Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2017/005 Issued: 04 April 2017 at 14:30

Comprehensive Reverse Titanium Shoulder Tray (specific lots) - risk of device fracture

Summary

Manufactured by Zimmer Biomet - recall due to increased risk of fracture for all titanium trays manufactured before September 2011 and distributed in the UK between September 2010 and January 2017.

Action

- Do not implant Comprehensive Reverse Shoulder Humeral trays from the lots listed in the manufacturer's field safety notice (FSN).
- Locate and return all affected products to Zimmer Biomet.
- Identify all patients implanted with the affected device and inform them of this issue.
- Advise patients to contact their orthopaedic surgeon if they develop symptoms such as pain, swelling, dislocation or a change in shoulder shape or function.
- Symptomatic patients should be investigated, which may include imaging* such as x-ray to identify a possible fracture of the device.
- Report all adverse events involving the Comprehensive Reverse Shoulder humeral tray to Zimmer Biomet and to the MHRA or the appropriate Devolved Administrations.

* 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

Deadlines for actions

Actions underway: 25 April 2017
Actions complete: 27 June 2017

Department of Health An Roinn Sláinte Männystrie O Poustie www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Device details

Example of fractured shoulder tray

Problem / background

In December 2016 Zimmer Biomet issued an FSN informing clinicians of the higher than anticipated rate of fracture of titanium Comprehensive Reverse Shoulder Humeral Trays manufactured prior to September 2011. The affected products were distributed between September 2010 and January 2017.

The mean time to fracture is approximately 3 years. The clinical symptoms of device failure include pain, swelling, loss of function and dislocation of the shoulder prosthesis.

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

Manufacturer contacts

Alison Hope
Zimmer Biomet, Waterton Point,
Waterton Ind Est.,
Bridgend,
South Wales CF31 3XA

Tel: 01656 761658
Email: fieldaction.uk@zimmerbiomet.com

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

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

- Orthopaedic surgeons
- Outpatient clinics
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

NHS England area teams

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

- General practitioners
- General practice managers
- General practice nurses

Independent distribution

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

- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

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.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2017/005** or 2016/012/030/701/004.

Technical aspects

Jillan Hussein, MHRA

Tel: 020 3080 7148

Email: jillan.hussein@mhra.gsi.gov.uk

Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: DCT@mhra.gsi.gov.uk

Reporting adverse incidents in England

Through Yellow Card https://yellowcard.mhra.gov.uk/

Northern Ireland

Alerts in Northern Ireland are distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre, CMO Group,
Department of Health, Social Services and Public Safety

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk
https://www.health-ni.gov.uk/niaic

Reporting adverse incidents in Northern Ireland

Please report directly to NIAIC using the forms on our website.

Scotland

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

Incident Reporting and Investigation Centre, Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575 Fax: 0131 314 0722

Email: nss.iric@nhs.net

Reporting adverse incidents in Scotland

NHS Boards and Local Authorities in Scotland – report to Health Facilities Scotland.

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to Health Facilities Scotland.

Private facilities providing care to private clients report to the Care Inspectorate and MHRA.

Wales

Enquiries in Wales should be addressed to:
Healthcare Quality Division, Welsh Government

Tel: 02920 823 624 / 02920 825 510

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

Reporting adverse incidents in Wales

Report to MHRA through Yellow Card https://yellowcard.mhra.gov.uk/ and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).