Boston Scientific

Urgent Medical Device Removal - Immediate Action Required

Zurpaz™ Steerable Sheath
8.5F Asymmetric and Symmetric Curve

XXX XX, 2017

Dear Materials Manager/ Field Action Contact:

Boston Scientific, a distributor of the Zurpaz™ Steerable Sheath, is initiating a voluntary removal of certain lots of the product. Boston Scientific became aware from the manufacturer, Creganna Medical also doing business as Creganna Tactx Medical, that a blister near the pouch seal may result in a compromised sterile barrier.

Pouch blistering might not be obvious to the user. If it is identified, the device can be readily exchanged resulting in an insignificant prolongation in procedure. If the sterile barrier was compromised and the device was used, the most severe expected harm is a potential infection; however no reports of patient harm have been received.

See below table for affected Material/Lot information; this removal does not include any product other than what is listed below. **Further distribution or use of the affected product listed below should cease immediately**.

Affected Product Listing

Product Description	Material Number (UPN) #	Lot/Batch #	Expiration Date
Zurpaz™ Steerable Sheath	M004EPTMCA85400 8.5F Asymmetric Curve (CE Model)	363848	5-Dec-2018
	M004EPTMC85300 8.5F Symmetric Curve (CE Model)	384797	12-Jan-2019
	M004USMCA85200 8.5F Asymmetric Curve (US Model)	364951	13-Dec-2018
	M004USMC85100 8.5F Symmetric Curve (US Model)	383271	3-Jan-2019

If you identify any product from the affected lots within your inventory, please segregate the product immediately and return it to Boston Scientific in accordance with the enclosed instructions. **If you are a distributor, please note that the removal is to the hospital level and this notification should be forwarded to your customers.**

Affected worldwide regulatory authorities are being notified of this action.

Please read carefully through the removal instructions included with this notification. Your local Sales Representative can answer any questions that you may have regarding this notification.

We regret any inconvenience that this action may cause, and we appreciate your understanding as we take action 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.

Sincerely,

Encl: Removal Instructions
Reply Verification Tracking Form
Field Action Return Shipping Label

Removal Instructions

The Reply Verification Tracking Form enclosed with this letter must be completed and returned **even if you do not have any remaining units from the recalled batch**.

- **Immediately discontinue use of and segregate affected product**.
  - Immediately remove all affected product from your inventory.
  - Segregate this product in a secure location for return to Boston Scientific.
- **Complete and return the Reply Verification Tracking Form.**
  - Complete the enclosed Reply Verification Tracking Form (even if you do not have any product to return), following the directions on this page and the Reply Verification Tracking Form.
  - Return the Reply Verification Tracking Form as described below:

    Email:
    or
    Fax to:

    Please email or fax your Account Reply Verification Tracking Form(s) immediately. You will be contacted by Boston Scientific and provided a Returned Goods Authorization (RGA) Number after your RVTF is received. When returning the product, place the original form with returned products.

    Replacements will be issued for all recalled product that is properly returned to Boston Scientific.

- **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.
  - Seal the box, and return to: