

<Hospital_Name>

<Users_Name>

<Department>

<Customer_Address>

<Zip_Code> <City>

<Country_Name>

<Referentni broj: 97645673-FA>

SRN: US-MF-000004702

16. rujna 2026.

Hitna sigurnosna obavijest – Hitni opoziv medicinskog proizvoda Direxion™ i Direxion HI-FLO™

Poštovani voditelji materijala i/ili zdravstveni djelatnici,

tvrtka Boston Scientific pokreće opoziv određenih serija mikrokatertera Direxion™ i Direxion HI-FLO™ zbog problema u proizvodnji koji mogu uzrokovati poteškoće pri izvlačenju proizvoda iz obruča nosača i poteškoće pri uvlačenju ili izvlačenju proizvoda kroz vodeći kateter. Ovaj opoziv odnosi se samo na serije navedene u Prilogu 1.

Problem se može otkriti tijekom pripreme i/ili uporabe proizvoda u pacijenta, a pojavljuje se u obliku povećanog otpora između mikrokatertera i ostalih komponenti. Taj povećani otpor, uključujući pokušaje uvlačenja ili izvlačenja proizvoda kada se naiđe na otpor, može oštetiti mikrokaterter. Potencijalne štetne zdravstvene posljedice uključuju produljeni postupak, ozljedu krvne žile, vazospazam, dodatnu intervenciju za uklanjanje odvojenog fragmenta proizvoda, neuklonjeni fragment proizvoda, trombozu ili emboliju.

Tvrtka Boston Scientific primila je povećan broj pritužbi povezanih s povećanim otporom i oštećenjima povezanim s otporom, što predstavlja stopu pritužbi od 0,352 %. Većina prijavljenih ishoda uključivala je zamjenu proizvoda / odgodu postupka bez ozljede pacijenta. Najozbiljniji zabilježeni ishod bio je jedan prijavljeni slučaj odvajanja tijela katetera unutar tijela pacijenta, zbog čega je bila potrebna dodatna intervencija radi uklanjanja zaostalog fragmenta. To je bila jedina prijavljena teška ozljeda. Najozbiljnija moguća štetna posljedica jest embolija opasna po život, za koju je procijenjeno da je vjerojatnost pojave vrlo mala. Do danas nije zaprimljena nijedna pritužba u kojoj je prijavljena ta štetna posljedica.

Prema našoj evidenciji vaša je ustanova primila neke od zahvaćenih proizvoda. **Tablica u nastavku (Prilog 1.) sadržava potpuni popis svih zahvaćenih proizvoda**, uključujući broj materijala (UPN), opis proizvoda, 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 Sigurnosnu obavijest.**

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 u nastavku (Prilog 1.) i uklonite sve zahvaćene jedinice iz svog inventara**, neovisno o lokaciji tih jedinica u vašoj ustanovi. **Izdvojite jedinice na sigurno mjesto do povrata tvrtki Boston Scientific.**

2. Odmah izložite ove informacije na vidljivom mjestu u blizini zahvaćenih proizvoda kako biste osigurali da su te informacije lako dostupne svim rukovateljima i korisnicima proizvoda.

3. **Nastavite primjenjivati standard skrb** prilikom praćenja pacijenata liječenih tim proizvodom.

4. **Ispunite priloženi Obrazac za provjeru čak i ako u inventaru nemate nijedan proizvod koji treba vratiti.**

5. **Nakon što ispunite Obrazac za provjeru, vratite ga u svoju lokalnu podružnicu tvrtke Boston Scientific na pažnju <Customer_Service_Fax_Number>, odmah po primitku, a najkasnije u roku od 10 radnih dana od primitka ove obavijesti.**

6. **Ako trebate vratiti proizvode**, zapakirajte ih u odgovarajuću kutiju za otpremu. **Nakon primitka Obrasca za provjeru tvrtka Boston Scientific obratit će vam se radi dogovora o povratu.**

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

Vaše nacionalno nadležno tijelo obaviješteno je o ovoj obavijesti.

Sve štetne događaje ili nedoumice u vezi s kvalitetom povezane s uporabom ovih proizvoda treba prijaviti tvrtki Boston Scientific te prema potrebi i nadležnim tijelima.

