ETHICON

PART OF THE Johnson&Johnson FAMILY OF COMPANIES

URGENT: FIELD SAFETY NOTICE

LIGAMAX – 5mm Endoscopic Multiple Clip Applier
Product Codes: EL5ML
(Multiple Lot Numbers) – Voluntary Product Recall (Removal)

[Insert Date]

Dear Valued Customer,

Ethicon has initiated a voluntary medical device recall (removal) of specific lots of LIGAMAX – 5mm Endoscopic Multiple Clip Applier distributed in Austria, Belgium, Denmark, Estonia, Finland, France, Germany, Great Britain, Ireland, Netherlands, Slovenia, Sweden, Switzerland.
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:

Table 1 – Product Subject to this Recall

PRODUCT NAME	PRODUCT CODE	PRODUCT	DESCRIPTION / SIZE
LIGAMAX	EL5ML	T9416M	5mm Endoscopic Multiple Clip Applier

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.

This voluntary medical device recall has been communicated to all impacted Health Authorities in EEA, Switzerland and Turkey.

IDENTIFICATION OF PRODUCT SUBJECT TO THIS RECALL (Removal):

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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 recall on hand and quarantine such product(s).

2. Remove the product subject to this 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 return to [Insert Affiliate Information] within three (3) business days. **Please return the BRF even if you do not have product subject to this recall**.

5. Follow instructions in the letter and immediately return any inventory of LIGAMAX – 5mm Endoscopic Multiple Clip Appliers subject to this recall no later than **January 31, 2020** to [Insert Affiliate Information].

6. Keep this notice visibly posted for awareness until all product subject to this recall has been returned. While processing your returns, please maintain a copy of this notice with the product subject to this recall and keep a copy for your records.

7. 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 credit reimbursement, customers must return product subject to this recall no later than **January 31, 2020**. **Any non-affected product and any product returned after the date specified will not receive replacement.**

8. To return product subject to this recall, photocopy the completed BRF, place it in the box with the product, and affix the pre-paid authorized shipping label included with the recall notification letter. [INSERT AFFILIATE NAME] will pay for the shipping charges only if the authorized label is used. Extra shipping labels may be obtained by contacting [INSERT AFFILIATE NAME] or [INSERT PHONE NUMBER].

If you require any assistance with returning product lots subject to this recall, please contact [INSERT AFFILIATE NAME] OR [INSERT AFFILIATE NUMBER].

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 recall, please contact [INSERT AFFILIATE INFORMATION].

As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to your Sales Representative, directly to Ethicon, or your National Health Authority. If you have any further

questions related to this notice or if you need any additional communications, please contact your local Sales Representative.

Attachments:

Attachment 1: Product Identification Tool
Attachment 2: Business Reply Form (BRF)

