Document 1

19/03/2019
SIGNED

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

DIR : 31 - ID : 420887

Released by s22 on 21/11/2018 10:36:59

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
56421		0703058556	Final

ARTG: 293808

Document Container URL

Report Informat on Sect on

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Death / Ser ous Injury	s22	19/03/2019
Date of Final Report:	**Date of Initial TGA Act on:**	**Reviewed by Team:**	**Date Response Received:**
05/04/2019	19/03/2019		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Conf dentiality:**
08/04/2019	Healthcare Professional		No
Source of Report:	**If 'Other' Source Selected:**	**Type of In tial Action:**	
Sponsor		Trend data only	

Event Descript on for Website Publication:

An infect on from anastomotic leak was noted.

Clinical Event Information:

According to the reporter, four days postoperative from a laparoscop c high anterior resection, an infection from anastomotic leak was noted. It is unknown if the leak is related to the stapler. The clinical anastomot c leak was determined by CT scan and regal contrast leaked out of anastomosis. There were no issues during the operat on. The stapler appeared to fire correctly, t passed an air leak test after the stapler had been used, and normal full tissue donuts were seen. The patient had initially undergone Hartmann's procedure and hospitalisation was extended for one week due to the leak.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Patient Informat on

Sex:	Weight:	Age:
s22	Unknown	s22

Patient Focused Corrective Act on Taken:

Hosp talisation was extended by one week due to the leak.

Patient History:

Crohn's disease and fistula between colon and bladder.

Patient Outcome/Consequences:

Alive - with injury, requiring extended hospitalisat on.

Additional Event Descript on:

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Consequence:	Other med cal devices currently using/implanted:
	Temporary Injury		
Medical Problem Dev ce Used For:	**Add tional Patients Added:**		
	0		

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
s22			
Reporter Title:	**First Name:**	**Surname:**	
s22	s22	s22	
Position:		**Company/Inst tution:**	
Post Market Vigilance Specialist		Medtron c Australasia Pty Ltd.	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**

2 Alma Road	2 Alma Road	Macquarie Park	NSW
Country:	Postcode:	Phone:	Fax:
Australia	2113	s22	
Mobile:	Email:	Are you happy for the device company to contact you about the incident?:	Last External Submission By:
	s22 @medtron c.com	☐	106402_837 - 05/04/2019 12:03

In tial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Conf dential:
No			Yes
Search Reporter By Surname:	In tial Reporter #:		Preferred Contact Method:
s22			
Title:	First Name:	Surname:	
	s22	s22	
Position:		Company/Inst tution:	
		PRINCESS ALEXANDRA HOSPITAL	
Address 1:	Address 2:	Town/Suburb:	State:
Ipswich Road		Brisbane	QLD
Postcode:	Country:	Phone:	Fax:
4102			
Mobile:	Email:	Allow the dev ce company to contact you about the incident:	
		☐	

Dev ce Information Sect on

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Dev ce ARTG #:	Therapeutic L cence Type:
No	293808	293808	Medical Dev ce
Product Licence Category:	Dev ce Class:	GMDN / UMDN Code:	GMDN / UMDN Text:
Included	Class IIb	59875	Intraluminal circular stapler, single-use
Brand Name:	In tial Dev ce Descript on:	Usage of Device:	Software Vers on:
Covidien EEA Circular Stapler - Intraluminal circular stapler, single-use	Covidien EEA Circular Stapler - Intraluminal circular stapler, single-use	Single Use	
Model #:	Serial #:	Batch #:	Lot #:
TRIEEA28MT			Unknown
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
Place of Implantation:	Reported Device Location:	Access Contact Title:	Access Contact First Name:
	Discarded		
Access Contact Surname:	Access Contact Phone:	Access Contact Fax:	Access Contact Email:

Add tional Dev ces Added:

0

Manufacturer Informat on Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Covidien llc		54968	15 Hampshire Street
Address 2:	Town/Suburb:	State/Province:	Country:
	Mansfield	MA	United States
Postcode:	Phone:	Fax:	Email:

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02048

Manufacturer Informed: Yes

Date Aware of Adverse Event: 15/03/2019

Contact T tle:

Contact First Name:

Contact Surname:

Supplier Informat on Section

Supplier Name:

Address 1:

Address 2:

Town/Suburb:

State:

Country:

Postcode:

Phone:

Fax:

Email:

Webs te:

Supplier Informed:

Date of Supplier Contact:

Contact T tle:

Contact First Name:

Contact Surname:

Contact Phone:

Contact Fax:

Contact Email:

Report Informat on - duplicated informat on from other parts of the report, for use in risk assessments.

Licence Start Date: 13/09/2017

Date of Initial TGA Action: 19/03/2019

Report Status: Closed

Problems Observed: ; ; ; Mechan cal Problem; Leak / Splash;

Report Status

For website publ cat on: Yes

Ready for Publ cation: Yes

Investigated: No

Investigation Reason: Device not returned

Team Assignment: Team B (IIb, Is & Im)

Report Pr or ty: 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:

In tial Risk Analysis

Date: 20/03/2019

Assessor: s22

L cence Status: Active

Status Reason:

Status Effective Date: 13/09/2017

Injured Party: Patient

Potential Effect: Ser ous Injury

Actual Effect: Temporary Injury

Found Prior To Use: No

Sample Received: No

Sterile: Yes

Invasive Device: Yes

Single Use: Yes

Human Origin: No

Genetically Modified: No

Reusable:

Risk Frequency:

Risk Severity:

Risk Rating:

Further Review Needed:

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No		Serious		Team Review

Risk Assessment Notes:

Final Risk Assessment:

No

RISK RATING	Severity				
Frequency	Life-threatening	Serious	Minor	Nil	Unknown
Frequently	Critical Risk	Critical Risk	Major Risk	Minor Risk	Major Risk
Sometimes	Critical Risk	Major Risk	Minor Risk	Minor Risk	Minor Risk
Rarely	Major Risk	Minor Risk	Minor Risk	Non-significant Risk	Minor Risk
Unlikely	Minor Risk	Minor Risk	Non-significant Risk	Non-significant Risk	Non-significant Risk
Unknown	Major Risk	Minor Risk	Minor Risk	Non-significant Risk	No risk assessment

Additional Risk Analysis

Cl ck 'N' to start a new risk analysis

Analysis Details	Statist cs Checklist Sect on				
Update Device Details?:	Date:	Assessor:	L cence Status:	Status Reason:	Status Effective Date:
Yes	08/04/2019	s22	Active	Active	13/09/2017
Copy Data From:	Injured Party:	Potential Effect:	Actual Effect:	Found Prior To Use:	Sample Received:
In tial	**Patient**	**Serious Injury**	**Temporary Injury**	No	**No**
	Sterile:	Invasive Dev ce:	Single Use:	Human Origin:	Genetically Modified:
	Yes	**Yes**	**Yes**	**No**	No
	Reusable:	Risk Frequency:	Risk Severity:	Risk Rating:	Final Risk Assessment:
	No	**Rarely**	**Serious**	**Minor Risk**	Yes
	Risk Assessment Notes:				

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtron c Australasia Pty Ltd		837
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22	PO Box 945		NORTH RYDE BC
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1670	s22	

Email:

s22 @medtron c.com

Investigat on Information Sect on - Submitted by Sponsor/Manufacturer

Device Analysis Results:

The reported EEA* Circular Stapler with Tri-Staple* Technology 28mm Medium/Thick sample or additional supporting materials from the account was not available for this incident. Therefore, a defin tive root cause could not be determined w th regard to the reported cond tion. Records from each manufacturing lot are thoroughly reviewed to ensure that products are released meeting all Medtronic qual ty release specifications at the time of manufacture. Should new informat on become available, the file will be re-opened and the investigat on will be amended as appropriate.

Corrective/Preventative Actions:

There are no actions deemed necessary at this time.

Details of Similar Events:

Add tional Details (use for tables):

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Nil other similar incidents in Australia.
Similar inc dents worldw de: 2/1,325. Austria 1, Germany 1

CAPA# Reference:

Risk Assessment

Frequency:	Sever ty:		
Rating:		Type Cause and Outcome:	Number of Similar Events:
Expected Rate:	Actual Rate:		

Countries Similar Events Also Occurred:

Austria 1, Germany 1

Completed Actions:	Planned Act ons and Proposed Timelines:

Addit onal Comments:

Cl ck **[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	Notes
☐	Final Report Due	TGA Regulatory Action	Regulatory Information Request (s41)		19/03/2019	27/06/2019			

List of Problem Observed Codes - Cl ck **[N]** to begin entering informat on.

Problem Observed Details

Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
			Infect on
Mechan cal Problem	Leak / Splash		

Investigation Findings

Finding Details

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

Investigation Conclusion

Conclus on Details

Investigation Conclus on (L1)	Investigation Conclusion (L2)	If Add tional Conclus on Detail Requested
Cause Not Established		

Investigation Outcomes

Outcome Details

Outcome of Investigation (L1)	Outcome of Investigat on (L2)	If Add tional Conclus on Detail Requested
Reviewed, for Trending Purposes Only		

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Investigation Summary

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

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time, however the TGA will continue to mon tor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generat on buttons disabled if report not ready for webs te publ cation or risk analysis not completed.

Device Lookup

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

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

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:

Model Number:	Batch #:	Lot #:	Expiry Date:

Related DIR Information - Cl ck **New** to begin entering informat on.

Rec No	
1	

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

Rec No	Details	Sample Details			Add t onal Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Dev ce Descript on:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Vers on Number:	
					Who sent the dev ce to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Cl ck **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:

Patient Focused Corrective Act on Taken:	Patient History:

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Injured - Extent of Injury:	Was dev ce directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Add tional Event Descript on:	Med cal Problem Device Used For:

Additional Device Information

Where did you get this dev ce from?:

How reliant is the affected person on correct/safe operation of this device?:

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

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Dev ce Access - Alternate Dev ce Contact Informat on Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Locat on Details

Occurred in Australia: Yes

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details DIR-REQ - Device Incident Request 165127

Request Details

ID	Type	Locat on	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
165127	DIR-REQ		Closed	s22	OPR Administration User	08/04/2019	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	08/04/2019 08:44:22	
Comment		

Document 2

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

DIR : 36 - ID : 459466

26/11/2019
SIGNED

Released by Theta Technologies on 13/02/2020 10:09:06

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
60703		0703474545	Final

ARTG: 293808 Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Death / Serious Injury	s22	26/11/2019
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
24/02/2020	26/11/2019	03/03/2020	27/11/2019
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
04/03/2020			N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		For IRIS Meeting	

Event Description for Website Publication:

The anastomosis dehisced

Clinical Event Information:

According to the reporter, post-operatively on a robotic laparoscopic anterior resection for endemetriosis procedure, after the stapler was fired and air leak test was performed and the donuts were inspected. it was also reported that the surgical procedure was extended for more than 30 minutes. It was reported that there were no air leaked and the donuts looked good. 4 days after the surgery the anastomosis dehiscence. There was a tissue loss and tissue damaged due to the reported event. Patient has undergone a procedure to create diverting ileostomy and another to repair a pelvic abscess that eroded into the bladder and vagina.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Appropriate Term/Code Not Available -> ->

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Infections -> Abscess -> ;
Procedural Complications -> Wound Dehiscence ->

Health Impact

Recorded Health Impacts:

Surgical Intervention -> Additional Surgery ->

Patient Information

Sex:	Weight:	Age:	
s22		s22	

Patient Focused Corrective Action Taken:

The patient spent 25 days in the hospital before being released. The patient underwent a Hartmann's reversal procedure.

