

Ihre Zeichen

Unsere Zeichen

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Datum

2013-10-16

Safety Notice

Product: GA508R
AIR HOSE ADAPTER ANGLED F/AESCULAP SMALL

Lot-No.: all lots

The angled air hose adapter GA508R is used as a connecting piece to angularly connect the air hose with the air motor. The angled air hose adapter is rotatable on the motor as well as on the air hose.

The System is used for microsurgery, for neurological, spinal, oral and otolaryngological surgeries as well as in orthopedics. The motor can be applied with the angled adapter as well as without it.

We received the information that during a surgery the AIR HOSE ADAPTER ANGLED F/AESFULAP SMALL , GA508R, disconnected from the motor, GA740R, on operation.

Due to the air pressure (up to 10 bar) the end of the air hose jerked upwards under application of pressure.

The root cause of the disconnection of the air hose adapter during surgery was the disassembling followed by the incorrect assembling of the angled air hose adapter in the hospital.

The lock washer of the adapter was deformed by the incorrect disassembling and assembling and therefore loosened, which caused the shifting of the bush. As a consequence of the shifting, the air hose adapter disconnected from the motor. Another potential consequence of the loosened lock washer and the shifted bush could be that the balls from the inside of the adapter could be freed and could fall out of the adapter.

Caution: Potential risk of injury when incorrectly assembled!

- For the safe application of the product please comply with the instructions in the IFU.
- Please especially inspect the correct position of the lock washer. It has to be positioned free of play and in the first flute (fig. 1).

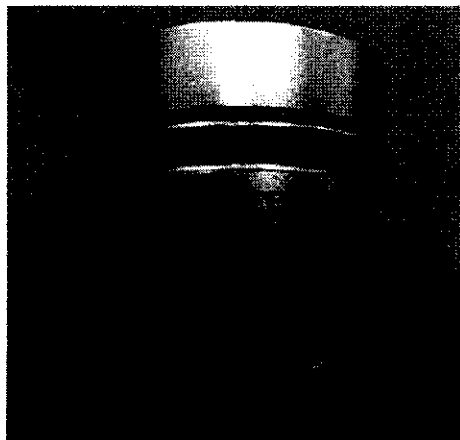


Figure 1: Position lock washer correct

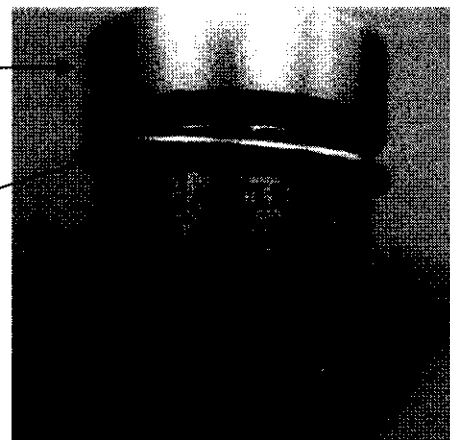


Figure 2: Position lock washer incorrect

Please make sure that any user of the above mentioned product and any other person that has to be informed within your organization, will take note of this safety information.

If you have forwarded the involved product to a third party, please provide a copy of this information to this party and also note Aesculap AG about this circumstance.

Please acknowledge the receipt of the safety information to :

**Aesculap AG
Dept. QMV
Ms Kerstin Rothweiler
Am Aesculap-Platz
DE-78532 Tuttlingen**

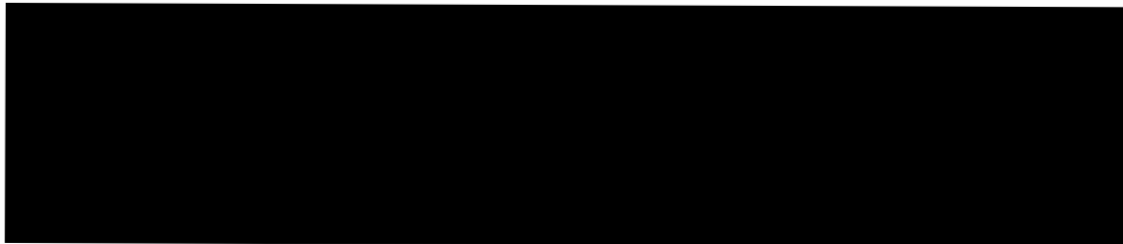
Tel.: + 49 7461 95-2182

Fax: + 49 7461 95-1555

kerstin.rothweiler@aesculap.de

p.p.

i p.p.



Please complete this form and return to Ms Kerstin Rothweiler, Dept. QMV
Fax: +49 7461-95 1555
E-mail: kerstin.rothweiler@aesculap.de

Acknowledgement
Safety Information
GA508R

1. We acknowledge receipt of the safety information.
2. Please mark accordingly:

User:

We have taken note of the safety information.

Retailer:

We have forwarded the safety information to our customers and attach an according customer list.

Facility _____ Location _____

Name _____

Department _____ Tel. _____

Signature _____ Date _____