

Your reference

Our reference
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1555Date
2015-01-23**FSCA – Product Recall****Product: NH102D – 52074933**
Product Description: SC/MSC BIOLOX DELTA INSERT 32MM 48/50 SYM.

We have received information that possibly for the ceramic BioloX delta **NH102D, 52074933**, which is a Plasmacup BioloX delta Insert head diameter 32 mm, singular products may have received incorrect printing on the secondary foil. We therefore precautionary initiated the product recall for this batch.

In case of this incorrect printing the secondary packaging (outer foil) could be labeled with **NH102D, 52074933**, the packed implant inside would be a NV113D, BIOLOX DELTA INSERT G 36MM SYM. 52080304. The primary packaging (inner foil) would correctly be labeled with NV113D, 52080304. As the two inserts belong to different systems and also are different size (32mm and 36mm) the failure can obviously be recognized. In this case another insert may be used to successfully finish surgery. Either this could be another insert NH102D out of different batch or an insert made of polyethylene.

Vorsitzender des Aufsichtsrates:
Prof. Dr. h.c. Ludwig Georg BraunVorstand:
Prof. Dr. Hanns-Peter Knäbel
(Vorsitzender)
Dr. Harald Stallforth
(stellv. Vorsitzender)
Dr. Joachim SchulzSitz 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 SOLADESTHausanschrift:
Aesculap AG
Am Aesculap-Platz
78532 Tuttlingen
Deutschland

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