

Address 1:

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

Address 2:

19/03/2019 SIGNED

**Document 1** 

DIR: 31 - ID: 420887 Released by 5222 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 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 If 'Other' Source Selected: Type of In tial Action: Source of Report: Trend data only Sponsor 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 laparoscopic high anterior resection, an infection from anastomotic leak was noted. It is unknown if the leak is related to the stapler. The clinical anastomotic 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: Unknown Patient Focused Corrective Act on Taken: Patient History: Hosp talisation was extended by one week due to the leak. Crohn's disease and fistula between colon and bladder. Patient Outcome/Consequences: Additional Event Descript on: Alive - with injury, requiring extended hospitalisat 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: Submitting Reporter Section Preferred Contact Method: Search Reporter By Surname: Reporter #: Reporter Title: First Name: Surname: Position: Company/Inst tution: Post Market Vigilance Specialist Medtron c Australasia Pty Ltd.

Town/Suburb:

State:

|   |   |   | Decument 4                                |
|---|---|---|---|
| 2 Alma Road   | 2 Alma Road   | Macquarie Park  | NSW Document 1                            |
| Country:  | Postcode:   | Phone:  | Fax:                                      |
| Australia   | 2113  | s22   |   |
| Mobile:   | Email:  | Are you happy for the device<br>company to contact you about the incident?: | Last External Submission By:              |
|   | @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  | II NO, IIII OUL the following:  |   | Yes                                       |
| Search Reporter By Surname:   | In tial Reporter #:   |   | Preferred Contact Method:                 |
| 522   |   |   |   |
| Title:  | First Name:   | Surname:  |   |
|   | s22   | s22   |   |
| Position:   |   | Company/Inst tution:  |   |
|   |   | PRINCESS ALEXANDRA HOSPITAL   |   |
| Address 1:  | Address 2:  | Town/Suburb:  | State:                                    |
|   | Addicas 2.  |   |   |
| Ipswich Road  | Country   | Brisbane Phone:   | QLD<br>Fave                               |
| Postcode:   | Country:  | Phone:  | Fax:                                      |
| 4102  |   | Allow the dev ce company  |   |
| Mobile:   | Email:  | 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:                          |
| Disco of Implantation   | Reserved Devices Legations  | Access Contact Title:   | Access Contact First Name:                |
| Place of Implantation:  | Reported Device Location:   | Access Contact Title:   | ACCESS CONLACT FIRST NAME:                |
| Access Contact Commence   | Discarded   | Access Graduat Servi  | Access Contact Smalls                     |
| 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 IIc  |   | 54968   | 15 Hampshire Street                       |
| Address 2:  | Town/Suburb:  | State/Province:   | Country:                                  |
|   | Mansfield   | MA  | United States                             |
| Postcode:   | Phone:  | Fax:  | Fmail:                                    |

18/09/2023, 11:41 Form Details **Document 1** 02048 Date Aware of Adverse Event: Manufacturer Informed: Contact T tle: Contact First Name: 15/03/2019 Yes Contact Surname: Supplier Informat on Section Address 1: Address 2: Supplier Name: 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: Date of Initial TGA Action: Report Status: 19/03/2019 13/09/2017 Closed Problems Observed: ; ; ; Mechan cal Problem; Leak / Splash; Report Status For website publ cat on: Ready for Publ cation: Investigated: Investigation Reason: Team Assignment: Yes No Yes Device not returned 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: Assessor: L cence Status: Status Reason: Status Effective Date: 20/03/2019 Active 13/09/2017 Injured Party: Potential Effect: Actual Effect: Found Prior To Use: Sample Received: Patient Ser ous Injury Temporary Injury Sterile: Invasive Device: Single Use: Human Origin: Genetically Modified: Yes Yes Yes No

Risk Severity:

Reusable:

Risk Frequency:

Risk Rating:

Further Review Needed:

| No                     | Serious |                |                      |               |                             | Team Re                     | <sub>view</sub> Docu        |
|------------------------|---------|----------------|----------------------|---------------|-----------------------------|-----------------------------|-----------------------------|
| Risk Assessment Notes: |         |                |                      |               |                             |                             |                             |
|                        |         | RISK<br>RATING | Severity             |               |                             |                             |                             |
|                        |         | Frequency      | Life-<br>threatening | Serious       | Minor                       | Nil                         | Unknown                     |
|                        |         | Frequently     | Critical Risk        | Critical Risk | Major Risk                  | Minor Risk                  | Major Risk                  |
| Final Risk Assessment: |         | Sometimes      | Critical Risk        | Major Risk    | Minor Risk                  | Minor Risk                  | Minor Risk                  |
|                        |         | Rarely         | Major Hisk           | Minor Risk    | Minor Risk                  | Non-<br>significant<br>Risk | Minor Risk                  |
|                        |         | Unlikely       | Minor Risk           | Minor Risk    | Non-<br>significant<br>Risk | Non-<br>significant<br>Risk | Non-<br>significant<br>Risk |
| No                     |         | Unknown        | Major Hisk           | Minor Risk    | Minor Risk                  | Non-<br>significant<br>Risk | No risk<br>assessment       |

#### Additional Risk Analysis

| Cl ck 'N' to start a new n | isk analysis         |                              |                  |                     |                        |  |  |  |  |
|----------------------------|----------------------|------------------------------|------------------|---------------------|------------------------|--|--|--|--|
| Analysis Details           | Statist cs Checklist | 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 P                  | 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 No   | otes:                        |                  |                     |                        |  |  |  |  |

| Sponsor/Manufacturer Information Section  | π  |   |               |  |
|---|--|---|---------------|--|
| 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:  |  |   |               |  |
| @medtron c.com  |  |   |               |  |
| Investigat on Information Sect on - Submi   | itted by Sponsor/Manufacturer  |   |               |  |
| Device Analysis Results:  |  | Corrective/Preventative Actions:        |               |  |
| from the account was not available for the<br>reported condition. Records from each m | Tri-Staple* Technology 28mm Medium/Thick sample or additional supporting materials<br>his incident. Therefore, a defin tive root cause could not be determined w th regard to the<br>nanufacturing lot are thoroughly reviewed to ensure that products are released meeting all<br>at the time of manufacture. Should new informat on become available, the file will be re- | There are no actions deemed necessary a | t this time.  |  |
| Details of Similar Events:  |  | Add tional Details (use for tables):    |               |  |

