

**Aesculap AG**  
**Quality Management**

Postfach 40  
78501 Tuttlingen  
Germany

Internet: <http://www.bbraun.com>

Date: June 06, 2019

## **Safety Information**

### **GA414 – DISP.FLEECE DRAPE F/GA419/GD417/GD421**



In the cause of an internal investigation it was noticed that the existing validation of the manufacturing process of a supplier does not fully guarantee the sterility of DISP.FLEECE DRAPE F/GA419/GD417/GD421.

The Disposable Fleece Drape is used for the intraoperative separation of the sterile and unsterile area. In use, the product has no direct contact with the sterile OR stuff, the surgeon or with the patient (figure 1). Therefore the transfer of potentially present contamination is unlikely.

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

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

**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 2122 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

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

The scope of the affected articles can be limited to the Disposable Fleece Drape with the article number GA414. The Aesculap AG decided to recall the product as a precaution.



Figure 1: Disposable Fleece Drape GA414 attached to sterile shield GA419 on a mobile stand GA415 according to intended use

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

**You have found a product in your organization that is affected, please enclose the return form "Product Recall" and address the shipment to:**

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

In this case you will receive a credit note. Based on the stop of production a replacement delivery unfortunately is not possible.

**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.

For questions about the product and the further proceeding our product management is at your disposal.

Please contact:

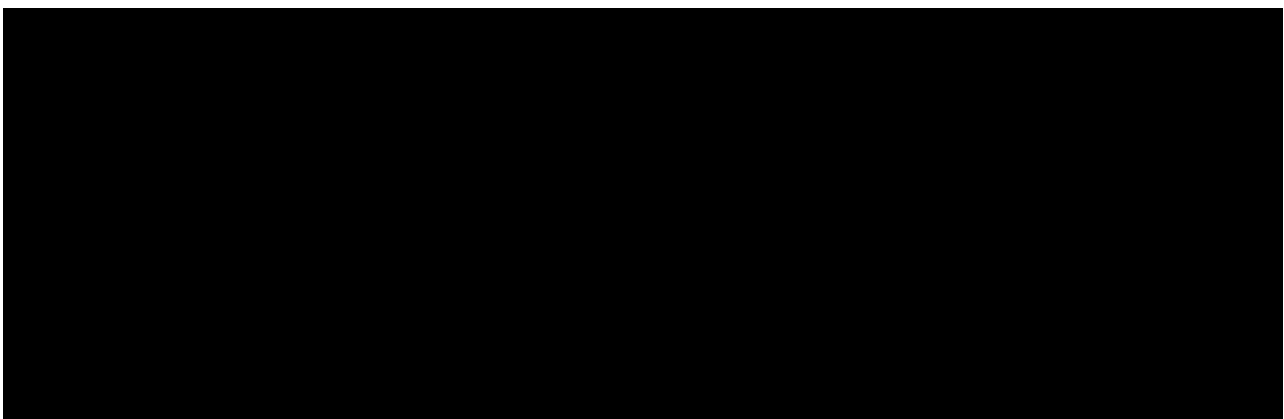
**Aesculap AG**  
**APS**  
**Marcus Schäfer**  
**Am Aesculap-Platz**  
**D-78532 Tuttlingen**  
**Phone: +49 7461 95-2913**  
**E-Mail: [marcus.schaefer@aesculap.de](mailto:marcus.schaefer@aesculap.de)**

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**  
**GA414 – DISP.FLEECE DRAPE F/GA419/GD417/GD421**

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 :**

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

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