Boston Scientific International S.A.
ZAC Paris Nord II/Bât Emerson - 33 rue des Vanesses – 93420 Villepinte
Siège social : Parc du Val Saint Quentin – 2 rue René Caudron
78960 Voisins le Bretonneux – France

Tel 33 (0)1 48 17 47 00
Fax 33 (0)1 48 17 47 01
www.bostonscientific.com

«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 - Medical Device Removal
Chariot™ Guiding Sheath

Dear «Users_Name»,

Boston Scientific is voluntarily 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 separation, which occurred during device preparation or use. 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.

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.

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**.
Further distribution or use of any remaining product affected by this action should cease immediately.

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 immediately discontinue use of the Boston Scientific product reported in the list and remove all of the affected units from your inventory**, irregardless of where these units are stored in your facility. Segregate the units in a secure place, pending return to Boston Scientific.

2- **Please complete and return the attached Verification Form** even if you do not have any product to return **or have already returned the Verification Form for the first notification sent earlier this month.**

3- **When completed, please return the Verification Form to your local Boston Scientific office** to the attention of «Customer_Service_Fax_Number» on or before **XX December 2015**.

4- **If you have products to return,** please package them in an 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,

[redacted]

Please Complete the form even if you do not have any affected product & send it to Your Local Office:
«Customer_Service_Fax_Number»

«Sold_to» - «Hospital_Name» - «City» - «Country_Name»

UPDATE Verification Form – Urgent Medical Device Recall
"Name of the Product"

91107242-FA

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1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated «Date_notif_sent».

2. **Boston Scientific records indicate you have received the following affected product** *(additionally please check inventory against complete list of affected product provided)*

Product Description	**Material N° (UPN)**	**Lot / Batch N°**	**Customer PO**	**Qty Sent** (Units)	**Qty to return** (Units)
«DESCRIPTION»					

3. We confirm that all areas where affected product could be located have been checked.

4. **TICK ONE OF THESE STATEMENTS*****, **SIGN THIS FORM** and send it to «Customer_Service_Fax_Number»

   - ❑ We do not have any affected product.
   - ❑ We have found affected product(s): Please confirm the quantity to return above. *If you are returning product not listed above, please **add the UPN, Lot/Batch/Serial number and the quantity to return.***

By signing this form, you are also indicating you have received the updated field action notification sent in December 2015.

TO RETURN PRODUCTS:
1. Contact «Customer_Service_Tel» of your Local Office to arrange return of any affected product
2. Prepare the package
3. Follow the instructions given by your Local Office about collection of the package

NAME* _____Title _____

Telephone _____ Department _____

Customer' **SIGNATURE*** _____ **DATE*** _____
* Required field dd/mm/yyyy

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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
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	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,

[redacted]

Please complete the form & send it to Your Local Office:
«Customer_Service_Fax_Number»

«Sold_to» - «Hospital_Name» - «City» - «Country_name»

Acknowledgement Form – Important Medical Device Information

"Name of the Product"
91107242-FA

I acknowledge receipt of the Boston Scientific Field Safety Notice

dated «Date_notif_sent» for the

"Name of the Product"

and took action as required in the "Instructions" of the letter.

NAME*_____Title _____

Telephone _____ Department _____

Customer' **SIGNATURE***_____**DATE***_____
* Required field DD/MM/YYYY