

«Hospital_Name»

«Users_Name»

«Department»

«Customer_Address»

«Zip_Code» «City»

«Country_name»

<Reference: 96993356-FA>

24 March 2023

Urgent Field Safety Notice - Urgent Medical Device Recall INTELLANAV STABLEPOINT™ Ablation Catheter

Subject: Removal of specific lots of INTELLANAV STABLEPOINT™ Ablation Catheter due to potential compromise in sterile barrier, Field Action Reference: 96993356-FA.

Dear «Users_Name»,

Boston Scientific is initiating a removal of specific lots of the INTELLANAV STABLEPOINT Ablation Catheter, because an improperly placed instructions for use (IFU) literature packet can potentially damage the sterile barrier of the catheter package. Our records indicate that your facility received an affected catheter.

Use of a non-sterile catheter could lead to an infection requiring treatment. To date, Boston Scientific has not received any reports of sterile barrier breach or potentially related infections from affected catheters, however, there has been one report of post-procedure fever which could not be ruled out as possibly related. Based on this sterile barrier investigation, the probability of a causal infection requiring treatment is estimated to be less than one in a million.

Since 24 January 2023, all shipments of INTELLANAV STABLEPOINT Ablation Catheters from our manufacturing facility have the IFU literature packet placed in the intended location. Therefore, not all inventory at your facility may be included in this removal.

Our records indicate that your facility received some of the concerned product. **The table below provides a complete list of all affected products, including Product Description, Material Number (UPN), GTIN, Lot/Batch numbers.** 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.

