From: "Recalls" <Recalls@health.gov.au>
Sent: Tue, 2 Apr 2019 10:52:41 +1100
To: [redacted]
Subject: Approval Letter for Intraluminal Staplers (ILS) - RC-2019-RN-00501-1 [SEC=OFFICIAL]
Attachments: Approval Letter - RC-2019-RN-00501-1.pdf; Draft Customer Letter with TGA amendments - RC-2019-RN-00501-1.docx; image001.jpg

Dear [redacted],

Please find attached a copy of the TGA's assessment for the proposed recall.

The text of the customer letter is acceptable **with the track changes in the attached document** and may be distributed to affected customers immediately.

Please forward a signed copy of the final letter to recalls@health.gov.au by 12:00pm, 4th of April 2019.

Sponsors are asked to note that;

1. When providing information about recalls to the TGA, please do not provide the names of individual patients;
2. The TGA collects personal information about surgeons/healthcare professionals so that we can contact them directly, where necessary, regarding recalls and actions related to recalls;
3. This practice is authorised under Australian Privacy Principle 3.6(b), Schedule 1 of the *Privacy Act 1998*. For general privacy information, go to Privacy information on the TGA website;
4. Appendix 1 of the Approval Letter regarding the ACCC Notification requirements has been updated and clarified in October 2018; and
5. As part of concluding this recall action, Sponsors are requested to ensure that the relevant staff contact details for your organisation that are stated in the TBS Portal are up to date.

Please confirm receipt of this email.

Kind Regards,

Recalls Section
Manufacturing Quality Branch

Phone: 02 6232 8935
Fax: 02 6203 1451
Email: recalls@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

Australian Government

Department of Health
Therapeutic Goods Administration

[redacted]
Johnson & Johnson Medical Pty Ltd
1-5 Khartoum Road
North Ryde NSW 2113 Australia

[redacted]

2/04/2019

Our Ref: RC-2019-RN-00501-1
Your Ref: JJM2019-003

Dear [redacted]

Subject: Potential for uncut washers and malformed staples

Intraluminal Staplers (ILS)

Curved Intraluminal Staplers, 21mm, 25mm, 29mm and 33mm diameter
Endoscopic Curved Intraluminal Stapler, 21mm, 25mm, 29mm and 33mm diameter
Straight Intraluminal Staplers, 25mm and 29mm diameter

Product Codes:
CDH21A, CDH25A, CDH29A, CDH33A, ECS21A, ECS25A, ECS29A, ECS33A, SDH25A and SDH29A

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

Thank you for your notification of the above mentioned subject.

Pursuant to the current URPTG, this recall action has been classified as per the below summary:

Hazard Classification:	**Class I**
Type of Recall:	**Urgent Product Defect Correction**
Recall Level:	**Hospital**
Reason for Recall:	**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.** **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% (circa 0.03% to 0.05%). Ethicon is implementing corrective actions to resolve the shift in product performance.
Product Distribution:	**201 hospitals, health services and distributors nationally**
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.**

Proposed recall action correspondence:

- The strategy for this recall action is acceptable;
- The text of the Customer Letter and Acknowledgement Form are both acceptable following implementation of the tracked changes in the attached document(s), after which they may be sent immediately;
- The TGA agrees with the immediate supply of stock currently on hold with JJM in Australia, circa 500 units; and
- The TGA agrees with the proposal for JJM to contact the relevant Global Distribution centre in order to secure allocated stock of a further 800 units for this jurisdiction, from the total of 4000 that were available as of last week.

The above information will be broadcast to the various state and territory recall coordinators for therapeutic goods. Additionally, this information will be published in the public domain via the TGAs searchable database, System for Australian Recall Actions (SARA).

Both the recall broadcast and SARA publication will occur on the second clear business day following this approval.

Please note:
1. Addressing of Recall Letters - Recall correspondence is to be addressed in accordance with pages 48-49 of the 2017 URPTG. A sample is given of page 54. In particular, where hospitals are involved, letters should be addressed to the "Chief Pharmacist" for medicines and to the "Chief Executive Officer" for device recalls. More targeted letters are acceptable on a case-by-case basis.

2. Dispatch of Recall Letters – Recall Action letters are required to be dispatched to affected customers within 2 clear working days of receiving this approval letter. Recall envelopes as described on page 52 of the URPTG must be used where mail distribution is the chosen method of communication. It is also acceptable to dispatch this notification electronically (facsimile or email) subject to the ability to confirm receipt.
If the Recall Action letter is dispatched via email, the subject line must reflect the appropriate title of the letter submitted, e.g. URGENT MEDICINE RECALL/URGENT PRODUCT DEFECT CORRECTION, followed by the name of the affected product.

Please advise the TGA if you are not able to initiate this Recall Action within 2 working days.

3. **Recall Actions for Consumer Goods that are also Therapeutic Goods** – When a therapeutic good is also a consumer good, the person carrying out the recall is required under the *Competition and Consumer Act 2010* (Schedule 2, Section 128 *'Notification requirements for a voluntary recall of consumer goods'*) to provide the Minister for Consumer Safety, written notification within 2 days after commencing the Recall Action. This can be done via the instructions outlined in Attachment 1 which also contains the URPTG definition of a Consumer Therapeutic Good.

