

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سِلاطَنَة عُمان
وَزَارَة الصِّحَة
وَالرِّقَابَة الدَّوْلِيَّة
مَسْقَط

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

Commanding Officer, Armed Forces Hospital (Al Khoudh & Salah)

Director General of Engineering Affairs, MOH

Director General of Royal Hospital

Director General of Khoula Hospital

Director General of Medical Supplies (MOH)

Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)

Hospital Director (Al Nahda Hospital)

Hospital Director (Al Massara Hospital)

The Head of Medical Services in SQU Hospital

The Head of Medical Services in Royal Oman Police

The Head of Medical Services in Ministry of Defence

The Head of Medical Services in The Diwan

The Head of Medical Services in The Sultan's Special Force

The Head of Medical Services in Internal Security Services

The Head of Medical Services in Petroleum Development of Oman

The Head of Medical Services in LNG Oman

ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No. 177 .. dated 27/8/20 Regarding NCMDR Recall of Hurricane™ RX Biliary Balloon Dilatation Catheter from (mfr: Boston Scientific).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



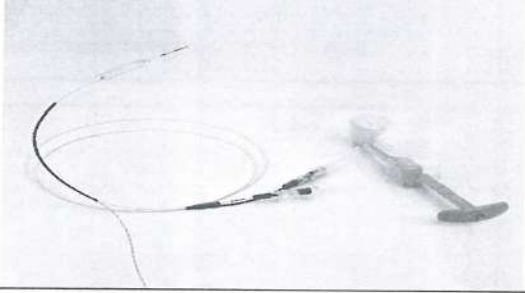
سلطنة عمان
وزارة الصحة
الديريته العامه للصيغ
والرقابة الدوائية
مسقط

Circular No. 177 / 2020

09 -02-1442 H

27 -09-2020

Recall of Hurricane™ RX Biliary Balloon Dilatation Catheter from Boston Scientific.

Source	NCMDR - National Centre Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=15356
Product	Hurricane™ RX Biliary Balloon Dilatation Catheter.
Description	Catheters, Vascular, Balloon.
Manufacturer	Boston Scientific.
The affected products	Attached.
Reason	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.
Action	1. Please immediately discontinue use of the Boston Scientific product reported in the list and remove all of the affected units from your inventory. 2. Contact local agent for remedial action.
Product image	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through an E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL





Medical Devices Sector

قطاع الأجهزة الطبية

- Home
- Published FSNs/Recalls
- About NCMDR
- Contact Us
- FAQ
- Login

NCMDR

National Center for Medical Devices Reporting


المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Recall

Reference Number: mdprc 027 09 20 000

[Back](#)

Date submitted: 9/17/2020

Manufacturer:	Boston Scientific
Device Type:	Hurricane™ RX Biliary Balloon Dilatation Catheter
Description:	Catheters, Vascular, Balloon
Medical Device Identifier:	Please see "Affected Product Listing" section in the attached FSN.
Reason of Field Safety Corrective Action:	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.
Remedy Action:	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.
Athorized Representative/Importer/Distributor:	Gulf Medical Co.
Report Source:	NCMDR
Source Ref. Number:	27477C941A198
SFDA Comments:	SFDA urges all hospitals that have devices subjected to this FSCA to contact the company.
Attachments:	 Boston Scientific.pdf

[View History](#)

Copyright © 2008 Saudi Food and Drug Authority. All rights reserved.

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, 25479581, 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