

GEOMED® Medizin-Technik GmbH & Co. KG • Postfach 4047 • D-78505 Tuttlingen

Executive Management

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Your sign

Your message from
Our sign
QMS-A

Date
06 DEC 2011

FIELD SAFETY CORRECTIVE ACTION – Product Recall

Affected: ASSISTO armsystems >CA xxx-**30**-zz< and CI 100-**30**-01
production batches **25** until **67** as well as batch **74** and

ASSISTO armsystems >CA xxx-**40**-zz< and CI 100-**40**-01
production batches **25** until **58**

Ladies and Gentlemen,

Through a production fault of a subcontractor, components which were used in the above mentioned arm-systems were not properly hardened. This has led in some cases – where the products were continuously reprocessed and heavily loaded – to a breakage of the retractor bracket. In the worst case, this can occur during the use of the arm-system.

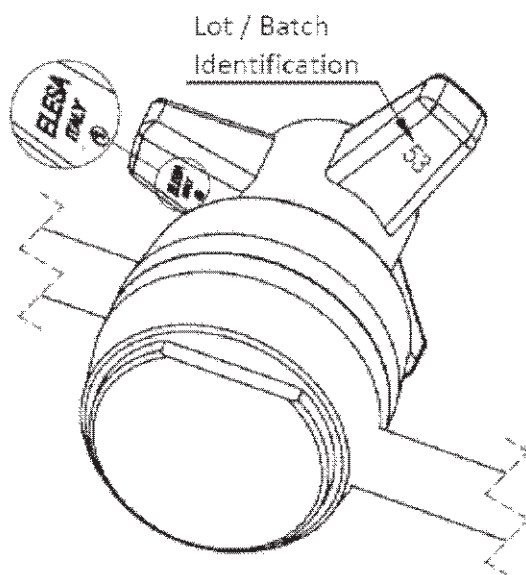
To avoid any risk to patients or users, we have decided to recall the affected products as a precaution measure. An acute risk of patients does not exist.

Please send us your arm-system(s) of the above-mentioned production batches for subsequent examination and exchange of the relevant parts as quickly as possible to the following address:

GEOMED Medizin-Technik GmbH & Co. KG
Ludwigstalerstrasse 27
at the hands of Service Department
78532 Tuttlingen
GERMANY

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The production batch is a two-digit number and can be identified at the bottom of the star handle:



Our records indicate that you have received subsequent deliveries of the affected product(s) according attached list.

Please use the included return form to send the arm-system(s) back to us with UPS – for the free return shipping, please use our **UPS account number 03710R**.

As proof, please send back the enclosed return form by fax to the following number:
+49 (0)7461- 935593

Unless you have sold the product(s) to third parties, please forward a copy of this letter or inform the contact person indicated below.

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Please address any questions regarding this safety information to Mr.

Hanno Haug
VP - QMB
Tel: +49 (0)7461 9355-30
E-Mail: hhaug@geomed.de

We are really sorry for any inconvenience that this recall may cause you. We will do everything we can to ensure a fast and convenient process of the recall. We are calculating a repair-time of 1 to max. 2 weeks.

We hope for your understanding and ask for your support for a rapid implementation of these measures.

Thank you!

Best regards,

GEOMED® Medizin-Technik GmbH & Co. KG

Thomas Haug
President

Andreas Schlatterer
VP

Hanno Haug
VP

Attachments: - Return form for product recall
 - List of delivered products