

Medical Device Alert

Ref: MDA/2011/070 Issued: 20 June 2011 at 14:00

Device

All pyramid clamp adaptors, part no. 409054, manufactured by Blatchford Products Ltd between October 2007 and February 2011.

The adaptor is also contained in some transtibial pyramid kits.



409054

Problem

A small number of incidents have occurred where this adaptor has cracked unexpectedly, resulting in a fall and injury to the user. The manufacturer issued a Field Safety Notice (FSN) on 18 April 2011 calling for the adaptor to be replaced as soon as possible. However, the manufacturer has not received sufficient information to demonstrate that the FSN has been acted upon.

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

Action by

All those involved in the supply, maintenance, and use of these adaptors. In particular; limb centre managers and prosthetists.

Action

- Identify all users of prosthetic lower limbs that include this component.
- Make the users aware of the problem.
- Arrange for the component to be replaced as indicated in the FSN.

CAS deadlines

Action underway: 20 July 2011

Action complete: 20 September 2011

Contact

Manufacturer

Sales Department

Blatchford Products Ltd

Tel: 01256 316600

Fax: 01256 316 910

Email: JohnR@blatchford.co.uk

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- 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)
- Primary care trusts in England (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:

- Prosthetists
- Prosthetic limb centre managers
- Risk managers

Primary care trusts

CAS liaison officers for onward distribution to all relevant staff including:

- Prosthetists
- Prosthetic limb centre managers
- Risk managers

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

Blatchford Products Ltd

Sales Department

Lister Road

Basingstoke

Hampshire

RG22 4AH

Tel: 01256 316 600

Fax: 01256 316 910

Email: JohnR@blatchford.co.uk

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/070** or 2010/002/017/401/003

James McVeigh or Brian Mather
Medicines & Healthcare products Regulatory Agency
Centre for Assistive Technology
241 Bristol Avenue
Bispham
Blackpool FY2 0BR
Tel: 01253 596 000
Fax: 01253 596 177
Email: bav@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.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

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Addressees may take copies for distribution within their own organisations

Appendix

BLATCHFORD PRODUCTS LTD

Lister Road
Basingstoke
Hampshire RG22 4AH
United Kingdom

Telephone: +44 (0)1256 316600
Facsimile: +44 (0)1256 316910
Web site: www.blatchford.co.uk

18th April 2011

Urgent Field Safety Notice

Endolite 30mm Pyramid Clamp Adaptors: Part Number 409054 & (P)409028.

Details of affected devices:

**Endolite 30mm Pyramid Clamp Adaptors- Part Number 409054 & (P)409028
Batch Numbered within this range:**

P265 to P365 – Manufactured October to December 2007

Q001 to Q365 – Manufactured January to December 2008

R001 to R365 – Manufactured January to December 2009

S001 to S365 – Manufactured January to December 2010

T001 to T048 – Manufactured January to February 2011

Adaptor 409054 is also contained within the following kits:

739069, 739045, 739068 Trans Tibial Pyramid Kits

739058, 739059 Trans Tibial Pyramid Kits (2 off per kit)

Description of problem:

A small number of failures (0.85%) have been reported where components have cracked unexpectedly, both at the fitting stage and after a period of use. Similar failures could result in the limb wearer falling and injuring themselves.

Analysis of the field failures that have been received and subsequent in-house testing show that the risk of failure is increased if:

- **The product has been immersed in water / liquids during use which can cause stress corrosion**
- **The product has been over torqued during assembly**

Action Plan required:

Blatchford Products Ltd recommends the 409054 Adaptor is replaced with the new AK30MI Titanium Adaptor on receipt of this notice.

- **Where the component is changed in accordance with the above recommendation, Blatchford Products Ltd will give a full refund for every returned 409054 Adaptor.**
- **Please contact our Customer Services Department informing them of the claim and requesting a returns RMA number.**
- **Please return the old Adaptor in the normal manner and the refund will be then be given.**



Directors:
D. S. Galloway M.Sc., B.A. (Chair) M. J. Blatchford
P. Harris M.A. (Finance)
Prof M. S. Zahed CBE FRCGS A. Stanton MBARQ SR Orth H Dip CPDSC
Robert Walsh

Registered in England No. 4266618 VAT Registration No. 767 4022 07

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those that need to be aware within your organisation or to any organisation where the affected devices have been transferred.
Blatchford Products Ltd confirms that the appropriate regulatory authority has been notified of this FSN.

Please contact Blatchford Customer Services for your RMA number on: +44(0)1142637900, or by your normal method of communication.

Please contact your local Sales Representative in the UK for any queries or questions, or the area Sales Manager covering your country.