Class 2 Device Recall CRE Wireguided 1215mm 240cm

See Related Information[22]

Date Initiated by Firm	May 21, 2026
Date Posted	July 01, 2026
Recall Status[1]	Open[3], Classified
Recall Number	Z-2635-2026
Recall Event ID	99067[23]
510(K)Number	K110833[24]
Product Classification	Duodenoscope and accessories, flexible/rigid[25] - **Product Code** FDT[26]
Product	CRE Wireguided 12-15mm 240cm
Code Information	UPN: M00558480; GTIN: 8714729339410; Lot No. 38033567, 38056239, 38056940, 38056941, 38215260, 38266854, 38266855, 38293330, 38391881, 38413876, 38413877, 38413878, 38413879, 38414080, 38422547, 38446204, 38466097, 38468862, 38468863, 38529518, 38529519, 38585004, 38622477, 38622478, 38640994, 38670501, 38670502, 38670504, 38686282, 38686283, 38693725, 38726666, 38726667, 38748254, 38767487, 38789996, 38800181, 38879160, 38879163, 38879164, 38911928, 38911929, 38911930, 38944841; Exp. October 24, 2028 February 24, 2029.
FEI Number	3005099803
Recalling Firm/ Manufacturer	Boston Scientific Corporation 100 Boston Scientific Way Marlborough MA 01752-1234
For Additional Information Contact	Renee Archie 508-683-4523
Manufacturer Reason for Recall	Potential sterile breach of the pouches in which devices are packaged.
FDA Determined Cause [2]	Package design/selection
Action	An Urgent Medical Device Removal - Immediate Action Required notification was mailed to consignees on 5/21/26. This notification informed consignees that Boston Scientific was conducting a removal of affected devices due to a potential sterile breach of product packaging (pouches). Consignees are instructed to immediately stop further use or distribution of product and quarantine them. Consignees are to complete and return the provided Reply Verification Tracking Form and return the product to Boston Scientific per the provided instructions. Consignees are to share the recall notification with any healthcare provider that uses the affected devices and with organizations to which product was further distributed. Consignees with any questions are to contact their Boston Scientific representative.
Quantity in Commerce	81,543 units
Distribution	Worldwide distribution - US Nationwide and the countries of Australia, Austria, Bahrain, Bangladesh, Belgium, Bulgaria, Canada, Chile, China, Costa Rica, Croatia, Czech Republic, Denmark, Dominican Republic, Ecuador, Estonia, Finland, France, Germany, Great Britain, Greece, Guatemala, Hong Kong, Hungary, India, Indonesia, Ireland, Israel, Italy, Japan, Jordan, Latvia, Lebanon, Luxembourg, Malaysia, Mexico, Mongolia, Netherlands, New Zealand, Norway, Pakistan, Paraguay, Peru, Philippines, Poland, Portugal, Romania, Russian Federation, Serbia, Singapore,

Slovakia, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Tobago, Trinidad, Tunisia, T¿rkiye, United Arab Emirates, Uruguay.

Total Product Life Cycle TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database 510(K)s with Product Code = FDT[29]

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22. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=99067
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28. https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=FDT&knumber=&applicant=Boston%20Scientific%20Corporation

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