| 3/09/2023, 1     | 09/2023, 11:41   |                               |   |              |                         |                       | n Details         |            |          |                  |            |   |
|------------------|--|-------------------------------|---|--------------|-------------------------|-----------------------|-------------------|------------|----------|------------------|------------|---|
| Nil other sim    | nilar incidents in Australia.<br>Ients worldw de: 2/1,325. Aus | stria 1. Germany 1            |   |              |                         |                       |                   |            |          |                  | Document   | 1 |
| CAPA# Refer      |  | stria 1, Germany 1            |   |              |                         |                       |                   |            |          |                  |            |   |
|                  |  |                               |   |              |                         |                       |                   |            |          |                  |            |   |
| Risk Assessme    | ent  |                               |   |              |                         |                       |                   |            | I        | 7                |            |   |
| Frequency:       |  | Se                            | ever ty:                                  |              |                         |                       |                   |            |          |                  |            |   |
|                  |  |                               |   |              |                         |                       |                   |            |          |                  |            |   |
| Rating:          |  |                               |   |              |                         | Type Cause a          | nd Outcome:       |            |          | Number of Simila | ar Events: |   |
| Expected Rat     | te:  | Ad                            | tual Rate:                                |              |                         |                       |                   |            |          |                  |            |   |
|                  |  |                               |   |              |                         |                       |                   |            |          |                  |            |   |
|                  | milar Events Also Occurred:                                    |                               |   |              |                         |                       |                   |            |          |                  |            |   |
| Austria 1, G     |  |                               |   |              |                         | Planned Act           | ons and Proposed  | Timelines: |          |                  |            |   |
| Completed A      | ctions.  |                               |   |              |                         | Tidillied Act         | nis ana i roposea | Timelines. |          |                  |            |   |
| Addit onal Co    | omments:   |                               |   |              |                         |                       |                   |            |          |                  |            |   |
|                  |  |                               |   |              |                         |                       |                   |            |          |                  |            |   |
|                  |  |                               |   |              |                         |                       |                   |            |          |                  |            |   |
|                  | egin a new Correspondence e                                    | entry. Note that the Email ad | dress specified here will rece            | ive a notifi | cation if the Date Rece | eived is not filled i | n by the Date Exp | pected.    |          |                  |            |   |
|                  | ce and Chronology Details                                      |                               |   |              |                         |                       |                   |            |          |                  |            |   |
| Include?         | Heading  | Type L1                       | Type L2                                   |              | nail                    | Sent                  | Expected          | Received   | Response |                  | Notes      |   |
|                  | Final Report Due   | TGA Regulatory Actio          | n Regulatory Information<br>Request (s41) | n            |                         | 19/03/2019            | 27/06/2019        |            |          |                  |            |   |
| List of Dustalan | Observed Codes Chale PRIS                                      | the best contented to former. |   |              |                         |                       |                   |            |          |                  |            |   |
|                  | m Observed Codes - Cl ck [N]                                   | to begin entering information | 011.                                      |              |                         |                       |                   |            |          |                  |            |   |
| Problem Obse     | rved (Level 1)   | Problem Observed (            | Level 2)                                  | Problem      | n Observed (Level 3)    | If 'Other' Selec      | ted               |            |          |                  |            |   |
| Troblem obse     | ived (Level 1)   | Troblem observed (            | Level 2)                                  | TTODIE       | ii Observed (Lever 5)   | Infect on             | teu               |            |          |                  |            |   |
| Mechan cal Pro   | ohlem  | Leak / Splash                 |   |              |                         |                       |                   |            |          |                  |            |   |
| Treeman car i i  | 00.0   | zeak / opiasii                |   |              |                         |                       |                   |            |          |                  |            |   |
| Investigation    | Findings   |                               |   |              |                         |                       |                   |            |          |                  |            |   |
|                  |  |                               |   |              |                         |                       |                   |            |          |                  |            |   |
| Finding Details  | s<br>Findings (Level 1)  | Investigat on Findin          | os (Level 2)                              | Invecti      | gation Findings (Level  | If 'Other' Selec      | ted               |            |          |                  |            |   |
|                  |  | investigat on i main          | gs (Level 2)                              | 3)           | gation i manigs (Lever  | n other select        | teu               |            |          |                  |            |   |
| No Findings A    | vailable   |                               |   |              |                         |                       |                   |            |          |                  |            |   |
|                  |  |                               |   |              |                         |                       |                   |            |          |                  |            |   |
| Investigation    | Conclusion   |                               |   |              |                         |                       |                   |            |          |                  |            |   |
| Conclus on De    | etails   |                               |   |              |                         |                       |                   |            |          |                  |            |   |
| Investigation    | Conclus on (L1)  | Investigation                 | Conclusion (L2)                           |              | If Add tional Conc      | lus on Detail Requ    | ested             |            |          |                  |            |   |
| Cause Not Est    | ablished   |                               |   |              |                         |                       |                   |            |          |                  |            |   |
|                  |  |                               |   |              |                         |                       |                   |            |          |                  |            |   |
| Investigation    | Outcomes   |                               |   |              |                         |                       |                   |            |          |                  |            |   |
| Outcome Deta     | ails   |                               |   |              |                         |                       |                   |            |          |                  |            |   |
| Outcome of In    | nvestigation (L1)  | Outcome of Ir                 | vestigat on (L2)                          |              | If Add tional Conc      | lus on Detail Requ    | ested             |            |          |                  |            |   |
| 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 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 Samples Record - Click [N] to begin entering information. Note: Sample # Generated on Save. Details Sample Details Add t onal Details Rec No Date Entered: LIMS #: Sample Requested: Sample Received: Manufacturer: GMDN: Dev ce Descript on: Brand Name: Serial Number: Reason for Testing: # Samples from # Samples from Outcome of TGA's Testing: Lot Number: Batch Number: Model Number: Vers on Number: Reporter: Sponsor: Why does the TGA have the sample?: Who sent the dev ce to the TGA?: **Additional Patients** Cl ck [N] to begin entering information. Patient Details Sex: Weight: Age: Patient Focused Corrective Act on Taken: Patient History:

| Injured - Extent o  | of Injury:                  |                          | Was dev ce dire        | ectly linked to death?:       | Was devi                | ce directly linked to permanent disabiltiy?: | Consequence:        | Doc           | ument 1 |
|---------------------|-----------------------------|--------------------------|------------------------|-------------------------------|-------------------------|--|---------------------|---------------|---------|
|                     |                             |                          |                        |                               |                         |  |                     |               |         |
| Other Consequence   | ce:                         |                          | Describe any to        | est (Lab, xray, etc.):        | Add tiona               | I Event Descript on:                         | Med cal Problem Dev | ice Used For: |         |
|                     |                             |                          |                        |                               |                         |  |                     |               |         |
|                     |                             |                          |                        |                               |                         |  |                     |               |         |
| Additional Devic    | e Information               |                          |                        |                               |                         |  |                     |               |         |
|                     | get this dev ce from?:      | How                      | reliant is the affects | ed person on correct/safe ope | eration of this device? |  |                     |               |         |
| Timere dia you g    | ,                           |                          | chancis and another    | eu person en correcçõare ope  | and device.             |  |                     |               |         |
| Any other releva    | ant information to aid asse | essing/investigating the | incident?:             |                               |                         |  |                     |               |         |
|                     |                             |                          |                        |                               |                         |  |                     |               |         |
| Similar Events      |                             |                          |                        |                               |                         |  |                     |               |         |
| Similar events -    | how many times?:            | Date                     | of Recent Report:      |                               |                         | Event Reported To:                           | Reporter Reference  | ce Number:    |         |
|                     |                             |                          |                        |                               |                         |  |                     |               |         |
| Dev ce Access - A   | Alternate Dev ce Contact I  | informat on Provided     |                        |                               |                         |  |                     |               |         |
| Title:              |                             | First                    | Name:                  |                               |                         | Last Name:                                   | Phone:              |               |         |
| Fave                |                             | Email                    |                        |                               |                         |  |                     |               |         |
| Fax:                |                             | Email                    | •                      |                               |                         |  |                     |               |         |
| Incident Locat on   | Dotails                     |                          |                        |                               |                         |  |                     |               |         |
| Occurred in Aust    |                             | Organ                    | nisation:              |                               |                         | Address Line 1:                              | Address Line 2:     |               |         |
| Yes                 |                             | o.ga.                    | nodelom.               |                               |                         | Address Line 11                              | , daress Eme Er     |               |         |
| Town/Suburb:        |                             | State                    | :                      |                               |                         | Postcode:                                    |                     |               |         |
|                     |                             |                          |                        |                               |                         |  |                     |               |         |
|                     |                             |                          |                        |                               |                         |  |                     |               |         |
| Flow Details DI     | R-REQ - Device Incident     | Request 165127           |                        |                               |                         |  |                     |               |         |
|                     |                             |                          |                        |                               |                         |  |                     |               |         |
| Request Details     |                             |                          |                        |                               |                         |  |                     |               |         |
| ID                  | Туре                        | Locat on                 | Status                 | Assigned By                   | Assigned To             | A  | Assigned On /       | Priority      | Attach  |
| 165127              | DIR-REQ                     |                          | Closed                 | s22                           | OPR Administration      | u User 0                                     | 08/04/2019          | Normal        | 0       |
|                     |                             |                          |                        | , <del></del>                 |                         |  |                     |               |         |
|                     |                             |                          |                        |                               |                         |  |                     |               |         |
| Signature Details   | s                           |                          |                        |                               |                         |  |                     |               |         |
|                     | IRIS Investigat             | or                       |                        |                               |                         |  |                     |               |         |
| Role                | IKIS IIIVestigat            |                          |                        |                               |                         |  |                     |               |         |
|                     | s22                         |                          |                        |                               |                         |  |                     |               |         |
| Role User Signed At | 922<br>08/04/2019 08        | 3:44:22                  |                        |                               |                         |  |                     |               |         |



