Safety Notice 004/19

JJM Intraluminal Proximate Circular Stapler (ILS)

4 April 2019

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director Regulation & Compliance Unit

Action required by:

- Chief Executives
- Directors of Clinical Governance
- Clinical Product Managers

We recommend you also inform:

- Directors and Managers of Operating Theatres
- Operating Theatres staff
- Critical Care staff
- Surgical Heads of Departments
- Nursing Unit Managers

Expert Reference Group

Content reviewed by:

- Office of the Chief Health Officer
- HealthShare
- Director Patient Safety
- ACI Surgical Services Taskforce
- Surgeons

Clinical Excellence Commission

Tel. 02 9269 5500
Fax. 02 9269 5599

Email:
CEC-Quality@health.nsw.gov.au

Internet Website:
http://www.health.nsw.gov.au/sabs

Intranet Website
http://internal.health.nsw.gov.au/quality/sabs/

Issue Identified

The Therapeutic Goods Administration (TGA) has released a product defect notice identifying an issue of uncut washers and malformed staples with the Johnson and Johnson Medical (JJM) Ethicon ILS circular staplers which can compromise the integrity of the staple line for anastomoses (attached).

The TGA has indicated there have been reports of serious harm to patients overseas however it is not known at this stage whether any patients in Australia have been affected. There are no reported incidents in NSW.

The ILS staples are used on the gastrointestinal tract, including for upper GI, bariatric and colorectal surgeries. Use of the affected JJM product may be associated with an increased risk of post-operative anastomotic leak. Anastomotic leak can lead to sepsis, haemorrhage, haemorrhagic shock and death. Signs of anastomotic leak become apparent in the first two weeks following surgery.

Affected product codes are:

PRODUCT CODE	All Lots within EXPIRATION Date Range
CDH21A CDH25A CDH29A CDH33A	December 2022 – March 2024
ECS21A ECS25A ECS29A ECS33A	February 2023 – March 2024
SDH25A SDH29A	March 2023 – March 2024

The TGA has advised that the occurrence rate of complaints for malformed staples has increased from 0.03% to approximately 0.05%.

Supply implications

JJM is the main supplier of circular staplers in Australia and has ceased global production of this product. It is estimated that production and supply will recommence in 3-4 months.

An alternative product from Medtronic® (also packaged under the trade name Covidien®) is in use in NSW. Supply of this product is very limited.

Operation of the Medtronic product is different to the JJM product, and training is required. Training is provided by Medtronic® representatives.

Users should expect a supply shortage of all circular stapler products in the coming months.

Recommended actions by local health districts/networks

Please see over page for actions and advice

Made Obsolete December 2021
TGA Recall Completed

Recommended actions by local health districts/networks

1. Please confirm receipt of this Safety Notice to CEC-Recalls@health.nsw.gov.au
2. Draw clinicians' attention to the 'Clinical Advice' outlined below and support clinicians to access appropriate product

   Clinical Advice

   - Use an alternative product if available and if surgeons are familiar with its use
   - If an alternative product is *not* available or clinicians are *not* familiar with it, the quarantined JJM product can be used, following a case-by-case clinical risk assessment including consideration of the following factors:
     - clinical urgency of the case
     - risk of using the quarantined JJM product (see above) noting the information provided by JJM in the customer letter (attached)
     - familiarity of the surgeon with available products/surgical techniques
   - Reflect the chosen approach as part of the patient consent process
   - Maintain vigilant post-surgical monitoring for anastomotic leak as per usual best practice care

3. Identify and quarantine affected JJM product but note that this product may still be used based on clinical risk assessment
4. Preferentially use unaffected JJM product or the Medtronic product (as available)
5. Share unaffected and alternative products across hospitals to support coverage
6. Contact Medtronic for urgent training if required
7. Distribute this Notice to all relevant clinical staff
8. Undertake a stocktake of circular stapler products available in your LHD facilities and make this information available to the CEC. Do not return stock to JJM prior to consultation with the CEC.
9. Report all clinical incidents involving circular staplers to the TGA, and via the Incident Information Management System (IIMS)

