«Hospital_Name»
«Users_Name» - «Department»
«Customer_Address»
«Zip_Code» «City» - «Country_name»

Reference: 90609919-FA July xx, 2010

Field Safety Notice
Urgent Medical Device Recall
Ultraflex™ Esophageal NG Stent System, Ultraflex™ Tracheobronchial Stent System and Ultraflex™ Precision Colonic Stent System

Dear «Users_Name»,

Boston Scientific is conducting a Medical Device Recall on specific batches of the Ultraflex™ Esophageal NG Stent System, Ultraflex™ Tracheobronchial Stent System and Ultraflex™ Precision Colonic Stent System. During internal testing, Boston Scientific identified an issue that may potentially result in the failure to deploy the stent due to the deployment suture breaking. If the deployment suture breaks, there could be difficulty deploying the stent, either partially or fully. The most serious injury reasonably expected to occur from the suture break issue could be a minor procedure delay or minor bleeding. Boston Scientific is not aware of any patient complications resulting from this issue.

Our records indicate that your facility received some of the concerned product. **The table below provides a complete list of all affected products**, including Product Description, Material Number (UPN) and Lot/Batch numbers. **Please note that only the material listed in the table below is affected. No other Boston Scientific product is involved by this Field Safety Notice**.

Product Description	**Material N° (UPN)**	**Lot/Batch Number**	
Ultraflex Uncovered Esophageal Stent System – Distal Release (18/23/15)	M00513720	13450513	
Ultraflex Covered Esophageal Stent System – Distal Release (18/23/12/9)	M00513740	13442098	
Ultraflex Uncovered Esophageal Stent System – Proximal Release (18/23/7)	M00513800	13469828	
Ultraflex Covered Esophageal Stent System – Proximal Release (18/23/10/7)	M00513840	13441743	
Ultraflex Covered Esophageal Stent System – Proximal Release (18/23/12/9)	M00513850	13435072	
Ultraflex Covered Esophageal Stent System – Proximal Release (18/23/15/12)	M00513860	13436212	
Ultraflex Covered Large Esophageal Stent System – Distal Release (23/28/10/7)	M00514200	13436624	
Ultraflex Uncovered Large Esophageal Stent System – Proximal Release (23/28/12)	M00514230	13419034	
Ultraflex Covered Large Esophageal Stent System – Proximal Release (23/28/12/9)	M00514250	13453530	
Ultraflex Uncovered Tracheobronchial Stent System – Proximal release (10/4)	M00564670	13485289	
Ultraflex Covered Tracheobronchial Stent System – Distal release (10/4/2.5)	M00564760	13432642	
Ultraflex Covered Tracheobronchial Stent System – Distal release (14/4/2.5)	M00564800	13473372	
Ultraflex Covered Tracheobronchial Stent System – Distal release (16/6/4.5)	M00564840	13439023	
Ultraflex Covered Tracheobronchial Stent System – Distal release (18/4/2.5)	M00564860	13433240	
Ultraflex Covered Tracheobronchial Stent System – Distal release (20/6/4.5)	M00564900	13432371	13436055
Ultraflex Precisions Colonic Stent System (25/30/87/100/105/22)	M00557360	13432574	

INSTRUCTIONS:

1. **Please immediately discontinue use of the Boston Scientific product** listed above **and remove all of the affected units from your inventory** (whether in Cath Lab., Radiology, Fluoroscopy Suite, Interventional Operating Room, Central Supply, Shipping & Receiving and any other relevant location). **Segregate the units in a secure place, pending return to Boston Scientific.**

2. **Please complete the attached Verification Form** even if you do not have any product to return.

3. **When completed,** please **fax the Verification Form** to your local Boston Scientific Office to the attention of «Customer_Service_Fax_Number» on or before **August xx, 2010.**

4. **If you have products to return,** please package them in appropriate shipping box and **contact** «Customer_Service_Tel» of **your local Boston Scientific Office,** to arrange return.

5. Please pass this notice to any health professional of your organization that need to be aware and to any organization where the potentially affected devices have been transferred (If appropriate). Please provide Boston Scientific with details of any affected devices that have been transferred to other organizations (if appropriate).

Your Competent Authority is being notified of this Field Safety Notice.

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.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,

Quality Department
Boston Scientific International S.A.