Sigurnost pacijenata najvažniji je prioritet tvrtke Boston Scientific. Stoga smo predani transparentnoj komunikaciji s liječnicima i zdravstvenim djelatnicima kako bismo vam pružili pravovremene i relevantne informacije potrebne za upravljanje pacijentima. Ako imate bilo kakvih pitanja ili vam je potrebna pomoć u vezi s ovom Sigurnosnom obavijesti, obratite se svom lokalnom prodajnom predstavniku.

Srdačan pozdrav



Richard Kirkendall
Potpredsjednik, Globalni odjel za kvalitetu

Prilog: obrazac za provjeru

FOR BOSTON SCIENTIFIC INTERNAL USE ONLY
Account Email: <Contact Email>
Language: <Language(s)>
LFAC Team: <LFAC_Distribution_Email_Address>
Country Code-Sold to: <Country_Code>-<Sold_to_b>

Prilog 1. – Zahvaćeni proizvod

Svi proizvodi navedeni u nastavku imaju rok valjanosti u rasponu od 23. listopada 2027. do 28. srpnja 2028.

Materijal	Opis materijala	GTIN	Serija
M001195200	NGMC/SINGLE/ 021/STRAIGHT/ 1RO/105	08714729839316	37942457, 37999053, 38224527, 38304916, 38415911, 38687159, 38707977, 38916519, 39029416, 39029419, 39029640, 39092278, 40476286, 40479386, 40523958, 40525677,
M001195210	NGMC/SINGLE/ 021/STRAIGHT/ 1RO/130	08714729839323	37914435, 37914436, 37956674, 37981343, 37981344, 38022632, 38022633, 38022634, 38149673, 38181211, 38224528, 38259475, 38259476, 38290713, 38290714, 38290715, 38290716, 38290717, 38399232, 38446223, 38479515, 38506196, 38530446, 38530447, 38629332, 38629333, 38647617, 38647618, 38649501, 38649508, 38687327, 38708440, 38708441, 38745184, 38769513, 38769514, 38934430, 39189795, 39189798, 40466471, 40466472, 40482683, 40482684, 40482685, 40487838, 40487839, 40487900, 40487954, 40487955, 40487956, 40487957, 40501048, 40501049, 40514122, 40514123, 40514222, 40514223, 40533342, 40533344, 40536165, 40536166,
M001195220	NGMC/SINGLE/ 021/STRAIGHT/ 1RO/155	08714729839330	37981345, 38022666, 38629565, 38629566, 38708453, 38745192, 38800928, 38800929, 38916517, 38937262, 38990881, 39074440, 39141261, 40482690, 40482691, 40485783, 40485784, 40489060, 40507284, 40510556, 40512867, 40512868, 40512869, 40512993, 40512994, 40512995, 40513031, 40513032, 40539143, 40539144,
M001195230	NGMC/SINGLE/ 021/BERN/1RO/ 105	08714729839347	37818205, 37942458, 37956675, 37981346, 38002441, 38224529, 38224530, 38304917, 38304918, 38415912, 38484288, 38506191, 38595896, 38629330, 38647611, 38647613, 38687220, 38687221, 38707976, 38876166, 38970274, 38970936, 39092279, 39092680, 40484896, 40484897, 40484952, 40523918, 40523919, 40525673, 40525674, 40525675, 40525676, 40531394, 40531395, 40531396,

