Urgent FIELD SAFETY NOTICE (Removal)

Cordis S.M.A.R.T.® CONTROL® Nitinol Stent System
All Catalog Numbers- (SEE RECALL PRODUCT LIST BELOW)
All unexpired lot numbers 15525516 and below

January 31, 2012

Dear Valued Customer,

The purpose of this communication is to inform you that Cordis is recalling (removing) all unexpired lots of Cordis S.M.A.R.T.® CONTROL® Nitinol Stent System product distributed at the time of this letter.

Overview:	Cordis has identified a potential sterility breach in the pouches of all unexpired lots of Cordis S.M.A.R.T.® CONTROL® Nitinol Stent System product.

Details on Affected Devices:	This letter applies to: • Specific lots of 65 catalog numbers of S.M.A.R.T.® CONTROL® Nitinol Stent System product sold only outside the United States. • The catalog numbers are readily identified as CxxyyyMV and CxxyyySV, where "xx" is the stent diameter in mm. and "yyy" is the stent length in mm. • The lot range includes all lot numbers from 15112447 through **15525516**, encompassing all unexpired lots distributed prior to mid-January 2012. A listing of product lots provided to your facility is included at the end of the Acknowledgement Form. This letter does NOT apply to: • Any lot numbers above the 15525516 lot number break. All product distributed from February 2012 forward will have higher lot numbers and will not be affected. • S.M.A.R.T.® Nitinol Stent System (Codes: C06120MV, C06150MV, C07120MV, C07150MV, C08120MV, C08150MV, C06120SV, C06150SV, C07120SV, C07150SV, C08120SV, C08150SV) Indications for Use: The Cordis S.M.A.R.T.® CONTROL® Nitinol Stent System is designed to deliver a self-expanding stent via a sheathed delivery system.

Actions requested on your part:	• Read the "Description of the problem" section. • Immediately identify and set aside all product listed below in a manner that ensures the affected product will not be used. • Review, complete, sign and return the enclosed Acknowledgement Form in accordance with the directions on the form. • Either return any affected product per the attached instruction, or contact your local sales representative to facilitate return of the affected product. Replacement product will be provided for consignment product when product is available, and credit will be provided for customer-owned product. • Pass on this notice to anyone in your facility that needs to be informed. • If any product listed below has been forwarded to another facility, contact that facility to arrange return. • Maintain awareness of this notice until all affected product in your facility has been returned to Cordis.

Description of the problem:	Cordis recently determined that some Cordis S.M.A.R.T.® CONTROL® Nitinol Stent System product may have small channels in the pouch seal. The potential

	defect was detected during in-house testing on non-production product as part of a development project. Further investigation determined that conditions leading to a potential pathway through the seal exist in a small percentage of distributed product. The compromised seal is not readily apparent to the unaided eye. To date, no complaints have been reported that are connected to this defect. This recall is not being undertaken on the basis of adverse medical events. In the event a pathway in the seal is present, loss of the sterile barrier could occur, leading to use of a non-sterile device in the procedure. Contamination may expose the patient to increase risk of infection. If an infection was to occur, medical intervention might be needed to prevent permanent injury or impairment. Infection of bare metal vascular stents occurs rarely. Patients that have had the stent implanted for less than 30 days should be carefully monitored for any signs of infection. In keeping with our commitment to provide customers with quality products, Cordis has voluntarily decided to recall the product. Cordis has performed a root cause investigation and will resume product distribution once corrective actions and/or inspections have been implemented.

Why you are being contacted:	You are receiving this letter because our records indicate that you have received affected unexpired lots of the listed catalog numbers. Cordis S.M.A.R.T.® CONTROL® Stent Delivery Systems have a 2 year shelf life.

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

Additional Information:	The applicable regulatory agencies are being notified. 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,

Jacqueline Maestri
WW Vice President, Quality, Regulatory & Compliance
Cordis Corporation

RECALL PRODUCT LIST

S.M.A.R.T.® CONTROL® Nitinol Stent System (65 Catalog Numbers)
All unexpired lot numbers 15525516 and below

C06020SV, C06030MV, C06030SV, C06040MV, C06040SV, C06060MV, C06060SV, C06080MV, C06080SV, C06100MV, C06100SV, C07020SV, C07030MV, C07030SV, C07040MV, C07040SV, C07060MV, C07060SV, C07080MV, C07080SV, C07100MV, C07100SV, C08020SV, C08030MV, C08030SV, C08040MV, C08040SV, C08060MV, C08060SV, C08080MV, C08080SV, C08100MV, C08100SV, C09020SV, C09030MV, C09030SV, C09040MV, C09040SV, C09060MV, C09060SV, C09080MV, C09080SV, C10020SV, C10030MV, C10030SV, C10040MV, C10040SV, C10060MV, C10060SV, C10080MV, C10080SV, C12030SV, C12040MV, C12040SV, C12060MV, C12060SV, C12080MV, C12080SV, C14030SV, C14040MV, C14040SV, C14060MV, C14060SV, C14080MV, C14080SV