

Urgent Medical Device Removal - Immediate Action Required

Carotid WALLSTENT™ Monorail Endoprosthesis

July 2025

Dear Healthcare Professional,

Cc: Chairman Medical Board and relevant Head of Department

Boston Scientific is initiating the removal of certain batches of Carotid WALLSTENT™ Monorail Endoprosthesis (Carotid WALLSTENT) devices due to an increase in complaints received in which physicians described encountering greater than anticipated resistance when attempting to withdraw/retract the stent delivery system (SDS) from the guidewire or embolic protection device (EPD), after successful stent deployment.

The affected device batches, shown in Attachment 1, were manufactured with equipment settings that led to an unintended change resulting in the inner guidewire lumen being narrower than the specified dimensions. This change in the guidewire lumen dimension causes restricted guidewire movement in the affected batches. Boston Scientific has corrected the manufacturing equipment.

Device Description

The Carotid WALLSTENT consists of a stent and delivery system. The role of the stent is to provide a patent lumen so that the flow of blood into the carotid artery is restored. The function of the delivery catheter is to advance the non-deployed stent over a guidewire to the desired lesion location and deploy the stent.

Clinical Impact

Due to the guidewire lumen restriction, the inability to withdraw the SDS results in the need to remove the SDS and EPD as a system while the EPD is still deployed. If the EPD contains debris, this may be dislodged and spill into the bloodstream with consequent embolization into the cerebral vasculature. Although not observed in any of the reported complaints to date, the most serious potential adverse health consequence would be a life-threatening cerebrovascular accident (CVA)/stroke.

Additionally, there may be difficulty in retracting the deployed EPD through the carotid artery and Carotid WALLSTENT which may result in vessel injury, vessel spasm or stent disruption/ damage necessitating additional endovascular or surgical interventions.

The most common adverse health consequence observed from this issue is a delay in the procedure beyond the expected timeframe. This may occur as the SDS and guidewire/EPD system is removed and access through the stented carotid artery is lost, potentially requiring replacement of guidewire access through the lesion to complete the procedure. If guidewire access through the Carotid WALLSTENT is required, there is a possibility of the guidewire not traversing through the true lumen of the stent which may result in vessel injury or stent disruption. This may necessitate additional endovascular or surgical interventions.

There is no need for any further specific patient management related to the issue described above if the Carotid WALLSTENT was successfully utilized and the procedure has been completed. Standard post-procedure care is appropriate.

Instructions:

- 1. Further distribution or use of any remaining devices (Attachment 1) affected by this removal should cease immediately.**

Do NOT use affected devices and remove those devices from your facility's inventory. Segregate the units in a secure place until they can be returned to Boston Scientific.

- 2. Immediately post** this information in a visible location near the affected devices to ensure it is readily accessible to all handlers and users of the device.

- 3. Forward this notice** to any healthcare professional from your organization and to any facilities where affected devices have been transferred, including hospitals or sites within your network.

If you are a distributor, this notice must be forwarded to your customers to ensure notification of this device removal is carried out to the end-user level.

- 4. Complete and return the enclosed Reply Verification Tracking Form** per the enclosed instructions on page four.

- 5. Return affected devices.**

This removal affects only the devices and batches listed in Attachment 1 (Affected Devices). No other material numbers or batches are impacted by this removal.

Any adverse events or quality concerns associated with use of these devices should be reported to Boston Scientific via email at ComplaintCallCenter@bsci.com or FDA's MedWatch Adverse Event Reporting program [www.fda.gov/MedWatch/report.htm or 1.800.FDA.1088 (332.1088)].

Patient safety is our highest priority. As such, we are committed to transparent communication to ensure that you have timely, relevant information for managing your patients. If you require additional assistance or more information regarding this communication, please contact your local Boston Scientific representative.

Sincerely,



Scott Heineman
Vice President, Global Quality
Boston Scientific Corporation

Encl: Removal Instructions
Reply Verification Tracking Form
Attachment 1: Affected Device List

Urgent Medical Device Removal - Instructions

The Reply Verification Tracking Form (RVTF) enclosed with this Removal Notice must be completed and returned even if you do not have any affected devices.

1. Immediately discontinue use and segregate affected devices.
2. Complete and return the RVTF.
 - Indicate the quantity of SINGLE units you will be returning for credit
 - If you have a device that is listed in Attachment 1 (Affected Device List) that is not included on your RVTF, provide the material number, batch number, and quantity you intend to return on your RVTF.
3. Package and ship affected product and return to Boston Scientific.
4. Credit will be issued for all returned Affected Product once received and confirmed by Boston Scientific.
5. If you have sent a response to this Removal Notice to anyone other than Boston Scientific, we would not have received your response. Please ensure response is sent to Boston Scientific.
6. Credit will be issued for all returned affected devices once received and confirmed by Boston Scientific. Reach out to your local Boston Scientific representative with any questions.

