

<Hospital_Name>

<Users_Name>

<Department>

<Customer_Address>

<Zip_Code> <City>

<Country_Name>

<Reference: 97622075-FA>

14 July 2026

SRN: US-MF-000004702

Urgent Field Safety Notice - Urgent Medical Device Recall OverStitch™ Suture Cinch and Suture Cinch–Long

Dear Materials Manager and/or Healthcare Professional,

Boston Scientific is initiating recall of specific lots of OverStitch™ Suture Cinch and Suture Cinch–Long (collectively “Suture Cinch”). These devices are accessories used with the OverStitch™ Endoscopic Suturing System, OverStitch™ NXT Endoscopic Suturing System, OverStitch™ SX Endoscopic Suturing System, and the X-Tack™ Endoscopic HeliX Tacking System to secure and cut the proximal end of a suture through the working channel of a gastroscope or colonoscope.

During device activation, the Suture Cinch may fail to deploy the cinch implant and/or fail to cut the suture as intended. The issue cannot be detected through pre-use inspection but becomes apparent once the user attempts to deploy the device during the procedure.

The most common reasonably foreseeable adverse health consequence is the need for an additional intervention because the user may be unable to deploy the Suture Cinch or cut the suture as intended. If excessive force is used to remove the device, alternative methods are required to remove or cut the suture, or additional endoscopic or surgical intervention is necessary to complete the procedure, more serious adverse health consequences—including infection, perforation, inflammation, hemorrhage, and tissue damage—may occur. To date, Boston Scientific has received no reports of patient injury related to this issue.

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> on or before **4 August 2026.**

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,



Dave Mason, Global Quality VP

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

Material Number/UPN	Material Description	GTIN	Batch	Expiration Date
M00505530	OVERSTITCH SUTURE CINCH 1PK	00191506060046	36159783, 36179248, 36179249, 36179250, 36179674, 36181153, 36193585, 36195262, 36195281, 36213130, 36213131, 36222433, 36223110, 36233350, 36233423, 36233424, 36238771, 36246477, 36247744, 36247745, 36257144, 36257145, 36264795, 36266604, 36285303, 36285304, 36291094, 36291142, 36296642, 36297718, 36298785, 36299374, 36307286, 36335098, 36336245, 36336246, 36336247, 36336248, 36336249, 36349543, 36358240, 36366410, 36368880, 36370038, 36376493, 36390716, 36400755, 36413832, 36429438, 36440653, 36440659, 36440798, 36441070, 36441390, 36443933, 36450076, 36451398, 36452061, 36454608, 36454861, 36461432, 36466525, 36472307, 36472448, 36472813, 36473087, 36475081, 36482317, 36482413, 36482837, 36482838, 36486869, 36488822, 36496658, 36498004, 36500343, 36500745, 36508877, 36509436, 36511012, 36519283, 36519622, 36564120, 36567088, 36567089, 36651483, 36651990, 36660007, 36670672, 36689082, 36691535, 36691536, 36692473, 36715146, 36715947, 36722429, 36733894, 36736063, 36737026, 36742475, 36747253, 36754086, 36756476, 36767158, 36770136, 36795290, 36802913, 36816032, 36816864, 36819466, 36829515, 36837613, 36840422, 36855429, 36859432, 36870323, 36884519, 36886399, 36887192, 36894183, 36906859, 37049911, 37053262, 37063221, 37071091, 37082225, 37256930, 37258435, 37265997, 37268058, 37276648, 37277853, 37332709, 37335148, 37341879, 37431423, 37462817, 37475144, 37479080, 37512600, 37516705, 37538409, 37614916, 37628854, 37701281, 37712590, 37747392, 37759135, 37768422, 37780435, 37804241, 37813732, 37824328, 37846636, 37861753, 37874884, 37906665, 37952534, 37976914, 37980916, 37987576, 38001581, 38020339, 38045267, 38055953, 38064514, 38087625, 38092029, 38119620, 38134479, 38149599, 38168976, 38265895, 38274202, 38277823, 38298897, 38307807, 38355532, 38404637, 38421970, 38438020, 38441891, 38448572, 38458999, 38480821, 38495024, 38498977, 38505659, 38526386, 38527090, 38540408, 38613546, 38620724, 38629370, 38672064, 38682255, 38692722, 38709195, 38711985, 38728857, 38738005, 38748320, 38759951, 38771565, 38787506, 38798542, 38808911, 38847193, 38866237, 38886764, 38917596, 38926776, 38936218, 38939941, 38948809, 39018825, 39029561, 39032429, 39043147, 39095582, 39114250, 39131778	25-Mar-2028 to 19-Apr-2029

Material Number/UPN	Material Description	GTIN	Batch	Expiration Date
M00505540	OVERSTITCH SUTURE CINCH 1PK	00191506049171	35965074, 35965077, 35967236, 35976437, 35976438, 36008493, 36019843, 36050655, 36055091, 36055092, 36055093, 36071017, 36071638, 36071639, 36096456, 36103681, 36105033, 36124313, 36124560, 36138359, 36147516, 36149264, 36149357, 36168094, 36168095, 36177686, 36508205, 36578573, 36580372, 36587883, 36588746, 36598637, 36599588, 36601267, 36602423, 36605880, 36607666, 36608703, 36613132, 36613249, 36722431, 36796694, 36897847, 36898252, 36899896, 36911702, 36919735, 36931142, 36932284, 36932757, 36938264, 36947997, 36951937, 36965484, 36967193, 37003596, 37004909, 37010202, 37032128, 37105012, 37146990, 37155812, 37179014, 37194609, 37282676, 37292127, 37295676, 37307313, 37352684, 37383274, 37402944, 37413381, 37441451, 37574668, 37642233, 37654900, 37688046, 37873807, 37895191, 37931392, 37940955, 38100899, 38158406, 38324701, 38334198, 38337305, 38344889, 38367084, 38368231, 38381355, 38390527, 38401217, 38554478, 38567112, 38575697, 38639504, 38651280, 38665306, 38819101, 38903080, 38906745, 38914237, 39007210, 39069318, 39073915	29-Feb-2028 to 12-Apr-2029
M00505550	SUTURE CINCH - LONG 1PK	00191506049188	35903543, 35948104, 35948105, 35976434, 35976435, 35976436, 36023412, 36054695, 36083619, 36116489, 36124315, 36138740, 36222818, 36222819, 36222960, 36231427, 36232903, 36238318, 36291083, 36298791, 36346089, 36346101, 36376494, 36390167, 36411916, 36428532, 36432020, 36443931, 36444025, 36453238, 36472920, 36472938, 36618380, 36624306, 36634952, 36646601, 36724691, 36846026, 36855626, 37019759, 37019868, 37031959, 37073352, 37086263, 37096406, 37108084, 37116726, 37124788, 37126750, 37128111, 37302211, 37399016, 37533710, 37586915, 37604205, 37663465, 38587149, 38598199, 38823176, 38833088, 39053113, 39091844	26-Feb-2028 to 14-Apr-2029

<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
OverStitch™ Suture Cinch and Suture Cinch–Long
 97622075-FA

1- We acknowledge receipt of the Boston Scientific Field Safety Notice dated 14 July 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