

«Customer_Name»
«Contact_Name» - «Department»
«Customer_Address»
«Zip_Code» «City» - «Country»

Reference: FCA 2005-41

December 27, 2005

Urgent Medical Device Recall - Immediate Action Required **1.9 FR ZERO TIP™ NITINOL STONE RETRIEVAL BASKETS**

Dear «Contact_Name»,

Boston Scientific Corporation is initiating a medical device recall on the 1.9 Fr ZeroTip™ Nitinol Stone Retrieval Baskets. We have received a limited number of reports that the basket wire assembly has detached from the drive wire. Therefore it was determined that there is a potential risk that the basket wire assembly may detach from the drive wire. The detachment of the basket could result in unsuccessful removal of the stone or the detached portion may be left behind in the patient. Should the detachment occur with the basket remaining in the patient a prolonged procedure or possible additional surgical intervention may be required.

The attachment A includes a full list of all recalled products. Please note that only the material and batch number listed is affected. No other Boston Scientific product is involved in this voluntary recall.

IMMEDIATE ACTIONS REQUIRED:

1. **Please immediately discontinue use of all the Boston Scientific product batches** listed in attachment A **and remove** all of the affected **units from your inventory** (whether in Surgical Unit, 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. Please indicate the quantity of products you are returning.
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 January 13, 2006.
4. **If you have products to return, please contact «Customer_Service_Tel» of your local Boston Scientific Customer Service**, to arrange return.

Your Competent Authority is being notified of this voluntary recall.

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 recall, please contact your local Sales Representative.

Yours sincerely,



Marie-Pierre Barlanga
Quality Department
Boston Scientific International S.A.

Attachment: - Verification form
- Attachment A

**ATTACHMENT A
AFFECTED PRODUCTS**

**Urgent Medical Device Recall - Immediate Action Required
1.9 FR ZERO TIP™ NITINOL STONE RETRIEVAL BASKETS
Reference: FCA2005-41**

Product Description	Catalog Number (UPN)	Lot/Batch Number
Nitinol Zero Tip 4 Wire Basket 9/90/12	M0063901040	5766249
Nitinol Zero Tip 4 Wire Basket 9/90/12	M0063901040	5778690
Nitinol Zero Tip 4 Wire Basket 9/90/12	M0063901040	5823724
Nitinol Zero Tip 4 Wire Basket 9/90/12	M0063901040	5831284
Nitinol Zero Tip 4 Wire Basket 9/90/12	M0063901040	5844089
Nitinol Zero Tip 4 Wire Basket 9/90/12	M0063901040	5844091
Nitinol Zero Tip 4 Wire Basket 9/90/12	M0063901040	5880746
Nitinol Zero Tip 4 Wire Basket 9/90/12	M0063901040	5944430
Nitinol Zero Tip 4 Wire Basket 9/90/12	M0063901040	5971070
Nitinol Zero Tip 4 Wire Basket 9/90/12	M0063901040	6365287
Nitinol Zero Tip 4 Wire Basket 9/90/12	M0063901040	6393971
Nitinol Zero Tip 4 Wire Basket 9/90/12	M0063901040	6418865
Nitinol Zero Tip 4 Wire Basket 9/90/12	M0063901040	6463662
Nitinol Zero Tip 4 Wire Basket 9/90/12	M0063901040	7148988
Nitinol Zero Tip 4 Wire Basket 9/90/12	M0063901040	7185677
Nitinol Zero Tip 4 Wire Basket 9/90/12	M0063901040	7224922
Nitinol Zero Tip 4 Wire Basket 9/90/12	M0063901040	7395312
Nitinol Zero Tip 4 Wire Basket 9/90/12	M0063901040	7482056
Nitinol Zero Tip 4 Wire Basket 9/90/12	M0063901040	7526045
Nitinol Zero Tip 4 Wire Basket 9/90/12	M0063901040	7634752
Nitinol Zero Tip 4 Wire Basket 9/90/12	M0063901040	7645612
Nitinol Zero Tip 4 Wire Basket 9/90/12	M0063901040	7750517
Nitinol Zero Tip 4 Wire Basket 9/90/12	M0063901040	7889029
Nitinol Zero Tip 4 Wire Basket 9/90/12	M0063901040	7990013
Nitinol Zero Tip 4 Wire Basket 9/90/12	M0063901040	8072882



