

Remoção Urgente de Dispositivo Médico - Ação Imediata Necessária

Hurricane™ RX, Cateter Balão de Dilatação Biliar

21 de outubro de 2021

Prezados Clientes:

A Boston Scientific Corporation (BSC) está dando início a uma remoção de lotes **específicos** dos Cateteres Balão de Dilatação Biliar Hurricane™ RX Registro ANVISA: 10341350373 em resposta a um aumento nas queixas reportadas de orifícios no balão. Pode vir acontecer que o usuário perceba que o balão perde pressão rapidamente ou não consegue ganhar ou manter a pressão. Não houve nenhum relato de lesão grave em pacientes.

Uma possível consequência e a mais comum, assim como a consequência mais grave de ocorrer de forma razoável um prolongamento do procedimento enquanto o dispositivo é trocado. Se ocorrer o prolongamento de um procedimento, não se espera que isto resulte em um atraso clinicamente significativo no procedimento.

Esta remoção afeta somente os lotes listados na Tabela de Produtos Afetados anexa. **Parar imediatamente qualquer distribuição ou uso de qualquer produto remanescente afetado por esta remoção.**

Verificar pelo número de lote na tabela anexa se qualquer produto em seu inventário está afetado. Caso exista, indicar no Formulário de Rastreabilidade e Verificação da Resposta do Recall a quantidade de unidades de cada lote que você devolverá.

Se você identificar qualquer produto dos lotes afetados em seu inventário, favor segregar o produto imediatamente e devolve-lo à Boston Scientific do Brasil seguindo as instruções anexas. **Se você é um distribuidor, favor observar que esta remoção deve chegar ao usuário final, e esta notificação deve ser encaminhada aos seus clientes. Se você é uma unidade que enviou produtos para outro(s) hospital(is) ou unidade(s) dentro de sua rede, favor assegurar-se de que esta notificação seja enviada a ele(s).**

A BSC está notificando as autoridades regulatórias a respeito desta remoção, conforme exigido.

Favor ler atenta e completamente as instruções de remoção incluídas nesta notificação. Seu Representante de Vendas Local pode esclarecer quaisquer dúvidas que você possa ter em relação a esta notificação.

Pedimos desculpas por quaisquer inconvenientes que esta ação possa causar, e apreciamos sua compreensão, ressaltando que estamos tomando as medidas necessárias para assegurar a segurança do paciente e a satisfação de nossos clientes.

Estamos comprometidos em continuar oferecendo produtos que atendam aos padrões de qualidade que você espera da Boston Scientific Corporation.

Atenciosamente,

Elisangela I. Molina
Gerente de Qualidade e Responsável Técnica
E-mail: qualidade@bsci.com

Anexo: Instruções de Remoção
Formulário de Rastreabilidade e Verificação da Resposta do Recall

Profissionais de saúde e consumidores podem relatar eventos adversos graves (efeitos colaterais) ou problemas de qualidade de produto com o uso deste produto à Boston Scientific ligando para 0800 162724.

Instruções de Remoção

O Formulário de Rastreabilidade e Verificação da Resposta do Recall (RVTF, *Reply Verification Tracking Form*) anexo a esta carta deve ser preenchido e devolvido **mesmo se você não tiver quaisquer unidades dos lotes afetados**.

1. Parar imediatamente o uso e segregar o produto afetado.

- Remover imediatamente todo produto afetado de seu inventário.
- Segregar este produto em um local seguro para devolução à Boston Scientific do Brasil.

Você deve preencher e enviar imediatamente por e-mail o Formulário de Rastreabilidade e Verificação da Resposta do Recall para que a Boston Scientific possa realizar a coleta dos materiais identificados.

- Informar em seu RVTF a quantidade de unidades de cada lote que você devolverá.

Enviar o RVTF por e-mail para qualidade@bsci.com

- OBSERVAÇÃO: Se você responder esta Remoção a qualquer outro que não seja a Boston Scientific, a Boston Scientific não receberá sua resposta. Favor responder utilizando a informação de e-mail fornecida acima.

Créditos serão emitidos para todos os produtos afetados que sejam devolvidos de forma adequada à BSC.

2. Embalagem/Envio de Produto Afetado.

- Acondicione qualquer produto que está sendo devolvido em uma caixa de envio adequada.

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Tabela de Produtos Afetados

Descrição do Produto	UPN # / Lotes	GTIN	Intervalo de Datas de Validade
HURRICANE RX DILATION BALLOON 4MM 2CM	M00545890	08714729283805	05/19/2022 to 05/13/2023
M00545890 Lotes	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	05/10/2022 to 05/31/2023
M00545900 Lotes	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,		

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Descrição do Produto	UPN # / Lotes	GTIN	Intervalo de Datas de Validade
HURRICANE RX DILATION BALLOON 4MM 4CM	M00545900 (Continua)	08714729283812	05/10/2022 to 05/31/2023
M00545900 Lotes (Continua)	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	05/23/2022 to 05/28/2023
M00545910 Lotes	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	05/10/2022 to 05/26/2023
M00545920 Lotes	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, ,		

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HURRICANE RX DILATION BALLOON 6MM 4CM	M00545920 (Continua)	08714729283836	05/10/2022 to 05/26/2023
M00545920 Lotes (Continua)	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,		

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Descrição do Produto	UPN # / Lotes	GTIN	Intervalo de Datas de Validade
HURRICANE RX DILATION BALLOON 6MM 4CM	M00545920 (Continua)	08714729283836	05/10/2022 to 05/26/2023
M00545920 Lotes (Continua)	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	05/27/2022 to 05/26/2023
M00545930 Lotes	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	05/18/2022 to 05/31/2023
M00545940 Lotes	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,		

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Descrição do Produto	UPN # / Lotes	GTIN	Intervalo de Datas de Validade
HURRICANE RX DILATION BALLOON 8MM 4CM	M00545940 (Continua)	08714729283850	05/18/2022 to 05/31/2023
M00545940 Lotes (Continua)	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, 26706795, 26706796, 26706797, 26706798, 26706799, 26706800, 26706801, 26706802, 26706803, 26706804, 26706805, 26706806, 26706807, 26706808, 26706809, 26706810, 26706811, 26706812, 26706813, 26706814, 26706815, 26706816, 26706817, 26706818, 26706819, 26706820, 26706821, 26706822, 26706823, 26706824, 26706825, 26706826, 26706827, 26706828, 26706829, 26706830, 26706831, 26706832, 26706833, 26706834, 26706835, 26706836, 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Hurricane™ RX, Cateter Balão de Dilatação Biliar

Tabela de Produtos Afetados

Descrição do Produto	UPN # / Lotes	GTIN	Intervalo de Datas de Validade
HURRICANE RX DILATION BALLOON 10MM 4CM	M00545960	08714729283874	05/18/2022 to 06/03/2023
M00545960 Lotes	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		