

<Hospital\_Name>

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<Customer\_Address>

<Zip\_Code> <City>

<Country\_Name>

<Referenca: 97434080-FA>

7. srpnja 2025.

## Hitna obavijest o sigurnosti uporabe uređaja – Hitno povlačenje medicinskog proizvoda Endoproteza Carotid WALLSTENT™ Monorail

Poštovani voditelju materijala i/ili pružatelju zdravstvene skrbi,

tvrtka Boston Scientific pokreće povlačenje određenih serija proizvoda endoproteza Carotid WALLSTENT™ Monorail (Carotid WALLSTENT) zbog porasta broja primljenih pritužbi u kojima liječnici opisuju veći otpor od očekivanog pri pokušaju izvlačenja/uvlačenja sustava za isporuku stenta (engl. stent delivery system, SDS) iz žice vodilice ili uređaja za zaštitu od embolije (engl. embolic protection device, EPD) nakon uspješne implementacije stenta.

Serije proizvoda na koje se ovo odnosi, prikazane u Prilogu 1., proizvedene su s postavkama opreme koje su dovele do neželjene promjene, što je rezultiralo time da je unutarnji lumen žice vodilice uži od specificiranih dimenzija. Ova promjena veličine lumena žice vodilice uzrokuje ograničeno kretanje žice vodilice u zahvaćenim serijama. Tvrtka Boston Scientific ispravila je opremu za proizvodnju.

### Opis proizvoda

Carotid WALLSTENT sastoji se od stenta i sustava za isporuku. Uloga stenta je osigurati prohodnost lumena radi ponovne uspostave protoka krvi u karotidnoj arteriji. Funkcija katetera za isporuku jest pomicanje nepostavljenog stenta preko žice vodilice do lokacije željene lezije i postavljanje stenta.

### Klinički utjecaj

Zbog suženja lumena žice vodilice onemogućeno je izvlačenje SDS-a, što zahtijeva uklanjanje SDS-a i EPD-a kao sustava dok je EPD još postavljen. Ako EPD sadrži ostatke, postoji mogućnost da se oni otpuste i uđu u krvotok s posljedičnom embolizacijom u moždane krvne žile. Iako takvi slučajevi do sada nisu zabilježeni u pritužbama, najozbiljnija potencijalna posljedica štetna za zdravlje bila bi cerebrovaskularni inzult (engl. cerebrovascular accident, CVA) / moždani udar opasan po život.

Također, može doći do poteškoća prilikom uvlačenja postavljenog EPD-a kroz karotidnu arteriju i Carotid WALLSTENT, što može rezultirati ozljedom krvne žile, spazmom krvne žile ili disrupcijom (engl. disruption) / oštećenjem stenta, za što mogu biti potrebne dodatne endovaskularne ili kirurške intervencije.

Najčešća posljedica ovog problema štetna za zdravlje jest produženje trajanja zahvata izvan očekivanog vremenskog okvira. To se može dogoditi kada se SDS i sustav žice vodilice / EPD-a uklone i izgubi se pristup kroz stentiranu karotidnu arteriju, što može zahtijevati ponovno uspostavljanje pristupa žicom vodilicom kroz leziju kako bi se dovršio zahvat. Ako je potrebno uvesti žicu vodilicu kroz Carotid WALLSTENT, postoji mogućnost da žica vodilica ne prođe kroz pravi lumen stenta, što može rezultirati ozljedom krvne žile ili disrupcijom (engl. disruption) stenta. To može zahtijevati dodatne endovaskularne ili kirurške intervencije.

Ako je Carotid WALLSTENT uspješno postavljen i zahvat je dovršen, nije potrebna dodatna specifična obrada pacijenta vezana uz prethodno opisani problem. Standardna postoperativna njega je dovoljna.

