

<Reference: 92762451-FA>

21 October 2021

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

Dear Sir or Madam,

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 reported for pinholes in the balloon. The user may notice that the balloon either rapidly loses pressure or fails to gain or maintain pressure. To date, there have been no serious patient injuries reported.

The most common potential consequence as well as the most serious potential consequence that is reasonably foreseeable to occur is a prolonged procedure while the device is exchanged. If a prolonged procedure were to occur it is not anticipated to result in a clinically significant delay in the procedure.

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), GTIN 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 CustomerService.Czech@bsci.com - Fax: 296 331 934 on or before **19 November 2021**.

4- If you have products to return, please package them in an appropriate shipping box and **contact +420 296 331 900 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,



Marie Pierre Barlanga
Quality Department
Boston Scientific International S.A.

Attachment: Verification Form

Attachment 1 : Affected Product Listing

Product Description	UPN # / Batches	GTIN	Expiration Date Range
HURRICANE RX DILATION BALLOON 4MM 2CM	M00545890	08714729283805	19/05/2022 to 13/05/2023
M00545890 Batches	25612668, 25649812, 25704208, 25771760, 25878552, 26000695, 26010387, 26058284, 26087172, 26087173, 26123181, 26324742, 26366746, 26406513, 26429808, 26499853, 26527374, 26573853, 26638827, 26651718, 26665448, 26893604, 27026984, 27074109, 27145234, 27162321, 27255235, 27306699		
HURRICANE RX DILATION BALLOON 4MM 4CM	M00545900	08714729283812	10/05/2022 to 31/05/2023
M00545900 Batches	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, 25771763, 25771764, 25771765, 25771766, 25771767, 25771768, 25771769, 25771770, 25771771, 25836081, 25836082, 25878553, 25878554, 25878555, 25894783, 25916270, 25916271, 25916445, 25916446, 25940122, 25940123, 25947675, 25947677, 25947678, 25947900, 25947902, 25947904, 25947905, 25975766, 25975767, 25975768, 25975769, 25975770, 25975771, 25975772, 25975773, 26000472, 26000473, 26000474, 26000475, 26000696, 26000697, 26000698, 26000699, 26010388, 26010389, 26010390, 26010391, 26058285, 26058286, 26087174, 26087175, 26087176, 26087177, 26087178, 26087179, 26087720, 26087721, 26087722, 26087723, 26087724, 26087725, 26087726, 26087727, 26087728, 26087729, 26087730, 26087731, 26087732, 26123182, 26123183, 26123184, 26123185, 26123244, 26123245, 26123246, 26175465, 26175466, 26175467, 26175468, 26207974, 26207975, 26207976, 26207977, 26207978, 26207979, 26207980, 26207981, 26207982, 26238131, 26240367, 26247246, 26247247, 26283625, 26283626, 26283627, 26283628, 26283629, 26283630, 26283631, 26324745, 26324747, 26344528, 26344529, 26348351, 26356445, 26366747, 26366748, 26366749, 26366750, 26366751, 26366752, 26406514, 26406515, 26406516, 26406517, 26406518, 26406519, 26406520, 26429809, 26435534, 26435535, 26435536, 26444430, 26447362, 26447363, 26449367, 26456914, 26456915, 26473765, 26473766, 26473767, 26473768, 26495948, 26499146, 26501878, 26511846, 26512444, 26512445, 26512446, 26512447, 26512448, 26512449, 26512450, 26512451, 26540309, 26556786, 26556787, 26559139, 26559540, 26559541, 26559546, 26559547, 26581401, 26581402, 26581403, 26581404, 26581405, 26582100, 26582101, 26582102, 26588068, 26588069, 26588070, 26588071, 26628440, 26628441, 26628442, 26638828, 26638829,		

Product Description	UPN # / Batches	GTIN	Expiration Date Range
HURRICANE RX DILATION BALLOON 4MM 4CM	M00545900 <i>(Continued)</i>	08714729283812	10/05/2022 to 31/05/2023
M00545900 Batches <i>(Continued)</i>	26651717, 26660956, 26665449, 26665450, 26665458, 26665560, 26677021, 26685872, 26685873, 26685874, 26699186, 26699187, 26699188, 26699189, 26699190, 26699191, 26728358, 26728359, 26728780, 26728781, 26769421, 26778891, 26778892, 26778893, 26792383, 26792384, 26792386, 26793780, 26793781, 26808194, 26808195, 26808196, 26818638, 26818639, 26818880, 26818881, 26848716, 26848717, 26848718, 26848719, 26872354, 26872355, 26872356, 26872357, 26872358, 26906626, 26906627, 26906628, 26906629, 26906630, 26906631, 26919043, 26919044, 26919045, 26919046, 26919047, 26940194, 26956470, 26956471, 26956472, 26956473, 26956474, 26956475, 26956476, 26956477, 26956478, 26956479, 27008818, 27008819, 27025671, 27027293, 27027294, 27027295, 27027296, 27027297, 27027298, 27027299, 27065828, 27065829, 27074111, 27074112, 27100015, 27100016, 27110095, 27121580, 27121581, 27121622, 27121623, 27121624, 27162322, 27162323, 27162324, 27162325, 27182893, 27182894, 27182895, 27183306, 27183307, 27183308, 27203712, 27203713, 27203714, 27203715, 27203716, 27203717, 27203718, 27203719, 27203760, 27203761, 27203762, 27203763, 27203764, 27203765, 27203766, 27203767, 27255211, 27255212, 27255213, 27255214, 27265231, 27269950, 27269951, 27269953, 27269954, 27269955, 27308420, 27308421, 27335099, 27335460, 27340626, 27340636, 27340637, 27347590, 27347591, 27384704, 27393782, 27408924		
HURRICANE RX DILATION BALLOON 6MM 2CM	M00545910	08714729283829	23/05/2022 to 28/05/2023
M00545910 Batches	25623385, 25678822, 25739151, 25771772, 25975774, 26010392, 26051928, 26087733, 26123186, 26175469, 26406521, 26429810, 26456904, 26579839, 26581406, 26601326, 26660957, 26793786, 26896864, 27026985, 27096335, 27226570, 27255234, 27400203		
HURRICANE RX DILATION BALLOON 6MM 4CM	M00545920	08714729283836	10/05/2022 to 26/05/2023
M00545920 Batches	25576770, 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, 25771774, 25771775, 25771776, 25771777, 25771778, 25836083, 25836084, 25836085, 25836086, 25836087, 25836088, 25836089, 25836090, 25836091, 25836092, 25878557, 25878558, 25878559, 25878980, 25878981, 25878982, 25878983, 25878984, 25878985, 25940124, 25940125, 25942723, 25947907, 25947909, 25947911,		

