

MAQUET

MAQUET GmbH & Co. KG | Postfach 2162, 76411 Rastatt

Rastatt, 30th September 2009

Field Safety Notice

Please forward this information to all the relevant product operators!

Preventive Corrective Action
in respect of
Connection Bracket 1180.36A0

Dear Sir / Madam,

We would like to inform you of a potential risk for the patient when using our connection bracket 1180.36A0, particularly if it is deployed during neurosurgery.

The connection bracket 1180.36A0 is an accessory for the MAGNUS OR Table System and is used for adapting head rest accessories.

As part of our product monitoring, we have been informed that the connection bracket shows too much mechanical play at the OR table interface for some procedures. This is particularly the case for applications where the patient's head must remain completely immobilized, for example when using the connection bracket in combination with the Mayfield Skull Clamp.

The cause of this play, is that the hole in the lock washer, which is responsible for locking the accessory to the OR table interface, is too large.

The only products that may be affected are those connection brackets that were delivered between February 2008 and August 2009. According to our sales records, we have determined that your connection bracket may also be affected.

In order to avoid any possible risk to patients, it is necessary to exchange the lock washers in the affected connection brackets. For this purpose, please get in touch with your contact partner at MAQUET, who will make immediate arrangements for the modification to be carried out free-of-charge.

With immediate effect, we would ask you not to use the connection bracket any further for applications where the patient's head must remain fully immobilized.

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This is a preventive action. No cases have been reported where a patient has been injured as a result of using the connection bracket.

Please make sure that all persons within your organisation who use the above-mentioned product and anybody else who needs to know receive this urgent safety information. If you have passed the products on to a third party, please forward a copy of this information sheet to them or inform your usual contact at MAQUET.

Please keep this information sheet at least until the corrective work has been completed.

We apologise for any inconvenience, however, consider this action as a preventive action to increase your safety. If you have any further questions please get in touch with your contact at MAQUET.

Best regards

MAQUET GmbH & Co. KG



Safety Representative for Medical Devices