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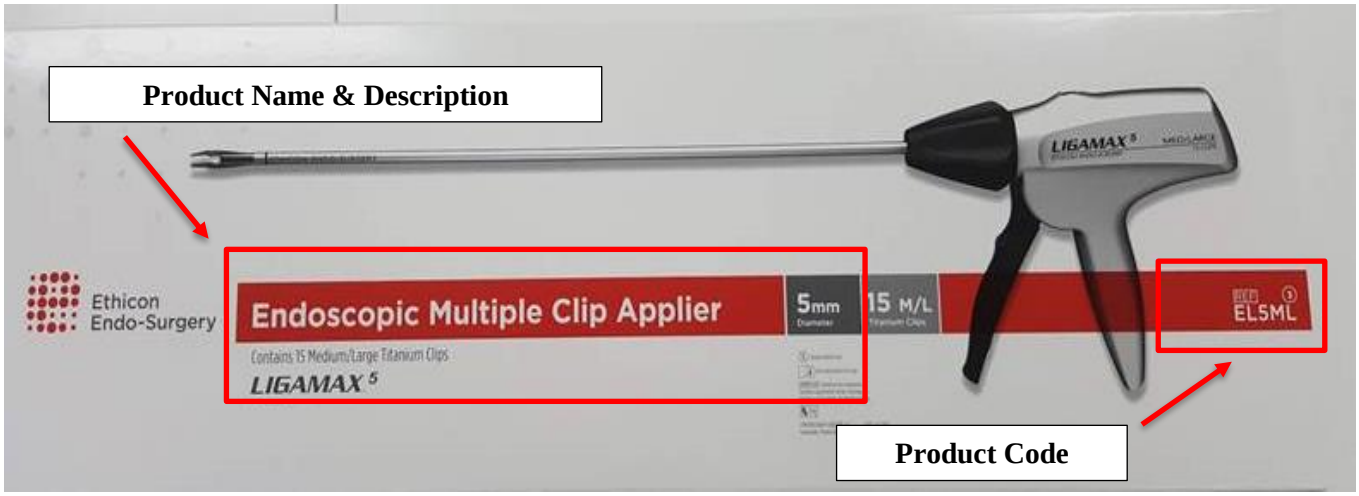
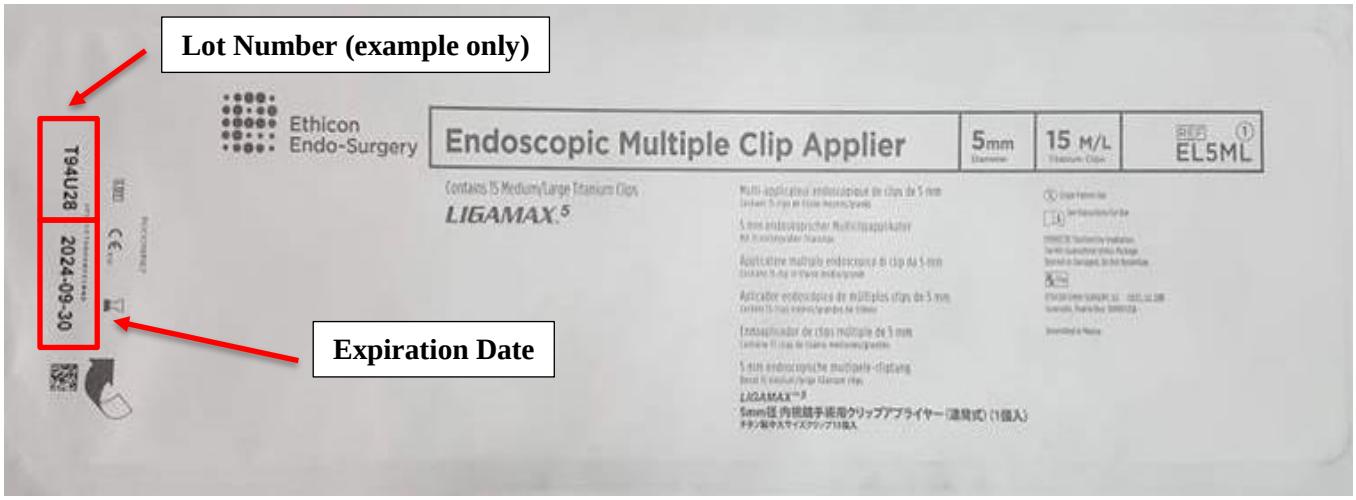
Attachment 1: Product Identification Tool for LIGAMAX– 5mm Endoscopic Multiple Clip Applier

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

Business Reply Form (BRF)

Your timely response to this customer notification is requested. Please complete and fax this form to [Insert Affiliate Information] **within 3 business days, even if you do not have product subject to this recall (removal) to return.**

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

[Account Name]
[Account Address]

Print Name of Person Completing Business Reply Form:	Telephone Number:
Account Number: (number used to order J&J product)	Date:
Replacement Product Shipping Address (If different from above) or reference PO for replacement shipment:	
Signed*: **Your signature provides confirmation that you have received and understood this notification*	
Your comments are welcome.	

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 (Eaches)