B|BRAUN

Content Customer information cementless Bicontact SD hip stems
Weight restriction for Bicontact SD Implants sizes 9 and 10 and Bicontact SD-Revision size 11 and instructions for intraoperative technique of femoral canal preparation

Dear user of the Bicontact hip system,

within the Bicontact hip system the implants of the SD- and N-Series offer a stem range for the treatment of severe dysplastic hip anatomies as well as for narrow femoral canal conditions. Within more than 300.000 Bicontact implantations the stems of the SD- and N-series represent today a percentage of 5%.

In case of heavy patients small implant sizes are exposed to high material loads. Especially under conditions as distal pressfit and/or insufficient proximal bone support combined with higher offset loads the prosthesis stem can be overloaded in vivo.

New preclinical testing conditions with hip simulators have been set with the ISO 7106-04. This new test set-up leads to a higher load applied to the hip implant stems. Three implants of the Bicontact hip system (Bicontact SD Implants sizes 9 and 10 and Bicontact SD-Revision size 11) did not pass these new loading conditions. Therefore these implants can be only offered with weight restrictions for patient with hip arthroplasty treatment.

Clinical experiences have shown, that in particular cases the SD prosthesis stems failed due to fatigue overloading. The analysis of these cases had always shown a strong distal press-fit and load transfer situation which represented the laboratory test situation of the new ISO test-set-up.

As Bicontact implants are intended to be implanted with a proximal load transfer situation, distal reaming is recommended in case of narrow distal femoral canal conditions. This surgical procedure has been always described in the Bicontact surgery manual, because the use of the A-Osteoprofilers can not ensure a distal "cutting-free" of the femoral canal in all cases of small bone conditions. An alternative to the use of small SD sizes also N implants which can be used in such indications because these stems do not have any weight restrictions.

Due to CE-approval and CE regulations we are committed to add the weight limitation to the instructions for use. This letter is intended to inform you about these contraindications and the content of the Bicontact SD instructions for use. Bicontact D implants are exclusively delivered to Japan and therefore also part of this instruction for use.

If you have any additional question please do not hesitate to contact your B. Braun Aesculap branch or contact Aesculap Tuttlingen per e-mail to [redacted]@aesculap.de.

Enclosure: Supplement to instructions for use Bicontact SD and D implants

(GB) (D)

BiCONTACT SD and D implants — BiCONTACT SD- und D-Implantate

(GB) **Supplement to instructions for use**
BiCONTACT SD and D implants

(D) **Ergänzung zur Gebrauchsanweisung**
BiCONTACT SD- und D-Implantate

(E) **Instrucciones complementarias**
Implantes BiCONTACT SD y D

(I) **Integrazione delle istruzioni per l'uso**
Impianti BiCONTACT SD ed D

(P) **Suplemento às instruções de utilização**
Implantes BiCONTACT SD e D

CE 0123

CE marking according to directive 93/42/EEC
CE-Kennzeichnung gemäß Richtlinie 93/42/EWG
Identificación CE en conformidad con la directriz 93/42/CEE
Marchio CE conforme alla direttiva 93/42/CEE
Símbolo CE, em conformeidade com a Directiva 93/42/CEE

Technical alterations reserved
Technische Änderungen vorbehalten
Sujeto a modificaciones técnicas
Con riserva di modifiche tecniche
Salvo alterações técnicas

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Contraindications – Weight restriction

WARNING

Implant failure due to excessive body weight of the patient and mainly distal fixation of the small BiCONTACT SD implants!

➢ **Observe maximum body weight of the patient for the implants listed below.**

Art. no.	Designation	Max. body weight
NK709T	BiCONTACT SD, size 9	50 kg
NK710T	BiCONTACT SD, size 10	50 kg
NK210T	BiCONTACT SD, Revision, size 11	65 kg
NJ208T	BiCONTACT D, size 8	60 kg
NJ209T	BiCONTACT D, size 9	60 kg

To avoid distal implant fixation, carry out the following additional surgical measures:

- ➢ Bore up the distal marrow cavity, using flexible marrow cavity drills.
- ➢ Ensure sufficiently deep prosthesis seat through proximal-medial support.
- ➢ Carry out intraoperative check of the prosthesis seat, using an imaging device.
- ➢ Alternatively, use BiCONTACT N implants.

Kontra-Indikationen – Gewichtsbeschränkung

WARNUNG

Implantatversagen bei zu hohem Gewicht des Patienten und überwiegend distaler Fixation der kleinen BiCONTACT SD-Implantate!

