Medtronic
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URGENT: MEDICAL DEVICE RECALL

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

Model Numbers – EEA25, EEAXL25, EEA2535, EEAXL2535

19 May 2022

Attention: Risk Management Director and O.R Materials Management
CC: The Chairman Medical Board and relevant Head of Departments

Dear Risk Manager/Healthcare Professional:

The purpose of this letter is to advise you that Medtronic is voluntarily 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 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 Numbers	Excluding Lot Numbers
EEA™ Autosuture™ 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.
- Return all unused affected product in your inventory to Medtronic by contacting your local Medtronic field representative.
- 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.
- Please complete the enclosed Customer Confirmation Form and hand or email back to your local Medtronic field representative

Additional Information:

Medtronic is communicating this information to the appropriate regulatory agency in your country.

Local contact details:

Adverse reactions or quality problems experienced with this product should be reported to your local Medtronic field representative

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 local Medtronic field representative.

Sincerely,

DocuSigned by:

Signer Name: Diana Teo
Signing Reason: I approve this document
Signing Time: 17 May 2022 | 09:19 SGT
05FB18D83D7745D787A6E905DEAE1FD1

Medtronic QRA Lead

Singapore & Malaysia

DocuSigned by:

Signer Name: Chloe Tan
Signing Reason: I approve this document
Signing Time: 16 May 2022 | 09:51 SGT
90D0724C9B1C402A99B286449A1644B8

Medtronic QRA Lead

Indochina & Frontier Markets Plus

DocuSigned by:

Signer Name: Parichart Bunjobchokchai
Signing Reason: I approve this document
Signing Time: 13 พฤษภาคม 2022 | 19:02 SEAST
1EE8203B3B0D401EAAC8FA853EBB987A

Medtronic QRA Lead

Thailand

Enclosures:

Attachment A: IDENTIFYING AFFECTED PRODUCT

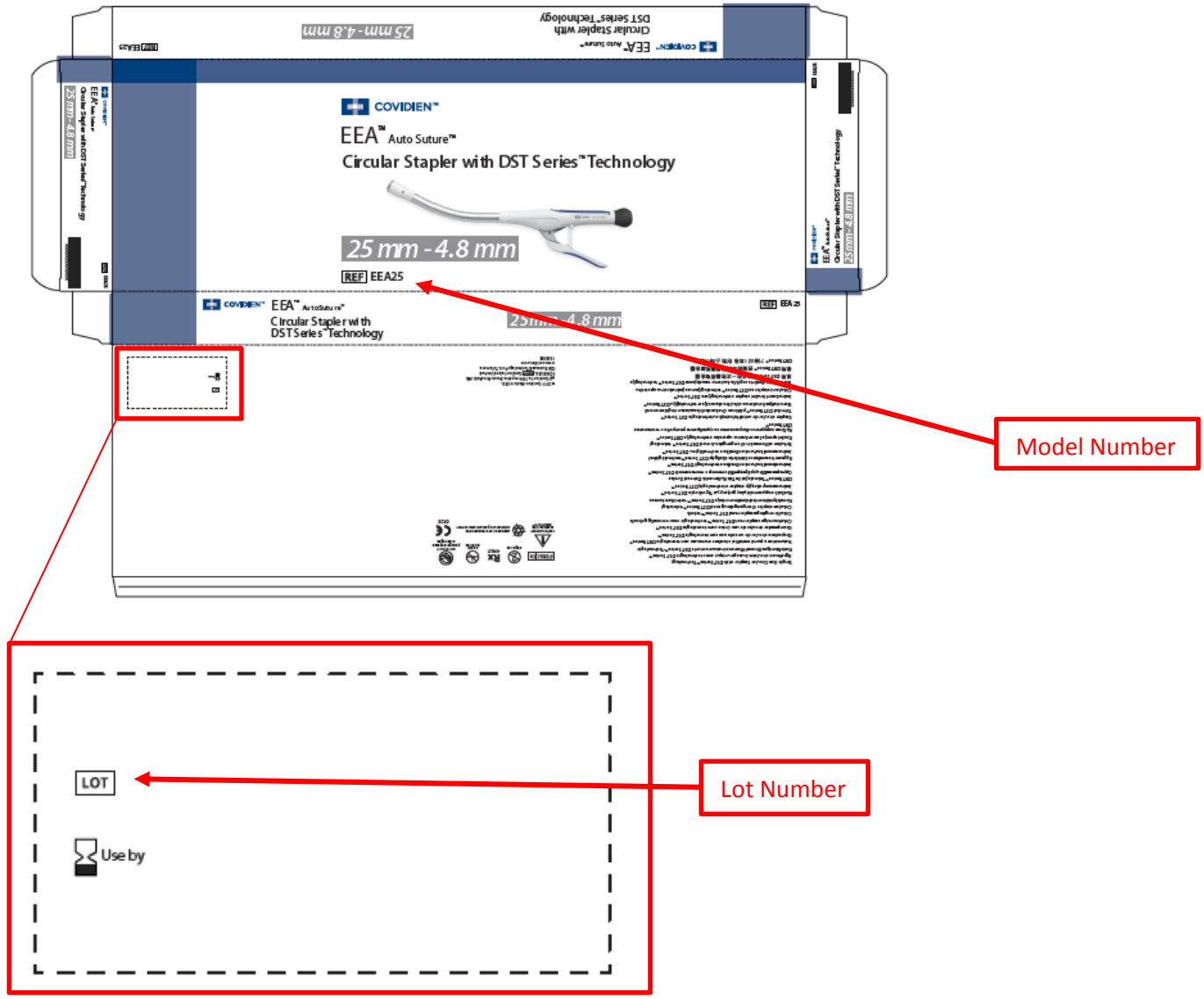
Attachment B: CUSTOMER CONFIRMATION FORM

Attachment A:

IDENTIFYING AFFECTED PRODUCT

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

Product Name	Models	Lot Numbers	Excluding Lot Numbers
EEA™ Autosuture™ 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



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CUSTOMER CONFIRMATION FORM

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

Model Numbers – EEA25, EEAXL25, EEA2535, EEAXL2535

Customers must complete the form even if you do not have inventory.

Customer Contact Details	Medtronic Contact Details
Distributor/HCP/Patient name:	**Name:**
	Contact:
Address:	**Email:**
Phone no:	
E-mail:	

How did you purchase this product? (Please select only ONE):

☐ direct from Medtronic ☐ from a distributor [Name of distributor: _____]

Do you have remaining inventory of the affected units? (Please select only ONE):

☐ no, none of the affected inventory to be returned. I have examined our inventory for product/s covered by this and confirm that all affected was/were previously consumed.

☐ yes, affected inventory to be returned. I have examined our inventory and have the following affected product/s that remain/s unconsumed and is to be returned:

Product Number / Item Code	Lot Number	Quantity

**If this table is not enough, please use the additional page provided. Additional page and/or attachments must be signed and dated.*

I acknowledge receipt of the EEA™ Autosuture™ Circular Stapler with DST Series™ Technology recall notification dated 19 May 2022 and understand the recall instructions provided.

Name (print): _____ Signature: _____ Stamp: _____ Date:_____

Use this page *****ONLY IF***** the space in the previous page is not enough.

This page must also be signed and dated.

Product Number / Item Code	Lot Number	Quantity

Name (print): _____ Signature: _____ Stamp: _____ Date:_____