

date: 17.12.2021

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

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.

Amtsgericht Jena HRB 510890 Geschäftsführer: Matthias Stahl Commerzbank Saalfeld IBAN: DE 16 8204 0000 0655 3259 00 SWIFT (BIC): COBADEFFXXX USt-IdNr.: DE298090449 Fon: +49 (0) 36 71 - 54 50-0 Fax: +49 (0) 36 71 - 54 50 20 info@hs-doms.eu





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

Commerzbank Saalfeld IBAN: DE 16 8204 0000 0655 3259 00 SWIFT (BIC): COBADEFFXXX USt-IdNr.: DE298090449 Fon: +49 (0) 36 71 - 54 50-0 Fax: +49 (0) 36 71 - 54 50 20 info@hs-doms.eu

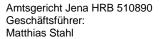
DIN EN ISO 13485



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
FSCA Number C-103 information sent.	ed the Field Safety Corrective Action, and that I read and understood the neasures were transmitted to all relevant tions.
Organisation / Company:	
Name, First Name:	
Place and Date:	
Signature:	
Please fill out and sign this form and then send it by email to colsner@bs.doms or	

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



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