

<Hospital_Name>

<Users_Name>

<Department>

<Customer_Address>

<Zip_Code> <City>

<Country_Name>

<Reference: 97434080-FA>

7 July 2025

Urgent Field Safety Notice - Urgent Medical Device Recall Carotid WALLSTENT™ Monorail Endoprosthesis

Dear Materials Manager and/or Healthcare Provider,

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.

Our records indicate that your facility has received some of the concerned product. **The table below (Attachment 1) 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 <Customer_Service_Fax_Number> on or before **30 July 2025**.

4- If you have products to return, please package them in an appropriate shipping box. **After receipt of the Verification Form, Boston Scientific will contact you to arrange return.**

5- Please pass this notice to any health 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.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,



Scott Heineman
Vice President, Global Quality
Boston Scientific Corporation

Attachment: Verification Form

Reference: 97434080-FA

7. juli 2025

Vigtig sikkerhedsmeddelelse – Vigtig meddelelse om tilbagekaldelse af medicinsk udstyr Carotid WALLSTENT™ Monorail-endoprotease

Kære materialeansvarlig og/eller sundhedsudbyder

Boston Scientific har startet en tilbagekaldelse af visse batcher af Carotid WALLSTENT™ Monorail-endoproteseenheder (Carotid WALLSTENT) på grund af en stigning i antallet af klager, hvor læger beskrev større modstand end forventet, når de forsøgte at trække stentindføringssystemet (SDS) ud af guidewiren eller den emboliske beskyttelsesenhed (EPD) efter vellykket stentanlæggelse.

De berørte enhedsbatcher, som er vist i bilag 1, blev fremstillet med udstyrsindstillinger, der førte til en utilsigtet ændring, hvilket resulterede i, at den indre guidewirelumen var smallere end de angivne dimensioner. Denne ændring i guidewirens lumendimension forårsager begrænset guidewirebevægelse i de berørte batcher. Boston Scientific har korrigeret produktionsudstyret.

Udstyrsbeskrivelse

Carotid WALLSTENT består af en stent og et indføringssystem. Stentens rolle er at skabe et åbent lumen, så blodgennemstrømningen til halspulsåren genoprettes. Indføringskateterets funktion er at fremføre den ikke-udfoldede stent over en guidewire til den ønskede læsion og anlægge stenten.

Klinisk effekt

På grund af begrænsningen af guidewirens lumen resulterer den manglende evne til at trække stentindføringssystemet ud i behovet for at fjerne stentindføringssystemet og EPD'en som et system, mens EPD'en stadig er anlagt. Hvis EPD'urenheder, kan disse løsne sig og løbe ud i blodbanen med deraf følgende embolisering i den cerebrale vaskulatur. Selvom det ikke er observeret i nogen af de hidtil rapporterede klager, ville den mest alvorlige potentielle helbredsrisiko være en livstruende cerebrovaskulær hændelse (CVA)/et stroke.

Derudover kan der være vanskeligheder med at trække den anlagte EPD tilbage gennem halspulsåren og Carotid WALLSTENT, hvilket kan resultere i karskade, karspasmer eller en ødelagt/beskadiget stent, hvilket nødvendiggør yderligere endovaskulære eller kirurgiske indgreb.

Den mest almindelige helbredsrisiko, der observeres som følge af dette problem, er en forsinkelse af indgrebet ud over den forventede tidsramme. Dette kan forekomme, når stentindføringssystemet og guidewiren/EPD-systemet fjernes, og adgangen gennem den stentede halspulsåre mistes, hvilket potentielt kræver udskiftning af guidewireadgangen gennem læsionen for at fuldføre indgrebet. Hvis adgang til guidewiren gennem Carotid WALLSTENT er påkrævet, er der risiko for, at guidewiren ikke passerer gennem stentens sande lumen, hvilket kan resultere i skade på karret eller en ødelagt stent. Dette kan nødvendiggøre yderligere endovaskulære eller kirurgiske indgreb.

Der er ikke behov for yderligere specifik patientbehandling relateret til ovennævnte problem, hvis Carotid WALLSTENT er blevet anlagt med succes, og indgrebet er blevet gennemført. Standardbehandling efter indgrebet er passende.

Ifølge vores oplysninger har din organisation modtaget mindst ét af de berørte produkter. **Nedenstående tabel (bilag 1) er en komplet liste over alle de berørte produkter**, inklusive produktbeskrivelse, produktnummer (UPN), GTIN og lot-/batchnummer samt udløbsdato. Bemærk venligst, at det **kun er det nedenfor anførte udstyr, der er berørt. Ingen andre produkter fra Boston Scientific er berørt af denne sikkerhedsrelaterede meddelelse.**

Yderligere distribution eller brug af et produkt, der er berørt af denne tilbagekaldelse, skal omgående indstilles.

VEJLEDNING:

1. I bedes med øjeblikkelig virkning indstille brugen af de Boston Scientific-produkter, der er angivet på listen, og fjerne alle de berørte produkter fra jeres lagerbeholdning, uanset hvor de opbevares hos jer, og placere dem et sikkert sted, indtil de kan returneres til Boston Scientific.

2. Udfyld den vedhæftede bekræftelsesformular, også selv om der ikke findes produkter, der skal returneres.

3. I bedes returnere den udfyldte bekræftelsesformular til dit Boston Scientific-kontor. Bekræftelsesformularen skal være stilet til <Customer_Service_Fax_Number> og skal indsendes senest den **30. juli 2025**.

