Medtronic

URGENT FIELD SAFETY NOTICE

Covidien EndoStitch™ Polysorb Single Use Loading Unit

Recall

Product Names	Model Number	Lot Number	GTIN
ENDOSTITCH POLYSORB 2/0 48" VIO DLU SU	170053	J5L2332Y	10884521126732 20884521126739
ENDOSTITCH POLYSORB 3/0 48" VIOLET DLUSU	170071	J5H2924Y	10884521126787 20884521126784

April 2026

Medtronic Reference: FA1560
EU Manufacturer Single Registration Number (SRN): US-MF-000028763

Dear Risk Manager/ Healthcare Professional,

The purpose of this letter is to advise that Medtronic is initiating a recall for a specific lot of the Endo Stitch™ Single Use Loading Unit, Model numbers 170053 and 170071, as listed above.

Issue Description:
Medtronic identified a manufacturing nonconformance in affected lots that could result in products not meeting specifications, including packaging integrity and sterile barrier performance.

As of April 6, 2026, there have been no customer complaints or patient harm reported in relation to this action. The manufacturing nonconformance was identified through Medtronic's robust quality management systems.

Risk to health:
While there have been no reports of patient harm in relation to this action, risks of compromised packaging integrity and sterile barrier performance include, but are not limited to, infection, dehiscence, tissue breakdown, blood loss, foreign body in patient, foreign body reaction, unintended radiation exposure, allergic reaction or prolonged surgery.

Patient Management:

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If product in scope of this field action has been used in patients under your care, please monitor for signs of infection or signs of tissue dehiscence due to the possibility of early suture degradation leading to inadequate tissue support.

Customer Actions:

Our records show that your facility has received impacted products. Medtronic requests you take the following actions:

- Immediately identify and quarantine all unused impacted product listed above.
- See **Appendix A** for guidance on identifying affected lots.
- Return all unused impacted product listed above to Medtronic.
- This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Actions being taken by Medtronic:

- Medtronic representatives will assist customers with the return of affected product, upon request.
- Medtronic representatives will work with customers to ensure replacement products are available to avoid interruptions in patient care.

Additional information:

Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact Medtronic representative.

Sincerely,

Local / OU manager

Enclosed:

Appendix A: Identifying affected lots

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