Product Description	UPN # / Batches	GTIN	Expiration Date Range
HURRICANE RX DILATION BALLOON 6MM 4CM	M00545920 <i>(Continued)</i>	08714729283836	10/05/2022 to 26/05/2023
M00545920 Batches <i>(Continued)</i>	25947913, 25947915, 25975775, 25975776, 25975777, 25975778, 25995786, 25996198, 26000471, 26000476, 26000477, 26000478, 26000479, 26000580, 26000700, 26010393, 26010394, 26010395, 26010396, 26058288, 26058291, 26058293, 26058294, 26058295, 26058296, 26058297, 26087734, 26087735, 26087736, 26087737, 26087738, 26087739, 26087740, 26087741, 26123187, 26123188, 26123189, 26123190, 26123191, 26123247, 26123248, 26123249, 26175470, 26175471, 26175472, 26175473, 26207983, 26207984, 26207985, 26207986, 26207987, 26207988, 26207989, 26207990, 26207991, 26238132, 26238133, 26238134, 26240368, 26240370, 26240371, 26240373, 26247248, 26247249, 26247250, 26247251, 26247252, 26247253, 26247254, 26247255, 26247256, 26247257, 26283632, 26283633, 26283634, 26283635, 26283636, 26283637, 26283638, 26283639, 26284140, 26284141, 26284142, 26284143, 26324749, 26324751, 26324752, 26324754, 26350404, 26350405, 26350406, 26350407, 26356444, 26366753, 26366754, 26366755, 26366756, 26366757, 26406522, 26406523, 26406524, 26406525, 26406526, 26406527, 26406528, 26406529, 26406530, 26406531, 26426921, 26426922, 26426923, 26428970, 26429811, 26429812, 26435537, 26435538, 26435539, 26435580, 26452047, 26456916, 26456917, 26462399, 26473523, 26473769, 26473770, 26473771, 26473772, 26473773, 26473774, 26495372, 26495950, 26500637, 26500638, 26512452, 26512453, 26512454, 26512455, 26512456, 26512457, 26512458, 26512459, 26512480, 26512481, 26512483, 26512485, 26549972, 26552065, 26556788, 26556789, 26559542, 26559543, 26559544, 26559548, 26581407, 26581408, 26582103, 26582104, 26582105, 26582106, 26582107, 26588072, 26588073, 26588074, 26588075, 26588076, 26628443, 26628444, 26638830, 26638831, 26651713, 26651714, 26651715, 26651716, 26665561, 26665567, 26665571, 26665572, 26665573, 26685875, 26685876, 26685877, 26685878, 26685879, 26699192, 26699193, 26699194, 26699195, 26699196, 26699197, 26728782, 26728784, 26728785, 26759345, 26760530, 26778894, 26778895, 26778896, 26778897, 26778898, 26779080, 26779081, 26779082, 26779083, 26793782, 26793783, 26793784, 26808197, 26808198, 26808199, 26808300, 26808301, 26808302, 26808303, 26848720, 26848721, 26848722, 26848723, 26848724, 26848725, 26871168, 26871169, 26871170, 26871171, 26871172, 26871173, 26871174, 26910997, 26910998, 26910999, 26911840, 26911841, 26911842, 26911845, 26919040, 26919041, 26919042, 26960166, 26960167, 26960168, 26960169, 26960170, 26960171, 26960172, 26960173, 26960174, 26960175, 27009668, 27027289, 27027290, 27027291, 27027292, 27062054, 27062055, 27062056, 27062057, 27065830, 27065831, 27065832,		

Product Description	UPN # / Batches	GTIN	Expiration Date Range
HURRICANE RX DILATION BALLOON 6MM 4CM	M00545920 (Continued)	08714729283836	10/05/2022 to 26/05/2023
M00545920 Batches (Continued)	27065833, 27065834, 27065835, 27100017, 27100018, 27100019, 27100240, 27100241, 27100242, 27110096, 27110097, 27121582, 27121583, 27121584, 27121585, 27121620, 27121621, 27121625, 27148636, 27148637, 27148638, 27162326, 27162327, 27162328, 27162329, 27182896, 27182897, 27182898, 27182899, 27203768, 27203769, 27203770, 27203771, 27203772, 27203773, 27255217, 27255219, 27255220, 27255221, 27255222, 27255223, 27308422, 27308423, 27308424, 27308425, 27335091, 27335092, 27335093, 27335094, 27340629, 27340630, 27340632, 27340633, 27340634, 27340638, 27347592, 27347593, 27384705, 27384706, 27384713, 27384715		
HURRICANE RX DILATION BALLOON 8MM 2CM	M00545930	08714729283843	27/05/2022 to 26/05/2023
M00545930 Batches	25644951, 25649190, 25650286, 25651334, 25654287, 25947916, 25947918, 26010397, 26058298, 26406532, 26435581, 26449368, 26533973, 26555544, 26868194, 27074110, 27269956, 27384708		
HURRICANE RX DILATION BALLOON 8MM 4CM	M00545940	08714729283850	18/05/2022 to 31/05/2023
M00545940 Batches	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, 25836093, 25836094, 25836095, 25836096, 25836097, 25836098, 25836099, 25836140, 25836141, 25836142, 25836143, 25836144, 25836145, 25878556, 25894780, 25894781, 25894782, 25916457, 25939485, 25939684, 25940126, 25940127, 25940131, 25947920, 25947921, 25975779, 25975780, 25975781, 25975782, 25975783, 25975784, 25975785, 25975786, 25975787, 26000581, 26000582, 26000583, 26000584, 26051925, 26051926, 26051927, 26058299, 26058420, 26058421, 26058422, 26058425, 26096221, 26096222, 26096223, 26099224, 26123192, 26123193, 26123194, 26123195, 26123196, 26123250, 26123251, 26175474, 26175475, 26175476, 26175477, 26175478, 26175479, 26175500, 26207992, 26207993, 26207994, 26207995, 26207996, 26207997, 26207998, 26238135, 26240374, 26240376, 26240377, 26240378, 26247258, 26247259, 26247280, 26247281, 26247282, 26247283, 26247284, 26247285, 26284144, 26284145, 26284146, 26284147, 26284148, 26284149, 26284150, 26284151, 26324756, 26324758, 26324760, 26324762, 26324764, 26324765, 26324767, 26350408, 26351999, 26356443, 26366758, 26366759, 26366760, 26366761, 26366762, 26366763, 26366764, 26366765, 26366766, 26395974, 26406533, 26406534, 26406535, 26406536, 26406537, 26406538, 26426920, 26435582, 26435583, 26435585, 26435586, 26435587,		

