



Urgent product safety information

200817996

regarding

Karl Storz: rubber bulb, for 436610

2020-07-06

Product description: Rubber bulb is used to supply the atomizer 436610 with air.

Item numbers: 437000

Batch numbers: all

Sender: Karl Storz SE & Co. KG,
Dr.-Karl-Storz Straße 34,
78532 Tuttlingen, Germany

Addressee:

All users, operators, and safety officers at clinics and hospitals

Identification of the medical devices concerned:

Item	Designation
437000	Rubber bulb, for 436610

Description of the problem including the identified cause:

Karl Storz has become aware that due to a mix-up, the reprocessing instructions incorrectly contain information that will directly lead to the destruction of the rubber bulb if followed. These reprocessing instructions are available on our homepage among other places. So far, one case has been reported in which the rubber bulb was destroyed. There is no danger to patients/users/third parties, as the product can no longer be used if the faulty reprocessing procedure is used.

What measures are to be taken by the addressee?

According to our records, you have been supplied with at least one of the products listed above and are therefore affected by this action.

Please read this letter carefully and take the following measures:

1. Immediately check your reprocessing instructions for item number 437000.
2. Forward this product safety information internally to any parties who may be interested or affected.
3. Destroy the outdated reprocessing instructions for the rubber bulb.
Replace the instructions for use with the updated version attached to this correspondence.
The updated version can also be downloaded from our homepage in the Service/Hygiene section.
4. Train your employees in the new reprocessing instructions
5. Fill in the attached reply and return it to the indicated address. With this reply, you confirm that all old instructions for use have been destroyed and that staff have been trained in the new instructions for use.
If the corresponding products are no longer in your stocks on site, please return the appropriately completed reply to us anyway. This will enable us to update our records, and you will avoid receiving further unnecessary correspondence about this subject from us.
6. No further action is required for treated patients.
7. Send the completed response form to the fax or e-mail address on the form by August 07, 2020.

If you have any questions about this action, please get in touch directly with the contact person listed below.

We hereby confirm that the relevant national authorities in your country have been informed about this safety-related corrective action.

Thank you in advance for your prompt response to this matter. We apologize for any inconvenience caused.

Contact:

Robert Herz
Karl Storz SE & Co. KG
Phone: +49 (0)7461 708 7348 (during business hours)
Fax: +49 7461 708 45581

Sincerely,

A handwritten signature in blue ink, appearing to read 'Robert Herz', is positioned below the 'Sincerely,' text.

p.p.
Robert Herz
Karl Storz SE & Co. KG

Customer response form: 200817996

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Batch numbers: all
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Customer no. _____
Hospital _____
ZIP, town _____
Contact _____
Phone no. _____

- I confirm that I have read and understood the product safety information 200817996 and that I have implemented it accordingly.
- We do not have any of the listed products in our stocks

Name: _____
Signature: _____
Date: _____

We have passed on affected products to the following facilities:

Contact data for facility

Please send this form to:
vigilance@karlstorz.com

or

Fax: +49 7461 708 45581

or by post to

Insert customer no.

KARL STORZ SE & Co. KG
z. H. Robert Herz
- Abteilungsleiter Vigilance -
Dr. Karl-Storz-Str. 34
78532 Tuttlingen, Germany