Product Description	Catalog Number (UPN)	Lot/Batch Number		
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	5778688	6784673	7150266
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	5825860	6852346	7150267
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	5829709	6865366	7176287
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	5830475	6866546	7183295
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	5854574	6867155	7184029
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	5860124	6878245	7294413
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	5860848	6896211	7296455
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	5860857	6945080	7296718
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6416733	6982065	7319680
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6466704	6992295	7321352
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6485709	6993327	7322098
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6493572	7004391	7323112
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6495179	7005240	7340320
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6578070	7016911	7340321
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6578866	7018651	7358092
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6578867	7018653	7358485
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6581635	7025411	7359690
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6581636	7025412	7363739
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6581827	7025886	7382619
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6638776	7044442	7383507
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6638782	7045034	7383508
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6675598	7074050	7385024
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6686290	7074926	7387257
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6688390	7074928	7389012
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6688391	7075438	7408181
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6689860	7075440	7410901
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6689861	7077761	7412661
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6718242	7094243	7430340
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6734691	7094250	7431882
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6747356	7094251	7434601
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6747357	7094438	7478140
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6765552	7096617	7478142
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6783896	7137659	7480640
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	6783897	7143351	7504071



Product Description	Catalog Number (UPN)	Lot/Batch Number		
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7504073	7787316	8021475
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7519528	7789046	8022276
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7522666	7806937	8033749
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7522667	7806938	8040903
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7541293	7825560	8047397
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7556575	7827204	8051207
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7560990	7841660	8051723
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7570029	7850481	
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7587436	7852448	
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7588293	7853405	
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7588299	7853675	
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7622862	7855979	
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7697327	7855980	
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7700250	7859919	
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7701094	7860297	
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7702647	7865323	
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7710999	7865324	
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7722610	7872392	
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7723481	7876705	
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7727480	7880501	
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7730961	7900080	
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7733530	7900238	
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7734056	7900308	
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7743966	7900773	
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7743967	7901389	
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7745772	7905109	
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7747506	7907767	
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7761047	7913193	
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7764310	7923784	
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7785096	7987583	
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7785097	7991427	
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7785098	8009036	
Nitinol Zero Tip 4 Wire Basket 1.9/120/12	M0063901050	7785909	8016944	

Please Complete and Fax Back to Your Local Customer Service:

«Customer_Service_Fax_Number»

Complete and return the form even if you do not have any product

«Sold_to» - «Customer_Name» - «City» - «Country»

Verification Form – Urgent Medical Device Recall

1.9 FR ZERO TIP™ NITINOL STONE RETRIEVAL BASKETS

FCA 2005-41

1. We acknowledge receipt of the Boston Scientific Product Recall notice dated December 27, 2005 on the **1.9 Fr ZeroTip™ Nitinol Stone Retrieval Baskets**.
2. We confirm that all areas where the product could be located have been checked.
3. TICK ONE OF THESE STATEMENTS:

- We do not have any product** (sign the Verification Form and Fax it to your local Customer Service office «Customer_Service_Fax_Number»)
- Product was redistributed to another facility** - Name of Facility: _____
- We are returning the following product(s)** (Please confirm the batch number(s) of the unit(s) and the quantity being returned in the table below, sign the Verification Form and Fax it to your local Customer Service office: «Customer_Service_Fax_Number»).

Product Description	Material Number	Batch Number(s) & Quantity Returned
Nitinol ZeroTip 4 Wire Basket 1.9/90/12	M0063901040	
Nitinol ZeroTip 4 Wire Basket 1.9/120/12	M0063901050	

To Return Products:

RGAN° _____

1. Contact «Customer_Service_Tel» of your Local Customer Service to arrange return of any affected product
2. Prepare the package
3. Follow the instructions given by your Local Customer Service about collection of the package

Authorised Signature _____

Name _____
(Please type/print)

Title _____ Department _____

Telephone _____ Date _____