Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/006 Issued: 08 February 2019 at 14:00 Valid until: February 2020

Orthopaedic implant rHead Radial Head and Uni-Elbow: risk of early loosening

Summary

Manufactured by Stryker – post-operative loosening of the implant which may require revision surgery.

Action

- Do not implant these devices (see details below).
- Identify and quarantine all affected devices
- Identify and advise all patients implanted with affected devices to contact their orthopaedic surgeon if they develop symptoms such as pain, loss of function or instability.
- Follow actions recommended in the manufacturer's Field Safety Notice.
- Report all adverse events involving this device to Stryker and through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales.

Action by

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

Deadlines for actions

Actions underway: 15 February 2019
Actions complete: 01 March 2019

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.

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

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Device details

All lots of the Stryker rHead Radial Head and Uni-Elbow are affected.

The manufacturer's Field Safety Notice has details of the affected part numbers.

Problem / background

Stryker issued a Field Safety Notice dated November 2017 informing clinicians of the recall of the rHead Radial Head and Uni-Elbow prosthesis. The manufacturer identifies the possibility of post-operative implant loosening (septic and aseptic), instability (moderate/severe), stress fracture (bone), cyst formation (bone resorption), stiffness, pain, impingement, heterotopic ossification with these devices.

This Medical Device Alert is being issued to ensure all hospitals are aware of the recall and that adequate action is taken to mitigate potential risk to patients.

MHRA continues to monitor the device performance and encourages reporting of adverse incidents through our Yellow Card scheme https://yellowcard.mhra.gov.uk/ or the appropriate national incident reporting authority: Scotland, Northern Ireland, Wales.

Manufacturer contacts

Stryker GmbH
c/o Stryker T&E Post Market Safety
Bohnackerweg 1
CH – 2545 Selzach
Switzerland
Tel: +41 (0)79 904 3871
Email: tnepfa@stryker.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:

- Fracture clinics
- Orthopaedic surgeons

Independent distribution

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

- 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 Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England
Send enquiries about this notice to MHRA, quoting reference number **MDA/2019/006 or 2017/010/016/701/063**

Technical aspects
Hasan Samee-Ahmed, MHRA
Tel: 020 3080 6807
Email: hasan.samee-ahmed@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
Northern Ireland Adverse Incident Centre (NIAIC), CMO Group, Department of Health, Social Services and Public Safety
Tel: 0208 9052 3868
Email: niaic@health-ni.gov.uk
To report an adverse incident involving a medical device in Northern Ireland use the forms on the website.
Alerts in Northern Ireland are distributed via the NICAS system.

Scotland
Incident Reporting and Investigation Centre (IRIC), Health Facilities Scotland, NHS National Services Scotland
Tel: 0131 275 7575
Email: nss.iric@nhs.net
To report an adverse incident involving a medical device in Scotland, email IRIC to request a webform account.
For more information, or if you can't access the webform, visit the website: how to report an adverse incident

Wales
Population Healthcare Division, Welsh Government
Tel: 03000 250986 / 03000 255510
Email: haz-aic@wales.gov
To report an adverse incident involving a medical device in Wales, use the Yellow Card reporting page and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).