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

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.

action by

healthcare professionals using these devices.

contact

manufacturer
colin moralee
maquet ltd

phone: 0191 519 6200
fax: 0191 519 6201
email: 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 and requesting this facility.

Contacts
Manufacturer
Colin Moralee
Maquet Ltd
14-15 BurfordWay
Boldon Business Park
Sunderland
Tyne & Wear
NE35 9PZ
Tel: 0191 519 6200
Fax: 0191 519 6201
Email: 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
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

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
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.iric@nhs.net

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

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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

C. Mars
Regulatory Affairs Officer

Incl: Field Safety Notice: Rastatt, 12 May 2011
Acknowledgement Form (to be returned)
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](image-url)
The joints have a surrounding toothed element in order to ensure form-fitted connection. They are fixed in place using star screws (Figure 2).

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 came 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.
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

[Signature]

Safety Representative for Medical Devices
Acknowledgement Form

Subject: Field Safety Notice: Connection Fixture 1002.65XX

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Distributor’s name</th>
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<tbody>
<tr>
<td></td>
<td>Maquet Ltd.</td>
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<tr>
<td></td>
<td>14-15 Burford Way</td>
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<td></td>
<td>Boldon Business Park</td>
</tr>
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<td></td>
<td>Tyne &amp; Wear</td>
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<td>NE35 9PZ</td>
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Comments :

I confirm:

a) Receipt of Field Safety Notice

Name: Signature:

Date:

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