

Urgent Safety Information to our Customers

Recall of Fit Rubber Dam Clamps

Duisburg, 30th April 2021

Sender / Responsible Manufacturer:

Hager & Werken GmbH & Co KG
Mr. Christian Nolden
Ackerstr. 1
47269 Duisburg
Germany

Addressees:

Downstream dealers, doctors, clinics, users

Dear Sir or Madam,

Please note that we have to recall the following articles due to any defects that might arise:

Identification of the medical devices in question:

1. REF 355404 - Fit Rubber Dam Clamp No. 12A

Affected batch / lot: 200609039
 200827048
 191121004
 1808A006
 190507036

2. REF 355405 - Fit Rubber Dam Clamp No. 13A

Affected batch / lot: 1810J011
 190722009
 191121005
 200609040

3. REF 355363 – Fit Rubber Dam Clamp No. 26

Affected batch / lot: 200609032

Delivery period:

August 2019 – April 2021

Product type:

Reprocessable clamp for fastening a rubber dam during a dental treatment

Background information on the product problem

Product problem

An increasing number of breakages in the clamps occurred within/during above-mentioned period. These breakages may be related to the raw material used and the reprocessing process (exposure to heat).

Possible danger

The possibly increased risk of breakage of the products could result in swallowing or aspiration of fragments by the patient, which in turn could lead to a considerable health risk. Risks for patients who have already been treated cannot be identified.

Risk assessment

The risk of a significant health hazard arising from the faulty product has been classified as unacceptable. Therefore, the affected goods are being recalled.

Corrective actions to be taken by the addressees

Description of the corrective action

Please identify the according products and batches and return them to the following address:

Häger & Werken GmbH & Co. KG
Ackerstr. 1
47269 Duisburg
Germany
Keyword „Recall 04-2021-01“

Any further delivery and / or use of the affected products has to be prevented immediately. Please block possible stocks and items in circulation with immediate effect and inform your customers about this safety information without delay.

It is not necessary to take actions for patients who have already been treated.

Passing on the communicated information:

Please make sure to inform not only every user of above-mentioned products in your own organization, but to also let know any other relevant person about this Urgent Safety Information. Should you have passed on the products to a third party, please forward a copy of this information to them.

We would like to ask you to keep this information at least until the corrective action has been completed.

Contact:

Please use the following contact details to let us have a confirmation of receipt of this safety information together with the quantities of any products returned to us:

Contact Person: Mr. Dirk Seelbach

Email: d.seelbach@hagerwerken.de

Fax: +49 203 99269-747

Tel.: +49 203 99269 47

You may be assured that we will let you have a replacement delivery as soon as possible. In case of further questions, please do not hesitate to contact us.

We would like to offer our sincere apologies for any inconvenience caused and thank you very much for your immediate assistance.