BIOMET

URGENT MEDICAL DEVICE SAFETY ALERT
March 4, 2014

Comprehensive Nano Humeral Component PPS
Part Numbers: 115730, 115732, 115734, 115736, 115738, 115740

Dear Biomet Customer,

This notification is to inform you of an Urgent Medical Device Safety Alert initiated by Biomet Orthopedics ("Biomet") which involves **Part Numbers: 115730, 115732, 115734, 115736, 115738, 115740 Comprehensive Nano Humeral Component PPS**.

Three complaints have been received alleging failures with the Comprehensive Nano Humeral Component PPS, **when used in a reverse construct**. All three complaints state that the patient underwent a revision procedure due to loosening of the Nano humeral component. In two of the complaints, the surgeons indicated that impingement, excessive range of motion prematurely, and/or poor bone quality were probable causes of the loosening. There have not been any complaints on the humeral component of the Nano loosening from the humerus when the device is implanted as an anatomic construct.

Please see below points to consider when using the Comprehensive Nano Humeral Component PPS in a reverse construct.

- After making the humeral head osteotomy, bone quality and quantity should be evaluated before implanting the Nano reverse construct. If there are visible cysts or if the bone quality/quantity is deemed inadequate to achieve good fixation, the surgeon should change to a stemmed prosthesis.
- It is important to make the humeral neck angle resection for the reverse Nano at 45 degrees. This angle is deemed most appropriate for the Comprehensive reverse construct in regard to the stability and mitigation of the bearing impingement on the inferior border of the scapula.
- It is recommended to impact the humeral tray of the Nano reverse flush with the humeral osteotomy. Note that this will push the distal end of the Nano humeral component closer to the lateral wall of the humerus; therefore the surgeon must be cognizant of the available space in the humerus to avoid contact with the lateral cortex and potential damage to the humerus..
- After trial reduction and during trial range of motion, the surgeon should check for impingement of the humeral bearing in all directions. If there is impingement, it is recommended to adjust the Versa-Dial offset of the glenosphere and/or use a more lateralized glenosphere option, or if necessary increase glenosphere size to alleviate impingement.
- The surgeon should also take care when prescribing post-surgical rehabilitation to avoid aggressive rehabilitation during the first 6-8 weeks after implantation. The post surgical rehabilitation should also avoid hyperextension of the humerus and excessive internal/external rotation.

To assist Biomet with this action, please ensure that all necessary individuals who may be affected by this Safety Alert are notified and provided with a copy of this notice.

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