

MAQUET GmbH | Kehler Str. 31 | 76437 Rastatt

Field Safety Notice

July 30, 2015

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

Preventive Corrective Action

concerning

Adjustable Positioning Elements 1007.28A0

Dear customers,

with this letter we would like to inform you of a potential issue with the adjustable positioning elements 1007.28A0.



Figure 1: Adjustable Positioning Elements 1007.28A0

The adjustable positioning elements are designed for the placement and positioning of patients in the prone position immediately before, during and after surgical interventions as well as for examination and treatment of the spine.

They consist of two chest and hip elements with padding.

The adjustable positioning elements may be used in conjunction with the universal frame for positioning patients (1007.24X0) and the positioning device for spinal surgery (1007.22X0).

Description of the problem including the determined cause:

Within the framework of our market surveillance, we have been made aware of a complaint in which two serious thromboembolic events have been reported.

Performed investigations have shown that the two hip elements may have a negative effect on the venous backflow under certain conditions. Therefore it cannot be excluded that the shape of the hip elements may be considered as a contributing factor to thromboembolic events.

Identification of the affected medical devices:

Potentially affected by this issue are all adjustable positioning elements 1007.28A0.

This affects both, the adjustable positioning elements delivered with the universal frame 1007.24X0 as well as the elements which are delivered separately for the use in conjunction with the device for spinal surgery 1007.22X0.

Which measures are to be taken by the user?

Our sales records indicate that you own one set of the affected adjustable positioning elements 1007.28A0.

In order to exclude the described problem, you should no longer use the adjustable positioning elements 1007.28A0.

MAQUET is working on an optimized version of the positioning elements. When they become available we will exchange the adjusting positioning elements with the new ones free of charge.

Until then for surgical interventions and examinations / treatments you can use for example the table top 1007.26X0 together with a prone positioning pad, e.g. the MAQUET product 1000.68C0.

For further assistance and questions regarding the positioning of the patient feel free to contact 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 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).

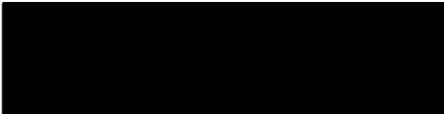
This is a voluntary corrective action.

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



Safety Officer for medical devices