Urgent MEDICAL DEVICE FIELD CORRECTION

Cordis SUPER TORQUE® MB Angiographic Catheter

Catalog Numbers			Modified Std Cat. Numbers	
532598A	532598B	532598C	SRD6875MB	SRD7040MB
NOTE: This is additional labeling. Retain this letter with affected product.				
NOTE: This is a Field Correction and does not involve removal of product.				

July 28, 2021

Dear Valued Customer,

The purpose of this communication is to inform you Cordis is issuing a Correction related to labeling of a specific subset of our angiographic catheters: Cordis **SUPER TORQUE® MB Angiographic Catheters** (with Marker Bands).

Overview:	Cordis has identified that the **SUPER TORQUE® MB** Angiographic Catheter (with Marker Bands) are being used in a manner that may allow entrapment of the catheter between endovascular devices and the vessel wall, which can lead to marker band movement or dislodgement. This letter provides important information concerning the decision by Cordis to add the following contraindication to the Instructions for Use (IFU) for the Cordis **SUPER TORQUE® MB Angiographic Catheters**: **Do not use the SUPER TORQUE® MB Angiographic Catheters in procedures where entrapment of the catheter between endovascular devices and the vessel wall may occur.** **Please share this information with any of your staff involved in endovascular procedures.**

Details on Affected Device, to assist in identification of the product involved:	**Product involved** This letter applies only to the Cordis **SUPER TORQUE® MB Angiographic Catheter** catalog numbers containing marker bands, listed above (all lots). This letter does NOT apply to **SUPER TORQUE® Angiographic Catheter** catalog numbers without marker bands. **Intended Use:** Cordis Angiographic Catheters with Marker Bands are designed to provide angiographic visualization and linear measurement of the vasculature when combined with the delivery of radiopaque contrast media to selected sites in the vascular system.

Why you are being contacted:	You are receiving this letter because our records indicate that you have purchased one or more of the Cordis **SUPER TORQUE® MB Angiographic Catheter** catalog numbers listed above that are not yet expired.

Actions requested on your part:	1) Read the “Description” and “Recommendations” sections carefully. ~~2)~~ Sign and return the enclosed Acknowledgement Form in accordance with the directions on the form. 3) Share this notification with anyone in your facility that needs to be informed. 4) Maintain awareness of this communication until the information has been incorporated into the SUPER TORQUE® MB Angiographic Catheter labeling.

Description of the problem:	Post market surveillance of the SUPER TORQUE® MB Angiographic Catheter (with marker bands) has identified that the product is being used in a manner that may allow entrapment of the catheter between endovascular devices and the vessel wall, for example, use in EVAR/covered stent procedures. During withdrawal, when the device is entrapped, the catheter may stretch and elongate enough for the marker bands to move or dislodge from the catheter during use. Cordis' investigation has concluded that these events are not related to a manufacturing defect. The potential impact of marker band movement or dislodgement include intraprocedural delay, damage to the vasculature, pulmonary embolism and/or additional intervention (peripheral/surgical). If a procedure has been completed successfully, there is no concern. Based on this review, Cordis has made the decision to add the following contraindication to the Instruction for Use (IFU) for the Cordis SUPER TORQUE® MB Angiographic Catheters (with Marker Bands): **Do not use the SUPER TORQUE® MB Angiographic Catheters in procedures where entrapment of the catheter between endovascular devices and the vessel wall may occur.**

Recommendations for Clinical Use:	Do not use the SUPER TORQUE® MB Angiographic Catheter in procedures where entrapment of the catheter between endovascular devices and the vessel wall may occur. As a reminder, the Instructions for Use (IFU) already include the following: **Warnings:** • Manipulation of the catheter under excessive friction due to interaction with other devices or while trapped in the vasculature, can lead to stretching or elongation of the catheter. • Stretching or elongation of the catheter during endovascular procedures could result in the marker bands moving along the catheter. In extreme cases, marker bands may come off the catheter and dislodge into the vascular system. **Complications:** • Movement of the marker bands along the catheter can result in inaccurate reference and device sizing. Dislodgement of the marker bands into the vascular system can result in additional intervention, embolism, thrombosis or other vascular complications. **Recommended Procedure:** • Do not advance or withdraw the **SUPERTORQUE® MB** Angiographic Catheter within the vascular system unless it is preceded by a guide wire. Exercise care when removing guidewires from multiple-curve catheters. • Avoid excessive tension on the device during manipulation. Extreme care to avoid stretching or elongation must be exercised during manipulation and withdrawal. • If resistance is felt during manipulation, determine the cause of resistance before proceeding and confirm **SUPERTORQUE® MB** Angiographic Catheter positioning under high quality fluoroscopic observation.

Available Assistance:	• If you have any questions regarding this recall, please contact your local sales representative or local sales office.

Additional Information:	**Regulatory Notification** The FDA and other applicable regulatory bodies have been notified and are aware 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,

Miguel Ávila
Vice President, Global Quality and Regulatory Affairs
Cordis Corporation
cc: Risk Manager, Director of Cardiac Cath Lab, Director of Radiology Services