

Your reference

Our reference

Tel. +49/74 61/95-

[REDACTED]

Fax +49/74 61/95-

2177

Date

July 24, 2009

Safety notice – Aesculap cementless Bicontact N hip stem size 9 – NJ009T
60kg patient weight restriction

Dear user of the Bicontact hip system,

within the Bicontact hip system the small stem implants of the SD/D- and N-Series offer a comprehensive stem range for the treatment of severe dysplastic hip anatomies as well as for narrow femoral canal conditions.

Within more than 500.000 Bicontact implantations the stems of the SD/D and N-series represent today a global usage of 4 % in European countries and more than 95% in Asia where patients have smaller femoral bone morphologies. About 8.000 Bicontact N stems have been implanted in Japan since 1996.

In case of heavy patients small implant sizes are exposed to high loads, and small sized prosthesis stems can be overloaded in vivo. This may also happen in cases of high patient activity. Implant strength may be also weakened if the stem surface is damaged during implantation.

After more than ten years of clinical experiences we have seen in Japan one single case of a Bicontact N hip stem size 9 with an XL modular head, which failed due to fatigue overloading. Current preclinical testing conditions with hip simulators have been set with the ISO 7206-04 & 06 and the ASTM F2068-03. This new test set-ups lead to higher load levels applied to the hip stems and induce additional contraindications for patient weight.

In addition to existing weight limitations of cementless Bicontact stems NK709T (9SD/10SD) (50kg), NJ208T (8D), NJ209T (9D), NJ210T (10D) (60kg) and NK710T (10SD-Revision) (65kg) also the Bicontact N stem size 9 (NJ009T) will be labeled in future with 60 kg weight limitation. Please consider this limitation for your further procedure planning.



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Therefore please pay attention not to hit the surface by sharp metal instruments.

We are committed to add the weight limitation to the instructions for use in the future.

If you have any additional questions please do not hesitate to contact your B. Braun Aesculap representative or contact Aesculap Tuttlingen:

Thomas Guettler (Group Productmanger Hip Arthroplasty)
Email: thomas.guettler@aesculap.de phone: +49 7461 95 2672

Yours sincerely

Aesculap AG

i. V.

i. A.