Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2020/006 Issued: 13 February 2020 at 12:00 Valid until February 2021

Self-expanding stents (S.M.A.R.T. and PRECISE) under MRI – various risks if MRI is operated outside the required conditions for these stents

Summary

Manufactured by Cordis – instructions for use contain incorrect MRI compatibility information.

Action

- Ensure you read and understand the updated MRI compatibility information in the manufacturer's Field Safety Notice (FSN), dated 13 November 2019.
- Develop a means to ensure that all healthcare professionals who use these devices, or carry out MR imaging, are provided with a copy of this FSN, which contains the updated MRI compatibility information.
- Complete the 'FSCA Acknowledgement Form' in the FSN even if you don't have affected devices left in stock, and return it to CordisCorp-FA-SS@cardinalhealth.com.
- Report suspected or actual adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales. You should also report directly to the manufacturer, Cordis.

Action by
All healthcare professionals who use these devices or carry out MR imaging.

Deadlines for actions
Actions underway: 27 February 2020
Actions complete: 12 March 2020

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 S.M.A.R.T. and PRECISE stents.
See Table 1 in the manufacturer's Field Safety Notice for a list of affected catalogue codes.

Manufacturer contacts

Cordis Corporation
Tel: +353-62-70062
Email: CordisCorp-FA-SS@cardinalhealth.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:

- Adult intensive care units
- Cardiac laboratory technicians
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- General surgeons
- General surgery
- General surgical units, directors of
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- MRI units, directors of
- Operating department practitioners
- Paediatric surgeons
- Paediatric surgery, directors of
- Radiographer superintendents
- Radiographers
- Radiologists
- Radiology departments
- Radiology directors
- Risk managers
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

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 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/2020/006** or **2019/011/014/291/002**.

Technical aspects

Ruth Lloyd-Williams, MHRA

Tel: 020 3080 6000

Email: DSS-TM@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the Yellow Card reporting page

Northern Ireland

Northern Ireland Adverse Incident Centre (NIAIC), CMO Group, Department of Health (Northern Ireland)

Tel: 028 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 255278 or 03000 255510
Email: Haz-Aic@gov.wales
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).

MHRA is a centre of the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health and Social Care.
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