Attachment 1-Affected Device List

Material	Material Description	GTIN	Batch	Expiration Date Range
H7493915010240	CAROTID WALLSTENT MONORAIL 10.0-24	08714729781097	35277608 ,35315983, 35315984, 35315985, 35380314, 35452835, 35452836, 35514614, 35551688, 35551689, 35664523, 35664524, 35750157, 35750158, 35750159, 35750400, 35879409, 35879410, 35921915, 35922951, 35926817, 35926818, 35942366, 36056965, 36058841, 36058842, 36058843, 36096638, 36121883, 36138618, 36138619, 36138801, 36138802, 36138803, 36159671, 36195057, 36195058, 36195059, 36195360, 36205167, 36209423, 36214805, 36214806, 36256192, 36322725, 36348207, 36348208, 36348209, 36498256, 36588496, 36607566, 36711321	14-May-2028 thru 8-Dec-2028
H7493915010310	CAROTID WALLSTENT MONORAIL 10.0-31	08714729781110	35294379, 35294540, 35295922, 35330503, 35330504, 35336132, 35347263, 35382292, 35383351, 35383352, 35453002, 35461487, 35461488, 35528579, 35529200, 35628964, 35628965, 35628966, 35641995, 35662047, 35664484, 35664485, 35750401, 35750402, 35750403, 35750404, 35750405, 35750406, 35750407, 35890012, 35893584, 35893585, 35894358, 35894359, 35938922, 35938923, 35938924, 35938925, 35938926, 36002641, 36002642, 36063291, 36063292, 36105446, 36133161, 36134808, 36144148, 36148535, 36154091, 36154092, 36154093, 36154094, 36154095, 36169871, 36169872, 36197809, 36197810, 36197811, 36197812, 36197813, 36200118, 36202762, 36204350, 36212466, 36212467, 36212468, 36256193, 36256194, 36256195, 36357711, 36357712, 36368143, 36368144, 36368145, 36516036, 36603362, 36603363, 36642784, 36683543, 36688775, 36811476, 36811477, 36818953	16-May-2028 thru 22-Dec-2028
H749391506220	CAROTID WALLSTENT MONORAIL 6.0-22	08714729781158	35582211, 35750408, 35947814, 35947815, 35950476, 36009906, 36292862, 36397124, 36652844	9-July-2028 thru 30-Nov-2028
H749391508210	CAROTID WALLSTENT MONORAIL 8.0-21	08714729781172	35343574, 35438658, 35487375, 35567637, 35652700, 35656388, 35750409, 35757024, 35873346, 35873347, 35901381, 35901382, 35999854, 35999855, 35999856, 36246587, 36246588, 36246589, 36292863, 36306518, 36376412, 36410418, 36410419, 36412851, 36479267, 36565560, 36636529, 36724350, 36777341	23-May-2028 thru 16-Dec-2028
H749391508290	CAROTID WALLSTENT MONORAIL 8.0-29	08714729781196	35339488, 35375416, 35375417, 35462381, 35529285, 35529286, 35617101, 35617102, 35618276, 35662042, 35662043, 35749222, 35750156, 35750410, 35750411, 35750412, 35750413, 35771618, 35944023, 35944024, 35946987, 35946988, 35950477, 35950478, 35950479, 35951080, 35951081, 35951082,	22-May-2028 thru 18-Dec-2028

			35951083, 35961400, 35978120, 36320917, 36320918, 36320919, 36321560, 36322143, 36458848, 36458849, 36458850, 36458851, 36458852, 36465397, 36465398, 36465399, 36505552, 36505553, 36607622, 36683540, 36792075	
H965SCH647010	CAROTID WALLSTENT MONORAIL 6.0-22	08714729263869	35347272, 35347273, 35347274, 35432322, 35432323, 35432324, 35432325, 35435587, 35496538, 35496539, 35510448, 35510449, 35549114, 35558691, 35558692, 35623470, 35623471, 35623472, 35641992, 35757022, 35891995, 35891996, 35903878, 35903879, 35904080, 35904081, 35911104, 35911106, 35926007, 35926017, 35990353, 35990354, 36009907, 36012786, 36012787, 36012788, 36012789, 36222681, 36222683, 36241106, 36241107, 36241108, 36292865, 36292866, 36292867, 36292868, 36292869, 36292870, 36297506, 36297507, 36348203, 36348204, 36357034, 36357035, 36357037, 36402896, 36402897, 36469383, 36469384, 36469385, 36493671, 36515107, 36609942, 36609943, 36609944, 36717345, 36722322, 36769772, 36769773, 36787067	23-May-2028 thru 17-Dec-2028
H965SCH647070	CAROTID WALLSTENT MONORAIL 8.0-21	08714729263876	35240183, 35240184, 35240185, 35241830, 35241831, 35242395, 35244198, 35302653, 35302654, 35345323, 35345324, 35345325, 35353957, 35353958, 35353959, 35355526, 35355527, 35355528, 35355529, 35355530, 35355531, 35355532, 35355533, 35355534, 35355535, 35388600, 35388601, 35388602, 35388603, 35388604, 35388605, 35390839, 35432326, 35435588, 35435589, 35435590, 35435591, 35435592, 35435593, 35435594, 35435595, 35435596, 35435597, 35435598, 35435599, 35435640, 35435641, 35435642, 35438652, 35438653, 35438654, 35438659, 35448174, 35448175, 35448261, 35448262, 35448263, 35448264, 35487376, 35487377, 35489534, 35489535, 35489536, 35494158, 35494159, 35495360, 35495361, 35495362, 35495363, 35497060, 35497061, 35497062, 35507545, 35507546, 35514618, 35548744, 35549113, 35553916, 35553917, 35553918, 35553919, 35556850, 35556851, 35558690, 35565001, 35565003, 35567636, 35567638, 35574827, 35580272, 35580273, 35580274, 35580275, 35580276, 35582209, 35582210, 35584963, 35588884, 35588885, 35588886, 35610418, 35610419, 35618278, 35618279, 35620887, 35620888, 35622207, 35643329, 35646460, 35646461, 35646462, 35646465, 35646466, 35646467, 35646469, 35646470, 35646471, 35646472, 35646473, 35652701, 35652702, 35652703, 35656390, 35771619, 35771720, 35771721, 35771722, 35771723, 35771724, 35774933, 35774935, 35912369, 35912370, 35912371, 35912372, 35913736, 35934661, 35934662, 35934663, 35934664, 35936385, 35936386, 35936388, 35937854, 35937855, 35937961, 35937962, 35938832, 35938833, 35944025, 35944026, 35944027, 35944028, 35946402, 35946403, 35952677, 35952678, 35952679, 35952740, 35960613, 35960614, 35960615, 35960616, 35960617, 35960618, 35960619, 35970056, 35970057, 35970482, 35970483, 35972008, 35972009, 35972010, 35972011, 35974039,	8-May-2028 thru 17-Dec-2028