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

26/11/2019 SIGNED

DIR: 36 - ID: 459466

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 extended for more than 30 minutes. It was reported that there were procedure to create diverting ileostomy and another to repair a pelvi | no air leaked and the donuts looked good. 4 days after the surg | was fired and air leak test was performed and the donuts were inspery the anastomosis dehiscence. There was a tissue loss and tissue of | cted. it was also reported that the surgical procedure was<br>lamaged due to the reported event. Patient has undergone a |
| 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 -> ;<br>Procedural Complications -> Wound Dehiscence ->  |   |   |  |
| Health Impact  |   |   |  |
| Recorded Health Impacts:   |   |   |  |
| Surgical Intervention -> Additional Surgery ->   |   |   |  |
| Patient Information  |   |   |  |
| Sex:   | Weight:   | Age:  |  |
| s22  |   | SV  |  |
| Patient Focused Corrective Action Taken:   |   | Patient History:  |  |
| The patient spent 25 days in the hospital before being released. The   | patient underwent a Hartmann's reversal procedure.              | Non-Smoker.   |  |
| Patient Outcome/Consequences:  |   | Additional Event Description:   |  |
| Alive.   |   |   |  |
| Describe any test (Lab, xray, etc.):   | Injured - Extent of Injury:                                     | Consequence:  | Other medical devices currently using/implanted:   |

| 8/09/2023, 11:56                                     |   | Form Details                       | Document 2                                |
|--|---|------------------------------------|---|
|  | 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:                 |
|  |   |                                    |   |
| Reporter Title:                                      | First Name:                                     | Surname:                           |   |
|  | e22   |                                    |   |
| Position:  | SEE   | Company/Institution:               |   |
| -727   |   | Medtronic Australasia              |   |
| Address 1:   | Address 2:                                      | Town/Suburb:                       | State:                                    |
| 2 Alma Road  | Tidd 655 E1                                     | Macquarie Park                     | NSW                                       |
| Country:   | Postcode:                                       | Phone:                             | Fax:                                      |
|  |   |                                    | TUX                                       |
| Australia Mobile:                                    | 2113<br>Email:                                  | Last External Submission By:       |   |
| Pioblie.   |   |                                    |   |
|  | @medtronic.com                                  | - 24/02/2020 12:54                 |   |
| Initial Reporter Section                             |   |                                    |   |
| As Above?:   | If No, fill out the following:                  |                                    | Initial Reporter Confidential:            |
| No   | a vie, im out the teneving.                     |                                    | Yes                                       |
| Search Reporter By Surname:                          | Initial Reporter #:                             |                                    | Preferred Contact Method:                 |
| s22  |   |                                    |   |
| Title:   | First Name:                                     | Surname:                           |   |
|  | s22   | 522                                |   |
| Position:  | <del>_</del>                                    | 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 Phone:

Access Contact Fax:

Access Contact First Name:

Access Contact Surname:

| 8/09/2023, 11:56                        |                                 |                               |                            | Form Details            |                 | Document 2            |                  |  |
|---|---------------------------------|-------------------------------|----------------------------|-------------------------|-----------------|-----------------------|------------------|--|
| Access Contact Email:                   |                                 | Licence Status:               |                            | Status Effective Date:  |                 | Additional Devices Ad | lded:            |  |
|   |                                 | Α                             |                            | 13/09/2017              |                 | 0                     |                  |  |
| Manufacturer Information Section        |                                 |                               |                            |                         |                 |                       |                  |  |
| Manufacturer Name:                      |                                 |                               |                            | Manufacturer Client Id: |                 | Address 1:            |                  |  |
| Covidien IIc                            |                                 |                               |                            | 54968                   |                 |                       |                  |  |
| Address 2:                              |                                 | Town/Suburb:                  |                            | State/Province:         |                 | Country:              |                  |  |
|   |                                 |                               |                            |                         |                 |                       |                  |  |
| Postcode:                               |                                 | Phone:                        |                            | Fax:                    |                 | Email:                |                  |  |
| Manufachusus Tafassa da                 |                                 | Data Assault of A             | Marine Frank               | Courte et Title         |                 | Contact Flort Name    |                  |  |
| Manufacturer Informed:                  |                                 | Date Aware of A<br>19/11/2019 | Adverse Event:             | Contact Title:          |                 | Contact First Name:   |                  |  |
| Yes Contact Surname:                    |                                 | 19/11/2019                    |                            |                         |                 |                       |                  |  |
|   |                                 |                               |                            |                         |                 |                       |                  |  |
| Supplier Information Section            |                                 |                               |                            |                         |                 |                       |                  |  |
|   |                                 |                               |                            | Address 1.              |                 | Address 2.            |                  |  |
| Supplier Name:                          |                                 |                               |                            | Address 1:              |                 | Address 2:            |                  |  |
| Town/Suburb:                            |                                 | State:                        |                            | Country:                | Country:        |                       |                  |  |
| , , , , , , ,                           |                                 |                               |                            |                         |                 |                       |                  |  |
| Phone:                                  |                                 | Fax:                          |                            | Email:                  |                 | Website:              |                  |  |
|   |                                 |                               |                            |                         |                 |                       |                  |  |
| Supplier Informed:                      |                                 | Date of Supplier Contact:     |                            | Contact Title:          | Contact Title:  |                       |                  |  |
|   |                                 |                               |                            |                         |                 |                       |                  |  |
| Contact Surname:                        |                                 | Contact Phone:                |                            | Contact Fax:            |                 | Contact Email:        |                  |  |
|   |                                 |                               |                            |                         |                 |                       |                  |  |
| Report Status                           |                                 |                               |                            |                         |                 |                       |                  |  |
| For website publication:                | Ready for Publication:          |                               | Investigated:              | Investigation Reason:   | Team Assignmen  | t:                    | Team Priority:   |  |
| Yes                                     | Yes                             |                               | No                         | Device not returned     | Team B (IIb, Is | & Im)                 | Not Investigated |  |
| Team Review                             |                                 |                               |                            |                         |                 |                       |                  |  |
| Reviewed by Team:                       | Reason Sent To Meetin           | g:                            | Outcome from team meeting: |                         |                 |                       |                  |  |
| 03/03/2020                              | Not enough information          | on has been                   | No further action          |                         |                 |                       |                  |  |
| Notes for Team meeting:                 | provided                        |                               |                            |                         |                 |                       |                  |  |
| send to meeting due to level 1 investig | jation - device not returned. n | o similar DIR in 6            | month. no recall/pmr       |                         |                 |                       |                  |  |
| Outcomes from Team Meeting:             |                                 |                               | · ·                        |                         |                 |                       |                  |  |
| NFA - Device not returned. No similar D | DIRs.                           |                               |                            |                         |                 |                       |                  |  |
| DPRC Review                             |                                 |                               |                            |                         |                 |                       |                  |  |
| Reviewed by DPRC:                       | DPRC Reason Sent To I           | Meeting:                      | Outcome from DPRC Meeting: |                         |                 |                       |                  |  |
| Meeting Notes:                          |                                 |                               |                            |                         |                 |                       |                  |  |
|   |                                 |                               |                            |                         |                 |                       |                  |  |
| Initial Risk Analysis                   |                                 |                               |                            |                         |                 |                       |                  |  |

