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Reference: 91004680-FA

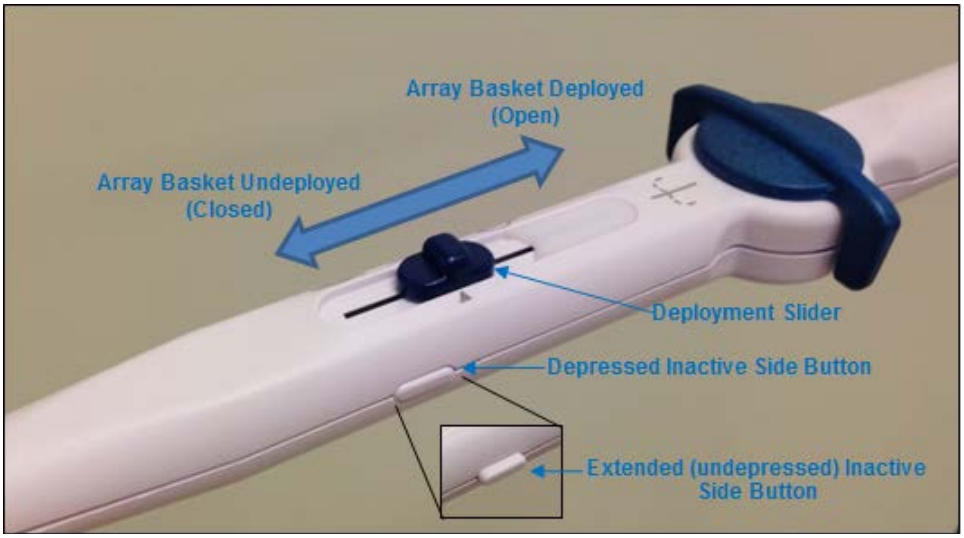
xx November 2014

Field Safety Notice - Important Medical Device Information
IntellaMap Orion™
High Resolution Mapping Catheter

Dear «Users_Name»,

Boston Scientific Corporation is initiating a Field Safety Corrective Action for Rhythmia Medical's IntellaMap Orion™ High Resolution Mapping Catheter. To date, Boston Scientific has received five complaints relating to difficulty deploying or undeploying the electrode array basket when the inactive side button on the catheter extends from its depressed state.

IntellaMap Orion™ High Resolution Mapping Catheter:



Observations to date from the five complaints have been limited to brief prolongation of the procedure. No patient harm has been encountered in connection with these events and all were corrected by pushing the side button back to the depressed position. The most serious *potential* patient risk is damage to cardiac structures or blood vessels if the button is not depressed and the catheter is extracted in the deployed state with the electrode array basket open.

It is very important that you read this entire Field Safety Notice and ensure that all users are aware of this notice. It provides users with additional steps required to mitigate risk in the event that the side button has become extended.

Mitigation Steps:

In accordance with the IntellaMap Orion™ High Resolution Mapping Catheter Directions For Use (DFU), always perform deployment and undeployment under fluoroscopy or other imaging techniques to ensure that the array basket does not generate excessive force on cardiac tissue or structures.

If the side button has become extended, push the side button so that it is flush with the handle casing, as shown in the image above. This will allow the array basket to be adjusted as normal by using the deployment slider. You may choose to remove the catheter from the patient when the array basket is undeployed (array basket closed position) and replace it with another catheter (ensuring its Inactive Side Button is depressed) to complete the procedure.

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

Product Description	Material Number (UPN)	Catalog Number	Lot	Expiration Date
IntellaMap Orion™ High Resolution Mapping Catheter	M004RC64S0	RC64S	17075550, 17075981, 17083913, 17088826, 17094081, 17101668, 17208445, 17218467, 17251661, 17258617, 17274937, 17292792, 17308586	June 25, 2015 to September 24, 2015

The affected IntellaMap Orion™ High Resolution Mapping Catheters are not being recalled and you are not required to return them to Boston Scientific.

INSTRUCTIONS:

1. **Please read carefully the Field Safety Notice letter and clearly post the information in a location near the affected product and/or take such other steps,** consistent with your internal policies and procedures**,** as may be necessary and appropriate, **to ensure that this important product information is easily accessible to all users of this product.**
2. **Please complete the attached Acknowledgement Form** even if you do not have any affected product.
3. **When completed, please fax the Acknowledgement Form to your local Boston Scientific office** to the attention of «Customer_Service_Fax_Number» on or before **xx December 2014.**
4. Please pass on 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,

Bernard Ismael
Quality Department
Boston Scientific International S.A.

Attachment: Acknowledgement Form