Urgent Field Safety Notice

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

November 13, 2019

Dear Valued Customer,

The purpose of this communication is to inform you that Cordis is issuing a field safety notice for Cordis S.M.A.R.T. and PRECISE stents.

Field Safety Notice Overview:	Cordis has initiated a labeling correction for S.M.A.R.T. and PRECISE stents due to incorrect MRI information on the Instructions for use (IFU). Specifically, the Instruction for Use (IFU) for the impacted products state that the products are "MRI safe". The correct classification is "MRI Conditional". More information regarding the MRI conditions is provided below. The impacted catalogs 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 this FSN will receive updated device labelling, Instructions for Use (IFU) and implant cards to reflect the device(s) as being MR Conditional.

Details on Affected Devices, to assist in identification of the product involved:	**Product involved** • All S.M.A.R.T. and Precise stents. See Table 1 below for list of impacted catalog codes. **Usage** The S.M.A.R.T. and PRECISE stents are intended to deliver a self-expanding stent to the peripheral vasculature.

Why you are being contacted:	You are receiving this letter because our records indicate that you have purchased Cordis S.M.A.R.T. and/or PRECISE stents.

Actions requested on your part:	1) Read this Field Safety Notice. 2) Review the list of affected product catalog codes in Table 1 3) Check your inventory to confirm whether you have any affected product. Check all storage and usage locations. 4) Retain a copy of this notice with the product. 5) Ensure that MR imaging is only carried out within the parameters specified for each device type in accordance with the below conditions 6) Share this letter with others in your facility who need to be made aware of this field safety notice and with any other facility that may have been sent the affected product from your facility. 7) Review, complete, sign and return the enclosed Acknowledgement Form in accordance with the directions on the form. 8) Maintain awareness of this notice until all affected product has been utilized.

Description of the problem:	What is the issue? Cordis became aware that the Instructions for Use (IFU) for the S.M.A.R.T. and PRECISE stents do not have correct language around the usage of the product with MRIs. The instructions for use (IFU) for multiple implantable products have "MRI safe" wording under the MRI compatibility information. This is not the currently correct terminology for implantable metals. Metallic implantable devices should be labeled as MRI conditional,

so the IFUs are being updated to meet current US (FDA) and OUS (international ISO) standards.

Why are we sending this Field Safety Notice for this product?
The Instructions for Use (IFU) for the S.M.A.R.T. and PRECISE stents state that they are "MRI safe" under the MRI compatibility information. Metallic implantable devices should be labeled as "MRI conditional". Cordis is updating the IFUs to meet current regulatory standards.

There is a risk of bleeding, thrombosis, migration, perforation, restenosis, burns, bilious leak, biliary peritonitis, or inappropriate diagnoses and/or therapies due to image artifacts if the MRI is operated outside of the required MRI conditions (such as below). Cordis has not received any reports of patient harm or injury

What other actions is Cordis taking?
Cordis is updating the IFUs and Implant Cards for S.M.A.R.T. and PRECISE stents. See below for updated MRI safety information.

S.M.A.R.T. Stents:

MRI Safety Information

A patient with the S.M.A.R.T. stent may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/identification of device	Cordis S.M.A.R.T. Stents
Nominal values of static magnetic field (T)	1.5 T and 3.0 T
Maximum spatial field gradient (T/m) and (Gauss/cm)	30 T/m (3000 Gauss/cm)
RF excitation	Circularly polarized (CP)
RF transmit coil type	Whole body transmit coil Head RF transmit-receive coil
RF receive coil type	Any receive only coil may be used
Maximum whole body SAR (W/kg)	1.0 W/kg for patient landmarks below the umbilicus 2.0 W/kg for patient landmarks above the umbilicus
Limits on scan duration	15 minutes of continuous RF (a sequence or back to back series/scan without breaks) followed by a wait time of 10 minutes if this limit is reached
MR image artifact	The presence of this implant produced an image artifact of approximately 9 mm when imaged with a spin echo pulse sequence and a 3.0 T MRI system
If information about a specific parameter is not included, there are no conditions associated with that parameter	

Precise Stents:

MRI Safety Information

A patient with the PRECISE stent may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/identification of device	Cordis PRECISE Stents
Nominal values of static magnetic field (T)	1.5 T and 3.0 T
Maximum spatial field gradient (T/m) and (Gauss/cm)	40 T/m (4000 Gauss/cm)
RF excitation	Circularly polarized (CP)
RF transmit coil type	Whole body transmit coil Head RF transmit-receive coil
RF receive coil type	Any receive only coil may be used
Maximum whole body SAR (W/kg)	2.0 W/kg
Limits on scan duration	15 minutes of continuous RF (a sequence or back to back series/scan without breaks) followed by a wait time of 10 minutes if this limit is reached
MR image artifact	The presence of this implant produced an image artifact of approximately 16 mm when imaged with a gradient echo pulse sequence and a 3.0 T MRI system
If information about a specific parameter is not included, there are no conditions associated with that parameter	

Available Assistance:	If you have any questions regarding this field safety notice, please contact your local sales representative, local sales office, or Cordis Corporate at CordisCorp-FA-SS@cardinalhealth.com or +353-62-70062.

