From: [redacted]
Sent: Tue, 2 Apr 2019 14:26:21 +1100
To: [redacted]
Cc: [redacted]
Subject: FOR INFORMATION: ILS Recieved DIR in relation to recall RC-2019-RN-00501-1 [SEC=OFFICIAL:Sensitive, ACCESS=Personal-Privacy, ACCESS=Commercial]
Priority: High
Attachments: DIR 56691.pdf; image001.gif

Hi [redacted]

An ILS related DIR received yesterday as attached.

The report verbatim is:

"Related to Recall Early Action Advice Intraluminal Staplers.
On look back 2 patients that underwent surgery with products listed in the advice (EC529A) have post-operative complications, including anastomotic leaks and are in a critical condition in ICU.
In one of the cases, the staple line has been sent to pathology rather than being discarded."

It would appear the Early Advice triggered a look back on patients which led to this DIR – so to my mind without the Early Advice we quite possibly wouldn't have this DIR.

FYI

[redacted]
Recalls Section
Manufacturing Quality Branch

From: [redacted]
Sent: Tuesday, 2 April 2019 2:18 PM
To: [redacted]
Subject: RE: Recieved DIR in relation to recall RC-2019-RN-00501-1 [SEC=OFFICIAL, ACCESS=Commercial]

Hi [redacted]

No problems, I have attached a copy of DIR 56691 in a PDF format.

Cheers
[redacted]

From: [redacted]
Sent: Tuesday, 2 April 2019 2:13 PM
To: [redacted]
Subject: FW: Recieved DIR in relation to recall RC-2019-RN-00501-1 [SEC=OFFICIAL, ACCESS=Commercial]

Thanks [redacted] could you pls sent it to me in PDF?

Thanks

[redacted]

[redacted]
Recalls Section
Manufacturing Quality Branch

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.

From: Recalls
Sent: Tuesday, 2 April 2019 1:25 PM
To: [redacted]
Subject: FW: Recieved DIR in relation to recall RC-2019-RN-00501-1 [SEC=OFFICIAL]

From: [redacted]
Sent: Tuesday, 2 April 2019 1:21 PM
To: Recalls
Subject: Recieved DIR in relation to recall RC-2019-RN-00501-1 [SEC=OFFICIAL]

Dear Recalls,

Just wanted to give you the heads up that we received a device incident report from a user yesterday in regards to the early advice action sent out for the J&J ILS staplers. I have closed the DIR, but if you wanted to look at it, it is DIR 56691.

Kind Regards

[redacted]

[redacted]
Devices Vigilance and Monitoring
Medical Devices Branch

[redacted]

Therapeutic Goods Administration
Department of Health

PO Box 100
Woden ACT 2606 Australia
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.

Device Incident Report: Medical Devices Branch - Device Vigilance and Monitoring

DIR : 31 - ID : 421341

Rele

Report #:	Records Management #:	Reporter's Reference #:
56691		ARTG reference number 124512

ARTG: 124512 Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:
Complete		18/03/2019
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**
01/04/2019	01/04/2019	
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**
02/04/2019	Doctor	
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**
Other	Safety and Quality	Trend data only

Event Description for Website Publication:

2 patients that underwent surgery have post operative complications, including anastomotic leaks and are in a critical condition in ICU.

Clinical Event Information:

Related to Recall Early Action Advice Intraluminal Staplers.
On look back 2 patients that underwent surgery with products listed in the advice (EC529A) have post operative complications, including anastomotic leaks and are in a critical condition in ICU.
In one of the cases, the staple line has been sent to pathology rather than being discarded.

Number of Incidents in Report:	Contact:	Alternative Person Title:
2	Initial Reporter	
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**

Patient Information

Sex:	Weight:	Age:
Female		

Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

Additional Event Description:

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Consequence:
	Serious Injury	
Medical Problem Device Used For:	**Additional Patients Added:**	
Procedure or Surgery	0	

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:	
[redacted]		
Reporter Title:	**First Name:**	**Surname:**
	[redacted]	[redacted]
Position:		**Company/Institution:**
[redacted]		Redcliffe Hospital
Address 1:	**Address 2:**	**Town/Suburb:**
Anzac Ave	Redcliffe	Redcliffe
Country:	**Postcode:**	**Phone:**
Australia	4020	[redacted]
Mobile:	**Email:**	**Are you happy for the device company to contact you about the incident?:**
	[redacted]	☐

Initial Reporter Section

As Above?:	*If No, fill out the following:*	
Yes		
Search Reporter By Surname:	**Initial Reporter #:**	
Title:	**First Name:**	**Surname:**
Position:		**Company/Institution:**
Address 1:	**Address 2:**	**Town/Suburb:**
Postcode:	**Country:**	**Phone:**
Mobile:	**Email:**	**Allow the device company to contact you about the incident:**
		☐

Device Information Section

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:

