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

<Reference: 92677024-FA> 25 March 2021

Urgent Field Safety Notice - Urgent Medical Device Recall
AMS 700™
Spherical and Conceal Reservoir with InhibiZone™

Dear «Users_Name»,

Boston Scientific (BSC) is voluntarily implementing a medical device removal of certain serial numbers of AMS 700 Reservoirs which may have been incorrectly labeled. Specifically, AMS 700 IZ 100 ml Conceal Reservoirs labeled as Spherical Reservoirs and AMS 700 IZ 100 ml Spherical Reservoirs labeled as Conceal Reservoirs. To date, BSC has received one complaint associated with this incorrect labeling, and there have been no reports of patient injury.

Description of Clinical Implications
The most common potential health consequence of this issue would be a negligible delay in procedure to exchange the Conceal Reservoir for a Spherical Reservoir, or vice versa. Exchange of the device would not result in an adverse consequence to the patient. As both the 100 ml IZ Conceal Reservoirs and the 100 ml IZ Spherical Reservoirs provide sufficient fluid volume to fill all cylinder configurations and sizes, the physician may also elect to implant the reservoir despite the incorrect labeling. The most serious potential health consequence would be a moderate prolongation in the procedure and associated anesthesia if a physician chooses to exchange the Conceal Reservoir for a Spherical Reservoir, or vice versa, and the replacement device is not readily available. To date, no adverse events or prolongation of procedures as a result of incorrectly labelled reservoirs have been reported.

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

- **To be taken if any Serial Number device(s) have been implanted:**

1- **Add this notice to the patient record**
This notification provides notice for the patient record and to appropriately document the product that was implanted.

- **To be taken for all affected serial number(s) within your inventory:**

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 **9 April 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,

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Quality Department
Boston Scientific International S.A.

Attachment: Verification Form

<u>Attachment 1</u> – Product Listing

Product Description	Material Number (UPN)	Serial #	GTIN
AMS 700 Conceal Reservoir with InhibiZone (100 ml)	**720185-01**	1000468984	00878953005669
		1000468985	00878953005669
		1000468986	00878953005669
		1000468987	00878953005669
		1000468988	00878953005669
		1000468989	00878953005669
		1000468991	00878953005669
		1000468992	00878953005669
		1000468993	00878953005669
		1000468994	00878953005669
		1000468995	00878953005669
		1000468996	00878953005669
		1000468997	00878953005669
		1000468998	00878953005669
		1000468999	00878953005669
		1000469000	00878953005669
		1000469001	00878953005669
AMS 700 Spherical Reservoir with InhibiZone (100 ml)	**72404156**	1000469415	00878953003214
		1000469416	00878953003214
		1000469419	00878953003214
		1000469420	00878953003214
		1000469423	00878953003214
		1000469429	00878953003214

«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
AMS 700™ *Spherical and Conceal Reservoir with InhibiZone™*
92677024-FA

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1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated 25 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