4. Progress Reporting Requirements - In accordance with the responsibilities of sponsors (Step 10) in the URPTG, there is a requirement to submit a total of **three reports on the progress of the Recall Action as per the dates given in the table below. Typically these are at two weeks, six weeks and a 12 week close out report after the date of this correspondence**. An alternate timeframe or additional reports may be agreed on a case-by-case basis. Templates are given in Attachment 2 and this represents the minimum information expected, alternatively a suitable email will suffice. In the event all actions are completed prior to the specified dates given below, the report may be submitted earlier.

Report type:	**2 week**	**6 week**	**Close out**
Latest Due Date:	**16 April 2019**	**14 May 2019**	**2 July 2019**

5. TBS Update – As part of conducting this recall action, Sponsors are requested to verify that the relevant staff contact details given in the TBS Portal are up to date as per the guidance given in this link: https://www.tga.gov.au/tga-business-services-questions-and-answers-administrators

Should you require any additional advice or further assistance with this recall, do not hesitate to contact me directly.

Yours sincerely,

[redacted]
Recalls Section
Manufacturing Quality Branch

Phone: 02 6232 8935
Email: recalls@health.gov.au

(Signed electronically)

Attachment 1:

NOTIFICATION OF A CONSUMER GOOD RECALL ACTION TO THE ACCC

Pursuant to subsection (7) of Section 128 of the *Competition and Consumer Act 2010.*

As per page 73 of the 2017 *Uniform Recall Procedure for Therapeutic Goods* (URPTG), this recall action is to be reported to the ACCC, if the product involved is a *therapeutic good* and also a *consumer good.*

The definition of consumer goods from the Australian Consumer Law is "… *goods that are intended to be used, or are of a kind likely to be used, for personal, domestic or household use or consumption…"*

To make a report to the ACCC for a recall of a good that is both a therapeutic good and a consumer good, complete and submit the webform on the ACCC website by clicking on the link below:
https://www.productsafety.gov.au/contact-us/for-retailers-suppliers/submit-a-recall

General information regarding ACCC recalls may be obtained here:
https://www.productsafety.gov.au/recalls/guidance-for-suppliers/conducting-a-recall

Should you need further assistance in determining whether or not your *therapeutic good* is also a *consumer good*, please contact the ACCC directly by:

- Emailing the ACCC Recalls inbox Recalls@accc.gov.au

or

- Phoning the ACCC Recalls Hotline on: (02) 6243 1262

In the event you have doubt as to the status of your product in view of the above, **please do not report this action to the ACCC** unless the above determination has clearly been made and the product fits the definition of a *consumer good.*

Australian Government
Department of Health
Therapeutic Goods Administration

Attachment 2: Reporting Requirements

Reports should be submitted electronically to the Recalls Section via:

Email: recalls@health.gov.au

Please include the relevant TGA Recall reference number in the email subject line – e.g. RC-XXXX-RN-XXXXX-X

2 WEEK REPORT REQUIREMENTS:

1. Has the recall/corrective action been initiated? Confirm that the agreed action has begun. e.g. the approved letter has been dispatched to all the customers previously provided to the TGA.	**[ ] YES**	**[ ] NO.** Please explain:
2. Has a signed copy of the customer letter been provided to TGA Recalls?	**[ ] YES**	**[ ] NO.** Please ensure a signed copy of the letter is provided.
3. Is the recall/corrective action progressing without major impediments? e.g. The recall/corrective action is progressing as per the agreed timelines	**[ ] YES**	**[ ] NO.** Please explain:
4. Have the initial investigation findings changed the scope of the recall/correction e.g. Additional units or products have not been identified with the same defect	**[ ] NO**	**[ ] YES.** Please advise:
5. For any product exported from Australia, has the overseas supplier(s) been informed of the recall/correction action being undertaken in Australia. Please list countries product has been exported to.	**[ ] YES** **[ ] No exports**	**[ ] NO.** Please explain:

6 WEEK REPORTING REQUIREMENTS:

1. Have ALL the customers that you contacted responded to your requested recall/corrective action? Have customers confirmed their amount of affected product (including none) and that they agree to the recall/corrective action.	**[ ] YES**	**[ ] NO.** Please advise the % of customers that have responded ……..% And; <u>Detail attempts made to contact non-responding customers:</u>
2. (a) Recall - Have ALL customers returned or destroyed their affected units; or **(b) Correction - Have ALL customers with units requiring correction been identified?**	**[ ] YES** **[ ] No goods left to recall or correct.**	**[ ] NO.** Please advise when this is expected to occur:
3. Is the recall/corrective action progressing without major impediments? e.g. The recall/corrective action is progressing as per the agreed timelines	**[ ] YES**	**[ ] NO.** Please detail:

3 MONTH CLOSE OUT REPORTING REQUIREMENTS (or by the previously agreed time):

1. (a) Recall - Has ALL returned stock been destroyed/disposed/returned to the manufacturer?*; or **(b) Correction - Have ALL units with customers been corrected (or have ALL customers been supplied with the correction?)** ***A Certificate of destruction is to be provided where the goods have been destroyed and consignment documentation is to be provided where the goods have been returned to the manufacturer.**	**[ ] YES**	**[ ] NO.** Please explain & advise when this is expected to occur: Please provide a list of non-responding customers:
2. What was the root cause of the defect that led to the recall/corrective action?	Please detail:	
3. What remedial action has the manufacturer proposed to prevent the recurrence of the defect that led to the recall/corrective action?	Please detail:	
4. If the response rate was not 100% at the time of the six week report, have ALL customers that you contacted now responded to your requested recall/corrective action?	**[ ] YES**	**[ ] NO.** Please advise the % of customers that have responded ……..% And; Detail attempts made to contact remaining customers