Materijal	Opis materijala	GTIN	Serija
M001195240	NGMC/SINGLE/ 021/BERN/1RO/ 130	08714729839354	37818206, 37818207, 37818208, 37818209, 37849382, 37849383, 37849384, 37849385, 37849386, 37849387, 37849388, 37849389, 37914437, 37914438, 37914439, 37914460, 37914461, 37956676, 37956677, 37981347, 38002442, 38022635, 38022636, 38049174, 38112465, 38112466, 38112467, 38112468, 38112469, 38149674, 38149675, 38149676, 38181212, 38181213, 38181214, 38224531, 38224532, 38224533, 38224534, 38259477, 38259478, 38259479, 38290718, 38290719, 38290720, 38290721, 38290722, 38290723, 38350139, 38350320, 38350321, 38350322, 38350323, 38361992, 38361993, 38361994, 38361995, 38361996, 38399233, 38399234, 38399235, 38399236, 38399237, 38399238, 38479516, 38479517, 38506194, 38530448, 38530449, 38560743, 38560744, 38560745, 38560746, 38560747, 38595897, 38595898, 38595899, 38596320, 38596321, 38629336, 38629339, 38629560, 38649503, 38649505, 38687328, 38687329, 38687330, 38687331, 38701165, 38708407, 38708408, 38708411, 38708414, 38708417, 38708418, 38708419, 38745186, 38745187, 38745189, 38769518, 38769519, 38769960, 38769961, 38810595, 38810596, 38810597, 38827709, 38827710, 38827711, 38827712, 38827713, 38827714, 38827715, 38827716, 38827717, 38904801, 38904802, 38904803, 38932705, 38970735, 38970736, 38990278, 38990279, 38990341, 38990343, 38990344, 38990345, 39029646, 39029647, 39029648, 39029649, 39029654, 39074444, 39074445, 39074446, 39074452, 39074453, 39074454, 39074455, 39074456, 39140982, 39140983, 39140984, 39140985, 39140986, 40466475, 40466476, 40466477, 40466585, 40466586, 40466587, 40482558, 40482559, 40482680, 40482681, 40482682, 40488088, 40488089, 40488090, 40488091, 40501038, 40501039, 40501080, 40501081, 40501082, 40501083, 40504691, 40504692, 40507428, 40507429, 40510781, 40510782, 40510783, 40510784, 40510785, 40514124, 40514125, 40521990, 40521991, 40533357, 40533358, 40533359, 40533361, 40533363, 40533365, 40536160, 40536161, 40536162, 40536163, 40536164, 40539613, 40539614, 40539615, 40539616,
M001195250	NGMC/SINGLE/ 021/BERN/1RO/ 155	08714729839361	37886785, 37981348, 38022667, 38022668, 38049175, 38149678, 38224535, 38259480, 38259481, 38323413, 38446235, 38506483, 38560459, 38560740, 38560741, 38595642, 38595643, 38644774, 38708452, 38745193, 38810251, 38904563, 38904564, 38937261, 38990880, 39027325, 39027326, 39092681, 39092682, 39140994, 39140995, 39141262, 39141263, 40482688, 40482689, 40502253, 40507285, 40512991, 40512992, 40525712, 40531379, 40537145,
M001195260	NGMC/SINGLE/ 021/J/1RO/105	08714729839378	37818211, 37881104, 37942459, 38002443, 38224536, 38415913, 38595894, 38595895, 38629331, 38687224, 38904567, 38904568, 38916620, 38970937, 38990576, 38990842, 39027322,
M001195270	NGMC/SINGLE/ 021/J/1RO/130	08714729839385	37914462, 37956678, 38079823, 38079827, 38079828, 38181215, 38224537, 38290724, 38399239, 38399240, 38399241, 38446224, 38460466, 38479514, 38479518, 38506192, 38506193, 38527327, 38527328, 38560748, 38560749, 38560750, 38560751, 38629561, 38647619, 38649500, 38649513, 38769494, 38769500, 38827706, 38990346, 38990347, 39074447, 39191592, 40476394, 40482557, 40487835, 40487836, 40507432, 40513948, 40521921, 40521922, 40524021, 40524022, 40533341, 40535977, 40539682,