Additional Information:	**Regulatory Notification** The applicable regulatory agencies and notified body are being notified that Cordis is voluntarily taking this action.

We apologize for any inconvenience this communication may cause. We know that you place high value in our products, and we appreciate your cooperation in this matter. Cordis is committed to maintaining your confidence in the safety and quality of the products that Cordis supplies.

Respectfully yours,

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Table 1

S.M.A.R.T.® Stents					
N6120BV	N1040EBR	N1020ABR	N640ABR	N760ABR	N880ABR
N7120BV	N1060EBR	N1020BBR	N640BBR	N760BBR	N880BBR
N8120BV	N840EBR	N1020TBR	N640TBR	N760TBR	N880TBR
	N860EBR	N1040ABR	N660ABR	N780ABR	N920ABR
	N880EBR	N1040BBR	N660BBR	N780BBR	N920BBR
	N1080EBR	N1040TBR	N660TBR	N780TBR	N920TBR
		N1060ABR	N680ABR	N820ABR	N940ABR
		N1060BBR	N680BBR	N820BBR	N940BBR
		N1060TBR	N680TBR	N820TBR	N940TBR
		N1080ABR	N720ABR	N840ABR	N960ABR
		N1080BBR	N720BBR	N840BBR	N960BBR
		N1080TBR	N720TBR	N840TBR	N960TBR
		N620ABR	N740ABR	N860ABR	N980ABR
		N620BBR	N740BBR	N860BBR	N980BBR
		N620TBR	N740TBR	N860TBR	N980TBR

S.M.A.R.T.® CONTROL™ stents					
C06020MB	C07020SB	C08030MB	C09030SB	C10040MB	C12040SB
C06020MV	C07020SV	C08030MV	C09030SV	C10040MV	C12040SV
C06020SB	C07030MB	C08030SB	C09040MB	C10040SB	C12060MB
C06020SV	C07030MV	C08030SV	C09040MV	C10040SV	C12060MV
C06030MB	C07030SB	C08040MB	C09040SB	C10060MB	C12060SB
C06030MV	C07030SV	C08040MV	C09040SV	C10060MV	C12060SV
C06030SB	C07040MB	C08040SB	C09060MB	C10060SB	C12080MB
C06030SV	C07040MV	C08040SV	C09060MV	C10060SV	C12080MV
C06040MB	C07040SB	C08060MB	C09060SB	C10080MB	C12080SB
C06040MV	C07040SV	C08060MV	C09060SV	C10080MV	C12080SV
C06040SB	C07060MB	C08060SB	C09080MB	C10080SB	C14030MB
C06040SV	C07060MV	C08060SV	C09080MV	C10080SV	C14030MV
C06060MB	C07060SB	C08080MB	C09080SB	C10100MB	C14030SB
C06060MV	C07060SV	C08080MV	C09080SV	C10100MV	C14030SV
C06060SB	C07080MB	C08080SB	C09100MB	C10100SB	C14040MB
C06060SV	C07080MV	C08080SV	C09100MV	C10100SV	C14040MV
C06080MB	C07080SB	C08100MB	C09100SB	C12020MB	C14040SB
C06080MV	C07080SV	C08100MV	C09100SV	C12020MV	C14040SV
C06080SB	C07100MB	C08100SB	C10020MB	C12020SB	C14060MB
C06080SV	C07100MV	C08100SV	C10020MV	C12020SV	C14060MV
C06100MB	C07100SB	C09020MB	C10020SB	C12030MB	C14060SB
C06100MV	C07100SV	C09020MV	C10020SV	C12030MV	C14060SV
C06100SB	C08020MB	C09020SB	C10030MB	C12030SB	C14080MB
C06100SV	C08020MV	C09020SV	C10030MV	C12030SV	C14080MV
C07020MB	C08020SB	C09030MB	C10030SB	C12040MB	C14080SB
C07020MV	C08020SV	C09030MV	C10030SV	C12040MV	C14080SV

PRECISE stents						
Catalog #'s						
N520SC	N1020SC	P0720RXCE	P08020RXB	N520SB	N830SB	N840SB
N530SC	N1030SC	P0730RXCE	P09020RXB	N530SB	N840SB	N830SB
N540SC	N1040SC	P0740RXCE	P10020RXB	N540SB	N1040SB	N1020SB
N620SC	N920SC	P0820RXCE	P05040RXB	N630SB	N940SB	N1030SB
N630SC	N930SC	P0830RXCE	P07020RXB	N640SB	N820SB	N1040SB
N640SC	N940SC	P0840RXCE	P07030RXB	N730SB	N1020SB	N820SB
N720SC		P0920RXCE	P07040RXB	N740SB	N920SB	N920SB
N730SC		P0930RXCE	P08030RXB	N620SB	N1030SB	N930SB
N740SC		P0940RXCE	P08040RXB	N720SB	N930SB	N940SB
N820SC		P1020RXCE	P09030RXB			
N830SC		P1030RXCE	P05020RXB			
N840SC		P1040RXCE	P05030RXB			
		P0520RXCE	P06020RXB			
		P0530RXCE	P06030RXB			
		P0540RXCE	P06040RXB			
		P0620RXCE				
		P0630RXCE				
		P0640RXCE				