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<http://www.bbraun.com>

Date:

February 27, 2019

## *Safety Notice – Product Recall*

### **GA336 – ACCULAN 4 OSCILLATING SAW STRAIGHT**



### **GA337 – ACCULAN 4 OSCILLATING STERNUM SAW**



As part of market surveillance, Aesculap AG received feedback that during an operation, the saw head of the demonstration device, ACCULAN 4 OSCILLATING SAW - GA336, detached from the handle during preparation at the instrument table.

Due to dimensional changes on the ACCULAN 4, it was also necessary to change the dimensions of the locking ring in relation to the previous version in order to ensure a secure attachment of the saw head. For products affected by the recall, this adjustment was not made.

The error could be narrowed down to the products GA336 and GA337.

According to our research, you have received articles of the affected product. Please check if such products are in use in your facility.

**Chairman of Supervisory Board:**  
Prof. Dr. Heinz-Walter Große

**Executive Board:**  
Dr. Joachim Schulz  
(Chairman)  
Dr. Jens von Lackum  
(Deputy Chairman)  
Dr. Katrin Sternberg

**Corporate Office: Tuttlingen**  
Register Court: Stuttgart HRB 726261  
VAT reg. no. DE812160059  
  
WEEE-Reg.-No. DE 65109852

**Bank Account:**  
**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

**Address:**  
Aesculap AG  
Am Aesculap-Platz  
78532 Tuttlingen  
Germany

**In case you have located an affected product:**

Please ensure that these products are no longer used.

Should you have a affected product, please return it with the attached "**Product Recall Form**" to:

**Aesculap AG**  
LRP  
Siegfried Schwarz  
Am Aesculap-Platz  
D-78532 Tuttlingen

The products GA336 / GA337 that you have returned will immediately be equipped with a new locking ring and sent back to you.

For any product-related requests, kindly do not hesitate to contact our product manager:

**Marcus Schäfer**  
☎ + 49 7461 95 2913  
☎ + 49 171 44 33 732  
[marcus.schaefer@aesculap.de](mailto:marcus.schaefer@aesculap.de)

**In case you could not locate any affected product:**

In the case you **do not have** any of the involved products, please send us the attached "**Feedback Form**" and tick as appropriate.

Please ensure that all users of the affected product are informed about this safety information in your organization. If you have distributed the products to a third party, please forward a copy of this information or inform the above mentioned contact person. The Competent Authority BfArM - Bundesinstitut für Arzneimittel und Medizinprodukte, has received a copy of this safety information.

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

With best regards,

Aesculap AG



**FEEDBACK FORM / FSCA****GA336 – ACCULAN 4 OSCILLATING SAW STRAIGHT  
GA337 – ACCULAN 4 OSCILLATING STERNUM SAW**

Please send back this feedback form via fax or e-mail to:

**Department QMV****Fax +49 7461-95 1555****vigilance\_aag.de@aesculap.de** We do not have affected product(s). We will return affected product(s).

HOSPITAL \_\_\_\_\_ LOCATION \_\_\_\_\_

NAME \_\_\_\_\_ DEPARTMENT \_\_\_\_\_ PHONE \_\_\_\_\_

SIGNATURE \_\_\_\_\_

DATE \_\_\_\_\_



## PRODUCT RECALL

Hygienic condition:

new good

used decontaminated

used not decontaminated

pos.no.	part no. article no.	serial / lot-no.	quantity	remark		

### RETURN ADDRESS :

Aesculap AG  
LRP  
Siegfried Schwarz  
Am Aesculap-Platz  
D-78532 Tuttlingen – Germany

### ADRESS / SENDER:

### DATE / SIGNATURE :

**Vorsitzender des Aufsichtsrates:**  
Prof. Dr. Heinz-Walter Große

**Vorstand:**  
Dr. Joachim Schulz  
(Vorsitzender)  
Dr. Jens von Lackum  
(Stellv. Vorsitzender)  
Dr. Katrin Sternberg

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

WEEE-Reg.-Nr. DE 65109852

**Bankverbindungen:**  
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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