Patient History:

Non-Smoker.

Patient Outcome/Consequences:

Alive.

Additional Event Description:

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Consequence:	Other medical devices currently using/implanted:

	Serious Injury	Required surgical intervention	
Medical Problem Device Used For:	Additional Patients Added:		
	0		

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
s22			
Reporter Title:	First Name:	Surname:	
s22	s22	s22	
Position:		Company/Institution:	
s22		Medtronic Australasia	
Address 1:	Address 2:	Town/Suburb:	State:
2 Alma Road		Macquarie Park	NSW
Country:	Postcode:	Phone:	Fax:
Australia	2113	s22	
Mobile:	Email:	Last External Submission By:	
	s22 @medtronic.com	s22 - 24/02/2020 12:54	

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
No			Yes
Search Reporter By Surname:	Initial Reporter #:		Preferred Contact Method:
s22			
Title:	First Name:	Surname:	
	s22	s22	
Position:		Company/Institution:	
		SYDNEY ADVENTIST HOSPITAL	
Address 1:	Address 2:	Town/Suburb:	State:
Theatres, Lvl 5		WAHROONGA	NSW
Postcode:	Country:	Phone:	Fax:
2076			
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 #:	Therapeutic Licence Type:
No	293808	293808	Medical Device
Product Licence Category:	Device Class:	GMDN / UMDN Code:	GMDN / UMDN Text:
Included	Class IIb	59875	Intraluminal circular stapler, single-use
Brand Name:	Initial Device Description:	Usage of Device:	Software Version:
EEA - Intraluminal circular stapler, single-use	EEA - Intraluminal circular stapler, single-use		
Model #:	Serial #:	Batch #:	Lot #:
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
Date of Inital Procedure:	Place of Implantation:	Reported Device Location:	Access Contact Title:
Access Contact First Name:	Access Contact Surname:	Access Contact Phone:	Access Contact Fax:

Access Contact Email:	Licence Status:	Status Effective Date:	Additional Devices Added:
	A	13/09/2017	0

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Covidien llc		54968	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Yes	19/11/2019		
Contact Surname:			

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	No	Device not returned	Team B (IIb, Is & Im)	Not Investigated

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
03/03/2020	Not enough information has been provided	No further action

Notes for Team meeting:
send to meeting due to level 1 investigation - device not returned. no similar DIR in 6 month. no recall/pmr

Outcomes from Team Meeting:
NFA - Device not returned. No similar DIRs.

DPRC Review

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

Meeting Notes:

Initial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D

Form Details

Document 2

Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentation:
27/11/2019	5 - An illness/injury was resolved or prevented with treatment by a health professional			s22 [redacted]	Unknown - updated information from the manufacturer is required
Incidents in last 24 months:	**Manufacturer action:**	**ESTIMATED LEVEL OF INVESTIGATION:**	**FINAL LEVEL OF INVESTIGATION:**	**Injured Party:**	**Device Recalls:**
		Level 1 Investigation (to complete screening)	Screening only	Patient	0. No recalls for similar incidents in Australia
Incidents in last 36 months:	**IVD status:**	**EXCEPTION TO INVESTIGATION LEVEL:**		**Found Prior To Use:**	**Is AE covered by current recall:**
		Awaiting final report		No	
Incidents Worldwide:	**Number of potential contributing factors:**			**Reusable:**	**Similar events (past 6 months):**
	Yes - some potential factors (up to 3)			No	1 incidents
Products supplied the last 12 months:	**Specific factors identified:**	**ESTIMATED LEVEL OF PRIORITY:**	**FINAL LEVEL OF PRIORITY:**		**3 or more events - batch/model:**
	Compatibility of device - patient characteristics, Use of device - operator/user error	Routine	Routine		No
Products supplied last 24 months:	**Number of potential sensitivities:**	**EXCEPTION TO PRIORITY LEVEL:**			**3 or more events - health district:**
	No	Low incidence			No
Products supplied last 36 months:	**Specific sensitivities identified:**				**3 or more events - organisation:**
					No
Products supplied Worldwide:	**Consultations during risk assessment:**	**Final Risk Assessment:**			
	I undertook an internet search (e.g., Google)	No			

Additional Risk Analysis

Click 'N' to start a new risk analysis

Analysis Details	Statistics Checklist Section					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
Yes	**Date:**	**Severity:**	**Incidents in the last 12 months:**	**Manufacturer analysis:**		
Copy Data From:	24/02/2020	**5 - An illness/injury was resolved or prevented with treatment by a health professional**		Yes		
Initial	**Assessor:**	**Manufacturer documentation:**	**Incidents in last 24 months:**	**Manufacturer action:**	**ESTIMATED LEVEL OF INVESTIGATION:**	**FINAL LEVEL OF INVESTIGATION:**
	s22 [redacted]	**Unknown - updated information from the manufacturer is required**		No	Level 1 Investigation (to complete screening)	**Screening only**
	Injured Party:	**Device Recalls:**	**Incidents in last 36 months:**	**IVD status:**	**EXCEPTION TO INVESTIGATION LEVEL:**	
	Patient	**0. No recalls for similar incidents in Australia**			Closed with NFA. Device not returned.	
	Found Prior To Use:	**Is AE covered by current recall:**	**Incidents Worldwide:**	**Number of potential contributing factors:**		
	No			Yes - some potential factors (up to 3)		
	Reusable:	**Similar events (past 6 months):**	**Products supplied the last 12 months:**	**Specific factors identified:**	**ESTIMATED LEVEL OF PRIORITY:**	**FINAL LEVEL OF PRIORITY:**
	No	**0 incidents**		Compatibility of device - patient characteristics, Use of device - operator/user error	Routine	**Routine**
		3 or more events - batch/model:	**Products supplied last 24 months:**	**Number of potential sensitivities:**	**EXCEPTION TO PRIORITY LEVEL:**	
		No		No		
		3 or more events - health district:	**Products supplied last 36 months:**	**Specific sensitivities identified:**		
		No				
		3 or more events - organisation:	**Products supplied Worldwide:**	**Consultations during risk assessment:**	**Final Risk Assessment:**	
		No			**Yes**	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtronic Australasia Pty Ltd		837
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22 [redacted]	PO Box 945		NORTH RYDE BC
State:	**Postcode:**	**Phone:**	**Fax:**
NSW	1670	s22 [redacted]	
Email:			
s22 [redacted]@medtronic.com			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:

The product sample or additional supporting materials from the account was not available for this incident. Records from each manufacturing lot are thoroughly reviewed to ensure that products are released meeting all Medtronic quality release specifications at the time of manufacture. There were no assembly or component issues identified; therefore, a Device History Record review will not be performed.
Without the physical product, a definitive root cause could not be identified. Post Market Vigilance will continue to monitor this condition for future potential action. Should new information become available, the file will be re-opened and the investigation will be amended as appropriate.

Corrective/Preventative Actions:

None at this time

Details of Similar Events:

0 Similar events (0%) from 2617 sales in Australia (past 3 years) .

12 Similar events (0.037%) from 32248 sales worldwide (past 3 years).

Additional Details (use for tables):

CAPA# Reference:

Risk Assessment

Frequency:	Severity:		
		Type Cause and Outcome:	**Number of Similar Events:**
Rating:			
Expected Rate:	**Actual Rate:**		

Countries Similar Events Also Occurred:

United States, United Kingdom, Netherlands, France, Australia, Sweden.

Completed Actions:

Planned Actions and Proposed Timelines:

Additional Comments:

DIR closed 4/3/20

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	Notes
☐		TGA Regulatory Action	Final Report Due		26/11/2019	05/03/2020	24/02/2020		

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

Appropriate Term/Code Not Available			anastomosis dehiscence	
Appropriate Term/Code Not Available			pelvic abscess	
Appropriate Term/Code Not Available			tissue loss	

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
Procedural Complications	Wound Dehiscence		
Infections	Abscess		

Health Impact

Details			
Level 1	Level 2	Level 3	
Surgical Intervention	Additional Surgery		

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	
Cause Not Established			

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:	Extension Number:

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

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 information manually.

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

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
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				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
					Who sent the device to the TGA?:			Why does the TGA have the sample?:	

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?:**	**Consequence:**
Other Consequence:	**Describe any test (Lab, xray, etc.):**	**Additional Event Description:**	**Medical Problem Device Used For:**

Additional Device Information

Where did you get this device from?:

How reliant is the affected person on correct/safe operation of this device?:

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

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details : DIR-REQ - Device Incident Request : 220343

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
220343	DIR-REQ		Closed	s22	OPR Administration User	04/03/2020	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	13/08/2020 11:13:35	
Comment		

Document 3

27/03/2020
SIGNED

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

DIR : 38 - ID : 493698

Released by s22 on 14/04/2020 09:01:24

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
62821		703683864	Final

ARTG: 293808

Document Container URL

Report Informat on Sect on

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Other	s22	27/03/2020
Date of Final Report:	**Date of Initial TGA Act on:**	**Reviewed by Team:**	**Date Response Received:**
30/07/2020	27/03/2020		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
05/08/2020	Healthcare Professional		N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of In tial Action:**	
Sponsor		Trend data only	

Event Descript on for Website Publication:

The surgeon was having difficulty aligning the two end of the dev ce.

