

**Aesculap AG
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Germany

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Date: June 06, 2019

Safety information

**Product counterfeiting of UNI-Graft® K DV (12 mm/15 cm)
Original article number: 1101129; Lot: 2173540157**

In the cause of an internal investigation Aesculap AG became aware of a product counterfeit of the UNI-Graft® K DV vascular prostheses.

Because Aesculap AG is not the manufacturer of the counterfeit products no statements regarding performance characteristics, mechanical properties, biocompatibility and sterility can be made. The counterfeit products are not available to us. No statement can be made about their quality. With this letter we inform you which preventive measures can be taken to ensure patient safety in the future.

As a precaution, please check all Uni-Graft® K DV (1101129; 12 mm/15 cm) vascular prostheses for correct packaging before use. Aesculap AG always delivers the products in double sterile packaging in cartons of 1 piece each. The counterfeit products are only single packed. On the photos available to us, this is recognizable (see figure 1). Furthermore the CE sign is missing on the counterfeit goods. Prostheses that are not correctly packed and labelled as described above must not be used.

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 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 SOLADEST

Address:
Aesculap AG
Am Aesculap-Platz
78532 Tuttlingen
Germany



Figure 1: Left: Original product; Right: Couterfeit

After our research you receive original articles of the product affected by the counterfeit. Please check whether there are any counterfeit products in your facility.

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

B. Braun Melsungen AG
AE-SM-DE 03 S
Dr. Michael Kohlhoff
Sieversufer 8
12359 Berlin
Phone: +49 30 58989-7114
E-Mail: michael.kohlhoff@bbraun.com

Please do not use the counterfeit products in any case.

In the event that you return counterfeit products or destroy them yourself, please enclose the "Product Recall" form and address the shipment to us:

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

In case you could not locate any affected product:

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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

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
1101129 - Uni-Graft® K DV (12 mm/15 cm)
Counterfeit products

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). Number: _____
- We have identified counterfeit products and destroyed them.. Number: _____

HOSPITAL _____ LOCATION _____

NAME _____ DEPARTMENT _____ PHONE _____

SIGNATURE _____ DATE _____

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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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