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<**Reference: 97645673-FA**> 16 September 2026
SRN: US-MF-000004702

Urgent Field Safety Notice - Urgent Medical Device Recall Direxion™ and Direxion HI-FLO™

Dear Materials Manager and/or Healthcare Professional,

Boston Scientific is initiating the recall of specific lots of Direxion™ and Direxion HI-FLO™ Microcatheters due to a manufacturing issue that may cause difficulty withdrawing the device from the carrier hoop and difficulty advancing or withdrawing the device through a guide catheter. This recall affects only the lots identified in Attachment 1.

The issue is detectable during device preparation and/or use in the patient and is experienced as increased resistance between the microcatheter and other components. This increased resistance, including attempts to advance or withdraw the device when resistance is encountered, may result in damage to the microcatheter. Potential adverse health consequences include prolonged procedure, vessel trauma, vasospasm, additional intervention to retrieve a separated device fragment, unretrieved device fragment, thrombosis, or embolism.

Boston Scientific has received an increased number of complaints associated with increased resistance and resistance-related damage, representing a complaint rate of 0.352%. Most reported outcomes involved device exchange/procedure delay without patient injury. The most serious observed outcome was a single reported event of shaft separation within the body requiring an additional intervention to retrieve the retained fragment. This was the only serious injury reported. The most serious potential harm is life-threatening embolism, which is assessed as a remote likelihood of occurrence. There have been no complaints reporting this harm to date.

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 Material Number (UPN), Product Description, GTIN, 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 below** (Attachment 1) **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- Immediately post this information in a visible location near the affected products to ensure this information is readily accessible to all handlers and users of the device.

3- **Continue to follow the standard of care** when monitoring patients treated with the product.

4- **Please complete the attached Verification Form** even if you do not have any product to return.

5- **When completed, please return the Verification Form to your local Boston Scientific office** for the attention of <Customer_Service_Fax_Number> promptly upon receipt and no later than **10 working days** from receipt of this notification.

6- **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.**

7- 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 National Competent Authority has been informed of this communication.
Any adverse events or quality concerns associated with use of these devices should be reported to Boston Scientific and Competent Authorities if appropriate.

Patient safety is Boston Scientific's highest priority. As such, we are committed to transparent communication with physicians and healthcare professionals to ensure you have timely, relevant information for managing your patients. If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,

Richard Kirkendall
Vice President, Global Quality

Attachment: Verification Form

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>*

Attachment 1 - Affected Product

All products listed below have an <u>expiration date range</u> from 23 October 2027 to 28 July 2028.

Material	Material Description	GTIN	Batch
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,

Material	Material Description	GTIN	Batch
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,

Material	Material Description	GTIN	Batch
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,

Material	Material Description	GTIN	Batch
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/1RO/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,

Material	Material Description	GTIN	Batch
M001195640	NGMC/FATHOM/021/BERN/1RO/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/FATHOM/021/BERN/1RO/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/FATHOM/021/STRAIGHT/2RO/130	08714729839651	37914476, 38629575, 38650015, 38687321, 39029882, 39029883, 40466020, 40466021, 40466135, 40507481, 40510684, 40539451,
M001195670	NGMC/FATHOM/021/BERN/2RO/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/FATHOM/027/STRAIGHT/1RO/130	08714729839682	38092414, 38149829, 38181972, 38259486, 38324071, 38416363, 38593058, 38595655, 38629567, 38649848, 38745196, 38810589, 38810590, 38937264, 39092268, 40465990, 40466018, 40466019, 40466137
M001195720	NGMC/FATHOM/027/STRAIGHT/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/FATHOM/027/BERN/1RO/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,

Material	Material Description	GTIN	Batch
M001195750	NGMC/FATHOM/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/TRANSEND/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/TRANSEND/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/TRANSEND/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/TRANSEND/027/STRAIGHT/1RO/130	08714729839828	38240235, 38273744, 39092271, 40464692, 40464699, 40531397,

Material	Material Description	GTIN	Batch
M001195940	NGMC/TRANSEND/027/BERN/1RO/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>

Please Complete the form even if you do not have any affected product & send it to your Local Office:
<Customer_Service_Fax_Number>

Verification Form – Urgent Medical Device Recall
Direxion™ and Direxion HI-FLO™
97645673-FA

1- We acknowledge receipt of the Boston Scientific Field Safety Notice dated 16 September 2026.

2- **Boston Scientific records indicate you have received the following affected products** (*additionally please check inventory against complete list of affected products provided)*

Material N° (UPN)	Lot / Batch N°	Customer PO	Qty Sent	Qty to return (Single)

3- We confirm that all areas where affected product could be located have been checked.

4- **Tick one of these statements***, **sign this Form** and send it to <Customer_Service_Fax_Number>

- ❑ We do not have any affected product.
- ❑ We have found affected product(s): Please confirm the quantity to return above. *If you are returning product not listed above, please* ***add the UPN, Lot/Batch/Serial number and the quantity to return.***

TO RETURN PRODUCTS:

1- After receipt of the Verification Form, Boston Scientific will contact you to arrange return.
2- Prepare the package.
3- Follow the instructions given by your Local Office about collection of the package.

NAME* _____Title _____

Telephone _____ Email _____

Customer' **SIGNATURE*** _____ **DATE*** _____
* Required field dd/mm/yyyy