

Medical supplies store XYZ

Street

City, Zip Code

Country

Urgent safety information

*Retrieval action
affecting
CAMILINO P1203*

Albstadt, 07 February 2020

Sender:

AAT Alber Antriebstechnik GmbH, Ehestetter Weg 11, D 72458 Albstadt – Ebingen, Germany

Addressee:

See address header above

Identification of the affected medical products:

Trade name: CAMILINO
Name of Model and/or number: P1203
Serial number: See supplementary sheet

Description of the problems including the detected cause:

In the gearing of the CAMILINO is a gearing wheel made of brass included. This brass gearing wheel is relevant for the power transmission between motor and wheels. A braking effect with the CAMILINO, with the help of a magnetic parking brake requires a frictional connection via the brass gearing wheel.

Measuring of the tensile force of the brass gearing wheel have shown, that we had gearing wheels in our production with too low tensile force.

Potential risk:

- a) Sudden loss of the propulsion and braking effect
- b) Device blocked and no further movements where possible

In both cases the test device was no longer functional. Particular in case a) it cannot be ruled out that this results in a safety risk for the user.

If the loss occurs on a steep gradient, the situation could arise under adverse conditions that the operator would not be able to manoeuvre the wheelchair correctly without the braking function of the pushing and braking aid.



The described issue relating to the components is solely occurred in a delimited batch-delivery.

Which measures should the addressees take?

- Use the concerned CAMILINO not any longer
- Contact the AAT Alber Antriebstechnik GmbH to clarify the collection of the device(s) and the further procedure - contact person see below - **contacting the AAT Service Center**
- The company AAT Alber Antriebstechnik GmbH will perform the repair fastest possible

Distribution of the here described safety information

Please make sure that all users of the above mentioned products and other persons involved are informed about these **Urgent Safety Informations**. Should you have given the product to a third party, please send a copy of this information along or inform the contact person stated below.

Please keep these informations at least until measures have been completed.

The Federal Institute for Drugs and Medical Devices received a copy of these „Urgent Safety Informations“.

Contact person:	<i>collection, reshipment, repair and/or exchange of affected medical products</i>	<i>§ 30 (2) Medical Devices Act, MPG</i>	<i>§ 30 (2) Medical Devices Act, MPG</i>
	<i>AAT Service – Center Richard Lindner</i>	<i>René Mey Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG</i>	<i>Holger Staib Assistant Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG</i>
Phone.:	<i>+ 49 7431 12 95 550</i>	<i>+ 49 7431 12 95 140</i>	<i>+ 49 7431 12 95 530</i>
Fax:	<i>+ 49 7431 12 95 540</i>	<i>+49.74 31.12 95-35</i>	<i>+49.74 31.12 95-35</i>
e-mail:	<i>servicecenter@aat-online.de</i>	<i>Sicherheitsbeauftragter-MP@aat-online.de</i>	<i>Sicherheitsbeauftragter-MP@aat-online.de</i>

We regret any inconvenience this may cause you and thank you in advance for your cooperation.

Best regards,

AAT Alber Antriebstechnik GmbH
René Mey / Holger Staib
Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG / Assistant Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG