Boston Scientific

**Urgent Medical Device Removal - Immediate Action Required**

**AMS 700™ with MS Pump™**

September 24, 2020

Dear Physician:

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 distributor, please note that this communication is to the hospital level and this notification should be forwarded to your customers. 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.

Boston Scientific is notifying regulatory authorities of this action as required.

Please read carefully through the enclosed instructions. Your local Sales Representative can answer any questions that you may have regarding this action.

Sincerely,

Encl: Instructions, Reply Form

Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to Boston Scientific by calling 1-866-868-4004 and to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.

Online: www.fda.gov/MedWatch/report.htm
Regular Mail: use postage-paid FDA form 3500 available at www.fda.gov/MedWatch/getforms.htm and mail to MedWatch, 5600 Fishers Lane, Rockville, MD, 20852-9787
Fax: (800) FDA-0178
Phone: (800) FDA-1088

# Table 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 |

## Removal Instructions

The Form enclosed with this Notice must be completed and returned **even if you do not have any of the units remaining of the recalled serial numbers or store inventory on your shelves**.

1. **If you have affected inventory, immediately discontinue use of and segregate recalled product**.
   - Immediately remove all affected recalled product from your inventory.
   - Segregate this product in a secure location for return to BSC.

2. **Complete and email or fax your form immediately.**

3. **If you have affected inventory, you will receive an RGA # after you email/fax your form. Please wait to return any product until you receive the RGA #.**
   - Indicate on your RVTF the quantity of units from each serial number that you will be returning.
   - Return the RVTF as described below:

     **Email: BSCFieldActionCenter@bsci.com**
     or
     **Fax to: Field Action Center 1-866-213-1806**

**You will be contacted by BSC and provided a Returned Goods Authorization (RGA) Number within 24-48 hours after your RVTF is received**

4. **Package/Ship the Recalled Product.**
   - Package any product that is being returned in an appropriate shipping box.
   - Affix the enclosed (red/white) shipping label to the outside of the shipping box.
   - Write the **RGA number** in large print on the outside of the box, on the shipping label.
   - Feel free to use our Federal Express Number 920525156 to return this package via second day delivery.
   - Seal the box, and return to: **Boston Scientific Corporation**
     **US Distribution Center**
     **Boston Scientific Marina Bay**
     **Customer Fulfillment Center**
     **500 Commander Shea Blvd.**
     **Quincy, Massachusetts 02171**
     **RGA: _____**