35974900, 35974902, 35974903, 35978121, 35978122, 35979584, 35979585, 35985615, 35985616, 35988023, 35989721, 35999859, 35999920, 35999976, 35999977, 36058848, 36058849, 36058850, 36058851, 36058852, 36058853, 36058854, 36066439, 36066960, 36067793, 36067794, 36067795, 36067796, 36067797, 36067798, 36067799, 36068080, 36072053, 36072054, 36091095, 36091096, 36091097, 36093208, 36093209, 36093740, 36093741, 36094572, 36094573, 36099091, 36099092, 36099093, 36103432, 36103433, 36230819, 36231140, 36233435, 36233436, 36233437, 36233438, 36241642, 36241643, 36241660, 36241661, 36243288, 36243289, 36243290, 36246584, 36246585, 36246586, 36246590, 36246591, 36246592, 36246593, 36246594, 36247809, 36247810, 36247811, 36247812, 36251034, 36251035, 36251036, 36251037, 36251038, 36261365, 36261704, 36266101, 36266102, 36266103, 36266104, 36278239, 36278520, 36278521, 36278522, 36278523, 36278524, 36278525, 36281013, 36281014, 36281015, 36281016, 36281017, 36281018, 36281019, 36281520, 36281521, 36281522, 36285859, 36286700, 36286701, 36286702, 36286703, 36286704, 36286705, 36286706, 36286707, 36286708, 36287360, 36287361, 36292139, 36292861, 36297762, 36301606, 36301607, 36301608, 36301609, 36301610, 36301611, 36301612, 36301613, 36301614, 36301615, 36306516, 36306517, 36352994, 36352996, 36352997, 36352999, 36353020, 36353022, 36353023, 36353025, 36353026, 36353028, 36357708, 36357709, 36357710, 36362685, 36362686, 36362687, 36362688, 36362689, 36362690, 36362691, 36362692, 36362693, 36362694, 36368150, 36368151, 36368152, 36368153, 36368154, 36372913, 36372914, 36372915, 36372916, 36372917, 36372918, 36372919, 36373140, 36373141, 36373142, 36376410, 36376411, 36402898, 36402899, 36403020, 36408269, 36408270, 36408271, 36408272, 36408273, 36408274, 36408275, 36408276, 36408277, 36408278, 36408279, 36410417, 36412854, 36423241, 36423242, 36469386, 36469387, 36469388, 36469389, 36475479, 36475580, 36475581, 36479261, 36479262, 36479263, 36479264, 36479265, 36479266, 36479268, 36480347, 36501126, 36515108, 36523367, 36525434, 36525435, 36525437, 36525438, 36565561, 36609945, 36609946, 36609947, 36609948, 36609950, 36609951, 36609952, 36616128, 36616129, 36616130, 36616131, 36616132, 36645415, 36645416, 36668237, 36668238, 36668239, 36668460, 36668461, 36668462, 36669215, 36672359, 36688777, 36712752, 36717346, 36717347, 36717348, 36719378, 36721745, 36721746, 36722177, 36722179, 36722320, 36724346, 36724347, 36724348, 36724349, 36728508, 36728509, 36729021, 36729022, 36729023, 36732219, 36732360, 36732361, 36732362, 36732974, 36732976, 36732977, 36743995, 36743996, 36743997, 36773856, 36773857, 36773858, 36782024, 36784204

H965SCH647080	CAROTID WALLSTENT MONORAIL 8.0-29	08714729263883	35243220, 35244199, 35244520, 35244521, 35247274, 35247275, 35247276, 35247277, 35247278, 35247279, 35247540, 35247541, 35248292, 35248293, 35248294, 35252806, 35252808, 35252809, 35302655, 35302656, 35302657, 35302658, 35304581, 35305305, 35305306, 35307512, 35307513, 35307514, 35339484, 35339485, 35339486, 35339487, 35357498, 35357499, 35357740, 35361258, 35361259, 35361460, 35361461, 35361462, 35361463, 35362807, 35362808, 35365037, 35365038, 35365039, 35365800, 35365801, 35365802, 35365803, 35365804, 35365805, 35367555, 35370836, 35370837, 35370838, 35370839, 35371180, 35371181, 35371182, 35371183, 35375418, 35375419, 35388606, 35388607, 35388608, 35388609, 35388610, 35388611, 35391026, 35391027, 35391028, 35391029, 35391030, 35393507, 35393508, 35393509, 35393510, 35393511, 35393512, 35394158, 35394159, 35395620, 35395621, 35395622, 35395623, 35395624, 35395625, 35395626, 35395627, 35397442, 35397443, 35397444, 35397445, 35402251, 35402254, 35402257, 35402280, 35402283, 35402284, 35406000, 35406001, 35448176, 35448177, 35450110, 35450111, 35450112, 35450113, 35456213, 35456215, 35456216, 35456217, 35457525, 35457526, 35458769, 35461739, 35461741, 35461742, 35462380, 35462382, 35462383, 35465421, 35465422, 35465423, 35465424, 35468042, 35468043, 35468044, 35468045, 35468046, 35468047, 35468048, 35468049, 35468050, 35468051, 35471389, 35471390, 35471391, 35471392, 35471393, 35476347, 35476348, 35514612, 35518815, 35519420, 35520154, 35520155, 35520156, 35522424, 35522425, 35522699, 35522780, 35522781, 35522782, 35522977, 35522978, 35522979, 35523220, 35523221, 35523222, 35525808, 35525809, 35525810, 35525811, 35526986, 35526987, 35526988, 35528577, 35528578, 35529284, 35529287, 35529629, 35529630, 35529631, 35529632, 35531670, 35531671, 35531672, 35541480, 35541481, 35541482, 35541483, 35542643, 35562259, 35562520, 35565634, 35565635, 35565636, 35585834, 35585835, 35585836, 35585838, 35589525, 35589526, 35590013, 35590014, 35611923, 35611924, 35612128, 35612129, 35612130, 35612131, 35612132, 35612143, 35612144, 35613461, 35613462, 35613463, 35613464, 35613465, 35616796, 35616797, 35616798, 35616799, 35617100, 35618178, 35618179, 35618277, 35620886, 35622733, 35622738, 35622760, 35622761, 35636552, 35636553, 35652778, 35652779, 35653341, 35653342, 35653343, 35655507, 35655508, 35655510, 35655513, 35655514, 35656381, 35656383, 35656384, 35656386, 35656387, 35662005, 35662006, 35662040, 35662041, 35662044, 35662045, 35662046, 35749223, 35755824, 35774932, 35781375, 35781376, 35781377, 35781378, 35781379, 35781880, 35866470, 35866471, 35867497, 35868573, 35868574, 35870253, 35871472, 35871476, 35872080, 35872081, 35873025, 35873026, 35876804, 35876805, 35879407, 35879408, 35881807,	9-May-2028 thru 22-Dec-2028
---------------	---	----------------	---	--------------------------------

35881808, 35887451, 35887452, 35887453, 35887454, 35891991, 35891992, 35891993, 35891994, 35896872, 35896873, 35899097, 35903147, 35903148, 35903149, 35903150, 35912756, 35912757, 35925347, 35926819, 35928104, 35928105, 35929567, 35929568, 35932458, 35932459, 35979594, 35979595, 35983716, 35988028, 35988445, 35988447, 35989162, 35989177, 35989178, 35989279, 35989720, 35989945, 35989946, 35994087, 35994089, 35994090, 35994091, 35995228, 35995229, 35995230, 35995231, 35997085, 35997978, 35997979, 35998240, 35998241, 35998242, 36006192, 36006193, 36006194, 36006195, 36006196, 36006197, 36006198, 36012790, 36012791, 36012792, 36012793, 36018044, 36018045, 36018046, 36018047, 36026734, 36026735, 36026736, 36026737, 36026738, 36026739, 36026960, 36026961, 36026963, 36026964, 36032712, 36032715, 36032717, 36032719, 36032981, 36036491, 36036492, 36036493, 36036494, 36036495, 36036496, 36038161, 36038162, 36038163, 36040721, 36040722, 36040723, 36040724, 36040725, 36040726, 36040727, 36040728, 36043491, 36043492, 36043493, 36043494, 36048928, 36048929, 36048930, 36048931, 36048932, 36048933, 36048934, 36048935, 36048936, 36048937, 36048938, 36048939, 36055143, 36055144, 36068081, 36068082, 36068083, 36068084, 36068085, 36068086, 36078464, 36078465, 36078466, 36078467, 36078468, 36087121, 36087122, 36087123, 36087124, 36087125, 36087126, 36092012, 36092013, 36219930, 36219931, 36219932, 36219933, 36224134, 36224135, 36224136, 36227992, 36227993, 36227994, 36227995, 36228449, 36228450, 36228451, 36228753, 36228754, 36233439, 36233900, 36256580, 36256581, 36256582, 36256583, 36256584, 36256585, 36256586, 36256587, 36258193, 36258194, 36258195, 36258196, 36261366, 36261367, 36261368, 36261369, 36261370, 36261371, 36261373, 36261374, 36261376, 36266106, 36266107, 36266110, 36266111, 36266112, 36268719, 36269061, 36269062, 36270877, 36270878, 36270879, 36271660, 36271661, 36306519, 36306780, 36306781, 36306782, 36306783, 36306784, 36306785, 36306786, 36311913, 36311914, 36311915, 36311916, 36314781, 36314782, 36314783, 36314784, 36314785, 36314786, 36314787, 36314788, 36315939, 36316920, 36316921, 36316922, 36316923, 36318889, 36318890, 36318891, 36318892, 36318893, 36318894, 36318895, 36318896, 36318897, 36318898, 36320911, 36320912, 36320913, 36320914, 36320915, 36320916, 36322144, 36325066, 36325067, 36325068, 36327346, 36327347, 36327352, 36327358, 36327662, 36369519, 36369780, 36369781, 36378265, 36378266, 36378267, 36378268, 36378269, 36378270, 36378271, 36386880, 36386881, 36386882, 36386883, 36386884, 36386885, 36392438, 36392439, 36392520, 36392521, 36392522, 36396975, 36396976, 36396977, 36396978, 36396979, 36397120, 36413022, 36413024, 36413025, 36413026, 36413027, 36413028, 36413029,