Materijal	Opis materijala	GTIN	Serija
M001195280	NGMC/SINGLE/ 021/J/1RO/155	08714729839392	38149679, 38323401, 38444072, 38506482, 38506491, 38560458, 38595645, 38810252, 38936816, 39140997, 39141264, 39189785, 39189791, 40482687, 40493382, 40512909,
M001195290	NGMC/SINGLE/ 021/SWAN/1RO /105	08714729839408	38362172, 38362173, 38530450, 38595659,
M001195300	NGMC/SINGLE/ 021/SWAN/1RO /130	08714729839415	37818213, 37818214, 37818215, 37818216, 37881115, 37886786, 37886787, 37886788, 37914463, 37914464, 37914465, 37943140, 37956679, 37957740, 37977611, 38002444, 38002445, 38085044, 38089225, 38092404, 38092405, 38092406, 38112470, 38112471, 38112472, 38149820, 38181217, 38191752, 38220950, 38330637, 38330638, 38415914, 38415915, 38444073, 38444074, 38484290, 38527320, 38527321, 38560452, 38573062, 38573063, 38585014, 38596980, 38596981, 38629571, 38629572, 38769972, 38769973, 38827700, 38827701, 38827702, 38827703, 38827704, 38827705, 38904809, 38904810, 38916514, 38916515, 38937265, 38990849, 38990852, 38990856, 38990857, 39029815, 39143228, 39143230, 40466130, 40466131, 40466631, 40471499, 40471940, 40476290, 40476291, 40476292, 40479473, 40479474, 40479716, 40479717, 40492475, 40493319, 40493333, 40493440, 40497672, 40499680, 40499681, 40505968, 40505969, 40512591, 40512592, 40512593, 40513026, 40513027, 40521923, 40521924, 40525798, 40525799, 40525860, 40531461, 40531462, 40533302, 40535971, 40535972,
M001195310	NGMC/SINGLE/ 021/SWAN/1RO /155	08714729839422	37818217, 37818218, 37818219, 37881110, 37881111, 37881112, 37886789, 37886790, 37886791, 37886792, 37928860, 37928862, 38585015, 38585016, 38745481, 38745482, 38745483, 39143525, 39143526, 39143527, 40466594, 40466595, 40466596, 40476306, 40476307, 40476308, 40482692, 40482693, 40482694, 40485789, 40485790, 40485791,
M001195320	NGMC/SINGLE/ 021/STRAIGHT/ 2RO/130	08714729839439	37818440, 37818441, 37981349, 38002446, 38200316, 38200317, 38224539, 38304087, 38330639, 38399242, 38399243, 38503335, 38530451, 38629573, 38629576, 38650063, 38650068, 38810584, 38904811, 40466632, 40466633, 40466634, 40476310, 40476442, 40476443, 40482607, 40482609, 40489044, 40491252, 40493253, 40493444, 40502171, 40502326, 40502327, 40504735, 40504736, 40504737, 40525535, 40531443, 40531445, 40533244, 40533305,
M001195330	NGMC/SINGLE/ 021/STRAIGHT/ 2RO/155	08714729839446	37957742, 38361997, 38361998, 38439368, 38527323, 38527324, 38527326, 38876179, 38916511, 39029983, 39029986, 39092697,
M001195340	NGMC/SINGLE/ 021/BERN/2RO/ 130	08714729839453	37818442, 38181218, 38181219, 38224580, 38240231, 38350326, 38361999, 38460468, 38484291, 38503334, 38530454, 38530455, 38629574, 38650064, 38745484, 38769974, 38769975, 38904812, 38904813, 38937271, 38937272, 38990884, 39092686, 39092687, 40476309, 40476444, 40482608, 40507288, 40510453, 40525536, 40525537,
M001195350	NGMC/SINGLE/ 021/BERN/2RO/ 155	08714729839460	37881102, 37881103, 37943142, 37943143, 37957743, 38439681, 38439682, 38484292, 38527325, 38876320, 38904816, 38904817, 38916510, 38916512, 38990272, 38990273, 38990274, 39029898, 39092695, 39092696,
M001195400	NGMC/SINGLE/ 027/STRAIGHT/ 1RO/105	08714729839477	38049178, 38415916, 38595648, 38708403, 39141268,

