ETHICON

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

URGENT: FIELD SAFETY NOTICE

LIGACLIP™ Applier: Product Code LC205, Lot QBCCLQA0

– Voluntary Product Recall (Removal) –

[Insert Date]

Dear Operating Room Supervisors and Materials Management Personnel:

Ethicon would like to notify customers of a voluntary product recall (removal) due to a product mix involving one (1) lot of LIGACLIP™ Applier; Product Code LC205, Lot QBCCLQA0. Sales unit boxes labeled as LIGACLIP™ Appliers may contain ABSOLOK™ Clip Appliers. Our records indicate that you may have ordered or received product subject to this recall.

PLEASE DISTRIBUTE THIS INFORMATION TO THE APPROPRIATE PERSONNEL AT YOUR FACILITY WHO MAY NEED THIS COMMUNICATION.

Within this specific lot, a portion of the eleven (11) distributed packages labeled as LIGACLIP™ Appliers may contain ABSOLOK™ Clip Appliers. There is no impact to the quality or device usability related to the mismatched product. However, the ABSOLOK™ Clip Applier is not compatible with LIGACLIP™ Extra Ligating Clips, which may lead to user inconvenience or necessity to obtain additional product. We apologize for any inconvenience this may have caused. Upon discovery and return to us, we will exchange the incorrect product for the correct product. Please see **Attachment 1** for a visual product comparison.

Ethicon has not received any complaints or reports of Adverse Events or Injuries related to this issue, and there is no anticipated patient safety impact as ABSOLOK™ Clip Appliers will not work with LIGACLIP™ Extra Ligating Clips. We have identified the root cause and are implementing corrective actions to address the issue.

AFFECTED PRODUCT INFORMATION:

PRODUCT NAME	PRODUCT CODE	PRODUCT LOT	DISTRIBUTION DATES	GTIN	DESCRIPTION / SIZE
LIGACLIP™ Applier	LC205	QBCCLQA0	26/11/2020 – 26/02/2021	10705031135284	Clip Applier for LIGACLIP ligating clips, medium, reusable, 14.5cm

This recall does NOT affect any other product codes or lots of reusable clip appliers and also does not affect product where the correct clip applier was included in the box.

IDENTIFICATION OF PRODUCT SUBJECT TO THIS RECALL:

Product subject to this voluntary recall in your inventory can be identified by sales unit box labeled as LIGACLIP™ Applier, Product Code LC205, Lot QBCCLQA0 and physical device labeled as Product Code AC207, Lot 1944348. The product code and lot number can be determined by using the Product Identification Tool in **Attachment 2**.

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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 action 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 3) 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 sales unit box labeled as LIGACLIP™ Applier, Product Code LC205, Lot QBCCLQA0 with physical device labeled as Product Code AC207, Lot 1944348 contained in the box. If the device has been removed from the box, returning the physical device labeled as Product Code AC207, Lot 1944348 will suffice. We request that product subject to this recall be returned no later than [Insert Date] to [Insert Affiliate Information]. Any non-affected product and any product returned after the date specified will not receive replacement.

6. Keep this notice visibly posted for awareness until all product subject to this recall has been returned to [Insert Affiliate Information]. 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.

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 voluntary product recall or require any assistance with returning product, 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 Comparison
Attachment 2: Product Identification Tool
Attachment 3: Business Reply Form

URGENT: FIELD SAFETY NOTICE

LIGACLIP™ Applier: Product Code LC205, Lot QBCCLQA0

– Voluntary Product Recall (Removal) –

ATTACHMENT 1: Product Comparison

FOR REFERENCE ONLY. This attachment provides a side-by-side comparison between the correct LIGACLIP™ Applier, Product Code LC205 and incorrect ABSOLOK™ Clip Applier, Product Code AC207, Lot 1944348 that may be contained in the box. Note: ABSOLOK™ Clip Appliers will not work with LIGACLIP™ Extra Ligating Clips.

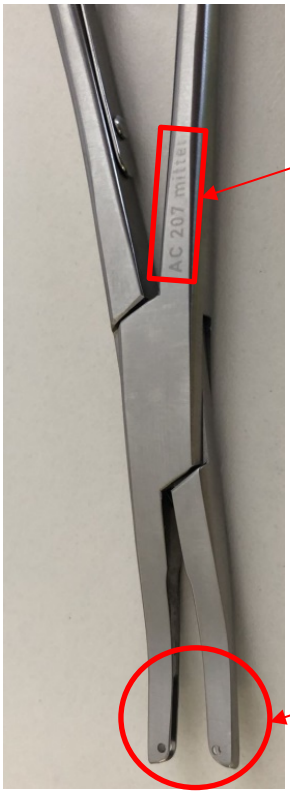
Correct Product (Representative Sample)

