

Aesculap AG
Quality Management

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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

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

i. V.



Thorsten Barthelmes

Director Quality Project and Risk Management
Safety Officer Medical Device

i. V.



Kerstin Rothweiler

Team Leader Quality Management Vigilance
Deputy Safety Officer Medical Devices

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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(Deputy Chairman)
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BLZ 600 501 01 Konto 487 1905
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