

Rastatt, June 19, 2013

Field Safety Notice

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

Preventive Corrective Action
concerning
Extension device 1150.59AC

Dear customers,

This letter is intended to inform you about a potential issue with the extension device 1150.59AC for the Alphamaquet 1150 operating table system.

Description of the issue including the cause determined:

Within the framework of our market surveillance, we have been made aware of two complaints in which the accessory came loose from the table top. As a result, the entire extension device could fall down to the floor.

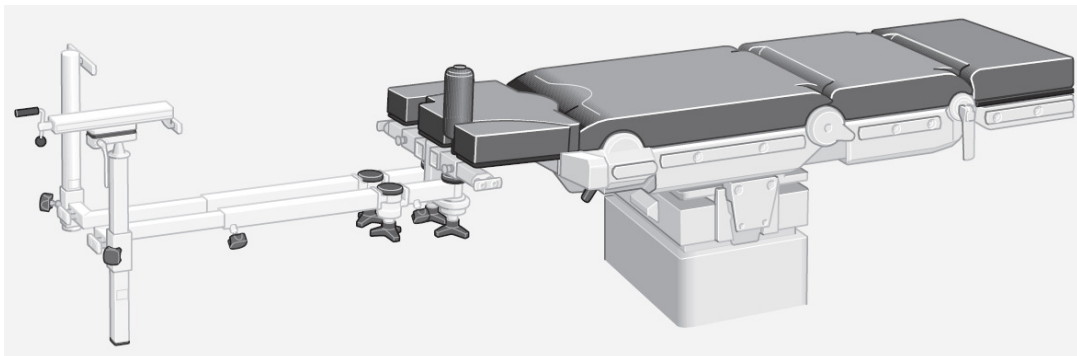


Figure 1: Extension device 1150.59AC

1. In one case, the leg plates were adjusted downwards and the longitudinal shift of the table top was subsequently adjusted in the direction to the head of the patient. During this movement, the accessory collided with the column. This led to the carrying frame being levered out of position. The problem basically only may occur when using the

extension device in combination with specific table tops and only then, when the atypical adjustment described above is carried out.

2. Detachment of the accessory may also occur if one of the adapters mounted to the left and right side of the mounting point for leg plates is not locked properly. In this case, the adapter could slip out of the mounting point by lateral forces towards the extension device. As soon as the pin does no longer join in the leg-side mounting points, the adapter can turn by the downwards weight of the patient, whereupon the extension could fall to the floor.

Identification of the affected medical devices:

1. The collision of the accessory with the column may theoretically occur when using the extension device together with the following table tops:

Model number of table top	Serial no.
1150.19BC	SN 00001 – SN 00010
1150.30A0	SN 00001 – SN 02401
1150.30B0	SN 00001 – SN 00429
1150.30D0	SN 00001 – SN 01181
1150.30F0	SN 00001 – SN 00026

All other table tops are fitted with an accessory recognition function and don't permit the adjustment of the leg plates and the longitudinal shift (cranial) of the table top when the extension device is fitted

2. The possible release of the accessory with not properly locked adapter, could basically affect all extension devices 1150.59AC.

Which measures are to be taken by the user?

Our sales records indicate that you own one of the affected 1150.59AC extension devices.

Once the parts are available, the MAQUET service or the MAQUET authorised service technician will be contacting you to arrange an appointment to carry out a free replacement of the left and right adapters. The new adapter prevents both scenarios described above.

1. Until exchange of the adapter, please use the extension device carefully in combination with one of the above mentioned table tops. In particular, do not adjust the leg plate interface and the longitudinal shift (cranial) of the table top when the extension device is fitted.

2. As described in the instructions for use in chapter 3, always check that the adapter is firmly seated after fitting, regardless of the table top used, to prevent a possible later release.

Passing on the information described here:

Please ensure that all persons within your organisation who use the above mentioned product 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 action has been completed.

Contact person:

We apologise for any inconvenience, however, consider this action as a preventive action to increase safety. For further questions please contact your MAQUET contact person. Should you require more information, please contact our safety representative for medical devices during normal business hours (contact data on the first page).

Yours faithfully

MAQUET GmbH



Safety Representative for medical devices