Medical Device Alert

Ref: MDA/2014/030 Issued: 23 July 2014 at 11:30

Device

External fixators.

Synthes trauma external fixation system (small, medium, distraction osteogenesis (DO) ring and large)

Manufactured by DePuy Synthes.

Specific part numbers affected.

Problem

The instructions for use have changed. These devices are now identified as being 'MR-Conditional'. This places additional restrictions on patient positioning. Failure to follow the updated instructions may result in patient harm.

DePuy Synthes issued a second Field Safety Notice (FSN) dated 4 July 2014, which is an extension to their original Field Safety Notice (FSN) dated 14 April 2014.

Action by

Medical directors
Orthopaedic departments
Orthopaedic surgeons
Staff involved in the management of patients with external fixation system
MR radiographers
Radiologists

Action

- Identify affected devices using the information provided in the manufacturer's FSNs dated 14 April 2014 and 4 July 2014
- Download or request from the manufacturer a copy of the new instructions for use.
- Ensure that relevant staff are made aware of the changes.
- Ensure that all DePuy Synthes external fixation products etched 'MR-Safe' are considered as MR-Conditional and used in accordance with the updated MR-Conditional labelling.
- Return the manufacturer's verification form.

CAS deadlines

Action underway: 06 August 2014

Action complete: 20 August 2014

Note: These deadlines are for systems to be in place to take actions.

Contact

Manufacturer
Dr Pierre van Iwaarden
DePuy Synthes Field Action Manager
Tel: +41 32 720 49 33
Email: vaniwaarden.pierre@synthes.com

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- 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)
- Special health authorities for information

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:

- Fracture clinics
- General surgical units, directors of
- Intensive care units
- Intensive care, directors of
- Medical directors
- Medical physics departments
- MRI units, directors of
- MRI radiographer superintendents
- Orthopaedic surgeons
- Radiology departments
- Theatres

Independent distribution

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

This alert should be read by:

- Hospitals in the independent sector

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

Stephanie Armstrong
Quality Regulatory Compliance Associate
Johnson & Johnson Medical Limited
Pinewood Campus
Nine Mile Ride
Wokingham
Berkshire RG40 3EW

Tel: 01344 871103

Email: sarmstr1@its.jnj.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/030** or **2014/004/023/081/004.**

Technical aspects
Patrick Sweeney or Michelle Kelly
Medicines and Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

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Fax: 020 8754 3965

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michelle.kelly@mhra.gsi.gov.uk

Clinical aspects
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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: improvingpatientsafety@wales.gsi.gov.uk