Product	UPN >INs	Batch
INTELLANAV STABLEPOINT Standard Curve	M004ERFSDS96200 08714729992257	26947374, 26954667, 26954896, 26961804, 26979707, 26987223, 27011259, 27011877, 27019922, 27020778, 27036646, 27084333, 27084419, 27085108, 27092758, 27093030, 27100833, 27106896, 27124745, 27125219, 27133231, 27133764, 27141825, 27149273, 27156276, 27166265, 27174677, 27181156, 27181912, 27196501, 27196762, 27250798, 27252201, 27266245, 27266484, 27274898, 27285462, 27287945, 27292484, 27298290, 27300505, 27309476, 27310149, 27316416, 27317348, 27320863, 27327439, 27336738, 27337045, 27342956, 27374494, 27379932, 27380737, 27380982, 27389329, 27415734, 27418380, 27419553, 27425417, 27432959, 27438869, 27438967, 27442084, 27442085, 27442573, 27447750, 27448297, 27448663, 27454897, 27455781, 27459289, 27462738, 27462797, 27471090, 27471780, 27478347, 27481991, 27482241, 27492381, 27492506, 27499884, 27500204, 27505713, 27505911, 27513488, 27514020, 27516331, 27521258, 27524502, 27532651, 27533363, 27538524, 27541067, 27545288, 27549901, 27556636, 27565659, 27572196, 27598002, 27605560, 27616556, 27617080, 27622591, 27622856, 27640475, 27642313, 27643180, 27653671, 27657544, 27660407, 27668263, 27668264, 27679946, 27680162, 27683634, 27723959, 27724446, 27751596, 27757341, 27757367, 27758702, 27758882, 27759336, 27771181, 27771865, 27781793, 27788478, 27789572, 27794185, 27796263, 27797461, 27812431, 27813312, 27813536, 27819586, 27865786, 27869745, 27891254, 27891664, 27899186, 27899195, 27906931, 27915072, 27921387, 27923524, 27932851, 27933318, 27939875, 27940719, 27947664, 27949199, 27955870, 27955879, 27963776, 27963980, 27966669, 27973037, 27977672, 27977900, 27984924, 27985180, 27992498, 28017629, 28018673, 28019075, 28025916, 28033153, 28041711, 28083983, 28096295, 28103059, 28110775, 28111473, 28118475, 28147563, 28148824, 28148825, 28153658, 28153811, 28154449, 28160733, 28162318, 28162662, 28168735, 28189753, 28191599, 28195788, 28196401, 28202772, 28203539, 28210866, 28211560, 28216163, 28222106, 28225640, 28229457, 28230172, 28239692, 28241076, 28248100, 28264896, 28277637, 28280385, 28280707, 28286930, 28287137, 28294921, 28313365, 28336542, 28336629, 28342024, 28349275, 28356325, 28356327, 28364259, 28364587, 28387634, 28411598, 28412251, 28418679, 28419142, 28423807, 28447554, 28447982, 28451299, 28451545, 28455171, 28455422, 28457156, 28458117, 28495040, 28495195, 28506009, 28506775, 28527808, 28537108, 28556079, 28559531, 28578384, 28578440, 28581831, 28582865, 28596106, 28597682, 28597826, 28601045, 28616850, 28617235, 28617919, 28623150, 28623546, 28625515, 28631277, 28631624, 28636586, 28637067, 28642698, 28665068, 28668117, 28703618, 28707176, 28707980, 28735854, 28736261, 28738526, 28743747, 28743883, 28745736, 28745876, 28751211, 28751990, 28759234, 28759865, 28766412, 28767223, 28772594, 28780433, 28780436, 28794458, 28803072, 28803218, 28810515, 28810649, 28815007, 28822261, 28822426, 28836778, 28837397, 28854491, 28855251, 28875732, 28876100, 28882355, 28883134, 28891114, 28891135, 28900465, 28900528, 28912116, 28918474, 28919405, 28927306, 28927316, 28934937, 28935018, 28947416, 28963060, 28987068, 28987071, 28997895, 28998255, 29005212, 29005270, 29013811, 29013825, 29021608, 29029005, 29029093, 29040763, 29041244, 29048336, 29048815, 29057086, 29063537, 29063730, 29068585, 29088302, 29088640, 29095904, 29096032, 29110826, 29123319, 29138785, 29138950, 29165815, 29182165, 29189772, 29282524, 29282525, 29282526, 29284584, 29289457, 29289458, 29289459, 29291169, 29291170, 29293464, 29293465, 29293466, 29305989, 29306332, 29314467, 29314471, 29322343, 29322759, 29339981, 29345923, 29346854, 29357324, 29363747, 29367467, 29428121, 29430878, 29433716, 29440453, 29451917, 29453333, 29471160, 29471512, 29479113, 29486760, 29487186, 29495423, 29502516, 29503932, 29510753, 29519063, 29520261, 29520346, 29527577, 29528110, 29528584, 29542236, 29552140, 29560820, 29560872, 29566977, 29586971, 29588373, 29688172, 29688538, 29693800, 29706570, 29757434, 29784950, 29792502, 29793425, 29834827, 29848397, 29850206, 30073044, 30185798, 30239172, 30424165, 30424166, 30426350, 30437945, 30445195, 30467219, 30475339, 30475380, 30475381, 30495908, 30495910, 30495911, 30676361, 30727595, 30773894, 30789697
INTELLANAV STABLEPOINT Large Curve	M004ERFSDS9620K20 08714729992264	27181087, 27189133, 27195115, 27217207, 27300177, 27344008, 27351449, 27353057, 27360927, 27364622, 27403194, 27416824, 27425741, 27572516, 27589618, 27589869, 27597673, 27605387, 27608952, 27616797, 27683635, 27684191, 27701805, 27710306, 27714856, 27725814, 27873655, 27878147, 27878239, 27884015, 27893892, 27899359, 27906690, 27914206, 27921393, 28041772, 28068250, 28068617, 28068753, 28078254, 28083075, 28087588, 28088860, 28096596, 28111475, 28245809, 28246491, 28247743, 28253109, 28255294, 28255600, 28258566, 28263403, 28264831, 28287238, 28365267, 28380124, 28387632, 28412072, 28423811, 28520502, 28536130, 28536490, 28563209, 28563407, 28579237, 29331292, 29337702, 29894793
INTELLANAV STABLEPOINT	M004IDERFS96200 08714729992271	26986708, 27388804, 27561039, 27700402, 28040886, 28961957, 29087049
INTELLANAV STABLEPOINT	M004IDERFS9620K20 08714729992288	26986383, 27388822, 27561091, 27699447, 28040889

INSTRUCTIONS:

1- **Please immediately discontinue use of the Boston Scientific product reported in the list and remove all of the affected units from your inventory**, regardless of where these units are stored in your facility. Segregate the units in a secure place, pending return to Boston Scientific.

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

3- **When completed, please return the Verification Form to your local Boston Scientific office** for the attention of «Customer_Service_Fax_Number», on or before **19 April 2023**.

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

5- Please pass this notice to any healthcare professional from your organization that needs to be aware and to any organization where the potentially affected devices have been transferred (if appropriate). Please provide Boston Scientific with details of any affected devices that have been transferred to other organizations (if appropriate).

Your Competent Authority is being notified of this Field Safety Notice.

Catheters currently being distributed have the IFU placed below the tray as intended and may continue to be used to support procedures. Please report any adverse events to Boston Scientific and your local regulatory authority in accordance with their adverse reporting system.

We regret any inconvenience that this action may cause, and we appreciate your understanding as we act to ensure patient safety and customer satisfaction.

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

Yours sincerely,



Marie Pierre Barlangua
Quality Department
Boston Scientific International S.A.

Attachment: Verification Form

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
INTELLANAV STABLEPOINT™ Ablation Catheter
96993356-FA**

1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated 24 March 2023.
2. **Boston Scientific records indicate you have received the following affected product** (*additionally please check inventory against complete list of affected product provided*)

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

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