

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 Disposable Laryngoscope Handle

20 October 2020

Sender:

P.J. Dahlhausen & Co. GmbH
Emil-Hoffmann-Strasse 53
50996 Cologne
Germany

Addressee:

Users and operators as well as distributors

Identification of the medical devices concerned:

Disposable laryngoscope handle for adults	REF 90.003.09.003	Lot FM167
--	--------------------------	------------------

Dear Sir or Madam,

With this letter we would like to inform you of an urgent safety notice regarding our disposable laryngoscope handle for adults, REF 90.003.09.003, Lot FM167.

According to our records, your institution has received products affected by this measure. The number of products delivered to your institution is listed in the attached feedback form.

Description of the problem:

Based on a feedback from the market, we have noted that during the application of the disposable laryngoscope handle, the light source may malfunction. This malfunction is manifested by the fact that the light source in the handle emits no or insufficient light. There is a risk that this may cause a delay in the patient's intubation.

Based on this feedback, we carry out a voluntary recall.

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 disposable laryngoscope handles in your institution and identify the affected Lot. 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 4 November 2020.
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

Margit Stöckmann
Assistant QM/QA
Phone: +49 2236-3913172
Fax: +49 2236-3913179
E-mail: m.stoeckmann@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:
Feedback form
Delivery note

Feedback form

Urgent Safety Notice

to Disposable Laryngoscope Handle for adults, REF 90.003.09.003, Lot FM167

Please return the completed form (by fax **+49 2236/3913-179** or e-mail **m.stoeckmann@dahlhausen.de**) by **4 November 2020** at the latest.

«customer»

Customer No.:

Delivered Quantity:

- ☐ 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 returned to P.J. Dahlhausen & Co. GmbH. We assure that these are not used on patients.

_____ quantity

- ☐ 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 (in block letters)

E-Mail

Telephone number

Place, Date

Signature/Stamp