Republic of the Philippines
Department of Health
**FOOD AND DRUG ADMINISTRATION**

26 FEB 2021

**FDA ADVISORY**
No. 2021-0401

**TO:** **ALL HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

**SUBJECT:** **Voluntary Recall of Hurricane™ RX Biliary Balloon Dilation Catheter**

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The Food and Drug Administration (FDA) warns all healthcare professionals and establishments on the voluntary recall of affected lots of Hurricane™ RX Biliary Balloon Dilatation Catheters with FDA registration number, DVR-8150, manufactured by Boston Scientific Corporation, imported and distributed by Boston Scientific Philippines, Inc.:

| 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 to 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, | 2/7/2022 to 6/27/2022 |

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| HURRICANE Rx DILATION BALLOON 4MM 4CM | M00545900 | 08714729283812 | 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 to 6/27/2022 |
| HURRICANE Rx DILATION BALLOON 6MM 2CM | M00545910 | 08714729283829 | 25456946, 25497472, 25571369, 25623385, 25678822, 25739151 | 3/22/2022 to 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, | 2/2/2022 to 6/27/2022 |

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| HURRICANE Rx DILATION BALLOON 6MM 4CM | M00545920 | 08714729283836 | 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 to 6/27/2022 |
| HURRICANE Rx DILATION BALLOON 8MM 2CM | M00545930 | 08714729283843 | 25509441, 25536741, 25644951, 25649190, 25650286, 25651334, 25654287 | 4/13/2022 to 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, | 2/4/2022 to 6/30/2022 |

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| HURRICANE Rx DILATION BALLOON 8MM 4CM | M00545940 | 08714729283850 | 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 to 6/30/2022 |
| HURRICANE Rx DILATION BALLOON 10MM 2CM | M00545950 | 08714729283867 | 25471587, 25571372, 25588303, 25673064 | 3/28/2022 to 6/6/2022 |

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| 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 to 6/20/2022 |


Figure 1. Hurricane™ RX Biliary Balloon Dilation Catheter

Boston Scientific Corporation initiated the voluntary recall of the above-mentioned 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.

In light of the foregoing, all concerned healthcare professional, establishments, and the general public are warned to discontinue further use, sale, and distribution of the said affected lots/batches of Hurricane™ RX Biliary Balloon Dilatation Catheters.

All FDA Regional Field Offices and Regulatory Enforcement Units, in coordination with law enforcement agencies and Local Government Units, are requested to ensure that product is not sold or made available in the market or areas of jurisdiction.

Any suspected adverse reaction experienced from the use of the medical device but not limited to the lot numbers stated above should be reported immediately to FDA.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through e-mail at **cdrrhr@fda.gov.ph**, or call **(02) 8857-1900 loc. 8301.**

Dissemination of this advisory to all concerned is hereby requested.

**ROLANDO ENRIQUE D. DOMINGO, MD**
Director General

DTN 20210107150208