MAQUET
GETINGE GROUP

MAQUET GmbH | Kehler Str. 31 | 76437 Rastatt

2016-09-09

Field Safety Notice

Please forward this notice to all relevant staff and potential users of the device!

Preventive Corrective Action

concerning

Accessory Adapter 600525A0

Dear customer,

with this letter we would like to inform you about a potential issue concerning the Accessory Adapter 600525A0.

The accessory adapter (600525A0) is designed for the mounting of MAQUET accessories with the dovetail guide interface immediately before, during and after surgical interventions as well as for examination and treatment.

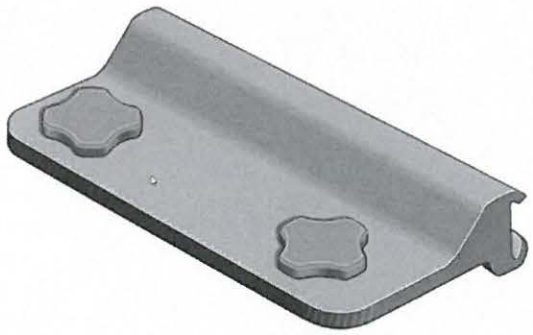

Fig. 1 Fixture 600525A0

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Steuer-Nr. 39487/29420
Geschäftsführer: Dr. Dieter Engel, Jan Merker
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Description of the problem including the determined cause:

As part of our Post Market Surveillance one case has been reported to Maquet GmbH in which a Head Rest was levered out of the dovetail profile of the Accessory Adapter (600525A0).

With the investigation it was identified that the raw material of the accessory adapter (600525A0) does not meet MAQUETs specifications. The tensile and the flexural strength of the used material are less than those of the specified materials. Furthermore it was identified that the Accessory Adapter (600525A0) does carry the specified weight of 11 kg at a distance of 300 mm, however does not meet our stringent quality requirements.

Thus far no incidence has been reported in which a person was injured.

Identification of the affected medical devices:

Potentially affected by this issue are Accessory Adapters (600525A0) manufactured in the period of 2002 to present.

Which measures are to be taken by the user?

Our sales records indicate that you own one or several of the potentially affected Products.

In order to exclude the described problem, you should no longer use the Accessory Adapter (600525A0).

As none of your devices can be explicitly excluded of being affected a replacement will be performed.

MAQUET service will be contacting you to provide the product and the necessary information free of charge.

Passing on the information described here:

Please ensure that all persons within your organization who use the above-mentioned devices and anybody else who needs to know receive this field safety notice. If you have passed the product on to third parties, please forward a copy of this notice or inform the MAQUET contact persons you are aware of.

Please keep this notice at least until the corrective measure has been performed.

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Contact person:

For further queries please do not hesitate to contact your MAQUET contact person. Should more information being required please contact our safety officer for medical devices during normal business hours (contact data on the first page).

This is a voluntary corrective action. Thus far no incidence has been reported in which a person has been injured.

The appropriate authorities have received a copy of this field safety notice.

We apologize for any inconvenience, however, consider this action as a preventive action to increase safety.

With kind regards

MAQUET GmbH

Holger Ullrich

Director Product Compliance
SW and P&PAC

Mario Mühe

Safety Officer for Medical Devices