Materijal	Opis materijala	GTIN	Serijski
M001195410	NGMC/SINGLE/ 027/STRAIGHT/ 1RO/130	08714729839484	38061296, 38092407, 38092408, 38112473, 38149821, 38181960, 38198831, 38224581, 38259482, 38273746, 38362200, 38362201, 38399244, 38445017, 38649517, 38649853, 38667794, 38810594, 38904807, 40470780, 40476390, 40482606, 40493383, 40495046, 40495047, 40495048, 40495049, 40502037, 40502268, 40510553, 40510554, 40512596, 40512597, 40512990, 40516627, 40518479, 40518820, 40518821, 40525714, 40525715, 40525716,
M001195420	NGMC/SINGLE/ 027/STRAIGHT/ 1RO/155	08714729839491	38049561, 38065517, 38092409, 38745199, 38745480, 39092274, 40482626, 40482629, 40497899, 40497980, 40502330, 40504597, 40504598, 40531426,
M001195430	NGMC/SINGLE/ 027/BERN/1 RO/105	08714729839507	38149822, 38210076, 38415917, 38595649, 38708406, 39141265,
M001195440	NGMC/SINGLE/ 027/BERN/1RO/ 130	08714729839514	38181961, 38198832, 38224582, 38259483, 38324070, 38460469, 38560455, 38560456, 38595654, 38649857, 38745194, 38745195, 38810586, 38810591, 38904805, 39092267, 39092272, 39143222, 40470259, 40478976, 40478977, 40492318, 40497671, 40497858, 40502038, 40502039,
M001195450	NGMC/SINGLE/ 027/BERN/1RO/ 155	08714729839521	38224583, 38273637, 38649877, 38707975, 38745198, 40470668, 40470669, 40476288, 40476289, 40476304, 40476305, 40495080, 40504684, 40512595, 40516625, 40516626, 40523967, 40525596, 40531425,
M001195470	NGMC/SINGLE/ 027/J/1RO/130	08714729839545	38112474, 38149823, 38181962, 38181963, 38399282, 38415919, 38416360, 38445015, 38649840, 38649849, 39143221, 40470762, 40470763, 40470782, 40476387, 40476388, 40478984, 40478985, 40502172,
M001195480	NGMC/SINGLE/ 027/J/1RO/155	08714729839552	38649876, 38668791, 39074172, 39074173, 40482627, 40482628,
M001195500	NGMC/SINGLE/ 027/SWAN/1RO /130	08714729839576	38061298, 38061299, 38092411, 38092412, 38092413, 38112475, 38112476, 38112477, 38167702, 38167705, 38181964, 38181965, 38181966, 38181967, 38181968, 38416361, 38416362, 38595650, 38595651, 38595652, 38650001, 38650003, 38746409, 38746410, 38810247, 38810248, 38904814, 38904815, 38937266, 38937267, 38937268, 38937270, 38990858, 39027320, 39092275, 39092276, 39092277, 40466592, 40466593, 40471963, 40471964, 40478978, 40478979, 40502334, 40502335, 40504653, 40504654, 40513028, 40513029, 40513030, 40524000,
M001195510	NGMC/SINGLE/ 027/SWAN/1RO /155	08714729839583	38061601, 38063600, 38434622, 38434623, 38650006, 38650007, 40482630, 40482631, 40502273, 40502274,
M001195610	NGMC/FATHOM/ 021/STRAIGHT/ 1RO/130	08714729839606	37775581, 37914469, 37914471, 38112478, 38149824, 38149825, 38181969, 38290725, 38342768, 38342769, 38647607, 38647608, 38647615, 38647616, 38649502, 38687333, 38687334, 38708446, 39029659, 40466126, 40466127, 40466473, 40476395, 40485647, 40485732, 40501047, 40504656, 40504657, 40508315, 40512996, 40512997, 40519832, 40519833,
M001195620	NGMC/FATHOM/ 021/STRAIGHT/ 1RO/155	08714729839613	37775591, 37886793, 37914472, 37914473, 37957744, 38112479, 38149826, 38167704, 38175797, 38444076, 38446234, 38530457, 38745190, 38990885, 39140998, 39140999, 40470358, 40499682, 40499683, 40502254, 40504732, 40504733, 40507436, 40524004, 40539147, 40539467,

