Medtronic

# Urgent Field Safety Notice

## Endo Stitch™ Single Use Loading Unit with V-Loc™ Reload

Recall

September 2022

Medtronic Reference: FA1281
EU Manufacturer Single Registration Number (SRN): US-MF-000028763

Dear Risk Manager/Healthcare Professional,

The purpose of this letter is to advise you that Medtronic has initiated a voluntary recall for specific lots of the Endo Stitch™ Single Use Loading Unit with V-Loc™ 180 Absorbable Reload and the Endo Stitch™ Single Use Loading Unit with V-Loc™ PBT Non-Absorbable Reload. You are receiving this letter as Medtronic records indicate your facility may have at least one of the Endo Stitch Single Use Loading Unit with V-Loc Reloads identified for recall in Appendix 1. Medtronic initiated this action to prevent the use of potentially affected Endo Stitch Single Use Loading Unit with V-Loc Reloads that may impact patients.

**Issue Description:**
Medtronic has received reports of needles breaking during endoscopic suturing. The potential harm(s) include a delay in treatment/therapy, the potential for a portion of the needle to remain in the patient, foreign body reaction, allergic reaction, tissue injury and unintended radiation exposure from additional imaging for both intra-op and postoperative scenarios.

As of 13 September 2022, Medtronic has received 210 complaints related to this issue worldwide. Of these, 119 reported injuries potentially related to the needle breakage. These injuries include foreign body in patient, tissue damage, extended operating room time, and unintended radiation exposure. The cause of the issue is related to a manufacturing nonconformance, and process improvements are in progress to address the nonconformance prior to resuming manufacturing and distribution of product.

There are no additional patient management recommendations for patients where an Endo Stitch Single Use Loading Unit with V-Loc Reload in scope of this recall was used during a procedure. These patients should continue to be monitored in accordance with your medical facility's standard care protocols.

Medtronic

**Product Scope:**

| Product Name | Models | Lot Numbers |
|---|---|---|
| Endo Stitch V-Loc™ 180 Absorbable Reload | VLOCA004L, VLOCA006L, VLOCA008L, VLOCA204L, VLOCA206L, VLOCA208L, VLOCA304L, VLOCA306L, VLOCA308L | Unexpired lots beginning with prefix "N0", "N1", "N9", "N2A", "N2B", "N2C", "N2D", and "N2E" |
| Endo Stitch V-Loc™ PBT Non-Absorbable Reload | VLOCN004L, VLOCN006L, VLOCN008L, VLOCN204L, VLOCN206L, VLOCN208L, VLOCN304L, VLOCN306L, VLOCN308L | Unexpired lots beginning with prefix "N0", "N1", "N9", "N2A", "N2B", "N2C", "N2D", and "N2E" |

**Customer Actions:**

- Identify and quarantine all unused affected Endo Stitch Single Use Loading Unit with V-Loc Reloads.
- Return all unused affected product in your inventory to Medtronic as indicated in the Shipping and Return Instructions below.
- Please complete the Customer Acknowledgment Form even if you **do not** have unused inventory.
- Pass on this notice to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

**Shipping and Return Instructions:**

| | Customer with inventory | Customer with zero inventory | Where to send the completed form |
|---|---|---|---|
| Purchased **directly** from Medtronic | Please complete the attached Returns Verification Form in its entirety.<br>Upon receiving your form, Medtronic Customer Care will contact you to organize the return of your products. You will receive credit for unused device(s) that you return | Complete form and check the box indicating "no inventory" | E-mail or fax the completed form to the Medtronic contact provided on the verification form. |

Medtronic

| | Customer with inventory | Customer with zero inventory | Where to send the completed form |
|---|---|---|---|
| Purchased from a **distributor** | Complete **all** fields on the form and contact your distributor directly to arrange for return of product. | Complete form and check the box indicating "no inventory" | E-mail or fax the completed form to your Distributor and to the Medtronic contact provided on the verification form. |

**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 your Medtronic representative.

Sincerely,

Local / BU Manager

Enclosures:

Attachment A: IDENTIFYING AFFECTED PRODUCT

Medtronic

## Attachment A:

# IDENTIFYING AFFECTED PRODUCT

**Endo Stitch™ Single use Loading Unit with V-Loc™ 180 Absorbable Reload**

**Endo Stitch™ Single Use Loading Unit with V-Loc™ PBT Non-Absorbable Reload**

| Product Name | Models | Lot Numbers |
|---|---|---|
| Endo Stitch V-Loc™ 180 Absorbable Reload | VLOCA004L, VLOCA006L, VLOCA008L, VLOCA204L, VLOCA206L, VLOCA208L, VLOCA304L, VLOCA306L, VLOCA308L | Unexpired all lots beginning with the "N0", "N1", "N9", "N2A", "N2B", "N2C", "N2D", and "N2E" |
| Endo Stitch V-Loc™ PBT Non-Absorbable Reload | VLOCN004L, VLOCN006L, VLOCN008L, VLOCN204L, VLOCN206L, VLOCN208L, VLOCN304L, VLOCN306L, VLOCN308L | Unexpired all lots beginning with the "N0", "N1", "N9", "N2A", "N2B", "N2C", "N2D", and "N2E" |