HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Cordis S.M.A.R.T. and PRECISE Stents

Priority 2 – Warning

HPRA Safety Notice: SN2019(33) **Issue Date: 13 December 2019**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Cordis	V42040

ISSUE
Cordis has initiated a labelling correction for S.M.A.R.T. and PRECISE stents due to incorrect MRI information on the Instructions for use (IFU). Specifically, the Instructions for Use (IFU) for the impacted products state that the products are "MRI Safe". The correct classification is "MRI Conditional". The manufacturer has provided information regarding the safe scanning conditions in the attached FSN. The impacted catalogues fall under the following product families: • Self-Expanding Stents (S.M.A.R.T. and PRECISE) Affected product catalogue codes listed in Table 1 of the manufacturer's FSN will receive updated device labelling, Instructions for Use (IFU) and implant cards to reflect the device(s) as being MR Conditional. However, imaging centre staff and radiographers are advised to review the MRI conditions specified in the attached FSN when reviewing any implant card which lists Cordis S.M.A.R.T and PRECISE device(s). Please see the accompanying manufacturer's field safety notice (FSN) for further information and a list of affected product catalogue codes.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1. Refer to the accompanying FSN and follow the instructions provided.
2. Review your inventory to determine if you hold any affected product.
3. Review the MRI conditions listed in the attached FSN when presented with an implant card for device(s) affected by this FSN .
4. Acknowledge receipt of the FSN to the supplier.
5. Forward a copy of this Safety Notice and the FSN, to all relevant personnel within your organisation, or to any organisation/persons to which/whom these devices have been transferred.
6. Report any adverse incidents associated with these devices to the manufacturer and to the HPRA.

TARGET GROUPS

Radiographers	Risk Managers
Radiologists	Supplies managers
Nuclear Medicine Technologists	Procurement / Purchasing Managers
Medical Physicists	Stores / Supplies Staff
Clinical Engineers	Directors of nursing
Imaging Centre Staff	Clinical Nurse Managers
A&E Consultants	All surgical wards and theatres
ICU Staff	Theatre Staff
Hospital Managers / CEOs	Theatre Managers

BACKGROUND

Cordis became aware that the Instructions for Use (IFU) for the S.M.A.R.T. and PRECISE stents do not contain the correct language for usage of the product with MRIs. The instructions for use (IFU) for multiple implantable products have 'MRI safe' wording under the MRI compatibility information. Cordis has stated that this is not the currently correct terminology for implantable metals. Metallic implantable devices should be labelled as MRI conditional. As such, the product IFUs are being updated to meet current US (FDA) and OUS (International ISO) standards.

Cordis have outlined the following risks which may occur if the MRI is operated outside of the required MRI conditions listed in the attached FSN; bleeding, thrombosis, migration, perforation, restenosis, burns, bilious leak, biliary peritonitis, or inappropriate diagnoses and/or therapies due to image artifacts. Cordis has not received any reports of patient harm or injury.

The HPRA is issuing this Safety Notice to raise awareness of this issue.

MANUFACTURER / AUTHORISED REPRESENTATIVE CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Cordis Corporation
14201 N.W. 60th Ave.
Miami Lakes
USA, 33014

josh.diercks@cardinalhealth.com
+614-757-9079
https://www.cardinalhealth.co.uk/en

Enquiries to the **authorised representative / distributor** should be addressed to:

Cordis Cashel
Cahir Road
Cashel,
Co. Tipperary
E25 RC92

anne.morrissey@cardinalhealth.com
353-62-70062
www.cardinalhealth. .co.uk/en

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie