ASSESSMENT FORM (WP2) – RECALL AND NON RECALL ACTIONS

RECALLS REFERENCE NUMBERRC-2019-RN-00501-1

Product Name:	**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 Number(s):	124512 (Johnson & Johnson Medical Pty Ltd - Fixation device, internal, staple, tissue)
Sponsor/Supplier:	Johnson & Johnson Medical Pty Ltd
Approval Area:	MEDDEV

Problem Description: **Try to cover off:** **1. A high level description of the problem itself;** **2. What is the Overall Risk and associated Hazard for customers and/or users; and** **3. An overarching mitigating statement as to the risk for patients/users. (e.g. no injuries have been reported to date etc)** **Note: The above needs to be covered in 1000 characters max to align with eBS & SARA limitations.**	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%. Ethicon is implementing corrective actions to resolve the shift in product performance.
Distribution of affected product:	TBC

Hazard Classification[1]	Class I
Hazard description:	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.
Likelihood[2] **What are the chances that the issue will occur?**	Possible
Overall Risk[3] **Likelihood and Hazard Classification combined – as given in the below table**	High

Any historically related recall actions for this defect?* **Or for this product for any defect?*** **Or is this product a historic 'Hot Issue' item for any defect?**** *** 3 or more issues in the last 2 years – then detail otherwise answer is no** **** Flagged in TRIM as a Hot Issue or otherwise known to be a Hot Issue.**	No

Proposed Recall Action or Non-Recall Action being taken for product in the Market:	- URGENT MEDICAL DEVICE RECALL Customer Action: If you have alternative product available, please return all product subject to this notification (Reference Table 1 for product listing). Ethicon recognizes due to worldwide supply issues with Intraluminal Staplers (ILS), alternative product may not be available. If alternative products to complete required surgeries are not available, it is critical to adhere to the following information. · 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 hemostasis 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. o 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.

Level of action	Hospital
All end users identifiable?	YES – Direct supply by sponsor or distributor will provide customer list
What is the Notification Method to end users/patients:	Mail Email/Fax Phone Personal Visit
End user action(s): **(Customer actions)**	Return Product;OR Institute workaround Read correspondence
Is Patient follow up required?	Customer discretion
Sponsor Action(s) being taken to fix the problem:	Provide correction to customer via a workaround Confirm receipt of correspondence
Future Supply:	Supply unaffected or corrected stock
Expected Close Out date:	Not expected to take more than 3 months *- all goods in the marketplace have been disposed or corrected and* *- remedial action has been identified*

Does the proposed action meet any of the criteria for Clinical advice from a Medicines, Biologicals or a Devices Medical Officer:	**[X]** When the clinical implications are unclear in relation to deficiency identified and/or the proposed workaround; AND/OR; [ ] When there is evidence of an actual death or permanent injury in any Jurisdiction, including any International reports; AND/OR; [ ] All Vaccine Recalls, TGA Immunology are also to be informed via emailing Immunobiology@health.gov.au AND/OR; [ ] All Medicines, Biologicals or Medical Devices supplied under the Special Access Scheme (SAS) or Authorised Prescriber (AP) Pathway are to be notified to TGAs Experimental Products Section (EPS) via emailing eps@health.gov.au AND/OR; [ ] Any recall actions that would require a TGA Web Statement. (i.e. Hazard Alerts and/or Consumer Level recalls, Vaccine recalls and other 'one-off' circumstances that have wider	

	health implications or where a Web Statement is determined to be necessary for any reason – please specify this detail in the comments section below); [X] Yes – Send to Clinical Delegate for advice; OR [ ] No – Recall Coordinator to sign off	
Clinical Delegate advice	*I consider the hazard classification to be appropriate. (If NO, provide reasoning and suggested classification in COMMENTS section below)* *I consider the proposed action to be appropriate. (If NO, provide reasoning and suggested change/s in COMMENTS section below)* *I consider the proposed correspondence to be appropriate. (If NO, provide reasoning in the COMMENTS section below and suggested amendments to the draft customer letter using tracked changes)* *Signed:* [redacted] *<signed electronically>* *Date: 26/03/2019*	*YES* *NO* *NO*
Recall Coordinator Sign off	*Agree with the hazard assessment?* *Agree with proposed action & correspondence?* *Signed: First Name Last Name <signed electronically>* *Date: / /*	*YES / NO* *YES / NO*

Hazard Classification System:

- **Class I – Most serious *safety-related*** - A situation in which there is a reasonable probability that the use of, or exposure to, the deficient therapeutic good(s) will cause serious adverse health consequences or death;

- **Class II – Urgent *safety-related*** - A situation in which use of, or exposure to, the deficient therapeutic good(s) may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote; and

- **Class III – Lowest risk – *non safety related*** - A situation in which use of, or exposure to, the deficient therapeutic good(s) is not likely to cause adverse health consequences.

	Class III [1]	Class II [1]	Class I [1]
Unlikely[2]	**Low[3]**	**Low[3]**	**Moderate[3]**
Possible[2]	**Low[3]**	**Moderate[3]**	**High[3]**
Likely[2]	**Moderate[3]**	**High[3]**	**High[3]**

Likelihood
Risk
Overall Risk

Comments:

Dear MO
Can you please confirm the suitability of this action and if the workaround is sufficient. J&J have 80% of the market so should we just do a correction in lieu of a Recall? Can product be tested prior to use so we know prior to surgery in any given unit is defective?
What are the alternative products? as hospitals may simply need a supply route to competitors as opposed to no competitor product being available.
The customer letter held at D19-5307587 is the USA version – the Aussie one isn't available yet but the US letter will be re-badged. If we have concerns it would be better to express those prior to J&J sending a proposed Aussie Letter. Thanks [redacted]

[redacted] *26/03/2019*

- The hazard classification as Class I is considered to be appropriate, keeping in view that at least one death could conceivably be related to the identified malformed stapling issue
- In the light of findings of investigations conducted by the sponsor, Product recall is considered the appropriate proposed action . However, sponsor must provide the expected timeframe for availability of unaffected product.
- It'll not be possible to identify the defect by testing the device before use.
- It would not be possible for us to identify alternative product. Alternative products can be any circular staplers not mentioned under table 1 provided by the sponsors. Every hospital can have different alternative products available on hand.
- Any elective surgery may be able to be delayed until an alternative device is obtained.
- Has the sponsor provided the expected timeframe for availability of unaffected stock?
- Customer list is still awaited from the sponsor

[redacted] – 26/3/19 – Agree with above.

- This is a Recall action. There is no defect that is being repaired and sent back.
- The HRE states the probability of harm as extremely rare or unusual, but it appears that a probability of 'sometimes' pH3 may be more indicative.

- Devices cannot be tested prior to use
- Surgeons and hospitals will know of alternative devices – it would not be for TGA to recommend a different brand device.
- Alternatives are, depending on clinical requirements:
    - To use an alternative device
    - to delay elective surgery until an alternative device is available; or
    - to undertake surgical procedure without using a stapler (a manual anastomosis is what the surgeons may end up doing if the device has misfired anyway)

These will be clinical decisions made by the treating practitioners.

- If the treating practitioner sees no alternative but to try and use a device identified for Recall, then the letter will draw attention to the recommended clinical procedure (but which is what a surgeon would usually do anyway when using a stapler)
- What evidence is there that J&J have 80% of the market?
- What is the estimated time period until J&J make unaffected devices available?