



Urgent Medical Device Field Correction - Immediate Action Required

**Boston Scientific**  
**Liberté® Bare-Metal Coronary Stents**  
MONORAIL® & OVER-THE-WIRE Coronary Stent System

September 18, 2009

Dear Risk Manager/Field Action Contact:

Boston Scientific is initiating a field correction for our Liberté bare-metal (**Liberté Bare-Metal**) coronary stent products. We have received reports from cardiac cath labs that TAXUS Liberté Paclitaxel-Eluting (**TAXUS® Liberté® Drug-Eluting**) coronary stents have been inadvertently selected when the interventional cardiologist intended to implant a **Liberté Bare-Metal** stent, and **Liberté Bare-Metal** stents have been inadvertently selected when the interventional cardiologist intended to implant a **TAXUS Liberté Drug-Eluting** stent. Selecting the wrong device may present a risk of serious injury, including death. As of August 31, 2009, Boston Scientific has received no reports of serious injuries or deaths resulting from this issue.

**Please Note: The product inside the Liberté Bare-Metal Stent package is unaffected by this field action. The only change is to the name and outer package of the Liberté Bare-Metal Stent. No changes are being made to the TAXUS Liberté Drug-Eluting stent packaging or product.**

Because of the importance of accurate device selection to patient safety, Boston Scientific is taking the following actions:

1. We are renaming the **Liberté Bare-Metal** stent. The new name will be "**VeriFLEX™ Bare-Metal**" stent.
2. Through September 25, 2009, representatives from Boston Scientific will be visiting all impacted health care facilities to re-label the outer boxes of all existing **Liberté Bare-Metal** stents held in your inventory to reflect the new name. An example of a re-labeled Bare-Metal stent package is shown below:



3. The pouch label, patient guide and Directions for Use (DFU) card will not be re-labeled and therefore will remain with the name Liberté for a period of time. These items will be updated with the new VeriFLEX™ Bare-Metal name at a later date.

**No product needs to be returned to Boston Scientific.** Boston Scientific representatives are immediately available to provide additional training to hospital and/or catheterization laboratory staff on accurate device selection. If you have not yet been contacted by a Boston Scientific representative, please call 800-811-3211 immediately to arrange for this important visit.

This field correction affects **ALL** non-expired **Liberté Bare-Metal** product. **Further distribution or use of any remaining Liberté Bare-Metal product affected by this field correction should cease immediately** until such time as the re-labeling of the Liberté Bare-Metal product is completed.

If you identify any **Liberté Bare-Metal** product within your inventory, please segregate the affected product immediately. A Boston Scientific Representative is responsible for completing all re-labeling of this affected product. Upon completion of the re-labeling, the new label to all outer boxes will identify those units as VeriFLEX product. An inventory of all product corrected at your facility will be produced by the BSC representative resulting in a Field Correction Inventory Document. This Field Correction Inventory Document and the enclosed Reply Verification Tracking Form must be completed, signed, and faxed back to Boston Scientific. Please see the attached DIRECTIONS FOR FIELD CORRECTION. Again, no product is required to be



returned to Boston Scientific. Once the field correction has been completed at your facility, the re-labeled product may be returned to your inventory.

Worldwide regulatory authorities are being notified of this Field Correction as appropriate.

Your local Sales Representative can answer any questions that you may have regarding this field correction. You may also contact us at (800) 811-3211.

We regret any inconvenience that this action may cause, and we appreciate your understanding as we take action to ensure patient safety and customer satisfaction. We are committed to continuing to offer products that meet the highest quality standards that you expect from Boston Scientific.

Sincerely,

A handwritten signature in cursive script that reads "Renee D. Vossen".

Renee Vossen  
Field Action Coordinator  
Boston Scientific, Inc.

cc: Cath Lab Manager (Only to hospitals without a designated Field Action Contact)

Encl: Directions for Field Correction  
Reply Verification Tracking Form

Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to AMO by calling 1-877-AMO-4LIFE and to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.

Online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)

Regular Mail: use postage-paid FDA form 3500 available at [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) and mail to MedWatch, 5600 Fishers Lane, Rockville, MD, 20852-9787

Fax: (800) FDA-0178

Phone: (800) FDA-1088



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**DIRECTIONS FOR FIELD CORRECTION**

The Reply Verification Tracking Form enclosed with this letter must be completed and returned even if you do not have any **Liberté Bare-Metal** stents in your inventory.

1. **Immediately discontinue use of and segregate all Liberté Bare-Metal product.**
  - Immediately remove all affected product from your inventory (whether in the Cath Lab, Central Service, Shipping and Receiving or any other location).
  - Segregate this product in a secure location.
  - A BSC Representative will re-label all product cartons with the new VeriFLEX labels
  
2. **Complete and return the Reply Verification Tracking Form with the Field Correction Inventory Document.**
  - Complete the enclosed Reply Verification Tracking Form (even if you do not have any product in your inventory), following the directions on this page and the Reply Verification Tracking Form.
  - If affected product is identified, your BSC Representative will scan and produce a Field Correction Inventory Document for you to sign and confirm completion of re-labeling.
  - Return the completed Reply Verification Tracking Form AND, if applicable, the Field Correction Inventory Document:

**Fax to: Customer Service Call Center  
(866) 213-1806**

Please fax Reply Verification Tracking Form and Field Correction Inventory immediately upon completion. **No product is required to be returned.**