From:	Recalls
To:	DL Recalls_Devices Group
Bcc:	s22 s22
Subject:	Hospital Level Product Defect Correction - Johnson & Johnson Medical - Intraluminal Staplers (ILS) [SEC=OFFICIAL]
Date:	Tuesday, 2 April 2019 4:24:17 PM
Attachments:	TGA Recall Notice - RC-2019-RN-00501-1.pdf TGA Distribution List - RC-2019-RN-00501-1.pdf

Dear All,

Please find attached a notice of a recall action.

This email and attached notice may be further distributed as required, however, **please do not pass on customer information/distribution lists to third parties.**

The sponsor of the product is contacting the attached customers.

Other relevant information: 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.

The attached information is being made available to you in accordance with section 61(7) of the *Therapeutic Goods Act 1989* for the purpose of alerting you to recall and other market actions conducted under the *Uniform Recall Procedure for Therapeutic Goods*. As the information may contain personal and commercially sensitive and confidential information, please safeguard the information and do not distribute this email to third parties.

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

Do you know all Recall Actions undertaken in Australia are on the System for Australian Recall Actions (SARA)? For further information, please refer to the TGA Website http://tga.gov.au/safety/sara.htm

Australian Government

Department of Health
Therapeutic Goods Administration

URGENT PRODUCT DEFECT CORRECTION*

LEVEL: Hospital

CLASS: Class I

REFERENCE: RC-2019-RN-00501-1

DATE AGREED: 2/04/2019

PRODUCT: **Intraluminal Staplers (ILS)**

Curved Intraluminal Staplers
21mm, 25mm, 29mm and 33mm diameter

Endoscopic Curved Intraluminal Stapler
21mm, 25mm, 29mm & 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)

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.

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