

Contact: [REDACTED]  
 Fon: [REDACTED]  
 Fax: [REDACTED]  
 Email: [vigilance\\_aag.de@aesculap.de](mailto:vigilance_aag.de@aesculap.de)  
 Internet: <http://www.bbraun.com>  
 Date: April 25, 2019

## Safety Notice – Product Recall

**PL770SU – CAIMAN MARYLAND NON ARTICULAT.D5/360MM – BATCH 52481830**



During the course of post-market surveillance, Aesculap AG received feedback that during an operation with a CAIMAN MARYLAND NON ARTICULAT.D5/360MM - PL770SU no acoustic warning signal was triggered despite the fact that the coagulation cycle was not successfully completed.

The complaint analysis revealed a deviation from the product specification that occurred during the production process of a specific batch (52481830). A non-compliant component has been installed in the jaw section of the device. Due to the resulting deviation from the specification, the jaw no longer closes flush. The failure could be limited to batch 52481830.

According to internal distribution tracking you have received articles of the affected batch. Please check if such products are in use in your facility. The identification of an affected product can be clearly carried out via the label on the sterile blister (see Figure 1 REF and LOT encircled in green).

Due to the deviation from the product specification there is the possibility that insufficient coagulation might lead to intraoperative or postoperative bleeding.



**Figure 1: Label sterile blister PL770SU of affected batch 52481830**

**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 DEUTDE33HAN33

**Baden-Württembergische Bank**  
BLZ 600 501 01 Konto 487 1905  
IBAN DE31 6005 0101 0004 8719 05  
SWIFT / BIC SOLADEST

**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

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

**Markus Bauer**  
☎ + 49 7461 95 31266  
☎ + 49 151 61 31 19 44  
[markus.bauer@aesculap.de](mailto:markus.bauer@aesculap.de)

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

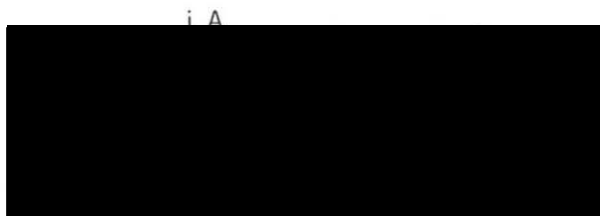
In the case you **do not have** an involved product, please send us the attached "**Feedback Form**" and tick as appropriate.

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****PL770SU – CAIMAN MARYLAND NON ARTICULAT.D5/360MM  
BATCH 52481830**

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

## ADDRESS / SENDER :

## DATE / SIGNATURE :

**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 DEUTDE33HAN30  
**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