			36413030, 36413031, 36413032, 36415159, 36416042, 36416043, 36416044, 36416334, 36416335, 36416336, 36416337, 36416338, 36416339, 36416420, 36422413, 36422414, 36422598, 36422599, 36423963, 36423964, 36423965, 36423995, 36423996, 36447747, 36447748, 36447749, 36448144, 36448145, 36448156, 36448157, 36449975, 36449976, 36449977, 36453798, 36455025, 36455026, 36458843, 36458844, 36458845, 36458846, 36458847, 36480348, 36480349, 36480350, 36480351, 36485714, 36485715, 36485716, 36485717, 36485718, 36485719, 36485800, 36485801, 36485802, 36485803, 36485851, 36485852, 36491169, 36491170, 36491171, 36491172, 36491173, 36491174, 36493672, 36493673, 36493674, 36493675, 36493676, 36493677, 36498253, 36498254, 36498255, 36501125, 36508768, 36508771, 36508772, 36508773, 36508774, 36525439, 36529070, 36529071, 36529072, 36529073, 36529074, 36529075, 36529076, 36529077, 36529078, 36529079, 36535347, 36535348, 36535349, 36535352, 36535353, 36535354, 36535355, 36539304, 36539306, 36545277, 36545278, 36545279, 36545760, 36545761, 36548829, 36548830, 36552374, 36553653, 36553654, 36553655, 36554562, 36554563, 36554564, 36554565, 36554566, 36555138, 36560052, 36560053, 36560054, 36560055, 36560056, 36566126, 36566127, 36566128, 36566129, 36567621, 36571196, 36571197, 36571198, 36571199, 36571780, 36571781, 36572200, 36572201, 36572202, 36572203, 36572204, 36574800, 36574801, 36574802, 36575688, 36575689, 36575690, 36577074, 36577075, 36578325, 36578327, 36578328, 36582969, 36586443, 36618329, 36620780, 36620781, 36620782, 36620783, 36620784, 36620785, 36620786, 36620787, 36620788, 36625778, 36625779, 36626060, 36626061, 36626062, 36626063, 36626064, 36626065, 36626066, 36626067, 36630781, 36630782, 36630783, 36630784, 36630785, 36630786, 36630787, 36630788, 36630789, 36630790, 36645417, 36645418, 36645419, 36673680, 36673681, 36673682, 36673683, 36675542, 36675543, 36675545, 36675546, 36675547, 36675549, 36675550, 36675551, 36675552, 36678442, 36678443, 36678444, 36678445, 36678446, 36678447, 36678448, 36683541, 36688432, 36688433, 36688434, 36712751, 36717343, 36738231, 36738232, 36739201, 36739203, 36739206, 36739207, 36739208, 36739209, 36741080, 36741081, 36742784, 36742785, 36742786, 36742787, 36742788, 36742789, 36748006, 36748007, 36748008, 36749662, 36749663, 36761491, 36761492, 36765445, 36765446, 36767807, 36784206, 36785292, 36785384, 36785385, 36787969, 36787970, 36787971, 36788799, 36792076, 36792077, 36793502, 36793503, 36793678, 36793679, 36795349, 36795350, 36795351, 36799042, 36799043, 36801653, 36803154, 36803155, 36817363, 36818518, 36818519
--	--	--	--

H965SCH647090	CAROTID WALLSTENT MONORAIL 8.0-36	08714729263890	35284214, 35284216, 35284217, 35296025, 35296026, 35296027, 35307517, 35309535, 35309536, 35313433, 35313434, 35313435, 35343571, 35376080, 35376081, 35376082, 35376083, 35395628, 35395629, 35395630, 35406003, 35452838, 35471394, 35471395, 35471396, 35471397, 35471398, 35476350, 35476351, 35476352, 35476819, 35476960, 35514613, 35541484, 35541485, 35541486, 35541487, 35542644, 35542645, 35542646, 35542647, 35588888, 35588889, 35588890, 35594003, 35600380, 35600381, 35600716, 35600717, 35600718, 35663304, 35663305, 35663307, 35663958, 35663959, 35664480, 35664482, 35667604, 35749225, 35749227, 35749228, 35778247, 35778248, 35778249, 35778250, 35893582, 35893583, 35928594, 35928595, 35950473, 35950474, 35950475, 35964009, 35964010, 35972012, 35980330, 35980331, 36007692, 36007693, 36007694, 36007695, 36007696, 36018041, 36018042, 36033496, 36033497, 36033498, 36033499, 36033880, 36043497, 36043498, 36043499, 36043780, 36055146, 36055147, 36055785, 36056677, 36078428, 36097193, 36116118, 36116119, 36116120, 36220947, 36322723, 36322724, 36328322, 36328323, 36328324, 36341859, 36342380, 36342381, 36342382, 36342383, 36342384, 36342385, 36342386, 36342387, 36342388, 36347198, 36347199, 36347220, 36347221, 36347222, 36347223, 36347224, 36347225, 36347226, 36357714, 36357715, 36378272, 36378273, 36465500, 36465501, 36469380, 36469381, 36469382, 36475477, 36475478, 36508775, 36508776, 36513257, 36513258, 36513259, 36513760, 36518682, 36518683, 36553656, 36553657, 36553658, 36553659, 36554560, 36563910, 36582970, 36582971, 36582972, 36582973, 36582974, 36595826, 36595828, 36635529, 36635530, 36635531, 36646050, 36646051, 36679165, 36688435, 36712758, 36717344, 36795885, 36817573	15-May-2028 thru 22-Dec-2028
H965SCH647120	CAROTID WALLSTENT MONORAIL 10.0-24	08714729263906	35258269, 35258270, 35258273, 35258274, 35260228, 35260229, 35265522, 35265523, 35266396, 35266397, 35266398, 35266399, 35267871, 35267872, 35272291, 35272292, 35273687, 35273688, 35273689, 35274001, 35274002, 35274003, 35274004, 35276183, 35276184, 35276185, 35276186, 35276187, 35277609, 35278162, 35278163, 35278164, 35278165, 35278167, 35281328, 35281329, 35289305, 35306610, 35306611, 35306612, 35310693, 35310694, 35310695, 35310696, 35315986, 35315987, 35315988, 35320538, 35320539, 35324563, 35324564, 35324565, 35324566, 35324567, 35324568, 35324569, 35376084, 35376085, 35376087, 35380104, 35380105, 35380315, 35380316, 35381858, 35381859, 35381980, 35381981, 35381982, 35381983, 35381984, 35395631, 35395632, 35395633, 35406004, 35406005, 35406007, 35406008, 35406009, 35406010, 35409844, 35409845, 35409847, 35409848, 35409849, 35409851, 35409852, 35409853, 35416153, 35416154, 35452819, 35453000, 35461486, 35480117, 35480118, 35480946, 35480947, 35480948, 35480949,	12-May-2028 thru 24-Dec-2028

