

18/08/2022

Urgent safety information (FSN-22-0728)

Carrying straps for Careclave 618

Sender:

MELAG Medizintechnik GmbH & Co. KG
Geneststraße 6-10
10829 Berlin
Germany

Addressee:

To all relevant users and specialist stockists

Identification of the medical devices concerned:

Product designation	Article number
Careclave 618	ME10618

Dear Madam/Sir,

In accordance with our obligations specified in the European Medical Device Regulation (MDR) we want to inform you of urgent safety information and ask for your assistance.

Description of the problem including the determined cause:

On delivery, our Careclave 618 product includes two carrying straps with which the device can be removed from the packaging and lifted onto the work surface. The straps are designed in accordance with EN 61010-1 and have been successfully verified by TÜV Rheinland.

An internal test has revealed that the strap might become damaged under certain circumstances, with the result that it can no longer carry the weight of the device. We have no reports from the field that this has actually happened.

Nonetheless, carrying straps included with devices with serial number 20226181185 and older (20226181184, 20226181183, etc.) must no longer be used!

The Careclave function is not affected. **The Careclave can still be used without restrictions.**

Preventive action

Devices beginning with the serial number 20226181186 are already equipped with a new design at delivery.

Actions to be carried out by the customer

1. Please no longer use the carrying straps included with devices with serial number 20226181185 and older (20226181184, 20226181183, etc.)!
2. Please inform every one within your organisation about this urgent safety information immediately. Confirm receipt and acknowledgement in writing by 15/09/2022 by email (FSN@melag.de).

If products have been passed on to third parties, forward this urgent safety information to them immediately and also confirm to us their receipt and acknowledgement of the information in writing, quoting the serial number of the product, by the given deadline.

3. If required, please let us know for which devices concerned we can send you new carrying straps by stating the serial number(s).

Please keep this information, at least until the action has been completed.

The Federal Institute for Medicinal Products and Medical Devices has received a copy of this “urgent safety information”.

We apologise for any inconvenience. Thank you for your cooperation.

If you have any further questions, do not hesitate to contact us.

Contact:

André Nikelat
Product manager Careclave 618
Telephone: +49 30 757911 - 3770
Fax: +49 30 7579977- 99
Email: nikelat@melag.de

Sincere regards,



MELAG Medizintechnik GmbH & Co. KG