Clinical Event Information:

According to the reporter, on a laparoscop c high anterior resect on converted to low anter or resection, during anastomosis, the surgeon was having difficulty aligning the two end of the device. The surgeon noticed after removing the stapler that the anvil tilted even when the device was not fired.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Compatibil ty Problem -> Component or Accessory Incompatibil ty -> ;
Mechanical Problem -> Mechanical Jam ->

Clinical Signs, Symptoms and Cond tions

Recorded Clinical Signs, Symptoms and Cond t ons:

Others -> Appropriate Term / Code Not Available ->

Health Impact

Recorded Health Impacts:

Unexpected Medical Intervention -> Additional Dev ce Required ->

Patient Informat on

Sex:	Weight:	Age:
		s22

Patient Focused Corrective Act on Taken:	Patient History:
Another device was used to complete the case.	
Patient Outcome/Consequences:	**Additional Event Descript on:**
Extra tissue loss occurred due to this.	

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Other med cal devices currently using/implanted:	Medical Problem Dev ce Used For:

Add tional Patients Added:

Document 3

Add tional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
s22			
Reporter Title:	**First Name:**	**Surname:**	
s22	s22	s22	
Position:		**Company/Inst tution:**	
s22		Medtron c Australasia Pty Ltd.	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
2 Alma Road, Macquarie Park, NSW, 2113	2 Alma Road, Macquarie Park, NSW, 2113	Macquarie Park	NSW
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2113	s22	
Mobile:	**Email:**	**Last External Submission By:**	
	s22 @medtron c.com	s22 - 30/07/2020 13:25	

In tial Reporter Section

As Above?:	*If No, fill out the following:*		In tial Reporter Conf dential:
No			Yes
Search Reporter By Surname:	**In tial Reporter #:**		**Preferred Contact Method:**
Title:	**First Name:**	**Surname:**	
Position:		**Company/Inst tution:**	
		LIVERPOOL HOSPITAL	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
Elizabeth Street LIVERPOOL NSW 2170			
Postcode:	**Country:**	**Phone:**	**Fax:**
		s22	
Mobile:	**Email:**	**Allow the dev ce company to contact you about the incident:**	
	accounts.payable2@email.cs.nsw	☐	

Dev ce Information Sect on

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Dev ce ARTG #:	Therapeutic L cence Type:
No	293808	293808	Medical Dev ce
Product Licence Category:	**Dev ce Class:**	**GMDN / UMDN Code:**	**GMDN / UMDN Text:**
Included	Class IIb	59875	Intraluminal circular stapler, single-use
Brand Name:	**In tial Dev ce Descript on:**	**Usage of Device:**	**Software Vers on:**
CIR STPLR TRIEEA28MT MEDTHK WT - In tial Report	CIR STPLR TRIEEA28MT MEDTHK WT - Initial Report	Single Use	
Model #:	**Serial #:**	**Batch #:**	**Lot #:**
TRIEEA28MT	P8J1197X		
Purchase Date:	**Expiry Date:**	**Date of Implant:**	**Date of Explant:**
Date of Inital Procedure:	**Place of Implantation:**	**Reported Device Locat on:**	**Access Contact T tle:**
		With Manufacturer	
Access Contact First Name:	**Access Contact Surname:**	**Access Contact Phone:**	**Access Contact Fax:**

Document 3

Access Contact Email:	L cence Status:	Status Effective Date:	Add tional Dev ces Added:
	A	13/09/2017	0

Manufacturer Informat on Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Covidien llc		54968	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact T tle:**	**Contact First Name:**
Yes	25/03/2020		
Contact Surname:			

Supplier Informat on Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Phone:	**Fax:**	**Email:**	**Webs te:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact T tle:**	**Contact First Name:**
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**

Report Status

For website publ cat on:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Pr ority:
Yes	Yes	No	Event determined to be most likely due to user error	Team B (IIb, Is & Im)	Not Investigated

Team Review

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

Notes for Team meeting:

Outcomes from Team Meeting:

DPRC Review

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

Meeting Notes:

In tial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Sever ty:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentat on:

27/03/2020	1 - No harm has been reported to occur			Chloe Chen	Unknown - updated informat on from the manufacturer is required
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
		Level 1 Investigat on (to complete screening)	Screening only	Not Appl cable	0. No recalls for similar inc dents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
				Yes	
Incidents Worldw de:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			No	0 inc dents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Routine	Routine		
Products supplied last 24 months:	Number of potential sens tivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				
Products supplied last 36 months:	Specific sens tivities dentified:				3 or more events - organisation:
Products supplied Worldw de:	Consultations during risk assessment:	Final Risk Assessment:			
		No			

Additional Risk Analysis

Cl ck 'N' to start a new risk analysis

Analysis Details	Statist cs Checklist Sect on					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
Yes	Date:	Severity:	Inc dents in the last 12 months:	Manufacturer analysis:		
Copy Data From:	05/08/2020	**5 - An illness/injury was resolved or prevented with treatment by a health professional**		Yes		
In tial	Assessor:	Manufacturer documentation:	Inc dents in last 24 months:	Manufacturer act on:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	s22	**Unknown - updated information from the manufacturer is required**		Not required (dev ce was performing within specified parameters)	Level 1 Investigat on (to complete screening)	**Screening only**
	Injured Party:	Device Recalls:	Inc dents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Patient	**0. No recalls for similar incidents in Australia**			Closed. no recall or PMRs. Low rates qlik and sponsor analysis.	
	Found Pr or To Use:	Is AE covered by current recall:	Inc dents Worldw de:	Number of potential contributing factors:	Likely to be user error.	
	Yes			Yes - some potential factors (up to 3)		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors dentified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
	No	**0 incidents**		Use of device - operator/user error	Routine	**Routine**
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitiv ties:	EXCEPTION TO PRIORITY LEVEL:	
		No		Yes - some potential sens tiv ties (up to 3)	Closed. no recall or PMRs. Low rates qlik and sponsor analysis.	
		3 or more events - health district:	Products supplied last 36 months:	Specific sensitiv ties identified:	Likely to be user error.	
		No		Dev ce used in high risk populations, Dev ce used in high acu ty clinical environments		
		3 or more events - organisation:	Products supplied Worldwide:	Consultat ons during risk assessment:	Final Risk Assessment:	
		No		I did none of the above incidents	**Yes**	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:	Client #:

Document 3

837	Medtron c Australasia Pty Ltd	837

Attention To:	Address 1:	Address 2:	Town/Suburb:
s22	PO Box 945		NORTH RYDE BC

State:	Postcode:	Phone:	Fax:
NSW	1670	s22	

Email:

s22 @medtron c.com

Investigat on Information Sect on - Submitted by Sponsor/Manufacturer

Device Analysis Results:

Medtronic conducted an investigat on based upon all received informat on.

The following complaint(s) were investigated:
It was reported that:
Significant surgical intervent on was required due to the product failure
Significant tissue loss occurred as a result of the product failure
The anvil tilted prematurely / pr or to firing.
- This complaint was confirmed based on the actual device. The most likely root cause was traced to the user.

The anvil did not easily attach to the stapler
- This complaint was confirmed based on the actual device. The most likely root cause was traced to the user.

A medical assessment was performed. The medical assessment determined there was no association to the complaint.
A risk assessment review was performed. The risk assessment review determined that there was a relat on to the complaint.

Product analysis occurred.
The primary analysis finding was:
- Damage consistent with an obstruction was noted on the knife blade and/or staple guide.

Corrective/Preventative Actions:

Further action was not required because the event had foreseen risk and is included in a data mon toring plan.

Should new informat on become available the file will be re-opened and the investigat on summary will be amended as appropriate.

Details of Similar Events:

Similar inc dents based off FDA Annex A code A040102 (LOSS OF OR FAILURE TO BOND):
Similar events in Australia in the past 3 years: 2
Similar events worldw de (Australia excluded) in the past 3 years: 22
Sales in Australia in the past 3 years: 4376
This correlates to a complaint rate of 0.046%
Sales worldwide (Australia excluded) in the past 3 years: 61876
This correlates to a complaint rate of 0.036%

Similar inc dents based off FDA Annex A code A051204 (DEVICE SLIPPED):
Similar events in Australia in the past 3 years: 1
Similar events worldw de (Australia excluded) in the past 3 years: 1
Sales in Australia in the past 3 years: 4376
This correlates to a complaint rate of 0.023%
Sales worldwide (Australia excluded) in the past 3 years: 61876
This correlates to a complaint rate of 0.002%

Add tional Details (use for tables):

CAPA# Reference:

Risk Assessment

Frequency:	Sever ty:		

Rating:		Type Cause and Outcome:	Number of Similar Events:

Expected Rate:	Actual Rate:

Countries Similar Events Also Occurred:

AustraliaFranceGermanyHong KongJapanNetherlandsSingaporeSwedenSwitzerlandUnited KingdomUnited States

Completed Actions:

Planned Act ons and Proposed Timelines:

Addit onal Comments:

Report Closed 05-08-2020.

Reason for Level 1 Investigation

Document 3

Details of Reasons	
Reason for Level 1 Investigat on	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

Details of Source			
Sources of Ev dence	If 'Others' please specify here	Expected Sourcing Date	Date of Ev dence Received

Evidence

Investigat on Quest ons (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis w thin the TGA:

Delays in reporting by other sources (e.g. clin cal registries):

Other Risks (wh ch need to be specified):

Next Steps for Level 1 & Level 2 Investigat ons

Next Steps for Level 1 Investigat on:

Next Steps for Level 2 Investigat on:

Cl ck **[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	Notes
☐		TGA Regulatory Action	Final Report Due		30/03/2020	08/07/2020	31/07/2020		

List of Problem Observed Codes - Cl ck **[N]** to begin entering informat on.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Compatibility Problem	Component or Accessory Incompatibility			
Mechan cal Problem	Mechan cal Jam			

Clinical signs symptoms and conditions

Details	

Document 3

Level 1	Level 2	Level 3	
Others	Appropriate Term / Code Not Available		

Health Impact

Details			
Level 1	Level 2	Level 3	
Unexpected Med cal Intervention	Add tional Dev ce Required		

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigat on Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
Mechan cal Problem Identified			likely due to User Error	

Investigation Conclusion

Conclus on Details			
Investigation Conclus on (L1)	Investigation Conclusion (L2)	If Add tional Conclus on Detail Requested	
Cause Traced to User			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigat on (L2)	If Add tional Conclus on Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

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

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time; however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generat on buttons disabled if report not ready for webs te publ cation or risk analysis not completed.

Device Lookup

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

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

Other Devices					
Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:

Document 3

Model Number:	Batch #:	Lot #:	Expiry Date:

Related DIR Information - Cl ck **New** to begin entering informat on.