			<p>35484493, 35484494, 35487378, 35487379, 35501516, 35501517, 35514615, 35514616, 35514617, 35515702, 35517161, 35519704, 35545687, 35545688, 35545689, 35545690, 35545691, 35546819, 35547736, 35547737, 35551690, 35551691, 35551692, 35565638, 35565640, 35565641, 35565642, 35565643, 35569825, 35569826, 35569827, 35594002, 35626901, 35665247, 35667601, 35667602, 35671453, 35671454, 35671455, 35671456, 35671457, 35673280, 35890013, 35890014, 35895660, 35895661, 35901388, 35901389, 35921353, 35921354, 35921355, 35921356, 35942368, 35998696, 35998697, 35998698, 36001798, 36001799, 36002640, 36009902, 36009903, 36009904, 36009905, 36012794, 36043495, 36043496, 36056678, 36056679, 36056960, 36056961, 36056964, 36058844, 36058845, 36058846, 36058847, 36063287, 36063288, 36063290, 36068087, 36068088, 36068089, 36068090, 36095403, 36095404, 36095405, 36095406, 36096639, 36101301, 36101302, 36101699, 36102320, 36102321, 36102324, 36102325, 36103434, 36103435, 36103436, 36105447, 36105448, 36111547, 36111548, 36111549, 36111551, 36111552, 36112953, 36112954, 36112955, 36112956, 36112957, 36121884, 36138616, 36138617, 36138800, 36138804, 36138805, 36159666, 36159667, 36159668, 36159669, 36159670, 36159672, 36159673, 36164841, 36164842, 36164843, 36169145, 36169146, 36169147, 36169148, 36169867, 36169868, 36169869, 36173875, 36173876, 36179702, 36179703, 36180136, 36193169, 36193170, 36193171, 36193172, 36193173, 36195518, 36195519, 36195580, 36195581, 36195582, 36205168, 36205169, 36208940, 36208941, 36209024, 36209025, 36209424, 36224696, 36224697, 36234046, 36234047, 36234048, 36498257, 36498258, 36498259, 36501127, 36586444, 36586445, 36586446, 36586447, 36588495, 36588497, 36591213, 36591214, 36593068, 36593069, 36607567, 36640275, 36640276, 36640277, 36679166, 36683542, 36688773, 36688774, 36698998, 36698999, 36711322, 36711323, 36787078, 36789908, 36789909, 36796820, 36800990, 36803152, 36834285</p>	
H965SCH647130	CAROTID WALLSTENT MONORAIL 10.0-31	08714729263913	<p>35258275, 35258276, 35258277, 35258278, 35258279, 35260230, 35260231, 35261618, 35261619, 35264188, 35264189, 35264190, 35264191, 35264192, 35266488, 35266489, 35268647, 35268648, 35278746, 35281326, 35281327, 35285493, 35285494, 35285495, 35285496, 35285497, 35285498, 35285499, 35285920, 35286196, 35286197, 35286198, 35286199, 35286540, 35287317, 35287319, 35287401, 35289015, 35289303, 35293059, 35293160, 35293161, 35293162, 35293163, 35293812, 35293813, 35293815, 35293816, 35320520, 35320521, 35320522, 35320523, 35320525, 35325953, 35325954, 35325955, 35329088, 35329090, 35329091, 35329092, 35329093, 35329094, 35329095, 35329096, 35329544, 35329545, 35329546, 35329547, 35329548, 35329549, 35329968, 35329969, 35329970, 35329971, 35330502, 35336128, 35336129,</p>	12-May-2028 thru 25-Dec-2028

35336130, 35336131, 35341680, 35353660, 35353661, 35353662, 35353663, 35353664, 35361464, 35361465, 35361466, 35361467, 35381985, 35382290, 35382291, 35383353, 35383354, 35383355, 35383356, 35383357, 35383358, 35383359, 35383620, 35383622, 35383623, 35386372, 35386373, 35386374, 35409855, 35409856, 35409857, 35409858, 35416156, 35416157, 35416158, 35416159, 35416460, 35416461, 35416462, 35416463, 35416464, 35416465, 35416466, 35416467, 35416468, 35416469, 35416470, 35422921, 35422928, 35422929, 35422930, 35424325, 35424326, 35424327, 35424328, 35424329, 35424330, 35424331, 35424332, 35424333, 35424335, 35424336, 35424337, 35424338, 35424339, 35428634, 35428635, 35428636, 35428637, 35428638, 35428639, 35438650, 35438651, 35461489, 35462384, 35462385, 35462386, 35462387, 35462388, 35480950, 35480951, 35480952, 35480953, 35480955, 35480956, 35484496, 35484497, 35484498, 35501518, 35501519, 35501920, 35501921, 35501922, 35501923, 35525176, 35525177, 35525806, 35525807, 35530632, 35530633, 35530634, 35531679, 35531880, 35533597, 35533598, 35533599, 35534100, 35534101, 35534102, 35553908, 35553909, 35553910, 35553911, 35553937, 35553938, 35556848, 35556849, 35569824, 35570978, 35570979, 35571040, 35571538, 35571539, 35574379, 35574500, 35574501, 35574502, 35574503, 35578673, 35578674, 35578675, 35594949, 35623467, 35623468, 35626636, 35626637, 35626638, 35626639, 35626900, 35627523, 35627524, 35630022, 35630023, 35632452, 35632454, 35632455, 35632638, 35632639, 35633487, 35633492, 35633901, 35633903, 35636548, 35636549, 35636550, 35636551, 35667603, 35668453, 35668454, 35671444, 35671445, 35671447, 35671448, 35671449, 35673282, 35673283, 35677031, 35777662, 35777664, 35781899, 35782160, 35782161, 35782162, 35782163, 35782164, 35873344, 35873345, 35881810, 35881811, 35881812, 35881813, 35884601, 35884602, 35890010, 35901386, 35901387, 35904064, 35904065, 35942369, 35964011, 35964012, 35964013, 35964014, 35985601, 35985602, 36012795, 36012796, 36012797, 36012798, 36012799, 36012980, 36032984, 36068091, 36068092, 36105449, 36105450, 36105451, 36106593, 36106594, 36106595, 36106596, 36109872, 36109874, 36111550, 36116121, 36116122, 36116123, 36119507, 36119508, 36121880, 36121881, 36121882, 36121885, 36121886, 36124483, 36124484, 36130876, 36130877, 36130878, 36130879, 36131000, 36132932, 36132933, 36132934, 36132935, 36132936, 36132937, 36144149, 36144150, 36144151, 36144152, 36144153, 36144154, 36144155, 36144156, 36148525, 36148526, 36148823, 36148825, 36148827, 36148829, 36148830, 36154096, 36154097, 36154098, 36154099, 36154980, 36154981, 36154982, 36154983, 36154984, 36154985, 36154987, 36164844, 36164845, 36164846, 36164847, 36173877, 36173878, 36173879, 36174740, 36174741, 36174742,

			<p>36174743, 36174744, 36180137, 36180138, 36185918, 36185919, 36186400, 36186401, 36186402, 36186403, 36187901, 36187903, 36187904, 36187905, 36187906, 36194716, 36195042, 36200119, 36200760, 36202408, 36202409, 36205165, 36205166, 36212469, 36214814, 36214815, 36214816, 36219092, 36219093, 36219094, 36219095, 36219096, 36422415, 36422416, 36422417, 36516037, 36516038, 36516039, 36518684, 36518685, 36518686, 36518687, 36518688, 36518689, 36518690, 36518691, 36518693, 36520868, 36593070, 36593071, 36595822, 36595823, 36595824, 36595825, 36597571, 36597572, 36597573, 36597574, 36603361, 36603364, 36603365, 36603366, 36605707, 36606062, 36606063, 36606064, 36606065, 36606066, 36606067, 36606068, 36606069, 36640278, 36640279, 36641940, 36641941, 36642785, 36644287, 36644288, 36644752, 36644753, 36644754, 36664959, 36664987, 36664990, 36666077, 36666520, 36666522, 36666524, 36669032, 36669035, 36669036, 36669037, 36699060, 36699061, 36700303, 36712756, 36717599, 36717900, 36717901, 36717902, 36717903, 36717904, 36722328, 36722330, 36750320, 36750321, 36750322, 36750323, 36750324, 36752754, 36752755, 36752756, 36752758, 36752759, 36752900, 36766975, 36766976, 36766977, 36768310, 36768752, 36768753, 36773943, 36795889, 36795890, 36800991, 36800992, 36803691, 36804582, 36811474, 36811478, 36811479, 36812060, 36813561, 36813562, 36815619, 36815667, 36817342, 36844079</p>	
H965SCH647140	CAROTID WALLSTENT MONORAIL 10.0-37	08714729263920	<p>35272289, 35272290, 35278747, 35278748, 35293817, 35293818, 35293819, 35309703, 35309704, 35309705, 35309706, 35320537, 35329976, 35329978, 35329979, 35341681, 35341682, 35344559, 35345321, 35345329, 35347267, 35347268, 35347269, 35383621, 35386679, 35386780, 35386781, 35388276, 35388277, 35428800, 35428801, 35428802, 35428803, 35484499, 35489527, 35489530, 35489533, 35496534, 35496535, 35496536, 35525178, 35530635, 35560220, 35560221, 35560222, 35566231, 35625591, 35625592, 35641157, 35641460, 35677035, 35677036, 35677037, 35677038, 35682786, 35682787, 35682788, 35682789, 35682790, 35682791, 35778251, 35778252, 35987778, 35987779, 36066437, 36066438, 36072052, 36072851, 36072852, 36072854, 36105453, 36115283, 36115284, 36124482, 36132938, 36132939, 36133160, 36134809, 36154986, 36159663, 36164696, 36164697, 36164698, 36164699, 36179704, 36179705, 36179706, 36195056, 36202763, 36205164, 36213495, 36213496, 36213572, 36213573, 36213574, 36213575, 36498341, 36501128, 36501129, 36606591, 36652845, 36652846, 36773180, 36773181, 36773182, 36775992, 36775994, 36818514, 36818515</p>	14-May-2028 thru 22-Dec-2028