Risk Assessment - Section C

Risk Assessment - Section D

Risk Assessment - Section B

**Background Information** 

Risk Assessment - Section A

## 18/09/2023, 11:56 Form Details Document 2

| Date:                                 | Severity:   | Incidents in the last 12 months:              | Manufacturer analysis:        | Assessor:           | Manufacturer documentation:                                     |
|---------------------------------------|---|---|-------------------------------|---------------------|---|
| 27/11/2019                            | <ul> <li>5 - An illness/injury was resolved or<br/>prevented with treatment by a health<br/>professional</li> </ul> |   |                               | s22                 | 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             | No recalls for similar incidents in<br>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.,<br>Google)  | No  |                               |                     |   |

#### Additional Risk Analysis

| Click 'N' to start a new ris | sk analysis                  |   |                                       |  |   |                               |  |
|------------------------------|------------------------------|---|---------------------------------------|--|---|-------------------------------|--|
| Analysis Details             | Statistics Checklist Section |   |                                       |  |   |                               |  |
| Jpdate 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 |                                       | Yes  |   |                               |  |
| nitial                       |                              | health professional   |                                       |  |   |                               |  |
|                              | Assessor:                    | Manufacturer documentation:   | Incidents in last 24 months:          | Manufacturer action:   | ESTIMATED LEVEL OF INVESTIGATION:             | FINAL LEVEL OF INVESTIGATION: |  |
|                              | s22                          | 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   |                               |  |

| Search Spons         | sors:                      | Name   | :                            |                                   |                   |                         |               |          | Client #:                 |            |  |
|----------------------|----------------------------|--|------------------------------|-----------------------------------|-------------------|-------------------------|---------------|----------|---------------------------|------------|--|
| -                    | 3013.                      |  |                              |                                   |                   |                         |               |          |                           |            |  |
| 837<br>Attention To: |                            | Addre  | ronic Australasia Pty Ltd    |                                   | Address 2         |                         |               |          | 837<br>Town/Suburb:       |            |  |
| Attention to:        |                            |  |                              |                                   | Address 2         | •                       |               |          |                           | _          |  |
| <b>SZZ</b>           |                            |  | ox 945                       |                                   | Dh                |                         |               |          | NORTH RYDE B              | С          |  |
| State:               |                            | Postco   |                              |                                   | Phone:            |                         |               |          | Fax:                      |            |  |
| NSW                  |                            | 1670   |                              |                                   | S22               |                         |               |          |                           |            |  |
| Email:               |                            |  |                              |                                   |                   |                         |               |          |                           |            |  |
| 522 @                | medtronic.com              |  |                              |                                   |                   |                         |               |          |                           |            |  |
| Investigation        | Information Section - Sub  | mitted by Sponsor/Manufacturer   |                              |                                   |                   |                         |               |          |                           |            |  |
| Device Analy         | sis Results:               |  |                              |                                   | Corrective        | e/Preventative Acti     | ons:          |          |                           |            |  |
|                      |                            | orting materials from the account w  |                              |                                   | None at           | this time               |               |          |                           |            |  |
|                      |                            | wed to ensure that products are re-<br>ure. There were no assembly or cor  |                              |                                   |                   |                         |               |          |                           |            |  |
| Record revie         | w will not be performed.   | -  |                              |                                   |                   |                         |               |          |                           |            |  |
|                      |                            | ive root cause could not be identifie<br>hould new information become avai |                              |                                   | ı                 |                         |               |          |                           |            |  |
|                      | as appropriate.            |  |                              |                                   |                   |                         |               |          |                           |            |  |
| Details of Sin       | nilar Events:              |  |                              |                                   | Additiona         | l Details (use for ta   | ibles):       |          |                           |            |  |
| 0 Similar ev         | ents (0%) from 2617 sale   | s in Australia (past 3 years) .  |                              |                                   |                   |                         |               |          |                           |            |  |
| 12 Similar e         | vents (0.037%) from 322    | 18 sales worldwide (past 3 years).   |                              |                                   |                   |                         |               |          |                           |            |  |
| CAPA# Refer          | ence:                      |  |                              |                                   |                   |                         |               |          |                           |            |  |
|                      |                            |  |                              |                                   |                   |                         |               | 1        |                           |            |  |
| Risk Assessme        | ent                        |  |                              |                                   |                   |                         |               | 4        | _                         |            |  |
| Frequency:           |                            | Severi   | itur                         |                                   |                   |                         |               |          |                           |            |  |
| requency.            |                            | Seven  | icy.                         |                                   |                   |                         |               |          |                           |            |  |
| Rating:              |                            |  |                              |                                   | Type Caus         | se and Outcome:         |               |          | Number of Simil           | ar Events: |  |
| racing.              |                            |  |                              |                                   | Type cau          | Type Cause and Outcome: |               |          | Number of Similar Events. |            |  |
| Expected Rat         | ·e:                        | Actual   | Rate:                        |                                   |                   |                         |               |          |                           |            |  |
| Expediced Nat        |                            | , tutuu  | Tital Co.                    |                                   |                   |                         |               |          |                           |            |  |
| Countries Sin        | nilar Events Also Occurred |  |                              |                                   |                   |                         |               |          |                           |            |  |
|                      |                            | rlands, France, Australia, Sweden.   |                              |                                   |                   |                         |               |          |                           |            |  |
| Completed A          |                            | rance, Australia, Stream   |                              |                                   | Planned A         | Actions and Propose     | ed Timelines: |          |                           |            |  |
| Completed A          |                            |  |                              |                                   | T idillied 7      | adding and Propose      | a rimeimes.   |          |                           |            |  |
| Additional Co        | mments:                    |  |                              |                                   |                   |                         |               |          |                           |            |  |
| DIR closed 4         |                            |  |                              |                                   |                   |                         |               |          |                           |            |  |
| DIT GIODGG           | ,, 0, 20                   |  |                              |                                   |                   |                         |               |          |                           |            |  |
| Click [M] to b       | ogin a now Correspondent   | e entry. Note that the Email addres  | a appointed hora will recei  | vo a notification if the Date Rec | nivad is not fill | ad in by the Date E     | vnostad       |          |                           |            |  |
|                      |                            |  | s specified fiere will recei | ve a notification if the Date Ret | cived is not nin  | ed iii by the bate t    | xpected.      |          |                           |            |  |
| -                    | ce 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 |  |  |  |  |

| 8/09/2023, 11:56  |   |                   |                  | Form Details                             |  | Document 2        |
|---|---|-------------------|------------------|--|--|-------------------|
| Appropriate Term/Code Not Available   |   |                   |                  | anastomosis dehiscence                   |  |                   |
| Appropriate Term/Code Not Available   | ropriate Term/Code Not Available pelvic absce           |                   |                  | 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)                        | nvestigation Find | dings (Level     | If 'Other' Selected                      |  |                   |
| No Findings Available   |   | ,                 |                  |  |  |                   |
| Investigation Conclusion Conclusion Details Investigation Conclusion (L1) Cause Not Established | Investigation Conclusion (L2)                           | If Add            | ditional Conclu  | sion Detail Requested                    |  |                   |
| Investigation Outcomes Outcome Details  |   |                   |                  |  |  |                   |
| Outcome of Investigation (L1)   | Outcome of Investigation (L2)                           | If Add            | ditional Conclu  | sion Detail Requested                    |  |                   |
| Reviewed, for Trending Purposes Only  |   |                   |                  |  |  |                   |
| Investigation Summary Investigation Type:   | Latest Investigation (DII) where this DIR is the Primar | ry DIR: Lates     | st Investigatior | n (DII) where this DIR is a Related DIR: | Investigator:                                    | Extension Number: |
| Investigator's Notes:   |   | Cume              | mary Findings:   |  |  | Recall Number:    |
| Investigator's Notes:   |   |                   |                  |  | e TGA will continue to monitor the rate and ate. | recall Number:    |

Device Lookup

| 18/09/2023, 11:56 | Form Details | Document 2 |
|-------------------|--------------|------------|
|-------------------|--------------|------------|

| This sect   | ion is used to match in | formation provided                             | d via UDIR forms to AR   | RTG information.   | You can select a Branc | d/Name from informa              | tion provided in the                                 | Other Devices Involved'    | table below or enter inform | nation manually.    |                 |  |  |
|---|-------------------------|--|--------------------------|--------------------|------------------------|----------------------------------|--|----------------------------|-----------------------------|---------------------|-----------------|--|--|
| Other D   | evice (Entered):        | Brar   | nd Name:                 |                    | Manufacturer Name:     |                                  | Device ARTG #:                                       |                            |                             |                     |                 |  |  |
|   |                         |  |                          |                    |                        |                                  |  |                            |                             |                     |                 |  |  |
| Other De  | evices                  |  |                          |                    |                        |                                  |  |                            |                             |                     |                 |  |  |
| Device A  |                         | Manufa   | acturer Name:            |                    | Sponsor/Supplier:      |                                  | GMD  | N / UMDN Text:             | Trade/Brand Nar             | ne:                 | Serial #:       |  |  |
|   |                         |  |                          |                    |                        |                                  |  |                            |                             |                     |                 |  |  |
| Model Nu  | ımber:                  | Batch #  | #:                       |                    | Lot #:                 |                                  | Expir  | y Date:                    |                             |                     |                 |  |  |
|   |                         |  |                          |                    |                        |                                  |  | ,                          |                             |                     |                 |  |  |
|   |                         |  |                          |                    |                        |                                  |  |                            |                             |                     |                 |  |  |
| Related I   | OIR Information - Click | New to begin ent                               | ering information.       |                    |                        |                                  |  |                            |                             |                     |                 |  |  |
| Rec No  |                         |  |                          |                    |                        |                                  |  |                            |                             |                     |                 |  |  |
| 1   |                         |  |                          |                    |                        |                                  |  |                            |                             |                     |                 |  |  |
|   |                         |  |                          |                    |                        |                                  |  |                            |                             |                     |                 |  |  |
| Samples   | Record - Click [N] to b |  |                          | e # Generated on   | Save.                  |                                  |  |                            |                             |                     |                 |  |  |
| Rec No  | Details                 | Sample Details                                 |                          |                    |                        | Additional Details               |  |                            |                             |                     |                 |  |  |
|   | Date Entered:           | LIMS #:  | Sample Requested         | 1: Sample Receiv   | ed:                    | Manufacturer:                    | GMDN:  |                            | Device Description:         | Brand Name:         | Serial Number:  |  |  |
|   |                         |  |                          |                    |                        |                                  |  |                            |                             |                     |                 |  |  |
| 1 R   | Reason for Testing:     | sting: # Samples from # Sam<br>Reporter: Spons |                          | Outcome of TG      | GA's Testing:          | Lot Number:                      | Batch Number:  | lumber:                    | Model Number:               | Version Number:     |                 |  |  |
|   |                         | ricporter:                                     | Spensor i                |                    |                        |                                  |  |                            |                             |                     |                 |  |  |
|   |                         |  |                          |                    |                        | Who sent the device to the TGA?: |  |                            |                             | Why does the TGA ha | ve the sample?: |  |  |
|   |                         |  |                          |                    |                        |                                  |  |                            |                             |                     |                 |  |  |
|   |                         |  |                          |                    |                        |                                  |  |                            |                             |                     |                 |  |  |
| Addition  | nal Patients            |  |                          |                    |                        |                                  |  |                            |                             |                     |                 |  |  |
| Click [N  | to begin entering info  | rmation.                                       |                          |                    |                        |                                  |  |                            |                             |                     |                 |  |  |
| Patient D   | etails                  |  |                          |                    |                        |                                  |  |                            |                             |                     |                 |  |  |
| Sex:  |                         |  | We                       | eight:             |                        |                                  | Age:   |                            |                             |                     |                 |  |  |
|   |                         |  |                          |                    |                        |                                  |  |                            |                             |                     |                 |  |  |
| Patient F   | ocused Corrective Actio | on Taken:                                      |                          |                    |                        |                                  | Patient History:                                     |                            |                             |                     |                 |  |  |
|   |                         |  |                          |                    |                        |                                  |  |                            |                             |                     |                 |  |  |
| Injured -   | Extent of Injury:       |  | Wa                       | as device directly | linked to death?:      |                                  | Was device directly linked to permanent disability?: |                            |                             | Consequence:        |                 |  |  |
|   |                         |  |                          |                    |                        |                                  |  |                            |                             |                     |                 |  |  |
| Other Consequence: Describe any test (Lab, xray, etc.): |                         |  |                          |                    | Additional Event       | Description:                     |  | Medical Problem Device Use | ed For:                     |                     |                 |  |  |
|   |                         |  |                          |                    |                        |                                  |  |                            |                             |                     |                 |  |  |
|   |                         |  |                          |                    |                        |                                  |  |                            |                             |                     |                 |  |  |
|   |                         |  |                          |                    |                        |                                  |  |                            |                             |                     |                 |  |  |
| A alalitia  | nal Device Information  |  |                          |                    |                        |                                  |  |                            |                             |                     |                 |  |  |
|   |                         |  |                          |                    |                        |                                  |  |                            |                             |                     |                 |  |  |
| Where   | did you get this device | from?:   | How reliant              | is the affected pe | rson on correct/safe o | operation of this devic          | ce:  |                            |                             |                     |                 |  |  |
| Anv oth   | er relevant information | n to aid assessing/i                           | investigating the incide | ent?:              |                        |                                  |  |                            |                             |                     |                 |  |  |
| , 00  | c.c.a illioimatioi      |  | socigating the include   |                    |                        |                                  |  |                            |                             |                     |                 |  |  |

|  | ument 2 |
|--|---------|
|--|---------|

| Similar Events       |                            |               |            |              |             |                      |                    |             |                         |          |        |
|----------------------|----------------------------|---------------|------------|--------------|-------------|----------------------|--------------------|-------------|-------------------------|----------|--------|
| Similar events - ho  | ow many times?:            |               | Date of Re | cent Report: |             |                      | Event Reported To: |             | Reporter Reference Numl | per:     |        |
|                      |                            |               |            |              |             |                      |                    |             |                         |          |        |
| Device Access - Alte | ernate Device Contact Info | rmation Prov  | ided       |              |             |                      |                    |             |                         |          |        |
| Title:               |                            |               | First Name | <b>:</b> :   |             |                      | Last Name:         |             | Phone:                  |          |        |
| Fax:                 |                            |               | Email:     |              |             |                      |                    |             |                         |          |        |
| Incident Location D  | etails                     |               |            |              |             |                      |                    |             |                         |          |        |
| Occurred in Austra   | alia:                      |               | Organisati | on:          |             |                      | Address Line 1:    |             | Address Line 2:         |          |        |
| Town/Suburb:         |                            |               | State:     |              |             |                      | Postcode:          |             |                         |          |        |
|                      |                            |               |            |              |             |                      |                    |             |                         |          |        |
| Flow Details : DIR-  | REQ - Device Incident Req  | quest : 22034 | 3          |              |             |                      |                    |             |                         |          |        |
| Request Details      |                            |               |            |              |             |                      |                    |             |                         |          |        |
| ID                   | Туре                       | Location      |            | Status       | Assigned By | Assigned To          |                    | Assigned On |                         | Priority | Attach |
| 220343               | DIR-REQ                    |               |            | Closed       | s22         | OPR Administration U | ser                | 04/03/2020  |                         | Normal   | 0      |
|                      |                            |               |            |              |             |                      |                    |             |                         |          |        |
| Signature Details    |                            |               |            |              |             |                      |                    |             |                         |          |        |
| Role                 | IRIS Investigator          |               |            |              |             |                      |                    |             |                         |          |        |

User

Signed At
Comment

13/08/2020 11:13:35

27/03/2020 SIGNED

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

DIR: 38 - ID: 493698

Add tional Dationto Addodu

|   |   | Released I  | 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 o when the device was not fired.      | n converted to low anter or resection, during anastomosis, the surg | geon was having difficulty aligning the two end of the device. The surg | geon noticed after removing the stapler that the anvil tilted even |
| 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 Device Required ->  | >   |   |  |
| Patient Informat on   |   |   |  |
| Sex:  | Weight:   | Age:  |  |
|   |   | 5 <u>2</u>  |  |
| 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:                                   |
|   |   |   |  |

Form Details

Submitting Reporter Section

| Search Reporter By Surname:  | Reporter #:                                     |   | Preferred Contact Method:                 |
|--|---|---|---|
| _  | reporter #.                                     |   | Figure Contact Piction.                   |
| Reporter Title:  | First Name:                                     | Surname:  |   |
| The state of the s | inst wante.                                     | Surfiame.   |   |
| Desition:  | \$22  | Garage Mark history   |   |
| 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:                                |   |
|  | @medtron c.com                                  | - 30/07/2020 13:25  |   |
| In tial Reporter Section   |   |   |   |
| As Above?:   |   |   | In tial Reporter Conf dential:            |
|  | If No, fill out the following:                  |   |   |
| 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:                       |
| Access Contact First Name:   | Access Contact Surname;                         | ACCESS COILECT FIIUIE:                                      | ALLESS CUITALL FAX:                       |
|  |   |   |   |

| Access Contact Email:            |                                      | L cence Status:     |                              | Status Effective Date:                               |                     | Add tional Dev ces Added | Document 3                |
|----------------------------------|--------------------------------------|---------------------|------------------------------|--|---------------------|--------------------------|---------------------------|
|                                  |                                      | Α                   |                              | 13/09/2017   |                     | 0                        |                           |
| Manufacturer Informat on Section |                                      |                     |                              |  |                     |                          |                           |
| Manufacturer Name:               |                                      |                     |                              | Manufacturer Client Id:                              |                     | Address 1:               |                           |
| Covidien IIc                     |                                      |                     |                              | 54968  |                     |                          |                           |
| Address 2:                       |                                      | Town/Suburb:        |                              | State/Province:                                      |                     | Country:                 |                           |
|                                  |                                      |                     |                              |  |                     |                          |                           |
| Postcode:                        |                                      | Phone:              |                              | Fax:   |                     | Email:                   |                           |
| Manufacturer Informed:           |                                      | Date Aware of Adver | rse Event:                   | Contact T tle:                                       |                     | Contact First Name:      |                           |
| Yes                              |                                      | 25/03/2020          |                              |  |                     |                          |                           |
| Contact Surname:                 |                                      |                     |                              |  |                     |                          |                           |
|                                  |                                      |                     |                              |  |                     |                          |                           |
| Supplier Informat on Section     |                                      |                     |                              | Address de   |                     | Address 2                |                           |
| Supplier Name:                   |                                      |                     |                              | Address 1:   |                     | Address 2:               |                           |
| Town/Suburb:                     |                                      | State:              |                              | Country:   |                     | Postcode:                |                           |
| Dhanas                           |                                      | F                   |                              | Family   |                     | Wahata                   |                           |
| Phone:                           |                                      | Fax:                | Email:                       |  | Webs te:            |                          |                           |
| Supplier Informed:               | plier Informed: Date of Supplier Cor |                     |                              | Contact T tle:                                       |                     | Contact First Name:      |                           |
| Contact Surname:                 | Contact Surname: Cont                |                     |                              | Contact Fax:   |                     | Contact Email:           |                           |
|                                  |                                      |                     |                              |  |                     |                          |                           |
| Report Status                    |                                      |                     |                              |  |                     |                          |                           |
| For website publ cat on:         | Ready for Publication:               |                     | Investigated:                | Investigation Reason:                                | Team Assignment:    | Tea                      | am Pr ority:              |
| Yes                              | Yes                                  |                     | No                           | Event determined to be most likely due to user error | Team B (IIb, Is & I | Im) No                   | t Investigated            |
| Team Review                      |                                      |                     |                              | to user error  |                     |                          |                           |
| Reviewed by Team:                | Reason Sent To Meetin                | ng:                 | Outcome from team meeting:   |  |                     |                          |                           |
|                                  |                                      |                     |                              |  |                     |                          |                           |
| Notes for Team meeting:          |                                      |                     |                              |  |                     |                          |                           |
| Outcomes from Team Meeting:      |                                      |                     |                              |  |                     |                          |                           |
| DPRC Review                      |                                      |                     |                              |  |                     |                          |                           |
|                                  | DPRC Reason Sent To                  | Meeting:            | Outcome from DPRC Meeting:   |  |                     |                          |                           |
| newened by Briter                | D. No Neason Selic 10                | . recting.          | outcome from 51 No Freezing. |  |                     |                          |                           |
| Meeting Notes:                   |                                      |                     |                              |  |                     |                          |                           |
|                                  |                                      |                     |                              |  |                     |                          |                           |
| In tial Risk Analysis            | Piolo Access 1 - 5                   |                     | Plate Assessment Co. 11      | Did a comment of the o                               | Plate A service     | Continue D               |                           |
| Background Information  Date:    | Risk Assessment - Se                 | ection A            | Risk Assessment - Section B  | Risk Assessment - Section C  Manufacturer analysis:  | Risk Assessment -   |                          | nufacturer documentat on: |

### 18/09/2023, 12:04 Form Details **Document 3**

| 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 ris | ·                            |   |                                       |  |  |                               |  |
|------------------------------|------------------------------|---|---------------------------------------|--|--|-------------------------------|--|
| Analysis Details             | Statist cs Checklist Sect on |   |                                       |  |  |                               |  |
| pdate 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:   |  |                               |  |
| opy Data From:               | 05/08/2020                   | 5 - An illness/injury was resolved or prevented with treatment by a |                                       | Yes  |  |                               |  |
| n tial                       |                              | health professional   |                                       |  |  |                               |  |
|                              | 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.<br>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.<br>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,<br>Dev ce used in high acu ty clinical<br>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 #: |

| 837  | Medtron c Australasia Pty Ltd   |  | B37 Document 3            |  |  |  |  |
|--|---|--|---------------------------|--|--|--|--|
| Attention To:  | Address 1:  | Address 2:   | Town/Suburb:              |  |  |  |  |
| 522  | PO Box 945  |  | NORTH RYDE BC             |  |  |  |  |
| State:   | Postcode:   | Phone:   | Fax:                      |  |  |  |  |
| NSW  | 1670  | s22  |                           |  |  |  |  |
| Email:   | 2070  |  |                           |  |  |  |  |
| @medtron c.com   |   |  |                           |  |  |  |  |
|  |   |  |                           |  |  |  |  |
| Investigat on Information Sect on - Submitted by Sponsor/Manufac   | tturer  |  |                           |  |  |  |  |
| Device Analysis Results:   |   | Corrective/Preventative Actions:   |                           |  |  |  |  |
| Medtronic conducted an investigat on based upon all received inform the following complaint(s) were investigated: It was reported that: Significant surgical intervent on was required due to the product Significant tissue loss occurred as a result of the product failured. The anvil tilted prematurely / pro ro firing. This complaint was confirmed based on the actual device. The anvil did not easily attach to the stapler This complaint was confirmed based on the actual device. The anvil did not easily attach to the stapler This complaint was confirmed based on the actual device. The medical assessment was performed. The medical assessment review was performed. The risk assessment review was performed. The risk assessment review was performed.            | at failure the most likely root cause was traced to the user. The most likely root cause was traced to the user. The etermined there was no association to the complaint. | 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. |                           |  |  |  |  |
| Product analysis occurred. The primary analysis finding was: - Damage consistent with an obstruction was noted on the kn   | ife blade and/or staple guide.  |  |                           |  |  |  |  |
| Details of Similar Events:   |   | Add tional Details (use for tables):   |                           |  |  |  |  |
| Similar inc dents based off FDA Annex A code A040102 (LOSS OF Similar events in Australia in the past 3 years: 2 Similar events worldw de (Australia excluded) in the past 3 years 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: Similar events in Australia in the past 3 years: 1 Similar events worldw de (Australia excluded) in the past 3 years 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% | : 22  | A  |                           |  |  |  |  |
| CAPA# Reference:   |   |  |                           |  |  |  |  |
|  |   |  |                           |  |  |  |  |
| Risk Assessment  |   |  |                           |  |  |  |  |
| Frequency:   | Severty:  |  |                           |  |  |  |  |
|  |   |  |                           |  |  |  |  |
| Rating:  |   | Type Cause and Outcome:  | Number of Similar Events: |  |  |  |  |
| Expected Rate:   | Actual Rate:  |  |                           |  |  |  |  |
| Expected Rate:   | Actual Rate:  |  |                           |  |  |  |  |
| Countries Similar Events Also Occurred:  |   |  |                           |  |  |  |  |
| AustraliaFranceGermanyHong KongJapanNetherlandsSingaporeSv   | vedenSwitzerlandUnited KingdomUnited States   | [  |                           |  |  |  |  |
| Completed Actions:   |   | Planned Act ons and Proposed Timelines:  |                           |  |  |  |  |
|  |   |  |                           |  |  |  |  |
| Addit onal Comments:   |   |  |                           |  |  |  |  |
| Report Closed 05-08-2020.  |   |  |                           |  |  |  |  |

| Details of Rea  | isons                             |                                |                           |                                   |                    |                    |                        |           | Documen                                       | t 3        |
|---|-----------------------------------|--------------------------------|---------------------------|-----------------------------------|--------------------|--------------------|------------------------|-----------|---|------------|
|   | vel 1 Investigat on               |                                |                           |                                   |                    |                    |                        |           |   |            |
|   |                                   |                                |                           |                                   |                    |                    |                        |           |   |            |
|   |                                   |                                |                           |                                   |                    |                    |                        |           |   |            |
| Focus of Lev  | el 2 Investigation                |                                |                           |                                   |                    |                    |                        |           |   |            |
| Details of Foc  |                                   |                                |                           |                                   |                    |                    |                        |           |   |            |
| Essential Princ   |                                   |                                |                           |                                   | If 'Other'         | Selected           |                        |           |   |            |
|   |                                   |                                |                           |                                   |                    |                    |                        |           |   |            |
|   |                                   |                                |                           |                                   |                    |                    |                        |           |   |            |
| Sources of E  | vidence for Level 2               |                                |                           |                                   |                    |                    |                        |           |   |            |
| Details of Sou  |                                   |                                |                           |                                   |                    |                    |                        |           |   |            |
| Sources of Ev   |                                   |                                |                           | If 'Others' please specify l      | nere               | E                  | Expected Sourcing Date | te        | Date of Ev dence Received                     |            |
|   |                                   |                                |                           | ,                                 |                    |                    | ,                      |           |   |            |
|   |                                   |                                |                           |                                   |                    |                    |                        |           |   |            |
| Evidence  |                                   |                                |                           |                                   |                    |                    |                        |           |   |            |
|   | Overhand (Level 1 and Level 3)    | ۸.                             |                           |                                   |                    |                    |                        |           |   |            |
| Investigat or   | n Quest ons (Level 1 and Level 2) | ):                             |                           |                                   |                    |                    |                        |           |   |            |
|   |                                   |                                |                           |                                   |                    |                    |                        |           |   |            |
| Potential Risk  |                                   |                                |                           |                                   |                    |                    |                        |           |   |            |
| Delays in res   | sponse by product manufacturers   | s: Delays                      | in response by incident   | reporters:                        | Delays in          | analysis w thin    | the TGA:               | Delays in | reporting by other sources (e.g. clin cal reg | gistries): |
| Other Risks   | (wh ch need to be specified):     |                                |                           |                                   |                    |                    |                        |           |   |            |
| Carrer raisits  | (m. a. need to be specimen).      |                                |                           |                                   |                    |                    |                        |           |   |            |
| Novt Stone fo   | r Level 1 & Level 2 Investigat on | c                              |                           |                                   |                    |                    |                        |           |   |            |
|   | or Level 1 Investigation:         | 5                              |                           |                                   | Nevt Ster          | ps for Level 2 In  | vestigat on:           |           |   |            |
| техе эсерэт   | or Level 1 investigation.         |                                |                           |                                   | Next Step          | p5 101 Level 2 111 | vestigue on.           |           |   |            |
|   |                                   |                                |                           |                                   |                    |                    |                        |           |   |            |
| Cl ck [N] to b  | egin a new Correspondence entr    | y. Note that the Email address | specified here will recei | ve a notification if the Date Rec | eived is not fille | ed in by the Date  | e Expected.            |           |   |            |
| Corresponden  | ice 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 Probler   | m Observed Codes - Cl ck [N] to   | begin entering information.    |                           |                                   |                    |                    |                        |           |   |            |
|   |                                   | begin entering information     |                           |                                   |                    |                    |                        |           |   |            |
| Problem Observed Details  Problem Observed (Level 2) Problem Observed (Level 3) |                                   |                                |                           |                                   | If 'Other' Se      | elected            |                        |           |   |            |
| Compatibility   |                                   | Component or Accessory         | •                         |                                   |                    |                    |                        |           |   |            |
| Mechan cal Problem  Mechan cal Jam  |                                   |                                |                           |                                   |                    |                    |                        |           |   |            |
|   |                                   |                                |                           |                                   |                    |                    |                        |           |   |            |
| Clinical aigns  | e eumntome and conditions         |                                |                           |                                   |                    |                    |                        |           |   |            |
| Details   | s symptoms and conditions         |                                |                           |                                   |                    |                    |                        |           |   |            |

