From: s22 [redacted]
To: s22 [redacted] Recalls
Cc: s22 [redacted]
Subject: Signed Customer Letter for Intraluminal Staplers (ILS) - RC-2019-RN-00501-1 [SEC=No Protective Marking]
Date: Tuesday, 2 April 2019 4:33:22 PM
Attachments: Customer Letter - ILS Staplers Product Defect Correction - Australia - RC-2019-RN-00501-1.pdf

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Hi s22 [redacted]

As requested, please find attached the signed customer letter for your files.

Please don't hesitate to contact me if you have any questions.

Kind regards,

s22 [redacted]
[redacted]
ANZ Recall and Stop Shipment Coordinator
Johnson & Johnson Medical Pty Ltd ABN 85 000 160 403
1-5 Khartoum Road, North Ryde, NSW 2113 Australia

[redacted] s22 [redacted]

Johnson & Johnson
MEDICAL COMPANIES

2nd April 2019
TGA Ref: RC-2019-RN-00501-1
ARTG: 124512

Chief Executive Officer
Attn: Nurse Unit Manager,
Operating Theatres

URGENT PRODUCT DEFECT CORRECTION
Intraluminal Staplers (ILS)

Product Codes:
ECS21A, ECS25A, ECS29A, ECS33A, SDH25A, SDH29A, CDH21A, CDH25A, CDH29A, CDH33A
All Lots within EXPIRATION Date Range December 2022- March 2024

Dear Sir/Madam,

Johnson & Johnson Pty. Ltd. (JJM), has initiated a Product Defect Correction for Intraluminal Staplers (ILS) regarding the product codes listed above, with expiration date ranges from December 2022 – March 2024.

Issue:

Through investigation of complaints and returned products, Ethicon Inc. has confirmed occurrences of uncut washers and malformed staples with the Ethicon ILS circular staplers, which can compromise staple line integrity.

Ethicon has received reports of Adverse Events related to this field action.

Clinical Implications:

If a problem with the staple line is not adequately addressed or is not recognised, there is a potential risk of postoperative anastomotic leak, gastrointestinal injury, haemorrhage, or haemorrhagic shock.

Based on Ethicon's analysis of complaints received to date and estimated device usage, the predicted occurrence of complaints for malformed staples has increased but is expected to remain below 0.1% (the occurrence rate has increased from 0.03% to a predicted rate of 0.05%). Ethicon is implementing corrective actions to resolve the shift in product performance.

Customer Options:

Option 1

If acceptable quantities of alternative product are available, please return all affected product subject to this notification as per the instructions below; OR

Option 2

Ethicon recognises due to worldwide supply issues with Intraluminal Staplers (ILS), alternative product may not be available in a timely manner. If alternative products to complete required surgeries are not available, consider on a case by case basis whether it is clinically appropriate (for example benign pathology) to defer surgery for a patient until an alternative ILS product becomes available.

If there is clinical necessity to proceed with surgery where product subject to this action will be used, it is critical to adhere to the following information:

Johnson & Johnson Medical Pty. Ltd. ABN 85 000 160 403
1-5 Khartoum Road, North Ryde, NSW 2113, Australia
PO Box 134, North Ryde, NSW 1670
Tel: +61 2 9815 4000 Toll Free: 1800 252 194

- The firing stroke must be completed. Do not partially fire the instrument. Incomplete firing can result in malformed staples, incomplete cut line, bleeding, and leakage from the staple line and/or difficulty removing the device:

  Ensure that the tissue thickness is within the indicated range, and that it is evenly distributed within the instrument. Excess tissue on one side may result in unacceptable staple formation and can result in staple line leakage;
  - Ensure that the firing trigger is fully squeezed to ensure proper staple formation and cutting of tissue;
  - The surgeon should notice both tactile and audible feedback during the firing sequence when cutting through the breakaway washer;
  - Ensure that donuts and cutting washer transections are both complete. If donuts or cutting washer transection are not complete, the anastomosis should be carefully checked for leakage and appropriate repairs made;
  - Always inspect the anastomotic staple line for haemostasis and check the completed anastomosis for integrity and leakage. Metal clips, staples, or sutures contained in the area to be stapled may affect the integrity of the anastomosis. Corrective action, if required, may include the use of sutures or electrocautery.
    - In addition:
      - If an intra-operative leak is observed, remediation should be dictated by your clinical judgement.
      - A negative peri-operative leak test does not guarantee the absence of a leak during the post-operative course; normal clinical surveillance remains essential.