Rec No	
1	

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

Rec No	Details	Sample Details			Add t onal Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Dev ce Descript on:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Vers on Number:	
					Who sent the dev ce to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Cl ck **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Act on Taken:		Patient History:	
Injured - Extent of Injury:	Was dev ce directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Add tional Event Descript on:	Med cal Problem Device Used For:

Additional Device Information

Where did you get this dev ce from?:

How reliant is the affected person on correct/safe operation of this device?:

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

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Dev ce Access - Alternate Dev ce Contact Informat on Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Document 3

Incident Locat on Details

Occurred in Australia:	Organisation:	Address Line 1:	Address Line 2:
Town/Suburb:	**State:**	**Postcode:**	

Flow Details DIR-REQ - Device Incident Request 259093

Request Details

ID	Type	Locat on	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
259093	DIR-REQ		Closed	s22	OPR Administration User	05/08/2020	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	05/08/2020 13:59:18	
Comment		

Document 4

03/09/2021
SIGNED

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

DIR : 44 - ID : 528946

Released by s22 on 18/03/2021 17:26:54

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
72184		704585197	Final

ARTG: 293808 Document Container URL

Report Informat on Sect on

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of In tial Report:
Closed	Other		03/09/2021
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
21/10/2021	03/09/2021		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
25/10/2021			N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Act on:**	
Sponsor		Trend data only	

Event Descript on for Website Publication:

3 weeks post operatively the patient had leakage on the anastomosis.

Clinical Event Information:

According to the reporter, during laparoscopic hemicolectomy, the device was able to fire w th no problem, but 3 weeks post operatively the patient had leakage on the anastomosis.
To resolve the issue the surgeon redo the surgery then, re-resect and re-staple the anastomosis of the patient. There was a tissue damage as a result of the device failure.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Insufficient Informat on -> ->

Clinical Signs, Symptoms and Cond tions

Recorded Clinical Signs, Symptoms and Cond t ons:

Gastrointestinal System -> ->

Health Impact

Recorded Health Impacts:

Surgical Intervent on -> Addit onal Surgery ->

Patient Informat on

Sex:	Weight:	Age:	

Patient Focused Corrective Act on Taken:

Patient History:

Patient Outcome/Consequences:

Addit onal Event Description:

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Other medical dev ces currently using/implanted:	Medical Problem Device Used For:

Add tional Patients Added:

Document 4

0

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
[redacted]			
Reporter Title:	**First Name:**	**Surname:**	
[redacted]	[redacted]	[redacted]	
Position:		**Company/Institut on:**	
[redacted]		Medtronic Australasia Pty Ltd	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
2 Alma Road		Macquarie Park	NSW
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2113	[redacted]	
Mobile:	**Email:**	**Last External Submiss on By:**	
	[redacted]@medtron c.com	113291_837 - 21/10/2021 15:42	

In tial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Conf dential:
No			Yes
Search Reporter By Surname:	**In tial Reporter #:**		**Preferred Contact Method:**
Title:	**First Name:**	**Surname:**	
Position:		**Company/Institut on:**	
		KNOX PRIVATE HOSPITAL	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
262 Mountain Highway		Wantirna	VIC
Postcode:	**Country:**	**Phone:**	**Fax:**
3152		[redacted]	
Mobile:	**Email:**	**Allow the device company to contact you about the inc dent:**	
	ap.callcentre@healthscope.com	☐	

Dev ce Information Sect on

Product Exempt *(Note: If not exempt, enter ARTG No)*:	Search Device ARTG:	Device ARTG #:	Therapeutic L cence Type:
No	293808	293808	Medical Device
Product Licence Category:	**Dev ce Class:**	**GMDN / UMDN Code:**	**GMDN / UMDN Text:**
Included	Class IIb	59875	Intraluminal circular stapler, single-use
Brand Name:	**In tial Dev ce Descript on:**	**Usage of Dev ce:**	**Software Vers on:**
EEA - Intraluminal circular stapler, single-use	EEA - Intraluminal circular stapler, single-use	Single Use	
Model #:	**Serial #:**	**Batch #:**	**Lot #:**
TRIEEA28MT	Unknown		
Purchase Date:	**Expiry Date:**	**Date of Implant:**	**Date of Explant:**
Date of Inital Procedure:	**Place of Implantation:**	**Reported Dev ce Location:**	**Access Contact Title:**
Access Contact First Name:	**Access Contact Surname:**	**Access Contact Phone:**	**Access Contact Fax:**
Access Contact Email:	**Licence Status:**	**Status Effective Date:**	**Additional Devices Added:**

Document 4

	A	13/09/2017	0

Manufacturer Informat on Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Covidien llc		54968	
Address 2:	Town/Suburb:	State/Province:	Country:
Postcode:	Phone:	Fax:	Email:
Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Yes	31/08/2021		
Contact Surname:			

Supplier Informat on Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Country:	Postcode:
Phone:	Fax:	Email:	Website:
Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:
Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:

Report Status

For website publ cat on:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Pr ority:
Yes	Yes	No	Rate cons dered low at this stage	Team B (IIb, Is & Im)	Not Investigated

Team Review

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

Notes for Team meeting:

Outcomes from Team Meeting:

In tial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Sever ty:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentat on:
03/09/2021	5 - An illness/injury was resolved or prevented with treatment by a health profess onal			s22	
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
		Screening only	Screening only	Patient	
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:
				No	
Incidents Worldw de:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):

	No			No	0 inc dents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Routine	Routine		
Products supplied last 24 months:	Number of potential sens tivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				
Products supplied last 36 months:	Specific sens tivities dentified:				3 or more events - organisation:
Products supplied Worldw de:	Consultations during risk assessment:	Final Risk Assessment:			
	I did none of the above incidents	No			

Additional Risk Analysis

Cl ck 'N' to start a new risk analysis

Analysis Details	Statist cs Checklist Sect on					
Update Device Details?:	Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Yes	Date:	Severity:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:	25/10/2021	5 - An illness/injury was resolved or prevented with treatment by a health professional		No		
In tial	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer act on:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	s22 [redacted]	Yes - manufacturer HAS documented issues or complications of this type		Unable to take act on (device was not returned for analysis)	Screening only	Screening only
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Patient	0. No recalls for similar incidents in Australia				
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	No	No		No		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specif c factors dentified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
	No	0 incidents			Routine	Routine
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sens tiv ties:	EXCEPTION TO PRIORITY LEVEL:	
				No		
		3 or more events - health district:	Products supplied last 36 months:	Specif c sensitiv ties identified:		
		3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:	
					Yes	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtron c Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22 [redacted]	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:
NSW	1670	s22 [redacted]	
Email:			
s22 [redacted] @medtron c.com			

Document 4

Investigat on Information Sect on - Submitted by Sponsor/Manufacturer

Device Analysis Results:

Medtronic conducted an investigat on based upon all received informat on.

The following complaint(s) were investigated:
It was reported that:
An unexpected content leak occurred along the staple line.
- There was not enough informat on to make any determination based on insuff cient evidence. The most likely root cause was not established.
The deployed staples did not hold the tissue and the staple line opened up
- There was not enough informat on to make any determination based on insuff cient evidence. The most likely root cause was not established.

A device history review was performed and the lot number was not prov ded. However, records from each manufacturing lot are thoroughly reviewed to ensure that products are released meeting all Medtron c quality release specificat ons at the time of manufacture. . The device history review determined that there was insuff cient informat on to conduct the specific Investigat on Action.
A medical assessment was performed. The medical assessment results were inconclusive.

Further action was not required because there was insufficient information.

Should new informat on become available the file will be re-opened and the investigation summary will be amended as appropriate.

Details of Similar Events:

Australia:
0 similar events from 3993 units (0%) sold in CY2019;
0 similar events from 2977 units (0%) sold in CY2020;
1 similar events from 2744 units (0.03644%) sold in CY2021 (Includes this event).
Worldw de:
8 similar events from 46210 un ts (0.01731%) sold in CY2019;
8 similar events from 41670 un ts (0.0192%) sold in CY2020;
21 similar events from 46093 units (0.04556%) sold in CY2021.

Similar inc dent rates were determined using FDD annex A code
(ADVERSE EVENT WITHOUT IDENTIFIED DEVICE OR USE PROBLEM - A24) for the platform family type of product reported per subject event.

Addit onal Details (use for tables):

CAPA# Reference:

Risk Assessment

Frequency:

Severity:

Rating:

Type Cause and Outcome:

Number of Similar Events:

Expected Rate:

Actual Rate:

Countries Similar Events Also Occurred:

Albania Argentina Armenia Australia Austria Bahrain Belgium Brazil Bulgaria Canada Canary Islands Chile China Colombia Costa Rica Croatia Cyprus Czech Republ c Denmark Finland France Germany Greece Guadeloupe Guatemala Hong Kong Hungary Iceland India Indonesia Ireland Israel Italy Korea, Republ c Of Kuwa t Latvia Lebanon Luxembourg Macao Malaysia Montenegro Netherlands New Zealand North Macedonia Norway Pakistan Panama Paraguay Peru Poland Portugal Puerto R co Qatar Reunion RomaniaRussian Federation San Marino Saudi Arabia Serbia Singapore Slovakia Slovenia South Afr ca Spain Sweden Sw tzerland Thailand Turkey UkraineUn ted Arab Emirates Un ted Kingdom Un ted States Viet Nam

Completed Actions:

Planned Actions and Proposed Timelines:

Addit onal Comments:

DIR closed on 25 OCT 2021

Should new informat on become available the file will be re-opened and the investigation summary will be amended as appropriate.

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigat on	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Document 4

Sources of Evidence for Level 2

Details of Source			
Sources of Ev dence	If 'Others' please specify here	Expected Sourcing Date	Date of Ev dence Received

Evidence

Investigat on Quest ons (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis w thin the TGA:

Delays in reporting by other sources (e.g. clin cal registries):

Other Risks (wh ch need to be specified):

Next Steps for Level 1 & Level 2 Investigat ons

Next Steps for Level 1 Investigat on:

Next Steps for Level 2 Investigat on:

Cl ck **[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	Notes

List of Problem Observed Codes - Cl ck **[N]** to begin entering informat on.