➢ **Bei den unten aufgeführten Implantaten maximales Körpergewicht des Patienten beachten.**

Art.-Nr.	Bezeichnung	Max. Körpergewicht
NK709T	BiCONTACT SD, Größe 9	50 kg
NK710T	BiCONTACT SD, Größe 10	50 kg
NK210T	BiCONTACT SD, Revision, Größe 11	65 kg
NJ208T	BiCONTACT D, Größe 8	60 kg
NJ209T	BiCONTACT D, Größe 9	60 kg

Um eine distale Implantatfixation zu vermeiden, zusätzlich folgende operative Maßnahmen durchführen:

- ➢ Distalen Markraum mit flexiblen Markraumbohrern aufbohren.
- ➢ Ausreichend tiefen Prothesensitz mit proximal-medialer Abstützung sicherstellen.
- ➢ Sitz der Prothese intraoperativ mit dem Bildwandler prüfen.
- ➢ Alternativ BiCONTACT N-Implantate verwenden.

(E) (I) (P)

Implantes BiCONTACT SD y D — Impianti BiCONTACT SD ed D — Implantes BiCONTACT SD e D

Contraindicaciones – Limitación de peso

ADVERTENCIA

El implante fracasará si el peso del paciente es demasiado elevado y si la fijación de los pequeños implantes BiCONTACT SD se realiza principalmente en distal.

➢ **Considerar el peso máximo del paciente en el caso de los implantes detallados más adelante.**

N.º art.	Descripción	Peso corporal máximo
NK709T	BiCONTACT SD, tamaño 9	50 kg
NK710T	BiCONTACT SD, tamaño 10	50 kg
NK210T	BiCONTACT SD, Revisión, tamaño 11	65 kg
NJ208T	BiCONTACT D, tamaño 8	60 kg
NJ209T	BiCONTACT D, tamaño 9	60 kg

Para evitar una fijación distal del implante deberán tomarse además las siguientes medidas quirúrgicas:

- ➢ Perforar la cavidad medular con brocas para cavidad medular flexibles.
- ➢ Garantizar un asiento de la prótesis lo suficientemente profundo con soporte proximal medial.
- ➢ Comprobar intraoperatoriamente el asiento de la prótesis con el intensificador de imágenes.
- ➢ Como alternativa, utilizar los implantes BiCONTACT N.

Controindicazioni – Limitazione del peso

AVVERTENZA

Fallimenti dell'impianto causati da sovrappeso del paziente e fissaggio principalmente distale dei piccoli impianti BiCONTACT SD!

➢ **Per gli impianti sottoindicati rispettare il peso corporeo massimo del paziente.**

Cod. art.	Designazione	Peso corporeo max.
NK709T	BiCONTACT SD, formato 9	50 kg
NK710T	BiCONTACT SD, formato 10	50 kg
NK210T	BiCONTACT SD, Revision, formato 11	65 kg
NJ208T	BiCONTACT D, formato 8	60 kg
NJ209T	BiCONTACT D, formato 9	60 kg

Per prevenire un fissaggio distale dell'impianto, adottare inoltre le seguenti misure operatorie:

- ➢ Alesare la cavità midollare con gli appositi alesatori flessibili.
- ➢ Assicurare che la sede della protesi sia sufficientemente profonda con supporto prossimal-mediale.
- ➢ Eseguire un controllo intraoperatorio della sede della protesi con il convertitore di immagini.
- ➢ Alternativamente usare gli impianti BiCONTACT N.

Contra-indicações – Limite de peso

AVISO

O implante não terá sucesso se o paciente apresentar um elevado excesso de peso, bem como se a fixação dos pequenos implantes BiCONTACT SD for nomeadamente distal!

➢ **Verifique o peso máximo do paciente no caso dos implantes pormenorizados seguidamente.**

Artº nº	Designação	Peso corporal máximo
NK709T	BiCONTACT SD, tamanho 9	50 kg
NK710T	BiCONTACT SD, tamanho 10	50 kg
NK210T	BiCONTACT SD, Revisão, tamanho 11	65 kg
NJ208T	BiCONTACT D, tamanho 8	60 kg
NJ209T	BiCONTACT D, tamanho 9	60 kg

Para evitar uma fixação distal do implante, deve-se também tomar as seguintes medidas cirúrgicas:

- ➢ Perfurar a cavidade medular com brocas para cavidade medular flexíveis.
- ➢ Garantir um embasamento da prótese suficientemente profundo com suporte proximal medial.
- ➢ Verificar intra-operatoriamente o embasamento da prótese com o intensificador de imagens.
- ➢ Como alternativa, utilizar os implantes BiCONTACT N.