Australian Government
Department of Health
Therapeutic Goods Administration

UPDATED - URGENT PRODUCT DEFECT CORRECTION*

LEVEL: Hospital CLASS: Class I

REFERENCE: RC-2019-RN-00501-1 DATE UPDATED: 3/04/2019

PRODUCT: **Intraluminal Staplers (ILS) - Johnson & Johnson Medical Pty Ltd**

ARTG: 124512
(Johnson & Johnson Medical Pty Ltd - Fixation device, internal, staple, tissue)

All Lots within EXPIRATION Date Range December 2022 - March 2024

PRODUCT NAME	PRODUCT CODE	All Lots within EXPIRATION Date Range	DESCRIPTION/SIZE
Curved Intraluminal Stapler (ILS)	CDH21A	December 2022 – March 2024	21mm Curved Intraluminal Stapler
Curved Intraluminal Stapler (ILS)	CDH25A	December 2022 – March 2024	25mm Curved Intraluminal Stapler
Curved Intraluminal Stapler (ILS)	CDH29A	December 2022 – March 2024	29mm Curved Intraluminal Stapler
Curved Intraluminal Stapler (ILS)	CDH33A	December 2022 – March 2024	33mm Curved Intraluminal Stapler
Endoscopic Curved Intraluminal Stapler (ILS)	ECS21A	February 2023 – March 2024	21mm Endoscopic Curved Intraluminal Stapler
Endoscopic Curved Intraluminal Stapler (ILS)	ECS25A	February 2023 – March 2024	25mm Endoscopic Curved Intraluminal Stapler
Endoscopic Curved Intraluminal Stapler (ILS)	ECS29A	February 2023 – March 2024	29mm Endoscopic Curved Intraluminal Stapler
Endoscopic Curved Intraluminal Stapler (ILS)	ECS33A	February 2023 – March 2024	33mm Endoscopic Curved Intraluminal Stapler
Straight Intraluminal Stapler (ILS)	SDH25A	March 2023 – March 2024	25mm Straight Intraluminal Stapler
Straight Intraluminal Stapler (ILS)	SDH29A	March 2023 – March 2024	29mm Straight Intraluminal Stapler

SPONSOR: Johnson & Johnson Medical Pty Ltd

PHONE: 1800 252 194 - JJM Customer Service or your Ethicon Product Specialist

REASON: An investigation by Johnson & Johnson Medical (JJM) regarding complaints and returned products has confirmed occurrence of uncut washers and malformed staples with specific ILS circular staplers, which can compromise staple line integrity. If a problem with the staple line is not adequately addressed or is not recognised, there is a potential risk of post-operative anastomotic leak, gastrointestinal injury, haemorrhage or haemorrhagic shock.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8444 Fax: 02 6232 8605 Email: info@health.gov.au www.tga.gov.au

TGA Health Safety Regulation

Based on an 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.

PROPOSED CUSTOMER ACTIONS:

1. If acceptable quantities of alternative product is available, please return all affected product subject to this notification as per the instructions given in the customer letter; OR

2. Due to worldwide supply issues with Intraluminal Staplers (ILS), alternative product may not be available in a timely manner. If alternative products 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 additional information given in the customer letter.

The sponsor is expected to dispatch letters to all affected customers within two working days of the agreed date. **Please do not contact the sponsor for further information unless you believe that you have the goods under recall and have not received a recall letter.**

Product Distribution: 201 hospitals, health services and distributors nationally

Product export status: Unknown

This issue was first identified by the Sponsor

*For further details about Recall Actions, please refer to http://tga.gov.au/safety/recalls-about.htm

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,

Grant Mellor
Director of Quality

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: 1 800 252 194

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**	

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: 1 800 252 194