

«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.**

<b>Product</b>	<b>UPN &amp; GTINs</b>	<b>Batch</b>
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, 27660720, 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

**Vigtig sikkerhedsmeddelelse – Øjeblikkelig tilbagekaldelse  
af medicinsk anordning  
Ablationskateter af typen INTELLANAV STABLEPOINT™**

**Emne:** Tilbagekaldelse af specifikke partier af ablationskatetre af typen INTELLANAV STABLEPOINT™ på grund af risiko for brud på den sterile barriere (referencenummer for vigtig produktmeddelelse: 96993356-FA)

Kære «Users\_Name»

Boston Scientific har igangsat en tilbagekaldelse af specifikke partier af ablationskatetre af typen INTELLANAV STABLEPOINT, fordi der er risiko for, at en forkert placeret brugsanvisning kan beskadige kateterets sterile barriere. Ifølge vores oplysninger har din organisation modtaget mindst ét af de berørte katetre.

Anvendelse af et ikke-sterilt kateter kan medføre infektion med deraf følgende behov for behandling. Boston Scientific har indtil videre ikke modtaget indberetninger om brud på den sterile barriere eller potentielt relaterede infektioner forårsaget af berørte katetre, men der har været én indberetning om feber efter et indgreb, som muligvis kan være relateret hertil. Ud fra vores undersøgelse vedrørende den sterile barriere anslås risikoen for infektion med deraf følgende behov for behandling at være under én ud af en million.

Siden den 24. januar 2023 har brugsanvisningen været placeret korrekt i alle forsendelser med ablationskatetre af typen INTELLANAV STABLEPOINT fra vores produktionsanlæg. Det er derfor ikke sikkert, at hele din organisations beholdning er omfattet af denne tilbagekaldelse.

Vore optegnelser viser, at Deres institution har modtaget nogle af de påvirkede produkter. **Den følgende tabel er en komplet liste over alle tilbagekaldte produkter**, herunder produktbeskrivelse, materialenummer (UPN), katalognummer, GTIN og Lot/Batch-numre. **Bemærk venligst, at det kun er nedenstående materiale og batchnumre, der er påvirkede. Intet andet produkt fra Boston Scientific er involveret.**

**Yderligere distribution eller brug af ethvert resterende produkt berørt af denne sag skal høre op omgående.**

Produkt-beskrivelse	UPN- og GTIN-numre	Lot/Batch-numre
INTELLANAV STABLEPOINT (standardkurve)	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, 27660720, 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, 28022591, 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 (stor kurve)	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

### **INSTRUKTIONER:**

1- I bedes med øjeblikkelig virkning standse brugen af de Boston Scientific produkter rapporteret i produkttabellen, og fjerne alle de berørte enheder fra jeres depoter, uanset hvor disse enheder opbevares i jeres institution. Isolér enhederne et sikkert sted, afventende returnering til Boston Scientific.

2- **Udfyld venligst den medfølgende bekræftelsesblanket også hvis I ikke har produkter, der skal returneres**

3- **Når bekræftelsesblanketten er udfyldt, sendes den via fax til den lokale Boston Scientific kundeservice til «Customer\_Service\_Fax\_Number» før den 19. april 2023.**

4- Hvis De har produkter at returnere, bedes De pakke dem i en passende forsendelsesæske. Efter modtagelse af bekræftelsesformularen. Boston Scientific vil kontakte Dem for at arrangere returnering.

5- Lad denne meddelelse gå videre til andre sundhedsmedarbejdere indenfor jeres organisation, der har behov for at være opmærksomme på dette og til enhver organisation, hvortil potentielt påvirkede anordninger kan være overført (hvis relevant). Giv venligst Boston Scientific detaljerede oplysninger (pr. telefon eller fax) om enhver påvirket anordning, der er overført til andre organisationer (hvis relevant).

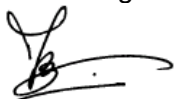
Den kompetente myndighed er ved at blive underrettet om denne tilbagekaldelse.

For de aktuelt distribuerede katetres vedkommende er brugsanvisningen placeret korrekt, dvs. under bakken, og disse katetre må fortsat anvendes i forbindelse med indgreb. Eventuelle bivirkninger skal indberettes til Boston Scientific og via de lokale myndigheders program til indberetning af bivirkninger.

Vi beklager enhver ulejlighed som denne handling måtte medføre, og vi værdsætter Deres forståelse, da vi handler ud fra at sikre patientsikkerheden og kundernes tilfredshed.

Skulle De have nogle spørgsmål eller ønsker hjælp med denne tilbagekaldelse af en medicinsk anordning, så kontakt Deres lokale salgsrepræsentant.

Med venlig hilsen,



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

Vedlagt: Verificeringsformular

Udfyld formularen, også selvom du ikke har noget involveret produkt & send det tilbage til din locale kundeservice: «Customer\_Service\_Fax\_Number»

**Verificeringsformular – Øjeblikkelig tilbagekaldelse af medicinsk anordning  
Ablationskateter af typen INTELLANAV STABLEPOINT™  
96993356-FA**

1. Vi anerkender modtagelse af Boston Scientific Sikkerhedsmeddelelse dateret 24 marts 2023.

2. **Boston Scientific registreringer indikerer, at De har modtaget følgende berørte produkt** (kontroller venligst yderligere Deres lager i henhold til den komplette, fremsendte liste over berørte produkter)

Materiale nummer	Batch nummer(e)	Kundeindkøbsordre	Antal Sendt	Antal at returnere (Enhed)

3. Vi bekræfter, at alle områder, hvor produktet kunne befinde sig, er kontrolleret.

4. **AFKRYDS EN AF DISSE UDTALELSER\***, **UNDERSKRIV DENNE FORMULAR** og send det til «Customer\_Service\_Fax\_Number»

- Vi har ikke** noget berørt produkt
- Vi har fundet berørte produkter: Bekræft venligst det kvantum, der skal returneres ovenfor. Hvis De returnerer et produkt, der ikke er anført ovenfor, tilføj venligst UPN, produktionsnummer samt det kvantum, der skal returneres.

**FOR AT RETURNERE PRODUKTER:**

- Efter modtagelse af bekræftelsesformularen vil Boston Scientific kontakte dig for at arrangere returnering.
- Klargør pakningen.
- Følg de instruktioner, der bliver givet fra jeres lokale kundeservice, om afhentning af pakningen.

NAVN\* \_\_\_\_\_ TITEL \_\_\_\_\_  
(blokbogstaver)

Telefon \_\_\_\_\_ E-mail \_\_\_\_\_

Autoriseret Underskrift\* \_\_\_\_\_ DATO\* \_\_\_\_\_  
\* Obligatoriske felter dd-mm-åå