Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2017/023 Issued: 18 August 2017 at 14:00

Shoulder system: Comprehensive Nano Humeral Components – increased risk of revision when used in reverse configuration

Summary

Manufactured by Zimmer Biomet – do not use this device in the reverse configuration.

Action

1. Immediately stop using the affected items **in the reverse configuration**.
2. Read the manufacturer's Field Safety Notice for further information.
3. Complete the certificate of acknowledgment attached to the Field Safety Notice and return it to the manufacturer.
4. Monitor patients who have already been implanted with this device in the reverse configuration for signs of loosening on X-ray* for 2 years post-implantation.
5. Advise patients to contact their implanting centre if they experience any increased pain or loss of shoulder movement or if their shoulder suddenly changes shape.
6. Report all adverse events involving this device to Zimmer Biomet and to MHRA or the appropriate Devolved Administration.

*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
All users of the affected medical devices.

Deadlines for actions
Actions underway: 04 September 2017
Actions complete: 18 September 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

The following components are affected:

Device Identifier	Item Number	Product Description	Size	NHS Supply Codes
(01)00880304530898	115730	Comprehensive Nano Humeral Component PPS	30mm	FQS196
(01)00880304530904	115732	Comprehensive Nano Humeral Component PPS	32mm	FQS197
(01)00880304530881	115734	Comprehensive Nano Humeral Component PPS	34mm	FQS198
(01)00880304530935	115736	Comprehensive Nano Humeral Component PPS	36mm	FQS199
(01)00880304530911	115738	Comprehensive Nano Humeral Component PPS	38mm	FQS200
(01)00880304530928	115740	Comprehensive Nano Humeral Component PPS	40mm	FQS201

Problem / background

Data collected by the manufacturer indicates that the Comprehensive Nano Humeral Component did not meet the expected performance rate (EPR) when used **in the reverse configuration.**
Therefore, the manufacturer has changed the indication for use and it must no longer be used in the reverse configuration. The component may still be used in the anatomic configuration.

MHRA is issuing this advice to ensure that you are aware of the change in indication for use and take appropriate action.

Manufacturer contacts

Zimmer Biomet
Mr Grayham Burnell,
Corrective Action Co-ordinator,
Complaints Department,
UK

Tel: 01656 678 308

Email: grayham.burnell@zimmerbiomet.com

If you haven't yet returned the certificate of acknowledgement form attached to the Field Safety Notice, please contact Mr Grayham Burnell.

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:
- Orthopaedic surgeons
- Supplies managers
- Theatre managers

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/2017/023** or **2017/006/007/291/011**.

Technical aspects
Alan McDonagh or Hasan Samee-Ahmed, Medical Device Specialists, MHRA
Tel: 020 3080 6268 / 6807
Email: alan.mcdonagh@mhra.gov.uk, hasan.samee-ahmed@mhra.gov.uk

Clinical aspects
Dr Kate Antrobus, Clinical Advisor, 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
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).