Product Description	UPN # / Batches	GTIN	Expiration Date Range
HURRICANE RX DILATION BALLOON 8MM 4CM	M00545940 <i>(Continued)</i>	08714729283850	18/05/2022 to 31/05/2023
M00545940 Batches <i>(Continued)</i>	26435588, 26456918, 26456919, 26473775, 26473776, 26473777, 26473778, 26491312, 26491313, 26491314, 26491319, 26491480, 26512487, 26512488, 26512490, 26527375, 26527376, 26527377, 26527378, 26551465, 26551466, 26551467, 26551468, 26551470, 26577498, 26613121, 26614494, 26614495, 26614496, 26614497, 26614498, 26614800, 26614801, 26628445, 26628446, 26628447, 26651711, 26651712, 26665036, 26665037, 26665038, 26665039, 26665360, 26665361, 26696684, 26696685, 26696686, 26696687, 26706788, 26706789, 26706790, 26706791, 26706792, 26706793, 26706794, 26760454, 26760456, 26760458, 26760459, 26760520, 26760521, 26760522, 26760523, 26760524, 26760525, 26779085, 26799125, 26799126, 26799127, 26799128, 26799129, 26818882, 26818883, 26818884, 26818885, 26818886, 26818887, 26818888, 26818889, 26818890, 26818891, 26818892, 26848726, 26848727, 26848728, 26848729, 26848730, 26848731, 26888163, 26888164, 26888165, 26888166, 26888167, 26888168, 26910996, 26919048, 26919049, 26919050, 26919051, 26919341, 26990595, 26990596, 26990598, 26990599, 26990980, 26990981, 26990982, 27008813, 27008814, 27008815, 27008816, 27008817, 27009671, 27027284, 27027285, 27027286, 27027287, 27027288, 27055010, 27055018, 27062058, 27065836, 27065837, 27065838, 27065839, 27074113, 27074114, 27100243, 27100244, 27110098, 27110099, 27110720, 27121586, 27121587, 27121588, 27121589, 27148635, 27162330, 27162331, 27162332, 27183300, 27183301, 27183302, 27203774, 27203775, 27203776, 27203777, 27203778, 27203779, 27255225, 27255226, 27255227, 27255228, 27255229, 27255230, 27255231, 27255232, 27255233, 27265232, 27269957, 27269958, 27269959, 27308426, 27308427, 27335095, 27335096, 27335097, 27347594, 27347595, 27347596, 27384709, 27393786, 27407169, 27408779, 27408920, 27408921		
HURRICANE RX DILATION BALLOON 10MM 2CM	M00545950	08714729283867	09/05/2022 to 27/05/2023
M00545950 Batches	25571372, 25673064, 25836146, 26010398, 26058426, 26123197, 26175501, 26216321, 26473779, 26759413, 26784680, 26848732, 26946145, 27121592, 27340635, 27393787		

