

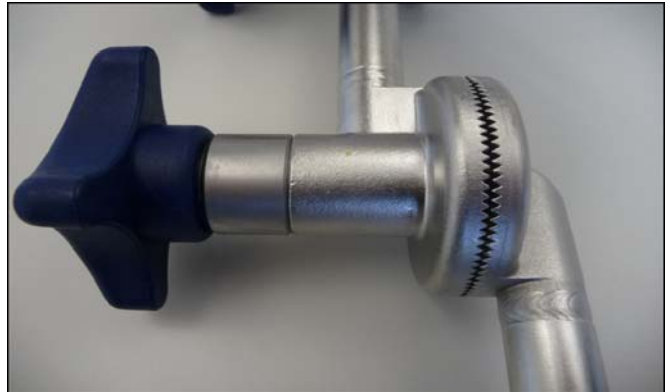
# Medical Device Alert

Ref: MDA/2011/075 Issued: 06 July 2011 at 14:30

## Device

Headrests attachment to operating tables with connection fixture:  
1002.65A0 or 1002.65S0

Manufactured by Maquet Ltd.



## Problem

The manufacturer issued a Field Safety Notice (FSN) for this device on 12 May 2011, but has not had sufficient confirmation from users that they have received and acted on this information.

A copy of the FSN is in the appendix of this alert, and it is also available on the MHRA website.

This alert has been issued in support of the manufacturer's actions.

## Action by

Healthcare professionals using these devices.

## CAS deadlines

Action underway: 20 July 2011

Action complete: 03 August 2011

## Action

- Ensure that relevant members of staff are aware of the problem.
- Carry out the actions described in the manufacturer's FSN, including sending any confirmation requests.

## Contact

**Manufacturer**  
Colin Moralee  
Maquet Ltd

Tel: 0191 519 6200

Fax: 0191 519 6201

Email: [cmoralee@maquet.co.uk](mailto:cmoralee@maquet.co.uk)

## Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)

### Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

#### Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E departments
- Anaesthetists
- Biomedical engineering staff
- Day surgery units
- EBME departments
- General surgical units, directors of
- Maternity units
- Medical directors
- Medical physics departments
- Nursing executive directors
- Operating theatre practitioners
- Outpatient theatre managers
- Risk managers
- Surgeons
- Theatre managers
- Theatre nurses

### Independent distribution

#### Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Hospitals in the independent sector
- Independent treatment centres

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: [safetyalerts@dh.gsi.gov.uk](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## Contacts

#### Manufacturer

Colin Moralee  
Maquet Ltd  
14-15 BurfordWay  
Baldon Business Park  
Sunderland  
Tyne & Wear  
NE35 9PZ

Tel: 0191 519 6200

Fax: 0191 519 6201

Email: [cmoralee@maquet.co.uk](mailto:cmoralee@maquet.co.uk)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/075** or **2011/005/013/081/001**

### Technical aspects

Ian Patterson-Waterston or Andy Marsden  
Medicines & Healthcare products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ  
Tel: 020 3080 7261 / 7205  
Fax: 020 8754 3965  
Email: [ian.patterson-waterston@mhra.gsi.gov.uk](mailto:ian.patterson-waterston@mhra.gsi.gov.uk)  
[andy.marsden@mhra.gsi.gov.uk](mailto:andy.marsden@mhra.gsi.gov.uk)

### Clinical aspects

Jonathan Plumb  
Medicines & Healthcare products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ  
Tel: 020 3080 7128  
Fax: 020 8754 3965  
Email: [jonathan.plumb@mhra.gsi.gov.uk](mailto:jonathan.plumb@mhra.gsi.gov.uk)

### How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>  
Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

## Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.  
Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre  
Health Estates Investment Group  
Room 17  
Annex 6  
Castle Buildings  
Stormont Estate  
Dundonald BT4 3SQ  
Tel: 02890 523 704  
Fax: 02890 523 900  
Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)  
<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

### How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>  
Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

## Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre

Health Facilities Scotland

NHS National Services Scotland

Gyle Square

1 South Gyle Crescent

Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

## Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes

Senior Medical Officer

Medical Device Alerts

Welsh Assembly Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

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Addressees may take copies for distribution within their own organisations

Appendix

**MAQUET**

GETINGE GROUP

14-15 Burford Way  
Boldon Business Park  
Sunderland  
Tyne & Wear  
NE35 9PZ

Tel: 0191 519 6200  
Fax: 0191 5196201

Website: [www.maquet.co.uk](http://www.maquet.co.uk)  
E-mail: [sales@maquet.co.uk](mailto:sales@maquet.co.uk)



25/5/11

Dear Sir or Madam:

**Important Information Concerning the use of Connection Fixture 1002.65XX**

Please find a Field Safety Notice attached concerning information for the safe use of connection fixture 1002.65.

When using this device it is essential to fully tighten the joint star screws after each adjustment to prevent failure of the toothed element and movement of the attachment.

Please bring this notice to the attention of all relevant users at your facility.

Should you have any questions or require additional information please contact your local Maquet representative.

