MAQUET
GETINGE GROUP

MAQUET GmbH | Kehler Str. 31 | 76437 Rastatt

July 19, 2016

Field Safety Notice

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

Preventive Corrective Action

concerning

Fixture 1002.65A0

Dear customer,
with this letter we would like to inform you about a potential issue concerning the Fixture 1002.65A0.

The Fixture (1002.65A0) is designed as a connecting element for the support and positioning of the patient's head on a MAQUET OR table immediately before, during and after surgical interventions as well as for examination and treatment. The Fixture is used to adapt a range of different head rests and horseshoe head rests with a central square mount.

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Steuer-Nr. 39487/29420
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Aufsichtsratsvorsitzender: Heinz Jacqui
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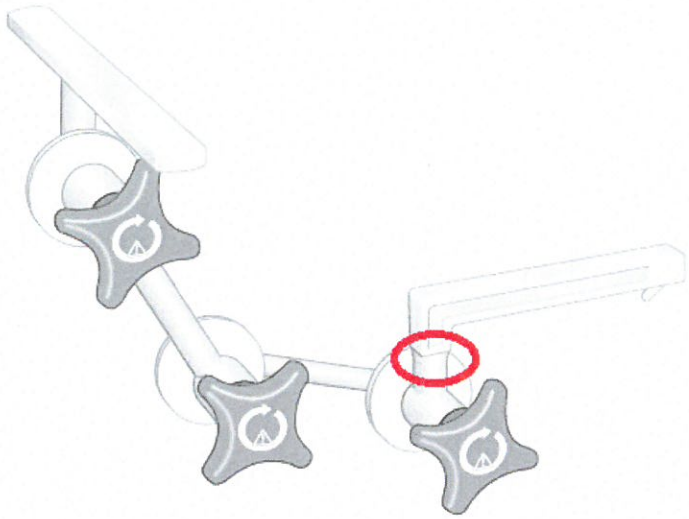

Fig. 1 Fixture 1002.65A0

Description of the problem including the determined cause:

As part of our Post Market Surveillance cases have been reported to Maquet GmbH which showed the welded joint between square mount and the first fixable swivel joint broken (see Fig. 1 red mark, page 2). This joint must bear the highest loads of all welded joints due to the cantilever.

It is likely that the breakage had been caused by a not ideally carried out welding in addition to a rough handling and multiple overload by the user respectively. In case the weld seam breaks during an procedure a serious injury cannot be ruled out.

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

Identification of the affected medical devices:

Potentially affected by this issue are Fixtures (1002.65A0) manufactured in the period of 2009 to 2013. The manufacturing year is indicated on the type plate of the device (see Fig. 2 below).

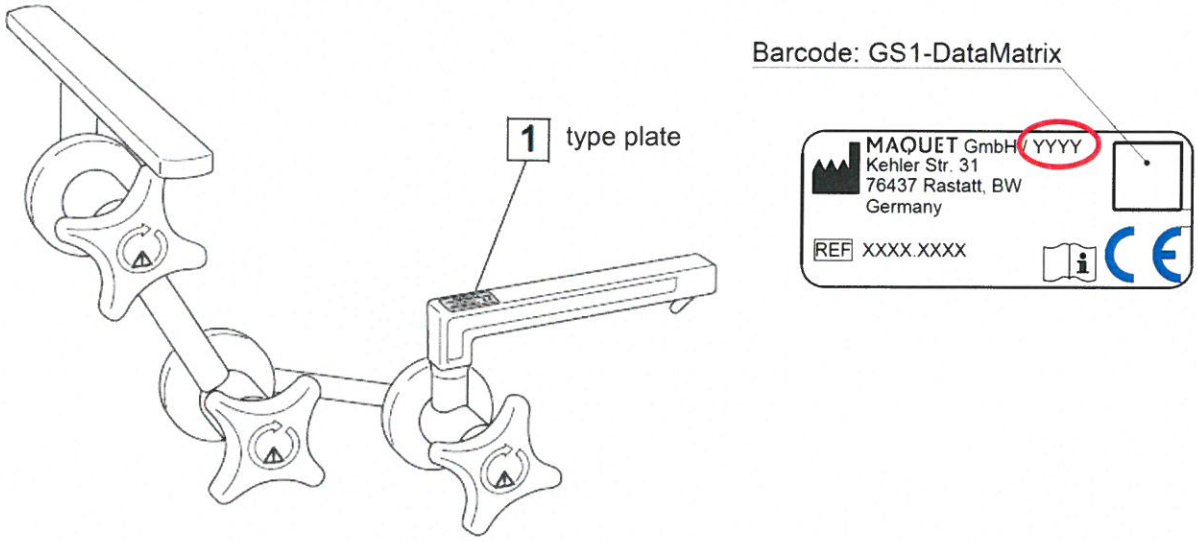

Fig. 2 Position of type plate / label

Which measures are to be taken by the user?

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

As we cannot ensure that other affected Fixtures with not ideally performed welding were placed on the market the affected component of all potentially affected Fixtures (1002.65A0) manufactured within the period of 2009 and 2013 will be replaced.

Therefore MAQUET service or a MAQUET authorised service technician will be contacting you to arrange an appointment to carry out the replacement free of charge.

The device should be inspected for damages before every use until the replacement has been performed. In this context particular attention should be paid to potential cracks at the weld (see Fig. 1 red mark, page 2). In case of doubt it is advised not to use the Fixture.

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 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

i.V.

Holger Ullrich

Director Product Compliance
SW and P&PAC

Mario Mühe

Safety Officer for medical devices