Product Code: LC205

Applier Tip

Size: 14.5cm

Incorrect Product (Representative Sample)



Product Code: AC207

Applier Tip

Size: 18.5cm

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LIGACLIP™ Applier: Product Code LC205, Lot QBCCLQA0

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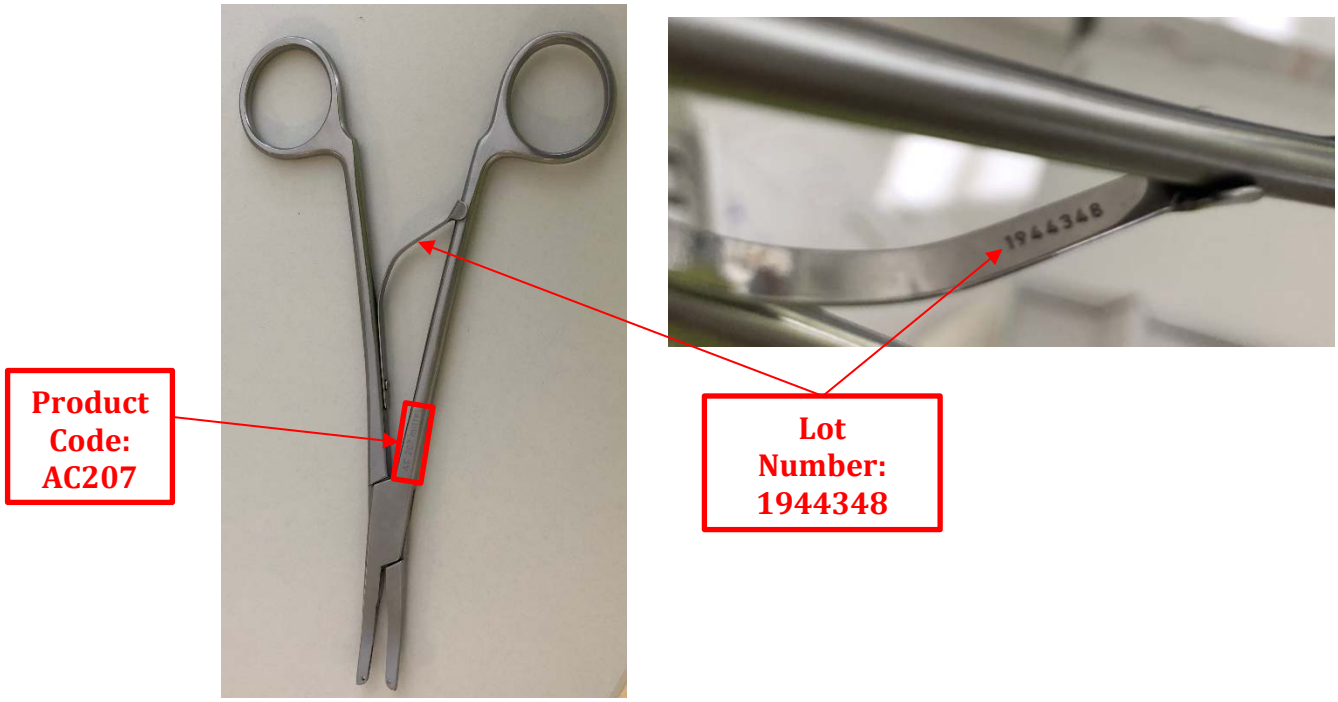
ATTACHMENT 2: Product Identification Tool

This tool will help customers identify the impacted product subject to this recall. This document applies to the sales unit box labeled as LIGACLIP™ Applier, Product Code LC205, Lot QBCCLQA0 and physical device labeled as Product Code AC207, Lot 1944348.

SALES UNIT BOX (Representative Sample)

PHYSICAL DEVICE (Representative Sample)



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ATTACHMENT 3: Business Reply Form (BRF)

Your timely response to this recall notification is requested. Please complete this form and fax or email it to [INSERT AFFILIATE NAME] at [INSERT FAX NUMBER] or e-mail the form to [INSERT AFFILIATE EMAIL ADDRESS] **within 3 business days, even if you do not have product subject to this recall 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:
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 product subject to this recall.**

☐ **We have product subject to this recall. We are returning the following products and requesting replacement product:**

PRODUCT NAME	PRODUCT CODE	PRODUCT LOT	QUANTITY RETURNING (EACHES)
LIGACLIP™ Applier	LC205	QBCCLQA0	QTY in box _____
ABSOLOK™ Clip Applier	AC207	1944348	QTY out of box _____