Prema našoj evidenciji, vaša je ustanova primila neke od zahvaćenih proizvoda. **U tablici u nastavku (Prilog 1.) nalazi se cjeloviti popis svih zahvaćenih proizvoda**, uključujući opis proizvoda, broj materijala (univerzalni broj proizvoda (UPN)), broj GTIN, brojeve lota / serije i datum isteka roka trajanja. Imajte na umu **da su zahvaćeni samo proizvodi koji su navedeni u nastavku. Nijedan drugi proizvod tvrtke Boston Scientific nije uključen u ovu obavijest o sigurnosti uporabe uređaja.**

**Treba odmah prekinuti daljnju distribuciju ili uporabu bilo kojeg preostalog proizvoda koji je zahvaćen ovom radnjom.**

#### **UPUTE:**

1- **Odmah prekinite s uporabom proizvoda tvrtke Boston Scientific navedenog na popisu i uklonite sve zahvaćene jedinice iz svog inventara**, neovisno o lokaciji tih jedinica u vašoj ustanovi. Izdvojite jedinice na sigurno mjesto do povratka tvrtki Boston Scientific.

2- **Ispunite priloženi Obrazac za provjeru čak i ako nemate nijedan proizvod koji treba vratiti.**

3- **Ispunjeni Obrazac za provjeru pošaljite natrag u lokalnu podružnicu tvrtke Boston Scientific**, na pažnju <Customer\_Service\_Fax\_Number>, najkasnije **30. srpnja 2025.**

4- **Ako trebate vratiti proizvode**, zapakirajte ih u odgovarajuću kutiju za slanje. **Po primitku Obrasca za provjeru tvrtka Boston Scientific obratit će vam se radi dogovora o povratu.**

5- **Prosljedite ovu obavijest svim zdravstvenim djelatnicima u vašoj organizaciji koji trebaju biti upoznati s njom kao i svim organizacijama u koje su preneseni potencijalno zahvaćeni proizvodi (ako je potrebno).** Tvrtki Boston Scientific dostavite pojedinosti o bilo kojim zahvaćenim proizvodima koji su preneseni u druge organizacije (ako je potrebno).

Vaše nadležno tijelo bit će obaviješteno o ovoj obavijesti o sigurnosti uporabe uređaja.

Žao nam je zbog neugodnosti koje ova radnja može izazvati i cijenimo vaše razumijevanje za naše osiguravanje sigurnosti pacijenata i zadovoljstva korisnika.

Ako imate bilo kakvih pitanja ili vam je potrebna pomoć u vezi s ovom obavijesti o sigurnosti uporabe uređaja, obratite se svom lokalnom prodajnom predstavniku.

Srdačan pozdrav,



Scott Heineman  
Potpredsjednik, Globalni odjel za kvalitetu  
Boston Scientific Corporation

Prilog: Obrazac za provjeru

## Prilog 1. – Popis zahvaćenih proizvoda

| UPN materijala | Opis materijala                    | GTIN           | Serija                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Raspon rokova valjanosti                   |
|----------------|------------------------------------|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| 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                                                                                                                                                                                                                                                                                                                       | Od 14. svibnja 2028. do 8. prosinca 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 | Od 16. svibnja 2028. do 22. prosinca 2028. |
| H749391506220  | CAROTID WALLSTENT MONORAIL 6.0-22  | 08714729781158 | 35582211, 35750408, 35947814, 35947815, 35950476, 36009906, 36292862, 36397124, 36652844                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Od 9. srpnja 2028. do 30. studenog 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Od 23. svibnja 2028. do 16. prosinca 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                                                                                                                                                                                                                                                                                                                                                     | Od 22. svibnja 2028. do 18. prosinca 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,                                                                                                                                                                                                                                                                                                                                          | Od 23. svibnja 2028. do 17. prosinca 2028. |

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| H965SCH647070 | CAROTID<br>WALLSTENT<br>MONORAIL<br>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, | Od 8. svibnja<br>2028. do 17.<br>prosinca 2028. |