Problem Observed Details			
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected
Insufficient Information			

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
Gastrointestinal System			

Health Impact

Details			
Level 1	Level 2	Level 3	
Surgical Intervention	Add tional Surgery		

Investigation Findings

Finding Details	

Document 4

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

Investigation Conclusion

Conclus on Details			
Investigation Conclus on (L1)	Investigation Conclusion (L2)	If Add tional Conclus on Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigat on (L2)	If Add tional Conclus on Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Latest Investigat on (DII) where this DIR is the Primary DIR:	Latest Investigat on (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
			No	
Investigator's Notes:		**Summary Findings:**		**Recall Number:**
		No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.		

Note: Letter generat on buttons disabled if report not ready for webs te publ cation or risk analysis not completed.

Device Lookup

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

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

Other Devices

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

Related DIR Information - Cl ck **New** to begin entering informat on.

Rec No	
1	

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

Rec No	Details	Sample Details			Add t onal Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Dev ce Descript on:	Brand Name:	Serial Number:

Document 4

Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:

Lot Number:	Batch Number:	Model Number:	Vers on Number:

Who sent the dev ce to the TGA?:	Why does the TGA have the sample?:

Additional Patients

Cl ck **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	

Patient Focused Corrective Act on Taken:	Patient History:

Injured - Extent of Injury:	Was dev ce directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:

Other Consequence:	Describe any test (Lab, xray, etc.):	Add tional Event Descript on:	Med cal Problem Device Used For:

Additional Device Information

Where did you get this dev ce from?:

How reliant is the affected person on correct/safe operation of this device?:

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

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Dev ce Access - Alternate Dev ce Contact Informat on Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Locat on Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details DIR-REQ - Device Incident Request 318468

Request Details

ID	Type	Locat on	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
318468	DIR-REQ		Closed	s22	OPR Administration User	25/10/2021	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	25/10/2021 19:04:18	
Comment		

Document 5

08/03/2022
SIGNED

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

DIR : 45 - ID : 538597

Released by Theta Technologies on 24/11/2021 14:57:03

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
76781		0704894000	Final

ARTG: 293808 Document Container URL

Report Informat on Sect on

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of In tial Report:
Closed		s22	08/03/2022
Date of Final Report:	**Date of In tial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
07/07/2022	08/03/2022	19/07/2022	
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
19/07/2022	Healthcare Profess onal		N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of In tial Action:**	
Sponsor		For Team Meeting	

Event Descript on for Website Publication:

The stapler was difficult to remove after firing and the anvil detached.

Clinical Event Information:

According to the reporter, during a laparoscop c high anterior resect on, the stapler was difficult to remove after firing and when t was removed, the anvil detached. The anvil was removed and the surgeon d d a leak test and sigmo doscopy. The surgeon was satisfied with the anastomosis. One week post operative, the patient was unwell and was taken back to the theatre. The anastomosis was not intact. Patient died from multiple organ failure due to sepsis secondary to anastomotic leak.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Mechanical Problem -> Detachment of Device or device Component -> ;
Mechanical Problem -> Retract on Problem ->

Clinical Signs, Symptoms and Cond tions

Recorded Clinical Signs, Symptoms and Cond t ons:

General Disorders -> Multiple Organ Dysfunction Syndrome -> ;
Infections -> Sepsis ->

Health Impact

Recorded Health Impacts:

Death -> -> ;
Surgical Intervent on -> Addit onal Surgery ->

Patient Informat on

Sex:	Weight:	Age:
s22		s22

Patient Focused Corrective Act on Taken:

Patient History:

Patient Outcome/Consequences:

Patient passed away.

Additional Event Descript on:

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Other med cal devices currently using/implanted:	Med cal Problem Dev ce Used For:

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Add tional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname:

s22

Reporter #:

Preferred Contact Method:

Reporter Title:

s22

First Name:

s22

Surname:

s22

Position:

s22

Company/Inst tution:

Medtron c Australasia Pty Ltd.

Address 1:

2 Alma Road, Macquarie Park, NSW, 2113

Address 2:

Town/Suburb:

Macquarie Park

State:

NSW

Country:

Australia

Postcode:

2113

Phone:

s22

Fax:

Mobile:

Email:

s22 @medtronic.com

Last External Submission By:

114395_837 - 07/07/2022 14:50

In tial Reporter Section

As Above?:

No

If No, fill out the following:

Initial Reporter Confidential:

Yes

Search Reporter By Surname:

In tial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Inst tution:

ST. ANDREWS

Address 1:

Address 2:

Town/Suburb:

Adelaide

State:

SA

Postcode:

Country:

Phone:

Fax:

Mobile:

Email:

Allow the dev ce company to contact you about the incident:

☐

Dev ce Information Sect on

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

No

Search Device ARTG:

293808

Device ARTG #:

293808

Therapeut c Licence Type:

Med cal Device

Product Licence Category:

Included

Device Class:

Class IIb

GMDN / UMDN Code:

59875

GMDN / UMDN Text:

Intraluminal circular stapler, single-use

Brand Name:

EEA - Intraluminal circular stapler, single-use

In tial Device Description:

EEA - Intraluminal circular stapler, single-use

Usage of Device:

Software Version:

Model #:

TRIEEA28MT

Serial #:

Batch #:

Lot #:

P1L0118

Purchase Date:

Expiry Date:

Date of Implant:

Date of Explant:

Date of Inital Procedure:

Place of Implantation:

Reported Dev ce Locat on:

Access Contact T tle:

Access Contact First Name:

Access Contact Surname:

Access Contact Phone:

Access Contact Fax:

Document 5

Access Contact Email:	Licence Status:	Status Effective Date:	Add t onal Devices Added:
	A	13/09/2017	0

Manufacturer Informat on Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Covidien llc		54968	
Address 2:	Town/Suburb:	State/Province:	Country:
Postcode:	Phone:	Fax:	Email:
Manufacturer Informed:	Date Aware of Adverse Event:	Contact T tle:	Contact First Name:
Yes	03/03/2022		
Contact Surname:			

Supplier Informat on Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Country:	Postcode:
Phone:	Fax:	Email:	Website:
Supplier Informed:	Date of Supplier Contact:	Contact T tle:	Contact First Name:
Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:

Report Status

For website publ cat on:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Pr ority:
Yes	Yes	No	Rate cons dered low at this stage	Team B (IIb, Is & Im)	Routine

Team Review

Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
	Death	Post-market Review is recommended

Notes for Team meeting:

0 similar events, 0 PMR's, 0 recalls, sent to team meeting because of death. Should we ask whether or not the dev ce was returned and why they haven't conducted any analysis if the dev ce was returned?

Outcomes from Team Meeting:

Closed as this is a known procedural complication.

In tial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Sever ty:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentat on:
11/07/2022	9 - Death		Yes	s22 [redacted]	Unknown - updated informat on from the manufacturer is required
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
	No	Level 2 Investigat on (for a single DIR)	Level 2 Investigat on (for a single DIR)	Patient	0. No recalls for similar inc dents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:

Document 5

				No	
Incidents Worldw de:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			Yes	0 inc dents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Expedite	Routine		
Products supplied last 24 months:	Number of potential sens tivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	Yes - some potential sens tivities (up to 3)	Sent to team meeting.			
Products supplied last 36 months:	Specific sens tivities dentified:				3 or more events - organisation:
	Device used in high acu ty clinical environments				
Products supplied Worldw de:	Consultations during risk assessment:	Final Risk Assessment:			
	I did none of the above incidents	Yes			

Additional Risk Analysis

Cl ck 'N' to start a new risk analysis

Analysis Details	Statist cs Checklist Sect on					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
	Date:	Sever ty:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:						
	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer act on:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors dentified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitiv ties:	EXCEPTION TO PRIORITY LEVEL:	
		3 or more events - health distr ct:	Products supplied last 36 months:	Specific sensitiv ties identified:		
		3 or more events - organisat on:	Products supplied Worldw de:	Consultat ons during risk assessment:	Final Risk Assessment:	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtron c Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:
NSW	1670		
Email:			

Document 5

Investigat on Information Sect on - Submitted by Sponsor/Manufacturer

Device Analysis Results:

Medtronic conducted an investigat on based upon all received informat on.

The following complaint(s) were investigated:
It was reported that:
There was difficulty removing the dev ce from the patient.
- There was not enough information to make any determinat on based on insufficient evidence. The most likely root cause was not established.
The anvil disengaged either fully or partially from the device.
- There was not enough information to make any determinat on based on insufficient evidence. The most likely root cause was not established.

A medical assessment was performed. The medical assessment results were inconclusive.
A device history review was performed. The device history review determined there was no association to the complaint.

Corrective/Preventative Actions:

Further action was not required because there was insuff cient informat on.

Details of Similar Events:

Australia:
2 similar events from 3993 un ts (0.05009%) sold in CY2019;
2 similar events from 2977 un ts (0.06718%) sold in CY2020;
1 similar events from 3517 un ts (0.02843%) sold in CY2021;
1 similar events from 1580 un ts (0.06329%) sold in CY2022 (Includes this event).

Worldw de:
17 similar events from 46545 un ts (0.03652%) sold in CY2019;
9 similar events from 45149 units (0.01993%) sold in CY2020;
9 similar events from 71491 units (0.01259%) sold in CY2021;
9 similar events from 37992 units (0.02369%) sold in CY2022.

Similar inc dent rates were determined using FDD annex A code (DIFFICULT TO REMOVE - A150207) for the platform family type of product reported per subject event.

Add tional Details (use for tables):

CAPA# Reference:

Risk Assessment

Frequency:	Sever ty:		
Rating:		**Type Cause and Outcome:**	**Number of Similar Events:**
Expected Rate:	**Actual Rate:**		

Countries Similar Events Also Occurred:

Austria, Finland, France, Germany, Ireland, Italy, Japan, Macao, Netherlands, New Zealand, Spain, Sweden, Switzerland, United Kingdom & United States

Completed Actions:	Planned Act ons and Proposed Timelines:

Addit onal Comments:

DIR Closed on 19 July 2022.

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigat on	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Document 5

Sources of Evidence for Level 2

Details of Source			
Sources of Ev dence	If 'Others' please specify here	Expected Sourcing Date	Date of Ev dence Received

Evidence

Investigat on Quest ons (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis w thin the TGA:

Delays in reporting by other sources (e.g. clin cal registries):

Other Risks (wh ch need to be specified):

Next Steps for Level 1 & Level 2 Investigat ons

Next Steps for Level 1 Investigat on:

Next Steps for Level 2 Investigat on:

Cl ck **[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	Notes

List of Problem Observed Codes - Cl ck **[N]** to begin entering informat on.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Mechan cal Problem	Retract on Problem			
Mechan cal Problem	Detachment of Device or dev ce Component			

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
Infections	Sepsis		
General Disorders	Multiple Organ Dysfunct on Syndrome		

Health Impact

Details			
Level 1	Level 2	Level 3	
Surgical Intervention	Add tional Surgery		
Death			

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Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigat on Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Findings Available				

Investigation Conclusion

Conclus on Details			
Investigation Conclus on (L1)	Investigation Conclusion (L2)	If Add tional Conclus on Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigat on (L2)	If Add tional Conclus on Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Latest Investigat on (DII) where this DIR is the Primary DIR:	Latest Investigat on (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
			No	

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time; however the TGA will continue to mon tor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generat on buttons disabled if report not ready for webs te publ cation or risk analysis not completed.

Device Lookup

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

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

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:

Model Number:	Batch #:	Lot #:	Expiry Date:

Related DIR Information - Cl ck **New** to begin entering informat on.

Rec No	
1	

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

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Rec No	Details	Sample Details			Add t onal Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Dev ce Descript on:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Vers on Number:	
					Who sent the dev ce to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Cl ck **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Act on Taken:		Patient History:	
Injured - Extent of Injury:	Was dev ce directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Add tional Event Descript on:	Med cal Problem Device Used For:

Additional Device Information

Where did you get this dev ce from?:

How reliant is the affected person on correct/safe operation of this device?:

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

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Dev ce Access - Alternate Dev ce Contact Informat on Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Locat on Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details DIR-REQ - Device Incident Request 335428

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Request Details

ID	Type	Locat on	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
335428	DIR-REQ		Closed	s22	OPR Administration User	19/07/2022	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	19/07/2022 14:12:18	
Comment		

Document 6

17/10/2022
SIGNED

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

DIR : 46 - ID : 547498

Released by s22 on 28/09/2022 14:44:45

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
82594		705260594	Final

ARTG: 293808

Document Container URL

Report Informat on Sect on

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of In tial Report:
Closed		s22	17/10/2022
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
02/02/2023	17/10/2022		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
09/02/2023			N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Act on:**	
Sponsor		Trend data only	

Event Descript on for Website Publication:

post-operatively, the staple line leaked and had to have a second procedure.

Clinical Event Information:

According to the reporter, two days post-operatively of laparoscop c low anterior bowel resection, the staple line leaked and had to have a second procedure. The patient is still in hosp tal and there is a high potential that the bowel cannot be re-anastomosed resulting in permanent colostomy bag for the patient. Further bowel needed to be resected due to the circular staple line dehiscence and t us unknown there will be enough bowel to rejoin. But during the first surgery, the dev ce that was used was funct oned as expected, no dev ce misfired, air leak was performed successfully, and distal and proximal donuts were both intact. A second procedure was performed wh ch is Hartmann's procedure and colostomy bag. These were to close rectal stump and create colostomy. Another operat on is required but patient will undergo chemotherapy and have a brief healing period before further surgeries required.

Number of Incidents in Report:	Contact:	Alternative Person T tle:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Mechanical Problem -> Leak / Splash -> Fluid Leak

Clinical Signs, Symptoms and Cond tions

Recorded Clinical Signs, Symptoms and Cond t ons:

Gastrointestinal System -> Rectal Anastomot c Leakage ->

Health Impact

Recorded Health Impacts:

Surgical Intervent on -> Addit onal Surgery ->

Patient Informat on

Sex:	Weight:	Age:
s22		s22

Patient Focused Corrective Act on Taken:

Patient History:

Patient Outcome/Consequences:

Add t onal Event Description:

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Other medical dev ces currently using/implanted:	Med cal Problem Device Used For:

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Add tional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname:

s22

Reporter #:

Preferred Contact Method:

Reporter Title:

s22

First Name:

s22

Surname:

s22

Position:

s22

Company/Institut on:

Medtronic Australasia Pty Ltd

Address 1:

2 Alma Road

Address 2:

Town/Suburb:

Macquarie Park

State:

NSW

Country:

Australia

Postcode:

2113

Phone:

s22

Fax:

Mobile:

Email:

s22 @medtron c.com

Last External Submiss on By:

113291_837 - 02/02/2023 12:45

In tial Reporter Section

As Above?:

No

If No, fill out the following:

Initial Reporter Conf dential:

Yes

Search Reporter By Surname:

In tial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institut on:

s47F

Address 1:

s47F

Address 2:

Town/Suburb:

s47F

State:

s4

Postcode:

s47

Country:

Phone:

s47F

Fax:

s47F

Mobile:

Email:

s47F

Allow the device company to contact you about the inc dent:

Dev ce Information Sect on

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

No

Search Device ARTG:

293808

Device ARTG #:

293808

Therapeutic L cence Type:

Medical Device

Product Licence Category:

Included

Dev ce Class:

Class IIb

GMDN / UMDN Code:

59875

GMDN / UMDN Text:

Intraluminal circular stapler, single-use

Brand Name:

EEA - Intraluminal circular stapler, single-use

In tial Device Descript on:

EEA - Intraluminal circular stapler, single-use

Usage of Dev ce:

Single Use

Software Vers on:

Model #:

TRIEEA28XT

Serial #:

Batch #:

Lot #:

P0C1305Y

Purchase Date:

Expiry Date:

Date of Implant:

Date of Explant:

Date of Inital Procedure:

Place of Implantation:

Reported Device Location:

Access Contact Title:

Access Contact First Name:

Access Contact Surname:

Access Contact Phone:

Access Contact Fax:

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Access Contact Email:	Licence Status:	Status Effective Date:	Addit onal Devices Added:
	A	13/09/2017	0

Manufacturer Informat on Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Covidien llc		54968	
Address 2:	Town/Suburb:	State/Province:	Country:
Postcode:	Phone:	Fax:	Email:
Manufacturer Informed:	Date Aware of Adverse Event:	Contact Title:	Contact First Name:
Yes	12/10/2022		
Contact Surname:			

Supplier Informat on Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Country:	Postcode:
Phone:	Fax:	Email:	Website:
Supplier Informed:	Date of Supplier Contact:	Contact Title:	Contact First Name:
Contact Surname:	Contact Phone:	Contact Fax:	Contact Email:

Report Status

For website publ cat on:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Pr ority:
Yes	Yes	No	Device not returned	Team B (IIb, Is & Im)	Not Investigated

Team Review

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

Notes for Team meeting:

Outcomes from Team Meeting:

In tial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	Sever ty:	Incidents in the last 12 months:	Manufacturer analysis:	Assessor:	Manufacturer documentat on:
09/02/2023	6 - Ongoing minor impairment		Yes	s22	Unknown - updated informat on from the manufacturer is required
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:	Injured Party:	Device Recalls:
	Unable to take action (device was not returned for analysis)	Level 1 Investigat on (to complete screening)	Screening only	Patient	0. No recalls for similar inc dents in Australia
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:		Found Prior To Use:	Is AE covered by current recall:

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		The dev ce was not returned - Low rate		No	
Incidents Worldw de:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			No	0 inc dents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Routine	Routine		
Products supplied last 24 months:	Number of potential sens tivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No				
Products supplied last 36 months:	Specific sens tivities dentified:				3 or more events - organisation:
Products supplied Worldw de:	Consultations during risk assessment:	Final Risk Assessment:			
	I did none of the above incidents	Yes			

Additional Risk Analysis

Cl ck 'N' to start a new risk analysis

Analysis Details	Statist cs Checklist Sect on					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
	Date:	Sever ty:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:						
	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer act on:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors dentified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitiv ties:	EXCEPTION TO PRIORITY LEVEL:	
		3 or more events - health distr ct:	Products supplied last 36 months:	Specific sensitiv ties identified:		
		3 or more events - organisat on:	Products supplied Worldw de:	Consultat ons during risk assessment:	Final Risk Assessment:	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtron c Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:
NSW	1670		
Email:			

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Investigat on Information Sect on - Submitted by Sponsor/Manufacturer

Device Analysis Results:

Medtronic conducted an investigat on based upon all received informat on.

The following complaint(s) were investigated:
It was reported that:
An unexpected content leak occurred along the staple line.
- There was not enough information to make any determinat on based on insufficient evidence. The most likely root cause was not established.
An incision of >1 inch was needed resulting from product failure.
- There was not enough information to make any determinat on based on insufficient evidence. The most likely root cause was not established.

A device history review was performed. The device history review determined there was no association to the complaint.

Further action was not required because there was insufficient information.

Should new informat on become available the file will be re-opened and the investigation summary will be amended as appropriate.

Details of Similar Events:

Australia:
0 similar events from 379 un ts (0%) sold in CY2020;
1 similar events from 567 un ts (0.17637%) sold in CY2021;
3 similar events from 294 un ts (1.02041%) sold in CY2022;
0 similar events from 81 units (0%) sold in CY2023 (Includes this event).

Worldw de:
14 similar events from 6400 un ts (0.21875%) sold in CY2020;
32 similar events from 14244 units (0.22466%) sold in CY2021;
64 similar events from 17296 units (0.37003%) sold in CY2022;
1 similar events from 2535 units (0.03945%) sold in CY2023.

Similar inc dent rates were determined using FDD annex A code (ADVERSE EVENT WITHOUT IDENTIFIED DEVICE OR USE PROBLEM - A24) for the platform family type of product reported per subject event.

Addit onal Details (use for tables):

CAPA# Reference:

Risk Assessment

Frequency:

Severity:

Rating:

Type Cause and Outcome:

Number of Similar Events:

Expected Rate:

Actual Rate:

Countries Similar Events Also Occurred:

Australia, Belgium, Brazil, Canada, Chile, Finland, France, Germany, Greece, Hong Kong, India, Ireland, Israel, Italy, Japan,Korea Republic Of, Malaysia, Mexico, Netherlands, Norway, Poland, South Afr ca, Spain, Sw tzerland, Thailand, Un ted Kingdom, Un ted States

Completed Actions:

Planned Actions and Proposed Timelines:

Addit onal Comments:

Similar inc dent rates were determined using FDD annex A code (DEVICE ALARM SYSTEM - A1601) for the platform family type of product reported per subject event.

