

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

Reference: 90693806AC-FA

August xx, 2011

Field Safety Notice Urgent Medical Device Recall Resolution™ II Clip

**This notification is a follow up to the previous Medical Device Correction dated
 July xx, 2011**

Dear «Users_Name»,

Boston Scientific Corporation is initiating a Medical Device Recall of the Resolution™ II Clip. Via product complaints, Boston Scientific was informed of situations in the field, where following clip deployment, the alignment of the clip and delivery system does not allow for the withdrawal of the delivery system away from the clip. This has resulted in tissue trauma, increased bleeding and the clip being pulled off tissue as the delivery system is withdrawn. **Based on the higher than anticipated incidence of difficulty to release the clip from the catheter, we are withdrawing the Resolution II Clip from the market.**

Please Note: This recall does not impact the original Resolution™ Clip. For customers that have been ordering Resolution II Clip they may order the original Resolution Clip, which continues to be available for use by all customers.

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.**

This list is identical to the list in the previous notifications.

Device Name	Material / UPN #	Lot/Batch#					Expiration date
Resolution II Clip – 155 cm – Box 1	M00522500	1ML1013103	ML00000004	ML00000129			31 Jan 2012 – 31 May 2014
Resolution II Clip – 155 cm – Box 10	M00522501	1ML1013104	ML00000071	ML00000148			31 Jan 2012 – 31 May 2014
Resolution II Clip – 155 cm – Box 20	M00522502	1ML1013102	ML00000042	ML00000131			31 Jan 2012 – 31 May 2014
Resolution II Clip – 235 cm – Box 1	M00522510	1ML1011201	1ML1013101	1ML1020202	1ML1021402	1ML1022202	31 Jan 2012 – 31 May 2014
		1ML1022213	ML00000013	ML00000019	ML00000058	ML00000073	
		ML00000098	ML00000120				
Resolution II Clip – 235 cm – Box 10	M00522511	1ML1010605	1ML1012602	1ML1013105	1ML1020203	1ML1021403	31 Jan 2012 – 31 May 2014
		1ML1022203	1ML1022214	ML00000014	ML00000020	ML00000043	
		ML00000059	ML00000074	ML00000099	ML00000119		
Resolution II Clip – 235 cm – Box 20	M00522512	1ML1011905	1ML1020201	1ML1021401	1ML1022201	1ML1022215	31 Jan 2012 – 31 May 2014
		ML00000018	ML00000032	ML00000040	ML00000072	ML00000097	
		ML00000135					

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, 2011.**
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,

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

Attachment: - Verification Form