Medtronic

Urgent Field Safety Notice

EEA™ Autosuture™ Circular Stapler with DST Series™ Technology, 25mm

Model Numbers – EEA25, EEAXL25, EEA2535, EEAXL2535

Recall

May 2022

Medtronic Reference: FA1245

Dear Risk Manager/Healthcare Professional,

The purpose of this letter is to advise you that Medtronic is recalling 25mm EEA™ Autosuture™ Circular Stapler with DST Series™ Technology, model numbers EEA25, EEAXL25, EEA2535, and EEAXL2535.

Issue Description:

Distributed 25mm EEA Autosuture Circular Staplers with DST Series Technology, with model numbers EEA25, EEAXL25, EEA2535, and EEAXL2535, have the potential for the staple guide to not be securely attached to the instrument. This issue is related only to the 25mm EEA Autosuture Circular Staplers with DST Series Technology. No other Medtronic products or other sizes of EEA Autosuture Circular Staplers with DST Series Technology are affected by this issue.

Through 04 April 2022, Medtronic has received 23 complaints potentially related to disengaged staple guides, of which two (2) complaints were directly confirmed through investigation of returned product. A staple guide not attached to the instrument could cause the component to disengage and if disengaged, could allow the device to transect tissue without forming staples. This could result in delay of treatment, extended hospital stay, unspecified tissue injury, unintended radiation exposure, unexpected medical intervention, foreign body in patient, failure to anastomose, and hemorrhage. Within the 23 complaints reported, twelve (12) reported serious injury potentially related to the failure mode associated with this recall. These serious injuries include tissue injury/loss, hemorrhage, failure to anastomose, foreign body in patient that was retrieved, extended procedure, and extended hospital stay.

There are no additional actions required for patients where a stapler 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.

Product Scope:

Product Name	Models	Lot Numbers	Excluding Lot Numbers
EEA™ Auto Suture™ Circular Stapler with DST Series™ Technology	EEA25, EEAXL25, EEA2535, EEAXL2535	All Lots beginning with "P0", "P1", "P7", "P8", "P9"	With suffix "FR", and P1K1303R, P1M0581R, P1L0580R, P1M0540R, P1L1169R, P1L1154RS, P1L1070R

Actions:

- Identify and quarantine all unused affected EEA Autosuture Circular Stapler with DST Series Technology, with model numbers EEA25, EEAXL25, EEA2535, and EEAXL2535. Please note the affected device may be located within a Procedural Solutions Kit. Please reference the Procedural Solutions Kit Model Numbers 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.
- 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. 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 is communicating this information to the appropriate regulatory agency in your country.