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|               |                                            |                | 36413024, 36413025, 36413026, 36413027, 36413028,<br>36413029, 36413030, 36413031, 36413032, 36415159,<br>36416042, 36416043, 36416044, 36416334, 36416335,<br>36416336, 36416337, 36416338, 36416339, 36416420,<br>36422413, 36422414, 36422598, 36422599, 36423963,<br>36423964, 36423965, 36423995, 36423996, 36447747,<br>36447748, 36447749, 36448144, 36448145, 36448156,<br>36448157, 36449975, 36449976, 36449977, 36453798,<br>36455025, 36455026, 36458843, 36458844, 36458845,<br>36458846, 36458847, 36480348, 36480349, 36480350,<br>36480351, 36485714, 36485715, 36485716, 36485717,<br>36485718, 36485719, 36485800, 36485801, 36485802,<br>36485803, 36485851, 36485852, 36491169, 36491170,<br>36491171, 36491172, 36491173, 36491174, 36493672,<br>36493673, 36493674, 36493675, 36493676, 36493677,<br>36498253, 36498254, 36498255, 36501125, 36508768,<br>36508771, 36508772, 36508773, 36508774, 36525439,<br>36529070, 36529071, 36529072, 36529073, 36529074,<br>36529075, 36529076, 36529077, 36529078, 36529079,<br>36535347, 36535348, 36535349, 36535352, 36535353,<br>36535354, 36535355, 36539304, 36539306, 36545277,<br>36545278, 36545279, 36545760, 36545761, 36548829,<br>36548830, 36552374, 36553653, 36553654, 36553655,<br>36554562, 36554563, 36554564, 36554565, 36554566,<br>36555138, 36560052, 36560053, 36560054, 36560055,<br>36560056, 36566126, 36566127, 36566128, 36566129,<br>36567621, 36571196, 36571197, 36571198, 36571199,<br>36571780, 36571781, 36572200, 36572201, 36572202,<br>36572203, 36572204, 36574800, 36574801, 36574802,<br>36575688, 36575689, 36575690, 36577074, 36577075,<br>36578325, 36578327, 36578328, 36582969, 36586443,<br>36618329, 36620780, 36620781, 36620782, 36620783,<br>36620784, 36620785, 36620786, 36620787, 36620788,<br>36625778, 36625779, 36626060, 36626061, 36626062,<br>36626063, 36626064, 36626065, 36626066, 36626067,<br>36630781, 36630782, 36630783, 36630784, 36630785,<br>36630786, 36630787, 36630788, 36630789, 36630790,<br>36645417, 36645418, 36645419, 36673680, 36673681,<br>36673682, 36673683, 36675542, 36675543, 36675545,<br>36675546, 36675547, 36675549, 36675550, 36675551,<br>36675552, 36678442, 36678443, 36678444, 36678445,<br>36678446, 36678447, 36678448, 36683541, 36688432,<br>36688433, 36688434, 36712751, 36717343, 36738231,<br>36738232, 36739201, 36739203, 36739206, 36739207,<br>36739208, 36739209, 36741080, 36741081, 36742784,<br>36742785, 36742786, 36742787, 36742788, 36742789,<br>36748006, 36748007, 36748008, 36749662, 36749663,<br>36761491, 36761492, 36765445, 36765446, 36767807,<br>36784206, 36785292, 36785384, 36785385, 36787969,<br>36787970, 36787971, 36788799, 36792076, 36792077,<br>36793502, 36793503, 36793678, 36793679, 36795349,<br>36795350, 36795351, 36799042, 36799043, 36801653,<br>36803154, 36803155, 36817363, 36818518, 36818519 |                                                  |
| H965SCH647090 | CAROTID<br>WALLSTENT<br>MONORAIL<br>8.0-36 | 08714729263890 | 35284214, 35284216, 35284217, 35296025, 35296026,<br>35296027, 35307517, 35309535, 35309536, 35313433,<br>35313434, 35313435, 35343571, 35376080, 35376081,<br>35376082, 35376083, 35395628, 35395629, 35395630,<br>35406003, 35452838, 35471394, 35471395, 35471396,<br>35471397, 35471398, 35476350, 35476351, 35476352,<br>35476819, 35476960, 35514613, 35541484, 35541485,<br>35541486, 35541487, 35542644, 35542645, 35542646,<br>35542647, 35588888, 35588889, 35588890, 35594003,<br>35600380, 35600381, 35600716, 35600717, 35600718,<br>35663304, 35663305, 35663307, 35663958, 35663959,<br>35664480, 35664482, 35667604, 35749225, 35749227,<br>35749228, 35778247, 35778248, 35778249, 35778250,<br>35893582, 35893583, 35928594, 35928595, 35950473,                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Od 15. svibnja<br>2028. do 22.<br>prosinca 2028. |

