Cordis.
a Johnson & Johnson company

Endovascular

October 21, 2008

RE: MEDICAL DEVICE RECALL – Cordis Savvy® LONG PTA Dilatation Catheter
Catalog Number 436-3022L – Lot 50005346 only, 16 units only
This lot was distributed in Germany and Australia only

Dear Valued Customer,

The purpose of this letter is to inform you that Cordis is recalling one lot of the Savvy® LONG Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter Catalog Number 436-3022L. The Savvy® LONG PTA Dilatation Catheter family is intended for balloon dilatation of the femoral, popliteal and infra-popliteal arteries.

Cordis recently determined that labeling of the inner pouch of Catalog Number 436-3022L, Lot 50005346 is incorrect. The carton label is correct in all aspects, correctly matching the 3.0 mm balloon catheter inside. However, the inner pouch label incorrectly states the Catalog Number as 436-2022L (should be 436-3022L), incorrectly states the balloon expanded diameter as 2.0 mm (should be 3.0 mm), and incorrectly states the shaft diameter as 3.6F (should be 3.9F). All other aspects of the labeling are correct, including the lot number.

No patient injuries have been reported as a result of this labeling discrepancy.

Since the standard practice is to store the product in the carton until use during a procedure, the likely consequence is that either the error would be recognized, and product set aside, or the 3.0 mm balloon catheter would be used as intended. In this likely scenario that the catheter is chosen based on the labeling on the carton, no harm would result.

In the unlikely event that the product is selected based on the inner pouch labeling, a 3.0 mm balloon catheter would be used when a 2.0 mm balloon is anticipated. If that were to occur, the larger 3.0 mm balloon could over-dilate a peripheral artery. Over-dilation could result in a perforation or dissection, which may require further percutaneous or surgical intervention. If a procedure has been completed successfully using the product, there is no concern.

In keeping with our commitment to provide customers with quality products, Cordis has voluntarily decided to recall this lot of the Savvy® LONG PTA Dilatation Catheter Catalog Number 436-3022L. As appropriate, the applicable regulatory bodies are being informed of this matter.

Why you are being contacted

Our records indicate that your hospital received one or more products affected by this recall. Additional details regarding the catalog number and lot number that has been shipped to your facility are provided with the enclosed Acknowledgement Form.

Actions requested on your part

- Immediately set aside any affected product in a manner that ensures they will not be used.
- Review, sign and return the enclosed Acknowledgement Form in accordance with the instructions on the form.
- Either return any product per attached instructions, or contact your local sales representative who will facilitate removal and return of the affected product. A credit will be issued for all returned product.
- If any affected product has been forwarded to another facility, contact that facility to arrange return.

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In addition to your local sales representative, you may contact the local Cordis sales office to assist you in details relative to return of affected product, to answer any questions related to availability of product, or to answer any other questions that you may have.

We apologize for any inconvenience this 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 quality of our products.

Respectfully yours,

[redacted]

Jacqueline Maestri

Vice President, Quality Assurance