Customer immediate actions:
Our records indicate that your facility may have received product subject to this action.

- Return a copy of the completed acknowledgement form, even if you do not have any affected product, by:
  - fax to **1800 241 101** or email to **ra-jnjau-recallsanz@its.jnj.com**
- If you have alternate product and wish to return the products subject to this notification, please return the product as soon as possible, but within 30 business days, by contacting JJM Customer Service on **1800 252 194**. You may wish to request assistance from your Ethicon Product Specialist.
- Forward this notice to anyone in your facility who needs to be informed.
- If any potentially affected product(s) has been forwarded to another facility, contact that facility to arrange inspection and return (if applicable).
- Maintain awareness of this notice by keeping a copy of this letter until actions are completed.

This notification is being undertaken following consultation with the Therapeutic Goods Administration. If you have questions about alternative devices or concerns with regards to this notification, please contact your Ethicon Product Specialist. We apologise for any inconvenience this action may cause and thank you for your cooperation.

Regards,

s22 [redacted]

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AUSTRALIA **CUSTOMER ACKNOWLEDGEMENT FORM**

2nd April 2019
TGA Ref: RC-2019-RN-00501-1
ARTG: 124512

URGENT PRODUCT DEFECT CORRECTION
Intraluminal Staplers (ILS)

Product Codes:
ECS21A, ECS25A, ECS29A, ECS33A, SDH25A, SDH29A, CDH21A, CDH25A, CDH29A, CDH33A
All Lots within EXPIRATION Date Range December 2022- March 2024

PLEASE COMPLETE THIS FORM, EVEN IF YOU DO NOT HAVE ANY AFFECTED PRODUCTS AND RETURN IT TO:

Jacqueline Simonsen by:

EMAIL: **ra-jnjau-recallsanz@its.jnj.com** **or**

FAX NO: **1800 241 101**

FACILITY:

☐ We acknowledge receipt of this notification from JJM AU regarding Intraluminal Staplers (ILS). We have distributed this information to all staff within our facility that use the impacted products and will maintain a copy of this notice with the identified product(s).

☐ We have NO impacted Intraluminal Staplers (ILS) subject to this field action (notification), however we will maintain a copy of this notice within our facility.

☐ We have impacted Intraluminal Staplers (ILS) subject to this field action (notification), however we do not have an acceptable alternative product and we chose to continue to use the product. We will maintain a copy of this notice within our facility.

☐ We are returning impacted Intraluminal Staplers (ILS) and below are the quantities noted. To arrange return please contact Customer Service (CS) on **1800 241 101** within 30 business days. **CS will advise a Return number (RAN) - please enter RAN in the box below.** You may wish to request the assistance of your Ethicon Product Specialist in the return process.

☐ We have sent this notification to any facility where we have transferred this product: _____

PLEASE RECORD BELOW THE NUMBER OF AFFECTED DEVICES FOR RETURN:

Part Number	Lot Number	Quantity	Part Number	Lot Number	Quantity	Part Number	Lot Number	Quantity

This document is enclosed with the Ethicon Intraluminal Staplers (ILS) Medical Device Product Defect Correction Letter, I have read and understood the letter and have taken the requested actions.

FACILITY NAME If the Acknowledgment form is answered on behalf of more than one facility, please clearly indicate the name of the facility on this page of the notification.	

NAME (of person completing the form)		**POSITION TITLE**	
SIGNATURE		**CONTACT NUMBER**	
RAN		**DATE**	

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