Medical Device Alert

Ref: MDA/2014/018 Issued: 28 May 2014 at 15:00

Device

Unicondylar sled knee prosthesis
Metal-backed tibial plateau Endo-Model® 7mm
Manufactured by Waldemar Link GmbH & Co. KG
Catalogue numbers: 15-2030/01, 15-2030/05 and 15-2030/09.

Problem

Risk of early wear of the ultra high molecular weight polyethylene (UHMWPE) plastic part of the tibial plateau of this device.

Action

- Identify patients implanted in the last 5 years with these devices.
- Consider annual review of patients for up to 5 years after implantation, including X-rays* to detect progression of bearing wear.
- Retain explanted devices to facilitate investigation by the manufacturer.
- Report all adverse events to the MHRA and to Waldemar Link.

* In all cases, the benefit of ionising radiation screening should be weighed against the risks from radiation exposure on an individual patient basis, in line with the requirements of The Ionising Radiation (Medical Exposure) Regulations 2000

Action by

- Medical directors.
- Orthopaedic departments.
- Orthopaedic surgeons.
- Staff involved in the management of patients with joint replacement implants.

CAS deadlines

Action underway: 04 June 2014

Action complete: 12 June 2014

Note: These deadlines are for systems to be in place to take actions and not for the completion of patient follow-up and testing.

Contact

Manufacturer
Dr Thomas Mehler
Waldemar Link GmbH & Co. KG
Tel: +49 (0)40 53995-305
Email: t.mehler@linkhh.de

Problem

In August 2013 Waldemar Link issued a Field Safety Notice informing clinicians that they had received reports of wear of the plastic part of the metal-backed tibial plateau Endo-Model® 7mm.
The manufacturer has informed the MHRA that the affected products have now been discontinued.

A total of 9 cases of wear of the plastic part of the device were reported to the manufacturer from outside of the UK. The implant failures occurred between 6 months and 5 years after implantation and analysis of the returned explants showed significant plastic wear. A definitive root cause for the wear events has not been determined by the manufacturer

Wear of the plastic part of the plateau could lead to pain and stiffness. The debris generated by the wear could cause osteolysis, requiring device revision. In instances where wear leads to metal-on-metal contact, the resulting wear debris may lead to soft tissue damage requiring device revision.

442 devices were distributed in the UK between 2003 and 2013.

The MHRA is issuing this Medical Device Alert to ensure that clinicians are aware of this issue and consider appropriate follow up of patients implanted with affected devices.

Device

The metal-backed tibia plateau consists of a UHMWPE (plastic) part attached to a cobalt-chromium alloy (metal) plate. The total height of the tibial plateau is 7 mm.

Distribution

This MDA has been sent to:

- Clinical commissioning groups (CCGs)
- Care Quality Commission (CQC) (headquarters) for information
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams for information
- NHS 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:

- CSSD
- Medical directors
- Orthopaedic clinics
- Orthopaedic surgeons
- Orthopaedic theatres
- Risk managers

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

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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/018** or **2013/008/029/081/002**

Technical aspects

Ms Bayode Adisa or Ms Michelle Kelly
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7223 / 7145
Fax: 020 8754 3965

Email: bayode.adisa@mhra.gsi.gov.uk
michelle.kelly@mhra.gsi.gov.uk

Clinical aspects

Dr Neil McGuire or Dr Camilla Fleetcroft
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 6800 / 6097
Fax: 020 8754 3965

Email: camilla.fleetcroft@mhra.gsi.gov.uk
neil.mcguire@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

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
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

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

Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team
Medical Directorate
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Email: Haz-Aic@wales.gsi.gov.uk