|               |                                             |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                  |
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|               |                                             |                | 35950474, 35950475, 35964009, 35964010, 35972012,<br>35980330, 35980331, 36007692, 36007693, 36007694,<br>36007695, 36007696, 36018041, 36018042, 36033496,<br>36033497, 36033498, 36033499, 36033880, 36043497,<br>36043498, 36043499, 36043780, 36055146, 36055147,<br>36055785, 36056677, 36078428, 36097193, 36116118,<br>36116119, 36116120, 36220947, 36322723, 36322724,<br>36328322, 36328323, 36328324, 36341859, 36342380,<br>36342381, 36342382, 36342383, 36342384, 36342385,<br>36342386, 36342387, 36342388, 36347198, 36347199,<br>36347220, 36347221, 36347222, 36347223, 36347224,<br>36347225, 36347226, 36357714, 36357715, 36378272,<br>36378273, 36465500, 36465501, 36469380, 36469381,<br>36469382, 36475477, 36475478, 36508775, 36508776,<br>36513257, 36513258, 36513259, 36513760, 36518682,<br>36518683, 36553656, 36553657, 36553658, 36553659,<br>36554560, 36563910, 36582970, 36582971, 36582972,<br>36582973, 36582974, 36595826, 36595828, 36635529,<br>36635530, 36635531, 36646050, 36646051, 36679165,<br>36688435, 36712758, 36717344, 36795885, 36817573                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                  |
| H965SCH647120 | CAROTID<br>WALLSTENT<br>MONORAIL<br>10.0-24 | 08714729263906 | 35258269, 35258270, 35258273, 35258274, 35260228,<br>35260229, 35265522, 35265523, 35266396, 35266397,<br>35266398, 35266399, 35267871, 35267872, 35272291,<br>35272292, 35273687, 35273688, 35273689, 35274001,<br>35274002, 35274003, 35274004, 35276183, 35276184,<br>35276185, 35276186, 35276187, 35277609, 35278162,<br>35278163, 35278164, 35278165, 35278167, 35281328,<br>35281329, 35289305, 35306610, 35306611, 35306612,<br>35310693, 35310694, 35310695, 35310696, 35315986,<br>35315987, 35315988, 35320538, 35320539, 35324563,<br>35324564, 35324565, 35324566, 35324567, 35324568,<br>35324569, 35376084, 35376085, 35376087, 35380104,<br>35380105, 35380315, 35380316, 35381858, 35381859,<br>35381980, 35381981, 35381982, 35381983, 35381984,<br>35395631, 35395632, 35395633, 35406004, 35406005,<br>35406007, 35406008, 35406009, 35406010, 35409844,<br>35409845, 35409847, 35409848, 35409849, 35409851,<br>35409852, 35409853, 35416153, 35416154, 35452819,<br>35453000, 35461486, 35480117, 35480118, 35480946,<br>35480947, 35480948, 35480949, 35484493, 35484494,<br>35487378, 35487379, 35501516, 35501517, 35514615,<br>35514616, 35514617, 35515702, 35517161, 35519704,<br>35545687, 35545688, 35545689, 35545690, 35545691,<br>35546819, 35547736, 35547737, 35551690, 35551691,<br>35551692, 35565638, 35565640, 35565641, 35565642,<br>35565643, 35569825, 35569826, 35569827, 35594002,<br>35626901, 35665247, 35667601, 35667602, 35671453,<br>35671454, 35671455, 35671456, 35671457, 35673280,<br>35890013, 35890014, 35895660, 35895661, 35901388,<br>35901389, 35921353, 35921354, 35921355, 35921356,<br>35942368, 35998696, 35998697, 35998698, 36001798,<br>36001799, 36002640, 36009902, 36009903, 36009904,<br>36009905, 36012794, 36043495, 36043496, 36056678,<br>36056679, 36056960, 36056961, 36056964, 36058844,<br>36058845, 36058846, 36058847, 36063287, 36063288,<br>36063290, 36068087, 36068088, 36068089, 36068090,<br>36095403, 36095404, 36095405, 36095406, 36096639,<br>36101301, 36101302, 36101699, 36102320, 36102321,<br>36102324, 36102325, 36103434, 36103435, 36103436,<br>36105447, 36105448, 36111547, 36111548, 36111549,<br>36111551, 36111552, 36112953, 36112954, 36112955,<br>36112956, 36112957, 36121884, 36138616, 36138617,<br>36138800, 36138804, 36138805, 36159666, 36159667,<br>36159668, 36159669, 36159670, 36159672, 36159673,<br>36164841, 36164842, 36164843, 36169145, 36169146,<br>36169147, 36169148, 36169867, 36169868, 36169869,<br>36173875, 36173876, 36179702, 36179703, 36180136, | Od 12. svibnja<br>2028. do 24.<br>prosinca 2028. |

|               |                                             |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                  |
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|               |                                             |                | 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                  |
| H965SCH647130 | CAROTID<br>WALLSTENT<br>MONORAIL<br>10.0-31 | 08714729263913 | 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, 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, | Od 12. svibnja<br>2028. do 25.<br>prosinca 2028. |

|               |                                             |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                 |
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|               |                                             |                | 36068092, 36105449, 36105450, 36105451, 36106593,<br>36106594, 36106595, 36106596, 36109872, 36109874,<br>36111550, 36116121, 36116122, 36116123, 36119507,<br>36119508, 36121880, 36121881, 36121882, 36121885,<br>36121886, 36124483, 36124484, 36130876, 36130877,<br>36130878, 36130879, 36131000, 36132932, 36132933,<br>36132934, 36132935, 36132936, 36132937, 36144149,<br>36144150, 36144151, 36144152, 36144153, 36144154,<br>36144155, 36144156, 36148525, 36148526, 36148823,<br>36148825, 36148827, 36148829, 36148830, 36154096,<br>36154097, 36154098, 36154099, 36154980, 36154981,<br>36154982, 36154983, 36154984, 36154985, 36154987,<br>36164844, 36164845, 36164846, 36164847, 36173877,<br>36173878, 36173879, 36174740, 36174741, 36174742,<br>36174743, 36174744, 36180137, 36180138, 36185918,<br>36185919, 36186400, 36186401, 36186402, 36186403,<br>36187901, 36187903, 36187904, 36187905, 36187906,<br>36194716, 36195042, 36200119, 36200760, 36202408,<br>36202409, 36205165, 36205166, 36212469, 36214814,<br>36214815, 36214816, 36219092, 36219093, 36219094,<br>36219095, 36219096, 36422415, 36422416, 36422417,<br>36516037, 36516038, 36516039, 36518684, 36518685,<br>36518686, 36518687, 36518688, 36518689, 36518690,<br>36518691, 36518693, 36520868, 36593070, 36593071,<br>36595822, 36595823, 36595824, 36595825, 36597571,<br>36597572, 36597573, 36597574, 36603361, 36603364,<br>36603365, 36603366, 36605707, 36606062, 36606063,<br>36606064, 36606065, 36606066, 36606067, 36606068,<br>36606069, 36640278, 36640279, 36641940, 36641941,<br>36642785, 36644287, 36644288, 36644752, 36644753,<br>36644754, 36664959, 36664987, 36664990, 36666077,<br>36666520, 36666522, 36666524, 36669032, 36669035,<br>36669036, 36669037, 36699060, 36699061, 36700303,<br>36712756, 36717599, 36717900, 36717901, 36717902,<br>36717903, 36717904, 36722328, 36722330, 36750320,<br>36750321, 36750322, 36750323, 36750324, 36752754,<br>36752755, 36752756, 36752758, 36752759, 36752900,<br>36766975, 36766976, 36766977, 36768310, 36768752,<br>36768753, 36773943, 36795889, 36795890, 36800991,<br>36800992, 36803691, 36804582, 36811474, 36811478,<br>36811479, 36812060, 36813561, 36813562, 36815619,<br>36815667, 36817342, 36844079 |                                                 |
