

«Hospital_Name»

«Users_Name» - «Department»

«Customer_Address»

«Zip_Code» «City» - «Country_name»

Reference: 92107437-FA

xx May 2017

Field Safety Notice - Urgent Medical Device Recall Zurpaz™ Steerable Sheath 8.5F Asymmetric and Symmetric Curve

Dear «Users_Name»,

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.

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) and Lot numbers. 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 affected product should cease immediately.**

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

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 **xx June 2017**.
- 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 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