DIR closed on 9/2/2023

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigat on	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

Sources of Evidence for Level 2

Details of Source			
Sources of Ev dence	If 'Others' please specify here	Expected Sourcing Date	Date of Ev dence Received

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Evidence

Investigat on Quest ons (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis w thin the TGA:

Delays in reporting by other sources (e.g. clin cal registries):

Other Risks (wh ch need to be specified):

Next Steps for Level 1 & Level 2 Investigat ons

Next Steps for Level 1 Investigat on:

Next Steps for Level 2 Investigat on:

Cl ck **[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	Notes	

List of Problem Observed Codes - Cl ck **[N]** to begin entering informat on.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Mechan cal Problem	Leak / Splash	Fluid Leak		

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
Gastrointestinal System	Rectal Anastomotic Leakage		

Health Impact

Details			
Level 1	Level 2	Level 3	
Surgical Intervention	Add tional Surgery		

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigat on Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Findings Available				

Investigation Conclusion

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Conclus on Details			
Investigation Conclus on (L1)	Investigation Conclusion (L2)	If Add tional Conclus on Detail Requested	
Cause Not Established			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigat on (L2)	If Add tional Conclus on Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Latest Investigat on (DII) where this DIR is the Primary DIR:	Latest Investigat on (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:
			No

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time; however, the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generat on buttons disabled if report not ready for webs te publ cation or risk analysis not completed.

Device Lookup

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

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

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:

Model Number:	Batch #:	Lot #:	Expiry Date:

Related DIR Information - Cl ck **New** to begin entering informat on.

Rec No	
1	

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

Rec No	Details	Sample Details			Add t onal Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Dev ce Descript on:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Vers on Number:	
					Who sent the dev ce to the TGA?:			Why does the TGA have the sample?:	

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Additional Patients

Cl ck **[N]** to begin entering information.

Patient Details			
Sex:	Weight:	Age:	
Patient Focused Corrective Act on Taken:		Patient History:	
Injured - Extent of Injury:	Was dev ce directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Add tional Event Descript on:	Med cal Problem Device Used For:

Additional Device Information

Where did you get this dev ce from?:

How reliant is the affected person on correct/safe operation of this device?:

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

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Dev ce Access - Alternate Dev ce Contact Informat on Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Locat on Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Flow Details DIR-REQ - Device Incident Request 352894

Request Details

ID	Type	Locat on	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
352894	DIR-REQ		Closed	s22	OPR Administration User	09/02/2023	Normal	0

Signature Details

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Role	IRIS Investigator	
User	s22 [redacted]	
Signed At	09/02/2023 15:47:26	
Comment		

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10/05/2023
SIGNED

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

DIR : 46 - ID : 564527

Released by s22 on 28/09/2022 14:44:45

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
87436		705600221	Final

ARTG: 293808

Document Container URL

Report Informat on Sect on

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of In tial Report:
Closed		s22	10/05/2023
Date of Final Report:	**Date of In tial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
04/07/2023	10/05/2023		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter consents to contact by sponsor:**
05/07/2023			N/A
Source of Report:	**If 'Other' Source Selected:**	**Type of In tial Act on:**	
Sponsor		Trend data only	

Event Descript on for Website Publication:

During the procedure no staples were not fired from the dev ce.

Clinical Event Information:

According to the reporter, during a reversal of hartmann's procedure, during firing the knife blade still cut, but no staples were fired. Surgical was intervent on needed to prevent a permanent impairment of a function. There was blood of about 300ml as rectal stump in pelvis and the surgeon had to get the proximal part of bowel out before and contaminat on and then come back to pelvis. The operat on was extended by 2.5 hours. The surgeon had to make a large pfannenstiel incision and suture in the pelvis. Another dev ce was opened to resolve the issue.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	**Alternative Person Email:**

Recorded Problems Observed

Recorded Problems Observed:

Mechanical Problem -> Firing Problem -> Failure to Fire

Clinical Signs, Symptoms and Cond tions

Recorded Clinical Signs, Symptoms and Cond t ons:

Procedural Complications -> Appropriate Term / Code Not Available ->

Health Impact

Recorded Health Impacts:

Surgical Intervent on -> Prolonged surgery ->

Patient Informat on

Sex:	Weight:	Age:	

Patient Focused Corrective Act on Taken:

Patient History:

Patient Outcome/Consequences:

Additional Event Description:

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Other med cal devices currently using/implanted:	Med cal Problem Dev ce Used For:

Add tional Patients Added:

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Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
s22			
Reporter Title:	**First Name:**	**Surname:**	
s22	s22	s22	
Position:		**Company/Institution:**	
s22		Medtronic Australasia Pty Ltd	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
2 Alma Road		Macquarie Park	NSW
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2113	s22	
Mobile:	**Email:**	**Last External Submission By:**	
	s22 v@medtronic.com	113291_837 - 04/07/2023 16:39	

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
No			Yes
Search Reporter By Surname:	**Initial Reporter #:**		**Preferred Contact Method:**
Title:	**First Name:**	**Surname:**	
Position:		**Company/Institution:**	
		ST VINCENT'S PUBLIC MELBOURNE	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
2 St Andrews Place		East Melbourne	VIC
Postcode:	**Country:**	**Phone:**	**Fax:**
3002			
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 #:	Therapeutic Licence Type:
No	293808	293808	Medical Device
Product Licence Category:	**Device Class:**	**GMDN / UMDN Code:**	**GMDN / UMDN Text:**
Included	Class IIb	59875	Intraluminal circular stapler, single-use
Brand Name:	**Initial Device Description:**	**Usage of Device:**	**Software Version:**
EEA - Intraluminal circular stapler, single-use	EEA - Intraluminal circular stapler, single-use	Single Use	
Model #:	**Serial #:**	**Batch #:**	**Lot #:**
TRIEEAXL28MT			P2M0484
Purchase Date:	**Expiry Date:**	**Date of Implant:**	**Date of Explant:**
Date of Initial Procedure:	**Place of Implantation:**	**Reported Device Location:**	**Access Contact Title:**
Access Contact First Name:	**Access Contact Surname:**	**Access Contact Phone:**	**Access Contact Fax:**

Form Details

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Access Contact Email:	Licence Status:	Status Effective Date:	Add t onal Devices Added:
	A	13/09/2017	0

Manufacturer Informat on Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Covidien llc		54968	
Address 2:	**Town/Suburb:**	**State/Province:**	**Country:**
Postcode:	**Phone:**	**Fax:**	**Email:**
Manufacturer Informed:	**Date Aware of Adverse Event:**	**Contact Title:**	**Contact First Name:**
Yes	05/05/2023		
Contact Surname:			

Supplier Informat on Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**

Report Status

For website publ cat on:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Pr ority:
Yes	Yes	No	Event determined to be most likely due to user error	Team B (IIb, Is & Im)	Not Investigated

Team Review

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

Notes for Team meeting:

Outcomes from Team Meeting:

In tial Risk Analysis

Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date:	**Sever ty:**	**Incidents in the last 12 months:**	**Manufacturer analysis:**	**Assessor:**	**Manufacturer documentat on:**
10/05/2023	5 - An illness/injury was resolved or prevented with treatment by a health profess onal		Yes	s22 [redacted]	Unknown - updated informat on from the manufacturer is required
Incidents in last 24 months:	**Manufacturer action:**	**ESTIMATED LEVEL OF INVESTIGATION:**	**FINAL LEVEL OF INVESTIGATION:**	**Injured Party:**	**Device Recalls:**
	No	Level 1 Investigat on (to complete screening)	Screening only	Patient	0. No recalls for similar inc dents in Australia
Incidents in last 36 months:	**IVD status:**	**EXCEPTION TO INVESTIGATION LEVEL:**		**Found Prior To Use:**	**Is AE covered by current recall:**

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		The most likely root cause was traced to the user.		No	
Incidents Worldw de:	Number of potential contributing factors:			Reusable:	Similar events (past 6 months):
	No			No	0 inc dents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:		3 or more events - batch/model:
		Routine	Routine		No
Products supplied last 24 months:	Number of potential sens tivities:	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
	No	The most likely root cause was traced to the user.			No
Products supplied last 36 months:	Specific sens tivities dentified:				3 or more events - organisation:
					No
Products supplied Worldw de:	Consultations during risk assessment:	Final Risk Assessment:			
	I did none of the above incidents	Yes			

Additional Risk Analysis

Cl ck 'N' to start a new risk analysis

Analysis Details	Statist cs Checklist Sect on					
Update Device Details?:	**Background Information**	**Risk Assessment - Section A**	**Risk Assessment - Section B**	**Risk Assessment - Section C**	**Risk Assessment - Section D**	
	Date:	Sever ty:	Incidents in the last 12 months:	Manufacturer analysis:		
Copy Data From:						
	Assessor:	Manufacturer documentation:	Incidents in last 24 months:	Manufacturer act on:	ESTIMATED LEVEL OF INVESTIGATION:	FINAL LEVEL OF INVESTIGATION:
	Injured Party:	Device Recalls:	Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL:	
	Found Prior To Use:	Is AE covered by current recall:	Incidents Worldwide:	Number of potential contributing factors:		
	Reusable:	Similar events (past 6 months):	Products supplied the last 12 months:	Specific factors dentified:	ESTIMATED LEVEL OF PRIORITY:	FINAL LEVEL OF PRIORITY:
		3 or more events - batch/model:	Products supplied last 24 months:	Number of potential sensitiv ties:	EXCEPTION TO PRIORITY LEVEL:	
		3 or more events - health distr ct:	Products supplied last 36 months:	Specific sensitiv ties identified:		
		3 or more events - organisat on:	Products supplied Worldw de:	Consultat ons during risk assessment:	Final Risk Assessment:	

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
837	Medtron c Australasia Pty Ltd		837
Attention To:	Address 1:	Address 2:	Town/Suburb:
	PO Box 945		NORTH RYDE BC
State:	Postcode:	Phone:	Fax:
NSW	1670		
Email:			

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Investigat on Information Sect on - Submitted by Sponsor/Manufacturer

Device Analysis Results:

Medtronic conducted an investigat on based upon all received informat on.

The following complaint(s) were investigated:
It was reported that:
The staples d d not deploy from the stapler after the handle was squeezed.
- This complaint was confirmed based on the actual device. The most likely root cause was traced to the user.

A medical assessment was performed. The medical assessment determined that there was a relat on to the complaint.

Product analysis occurred.
The primary analysis finding was:
- The anvil was tilted. Microscopic inspect on of the anvil mylar ring noted that t was crushed.

Further action was not required because the event had foreseen risk and is included in a data monitoring plan.

Should new informat on become available the file will be re-opened and the investigation summary will be amended as appropriate.

Corrective/Preventative Actions:

Further action was not required because the event had foreseen risk and is included in a data mon toring plan.
Should new informat on become available the file will be re-opened and the investigat on summary will be amended as appropriate.