| H965SCH647140 | CAROTID<br>WALLSTENT<br>MONORAIL<br>10.0-37 | 08714729263920 | 35272289, 35272290, 35278747, 35278748, 35293817,<br>35293818, 35293819, 35309703, 35309704, 35309705,<br>35309706, 35320537, 35329976, 35329978, 35329979,<br>35341681, 35341682, 35344559, 35345321, 35345329,<br>35347267, 35347268, 35347269, 35383621, 35386679,<br>35386780, 35386781, 35388276, 35388277, 35428800,<br>35428801, 35428802, 35428803, 35484499, 35489527,<br>35489530, 35489533, 35496534, 35496535, 35496536,<br>35525178, 35530635, 35560220, 35560221, 35560222,<br>35566231, 35625591, 35625592, 35641157, 35641460,<br>35677035, 35677036, 35677037, 35677038, 35682786,<br>35682787, 35682788, 35682789, 35682790, 35682791,<br>35778251, 35778252, 35987778, 35987779, 36066437,<br>36066438, 36072052, 36072851, 36072852, 36072854,<br>36105453, 36115283, 36115284, 36124482, 36132938,<br>36132939, 36133160, 36134809, 36154986, 36159663,<br>36164696, 36164697, 36164698, 36164699, 36179704,<br>36179705, 36179706, 36195056, 36202763, 36205164,<br>36213495, 36213496, 36213572, 36213573, 36213574,<br>36213575, 36498341, 36501128, 36501129, 36606591,<br>36652845, 36652846, 36773180, 36773181, 36773182,<br>36775992, 36775994, 36818514, 36818515                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Od 14. svibnja<br>2028. do 22.<br>prosina 2028. |

|            |                                                |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                  |
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| M001719000 | CAROTID<br>WALLSTENT<br>MR 6X22 5F<br>135CM    | 08714729781165 | 35438655, 35438656, 35438657, 35641993, 35641994, 36053998, 36053999, 36223361, 36223362, 36348206, 36523368, 36616127, 36777256                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Od 6. lipnja<br>2028. do 16.<br>prosina 2028.    |
| M001719010 | CAROTID<br>WALLSTENT<br>MR 8X21 5F<br>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                                                                                                                                                                                                                                                                                                                                                               | Od 11. svibnja<br>2028. do 11.<br>prosina 2028.  |
| M001719020 | CAROTID<br>WALLSTENT<br>MR 8X29 5F<br>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 | Od 11. svibnja<br>2028. do 15.<br>prosina 2028.  |
| M001719030 | CAROTID<br>WALLSTENT<br>MR 8X36 5F<br>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                                                                                                                                                                                                                                                                                                                                                                         | Od 23. svibnja<br>2028. do 27.<br>studenog 2028. |
| M001719040 | CAROTID<br>WALLSTENT<br>MR 10X24<br>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                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Od 15. svibnja<br>2028. do 8.<br>prosina 2028.   |
| M001719050 | CAROTID<br>WALLSTENT<br>MR 10X31<br>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                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Od 16. svibnja<br>2028. do 22.<br>prosina 2028.  |
| M001719060 | CAROTID<br>WALLSTENT<br>MR 10X37<br>5.9F 135CM | 08714729781141 | 35310697, 35315981, 35315982, 35347270, 35388279, 35496537, 35566234, 35682793, 35978123, 36043781, 36105452, 36159664, 36159665, 36164840, 36498342                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Od 19. svibnja<br>2028. do 10.<br>studenog 2028. |

