URGENT: MEDICAL DEVICE RECALL (REMOVAL)

LIGAMAX – 5mm Endoscopic Multiple Clip Applier (Multiple Lot Numbers)

13 November, 2019

Dear Operating Room Supervisors, Materials Management Personnel, and Chief of Surgery:

Ethicon has initiated a voluntary medical device recall (removal) of specific lots of LIGAMAX – 5mm Endoscopic Multiple Clip Applier. Ethicon identified that a potential exists that certain LIGAMAX devices within the impacted lots may have small holes in the Tyvek lidding which could result in a breach of sterility. In the event that the sterility barrier has been breached, there is a chance that a pathogen may be introduced and if unrecognized or untreated may cause life threatening infection. As the population at risk is most likely to receive prophylactic antibiotics the probability of harm is extremely rare. We have identified the root cause and have implemented corrective actions to address the issue and prevent reoccurrence. As of the date of this communication, no adverse events or complaints have been reported for this issue.

Our records indicate that you may have ordered or received product subject to this recall**. PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO USE LIGAMAX – 5mm ENDOSCOPIC MULTIPLE CLIP APPLIER.** The dates of distribution for affected products were from July 31, 2019 thru October 4, 2019.

EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE THE FOLLOWING PRODUCT CODE/ LOT:

PRODUCT NAME	PRODUCT CODE	PRODUCT LOT					DESCRIPTION / SIZE
LIGAMAX	EL5ML	T9491A	T9422K	T93X4R	T93Z52	T94721	5mm Endoscopic Multiple Clip Applier
		T9401C	T94A9K	T9484Y	T93Z76	T94758	
		T94F3C	T9416M	T93Y2Z	T94118	T94807	
		T93X9D	T9461M	T9426Z	T94402	T94E66	
		T9408F	T94C8N	T94C2Z	T94536	T94G99	
		T94F7F	T94D2N	T93Y70	T94567	T94H78	
		T9487J	T94H1N	T93Y96	T94667	---	

Health care practitioners who have treated patients using this product should follow those patients post-operatively in the usual manner with no additional action required.

Johnson & Johnson Medical Singapore
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Business Reg No. 52836279L Company Reg No. 197402104W

IDENTIFICATION OF PRODUCT SUBJECT TO THIS RECALL (Removal):

Product subject to the recall in your inventory can be identified by product code described in above table. All unused LIGAMAX – 5mm Endoscopic Multiple Clip Appliers subject to this recall are required to be returned. Please utilize attachment 1 for assistance in identifying the product lots subject to this recall.

ACTION REQUIRED:

1. Examine your inventory immediately to determine if you have product subject to this action on hand and quarantine such product(s).

2. Remove the products subject to this voluntary recall and communicate the issue to relevant operating room or materials management personnel, or anyone else in your facility who needs to be informed.

3. If any product subject to this recall has been forwarded to another facility, contact that facility to arrange return. Please consider including a copy of this recall letter when communicating.

4. Complete the Business Reply Form (BRF) (Attachment 2) confirming receipt of this notice and hand it to your Ethicon Sales Representative within three (3) business days. **Please return the BRF even if you do not have product subject to this recall (removal).**

5. Keep this notice visibly posted for awareness until all products subject to this recall has been returned to your Ethicon sales representative. While processing your returns, please maintain a copy of this notice with the products subject to this recall (removal) and keep a copy for your records.

6. Customers are required to return unused **impacted LIGAMAX – 5mm Endoscopic Multiple Clip Appliers** subject to this recall that are in their inventory immediately. To receive replacement product, customers must return products subject to this recall (removal) by 31 January 2020. **Any non-affected product or impacted products returned after the date specified will not be replaced.**

7. To return products subject to this action, please contact your Ethicon sales representative.

If you require any assistance with returning the impacted products, please contact your Ethicon sales representative.

At Ethicon, our first priority is to our customers and their patients, and that includes the safe and effective use of our products. We recognize the recall of this product may be disruptive to your facility and we apologize for any inconvenience this may cause.

If you have additional questions regarding this action or to report any customer complaints, please contact your Ethicon sales representative.

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Attachments:
Attachment 1: Product Identification Tool
Attachment 2: Business Reply Form

Yours sincerely,

[redacted]

