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.
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
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

## Table

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<th>serial / lot-no.</th>
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## RETURN ADDRESS:
Aesculap AG
LRP
Siegfried Schwarz
Am Aesculap-Platz
D-78532 Tuttlingen – Germany

## ADDRESS / SENDER:

## DATE / SIGNATURE:

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Chairman of Supervisory Board: Prof. Dr. Heinz-Walter Erbde
Executive Board: Dr. Joachim Schulz (Chairman)
Dr. Jens van Laack (Deputy Chairman)
Dr. Karin Sternberg

Corporate Office: Tuttlingen
Register Court: Stuttgart HRB 7286/0
VAT reg. no. DE1219901
AEGEE-Reg-No. DE 6510982

Bank Account:
Deutsche Bank AG Tuttlingen
BLZ 663 700 75 Konto 2122 000 00
IBAN DE54 6537 0073 0212 2000 00
SWIFT / BIC DEUTDEDD096

Address: Aesculap AG
Am Aesculap-Platz
78532 Tuttlingen
Germany