



ZIMMER BIOMET

15 March 2017

To: Risk Managers and Surgeons

Subject: **URGENT FIELD SAFETY NOTICE - Advisor r Notice**

Affected Product: Cementless Oxford Partial Knee Unicompartmental Knee Replacement system, OXF UNI C/LESS TIB TRAYS LM size AA through to OXF UNI C/LESS TIB TRAY RM size F

Item Number	Lot Numbers
166570,166571,166845,166846,166572,166573, 166574,166575,166576,166577,166578,166579, 166580, 166581	All lots
154913,154914,154915,154916,154917, 154918, 154919,154920,154921,154922,154923,154924	All lots
US166570, US166571, US166845, US166846, US16657 US16657 US166574,US166575, US166576,US166577,US166578,US166579, US166580, US166581	All lots

This notice is to inform you of a VOLUNTARY FIELD SAFETY CORRECTIVE ACTION that has been initiated by Biomet UK Ud which involves the **Cementless Oxford Partial Knee Unicompartmental Knee Replacement System**. Our records show that partial knee arthroplasty surgeries involving the above listed components are, or have been carried out at your hospital and we are issuing this notice following a certain trend in reported tibial plateau fractures.

Analysis of complaint rates identified a **world-wide occurrence of 0.12%** of patients experiencing tibial plateau fractures.

Analysis of the reported complaints has shown that should a tibia fracture occur, it is identified by the treating orthopedie consultant within an average of 25 days from primary surgery, and available data indicate that 17% of those fractures have been treated conservatively.

The Oxford Cementless Tibial Trays have been manufactured according to pre-defined specifications. An investigation into the cause of the reported tibial plateau fractures has revealed the importance that certain steps described in the applicable surgical technique are followed to reduce the risk of tibia plateau fractures. By means of this notice we would like to emphasize the importance of adhering to the applicable surgical technique and the appropriate sections in the Instruction for Use packaged with the products.



The Oxford Partial Knee Microplasty Instrumentation Complete Cemented and Cementless Surgical Technique Form No. 0338.1-EMEA-en-REV0116

Instruction For Use 5400000431 Rev 2 dated January 2015

Risks

Immediate health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	Immediate health consequences would be those associated with plating and screwing with the implant in situ during the primary procedure.	The need to change to a total revision knee prosthesis with plates and screws during the primary procedure
Long range health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	No long term health consequence is anticipated if the rectification action is plating and screwing upon detection of tibia plateau fracture.	The worst case long term health consequence could be the need to revise the components at a later date from a partial to a total revision knee prosthesis.

The appropriate package insert Instruction For Use 5400000431 Rev 2 dated January 2015 states the following under the Warnings section:

3. Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components.

4. In the event of excessive bone removal or inaccuracies in bone cuts leading to loose fit of cementless implants into the prepared bone, the Oxford cemented implants should be used. In this case the cemented Oxford instrument kits must be used and trial reduction must be conducted to ensure the natural knee kinematics are maintained.

Additionally, the Possible Adverse Effect section states:

8. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.

The Oxford Partial Knee Microplasty Instrumentation Complete Cemented and Cementless Surgical Technique Form No. 0338.1-EMEA-en-REV0116 states the following:

Tibial Preparation for Cementless Fixation:

To optimize cementless tibial fixation and minimize the risk of fracture it is important to achieve flat bone surfaces, with no stress risers and to use the largest component possible. To avoid re-cutting the tibia, which may result in an uneven surface, use the 4 G clamp (Figure 44). For small patients the 3 G clamp is acceptable, but ensure to use a spoon that is not tightly gripped. Do not use the +2 shim. Only recut if, at trial reduction with a trial template, a 3 bearing is too tight. The vertical saw cut should be made just medial to the apex of the medial tibial spine and must not be too deep (Figure 45). To prevent the cut from being too deep the saw blade should be parallel to the tibial resection guide and the surgeon must not lift his hand whilst sawing (Figure 46).

The slotted zero shim must be used for the horizontal cut. Alternatively, the horizontal resection can be made first. Mark the position of the vertical cut using bovie and extend the line in the flexion plane. This line should be just medial to the apex of the tibial spine. With the slotted zero shim assembled to the tibial resection guide, make the horizontal resection first. This resection can slightly undermine the ACL insertion of the tibia up to 5 mm. After the resection is complete, replace the slotted zero shim with the un-slotted zero shim. A saw blade or Vertical Resection Shim can be inserted into the horizontal resection and positioned laterally. This instrument serves as a reciprocating saw stop. With the reciprocating saw, make the vertical resection on the line identified with the bovie. The vertical cut is complete when the reciprocating saw blade comes into contact with the retained saw blade or the Vertical Resection Shim that was positioned in the horizontal resection. This may help minimize over-resection of the posterior tibial cortex.

The excised tibial plateau should be compared with a tibial template. If a template of an appropriate width is too short the vertical cut should be repeated so that a larger tibial component can be inserted. The component should fit the tibia and reach the posterior medial and anterior cortex. Avoid re-cutting the tibia if possible: If it is found that the femoral drill guide set to 3 mm cannot be inserted easily it should be pushed in instead of re-cutting the tibia (assuming the zero shim was used). This will either compressor remove some of the cartilage of the back of the femur, which will elevate the joint line slightly. It is preferable to elevate the joint line rather than recut the tibia.

Final Preparation of the Tibial Plateau section:

Thoroughly wash the tibial plateau and keel slot and then insert the trial tibial component by hand (Figure 50). If the trial does not fully seat in the identical position to the template ensure there is no soft tissue obstructing it and give it a gentle tap with the Toffee Mallet. If the trial still does not fit, replace the tibial template and revisit the keel cut. If necessary the cementless tibial keel pick can be used to remove small bone fragments that are preventing the component from seating (the cementless pick should only be used with the template in place and care should be taken to pick gently, especially in the posterior portion of the keel cut).

Action to be taken:

Zimmer Biomet encourages health care professionals to observe the care point below.

To achieve optimal results, it is critical that the operative technique is followed carefully. Care should be taken when preparing for the keel of the implant. If preparing the keel slot for the Cementless Oxford Partial Knee is difficult and the keel may hit the cortex, the Cemented Oxford Partial Knee should be considered.

Risk Manager/ Surgeon Responsibilities:

1. Review this notification and ensure affected personnel are aware of the contents.
2. Complete Attachment 1 - Certificate of Acknowledgement.
 - a. Return a digital copy to your local distributor as indicated on the Certificate of Acknowledgement.
 - b. Retain a copy of the Acknowledgement Form within your records in the event of a compliance audit of your facilities documentation.
3. If after reviewing this Urgent Field Safety Notice you have further questions or concerns please contact your local Zimmer Biomet representative.



Other Information

This voluntary Urgent Field Safety Notice - Advisory Notice will be reported to Competent Authorities , Notified Bodies, and Regulatory Authorities as required under the applicable regulations.

Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported according to MEDDEV 2.12-1 Rev. 8 or any relevant requirements to the local Regulatory Authority in your country.

Please keep Biomet UK Ud informed of any adverse events associated with this device or any other Zimmer Biomet product. Adverse events may be reported to Zimmer Biomet at per.nl@zimmerbiomet.com, or to your local Zimmer Biomet representative.

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Authorities.

We would like to thank you for your co-operation in advance and regret any inconveniences caused by this Urgent Field Safety Notice.

Sincerely,

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ATTACHMENT 1
Certificate of Acknowledgement

By signing below, I acknowledge that the required actions have been taken in accordance with the Field Safety Notice.

Hospital Facility Risk Manager/ Surgeon (Please check one as applicable)

Printed Name: _____ Signature: _____

Title: _____ Telephone: () _____ Date: __ / __ / __

Facility Name: _____

Facility Address: _____

City: _____ State: _____ ZIP: _____

Note: This form must be returned to Zimmer Biomet before this action can be considered closed for your account. It is important that you complete this form and email a copy to: fieldaction.netherlands@zimmerbiomet.com