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

Reference: FCA 2007-09

May 24, 2007

Urgent Medical Device Recall – Immediate Action Required NexStent™ Carotid Stent and Monorail™ Delivery System

Dear «Users_Name»,

On May 11, 2007, Boston Scientific sent you an Important Customer Notification letter identifying a manufacturing issue with our NexStent Carotid Stent and Monorail Delivery System. We also advised you that all concerned regulatory authorities were being notified of the issue. Following discussion with these regulatory authorities, Boston Scientific has initiated a Recall of all NexStent Carotid Stent and Monorail Delivery System products that were shipped to accounts in Germany prior to March 9, 2007.

The products affected by this Recall are listed in ***Attachment A*** to this letter. **Further distribution or use of any remaining product affected by this Recall should cease immediately.** Please note that this Recall does **not** affect or involve Boston Scientific products other than those listed on ***Attachment A***.

As stated in our original Customer Notification letter, during routine final product lot release testing, a NexStent Carotid Stent device failed to deploy when the outer catheter (proximal outer and distal sheath) did not pull back and expose the self-expanding stent. An investigation was initiated which subsequently determined that the proximal shaft-to-luer junction of the device that failed to deploy did not meet necessary tensile strength requirements. Since the NexStent Carotid Stent was launched, Boston Scientific has received a total of four reported complaints which may be related to this shaft-to-luer failure. Boston Scientific is not aware of any patient complications, serious injuries, and/or deaths related to this failure.

The most likely potential injury/risk to the patient from this type of device failure would be an extension of procedure time if the physician were required to remove the device and replace it with another. Other potential risks from this type of device failure include vessel spasm or release of additional embolic debris as the lesion is re-crossed upon removal and replacement of the device.

Our records indicate that your facility received one or more shipments of the affected product. ***Attachment A*** includes a full list of all NexStent Carotid Stent and Monorail Delivery System products affected by this Recall, including Product Description, UPNs, Catalog Numbers, Lot/Batch Numbers, and Expiry Date for those products.

INSTRUCTIONS:

1. **Please immediately discontinue use of all the Boston Scientific product** listed in Attachment A **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 Customer Service** to the attention of «Customer_Service_Fax_Number» on or before **June 7, 2007.**
4. **If you have products to return,** please package them in an appropriate shipping box and **contact** «Customer_Service_Tel» **of your local Boston Scientific Customer Service,** 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).

Your Competent Authority is being notified of this additional action and Recall.

We regret any inconvenience that this issue may cause, and we appreciate your understanding as we take the necessary steps to ensure patient safety and customer satisfaction.

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

Yours sincerely,

[redacted]
Quality Department
Boston Scientific International S.A.

Attachment: - Reply Verification Form
- Attachment A

Boston Scientific

Anhang A
Betroffene Produkte

Important Customer Notification - *Wichtige Kundeninformation*
NexStent™ Karotis-Stentsystem mit Monorail™ Applikationssystem
Referenz: FCA2007-09

Product Description - *Produktbeschreibung*	**Material Number (UPN)** - *Materialnummer (UPN)*	**Catalog Nr** - *Katalognummer*	**Lot/Batch Number** - *Lotnummer*		**Expiration Date** - *Verfallsdatum*
NexStent Monorail Carotid Stent System	M001553000	55-300	C51301	C61803	31. Mrz 07 bis 31. Jan 08
			C52501	C61804	
			C52502	C61805	
			C52703	C61901	
			C61401	C61902	
			C61402	C62001	
			C61403	C62002	
			C61501	C62003	
			C61502	C62004	
			C61503	C63701	
			C61601	C63901	
			C61602	C64001	
			C61603	C64002	
			C61604	C64101	
			C61605	C64102	
			C61701	C64501	
			C61702	C65101	
			C61801	C65102	
			C61802	C65103	