

MEDICAL DEVICE CUSTOMER NOTIFICATION

LIGACLIP™ Applier
Product Code LC205, Lot QBCCLQA0

[Insert Date]

Dear Operating Room Supervisors and Materials Management Personnel:

Ethicon would like to notify customers of a non-safety related 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 notification.

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

Within this specific lot, a small 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 and would like to take this opportunity to provide you with the option to 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 notification does NOT affect any other product codes or lots of reusable clip appliers.

IDENTIFICATION OF PRODUCT SUBJECT TO THIS NOTIFICATION:

Product subject to the notification 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. Products subject to this notification are required to be returned in order to receive replacement product. The product code and lot number can be determined by using the Product Identification Tool in **Attachment 2**.

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LIGACLIP™ Applier: Product Code LC205, Lot QBCCLQA0

ACTION REQUIRED:

1. Examine your inventory to determine if you have product subject to this notification on hand and need replacement.
2. Remove the product subject to this notification for exchange 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 notification has been forwarded to another facility, contact that facility to provide awareness. Please consider including a copy of this notification 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 notification.
5. To receive replacement, follow instructions in the letter and 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 notification 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 notification has been returned to **[Insert Affiliate Information]**. While processing your returns, please maintain a copy of this notice with the product subject to this notification and keep a copy for your records.

If you have additional questions regarding this medical device customer notification, please contact **[INSERT AFFILIATE NAME]** at **[INSERT PHONE NUMBER]**.

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 Partner.

ATTACHMENTS:

Attachment 1: Product Comparison

Attachment 2: Product Identification Tool

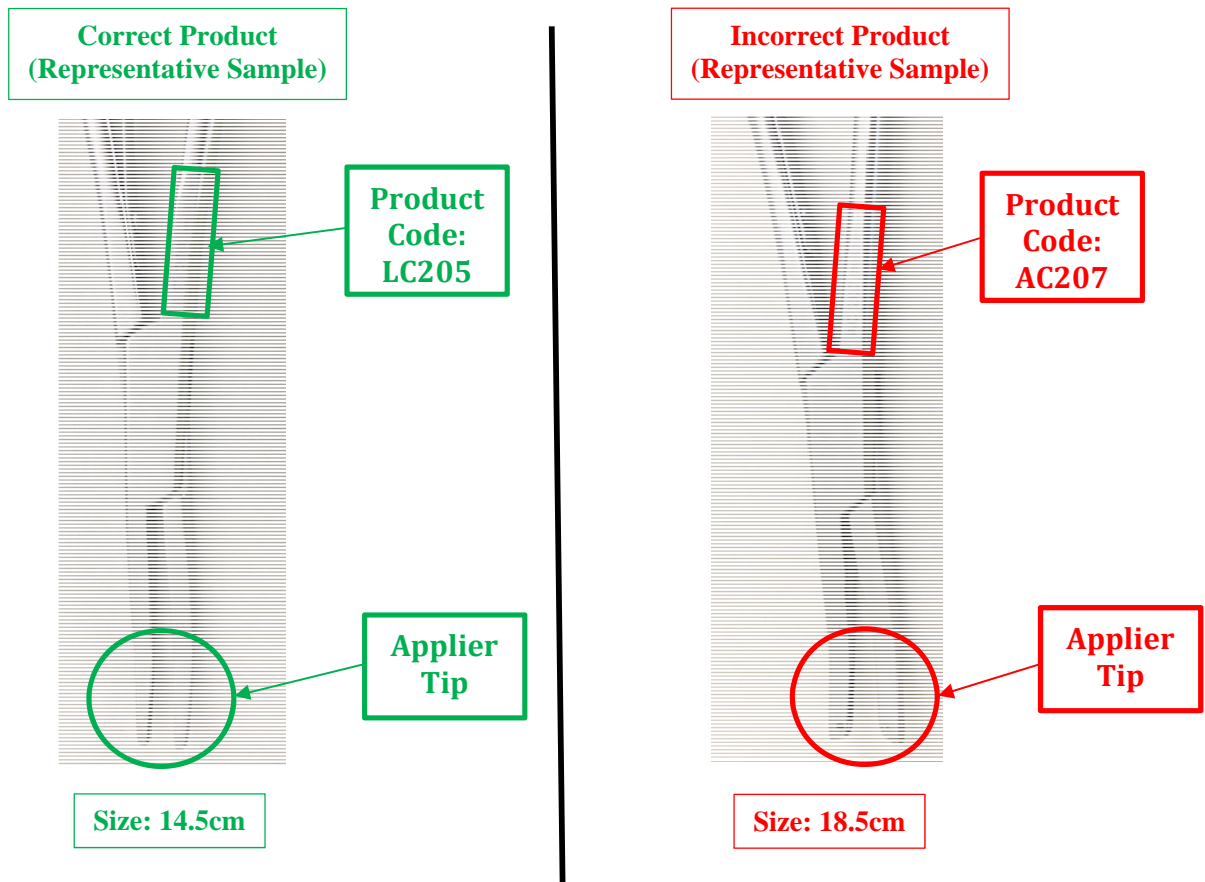
Attachment 3: Business Reply Form

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LIGACLIP™ Applier: Product Code LC205, Lot QBCCLQA0

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.



