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Zimmer GmbH
P.O.Box
CH-8404 Winterthur

Phone +41 (0)52 262 60 70
Fax +41 (0)52 262 01 39
www.zimmer.com

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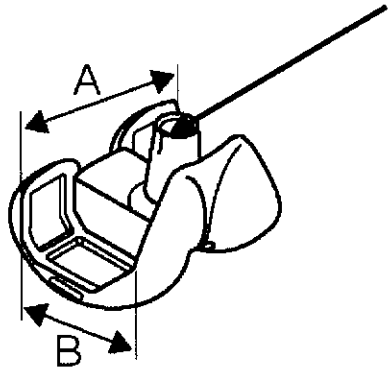
Customer information on:

Wallaby III Femoral Revision Component
REF # 43.26.40-01, LOT #: 2301210

Wallaby III Femoral Revision Component
REF # 43.26.43-02, LOT #: 2260220

To whom it may concern:

Zimmer has recalled these two lots of Wallaby III Revision Femoral components due to missing laser marking. The missing laser marking is used for orientation of the stem when an angled stem is implanted.



Use of the laser marking on the product:

The marking on the turret of the Wallaby III femoral component – see drawing above – serves to position a 2° angled stem extension. By using a 2° angled stem extension a valgus angle of 3° or 7° can be obtained (versus a 5° standard valgus angle when using a straight stem extension). The marking is only relevant when using an angled stem extension. It does not have any function when using a straight stem extension. The use of angled stem extensions is relatively uncommon. For Wallaby stem extensions sold in 2006, 84% were straight stems and 16% were angled stems.

Risk from recalled devices already implanted:

Straight Stem Surgery: If the recalled device was implanted in combination with a straight stem extension, no risk exists for the patient. The turret marking is not used when implanting a straight stem. About 5 of every 6 Wallaby III surgeries use a straight stem. For these surgeries, the missing marking is of no consequence.

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Angled Stem Surgery – Discovered in Surgery: If a surgery were occurring where an angled stem was being used, the missing laser marking on the femoral would very likely be discovered at the time that the implant is opened. The implants would be opened after the femoral bone cuts have been made and the trial fit has already been done. When discovered, the surgeon would have several potential courses of action to complete the procedure.

- If available, another femoral component of the same size could be opened and implanted. The component with the missing mark is unused.
- The surgeon uses the trial ("test" or "provisional") femoral and angled stem components for comparison and is able to correctly orient the angled stem. The original component is implanted with the angled stem oriented as intended.
- Another femoral component of the same orientation ("Left" or "Right") is opened to confirm the position of the mark by comparing the two components. The original component is implanted with the angled stem oriented as intended.

In all of these instances, the missing marking is noticed during the surgery and the surgeon has other ways to successfully complete the procedure. It is very unlikely that a surgeon would choose to implant a different sized device.

Angled Stem Surgery – Not Discovered in Surgery: The least probable outcome is that a surgery with an angled stem occurred and the end user did not detect the missing marking when assembling an angled stem to the femoral implant. If the surgeon had planned for a 7° valgus angle and assembled the components at 3° valgus, the difference in fit between the trial components and the definitive implants would have a high probability of detection, at which time the implant construct could be reassembled and implanted as intended.

In summary, the probability is very low that any of the patients implanted with one of these recalled Wallaby III femoral components was implanted with an incorrect valgus angle.

Should you have concerns with implanted devices, we recommend that the original patient chart be reviewed to determine if an angled stem was used (1 in 6). If an angled stem was used, we recommend review of postoperative radiographs to confirm the intended valgus angle. In a surgery where the incorrect valgus angle occurred undetected, this could affect the knee kinematics and long stem stability of the knee implant. However, we reiterate that there is a very low probability that this would have been undetected during the surgical procedure.

We apologize for any inconvenience which might have been caused to you by this product recall. Please do not hesitate to contact your Zimmer representative if you have any questions or concerns.

Yours faithfully

Zimmer GmbH

[redacted]
Manager Product Surveillance