Product Description	UPN # / Batches	GTIN	Expiration Date Range
HURRICANE RX DILATION BALLOON 10MM 4CM	M00545960	08714729283874	18/05/2022 to 03/06/2023
M00545960 Batches	25608761, 25640116, 25640117, 25644834, 25649819, 25649824, 25649829, 25649834, 25678825, 25678830, 25678835, 25678839, 25678880, 25680560, 25704230, 25704231, 25704232, 25739169, 25739170, 25806714, 25819946, 25819947, 25819948, 25836147, 25836148, 25850475, 25850476, 25850477, 25850478, 25850479, 25850540, 25850541, 25878986, 25878987, 25878988, 25878989, 25878990, 25878991, 25930854, 25940128, 25940129, 25940130, 25963979, 25969161, 25969162, 25975788, 25975789, 25975790, 25975791, 26010399, 26010400, 26047895, 26047896, 26047897, 26047898, 26047899, 26048760, 26058432, 26059172, 26123198, 26123199, 26123240, 26123241, 26123242, 26123243, 26123252, 26123253, 26175502, 26175503, 26175504, 26175505, 26207999, 26208000, 26208001, 26208002, 26208003, 26240379, 26247286, 26247287, 26247288, 26247289, 26284152, 26284153, 26284154, 26284155, 26284156, 26324769, 26324771, 26324773, 26324775, 26350409, 26356442, 26366767, 26366768, 26366769, 26366770, 26366771, 26366772, 26366773, 26366774, 26406539, 26406560, 26406561, 26406562, 26435589, 26435590, 26435591, 26440046, 26457040, 26457041, 26473800, 26473801, 26489988, 26491481, 26491482, 26491483, 26491484, 26499145, 26543699, 26545849, 26545850, 26545851, 26546369, 26549973, 26559545, 26581409, 26581410, 26581827, 26600543, 26600544, 26621751, 26628098, 26638074, 26651704, 26651705, 26651706, 26651709, 26674679, 26675080, 26675081, 26677000, 26677001, 26677002, 26686240, 26696688, 26696689, 26706795, 26706796, 26706797, 26718376, 26718377, 26739329, 26739331, 26739335, 26758738, 26759340, 26759342, 26760526, 26760527, 26760528, 26760529, 26779086, 26779087, 26779088, 26779089, 26779090, 26779092, 26779093, 26808304, 26808305, 26808306, 26808307, 26848733, 26848734, 26848735, 26848736, 26848737, 26888169, 26888170, 26888171, 26888172, 26919342, 26919343, 26919344, 26919345, 26940195, 26940196, 26940197, 26940198, 26990983, 26990984, 26990985, 26990986, 26990987, 26990988, 26990989, 26990990, 26990991, 27008809, 27008810, 27008811, 27008812, 27055019, 27055120, 27062059, 27065900, 27065901, 27074115, 27074116, 27121590, 27121591, 27121596, 27121598, 27121599, 27121626, 27148639, 27148780, 27148781, 27183303, 27183304, 27183305, 27183311, 27183312, 27219848, 27220333, 27233915, 27263158, 27263159, 27265233, 27265234, 27269980, 27269981, 27269982, 27308428, 27335462, 27347597, 27347598, 27384710, 27428069		

Verification Form – Urgent Medical Device Recall
Hurricane™ RX Biliary Balloon Dilatation Catheter
92762451-FA

1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated 21 October 2021.

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 CustomerService.Czech@bsci.com - Fax: 296 331 934

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 +420 296 331 900 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