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Kontakt:

Datum: 11.12.2017

Urgent Field Safety Notice

Affected Medical Device: Steam Sterilizer ProtoCERT

Belgium: Serial Number 1988

Denmark: Serial Number 2234

Iceland: Serial Number 2024

Turkey: Serial Number 2235

Ladies and Gentlemen,

As the manufacturer of the steam sterilizer "ProtoCERT" we are writing to you today, to draw your attention to the following Urgent Field Safety Notice:

Clarification of the potential hazard:

In the use of the sterilizer "ProtoCERT" which is produced by us, the following risk which caused an incident with unanticipated serious deterioration of health to an professional user became known to us:

To close the sliding door of the sterilizer „ProtoCERT“, the door is pulled upwards by a handle. Below the door, there is a piston filled with compressed air which is used to carry the dead weight of the door. The pressure inside the piston is adjusted so that the door cannot close automatically. When closing, the door must be actively pulled upwards with a slight effort. If the door moves upwards automatically a malfunction has occurred that needs to be corrected by customer service.

The pressure inside the piston is adjusted with a pressure reducer. In the case which became known to us the pressure reducer was defective and showed a leakage. Due to the uncontrolled increase of pressure the door slowly moved upwards automatically. Although this malfunction was noticed by the user hours before the accident, the sterilizer was used further without restriction.



In this particular case, there was a shelf used to load the sterilizer in the doorway. Due to the faulty closing of the door, the shelf got wedged tightly in the doorway. The user now undertook an unauthorized repair attempt to clear the blockade. With one hand and with considerable effort to compensate the increased pressure inside the piston, the user pressed down the door by the handle. With the other hand he pushed the wedged shelf into the chamber. As the blockade was cleared the door closed promptly. The user's hand protruding into the chamber was trapped between door and chamber wall and suffered severe bruising and burns.

The user worked alone during this repair attempt and could not free himself from the sterilizer which further worsened the accident consequences.

Advice on action to be taken by the user:

Please be sure to pay attention to the following safety instructions when using the sterilizer "ProtoCERT":

1. The door of the sterilizer „ProtoCERT“ must be operated manually. The door of the sterilizer must not close automatically. If the door closes automatically, regardless of its speed, there is a hardware error and the sterilizer has to be taken out of operation. Never stop or block a door which is moving automatically, for instance with one of the shelves. Do not reach into the chamber. Do not use the sterilizer anymore. Contact customer service.
2. Check the closing force of the door once a week. This is what the instructions for use provide.
3. Do not undertake any repair attempt without having appropriate expertise. Always consult the instruction for use. Never fix an error without a second person nearby. In case of doubt, always contact customer service first.
4. Please send us back the attached confirmation of receipt.

The sterilizer „ProtoCERT“ is available as a model with either one or two chamber doors. Both models are affected by this field safety notice.

Transmission of this Field Safety Notice:

This „Urgent Field Safety Notice“ needs to be passed to all those who need to be aware within your organisation.

Please transfer this notice to any other organisation where the affected device has been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The undersign confirms that this notice has been notified the appropriate Regulatory Agency.

Further steps:

As a technical measure, safety valves shall be installed in the door pipings of the affected sterilizers. The safety valves are adjusted in a way, that the door can be opened manually with very little physical effort. The safety valves will prevent any sudden closing of the door as well. Please install the retrofit kits within four weeks after receiving and give us feedback on it.

Contact reference person:

XXXXXXXXXXXXXXXXXXXX

Tel.: +49 221 35017-XX

e-mail: service@lautenschlaeger.net

With best regards

F. & M. Lautenschläger GmbH & Co. KG

**Confirmation of Receipt for the Urgent Field Safety Notice Sterilizer „ProtoCERT“
dated 11.12.2017**

Please complete this confirmation of receipt, tick the appropriate boxes and send the confirmation to the following fax number: +49 221 35017-15 or send an e-mail to service@lautenschlaeger.net

Please inform us as well, if you should no longer have stock of the listed medical devices.

Medical device: Sterilizer „ProtoCERT“

Manufacturer: F. & M. Lautenschläger GmbH & Co. KG

Serial number: xxxx

- We herewith confirm the receipt of this Urgent Field Safety Notice and confirm the implementation of the measure.

- We herewith confirm the receipt of this Urgent Field Safety Notice and we do not have any of the affected medical devices in house.

Name of institution:

Name of contact person:

Address:
.....
.....

Date: Signature: