Medtronic

Urgent Field Safety Notice

Tri-Staple™ 2.0 Black Intelligent Reload - Model SIG60AXT

Recall

January 2023

Medtronic Reference: FA1309

<For use in countries that follow EU MDR: 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 is recalling specific lots of Tri-Staple™ 2.0 Black Intelligent Reload, model SIG60AXT.

Issue Description:

Specific lots of Tri-Staple™ 2.0 Black Intelligent Reload have the potential for a broken sled vane component. A broken sled vane may cause the staple to misfire leading to non-functional staple line closure, transecting tissue without forming staples, and tissue hang-up. These hazards are associated to a delay to treatment, unspecified infection, hemorrhage/blood loss/bleeding, failure to anastomose, peritonitis, sepsis, pneumothorax, tissue trauma, and death.

Through 9 January 2023, Medtronic has received one complaint related to this issue. Included with this complaint is the report of one serious injury which included a delay in treatment and tissue trauma. No deaths have been reported.

There are no additional actions required for patients where a stapler in scope of this voluntary recall was used during a procedure. These patients should continue to be monitored in accordance with your medical facility's standard care protocols.

Product Scope:

Product Name	Models	Lot/Serial Number	GTIN Number
Tri-Staple™ 2.0 Black Intelligent Reload	SIG60AXT	N2D0004Y, N2D0195Y, N2D0002Y	20884521543598 10884521543591

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Actions:

- Immediately identify and quarantine all unused affected Tri-Staple™ 2.0 Black Intelligent Reload, Model SIG60AXT (Refer to Attachment A for identifying affected product). Please note the affected device may be located within a Procedural Solutions Kit. Please reference kits listed in Attachment A to help locate the affected product.
- 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 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. 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.
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: Product Identification
- Attachment B: Customer Acknowledgment Form

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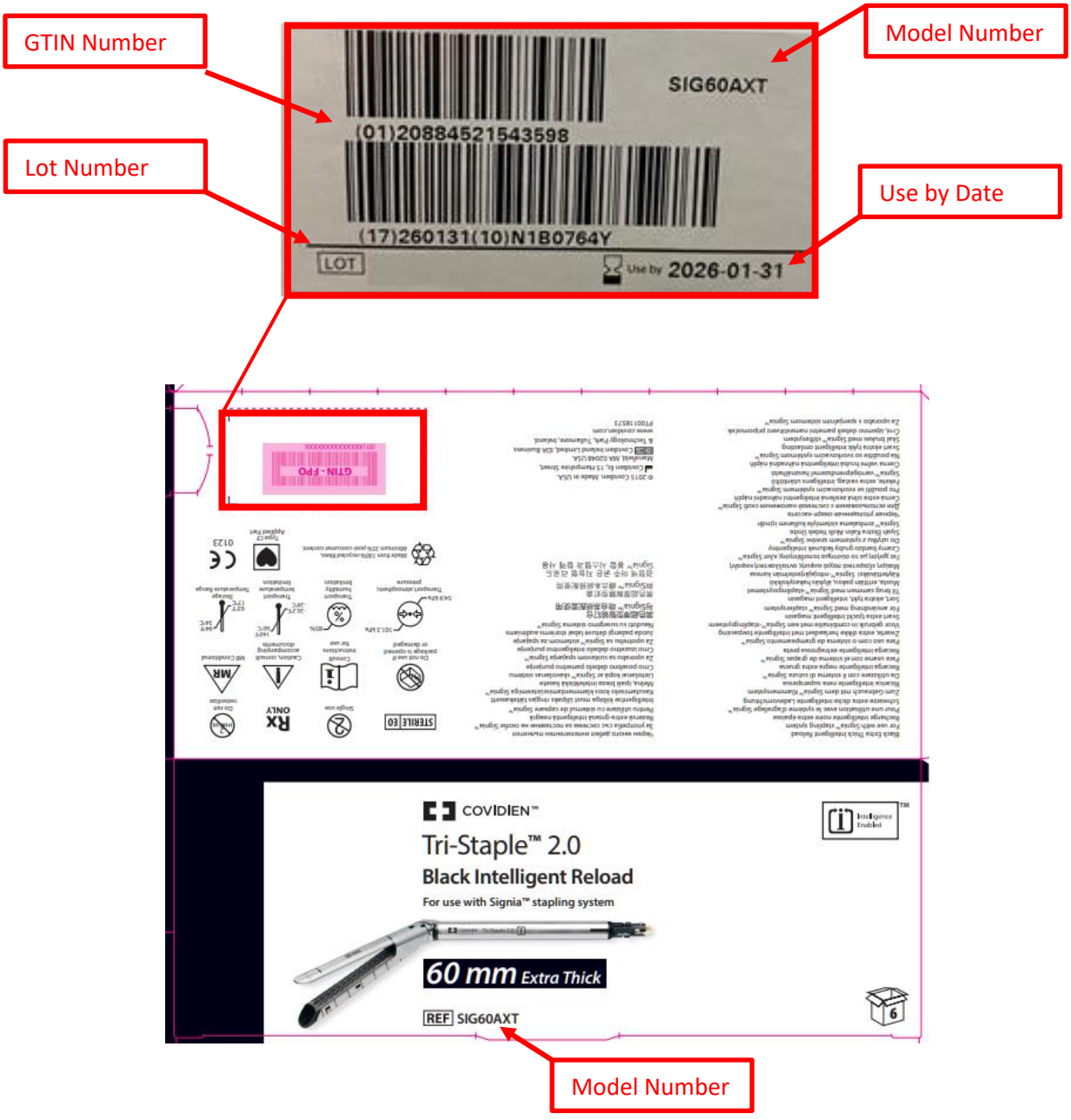
Attachment A: IDENTIFYING AFFECTED PRODUCT

Locate product information on product labels in your inventory and compare to affected product information below.

Product Name	Models	Lot/Serial Number	GTIN Number
Tri-Staple™ 2.0 Black Intelligent Reload	SIG60AXT	N2D0004Y, N2D0195Y, N2D0002Y	20884521543598 10884521543591



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Attachment A: IDENTIFYING AFFECTED PRODUCT

Locate product information on product labels in your inventory and compare to affected product information below.

Associated Kits	Kit Parent Code
Procedural Solution Kit	BOX00807V1, BOX02988V1, K402BA, MSZSG01, PST04077