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ATTACHMENT 2: Product Identification Tool

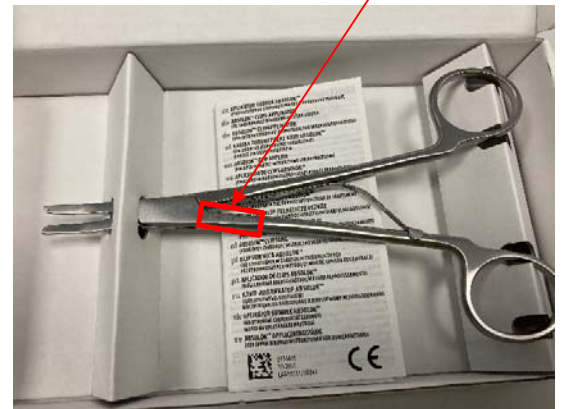
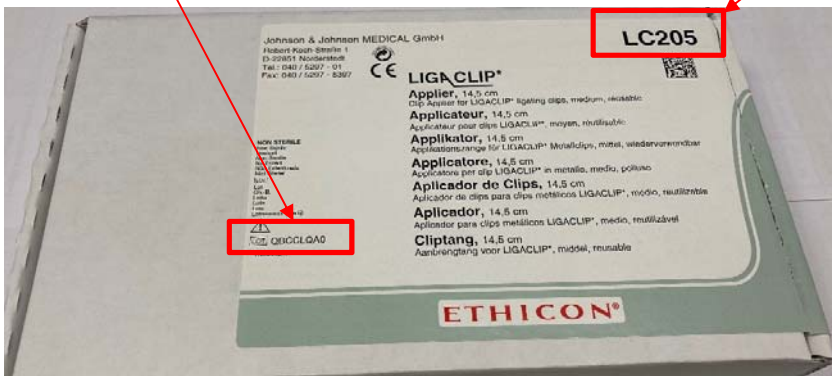
This tool will help customers identify the impacted product subject to this notification. This document applies to the sales unit box labeled as LIGACLIP™ Applier, Product Code LC205, Lot QBCCLQA0 and physical device labeled as Product Code AC207, Lot 1944348.

SALES UNIT BOX (Representative Sample)

**Lot Number:
QBCCLQA0**

**Product Code:
LC205**

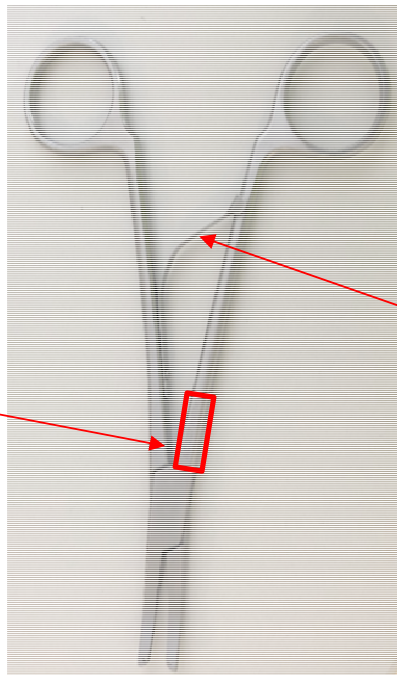
**Product Code: AC207
w/ ABSOLOK™ IFU**



PHYSICAL DEVICE (Representative Sample)

**Product
Code:
AC207**

**Lot
Number:
1944348**



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ATTACHMENT 3: Business Reply Form (BRF)

Your timely response to this 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 notification to return.**

If you have product subject to this notification 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: <small>(number used to order J&J product)</small>	Date:
Signed*:	
<small>*Your signature provides confirmation that you have received and understood this notification</small>	
<i>Your comments are welcome.</i>	

Product Inventory – please check one

- We have **NO** product subject to this notification in current inventory.
- We will keep any ABSOLOK Clip Appliers we may have received that are subject to this notification.
- We have product subject to this notification. 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 _____