Materijal	Opis materijala	GTIN	Serija
M001195640	NGMC/FATHO M/021/BERN/1R O/130	08714729839637	37849390, 37914474, 37914475, 37957745, 38022639, 38022640, 38112640, 38181970, 38181971, 38224584, 38259484, 38290726, 38290727, 38290728, 38399245, 38399246, 38399247, 38444840, 38444841, 38444842, 38460462, 38479512, 38484293, 38484294, 38530458, 38530459, 38560742, 38560752, 38708442, 38708443, 38708444, 38708445, 38769962, 38769963, 38769964, 38810598, 38810599, 38810760, 38810761, 38876169, 38916621, 38970725, 38970726, 38970727, 38970728, 38970732, 38970733, 38970734, 39029800, 39074448, 40466474, 40466590, 40466591, 40476391, 40476392, 40476393, 40485646, 40485726, 40485727, 40485728, 40501045, 40501046, 40504841, 40504842, 40507430, 40507431, 40508310, 40508311, 40512998, 40512999, 40513080, 40523938, 40523939, 40524020, 40533345, 40535978,
M001195650	NGMC/FATHO M/021/BERN/1R O/155	08714729839644	37886794, 37957747, 38022670, 38049176, 38149828, 38175798, 38224585, 38259485, 38323409, 38506199, 38531120, 38560457, 38595646, 38595647, 38745191, 38769968, 38769971, 38916516, 38970729, 38990859, 38990882, 39027327, 39141260, 39189845, 40466132, 40466133, 40466134, 40485781, 40493314, 40502331, 40502332, 40502333, 40504594, 40507434, 40507435, 40531377, 40535710, 40535711, 40537146,
M001195660	NGMC/FATHO M/021/STRAIG HT/2RO/130	08714729839651	37914476, 38629575, 38650015, 38687321, 39029882, 39029883, 40466020, 40466021, 40466135, 40507481, 40510684, 40539451,
M001195670	NGMC/FATHO M/021/BERN/2R O/130	08714729839668	37881100, 37889829, 37914477, 37914478, 37914479, 37943144, 37981351, 37981352, 38002448, 38002449, 38002450, 38017051, 38017052, 38022674, 38022676, 38073300, 38073301, 38273216, 38330740, 38350327, 38362202, 38399248, 38399249, 38434624, 38434625, 38439685, 38439687, 38445013, 38560448, 38560451, 38687322, 38810583, 38810585, 38827798, 38827799, 38902297, 38902298, 38916513, 38990275, 38990276, 38990277, 39092688, 39092689, 39143520, 39189848, 40466136, 40466717, 40476440, 40476441, 40492317, 40492357, 40493443, 40507482, 40510454, 40510455, 40510683, 40510769, 40525862, 40531441, 40531444
M001195710	NGMC/FATHO M/027/STRAIG HT/1RO/130	08714729839682	38092414, 38149829, 38181972, 38259486, 38324071, 38416363, 38593058, 38595655, 38629567, 38649848, 38745196, 38810589, 38810590, 38937264, 39092268, 40465990, 40466018, 40466019, 40466137
M001195720	NGMC/FATHO M/027/STRAIG HT/1RO/155	08714729839699	38049560, 38092415, 38112641, 38112642, 38181973, 38210072, 38224586, 38224587, 38239068, 38399299, 38595657, 38595658, 38629568, 38650000, 40493316, 40493317, 40495081, 40504596, 40504689, 40504690, 40512594, 40523965, 40525821,
M001195740	NGMC/FATHO M/027/BERN/1R O/130	08714729839712	38092416, 38112643, 38149830, 38181974, 38224588, 38224589, 38259488, 38273747, 38273748, 38290697, 38330742, 38399250, 38416365, 38445016, 38484295, 38593059, 38595656, 38649843, 38649864, 38745197, 38810587, 38810592, 38876171, 38876172, 38904806, 38937263, 38990883, 39092270, 39143220, 39189853, 39189855, 40485616, 40485617, 40492473, 40493384, 40497670, 40497857, 40499760, 40499761, 40502300, 40502325, 40507454, 40518477, 40518478, 40525595, 40525718, 40525719, 40536127,

