URGENT FIELD SAFETY NOTICE
Recommendations for Clinical Use - SUPER TORQUE® MB Angiographic Catheter

Catalog Numbers		Modified Standard Catalog Numbers		
532598A	532598B	SRD5724MB	SRD6093MB	SRD6875MB
532598C	532598D	SRD6903MB	SRD7039MB	SRD7040MB

Note: This is additional labeling. Retain this letter with affected product.
Note: This is NOT a product removal.

November 24, 2011

Dear Valued Customer,

The purpose of this communication is to inform you that Cordis has issued a Field Safety Notice related to a specific subgroup of Cordis angiographic catheters.

Overview:	This letter provides important information concerning the potential for marker band displacement in the SUPER TORQUE® MB Angiographic Catheter during endovascular procedures when the catheter is stretched or elongated, and important recommendations for clinical use. **Please share this information with any of your staff involved in endovascular procedures.**

Details on Affected Devices:	This Field Safety Notice applies to the 10 Cordis SUPER TORQUE® MB Angiographic Catheter catalog numbers containing marker bands, listed above. This Field Safety Notice does NOT apply to SUPER TORQUE® Angiographic Catheter Catalog Numbers without marker bands. Indications for 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.

Actions requested on your part:	• Read the “Description” and “Recommendations” sections carefully. • Sign and return the enclosed Acknowledgement Form to your local sales representative. • Pass on this notice to anyone in your facility that needs to be informed. • Maintain awareness of this communication until the information contained herein has been incorporated into the Instructions For Use

Description of the problem:	In the past, Cordis has received complaints related to marker band movement along the catheter. Recently, Cordis received the first report in which the **marker bands dislodged from (came off) the catheter in the patient’s vasculature and required additional stent placement in the left iliac artery to trap the dislodged marker bands against the vessel wall.** The patient was reported to be in good condition with no other consequences. There have been no deaths and no other serious events associated with any of the previously reported events. The complaint rate over the last two years is 0.0175%. Most of the reports occurred during endovascular aortic repair (AAA, TEVAR), including the recent report in which the marker bands dislodged from the catheter.

	Through analysis of returned units and engineering studies, Cordis has concluded that the event is not related to a manufacturing defect. It is possible that during specific situations in clinical practice, the catheter might be stretched and elongated enough for the marker bands to dislodge from the catheter during clinical use. If a procedure has been completed successfully, there is no concern.

Recommendations for Clinical Use:	• Manipulation of the SUPER TORQUE® MB Angiographic 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 SUPER TORQUE® MB Angiographic Catheter during endovascular procedures could result in the marker bands moving along the catheter. **In extreme cases, marker bands may come off the SUPER TORQUE® MB Angiographic Catheter and dislodge into the vascular system.** • Movement of the marker bands along the SUPER TORQUE® MB Angiographic 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**. • Prior to using the device, inspect for bends, kinks or other damage. • Do not advance or withdraw the SUPER TORQUE® MB Angiographic Catheter within the vascular system unless it is preceded by a guide wire. • 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 SUPER TORQUE® MB Angiographic Catheter positioning under high quality fluoroscopic observation. • Avoid entrapment of the SUPER TORQUE® MB Angiographic Catheter between other endovascular devices and the vessel wall. • Avoid excessive friction on the SUPER TORQUE® MB Angiographic Catheter. • Avoid simultaneous introduction of the SUPER TORQUE® MB Angiographic Catheter and aortic graft devices through the same sheath. Cordis is in the process of supplementing the SUPER TORQUE® MB Angiographic Cather labeling to address the above points.

Why you are being contacted:	You are receiving this letter because our records indicate that you have received product of the listed catalog numbers that has not yet expired. Cordis SUPER TORQUE® MB Angiographic Catheters have a 3 year shelf life.

Available Assistance:	In addition to your local sales representative, you may contact the local Johnson & Johnson sales office to answer any questions you may have.

Additional Information:	The applicable regulatory agencies are being notified. 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 products that Cordis supplies.

Respectfully yours,

[redacted]
WW Vice President
Quality, Regulatory & Compliance
Cordis Corporation