

«Hospital_Name»

«Users_Name»

«Department»

«Customer_Address»

«Zip_Code» «City»

«Country_name»

<Reference: 92762451-FA>

21 October 2021

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 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 Fax: 80 30 80 05 - Email: NordicProdQuality@bsci.com on or before **19 November 2021**.

4- **If you have products to return**, please package them in an appropriate shipping box and **contact Customer Service: Tel: +46 (0)42 25 69 50 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

Reference: 92762451-FA

21 oktober 2021

Field Safety Notice - Øjeblikkelig tilbagekaldelse af medikoteknisk produkt Hurricane™ RX ballondilatationskateter

Kære «Users_Name»,

Boston Scientific Corporation (BSC) har igangsat en tilbagekaldelse af specifikke partier/batch af Hurricane™ RX ballondilatationskatetre som følge af en stigning i antallet af klager over små huller i ballonen. Brugeren kan opleve, at ballonen hurtigt taber trykket, eller at det ikke er muligt at puste den op til det ønskede tryk. Der er indtil nu ikke indberettet alvorlige skader som følge af dette problem.

Den typiske konsekvens, der med rimelighed kan forudses, er en forlængelse af proceduren, som følge af, at enheden skal udskiftes.. Hvis proceduren forlænges, forventes forlængelsen ikke at være klinisk signifikant.

Vore optegnelser viser, at din enhed har modtaget nogle af de påvirkede produkter. **Den følgende tabel (Bilag 1) er en komplet liste over alle tilbagekaldte produkter**, herunder produktbeskrivelse, materialenummer (UPN), katalognummer, GTIN, og Lot/Batch-numre og udløbsdato. **Bemærk venligst, at det kun er nedenstående materiale og batchnumre, der er påvirkede. Intet andet produkt fra Boston Scientific er involveret.**

Yderligere distribution eller brug af ethvert resterende produkt berørt af denne sag skal høre op omgående.

INSTRUKTIONER:

1- I bedes med øjeblikkelig virkning standse brugen af de Boston Scientific produkttabellen der er angivet, og fjerne alle de berørte enheder fra jeres depoter, uanset hvor disse enheder opbevares i jeres institution. Isolér enhederne et sikkert sted, afventende returnering til Boston Scientific.

2- Udfyld venligst den medfølgende bekræftelsesblanket selvom der ikke findes påvirkede produkter.

3- Når bekræftelsesblanketten er udfyldt, sendes den via fax til den lokale Boston Scientific kundeservice til Fax: 80 30 80 05 - Email: NordicProdQuality@bsci.com før den **19. november 2021**.

4- Hvis du har produkter, der skal returneres, så pak dem i en passende forsendelsesæske og kontakt Customer Service: Tel: +46 (0)42 25 69 50 hos din lokale Boston Scientific kundeservice, for at arrangere tilbagesendelsen.

5- Lad denne meddelelse gå videre til andre sundhedsmedarbejdere indenfor jeres organisation, der har behov for at være opmærksomme på dette og til enhver organisation, hvortil potentielt påvirkede anordninger kan være overført (hvis relevant). Giv venligst Boston Scientific detaljerede oplysninger (pr. telefon eller fax) om enhver påvirket anordning, der er overført til andre organisationer (hvis relevant).

Din kompetente myndighed er ved at blive underrettet om denne tilbagekaldelse.

Vi beklager enhver ulejlighed som denne handling måtte medføre, og vi værdsætter jeres forståelse, da vi handler ud fra at sikre patientsikkerheden og kundernes tilfredshed.

Skulle du have nogle spørgsmål eller ønsker hjælp med denne tilbagekaldelse af en medicinsk anordning, så kontakt din lokale salgsrepræsentant.

Med venlig hilsen,



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

Vedlagt: Verificeringsformular

Bilag 1 – liste over produkter

Produktbeskrivelse	UPN-nr./batch	GTIN	Udløbsdato (interval)
HURRICANE RX DILATION BALLOON 4MM 2CM	M00545890	08714729283805	19.05.2022 til 13.05.2023
M00545890 Batch	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 til 31.05.2023
M00545900 Batch	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,		

Produktbeskrivelse	UPN-nr./batch	GTIN	Udløbsdato (interval)
HURRICANE RX DILATION BALLOON 4MM 4CM	M00545900 (fortsat)	08714729283812	10.05.2022 til 31.05.2023
M00545900 Batch (fortsat)	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 til 28.05.2023
M00545910 Batch	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 til 26.05.2023
M00545920 Batch	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,		

Produktbeskrivelse	UPN-nr./batch	GTIN	Udløbsdato (interval)
HURRICANE RX DILATION BALLOON 6MM 4CM	M00545920 (fortsat)	08714729283836	10.05.2022 til 26.05.2023
M00545920 Batch (fortsat)	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,		

Produktbeskrivelse	UPN-nr./batch	GTIN	Udløbsdato (interval)
HURRICANE RX DILATION BALLOON 6MM 4CM	M00545920 (fortsat)	08714729283836	10.05.2022 til 26.05.2023
M00545920 Batch (fortsat)	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 til 26.05.2023
M00545930 Batch	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 til 31.05.2023
M00545940 Batch	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,		

Produktbeskrivelse	UPN-nr./batch	GTIN	Udløbsdato (interval)
HURRICANE RX DILATION BALLOON 8MM 4CM	M00545940 (fortsat)	08714729283850	18.05.2022 til 31.05.2023
M00545940 Batch (fortsat)	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 til 27.05.2023
M00545950 Batch	25571372, 25673064, 25836146, 26010398, 26058426, 26123197, 26175501, 26216321, 26473779, 26759413, 26784680, 26848732, 26946145, 27121592, 27340635, 27393787		

Produktbeskrivelse	UPN-nr./batch	GTIN	Udløbsdato (interval)
HURRICANE RX DILATION BALLOON 10MM 4CM	M00545960	08714729283874	18.05.2022 til 03.06.2023
M00545960 Batch	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		

Udfyld formularen, også selvom du ikke har noget involveret produkt & send det tilbage til din locale kundeservice: **Fax: 80 30 80 05 - Email: NordicProdQuality@bsci.com**

**Verificeringsformular – Øjeblikkelig tilbagekaldelse af medicinsk anordning
Hurricane™ RX ballondilatationskateter
92762451-FA**

1. Vi anerkender modtagelse af Boston Scientific Field Safety Notice dateret 21 oktober 2021.

2. **Boston Scientific registreringer indikerer, at De har modtaget følgende berørte produkt** (kontroller venligst yderligere Deres lager i henhold til den komplette, fremsendte liste over berørte produkter)

Materiale nummer	Batch nummer(e)	Kundeindkøbsordre	Antal Sendt	Antal at returnere (Enhed)

3. Vi bekræfter, at alle områder, hvor produktet kunne befinde sig, er kontrolleret.

4. **AFKRYDS EN AF DISSE UDTALELSER***, **UNDERSKRIV DENNE FORMULAR** og send det til Fax: 80 30 80 05 - Email: NordicProdQuality@bsci.com

Vi har ikke noget berørt produkt

Vi har fundet berørte produkter: Bekræft venligst det kvantum, der skal returneres ovenfor. Hvis De returnerer et produkt, der ikke er anført ovenfor, **tilføj venligst UPN, produktionsnummer samt det kvantum, der skal returneres.**

FOR AT RETURNERE PRODUKTER:

1. Kontakt Customer Service: Tel: +46 (0)42 25 69 50 hos jeres lokale kundeservice for at arrangere tilbagesendelse af ethvert berørt produkt
2. Klargør pakningen
3. Følg de instruktioner, der bliver givet fra jeres lokale kundeservice, om afhentning af pakningen

NAVN* _____ **TITEL** _____
(blokbogstaver)

Telefon _____ E-mail _____

Autoriseret **Underskrift*** _____ **DATO*** _____
* Obligatoriske felter dd-mm-åå