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Class 2 Device Recall Surgipro



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Class 2 Device Recall Surgipro



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Date Initiated by Firm	June 24, 2026
Date Posted	August 07, 2026
Recall Status ¹	Open ³ , Classified
Recall Number	Z-2921-2026
Recall Event ID	99390 ²³
Product Classification	Suture, nonabsorbable, synthetic, polypropylene ²⁴ - Product Code GAW ²⁵
Product	Surgipro SP-623 SURGIPRO* 2-0 BLU 75CM SC2 X36 SP-623
Code Information	SP-623 UDI-DI 20884521037073 Lot D6A2963Y
FEI Number	1219930
Recalling Firm/ Manufacturer	Covidien, LP 60 Middletown Ave North Haven CT 06473-3908
For Additional Information Contact	Medtronic Technical Services 800-255-6774
Manufacturer Reason for Recall	Product may contain a perforation or tear in the sterile barrier packaging. This issue may result in biocontamination of the sterile sutures, which may lead to infection, loss of vision if in ophthalmic utilization, or prolonged surgery.
FDA Determined Cause ²	Equipment maintenance
Action	The firm began notifying consignees on 7/7/26 via email, mail, or electronically. Notices were titled, "URGENT: VOLUNTARY MEDICAL DEVICE RECALL." Customers were informed of the manufacturing nonconformance. If products in scope of this field action have been used in patients under the customer's care, the customer is instructed to monitor for signs of infection or vision issues due to the possibility of biocontamination. Customers were instructed to immediately identify, cease use, and quarantine all unused impacted product. Unused impacted product is to be returned to Medtronic. The recall notice should be passed on to all those who need to be aware within the customer's organization or to any organization where devices have been transferred.
Quantity in Commerce	135,875 total
Distribution	US Nationwide and the countries of Australia, Austria, Belgium, Bulgaria, Canada, Canary Islands, Chile, China, Colombia, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Guadeloupe, Guatemala, Honduras, Hong Kong, Hungary, Iceland, India, Ireland, Israel, Italy, Japan, Kosovo, Lebanon, Lithuania, Luxembourg, Mexico, Namibia, Netherlands, North Macedonia, Northern Ireland, Norway,

Oman, Panama, Poland, Portugal, Qatar, Reunion, Romania, Russia, Saudi Arabia, Singapore, Slovakia, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, Ukraine, United Arab Emirates, United Kingdom, Uzbekistan.

Total Product Life Cycle [TPLC Device Report](#)²⁶

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](#)²⁷.

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.

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Page Last Updated: 08/31/2026

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