

MAQUET GmbH | Kehler Str. 31 | 76437 Rastatt

Field Safety Notice

December 17, 2015

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

Preventive Corrective Action

concerning

Extension Device 1180.19X0

Dear customers,

with this letter we would like to inform you of an important aspect concerning the use of the Extension Device 1180.19X0.

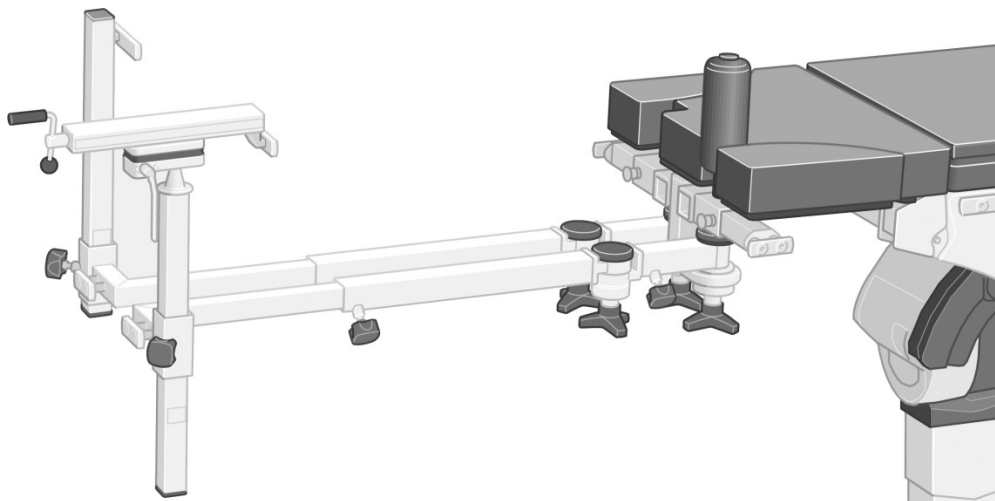


Figure 1: Extension Device 1180.19X0

The Extension Device (1180.19X0) is a table top module for use with the MAGNUS operating table system.

It is used to support the upper and lower extremities immediately before, during and after fraction care. The extension device is attached to the basic mounting point.

Description of the problem including the determined cause:

Within the framework of our market surveillance, we have been made aware that due to wrong handling under unfavorable circumstances, the Extension Device could unlock itself from the table top and could fall down.

This issue may occur when the device is used not in accordance with the description in the instructions for use and it is not paid attention to possible collisions. In extreme cases, collisions with an obstacle below the table top could lead to the problem described above.

Identification of the affected medical devices:

Potentially affected by this issue are the following Extension Devices:

1180.19A0	SN 00001 – SN 00024, SN 00026 – SN 00105, SN 00107 – SN 00250
1180.19F0	SN 00002 – SN 00004

Model number and serial number are located on the type label.

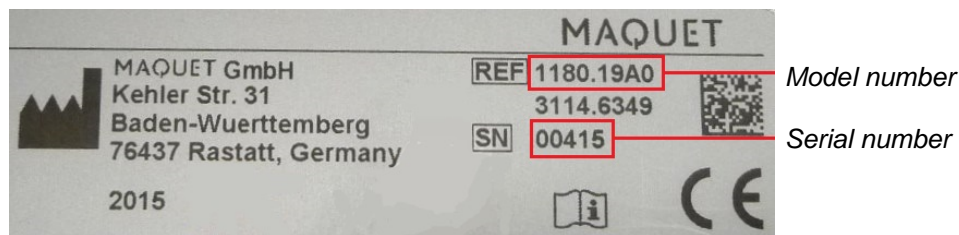


Figure 2: Type label

Which measures are to be taken by the user?

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

In order to exclude the described problem, we would like to ask you to use the device according to the operating instructions and to avoid any collisions. In this context, especially the following safety notes have to be considered:



WARNING!

Risk of injury!

The extension device can be leveraged off the mounting point of the operating table if:

- The table top with accessories mounted is moved to stationary obstacles (e.g. C-arm),
- or
- the table top with accessories mounted is transferred to the transporter incorrectly with inverted head end and foot end,

Do not run table top against stationary obstacles. Transfer the table top correctly to the transporter (extension device is on the opposite side of battery holder and handle).

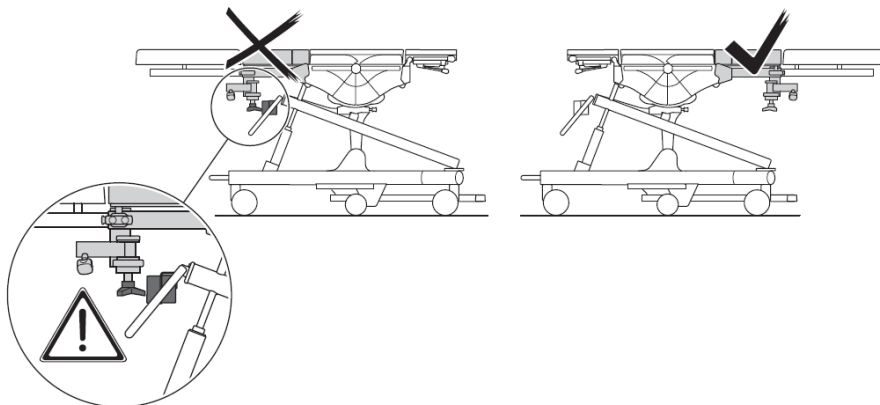


DANGER!

Risk of collision!

If the extension device (1180.19X0) is mounted to the basic table top, the extension device will collide with the transporter (1180.64X0/65XX) if the extension device is mounted to the side where the battery holder and the handle bar of the transporter are located (see illustration).

If the basic table top is locked on the transporter or is to be transferred to the transporter, ensure that the extension device is attached to the side opposite the battery holder and handle bar of the transporter.



As further optional measure you could let retrofit the Extension Device with the Support Frame Lock 3115.0973. The Support Frame Lock prevents leverage of the Extension Device during a collision. If you would like to get this retrofitting, you can order it by contacting the MAQUET contact you are aware of.

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 together with the instructions for use of the device.

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.

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,

Bernd Rakow

Bernd Rakow

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