No	124512	124512
Product Licence Category:	**Device Class:**	**GMDN / UMDN Code:**
Included	Class IIb	35615
Brand Name:	**Initial Device Description:**	**Usage of Device:**
Intraluminal Staplers (IRS) - Surgical staple, non-bioabsorbable	Intraluminal Staplers (IRS) - Surgical staple, non-bioabsorbable	
Model #:	**Serial #:**	**Batch #:**
ECS29A		
Purchase Date:	**Expiry Date:**	**Date of Implant:**
		18/03/2019
Place of Implantation:	**Reported Device Location:**	**Access Contact Title:**
Staple Line for colon/bowel	Discarded	
Access Contact Surname:	**Access Contact Phone:**	**Access Contact Fax:**

Additional Devices Added:

0

Manufacturer Information Section

Manufacturer Name:		**Manufacturer Client Id:**
Ethicon Endo Surgery LLC		48099
Address 2:	**Town/Suburb:**	**State/Province:**
Postcode:	**Phone:**	**Fax:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**

Contact Surname:

Supplier Information Section

Supplier Name:		**Address 1:**
Johnson & Johnson		
Town/Suburb:	**State:**	**Country:**
Phone:	**Fax:**	**Email:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**
No		
Contact Surname:	**Contact Phone:**	**Contact Fax:**

Report Information - duplicated information from other parts of the report, for use in risk assessments.

Licence Start Date:	**Date of Initial TGA Action:**	**Report Status:**	
22/12/2005	01/04/2019	Complete	

Problems Observed:

Mechanical Problem; Structural Problem;

Report Status

For website publication:	**Ready for Publication:**	**Investigated:**	**Investigation Reason:**
Yes	Yes	No	Known complication

Report Priority:

Not Investigated

Team Review

Reviewed by Team:	**Reason Sent To Meeting:**	**Outcome from team meeting:**	

Team Meeting Notes:

DPRC Review

Reviewed by DPRC:	**DPRC Reason Sent To Meeting:**	**Outcome from DPRC Meeting:**	

Meeting Notes:

Initial Risk Analysis

Date:	**Assessor:**	**Licence Status:**	**Status Reason:**
02/04/2019	[redacted]	Active	
Injured Party:	**Potential Effect:**	**Actual Effect:**	**Found Prior To Use:**
Patient	Serious Injury	Serious Injury	No
Sterile:	**Invasive Device:**	**Single Use:**	**Human Origin:**
Yes	Yes	Yes	No

Reusable:	Risk Frequency:	Risk Severity:	Risk Rating:
No	Unknown	Serious	Minor Risk

Risk Assessment Notes:

Final Risk Assessment:
Yes

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:	
267	Johnson & Johnson Medical Pty Ltd	
Attention To:	**Address 1:**	**Address 2:**
[redacted]	PO Box 134	
State:	**Postcode:**	**Phone:**
NSW	1670	[redacted]

Email:
complaintanz@medau.jnj com

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:	Details of Similar Events:
Additional Details (use for tables):	CAPA# Reference:
	Risk Assessment
	Frequency:
	Rating:

Type Cause and Outcome:	Number of Similar Events:	Expected Rate:

Countries Similar Events Also Occurred:

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

Click [N] to begin a new Correspondence entry. Note that the Email address specified here will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response

List of Problem Observed Codes - Click [N] to begin entering information.

Problem Observed Details

Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Mechanical Problem	Structural Problem			

Investigation Findings

Finding Details

Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Findings Available				

Investigation Conclusion

Conclusion Details

Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Conclusion Not Yet Available			

Investigation Outcomes

Outcome Details

Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:

Investigator's Notes:	Summary Findings:
Recall action early advice notification - D19-5325030. Further recall action has not been released as of 02/04/19.	

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

Device Lookup

This section is used to match information provided via UDIR forms to ARTG information. You can select a Brand/Name from information provided in the 'Other Devices Involved' table below or enter in

Other Device (Entered):	Brand Name:	Manufacturer Name:	Device ARTG #:

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Nam
Model Number:	**Batch #:**	**Lot #:**	**Expiry Date:**	

Related DIR Information - Click **New** to begin entering information.

Rec No	
1	

Samples Record - Click **[N]** to begin entering information. **Note:** Sample # Generated on Save.

Rec No	Details	Sample Details			Additional Details		
	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:
1					Who sent the device to the TGA?:		

Additional Patients

Click **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:
Patient Focused Corrective Action Taken:		**Patient History:**
Injured - Extent of Injury:	**Was device directly linked to death?:**	**Was device directly linked to permanent disabiltiy?:**
Other Consequence:	**Describe any test (Lab, xray, etc.):**	**Additional Event Description:**

Additional Device Information

Where did you get this device from?:	How reliant is the affected person on correct/safe operation of this device?:
Supplier	Very

Any other relevant information to aid assessing/investigating the incident?:

Company will be contacted 1 April 2019

Similar Events

Similar events - how many times?:	Date of Recent Report:	Event Reported To:	Reporter Reference Nur

Device Access - Alternate Device Contact Information Provided

Title:	First Name:	Last Name:	Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia: Yes

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Attachment(s) Details

Type	Open	Name	Size	Attached Within
FILE		DIR 56691 - original user report	239	Form

Flow Details : DIR-REQ - Device Incident Request : 166214

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned O
166214	DIR-REQ		Triage	[redacted]	Device Support Team	02/04/2019

Signature Details

Role	IRIS Investigator	
User		
Signed At		
Comment		