

**Aesculap AG  
Quality Management**

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Germany

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Internet: <http://www.aesculap.de>  
Date: 2/12/2016

**Field Safety Corrective Action – Product Recall**

**Product:** PO830SU, PO831SU, PO833SU – all batches  
**Product description:** DISP.METZENBAUM SCISSORS D:3.5/290MM,  
DISP.MARYLAND FORCEPS D:3.5/290MM,  
DISP.ATR.GRASPING FCPS D:3.5/290MM

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Microscopically small holes were found in the packaging of articles PO830SU, PO831SU and PO833SU, as part of a transport simulation during the development phase. The holes are present both on the sharp-edged transitions of the thermoform as well as in the packaging around the circular disc. They cannot be detected with the naked eye.



**Figure 1: Packaging of PO831SU (left), critical parts of the packaging (right)**

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

**Vorstand:**  
Prof. Dr. Hanns-Peter Knaebel  
(Vorsitzender)  
Dr. Dirk Freund  
Dr. Joachim Schulz

**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 SOLADEST

**Hausanschrift:**  
Aesculap AG  
Am Aesculap-Platz  
78532 Tuttlingen  
Deutschland

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The risk of contamination of the packaged tool or an infection of the patient based on it is estimated to be low. However, it cannot be entirely ruled out.

Therefore a product recall of all affected batches has been decided on as a precautionary measure. Using the attached return form, please send these articles to:

**Aesculap AG**  
**Gebäude 75 – Abteilung LRP / Produktrückruf**  
**Siegfried Schwarz**  
**Am Aesculap-Platz**  
**DE – 78532 Tuttlingen**

You will receive the choice of either credit or a replacement delivery as soon as possible, estimated in about four weeks.

Please fill out the attached return form.

If you have any questions concerning this Field Safety Corrective Action, please contact our product management for endoscopy or our customer service for surgery/neurosurgery/endoscopy:

**Mr Gunnar Moeller**

**Tel:** + 49 7461 95-1118  
**Fax:** + 49 7461 95-2131  
**E-Mail:** [gunnar.moeller@aesculap.de](mailto:gunnar.moeller@aesculap.de)

**Mr Tilo Philipp**

**Tel.:** + 49 7461 95-2688  
**Fax:** + 49 7461 95-2943  
**E-Mail:** [tilo.philipp@aesculap.de](mailto:tilo.philipp@aesculap.de)

Please notify all users of the above product and any other persons who need to be informed within your organisation about this *FSCA*. If you have provided the products to third parties, please forward a copy of this information to them or inform the contact person named below. Please retain this information until the action is closed. Your national competent authority has received a copy of this *FSCA*.

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Please accept our apologies for the inconvenience caused by this action.

Kind regards,

Aesculap AG

**FEEDBACK FORM / FSCA**  
**DISP.METZENBAUM SCISSORS D:3.5/290MM,**  
**DISP.MARYLAND FORCEPS D:3.5/290MM,**  
**DISP.ATR.GRASPING FCPS D:3.5/290MM**

Please return this form by fax or e-mail to:

**Jana Zibulski / Department QMV**

**Fax +49 7461-95 1555**

**vigilance\_aag.de@aesculap.de**

We confirm having received the product recall of articles P0830SU, P0831SU and P0833SU. We will implement the recommended measures:

- We do not have any of the affected products in use.
- We send back the affected products from our establishment.

HOSPITAL \_\_\_\_\_

CITY \_\_\_\_\_

NAME \_\_\_\_\_

DEPARTMENT \_\_\_\_\_

PHONE \_\_\_\_\_

\_\_\_\_\_  
SIGNATURE DATE