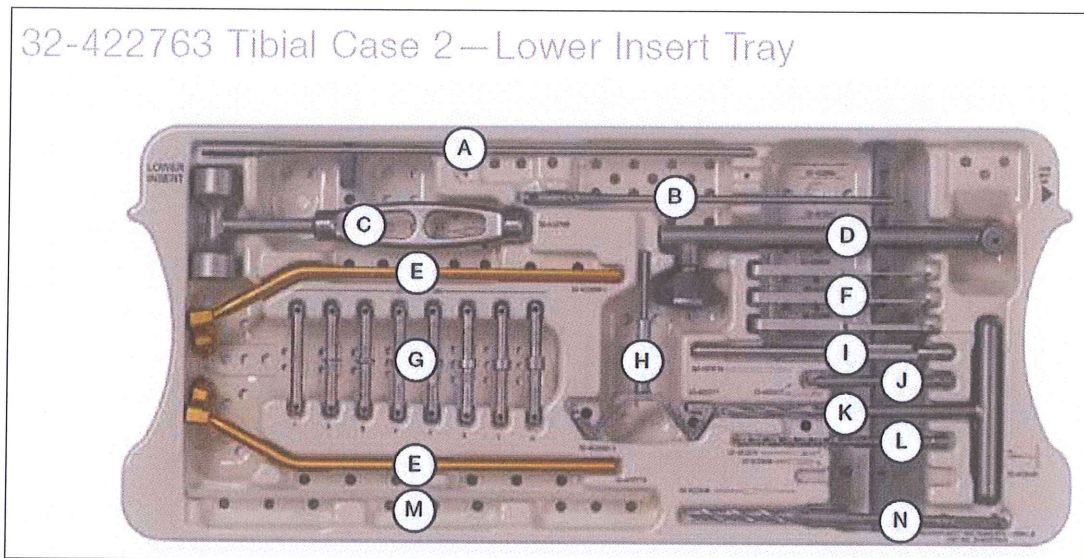


Biomet UK Ltd has initiated this action following an investigation that indicated that excessive use of the instrument could result in cracking on the weld between the head and the handle. This could lead to part of the head becoming detached from the handle.

It is not anticipated that the reported detachment of the head will result in an adverse health outcome. Where part of the head has become detached, the other side of the hammer could be used to complete the operation. In the event that the surgeon considered the instrument to be unusable, a small delay could be encountered whilst a replacement item is sourced.

This FSCA only affects instruments with the lot numbers listed above.

The Toffee Hammer is located in the instrument set Lower Insert Tray item C



Replacement products are on order; please contact your local Biomet distributor for availability.

**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 "Fax-Back 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 CORRECTIVE ACTION 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 Fax-Back 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 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,  
UK Director of RA/QA  
Biomet UK Ltd



## FAX BACK RESPONSE FORM

<b>Biomet Reference Number:</b>	<b>HHE2013-002</b>
<b>Description:</b>	<b>Oxford Uni Toffee Hammer</b>
	<b>Item: Reference 32-422760</b>
	<b>Lot numbers: ZB100901, ZB110201, ZB110301, ZB110302, ZB110303, ZB110304, ZB110601, ZB110602, ZB110701, ZB111201, ZB111202, ZB120201, ZB120202, ZB120701, ZB120801, ZB120802, ZB121102, ZB121103</b>

**PLEASE TICK APPROPRIATE SECTION:**

- WE CONFIRM ALL RELEVANT 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 RELEVANT STOCK HAS BEEN CHECKED AND THAT THEY DO NOT CONTAIN THE AFFECTED INSTRUMENTS.

<u>REFERENCE NUMBER and LOT NUMBER</u>	<u>QTY</u>

**Please sign and return this form to acknowledge receipt of this Field Safety Notice.**

<b>Name and Address:</b>	
<b>Contact Name:</b>	
<b>Contact Title:</b>	
<b>Contact Signature:</b>	
<b>Contact Phone No:</b>	
<b>Date:</b>	

**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@biomet.com**