

Your reference

Our reference

Tel. +49/74 61/95-
2182Fax +49/74 61/95-
1555Date
2014-12-22**FSCA – Product Recall**

Product: NV113D – 52080304
Product Description: BIOLOX DELTA INSERT G 36MM SYM.

In your hospital you use the cementless acetabular system Plasmefit from Aesculap.

It is possible that for the ceramic BioloX delta insert with the part No. **NV113D, lot 52080304**, which is a Plasmefit BioloX delta Insert Type G head diameter 36 mm, a mix-up for a single product happened during packaging. We therefore precautionary initiated the product recall for this lot.

In case of this mix-up the outside packaging will be labeled with the part No. **NV113D, lot 52080304**, the packed implant inside would be a NH102D, SC/MS BIOLOX DELTA INSERT 32MM 48/50 SYM. lot 52074933 for Plasmacup. This insert will not fit into the Plasmefit cup, which you can obviously recognize during surgery. In this case another insert may be used to successfully finish surgery. Either this could be another insert NV113D out of different lot or an insert made of highly crosslinked polyethylene.

Vorsitzender des Aufsichtsrates:
Prof. Dr. h.c. Ludwig Georg Braun

Vorstand:
Prof. Dr. Hanns-Peter Knaebel
(Vorsitzender)
Dr. Harald Stallforth
(stellv. Vorsitzender)
Dr. Joachim Schütz

Sitz der Gesellschaft: Tuttlingen
Reg. Gericht: Stuttgart HRB 726261
USt. Id.-Nr. DE812160059
WEEE-Reg.-Nr. DE 65109852

Bankverbindungen:
Deutsche Bank AG Tuttlingen
BLZ 653 700 75 Konto 21 22 000 00
IBAN DE44 6537 0075 0212 2000 00
SWIFT / BIC DEUTDE33
Baden-Württembergische Bank
BLZ 600 501 01 Konto 487 1905
IBAN DE31 6005 0101 0004 8719 05
SWIFT / BIC SOLADE33

Hausanschrift:
Aesculap AG
Am Aesculap-Platz
78532 Tuttlingen
Deutschland

...

Each implant range includes XLPE inserts from highly crosslinked polyethylene. The fitting insert would be part No. NV213 Plasmafit XLPE Vitelene Insert size G.

There is no risk for patients who have already received treatment with the affected lot.
In case of implant stock of the affected lot please return the parts to:

Aesculap AG
Building 12 – Dept. QMV / Product Recall
Kerstin Rothweiler
Am Aesculap – Platz
78532 Tuttlingen
Germany

You will receive a credit note for the returned implants.
Please contact your customer service for a spare delivery.

Please make sure that any user of the above mentioned product and any other person who has to be informed within your organization, will take note of this safety information.

If you have forwarded the involved product to a third party, please provide a copy of this information to this party and also note Aesculap AG about this.

We apologize for any inconvenience this may cause and thank you very much for your support.

With best regards,

Aesculap AG