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

<**Reference: 92589899-FA**> «Date_notif_sent»

Urgent Field Safety Notice - Urgent Medical Device Recall
AMS 700™ with MS Pump™

Dear «Users_Name»,

Boston Scientific is voluntarily implementing a product removal of unused inventory of the AMS 700 MS (Momentary Squeeze) Pump following an increase in complaints related to the initial activation of the device. An “initial activation” complaint refers to a problem encountered during the initial activation of the device, typically within the first 2 months after an AMS 700 implant procedure, in which the patient and/or physician is unable or has difficulty activating the pump in order to achieve cylinder inflation, even after exhaustive troubleshooting and patient training. An MS Pump that is found to activate and function properly during the initial post-operative user interactions is not impacted by the issue described in this removal. In other words, as described below, other pump activation concerns your patients may have encountered in the past, or may encounter in the future, that did not manifest in the first two months after implant are NOT related to this product removal.

If you are a short-term consignment (Loaner Kit) customer BSC controls all inventory through the loaner kit model and our records indicate you have no product to return. All impacted product in loaner kits has been placed on an internal hold and all loaner kit inventory currently in circulation is not impacted by this product removal.

Please review this important information and follow the instructions included.

Description and Clinical Implications

An internal investigation into an increasing rate of complaints observed in 2020 has estimated up to 2% of all MS Pumps are affected and at risk for initial activation issues. The root cause has been attributed to one mold cavity used in the production of the silicone MS Pump valve block component. Not all pumps manufactured through this cavity are susceptible to an initial activation failure, but a higher rate of complaints has been observed for pumps manufactured through this mold cavity.

The majority of pumps within the scope of this removal (> 98%) should exhibit normal performance with respect to initial activation. However, as the specific mold cavity cannot be determined based on MS Pump finished device serial number alone, Boston Scientific decided to broadly scope this voluntary product removal to capture all potentially impacted product.

All MS Pump valve blocks manufactured through this mold cavity are within dimensional specifications. However, minor dimensional differences in components manufactured through this cavity, combined with normal manufacturing variation and patient-related factors (including but not limited to dexterity, obesity, and anatomy), create the potential for an interference fit within the pump and could contribute to difficulty or inability to activate the implanted pump.

The most common and most severe health consequence that could result from the described pump failure would be a pump replacement procedure and the normal risks associated with anesthesia and surgery.

Recommendations regarding previously implanted devices

BSC recognizes that MS Pump inflation issues can occur throughout the lifetime of a device for a variety of reasons and it may be difficult to distinguish this problem from other pump inflation issues. The cause of initial activation failures associated with this removal is present in the device at the time of manufacture. If a Pump is found to activate and function properly during the initial post-operative patient interactions the pump is not impacted by the problem described in this letter.

If a pump is found not to operate as expected during the initial post-operative activations, particularly when attempted by the physician using standard troubleshooting techniques, the patient may have a device that is affected by this issue. Note that with any newly implanted AMS 700 device, patient education and training and physician troubleshooting are considered normal activities during the initial post-operative user interactions. If your patient encounters initial activation issues, the widely accepted troubleshooting steps should be employed.

If you suspect a patient has a device that is affected by this issue, it is recommended that you manage the patient as you would in the normal course of clinical practice, but with this notification in mind. There is no need to remove normally functioning devices. Your BSC representative is available to evaluate the situation and help support your patient’s continued health and safety.

Next Steps

This action affects the UPN and serial numbers listed in your reply verification tracking form which we have record of sending to your facility. Complete the enclosed reply verification form with the affected devices requiring return to Boston Scientific.

For short-term consignment (Loaner Kit) customers, BSC controls all inventory through the loaner kit model and our records indicate you have no product to return. However, the attached reply verification tracking form includes a list of the specific serial numbers that have been shipped to your facility. Complete the enclosed reply verification form confirming you are aware of this action and have no product to return.

If you are a facility that has sent products to another hospital within your network, please ensure that this notification is forwarded to them. If you are aware that a patient receiving one of these devices is followed by another physician/hospital, please ensure this notification is forwarded to them.

Our records indicate that your facility received some of the concerned product. The **Attachment 1 below provides a complete list of all affected products**, including Material Number (UPN), GTIN and Serial numbers. 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.

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 **30 October 2020**.

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 healthcare 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. We are committed to continuing to offer products that meet the highest quality standards that you expect from Boston Scientific.

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

Attachment 1 : Affected Product Listing

Expiration Date Range: August 26, 2020 through March 18, 2025

Only a subset of serial numbers are associated with this removal activity. To determine if a UPN/serial number is impacted, visit: www.bostonscientific.com/lookup

Material Number (UPN) and GTIN	Material Number (UPN) and GTIN
72404209, 00878953003351	72404280, 00878953003832
72404230, 00878953003436	72404281, 00878953003849
72404231, 00878953003443	72404282, 00878953003856
72404232, 00878953003450	72404283, 00878953003863
72404233, 00878953003467	72404284, 00878953003870
72404234, 00878953003474	72404285, 00878953003887
72404235, 00878953003481	72404286, 00878953003894
72404236, 00878953003498	72404287, 00878953003900
72404237, 00878953003504	72404288, 00878953003917
72404238, 00878953003511	72404289, 00878953003924
72404239, 00878953003528	72404300, 00878953005713
72404250, 00878953003580	72404301, 00878953005720
72404251, 00878953003597	72404302, 00878953005737
72404252, 00878953003603	72404303, 00878953005744
72404253, 00878953003610	72404305, 00878953005751
72404255, 00878953003634	72404306, 00878953005768
72404256, 00878953003641	72404307, 00878953005775
72404257, 00878953003658	72404308, 00878953005782
72404258, 00878953003665	72404310, 00878953003986
72404260, 00878953003689	72404232-10, 00878953009780
72404261, 00878953003696	72404233-12, 00878953009797
72404262, 00878953003702	72404234-14, 00878953009803
72404263, 00878953003719	72404252-10, 00878953009810
72404264, 00878953003726	72404253-12, 00878953009827
72404265, 00878953003733	72404282-10, 00878953009834
72404266, 00878953003740	72404283-12, 00878953009841
72404267, 00878953003757	72404284-14, 00878953009858
72404268, 00878953003764	72404302-10, 00878953009865
72404269, 00878953003771	72404303-12, 00878953009872

«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»

Verification Form – Urgent Medical Device Recall
"Name of the Product"
92589899-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)*

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

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