M001719000	CAROTID WALLSTENT MR 6X22 5F 135CM	08714729781165	35438655, 35438656, 35438657, 35641993, 35641994, 36053998, 36053999, 36223361, 36223362, 36348206, 36523368, 36616127, 36777256	6-June-2028 thru 16-Dec-2028
M001719010	CAROTID WALLSTENT MR 8X21 5F 135CM	08714729781189	35252807, 35307515, 35307516, 35355536, 35450114, 35450115, 35504179, 35504200, 35504201, 35571041, 35583635, 35583636, 35583637, 36223363, 36223364, 36224129, 36224132, 36224133, 36230818, 36297515, 36297516, 36297518, 36297761, 36368141, 36368142, 36412855, 36475475, 36539307, 36616133, 36616134, 36739202	11-May-2028 thru 11-Dec-2028
M001719020	CAROTID WALLSTENT MR 8X29 5F 135CM	08714729781202	35252812, 35343568, 35343569, 35343570, 35343572, 35355537, 35379661, 35406002, 35476349, 35480115, 35480116, 35542648, 35560230, 35560231, 35629995, 35629996, 35629997, 35636546, 35636547, 35662002, 35662003, 35961401, 35961402, 35961403, 35961404, 35961405, 35970484, 35972013, 35977619, 36006440, 36007615, 36007616, 36007618, 36271662, 36271663, 36271664, 36271665, 36271666, 36275712, 36275713, 36275714, 36275715, 36275716, 36299150, 36299151, 36299152, 36299153, 36299154, 36306787, 36306788, 36397121, 36397122, 36453791, 36453792, 36453793, 36453795, 36475476, 36552375, 36552376, 36565457, 36617888, 36630791, 36633072, 36635526, 36767805, 36767806	11-May-2028 thru 15-Dec-2028
M001719030	CAROTID WALLSTENT MR 8X36 5F 135CM	08714729781226	35343573, 35347264, 35379662, 35476961, 35476962, 35545686, 35550309, 35550605, 35589532, 35664483, 35749224, 35980332, 35980333, 35997086, 36018043, 36078429, 36087098, 36087099, 36087540, 36096632, 36096633, 36347227, 36397123, 36416430, 36416431, 36563911, 36565458, 36565459, 36635532, 36635533	23-May-2028 thru 27-Nov-2028
M001719040	CAROTID WALLSTENT MR 10X24 5.9F 135CM	08714729781103	35281323, 35281324, 35281325, 35324570, 35324571, 35416155, 35484495, 35547738, 35623469, 36113886, 36113887, 36115281, 36115282, 36124259, 36124480, 36124481, 36169150, 36209425, 36498340, 36711739, 36712757, 36713869	15-May-2028 thru 8-Dec-2028
M001719050	CAROTID WALLSTENT MR 10X31 5.9F 135CM	08714729781127	35293814, 35295923, 35347265, 35347266, 35388278, 35485560, 35553939, 35641991, 35682792, 35939213, 35939214, 35939215, 35939216, 36065524, 36065525, 36065526, 36148529, 36148532, 36508770, 36606592, 36771557, 36817706	16-May-2028 thru 22-Dec-2028
M001719060	CAROTID WALLSTENT MR 10X37 5.9F 135CM	08714729781141	35310697, 35315981, 35315982, 35347270, 35388279, 35496537, 35566234, 35682793, 35978123, 36043781, 36105452, 36159664, 36159665, 36164840, 36498342	19-May-2028 thru 10-Nov-2028



RECALL REMOVAL REPLY VERIFICATION TRACKING FORM
PRODUCT NAME: Carotid WALLSTENT

Instructions: This form must be completed and returned in all cases even if you do not have any affected product.

Account #:		Customer Name:			
Contact Name:					
Address:					
City:		State:	Province:	Postal Code:	
Country:					

Our records indicate you have received the following affected product:

UPN/Material Number	Lot/Batch/Serial Number	Quantity Shipped	Shipment Date	P.O. Number	Quantity Single Units to be Returned
---------------------	-------------------------	------------------	---------------	-------------	--------------------------------------

Section to be filled out by Customer:

1. Please Indicate:

We have checked all areas where affected product could be located and have determined we do not have any affected product.

OR

We have found affected product and have quarantined as instructed in this Recall Notification. Please indicate the quantity to be returned (in single units) in the above table. To return affected product, follow the instructions provided within this notification or from your (country) local office.

Please also indicate:

Are you a Distributor? Yes, and we have notified all customers that have been shipped/sold affected product
 No

2. Sign and Date to acknowledge this Field Action Notification (must be completed):

Print Name: _____ Signature: _____ Date: _____

THESE DOCUMENTS ARE THE PROPERTY OF BOSTON SCIENTIFIC CORPORATION AND SHALL NOT BE REPRODUCED, DISTRIBUTED, DISCLOSED OR USED FOR MANUFACTURE OR SALE OF APPARATUS WITHOUT THE EXPRESS WRITTEN CONSENT OF BOSTON SCIENTIFIC CORPORATION.