Yours faithfully

A handwritten signature in black ink that reads "C. Moralee".

C. Moralee  
Regulatory Affairs Officer

Incl: Field Safety Notice: Rastatt, 12 May 2011  
Acknowledgement Form (to be returned)





MAQUET GmbH & Co. KG | PO Box 2162, 76411 Rastatt

Rastatt, 12 May 2011

## Field Safety Notice

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

*Information for users to enable safe use  
concerning  
Connection fixtures 1002.65A0 and 1002.65S0*

Dear Customer,

We would like to draw your attention to an important aspect with regard to the use of the product named above.

The connection fixture is used to mount various head rests and horseshoe-shaped head rests with central square socket. It has 3 joints designed to enable optimum positioning of the patient's head.

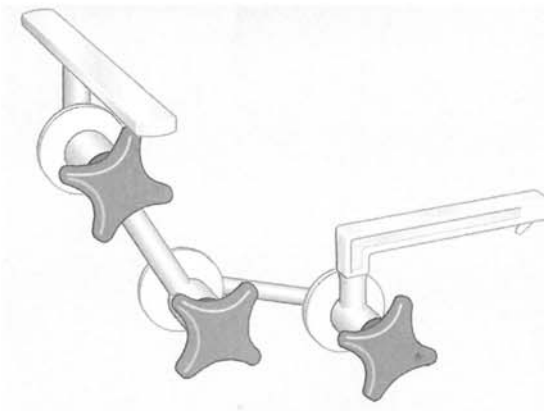


Figure 1: Connection fixture 1002.65x0

MAQUET GmbH & Co. KG  
SURGICAL WORKPLACES  
Kehler Strasse 31  
D-76437 Rastatt  
Telephone: +49 (0) 7222 932-0  
Fax: +49 (0) 7222 932-571  
www.maquet.com

MEMBER OF THE GETINGE GROUP

Limited partnership, head office: Rastatt  
Registration Court: Rastatt HRA 1163  
VAT ID No. DE 144021332  
G.P.: Getinge-Maquet Verwaltungs GmbH, Head Office: Rastatt  
Registration Court: Rastatt HRB 2075  
Managing directors: Dr. Heribert Ballhaus, Michael Rieder  
Commerzbank AG Rastatt (sort code 660 400 18) 2 502 300  
Dresdner Bank AG Rastatt (sort code 662 800 53) 6 321 185

**Thomas Biehl**  
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sicherheitsbeauftragter.medizinprodukte@  
maquet.de



The joints have a surrounding toothed element in order to ensure form-fitted connection. They are fixed in place using star screws (Figure 2).



Figure 2: Surrounding toothed element and star screw

Within the framework of our market surveillance, we became aware of a complaint: two times, a fixing screw came loose unintentionally and the head rest fell after the intervention.

Investigations have shown that the star screws might come gradually loose only when the following conditions occur simultaneously:

1. The star screws are not tightened.
2. The head rest is rocked back and forth by considerable forces.

An incorrectly tightened star screw can be recognised by the clearly visible and perceptible play in the toothed element (Figure 3). Since the teeth still mesh, the joint remains in position in this state.



Figure 3: Insufficiently tightened star screw



Figure 4: Open joint



The play can be increased by extreme alternate motion until the teeth no longer mesh and the joint is able to move (Figure 4).

In order to avoid any hazard to patients, it is necessary to tighten the star screws securely after each adjustment in order to ensure that there is no play in the toothed element. Please also follow the notes in the operating instructions.

Generally speaking, for all products with a similar fixture principle, attention should be paid to ensure that the fixtures are tightened after each adjustment procedure in accordance with the operating instructions.

Please make sure that all persons within your organisation who use the above mentioned products and anybody else who needs to know receive this field safety notice. If you have passed the product on to a third party, please forward a copy of this notice or inform the MAQUET contact persons you are aware of.

We apologise for any inconvenience, however, consider this action a preventive measure to increase safety. For further questions please contact your MAQUET contact person. Should you require more information, you can also contact our safety representative for medical devices during normal business hours (contact data on the first page).

Yours faithfully

MAQUET GmbH & Co. KG

A handwritten signature in blue ink, appearing to read "Th. Baill".

Safety Representative for Medical Devices





CP10-F025  
Appendix 4

**Acknowledgement Form**

**Subject:** Field Safety Notice: Connection Fixture 1002.65XX

<b>For the attention of: C.Moralee</b>	<b>Fax : 0191 5196201</b> <b>Email: cmoralee@maquet.co.uk</b>
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<b>Hospital</b>	<b>Distributor's name</b>
.....	Maquet Ltd.
.....	14-15 Burford Way
.....	Boldon Business Park
.....	Tyne & Wear
.....	NE35 9PZ

Comments :
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**I confirm:**

**a) Receipt of Field Safety Notice**

**Name:**

**Signature:**

**Date:**

Please fax this form to:- Colin Moralee Regulatory Affairs Officer 0191 5196201