4. Hvis I har produkter, der skal returneres, skal de emballeres forsvarligt. Når vi har modtaget bekræftelsesformularen, bliver I kontaktet af en repræsentant for Boston Scientific med henblik på at træffe aftale vedrørende returnering.

5. Send denne meddelelsen videre til alt sundhedspersonale i jeres institution, der skal være bekendt med dette, og til enhver organisation, hvortil de muligt berørte produkter er videresendt (hvis relevant). Giv Boston Scientific nærmere oplysninger om eventuelle berørte produkter, der måtte være blevet videresendt til andre organisationer (hvis det er relevant).

De ansvarlige myndigheder er blevet informeret om denne sikkerhedsrelaterede meddelelses indhold.

Vi beklager enhver ulejlighed, dette har måttet medføre, og vi sætter pris på din forståelse, da vi handler for at sikre patienternes sikkerhed og vores kunders tilfredshed.

Hvis I har spørgsmål eller behov for hjælp vedrørende denne sikkerhedsrelaterede meddelelse, kan I kontakte den lokale salgsrepræsentant.

Med venlig hilsen



Scott Heineman
Vice President, Global Quality
Boston Scientific Corporation

Vedhæftede filer: Bekræftelsesformular

Bilag 1 – Liste over berørte enheder

Produktnummer (UPN)	Materiale- beskrivelse	GTIN	Batch	Udløbsdato (interval)
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. maj 2028 til 8. december 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. maj 2028 til 22. december 2028
H749391506220	CAROTID WALLSTENT MONORAIL 6.0-22	08714729781158	35582211, 35750408, 35947814, 35947815, 35950476, 36009906, 36292862, 36397124, 36652844	9. juli 2028 til 30. november 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. maj 2028 til 16. december 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, 35951083, 35961400, 35978120, 36320917, 36320918, 36320919, 36321560, 36322143, 36458848, 36458849, 36458850, 36458851, 36458852, 36465397, 36465398, 36465399, 36505552, 36505553, 36607622, 36683540, 36792075	22. maj 2028 til 18. december 2028
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,	23. maj 2028 til 17. december 2028

			36348203, 36348204, 36357034, 36357035, 36357037, 36402896, 36402897, 36469383, 36469384, 36469385, 36493671, 36515107, 36609942, 36609943, 36609944, 36717345, 36722322, 36769772, 36769773, 36787067	
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, 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,	8. maj 2028 til 17. december 2028

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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,	15. maj 2028 til 22. december 2028

			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	
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, 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,	12. maj 2028 til 24. december 2028

			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, 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	
H965SCH647140	CAROTID WALLSTENT MONORAIL 10.0-37	08714729263920	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	14. maj 2028 til 22. december 2028

M001719000	CAROTID WALLSTENT MR 6X22 5F 135CM	08714729781165	35438655, 35438656, 35438657, 35641993, 35641994, 36053998, 36053999, 36223361, 36223362, 36348206, 36523368, 36616127, 36777256	6. juni 2028 til 16. december 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. maj 2028 til 11. december 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. maj 2028 til 15. december 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. maj 2028 til 27. november 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. maj 2028 til 8. december 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. maj 2028 til 22. december 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. maj 2028 til 10. november 2028

<Sold_to> - <Hospital_Name> - <City> - <Country_Name>

Udfyld formularen, også selv om der ikke findes berørte produkter, og send den til den lokale afdeling:
<Customer_Service_Fax_Number>

Bekræftelsesformular – vigtig meddelelse om tilbagekaldelse af medicinsk udstyr
Carotid WALLSTENT™ Monorail-endoprotease
97434080-sikkerhedsrelateret korrigerende handling

1. Vi bekræfter at have modtaget den vigtige sikkerhedsrelaterede meddelelse fra Boston Scientific dateret dateret den 7. juli 2025.

2. **Ifølge Boston Scientifics oplysninger har I modtaget nedenstående berørte produkt (sammenhold produkterne i jeres produktbeholdning med produkterne på den medfølgende fuldstændige liste over berørte produkter).**

Produktnummer (UPN)	Lot-/partinummer	Kundens købsordrenummer	Antal sendt	Antal, der skal returneres (antal produkter)

3. Vi bekræfter, at alle områder, hvor det berørte produkt kunne tænkes at være, er blevet kontrolleret.

4. **SÆT KRYDS UD FOR ET AF NEDENSTÅENDE UDSAGN*, UNDERSKRIV DENNE FORMULAR**, og send den til
 <Customer_Service_Fax_Number>

- ☐ Vi har ikke fundet nogen berørte produkter.
- ☐ Vi har fundet et eller flere af de berørte produkter: Angiv det antal, der skal returneres, ovenfor. Hvis I returnerer et andet produkt end det, der er angivet ovenfor, bedes I angive UPN, lot-/parti-/serienummer og det antal, der skal returneres.

RETURNERING AF PRODUKTER:

- Når vi har modtaget bekræftelsesformularen, bliver I kontaktet af en repræsentant for Boston Scientific med henblik på at træffe aftale vedrørende returnering.
- Klargør pakken
- Følg den lokale afdelings anvisninger vedrørende afhentning af pakken

NAME* _____ Stilling _____

Telefonnummer: _____ E-mailadresse: _____

Kundens
DATO* _____
 * Skal udfyldes

UNDERSKRIFT* _____

dd/mm/åååå