Urgent Field Safety Notice

Additional labeling- Instructions if resistance is felt during balloon cover removal

Cordis EMPIRA™ NC RX PTCA Dilatation Catheter ("75RxxyyyN")
and
Cordis EMPIRA™ RX PTCA Dilatation Catheter ("85RxxyyyS")

All Catalog Numbers, All unexpired Lots

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

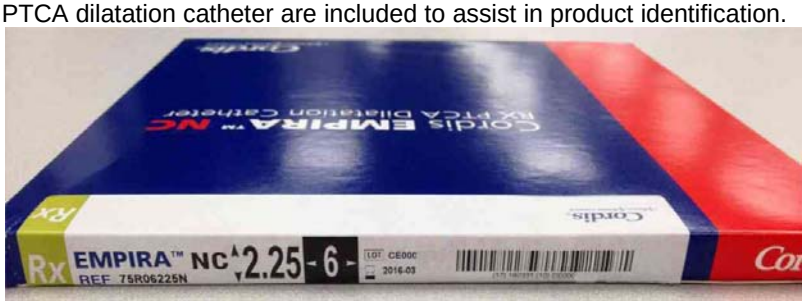
June 23, 2014

Dear Valued Customer,

The purpose of this communication is to inform you that Cordis Corporation, Inc. (Cordis) and Creganna-Tactx Medical, Inc. (Creganna-Tactx) are providing reminders and additional information relative to the labeling of the Cordis EMPIRA™ NC RX and EMPIRA™ RX PTCA product. Cordis and Creganna-Tactx are taking this action as the result of a small number of complaints regarding balloon cover removal difficulty when preparing the affected products for use. The EMPIRA™ NC RX and EMPIRA™ RX PTCA Dilatation Catheters are manufactured by Creganna-Tactx and distributed by Cordis.

Correction Overview:	This letter provides important reminders and additional labeling information. Please share this information with any of your staff involved in cardiovascular procedures. The existing labeling in the Instructions For Use states, as part of the "Preparation and Inspection Procedure": ***"Gently remove the shipping stylet along with the balloon cover from the catheter"***, and ***"Store in a cool, dark, dry place".*** In addition to the existing labeling, the following instructions should be followed: ***If unusual resistance is felt during the removal of the shipping stylet and/or balloon cover, do not use this product and replace it with another product***. Excessive force may damage the balloon region of the catheter. It is known that balloons with hydrophilic coating are susceptible to expansion of the coating at extremely elevated humidity. Therefore, it is important to follow the current labeling, to store the product in a cool, dark and dry place.

Details on Affected Product, to assist in identification of the product involved:	Affected product details: • This letter applies to all 133 catalog numbers of the Cordis EMPIRA™ NC RX and EMPIRA™ RX PTCA Dilatation Catheter. • The catalog sequences are "75RxxyyyN" and "85RxxyyyS". The nomenclature "xxyyy" refers to balloons with length xx millimeters and diameter y.yy millimeters. A listing of all catalog numbers is provided in Table 1 at the end of this letter. • This additional labeling applies to all EMPIRA™ NC RX and EMPIRA™ RX lots until the labeling shipped with the product is updated. The Correction is not lot-specific since there is no manufacturing defect.

Details on Affected Product (Cont'd):	The following sample photos of the Cordis EMPIRA™ NC RX and EMPIRA™RX PTCA dilatation catheter are included to assist in product identification.   Product Indications: The Cordis EMPIRA™ NC RX and EMPIRA™ RX PTCA Dilatation Catheters are indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. The EMPIRA™ NC RX is also indicated for post-delivery expansion of balloon expandable stents.

Actions requested on your part:	• Read this Field Safety Notice carefully. • Sign and return the enclosed Acknowledgement Form to your local sales representative. • Pass on this notice to anyone who needs to be informed in your facility and in any facility where potentially affected devices may have been transferred. • Maintain awareness of this communication until the information has been incorporated into the Cordis EMPIRA™ NC RX and EMPIRA™ RX PTCA dilatation catheter labeling. • Retain this letter with affected product. • Report all balloon cover removal difficulties through the standard complaint process.

