

Rastatt, May 05, 2014

## Field Safety Notice

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

*Preventive Corrective Action*  
concerning  
*Adapter for extension device 1150.59AC*

Dear customers,

With this letter we would like to inform you of a potential issue with the adapters for extension device 1150.59AC for the Alphamaquet 1150 operating table system.

### **Description of the problem including the determined cause:**

Within the framework of our market surveillance, we have been made aware of complaints in which handling problems have occurred with both adapters for the extension device.

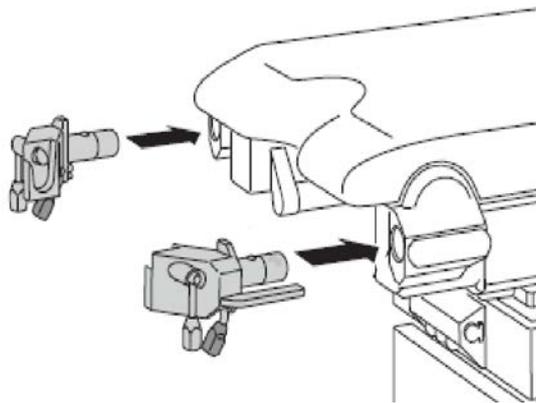


Figure 1: Adapter for extension device 1150.59AC

The root cause analysis has shown that the latch designed for safe lock of the seat plate (support frame) was incorrectly mounted on affected adapters. This makes handling difficult

when mounting and removing the support frame. The latches are designed to prevent the levering of the support frame upwards in the event of a collision (e.g. with the column head of the OR table column). Due to the incorrect mounting we cannot guarantee that the latches fulfil this function.

**Identification of the affected medical devices:**

The problem can potentially only occur with the adapters (material number for the adapter pair: 3115.2469) that were delivered between February 7, 2014 and March 27, 2014.

With the incorrectly mounted latches, the mounting and removal of the support frame does not function in the way described in the operating instructions. The affected adapters can also be easily recognised by visual inspection:

The latch is incorrectly mounted when the angle of the latch points down when the lever is pointing down.



Figure 2: **Incorrectly** mounted latch

When the angle of the latch points upwards with the lever in the same position, then the latch is mounted correctly:

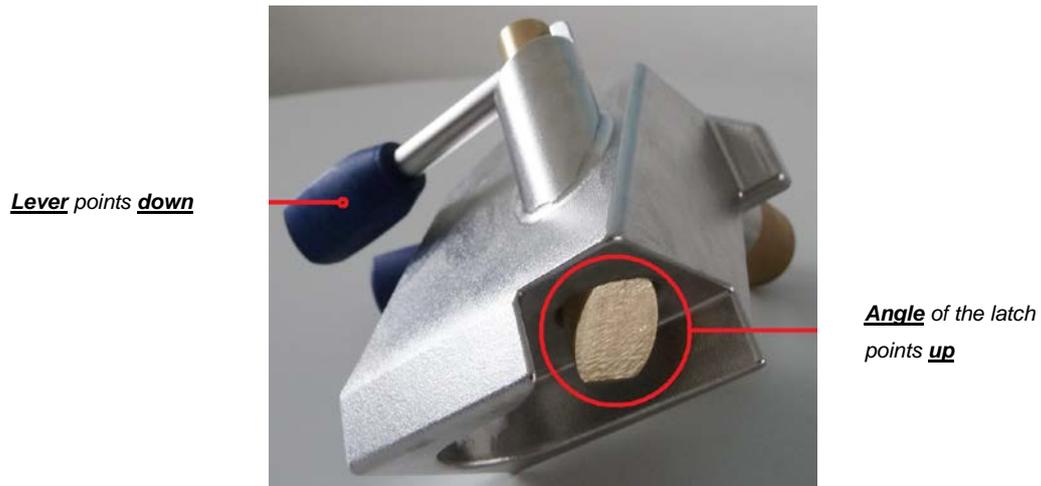


Figure 3: Correctly mounted latch

**Which measures are to be taken by the user?**

Our sales records indicate that you own potentially affected adapters.

Please check according to the characteristics described above whether the latches of your adapters were mounted correctly.

If you are in possession of faulty adapters, please contact MAQUET service immediately in order to arrange a free replacement of the adapters.

**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 products 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:**

For further questions, please do not hesitate to contact your MAQUET contact person. Should you require more information, 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 or endangered.

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

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

Yours faithfully,

MAQUET GmbH

A handwritten signature in blue ink, appearing to read 'Th. Buhl'.

Safety Representative for medical devices