

«Description»

«Client»

«Road»

«Postcode» «Town»

Eitorf, 21st December 2004

Our delivery dated «date», delivery note no.: «LI»«delivery no. »,
series no.: «series no.»

LETTER OF WARNING

**in accordance with § 14 par. 2 MPSV [Safety Plan Ordinance for
Medical Products]**

Upper frame of the seat shell undercarriage "SIMPLY" BfArM-no. 1901/04

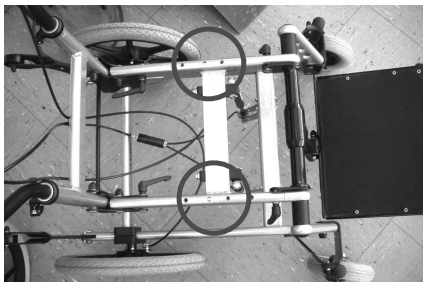
Dear Madam / Sir,

Whilst exercising medical product law, the Federal Institute for Drugs and Medical Devices (BfArM) has reported that the upper frame of a SIMPLY seat shell has broken. A total of 4 cases are now known.

We must avoid the foreseeable misuse as described above with this letter of warning in accordance with the MPSV.

We refer herewith explicitly to the observance of the safety instructions on page 15, paragraph 10 of our assembly and operating instructions. We enclose a copy of the operating instructions for your information with this letter.

We request you to pass on the available information to the users.



In this respect, it is very urgent to check the endangered areas (encircled) for breakages!

Page –2 of the SIMPLY letter of warning

Deliveries of products manufactured during the period 1998-2004 are effected.

Observations of the market have now shown that the upper wheelchair frame is often used for the attachment of transport safety systems in transport vehicles for the handicapped which have not been approved and tested for the Simply. In extreme cases, this can lead to forces from belt system attachment and/or attachment claws which are too strong having an effect on the frame, leading to deformation and possibly even breaking the frame. Fundamentally, only approved transport safety systems – pro-safe systems - may be used for the Simply seat shell undercarriage.

Further examinations have shown that the installation of third-party seat shells may cause problems if the installation statics and the adaptation position have not been adequately checked by the respective seat shell manufacturer. Prior examination and approval should definitely be provided by the manufacturer.

Furthermore, market observations have shown improper changes to the original version by third parties which have led to changes to the product's statics and have therefore caused frame breakages.

Later changes to the product by making attachments or re-construction must be agreed on by us as the product manufacturer.

We have introduced further construction measures at our own free will and these will be implemented for the wheelchairs manufactured as of 2005 in order to restrict the possible misuse still further.

If you have any questions regarding this topic, you can reach our medical safety officer – Mrs. Ute Markwald – daily from 8:00am to 4:00pm on the following telephone numbers: +49 (0) 2243-8807 14 or +49 (0) 171-4551221

Kind regards
InterCo GmbH

Dipl.-Kfm. Ute Markwald
MsiB



Encl.: Assembly and operating instructions for the seat shell undercarriage "SIMPLY", Version 1.K