



## **FIELD SAFETY CORRECTIVE ACTION**

**DATE:** 3 February 2014

**SUBJECT:** AGC DA 2000 Femoral Components

**REF:** 154800, 154801, 154802, 154803, 154805, 154806 & 154807

**Lot:** See attached list

**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 ("FSCA") that has been initiated by Biomet UK Ltd which involves the AGC DA 2000 femoral components referenced above. Our records show that the implants involved may have been distributed to your hospital. We are requesting that you immediately locate and discontinue use of the implant.

The AGC Dual Articular 2000 knee system has been specifically designed to deal with unexpected situations faced by the surgeon during revision arthroplasty. It is also designed for primary knee surgeries involving individuals with severe deformities and/or bone loss.

An investigation has revealed that some of above referenced AGC DA 2000 femoral components have not been manufactured in accordance with its pre-defined manufacturing specifications. A detailed investigation is on-going to assess its (clinical) implications. Further information will be provided to you in a separate letter after this assessment has been completed.

This FSCA affects solely the AGC DA 2000 femoral components with the reference/lot numbers listed above.

**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 issue and are fully informed of the matter.
2. To assist us with this action, please ensure that the operating staff are made aware of this issue without delay and that all the affected implants are identified and withdrawn from use at your facility as soon as possible.
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 understand the attached FIELD SAFETY CORRECTIVE ACTION Notice, informed relevant theatre staff and have physically checked all inventory and hospital locations.

