

Boston Scientific International S.A.

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

Reference: 92338453-FA

31 December 2018

Field Safety Notice Urgent Medical Device Recall **Flexima™ Duodenal Bend Biliary Stent with Delivery System**

Dear «Users_Name»,

Boston Scientific Corporation is conducting a Medical Device Recall of the Flexima Biliary Stent System. Boston Scientific has determined through internal inspection, for affected products, the sterile barrier may contain seal defects. The breach of sterility could lead to a device being non-sterile. Boston Scientific is not aware of any patient complications resulting from this issue.

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/Batch numbers and expiry 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	Material Number (UPN)	Lot/Batch Number	GTIN	Expiry date
Flexima™ Duodenal Bend Biliary Stent with Delivery System	M00539220	22960202	08714729162537	18 November 2021
	M00539210	22960201	08714729162520	

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 **18 January 2019**.
- 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 Barlanga
Quality Department
Boston Scientific International S.A.

Attachment: Verification Form