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

Reference: 91107242-FA
Additional Recommendation

xx December 2015

Urgent Update Field Safety Notice
Chariot™ Guiding Sheath

Dear «Users_Name»,

In the previous notification sent on DATE, Boston Scientific advised that it is recalling its Chariot™ Guiding Sheath. To date, Boston Scientific has received fourteen complaints for shaft separation, four of which involved separation of the distal shaft. These events occurred during device preparation or use.

Although our records indicate you have already responded to BSC's initial field action notification, we are contacting you to provide additional guidance and request acknowledgment of this communication:

Physicians are encouraged to contact all patients who have undergone procedures involving Chariot to confirm their post-procedure status, as device shaft separation and embolized fragments may not have been recognized at the time of the procedure. To date, no permanent impairments or patient deaths have been reported.

The most severe outcome of this failure is embolism of device fragments, which could lead to obstruction of blood flow or additional intervention to remove a device fragment. Obstruction of blood flow can result in injuries such as stroke, kidney damage or damage to the intestines or limbs.

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 below is affected. No other Boston Scientific product is involved by this Field Safety Notice**.

Product Description	Material Number (UPN)	Batch	Batch Expiration Date Range
Chariot™ Guiding Sheath	H74939277645110	See Attached Affected Product Listing	31 March 2016 - 30 November 2018
	H74939277690210		
	H74939277690220		
	H74939277845210		
	H74939277745210		
	H74939277645210		
	H74939277745110		
	H74939277665110		
	H74939277690110		
	H74939277765110		
	H74939277545110		
	H74939277690120		
	H74939277845110		
	H74939277790110		
	H74939277865110		
	H74939277545210		
	H74939277790220		
	H74939277665120		

	H74939277645220		
	H74939277645120		
	H74939277745120		
	H74939277790210		
	H74939277790120		
	H74939277890110		
	H74939277765120		
	H74939277865120		
	H74939277890120		
	H74939277845120		
	H74939277745220		

INSTRUCTIONS:

1- Please read this notice and the instructions attached to this letter.

2- **Please complete the attached Acknowledgement Form**, even if you have already responded to the first recall notification and returned any remaining recalled units.

3- **When completed, please return the Acknowledgement Form to your Boston Scientific office** to the attention of «Customer_Service_Fax_Number» on or before **DATE**.

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,

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

Attachments: - Acknowledgement Form
- Full affected Product listing