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

<**Reference: 97273653-FA**> 28 October 2024

# Urgent Field Safety Notice - Urgent Medical Device Recall
# AMS 800™ Artificial Urinary Sphincter

Dear «Users_Name»,

Boston Scientific is initiating a removal of specific lots of the AMS 800™ Artificial Urinary Sphincter devices, detailed in below table, which may be labeled incorrectly. We have received a report of one (1) device labeled as a Pressure Regulating Balloon (UPN 72400024) which instead contained a Control Pump (UPN 72400098).

The most common outcome reasonably foreseeable as a result of a mislabeled package is a negligible prolongation of procedure while a backup device is retrieved. The most serious reasonably foreseeable outcome of this issue is an inability to complete the procedure if, after the patient is sedated, a backup device is not available, potentially requiring the patient to return at a later time to be re-sedated to complete 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, Lot/Batch/Serial numbers** and expiration 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 | UPN | GTIN | Lot/Batch/Serial # | | | Expiration Date |
|---|---|---|---|---|---|---|
| AMS™ Artificial Urinary Sphincter *Pressure Regulating Balloon* | 72400024 | 00878953000626 | 1100366088 | 1100366106 | 1100366145 | 23 September 2028 |
| | | | 1100366089 | 1100366107 | 1100366146 | |
| | | | 1100366090 | 1100366108 | 1100366147 | |
| | | | 1100366091 | 1100366109 | 1100366148 | |
| | | | 1100366092 | 1100366110 | 1100366149 | |
| | | | 1100366093 | 1100366111 | 1100366150 | |
| | | | 1100366094 | 1100366112 | 1100366151 | |
| | | | 1100366095 | 1100366113 | 1100366152 | |
| | | | 1100366096 | 1100366115 | 1100366153 | |
| | | | 1100366097 | 1100366116 | 1100366154 | |
| | | | 1100366098 | 1100366117 | 1100366155 | |
| | | | 1100366099 | 1100366118 | 1100366156 | |
| | | | 1100366100 | 1100366119 | 1100366157 | |
| | | | 1100366101 | 1100366120 | 1100366158 | |
| | | | 1100366102 | 1100366121 | 1100366159 | |
| | | | 1100366103 | 1100366122 | 1100366160 | |
| | | | 1100366104 | 1100366123 | 1100366114 | |
| | | | 1100366105 | 1100366144 | | |
| AMS™ Artificial Urinary Sphincter *Control Pump* | 72400098 | 00878953000688 | 1100366307 | 1100366314 | 1100366321 | 24 September 2028 |
| | | | 1100366309 | 1100366315 | 1100366323 | |
| | | | 1100366310 | 1100366316 | 1100366324 | |
| | | | 1100366311 | 1100366317 | 1100366325 | |
| | | | 1100366312 | 1100366319 | | |
| | | | 1100366313 | 1100366320 | | |

**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 **15 November 2024**.

4- **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.**

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.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,

[redacted]

Marie Pierre Barlangua
Quality Department
Boston Scientific International S.A.

Attachment: 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»**

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## Verification Form – Urgent Medical Device Recall
## AMS 800™ Artificial Urinary Sphincter
**97273653-FA**

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1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated 28 October 2024.

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 / 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. After receipt of the Verification Form, Boston Scientific will contact you to arrange return.
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