

«Hospital_Name»

«Users_Name»

«Department»

«Customer_Address»

«Zip_Code» «City»

«Country_name»

<Reference: 96993356-FA>

24 March 2023

Cover letter for Distributor – Urgent Medical Device Recall INTELLANAV STABLEPOINT™ Ablation Catheter

Dear «Users_Name»,

Boston Scientific is conducting a Medical Device Removal of specific lots of the INTELLANAV STABLEPOINT Ablation Catheter. Please find more information in the attached Field Safety Notice.

You are kindly requested to follow the below instructions:

- 1- **Check your Inventory for the products affected by this Field safety Notice.**
- 2- **Please segregate and do not distribute any of the affected products found in your inventory.**
- 3- **Please notify all your customers that have received affected product of the below Field Safety Notice.** To effectively manage this Field Safety Notice, your accounts are to communicate directly with you, not Boston Scientific. If any of your customers are distributors, please notify them that they must communicate this Field Action to the medical facility level.
- 4- **Have all affected product returned to your facility** and held in quarantine for reconciliation.
- 5- **Please complete the attached Verification Form, even if you do not have any product to return.**
- 6- **When completed, please return the Verification Form to your local Boston Scientific office** for the attention of «Customer_Service_Fax_Number» on or before **19 April 2023.**
- 7- **If you have products to return, please package them in an appropriate shipping box. After receipt of the Verification Form, Boston Scientific will contact you to arrange return.**

Your Competent Authority is being notified of this Field Safety Notice, unless if per local regulation, this task is to be performed by you as a Distributor.

We regret any inconvenience that this action may cause, and we appreciate your understanding as we act 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.

Attachments: - Field Safety Notice
- Distributor Verification Form



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

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

Distributor's Verification Form – Urgent Medical Device Recall
INTELLANAV STABLEPOINT™ Ablation Catheter
96993356-FA

1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated 24 March 2023.

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

Material N° (UPN)	Lot / Batch N° / Serial N°	Customer PO	Qty Sent	Qty to return (Units)

3. We confirm that all areas where affected product could be located, **including at our customers' location**, 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**.*

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 _____ Email _____

Distributor' SIGNATURE* _____ DATE* _____

* Required field

dd/mm/yyyy