Ispunite obrazac čak i ako nemate nijedan zahvaćeni proizvod i pošaljite ga svojoj lokalnoj podružnici:  
<Customer\_Service\_Fax\_Number>

**Obrazac za provjeru – Hitno povlačenje medicinskog proizvoda**  
**Endoproteza Carotid WALLSTENT™ Monorail**  
**97434080-FA**

1. Potvrđujemo primitak obavijesti o sigurnosti uporabe uređaja tvrtke Boston Scientific od 7. srpnja 2025.
2. **Prema evidenciji tvrtke Boston Scientific, primili ste sljedeći zahvaćeni proizvod (dodatno provjerite inventar i usporedite ga s cjelovitim popisom isporučenih zahvaćenih proizvoda)**

| Material N° (UPN) | Lot / Batch N° | Customer PO | Qty Sent (Box) | Qty to return Units |
|-------------------|----------------|-------------|----------------|---------------------|
| H965SCH647010     | 35549114       | 164         | 1              | 0                   |
| H965SCH647010     | 35558691       | 164         | 2              | 1                   |
| H965SCH647010     | 35911106       | 376         | 2              | 2                   |
| H965SCH647010     | 36012786       | 7032025     | 2              | 2                   |
| H965SCH647010     | 36292870       | 900         | 2              | 2                   |
| H965SCH647070     | 35494158       | 164         | 2              | 0                   |
| H965SCH647070     | 35588884       | 376         | 4              | 1                   |
| H965SCH647070     | 35588886       | 376         | 2              | 1                   |
| H965SCH647070     | 36103433       | 7032025     | 5              | 3                   |
| H965SCH647070     | 36353028       | 900         | 3              | 3                   |
| H965SCH647080     | 35519420       | 164         | 2              | 1                   |
| H965SCH647080     | 35520154       | 74          | 1              | 0                   |
| H965SCH647080     | 35522425       | 164         | 2              | 0                   |
| H965SCH647080     | 35531672       | 376         | 3              | 0                   |
| H965SCH647080     | 35656387       | 7032025     | 4              | 2                   |
| H965SCH647080     | 36553654       | 900         | 2              | 2                   |
| H965SCH647130     | 35462384       | 164         | 1              | 0                   |
| H965SCH647130     | 35480950       | 203         | 2              | 0                   |
| H965SCH647130     | 35480951       | 220         | 2              | 2                   |
| H965SCH647130     | 35501921       | 376         | 6              | 6                   |
| H965SCH647130     | 35881811       | 7032025     | 1              | 1                   |

3. Potvrđujemo da su provjerene sve lokacije na kojima se zahvaćeni proizvod može nalaziti.
4. **OZNAČITE JEDNU OD IZJAVA\***, **POTPISITE OVAJ OBRAZAC** i pošaljite ga na pažnju <Customer\_Service\_Fax\_Number>
- ☐ Ne posjedujemo nijedan zahvaćeni proizvod.
- ☐ Pronašli smo zahvaćeni/e proizvod/e: Količinu za povrat potvrdite gore. Ako vraćate proizvod koji nije prethodno naveden, **dodajte UPN, broj lota / serije / serijski br. i količinu koju treba vratiti.**

**ZA POVRAT PROIZVODA:**

1. Po primitku Obrasca za provjeru tvrtka Boston Scientific obratit će vam se radi dogovora o povratu.
2. Pripremite paket
3. Slijedite upute o prikupljanju paketa koje vam je isporučila lokalna podružnica

IME I PREZIME\* ANDREA CAULINA Funkcija VOĐELEG NABAVE

Broj telefona +385 91 2000813 E-pošta andrea.caulina@pharm-lab.hr

Kupčev POTPIS\* Andrea Caulina **PHARM-LAB d.o.o.**  
\* Obavezno polje Zagreb DATUM\* 17.07.2025.  
dd. mm. gggg.