Details of Similar Events:

Australia:
#DIV/0!
0 similar events from 124 units (0%) sold in CY2021;
0 similar events from 257 units (0%) sold in CY2022;
1 similar events from 109 units (0.91743%) sold in CY2023 (Includes this event).
Worldw de:
1 similar events from 81 un ts (1.23457%) sold in CY2020;
2 similar events from 855 units (0.23392%) sold in CY2021;
7 similar events from 1622 un ts (0.43157%) sold in CY2022;
6 similar events from 1271 un ts (0.47207%) sold in CY2023.

Similar inc dent rates were determined using FDD annex A code (MECHANICS ALTERED - A0507) for the platform family type of product reported per subject event.

Add tional Details (use for tables):

CAPA# Reference:

Risk Assessment

Frequency:

Sever ty:

Rating:

Type Cause and Outcome:

Number of Similar Events:

Expected Rate:

Actual Rate:

Countries Similar Events Also Occurred:

Australia, Belgium, Brazil, France, Germany, Italy, Japan, Saudi Arabia, Singapore, Switzerland, Thailand, United States

Completed Actions:

Planned Act ons and Proposed Timelines:

Addit onal Comments:

DIR closed on 05/07/2023.

Reason for Level 1 Investigation

Details of Reasons	
Reason for Level 1 Investigat on	

Focus of Level 2 Investigation

Details of Focus	
Essential Principles	If 'Other' Selected

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Sources of Evidence for Level 2

Details of Source			
Sources of Ev dence	If 'Others' please specify here	Expected Sourcing Date	Date of Ev dence Received

Evidence

Investigat on Quest ons (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis w thin the TGA:

Delays in reporting by other sources (e.g. clin cal registries):

Other Risks (wh ch need to be specified):

Next Steps for Level 1 & Level 2 Investigat ons

Next Steps for Level 1 Investigat on:

Next Steps for Level 2 Investigat on:

Cl ck **[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	Notes	

List of Problem Observed Codes - Cl ck **[N]** to begin entering informat on.

Problem Observed Details				
Problem Observed (Level 1)	Problem Observed (Level 2)	Problem Observed (Level 3)	If 'Other' Selected	
Mechan cal Problem	Firing Problem	Failure to Fire		

Clinical signs symptoms and conditions

Details			
Level 1	Level 2	Level 3	
Procedural Compl cat ons	Appropriate Term / Code Not Available		

Health Impact

Details			
Level 1	Level 2	Level 3	
Surgical Intervention	Prolonged surgery		

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Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigat on Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
Usage Problem Identified			Root cause was likely traced to the user	

Investigation Conclusion

Conclus on Details			
Investigation Conclus on (L1)	Investigation Conclusion (L2)	If Add tional Conclus on Detail Requested	
Cause Traced to User			

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigat on (L2)	If Add tional Conclus on Detail Requested	
Reviewed, for Trending Purposes Only			

Investigation Summary

Latest Investigat on (DII) where this DIR is the Primary DIR:	Latest Investigat on (DII) where this DIR is a Related DIR:	Investigator:	Peer Review:	
			No	

Investigator's Notes:	Summary Findings:	Recall Number:
	No further investigation will occur at this time; however, the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.	

Note: Letter generat on buttons disabled if report not ready for webs te publ cation or risk analysis not completed.

Device Lookup

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

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

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:

Model Number:	Batch #:	Lot #:	Expiry Date:

Related DIR Information - Cl ck **New** to begin entering informat on.

Rec No	
1	

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

Rec No	Details	Sample Details	Add t onal Details

	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Dev ce Descript on:	Brand Name:	Serial Number:
1	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Vers on Number:	
					Who sent the dev ce to the TGA?:			Why does the TGA have the sample?:	

Additional Patients

Cl ck **[N]** to begin entering information.

Patient Details

Sex:	Weight:	Age:	
Patient Focused Corrective Act on Taken:		Patient History:	
Injured - Extent of Injury:	Was dev ce directly linked to death?:	Was device directly linked to permanent disabiltiy?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	Add tional Event Descript on:	Med cal Problem Device Used For:

Additional Device Information

Where did you get this dev ce from?:

How reliant is the affected person on correct/safe operation of this device?:

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

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Dev ce Access - Alternate Dev ce Contact Informat on Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Locat on Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

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Request Details

ID	Type	Locat on	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
383149	DIR-REQ		Closed	s22	OPR Administration User	05/07/2023	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	05/07/2023 16:06:44	
Comment		

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

06/05/2014
SIGNED

DIR : 20 - ID : 275697

Released by s22 on 25/06/2015 15:11:06

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
34124		US201404-0480	Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed	Other	s22	06/05/2014
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
31/03/2015	06/05/2014		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
31/03/2015	Healthcare Professional		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

On day 6 post-operatively, the patient developed peritonitis due to a suspected anastomotic leak after the first attempt at opening their bowels. The surgeon had to re-operate on the patient and noted that on one of the lateral sides of the anastomosis there was a leak (detected only by the air-leak test).

Clinical Event Information:

The surgeon provided feedback regarding two (2) recent colectomies. One case was a laparoscopic anterior resection of rectum with reconstruction via end-to-end anastomosis using a Covidien size 28 stapler. The operation went well and the anastomosis leak tests using dye and air demonstrated no leak. The anastomotic donuts were noted to be complete. As the procedure was done entirely laparoscopically, no reinforcement of the staple line with sutures occurred. On day 6 post-operatively, the patient developed peritonitis due to a suspected anastomotic leak after the first attempt at opening her bowels. The surgeon had to re-operate on the patient and noted that on one of the lateral sides of the anastomosis there was a leak (detected only by the air-leak test). The surgeon noted thatthe bowel was well vascularized and there was no tissue tension. The patient required an ileostomy and prolonged rehabilitation. The surgeon has questioned whether the leak was device-related.

Number of Incidents in Report:	Contact:	Alternative Person Title:	Alternative Person First Name:
1			
Alternative Person Surname:	**Alternative Person Phone:**	**Alternative Person Fax:**	

Patient Information

Sex:	Weight:	Age:

Patient Focused Corrective Action Taken:

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Patient History:

Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22			
Reporter Title:	**First Name:**	**Surname:**	
s22	s22	s22	
Position:		**Company/Institution:**	
s22		Covidien Pty Ltd	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
166 Epping Road	Lane Cove	Sydney	NSW
Country:	**Postcode:**	**Phone:**	**Fax:**
Australia	2066	s22	
Mobile:	**Email:**		**Last External Submission By:**
	australia-regulatory-affairs@covidien.com		

Initial Reporter Section

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
No			Yes
Search Reporter By Surname:	**Initial Reporter #:**		
s22			
Title:	**First Name:**	**Surname:**	
s22	s22	s22	
Position:		**Company/Institution:**	
Consultant		Shepparton Private Hospital	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
20 Fitzgerald St		20 Fitzgerald St	VIC
Postcode:	**Phone:**	**Fax:**	**Mobile:**
3630			

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Email:

Device Information Section

Product Exempt: No	*If No, fill out ARTG No:*	Search Device ARTG: 178517	Device ARTG #: 178517
Therapeutic Licence Type: Medical Device	Product Licence Category: Included	Device Class: Class IIb	GMDN / UMDN Code: 45183
GMDN / UMDN Text: Applier, surgical staple, cutting		Brand Name: DST EEA 28MM Single-Use Stapler	
Initial Device Description: DST EEA 28MM Single-Use Stapler			
Usage of Device: Single Use	Software Version:		
Model #: EEA28	Serial #:	Batch #:	Lot #: unknown
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
Access Contact Phone:	Access Contact Fax:		

Manufacturer Information Section

Manufacturer Name: Covidien llc		Manufacturer Client Id: 54968	Address 1: 15 Hampshire Street
Address 2:	Town/Suburb: Mansfield	State/Province: MA	Country: United States
Postcode: 02048	Phone: s22 [redacted]	Fax:	
Email: australia-regulatory-affairs@covidien.com		Manufacturer Informed: Yes	Date Aware of Adverse Event: 08/04/2014
Contact Title: s22 [redacted]	Contact First Name: s22 [redacted]	Contact Surname: s22 [redacted]	

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Supplier Information Section

Supplier Name:	Address 1:	Address 2:

Town/Suburb:	State:	Postcode:	Phone:

Fax:	Email:	Supplier Informed:

Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:

Contact Phone:	Contact Fax:

Statistics Checklist Section

Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
31/03/2015	s22 [redacted]	Yes	Yes	☑

Sample Received:	Sterile:	Reusable:	Single Use:	Potential Effect:
No	Yes	No	Yes	Serious Injury

Actual Effect:	Injured Party:	Risk Frequency:
Serious Injury	Patient	Unlikely

Risk Severity:	Risk Detectability:	Classification:	Investigated:	Date of DIRE Meeting:
Serious	Unlikely	Not Investigated	No	

DIRE Meeting Notes:

This report has been reassessed due to age of the report, as the final report was not submitted by the sponsor. A search of the IRIS database has not shown an increasing trend in this type of event.

Sponsor Information Section

Search Sponsors:	Name:	Client #:
Covidien	Covidien Pty Ltd	283

Attention To:	Address 1:	Address 2:	Town/Suburb:
s22 [redacted]	Locked Bag 2020		LANE COVE DC

State:	Postcode:	Phone:	Fax:
NSW	2066	s22 [redacted]	s22 [redacted]

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Email:

Australia.Regulatory.Affairs@covidien.com

Investigation Information Section

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Additional Comments:

DIR closed –31/03/2015

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 information manually.

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

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text

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

Incident Details

DIR #	Brand Name	Reporter First Name	Reporter Surname	Company/Institution

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Samples Record - Click **[N]** to begin entering information.

Sample Details						
Sample #	Sample Requested	Sample Received	# Samples from Reporter	# Samples from Sponsor	Outcome of TGA's Testing	

Correspondence Information Section. Note that the Correspondence Recipient will receive a notification if the Date Received is not filled in by the Date Expected.

Correspondence Details							
Correspondence Type	Correspondence recipient (email)	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes	

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

Type Details			
Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected	
Usability	Use of Device Issue		

Investigation Problem Causes

Cause Details			
Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	
Unable to confirm complaint	Device not returned		

Investigation Outcomes

Outcome Details		
Outcome of Investigation	If Additional Outcome Detail Requested	
Reviewed, for Trending Purposes Only		

Recall Number:

Investigation Summary:

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No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.

Flow Details : DIR-REQ - Device Incident Request : 46126

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
46126	DIR-REQ		Closed	s22	OPR Administration User	31/03/2015	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	31/03/2015 15:16:42	
Comment		