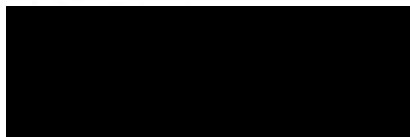


7 June 2019



TO WHOM IT MAY CONCERN

CC Chairman Medical Board and relevant Head of Departments

Safety information

Product counterfeiting of UNI-Graft® K DV (12 mm/15 cm)

Original article number: 1101129

In the course 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.

600 North Bridge Road
#15-05 Parkview Square
Singapore 188778

Tel: (65) 62130933
Fax: (65) 62130930
<http://www.bbraun.com.sg>

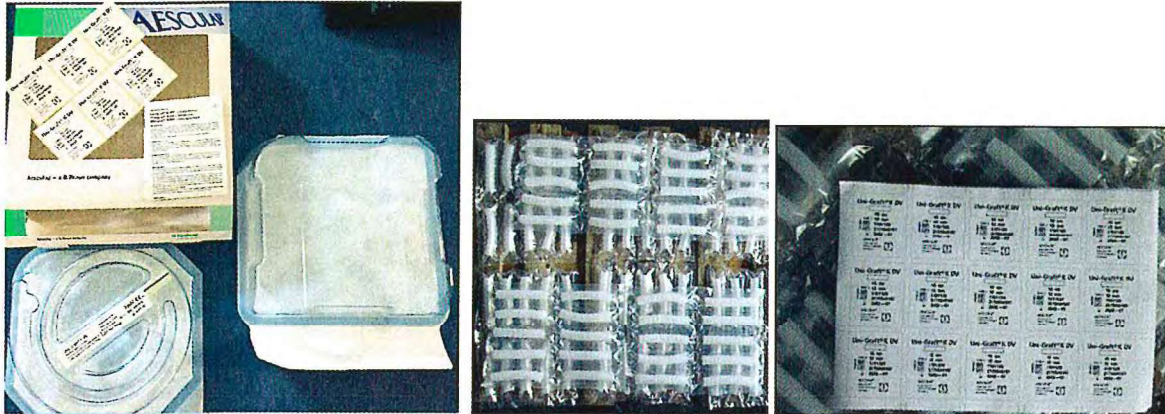


Figure 1: **Left: Original product;**

Right: Counterfeit

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 Singapore Pte Ltd
Ms Agnes Seah
600 North Bridge Road
#15-05 Parkview Square
Singapore 188778
Phone: 62130951

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:

B. Braun Singapore Pte Ltd
Ms Agnes Seah
600 North Bridge Road
#15-05 Parkview Square
Singapore 188778

600 North Bridge Road
#15-05 Parkview Square
Singapore 188778

Tel: (65) 62130933
Fax: (65) 62130930
<http://www.bbraun.com.sg>

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.

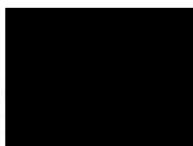
Please ensure that all users of the affected product are informed about this safety information in your organization. If you have distributed the products to a third party, please forward a copy of this information or inform the above mentioned contact person. The Competent Authority, Health Sciences Authority, 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,



Lee Bee Keong
General Manager, Sales



Agnes Seah
Senior Sales Manager

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:

B.Braun Singapore Pte Ltd

Fax: 62130930

Email: bbraun.sg@bbraun.com

- ☐ 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 _____

600 North Bridge Road
#15-05 Parkview Square
Singapore 188778

Tel: (65) 62130933
Fax: (65) 62130930
<http://www.bbraun.com.sg>



PRODUCT RECALL

Hygienic condition:

☐ new good

☐ used decontaminated

☐ used not decontaminated

pos. no.	part no. article no.	serial / lot-no.	quantity	remark		

RETURN ADDRESS :

B.Braun Singapore Pte Ltd
600 North Bridge Road
#15-05 Parkview Square
Singapore 188778

ADDRESS / SENDER:

DATE / SIGNATURE :

600 North Bridge Road
#15-05 Parkview Square
Singapore 188778

Tel: (65) 62130933
Fax: (65) 62130930
<http://www.bbraun.com.sg>

