

Boston Scientific International S.A.

ZAC Paris Nord II/Bât Emerson - 33 rue des Vanesses – 93420 Villepinte

Siège social : Parc du Val Saint Quentin – 2 rue René Caudron

78960 Voisins le Bretonneux – France

Tel 33 (0)1 48 17 47 00

Fax 33 (0)1 48 17 47 01

www.bostonscientific.com

«Hospital_Name»

«Users_Name»- «Department»

«Customer_Address»

«Zip_Code» «City» - «Country_name»

Reference: 92336940-FA

xx January 2019

Field Safety Notice Urgent Medical Device Recall Agile™ Biliary RX Fully Covered Stent System

Dear «Users_Name»,

Boston Scientific is conducting a medical device recall of the Agile Biliary RX Fully Covered Stent System. We have become aware of situations where the stent has migrated requiring additional intervention and re-stenting due to lack of stricture resolution. We do not recommend removal of already implanted devices which are performing adequately. Please continue to monitor your patients according to standard care. **Based on the higher than anticipated incidence of stent migrations, we are withdrawing the Agile Biliary RX Fully Covered Stent System from the market.**

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 and Lot/Batch 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 product affected by this action should cease immediately.

Product Description	Material Number (UPN)	GTIN	Batch number
Agile™ Biliary RX Fully Covered Stent	M00586000	08714729950202	All
	M00586010	08714729950219	
	M00586020	08714729950226	
	M00586060	08714729950264	
	M00586070	08714729950271	
	M00586080	08714729950288	

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 February 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 Barlangua
Quality Department
Boston Scientific International S.A.

Attachment: Verification Form