

HS DOMS GmbH, Langenschader Strasse 67, D-07318 Saalfeld

«Firma»
«Straße» «Haus_Nr»
«Plz» «Ort»
«Land»

Department: Quality Management
Contact person: Andy Ölsner
FSCA reference C-103

date: 17.12.2021

Field Safety Corrective Action (FSCA)
Urgent recall at a medical product:
Replacement of backrest support (patient chair)

Dear Sir or Madam

Hereby we want to inform you about a Field Safety Corrective Action. This corrective action contains the exchange of a backrest support of the patient chair and applies to the following medical products:

Centric
Concentric
Telecentric
Ecocentric
Sinus
HS-810
HS-1410
HS-2010

identification of concerned medical products:

You can find the device name and serial number at the name plate of the device. Have a look to the attached list, where the effected devices, which were sent to you, are listed.

problem description

At examination of a broken backrest, we saw, that the welds were not done well by our supplier and so the backrest broke into two parts.

There are 4 welds that broke step by step. So luckily the fault was noticed and no one was injured. But if all welds brake at the same time, when a patient sits in the chair and leans against the back rest, it can happen, that the patient falls back and gets hurt seriously.

Measures that the customer must execute

The user must take care, that no one leans against the back rest of the chair. If this is not possible during the device is in use, you must not use the device until the backrest will be exchanged.

Please fill out the enclosed letter of acknowledgement and send it to the specified mail address

We or your responsible service partner will contact you to schedule the exchange of the backrest.

Forwarding this information

Please ensure in your organisation, that all users of the product above-mentioned and all other relevant persons will be informed about this Field Safety Corrective Action. If you delivered the product to others, please forward a copy of this information to them, or inform the contact person specified below.

Please keep this information at least until this Field Safety Corrective Action is finished.

The German federal Institute for Drugs and Medical Devices has received a copy of this Field Safety Corrective Action.

Contact person

If you have questions about this Field Safety Corrective Action, you can contact the following person:

Mr. Andy Ölsner

Tel. 03671 / 545018

E-Mail: oelsner@hs-doms.eu

We regret the inconvenience caused and want to apologize for that.

With best regards

HS DOMS GmbH

Attachments

List of serial numbers

Letter of acknowledgement

Letter of acknowledgement

Field Safety Corrective Action: C-103

Date: 17/12/2021

Affected Products: Centric
Concentric
Telecentric
Ecocentric
Sinus
HS-810
HS-1410
HS-2010

<input type="checkbox"/>	I confirm, that I received the Field Safety Corrective Action, FSCA Number C-103 and that I read and understood the information sent.
<input type="checkbox"/>	The information and measures were transmitted to all relevant persons and organisations.

Organisation / Company: _____

Name, First Name: _____

Place and Date: _____

Signature: _____

Please fill out and sign this form and then send it by email to oelsner@hs-doms.eu.