Description of the problem:	Through the investigation of a small number of complaints, Cordis and Creganna-Tactx have observed that the balloon of the affected product, which is covered with a hydrophilic coating, may exhibit resistance to the removal of the balloon cover. Weakening of the affected product in the region of the proximal balloon seal may occur when excessive force is applied to remove the balloon cover. Use of a weakened catheter may lead to balloon burst, shaft separation or deflation difficulties, which could result in procedural delay, vessel trauma or surgery. There is no concern for patients who have already been treated successfully with the affected product.

Updated Labeling:	The existing labeling in the Instructions For Use states, as part of the "Preparation and Inspection Procedure": ***Gently remove the shipping stylet along with the balloon cover from the catheter***, and ***"Store in a cool, dark, dry place"*** In addition to the existing labeling, the following instructions should be followed: ***If unusual resistance is felt during the removal of the shipping stylet and/or balloon cover, do not use this product and replace it with another product***.

Why you are being contacted:	You are receiving this notice because our records indicate that you have received product of the listed catalog numbers that has not yet expired. Cordis EMPIRA™ NC RX and EMPIRA™ RX PTCA dilatation catheters have a 2 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 that Cordis and Creganna-Tactx are 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 and Creganna-Tactx are committed to maintaining your confidence in the safety and quality of the products that Creganna-Tactx manufactures and Cordis supplies.

Respectfully yours,

Andrew Aquart
Sr. Director, Quality & Regulatory Compliance
Cordis Corporation

Joan McCabe
Global V.P., Quality and Regulatory Affairs
Creganna-Tactx Medical, Inc.

Table 1: Listing of Catalog numbers.

EMPIRA™ RX NC RX PTCA Dilatation Catheter (Post-dilatation, non-compliant)						
63 catalog numbers						
75R06200N	75R10200N	75R12200N	75R15200N	75R20200N	75R25200N	75R30200N
75R06225N	75R10225N	75R12225N	75R15225N	75R20225N	75R25225N	75R30225N
75R06250N	75R10250N	75R12250N	75R15250N	75R20250N	75R25250N	75R30250N
75R06275N	75R10275N	75R12275N	75R15275N	75R20275N	75R25275N	75R30275N
75R06300N	75R10300N	75R12300N	75R15300N	75R20300N	75R25300N	75R30300N
75R06325N	75R10325N	75R12325N	75R15325N	75R20325N	75R25325N	75R30325N
75R06350N	75R10350N	75R12350N	75R15350N	75R20350N	75R25350N	75R30350N
75R06375N	75R10375N	75R12375N	75R15375N	75R20375N	75R25375N	75R30375N
75R06400N	75R10400N	75R12400N	75R15400N	75R20400N	75R25400N	75R30400N

EMPIRA™ RX PTCA Dilatation Catheter (Pre-diltation Semi-compliant)						
70 catalog numbers						
85R06150S	85R10150S	85R12150S	85R15150S	85R20150S	85R25150S	85R30150S
85R06200S	85R10200S	85R12200S	85R15200S	85R20200S	85R25200S	85R30200S
85R06225S	85R10225S	85R12225S	85R15225S	85R20225S	85R25225S	85R30225S
85R06250S	85R10250S	85R12250S	85R15250S	85R20250S	85R25250S	85R30250S
85R06275S	85R10275S	85R12275S	85R15275S	85R20275S	85R25275S	85R30275S
85R06300S	85R10300S	85R12300S	85R15300S	85R20300S	85R25300S	85R30300S
85R06325S	85R10325S	85R12325S	85R15325S	85R20325S	85R25325S	85R30325S
85R06350S	85R10350S	85R12350S	85R15350S	85R20350S	85R25350S	85R30350S
85R06375S	85R10375S	85R12375S	85R15375S	85R20375S	85R25375S	85R30375S
85R06400S	85R10400S	85R12400S	85R15400S	85R20400S	85R25400S	85R30400S