Materijal	Opis materijala	GTIN	Serija
M001195750	NGMC/FATHO M/027/BERN/1RO/155	08714729839729	38049562, 38112644, 38112645, 38181975, 38259489, 38273638, 38342770, 38346223, 38399380, 38707974, 39074174, 39074176, 39092273, 40470667, 40476303, 40485786, 40485787, 40493318, 40495100, 40507439, 40512986, 40512987, 40523966, 40524003, 40531398, 40531399,
M001195810	NGMC/TRANSE ND/021/STRAIGHT/1RO/130	08714729839743	37914480, 37957748, 38022641, 38149831, 38224590, 38446222, 38649514, 39074449, 39074450, 39074451, 39187259, 39187840, 39187841, 40476396, 40485725, 40493312, 40504693, 40507433, 40510780, 40513102, 40513103,
M001195840	NGMC/TRANSE ND/021/BERN/1RO/130	08714729839774	37818448, 37818450, 37849391, 37849392, 37849393, 37849394, 37914481, 37914482, 37914483, 37957749, 37957750, 37957751, 37957752, 37981353, 37981354, 37981355, 37981356, 38002451, 38002452, 38002453, 38002454, 38002455, 38002456, 38022642, 38022643, 38022644, 38022645, 38049173, 38065519, 38065520, 38065522, 38065523, 38065524, 38065525, 38065527, 38065528, 38065529, 38065531, 38065532, 38065533, 38106627, 38106628, 38106630, 38149832, 38149833, 38149834, 38149835, 38149836, 38181976, 38181977, 38181978, 38181979, 38181980, 38259490, 38259491, 38290729, 38290730, 38290731, 38290732, 38290733, 38350328, 38350329, 38350330, 38350331, 38350332, 38350333, 38362203, 38362205, 38362206, 38531121, 38629563, 38649510, 38687335, 38708448, 38708449, 38708450, 38708451, 38769965, 38769966, 38769967, 38827707, 38827708, 38876170, 38904804, 38932706, 38932707, 38934432, 38934433, 38934434, 39029655, 39029656, 39029657, 39029658, 39074458, 39074459, 39074600, 39074601, 39074602, 39074603, 39140987, 39140988, 39140989, 39140990, 39140991, 39140992, 39187842, 39187844, 39187845, 39187846, 39219921, 40466468, 40466469, 40466470, 40466588, 40466589, 40466607, 40466608, 40466609, 40466610, 40471679, 40471960, 40471961, 40476398, 40476480, 40476481, 40476482, 40485645, 40485722, 40485723, 40485724, 40485729, 40485730, 40485731, 40493372, 40493373, 40493374, 40493375, 40493376, 40493377, 40493378, 40493379, 40493380, 40493381, 40494944, 40494945, 40494946, 40502255, 40502258, 40502259, 40504658, 40504659, 40504840, 40508312, 40508313, 40510558, 40510559, 40512915, 40512916, 40512918, 40513100, 40513101, 40521985, 40521986, 40521987, 40521988, 40521989, 40523930, 40523931, 40523932, 40523933, 40523934, 40523935, 40523936, 40523937, 40526446, 40526447, 40526448, 40526449, 40526450, 40526451, 40528687, 40528688, 40528689, 40528690, 40528691, 40533346, 40533347, 40533348, 40533349, 40535973, 40535974, 40535976, 40539619,
M001195850	NGMC/TRANSE ND/021/BERN/1RO/155	08714729839781	37996606, 38022677, 38022678, 38065534, 38065535, 38112646, 38149837, 38224591, 38259492, 38290688, 38446231, 38769969, 38769970, 38810249, 38875417, 38936818, 38970730, 38970731, 38990886, 39074178, 40466463, 40466605, 40466606, 40470665, 40470666, 40476198, 40484940, 40485711, 40485712, 40485782, 40492387, 40507437, 40512910, 40512911, 40512912, 40512914, 40523982, 40524002, 40525713, 40531378, 40537147,
M001195910	NGMC/TRANSE ND/027/STRAIGHT/1RO/130	08714729839828	38240235, 38273744, 39092271, 40464692, 40464699, 40531397,

Materijal	Opis materijala	GTIN	Serija
M001195940	NGMC/TRANSE ND/027/BERN/1 RO/130	08714729839842	38061297, 38092418, 38149838, 38181982, 38224592, 38240234, 38240236, 38273745, 38649863, 38810593, 39143039, 39189852, 40466138, 40466139, 40466464, 40470781, 40476389, 40478986, 40497669, 40502265, 40507286, 40512989, 40525717,

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

Molimo ispunite obrazac čak i ako u inventaru nemate nijedan zahvaćeni proizvod i pošaljite ga u svoju lokalnu podružnicu: <Customer_Service_Fax_Number>

Obrazac za provjeru – Hitni opoziv medicinskog proizvoda
Direxion™ i Direxion HI-FLO™
 97645673-FA

- Potvrđujemo primitak Sigurnosne obavijesti tvrtke Boston Scientific od 16. rujna 2026.
- Prema evidenciji tvrtke Boston Scientific primili ste sljedeće zahvaćene proizvode (dodatno provjerite inventar i usporedite ga s cjelovitim popisom zahvaćenih proizvoda.)**

Br. materijala (UPN)	Br. lota/serije	Br. narudžbenice kupca	Isporučena količina	Količina za povrat (pojedinačno)

- Potvrđujemo da su provjerene sve lokacije na kojima se zahvaćeni proizvod može nalaziti.
- Označite jednu od izjava u nastavku*, potpišite ovaj Obrazac** i pošaljite ga na pažnju <Customer_Service_Fax_Number>
 - ☐ Ne posjedujemo nijedan zahvaćeni proizvod.
 - ☐ Pronašli smo zahvaćene proizvode: Iznad potvrdite količinu za povrat. Ako vraćate proizvod koji nije prethodno naveden, dodajte UPN, broj lota / serije / serijski br. i količinu koju treba vratiti.

ZA POVRAT PROIZVODA:

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

IME I PREZIME* _____ Funkcija _____

Broj telefona _____ E-pošta _____

POTPIS KUPCA* _____ DATUM* _____

* Obvezno polje

dd. mm. gggg.