MDA/2018/007(Wales)

Medical Device Alert

16th February 2018

Parc Cathays
Caerdydd CF10 3NQ

Llywodraeth Cymru
Welsh Government

Cathays Park
Cardiff CF10 3NQ

Zimmer Biomet, specific hip and trauma instruments: risk of infection

Sent to:
NHS Wales Shared Services Partnership
Directors of Public Health,
Chief Executives, NHS Trusts
Chief Executives, LHBs
Medical Directors, NHS Trusts
Nurse Directors, LHBs
Executive Nurses, NHS Trusts
NHS Direct
CSSIW
Social Services
HIW

A list of people who need to have early sight of this information is given in the Notice.
This Notice has been endorsed by the Welsh Government as being relevant to NHS Wales.

Points of particular importance in Wales:

Healthcare Quality Division
Welsh Government
Cathays Park
Cardiff CF10 3NQ

This document is available online at:
https://www2.nphs.wales.nhs.uk/contacts.nsf

Ffôn/Tel: 029 2082 3624/029 2082 5510
Ebost/Email: Haz-Aic@wales.gsi.gov.uk

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2018/007 Issued: 15 February 2018 at 15:00 Valid until: February 2019

Zimmer Biomet, specific hip and trauma instruments: risk of infection

Summary

Manufactured by Zimmer GmbH – recall due to risk of infection as affected instruments may not be adequately cleaned when using standard cleaning instructions.

Action

- Quarantine affected devices and obtain replacements from the manufacturer.
- Refer to the manufacturer's Field Safety Notice (ref ZFA2017-332) for a full list of affected devices.
- Report all adverse events involving these devices to Zimmer Biomet and the MHRA or the appropriate Devolved Administration.

Action by

- Medical directors
- Orthopaedic departments
- Orthopaedic and trauma surgeons
- Decontamination and sterilisation departments

Deadlines for actions
Actions underway: 01/03/2018
Actions complete: 15/03/2018

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

Remember: if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

Problem / background

The affected devices are being recalled by the manufacturer and replaced with alternative instruments which are already available and can be adequately cleaned using standard cleaning instructions.

This Medical Device Alert is being issued to ensure adequate awareness of the issue and appropriate action is taken.

Manufacturer contacts

Anne-Catherine Morancy Meister
Zimmer GmbH
Sulzer Allee 8
Winterthur
8404
Switzerland
Tel: +41 58 854 82 37
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 NICAS liaison officers for onward distribution to all relevant staff including:

- Infection control & prevention directors
- Infection control departments
- Infection control nurses
- MDSOs
- Microbiologists
- Operating department practitioners
- Operating theatres managers
- Orthopaedic surgeons
- Sterile services departments

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/2018/007** or **2017/010/003/701/010**.

Technical aspects

Jacques Pouget, MHRA

Tel: 020 3080 6143

Email: jacques.pouget@mhra.gov.uk

Clinical aspects
Devices Clinical Team, MHRA
Tel: 020 3080 7274
Email: dct@mhra.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 NICAS 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
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).