

«Hospital\_Name»

«Users\_Name»

«Department»

«Customer\_Address»

«Zip\_Code» «City»

«Country\_name»

<Reference: 97005302-FA>

5 April 2023

## Urgent Field Safety Notice - Urgent Medical Device Recall WATCHDOG™ Hemostasis Valve Kit

Dear «Users\_Name»,

Boston Scientific is initiating a removal of specific batches of the WATCHDOG™ Hemostasis Valve Kit due to complaints of the Insertion Tool component being occluded, resulting in the inability to pass a guidewire through the tool. Our investigation has concluded that the occlusion was generated by a variation in the manufacturing process of the affected batches, which has been resolved.

The most serious adverse health consequence resulting from the occlusion of the insertion tool is a limited procedure prolongation to exchange the insertion tool or guidewire. To date, the most common outcome is no adverse health consequence.

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 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.**

**PLEASE NOTE:** We are aware that hospitals often remove products from the outer carton and store on the shelves in the inner-pouch only. If this is a practice at your facility, **it is very important that you carefully use the product table and consider both the inner and outer packaging UPN codes when searching for affected product, as the UPN numbers on the inner and outer labelling may be different. The product information listed on your specific Verification Form (enclosed with this letter) provides outer package product coding only and should be utilized when reporting product to return.**

Verify by product batch/lot number in the product table to determine if the batch within your inventory is affected. If so, indicate on your Verification Form the quantity of units from each batch that you will be returning. **As the product within these batches are sold as 5-packs and 20-packs, it is important that all reported quantities represent the actual number of single unit being returned and not the number of cartons/boxes or multi-packs.**

Product Description	Outer Package UPN #	Inner Package UPN #	GTIN	Batch #	Expiration Date
WATCHDOG™ ACCESSORY KIT (20-PACK)	H74939343A021	H74939343A020	08714729965770	30319836,30359588,30368418, 30392647,30409465,30421836, 30442123,30522919,30564343, 30577971,30593836,30600837, 30600839,30601021,30616553, 30620297,30625219,30638465, 30638467,30638469,30638471, 30665570,30666996,30681966, 30681968,30681970,30712588, 30725194,30780665,30801487, 30801489,30801491,30811488, 30845828,30845830,30845832, 30885087,30890263,30890265, 30914070,30922072,30929565, 30935495,30935497,30935499, 30981820,	3-Oct-24 through 2-Feb-25
WATCHDOG™ HEMOSTASIS VALVE KIT (5- PACK)	H74939343A022	H74939343A020	08714729996019	30272850,30542947,30661041, 30845826, 30935565	3-Oct-24 through 26-Jan-25

## **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 **28 April 2023**.

**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,



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  
WATCHDOG™ Hemostasis Valve Kit  
97005302-FA**

1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated 5 April 2023.
2. **Boston Scientific records indicate you have received the following affected product** (*additionally please check inventory against complete list of affected product provided*)

**/!\ REPORT QUANTITY IN SINGLE UNITS AND NOT IN CARTON/BOX/MULTIPACK (IF APPLICABLE)**

Material N° (UPN)	Lot / Batch N°	Customer PO	Qty Sent (Box)	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. 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