

«Hospital_Name»

«Users_Name»

«Department»

«Customer_Address»

«Zip_Code» «City»

«Country_name»

<Reference: 92583333-FA>

«Date_notif_sent»

Urgent Field Safety Notice - Urgent Medical Device Recall Hurricane™ RX Biliary Balloon Dilatation Catheter

Dear «Users_Name»,

Boston Scientific Corporation (BSC) is initiating a removal of specific lots/batches of Hurricane™ RX Biliary Balloon Dilatation Catheters in response to an increase in complaints of the RX tunnel component (black sheath) detaching from the catheter shaft. Investigation has shown this is due to a lower bond strength of the tunnel component which may lead to detachment.

The most common potential consequences related to a detached RX tunnel component would be a prolonged procedure duration while the device is exchanged. The most severe potential injury would include hemorrhage and/or tissue damage/perforation to the common bile duct during the retrieval of a detached RX tunnel component. There have been no patient harms reported to date related to this issue.

Our records indicate that your facility received some of the concerned product. **The Attachment 1 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.

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 **16 October 2020**.

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. We are committed to continuing to offer products that meet the highest quality standards that you expect from Boston Scientific.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,



Attachment: Verification Form

Boston Scientific International S.A.

Attachment 1 : Affected Product Listing

Product Description	UPN #	GTIN	Lot/Batch #	Expiration Date Range
HURRICANE Rx DILATION BALLOON 4MM 2CM	M00545890	08714729283805	25509445, 25536219, 25612668, 25649812, 25704208	4/13/2022 through 6/13/2022
HURRICANE Rx DILATION BALLOON 4MM 4CM	M00545900	08714729283812	25326198, 25344165, 25344168, 25366542, 25366543, 25379240, 25379241, 25392546, 25447687, 25447688, 25447689, 25447690, 25447691, 25447692, 25453103, 25453105, 25453108, 25466435, 25468596, 25468597, 25471588, 25479171, 25479176, 25479177, 25479178, 25479521, 25481983, 25481984, 25481985, 25481986, 25497466, 25497467, 25497468, 25506678, 25509440, 25509446, 25509447, 25509450, 25518274, 25518305, 25518314, 25533944, 25536416, 25536680, 25536860, 25543967, 25543969, 25571363, 25575934, 25575935, 25576717, 25576718, 25576719, 25576720, 25576721, 25576769, 25611564, 25612669, 25612670, 25612671, 25612673, 25612674, 25623377, 25623378, 25623379, 25623380, 25623381, 25623382, 25623383, 25623384, 25640115, 25649813, 25649816, 25678821, 25678826, 25678831, 25678836, 25680096, 25704209, 25704210, 25704211, 25704212, 25704213, 25704214, 25704215, 25704216, 25739146, 25739147, 25739149, 25739150, 25771761, 25771762, 25771765	2/7/2022 through 6/27/2022
HURRICANE Rx DILATION BALLOON 6MM 2CM	M00545910	08714729283829	25456946, 25497472, 25571369, 25623385, 25678822, 25739151	3/22/2022 through 6/20/2022
HURRICANE Rx DILATION BALLOON 6MM 4CM	M00545920	08714729283836	25305803, 25326193, 25326194, 25326195, 25326199, 25334817, 25334818, 25366544, 25366545, 25366546, 25366547, 25392549, 25392551, 25392553, 25392554, 25392555, 25397943, 25397944, 25447697, 25447698, 25453106, 25453109, 25461680, 25466436, 25468598, 25472425, 25475235, 25475236, 25479172, 25479173, 25479179, 25481987, 25481988, 25481989, 25481990, 25481991, 25497469, 25497470, 25497473, 25497474, 25497475, 25509412, 25509413, 25509414, 25509451, 25509452, 25509453, 25518276, 25518306, 25518307, 25518315, 25518316, 25536681, 25536739, 25536740, 25543970, 25543971, 25543972, 25543973, 25571370, 25571373, 25576770, 25576771, 25576772, 25576773, 25576881, 25576882, 25576883, 25576884, 25576885, 25608762, 25623386, 25623387, 25623388, 25623389, 25623390, 25623391, 25623392, 25623393, 25623394, 25623395, 25623396, 25623397, 25623398, 25649814, 25649817, 25649820, 25649821, 25649825, 25649826, 25649830, 25649831, 25678823, 25678827, 25678832, 25678837, 25680097, 25704217, 25704218, 25704219, 25704220, 25704221, 25704222, 25704223, 25739152, 25739153, 25739154, 25739155, 25739157, 25739158, 25771773	2/2/2022 through 6/27/2022
HURRICANE Rx DILATION BALLOON 8MM 2CM	M00545930	08714729283843	25509441, 25536741, 25644951, 25649190, 25650286, 25651334, 25654287	4/13/2022 through 5/31/2022
HURRICANE Rx DILATION BALLOON 8MM 4CM	M00545940	08714729283850	25317077, 25326196, 25326220, 25326221, 25326222, 25334819, 25344169, 25366548, 25366549, 25392556, 25392557, 25397079, 25447693, 25447694, 25453104, 25453107, 25453110, 25466437, 25468599, 25471589, 25471590, 25475234, 25479174, 25479175, 25479520, 25479580, 25481992, 25497051, 25497052, 25502738, 25509415, 25509416, 25509417, 25509418, 25509419, 25509442, 25509448, 25509454, 25509546, 25518277, 25518278, 25518317, 25518318, 25536682, 25536742, 25536743, 25543975, 25543976, 25543977, 25543978, 25543979, 25544020, 25571371, 25571374, 25596599, 25602458, 25608760, 25612672, 25649815, 25649818, 25649822, 25649823, 25649827, 25649828, 25649832, 25649833, 25678824, 25678828, 25678829, 25678833, 25678834, 25678838, 25680098, 25680099, 25704224, 25704225, 25704226, 25704227, 25704228, 25704229, 25739159, 25739160, 25739161, 25739162, 25739163, 25739164, 25739165, 25739166, 25739167, 25739168, 25788242, 25789369, 25789801	2/4/2022 through 6/30/2022
HURRICANE Rx DILATION BALLOON 10MM 2CM	M00545950	08714729283867	25471587, 25571372, 25588303, 25673064	3/28/2022 through 6/6/2022
HURRICANE Rx DILATION BALLOON 10MM 4CM	M00545960	08714729283874	25334980, 25344170, 25344171, 25366550, 25378999, 25397945, 25397950, 25447685, 25447695, 25447696, 25461681, 25464817, 25466438, 25471591, 25471592, 25484487, 25493901, 25497471, 25497476, 25509443, 25509444, 25509449, 25518279, 25518308, 25518309, 25536683, 25544022, 25544023, 25544024, 25544025, 25571375, 25602323, 25608761, 25640116, 25640117, 25644834, 25649819, 25649824, 25649829, 25649834, 25678825, 25678830, 25678835, 25678839, 25678880, 25680560, 25704230, 25704231, 25704232, 25739169, 25739170	2/8/2022 through 6/20/2022

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

"Name of the Product"

92583333-FA

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

Material N° (UPN)	Lot / Batch N°	Customer PO	Qty Sent	Qty to return

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. Contact «Customer_Service_Tel» of your Local Office to arrange return of any affected product
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