

«Hospital\_Name»  
 «Users\_Name» - «Department»  
 «Customer\_Address»  
 «Zip\_Code» «City» - «Country\_name»

Reference: 90902129-FA

November , 2013

**Field Safety Notice  
 Urgent Medical Device Recall  
 Boston Scientific Vessix™ Generator System**

Dear «Users\_Name»,

Boston Scientific is initiating a Recall Removal of the Vessix™ Generator System. An investigation has found that the units manufactured since 2013-04 (April 2013) were not manufactured according to specification. This manufacturing issue may cause an electrical short in the generator. To date, there have been no reports of patient injury. While there are no reports of patient injury, the issue could result in excessive RF energy being delivered to the renal artery. The potential health hazards associated with the delivery of excessive RF energy include thrombosis formation, nerve damage and thermal damage to the renal artery or adjacent structures.

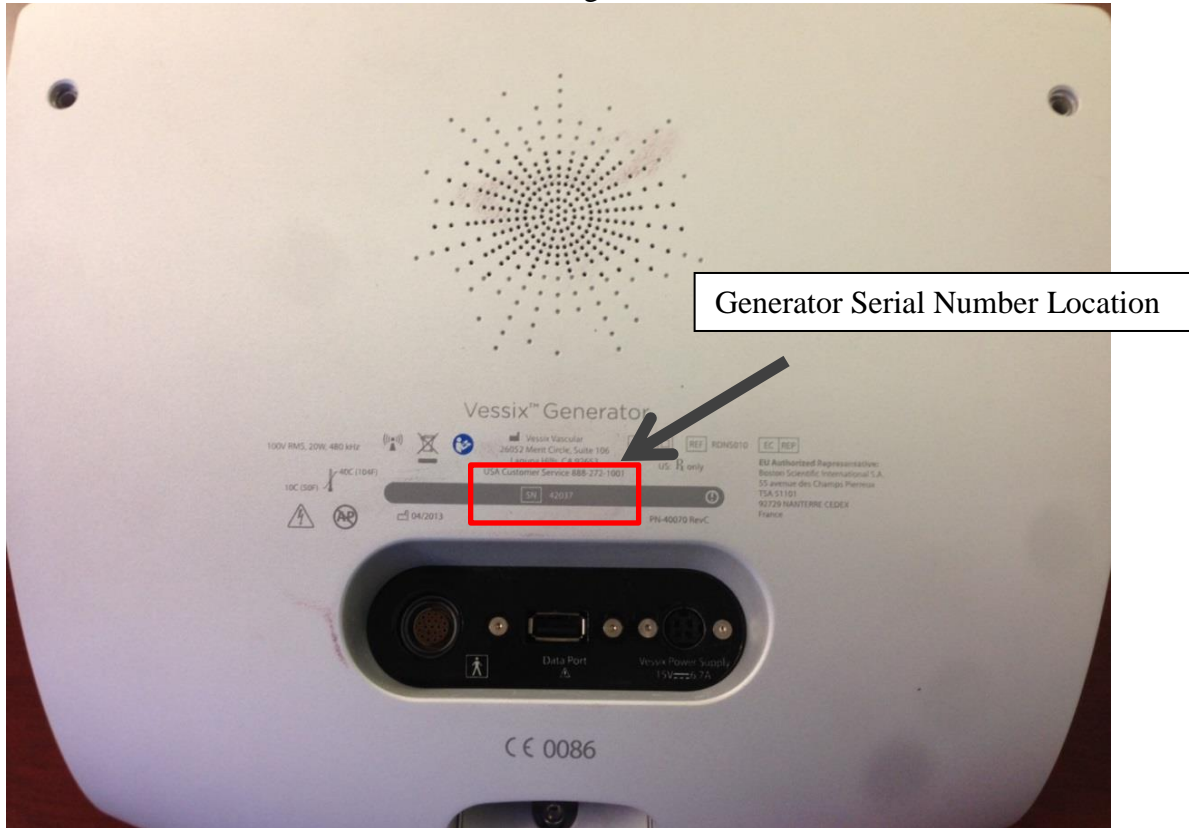
Our records indicate that your facility received some of the concerned product. **The table below provides a complete list of all affected products**, including Product Description, Material Number (UPN), Lot/Batch numbers. **Please note that only the material listed in the table below is affected. No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

Product Description	Material # (UPN)	Catalog #	Lot/Batch/Serial #			
Vessix™ Generator System	H749RDNS0100	RDNS010	42002	42003	42005	42006
			42015	42019	42027	42030
			42033	42038	42039	42043
			42045	42047	42059	42062
			42067	42068	42070	

**INSTRUCTIONS:**

1. **Please immediately discontinue use of the Boston Scientific product listed above and remove all of the affected units from your inventory. Segregate the units in a secure place, pending return to Boston Scientific.**

The serial number can be found on the bottom of the generator. See below.



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 **November xx, 2013.****
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).

You will receive replacements for all recalled product that is returned to Boston Scientific.

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.

Attachment: Verification Form