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,

Attachment A:
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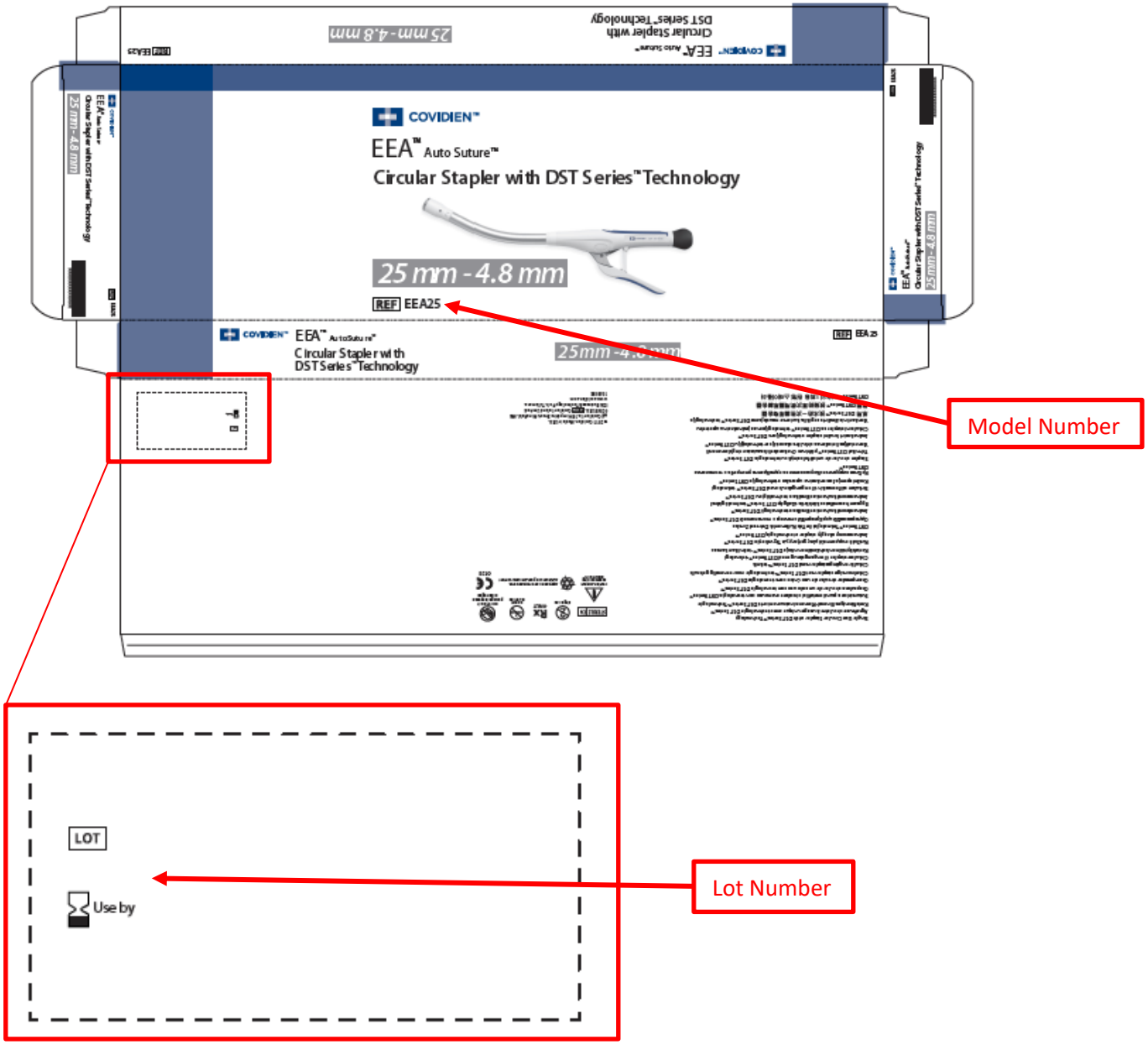
IDENTIFYING AFFECTED PRODUCT

EEA™ Autosuture™ Circular Stapler with DST Series™ Technology, 25mm

Product Name	Models	Lot Numbers	Excluding Lot Numbers
EEA™ Auto Suture™ Circular Stapler with DST Series™ Technology	EEA25, EEAXL25, EEA2535, EEAXL2535	All Lots beginning with "P0", "P1", "P7", "P8", "P9"	With suffix "FR", and P1K1303R, P1M0581R, P1L0580R, P1M0540R, P1L1169R, P1L1154RS, P1L1070R



Attachment A:
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IDENTIFYING AFFECTED PRODUCT

EEA™ Autosuture™ Circular Stapler with DST Series™ Technology, 25mm

Associated Kits	Parent Code
Procedural Solutions Kit	00KVES021116, BOX00063V2, BOX00066V1, BOX00066V2, BOX00113V1, BOX00146V1, BOX00195V1, BOX00202V1, BOX00210V1, BOX00294V1, BOX00294V2, BOX00606V1, BOX00805V3, BOX00830V1, BOX00901V1, BOX01097V1, BOX01129V1, BOX01510V1, BOX01511V4, BOX01512V3,

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Associated Kits	Parent Code
	BOX01619V1, BOX01619V2, BOX01779V1, BOX03536V1, ILAPGAR6, KBAR061, K-BE-BAR201-202, K-BE-LGBP10-100, K-BE-LGBP13-113, K-BE-VATS50-500, KIT00066R1, KIT00362B1, KIT00362B2, KIT00486R, KIT00786, KIT00786V1, KIT00924, KIT014006GASTB2, KITDE0237, KITDE0246, KLGBP212, LAPGAR2, LAPGAR6, LAPIGAR6, LARMAX25, LGBPTOR1, LGBPTORI, PST00551, PST01199, PST02268, PST02283, PST02789, PST03007, PST03813, PST04161, PST04399, PST04663, PST04663LF5637, PST04896V2, PST05736, PST05736V2, PST06997, PST561531165, PST620811020, ROGASTRIC