Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2018/026 Issued: 23 July 2018 at 14:00 Valid until: July 2019

First generation JOURNEY BCS Knee System– Higher than expected risk of revision

Summary

Manufactured by Smith & Nephew – The device has a higher than expected risk of revision due to early component loosening.

Action

1. Do not implant affected devices.
2. Locate and return affected devices to Smith & Nephew as detailed in the Field Safety Notice.
3. Monitor patients implanted with affected devices for signs of loosening.*
   Consider annual review for the first 5 years post implantation then every 2 years to 10 years post implantation.
4. Report adverse events involving these devices to your local incident reporting system, the manufacturer, and your national incident reporting authority: England, Scotland, Northern Ireland, Wales.

**Please note*
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 device.

Deadlines for actions
Actions underway: 06 August 2018
Actions complete: 20 August 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.

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 batches of the first generation JOURNEY BCS Knee System are affected. Please refer to the Field Safety Notice for affected Catalogue Numbers.

NB: The JOURNEY II BCS Knee system is not subject to this notice.

Problem / background

In June 2018, Smith & Nephew issued a Field Safety Notice in relation to the first generation JOURNEY BCS femoral and tibial insert components informing healthcare professionals that the knee system has a higher than expected revision rate. Component loosening has been identified a main cause of device failure.

The National Joint Registry of England, Wales and Northern Ireland (NJREWNI) shows the revision rate for the affected device is more than double the average rate for primary total knee replacements. The first generation JOURNEY BCS femoral knee components were phased out globally in 2013-14 and are no longer available for sale.

Smith & Nephew is not recommending pro-active revision surgeries for patients implanted with this device.

MHRA sought expert clinical advice and recommends all patients should be monitored for signs of device loosening.

Manufacturer contacts

Smith & Nephew
Jason Sells
Tel: +1 901-399-5520
Email: jason.sells@smith-nephew.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/2018/026** or **2017/009/007/264/002**.

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
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).