ZIMMER BIOMET
Your progress. Our promise.

FIELD SAFETY CORRECTIVE ACTION

DATE: 6th April 2016

SUBJECT: **BIOMET 360 TIBIAL AUGMENT**

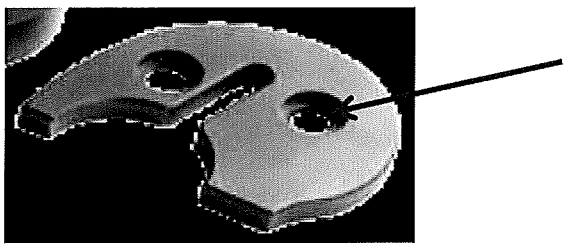
REF **See Attachment**

LOT **See Attachment**

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 BIOMET 360 TIBIAL AUGMENT implants referenced above. Our records show that the implants may have been distributed to your hospital. We are requesting that you immediately locate and discontinue use of any implants with the listed reference/lot number combinations.

Biomet 360 tibial augments are intended to be mechanically attached to a Knee tibial tray to help restore the joint line, and make up for bone defect.



Biomet UK Ltd has initiated this action following an investigation that indicated the depth of the counter bore holes is too deep resulting in the implant not sitting in the sagittal plane correctly when screwed down. It would be able to move approximately 1mm, but it would not become detached.

No health risks are expected. A possible delay in the surgical procedure can occur if another tibial augment of the same size is unavailable. If the surgeon is augmenting both sides of the knee he/she would have the option of using thinner tibial augments and could make up the difference by adjusting the thickness of the bearing used. If the tibial augment was for only one compartment of the knee, a small amount of bone may need to be resected to obtain a flat resection. Alternatively the surgeon could proceed to use the tibial augment and cement it into position as the Biomet 360 is a cemented system.

BIOMET 360 TIBIAL AUGMENT Attachment

Part No	Lot No
185220	1513670
185221	1513672
185222	1513673
185223	1513674
185224	1513675
185225	1513676
185226	1513677
185230	1513679
185231	1513680
185232	1513681
185233	1513684
185234	1513688
185235	1513702
185236	1513715
185240	1513788
185241	1513816
185242	1513845
185243	1513867
185244	1513883
185245	1513901
185246	1513940
185250	1513990
185252	1514027
185253	1514054
185254	1514055
185255	1514056
185256	1514057

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 Zimmer 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

[redacted]

Biomet UK Ltd