

«Hospital_Name»

«Users_Name»

«Department»

«Customer_Address»

«Zip_Code» «City»

«Country_name»

<Reference: 92680660-FA>

16 March 2021

Urgent Field Safety Notice - Urgent Medical Device Recall MAMBA™ 135 and MAMBA™ Flex 135 Microcatheters

Dear «Users_Name»,

Boston Scientific (BSC) is voluntarily initiating a removal of certain batches of MAMBA™ 135 and MAMBA™ Flex 135 Microcatheters due to incorrect labeling and packaging. BSC has received complaints that the MAMBA 135 Microcatheter (red strain relief) was found to have the label and packaging of the MAMBA Flex 135 Microcatheter (green strain relief) and vice versa. While these batches are incorrectly labeled and packaged, the microcatheters meet design specifications. To date there have been no reports of patient injury associated with this incorrect labeling and packaging issue.

This labeling and packaging issue is readily identifiable as the color coding on the box and on the catheter strain relief will not match. While not expected to occur, the most serious adverse health consequence would be procedure prolongation due to the difficulty to maneuver the microcatheter or inability to reach the desired/targeted anatomic locations. This could result in a necessity for a microcatheter exchange during the catheter preparation and/or during the procedure.

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), GTIN and Lot/Batch numbers and expiry date. Please note that **only the devices listed below are affected. No other Boston Scientific product is involved in 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	GTIN	Expiration Date
MAMBA™ Flex 135 CM US microcatheter	H7493928713540	26578463	8714729940289	4-Jan-23
MAMBA™ 135 CM US microcatheter	H7493928713500	26578155	8714729940241	4-Jan-23
MAMBA™ Flex 135 CM US microcatheter	H7493928713540	26578470	8714729940289	4-Jan-23
MAMBA™ 135 CM OUS microcatheter	H7493928713520	26578465	8714729940265	4-Jan-23

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**, regardless of where these units are stored in your facility. Segregate the units in a secure place, pending return to Boston Scientific.

2- **Please complete the attached Verification Form even if you do not have any product to return.**

3- **When completed, please return the Verification Form to your local Boston Scientific office** for the attention of «Customer_Service_Fax_Number» on or before **31 March 2021**.

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 from your organization that needs 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 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 Barlangua
Quality Department
Boston Scientific International S.A.

Attachment: Verification Form

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

Verification Form – Urgent Medical Device Recall
MAMBA™ 135 and MAMBA™ Flex 135 Microcatheters
92680660-FA

1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated 16 March 2021.
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 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 _____

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