Lee Ching Hwee
Manager, Regulatory Affairs

cc: Chairman Medical Board
Relevant Head of Departments

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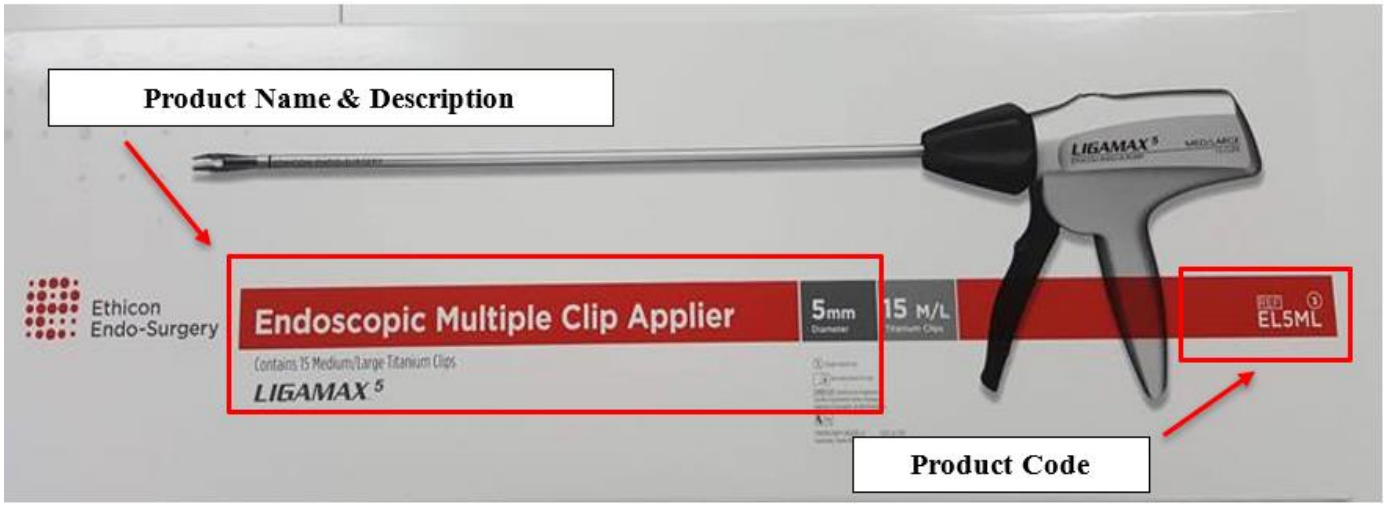
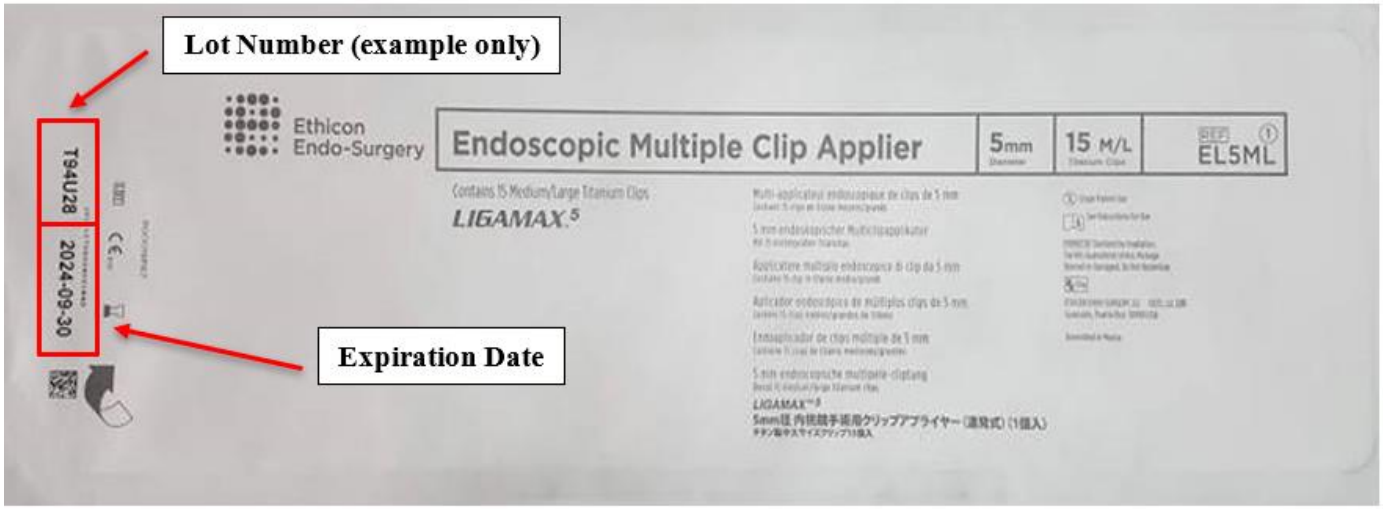
ATTACHMENT 1: Product Identification Tool for LIGAMAX– 5mm Endoscopic Multiple Clip Applier

Please refer to below in order to identify location of product code, expiration date, and lot number for LIGAMAX– 5mm Endoscopic Multiple Clip Applier subject to this recall by using the packaging labels.

FRONT OF DEVICE CARTON



Sealed Device Tyvek Package



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ATTACHMENT 2: Business Reply Form (BRF)

Your timely response to this customer notification is requested. Please complete this form and hand it to your Ethicon Sales Representative **within 3 business days, even if you do not have product subject to this recall (removal) to return.**

If you have product lots subject to this recall (removal) to return, please make a photocopy of your completed Business Reply Form and enclose with your return. Thank you for your cooperation.

Product Inventory – *please* check one

☐ **We have NO inventory of product subject to this recall (removal).**
☐ **We have product subject to this recall (removal) and are returning the following products:**

PRODUCT NAME / CODE	LOT NUMBER	EXPIRATION DATE	RETURNING QUANTITY (EACH)
LIGAMAX / EL5ML			

Print Name of Person Completing Business Reply Form:	Sign & Date:
Customer Account Details (Name and Address)	

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