

P. J. Dahlhausen & Co. GmbH · Postfach 56 01 32 · 50986 Köln
«Customer»

P. J. Dahlhausen & Co. GmbH
Alles Gute fürs Krankenhaus

Emil-Hoffmann-Straße 53
50996 Köln · Germany

Tel.: +49 (0) 2236 3913-0
Fax: +49 (0) 2236 3913-109
info@dahlhausen.de
www.dahlhausen.de

Urgent Safety Notice

**concerning
sterile medical devices for single use**

24 February 2023

Addressee:

Users and operators as well as distributors

Identification of the medical devices concerned:

Sterile medical devices for single use according to the attachment

Dear Sir or Madam,

With this letter we would like to inform you of an urgent safety notice regarding our sterile medical devices for single use indicated in the attachment.

According to our records, your institution has received products affected by this measure. The product delivered to your institution are listed in the attached feedback form and the attached delivery notes.

Description of the problem:

Within an internal control, we have noted that the sterilization process of the medical devices listed in the attachment was not carried out properly. Due to this error, the products may be non sterile.

Based on this determination, we carry out a voluntary product recall.

Please note that we have not received any customer complaint, report or notification of an incident regarding possible compromised sterility until today.

What action should be taken by the addressee?

We kindly ask you to take the following measures based on this safety notice:

1. Check the affected medical devices in your institution and identify the affected products. The use and distribution of the affected products should be stopped and the products should be separated.
2. If you have products that are affected by these measures, please return them to us at our expense. You will receive a corresponding replacement delivery.
3. Fill in the enclosed feedback form and return it to us by 10 March 2023.
4. Please keep this safety notice at least until the measure has been completed.

Transmission of the described information:

Please ensure in your institution that all users of the above mentioned products and other persons to be informed are aware of this **Urgent Safety Notice**. If you have supplied products to third parties, please forward a copy of this safety notice to them.

The Federal Institute for Drugs and Medical Devices has received a copy of this urgent safety notice.


If you have any questions regarding this urgent safety notice, please contact one of the contact persons listed below:

Petra Hardt
Manager QM/RA
Phone: +49 2236-3913171
Fax: +49 2236-3913179
E-mail: petra.hardt@dahlhausen.de

Ute Wanders
QM/QA
Phone: +49 2236-3913178
Fax: +49 2236-3913179
E-mail: ute.wanders@dahlhausen.de

We apologize for any inconvenience caused by these measures and assure you that safety and quality are our top priority. We thank you in advance for your support.

Best regards,


Petra Hardt
Manager QM/RA

Attachments: Attachment_ Feedback form, delivery notes

Attachment**Identification of the medical devices concerned:**

REF	Description	Lot
07.011.14.143	Atrauma suction catheter 60 cm Ch 14	230419
07.011.16.143	Atrauma suction catheter 60 cm CH 16	230419
07.022.18.522	Stomach tube with mandrin 80 cm Ch 18	230419
07.023.00.016	Duodenal tube Levin Ch 16	230419
07.049.04.207	Suction cannula Yankauer 11/4 mm	230319
07.049.06.001	Suction cannula Yankauer 6/4 mm	230319
07.049.06.207	Suction cannula Yankauer 12/6 mm	230319
07.049.08.207	Suction cannula Yankauer 13/8 mm	230319
07.049.08.210	Suction cannula Yankauer 8 mm	230419
07.049.08.215	Suction cannula Standard 8 mm	230419
07.078.10.235	Suction catheter 50 cm Ch 10	230319
07.079.16.210	Suction catheter 60 cm Ch 16	230419
07.079.16.215	Suction catheter 60 cm Ch 16	230419
07.084.14.131	Suction catheter 50 cm Ch 14	230419
07.085.14.211	Suction catheter 60 cm Ch 14	225119
07.086.14.236	Suction catheter 50 cm Ch 14	230419

Feedback form

Urgent Safety Notice

to sterile medical devices for single use

Please return the completed form
(by fax +49 2236/3913-179 or e-mail ute.wanders@dahlhausen.de)
by **10 March 2023** at the latest.

«Customer»

Customer No:

Delivered products: REF

- We have received this safety notice and have taken the necessary measures contained therein.
- We confirm that we have NO products in stock that are affected by this measure. All products have been used without complaint.
- We confirm that we have the following quantity of products affected by this measure on stock. We have immediately stopped the use and distribution of the products concerned. All products have been separated and will be respectively have been returned to P.J. Dahlhausen & Co. GmbH. We assure that these will not be used on patients:

REF	Product description	Lot	Returned products
07.011.14.143	Atrauma suction catheter 60 cm Ch 14	230419	
07.011.16.143	Atrauma suction catheter 60 cm Ch 16	230419	
07.022.18.522	Stomach tube with mandrin 80 cm Ch 18	230419	
07.023.00.016	Duodenal tube Levin Ch 16	230419	
07.049.04.207	Suction cannula Yankauer 11/4 mm	230319	
07.049.06.001	Suction cannula Yankauer 6/4 mm	230319	
07.049.06.207	Suction cannula Yankauer 12/6 mm	230319	
07.049.08.207	Suction cannula Yankauer 13/8 mm	230319	
07.049.08.210	Suction cannula Yankauer 8 mm	230419	

REF	Product description	Lot	Returned products
07.049.08.215	Suction cannula Standard 8 mm	230419	
07.078.10.235	Suction catheter 50 cm Ch 10	230319	
07.079.16.210	Suction catheter 60 cm Ch 16	230419	
07.079.16.215	Suction catheter 60 cm Ch 16	230419	
07.084.14.131	Suction catheter 50 cm Ch 14	230419	
07.085.14.211	Suction catheter 60 cm Ch 14	225119	
07.086.14.236	Suction catheter 50 cm Ch 14	230419	

- The products concerned by this measure have not been sold to third parties.
- The products concerned by this measure have been transferred to third parties. We will inform the clientele about this safety information and non-use of the affected products.
- The products affected by this measure and owned by third parties will be returned to P. J. Dahlhausen & Co. GmbH.

Contact

Contact person customer (in block letters)

E-Mail

Telephone number

Place, Date

Signature/Stamp