| Level 1  |               | Level 2                                  |   | Level 3              |                |   |              |                                   |          | Document 3 |
|--|---------------|--|---|----------------------|----------------|---|--------------|-----------------------------------|----------|------------|
| Others   |               | Appropriate Term / Code Not Availal      | ble                                     |                      |                |   |              |                                   |          |            |
|  |               |  |   |                      |                |   |              |                                   |          |            |
| Health Impact  |               |  |   |                      |                |   |              |                                   |          |            |
| Details  |               |  |   |                      |                |   |              |                                   |          |            |
| Level 1  |               | Level 2                                  |   | Level 3              | Level 3        |   |              |                                   |          |            |
| Unexpected Med cal Intervention Add tional Dev ce Required |               |  |   |                      |                |   |              |                                   |          |            |
|  |               |  |   |                      |                |   |              |                                   |          |            |
| Investigation Findings                                     |               |  |   |                      |                |   |              |                                   |          |            |
| Finding Details  |               |  |   |                      |                |   |              |                                   |          |            |
| Investigation Findings (Level 1)                           | Inve          | estigat on Findings (Level 2)            | Investiga                               | tion Findings (Level | If 'Other' S   | elected   |              |                                   |          |            |
| Mechan cal Problem Identified                              |               |  | 3)                                      |                      | likely due t   | o User Error  |              |                                   |          |            |
|  |               |  |   |                      |                |   |              |                                   |          |            |
| Investigation Conclusion                                   |               |  |   |                      |                |   |              |                                   |          |            |
| Conclus on Details   |               |  |   |                      |                |   |              |                                   |          |            |
| Investigation Conclus on (L1)                              |               | Investigation Conclusion (L2)            |   | If Add tional Conclu | ıs on Detail R | equested  |              |                                   |          |            |
| Cause Traced to User                                       |               |  |   |                      |                |   |              |                                   |          |            |
|  |               |  |   |                      |                |   |              |                                   |          |            |
| Investigation Outcomes                                     |               |  |   |                      |                |   |              |                                   |          |            |
| Outcome Details  |               |  |   |                      |                |   |              |                                   |          |            |
| Outcome of Investigation (L1)                              |               | Outcome of Investigat on (L2)            |   | If Add tional Conclu | ıs on Detail R | equested  |              |                                   |          |            |
| Reviewed, for Trending Purposes Only                       |               |  |   |                      |                |   |              |                                   |          |            |
|  |               |  |   |                      |                |   |              |                                   |          |            |
| Investigation Summary                                      |               |  |   |                      |                |   |              |                                   |          |            |
| Investigation Type:  | Lates         | st Investigat on (DII) where this DIR is | s the Primary DIR:                      | Latest Investigat o  | n (DII) where  | e this DIR is a Related DIR:                                | Investig     | ator:                             | Extens o | n Number:  |
| ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,                    |               |  |   |                      | (===)          |   |              |                                   |          |            |
| Investigator's Notes:                                      |               |  |   | Summary Findings     | :              |   |              |                                   | Recall N | umber:     |
|  |               |  |   | No further investig  | gation will oc | cur at this time; however the re-open the file as appropria | e TGA will o | continue to monitor the rate and  |          |            |
|  |               |  |   | pattern or occurre   | nee and may    | Te open the me as approprie                                 | utc.         |                                   |          |            |
| Note: Letter generat on buttons disabled if                | report not r  | ready for webs te publication or risk ar | nalysis not complete                    | d.                   |                |   |              |                                   |          |            |
| 3  |               | ,  | , |                      |                |   |              |                                   |          |            |
|  |               |  |   |                      |                |   |              |                                   |          |            |
| Device Lookup  |               |  |   |                      |                |   |              |                                   |          |            |
| This section is used to match informat on p                | rov ded via l | UDIR forms to ARTG information. You      | can select a Brand/I                    | Name from informat o | n prov ded ir  | n the 'Other Devices Involved                               | d' table bel | ow or enter information manually. |          |            |
| Other Device (Entered):                                    | Brand Nar     | me: Ma                                   | nufacturer Name:                        |                      | Device ARTO    | G #:  |              |                                   |          |            |
|  |               |  |   |                      |                |   |              |                                   |          |            |
| Other Devices  | Other Devices |  |   |                      |                |   |              |                                   |          |            |
|  | Manufacture   | r Name: S                                | ponsor/Supplier:                        |                      |                | GMDN / UMDN Text:   |              | Trade/Brand Name:                 |          | Serial #:  |
|  |               |  | . ,                                     |                      |                | ,   |              | ,                                 |          |            |

| Model Nu          | ımber:                   | Batch #:                    |                             |                      | Lot #:                  |  |               | Expiry Date:              |           | Document 3                       |                              | Document 3 |  |
|-------------------|--------------------------|-----------------------------|-----------------------------|----------------------|-------------------------|--|---------------|---------------------------|-----------|----------------------------------|------------------------------|------------|--|
|                   |                          |                             |                             |                      |                         |  |               |                           |           |                                  |                              |            |  |
| Related I         | DIR Information - Cl ck  | New to begin enteri         | ing informat on.            |                      |                         |  |               |                           |           |                                  |                              |            |  |
| Rec No            |                          |                             |                             |                      |                         |  |               |                           |           |                                  |                              |            |  |
| 1                 |                          |                             |                             |                      |                         |  |               |                           |           |                                  |                              |            |  |
| Samples           | Record - Click [N] to b  | egin entering inform        | nation. <b>Note:</b> Sample | # Generated on S     | Save.                   |  |               |                           |           |                                  |                              |            |  |
| Rec No            | Details                  | Sample Details              |                             |                      | ,                       | Add t onal Details                                   |               |                           |           |                                  |                              |            |  |
|                   | Date Entered:            | LIMS #:                     | Sample Requested            | : Sample Receive     | d: N                    | Manufacturer:  | GI            | GMDN: Dev ce Descript on: |           | Brand Name:                      | Serial Number:               |            |  |
|                   |                          |                             |                             |                      |                         |  |               |                           |           |                                  |                              |            |  |
| 1                 | Reason for Testing:      | # Samples from<br>Reporter: | # Samples from Sponsor:     | Outcome of TGA       | 's Testing:             | ot Number:   | Ва            | atch Number:              | Model Num | iber:                            | Vers on Number:              |            |  |
|                   |                          |                             |                             |                      | ,                       | Who cant the day so                                  | to the TCA2   |                           |           |                                  | Why does the TCA have the sa | mplo?      |  |
|                   |                          |                             |                             |                      | V                       | Who sent the dev ce                                  | to the TGA?:  | a:.                       |           |                                  | Why does the TGA have the sa | impier:    |  |
|                   |                          |                             |                             |                      |                         |  |               |                           |           |                                  |                              |            |  |
| Addition          | nal Patients             |                             |                             |                      |                         |  |               |                           |           |                                  |                              |            |  |
| Cl ck [N          | to begin entering infor  | rmation.                    |                             |                      |                         |  |               |                           |           |                                  |                              |            |  |
| Patient D         | Petails                  |                             |                             |                      |                         |  |               |                           |           |                                  |                              |            |  |
| Sex: Weight: Age: |                          |                             |                             |                      |                         |  |               |                           |           |                                  |                              |            |  |
|                   |                          |                             |                             |                      |                         |  |               |                           |           |                                  |                              |            |  |
| Patient F         | ocused Corrective Act of | n Taken:                    |                             |                      |                         |  | Patient Histo | ory:                      |           |                                  |                              |            |  |
|                   |                          |                             |                             |                      |                         |  |               |                           |           |                                  |                              |            |  |
| Injured -         | Extent of Injury:        |                             | Wa                          | s dev ce directly li | nked to death?:         | Was device directly linked to permanent disabiltiy?: |               |                           | Co        | Consequence:                     |                              |            |  |
|                   |                          |                             |                             |                      |                         |  |               |                           |           |                                  |                              |            |  |
| Other Co          | nsequence:               |                             | Des                         | scribe any test (La  | b, xray, etc.):         | Add tional Event Descript on:                        |               |                           | Me        | Med cal Problem Device Used For: |                              |            |  |
|                   |                          |                             |                             |                      |                         |  |               |                           |           |                                  |                              |            |  |
|                   |                          |                             |                             |                      |                         |  |               |                           |           |                                  |                              |            |  |
|                   |                          |                             |                             |                      |                         |  |               |                           |           |                                  |                              |            |  |
| Addition          | nal Device Information   |                             |                             |                      |                         |  |               |                           |           |                                  |                              |            |  |
| Where             | did you get this dev ce  | from?:                      | How reliant i               | s the affected pers  | son on correct/safe ope | ration of this device?                               | <b>'</b> :    |                           |           |                                  |                              |            |  |
| A                 |                          | he aid accessor/in          |                             | -+3.                 |                         |  |               |                           |           |                                  |                              |            |  |
| Any our           | ner relevant information | to aid assessing/inv        | restigating the incide      | itr:                 |                         |  |               |                           |           |                                  |                              |            |  |
| Similar E         | Events                   |                             |                             |                      |                         |  |               |                           |           |                                  |                              |            |  |
| Similar           | events - how many tim    | ies?:                       | Date of Rece                | nt Report:           |                         |  |               | Event Reported To:        |           |                                  | Reporter Reference Number:   |            |  |
|                   |                          |                             |                             |                      |                         |  |               |                           |           |                                  |                              |            |  |
| Dev ce A          | access - Alternate Dev c | e Contact Informat o        | on Provided                 |                      |                         |  |               |                           |           |                                  |                              |            |  |
| Title:            |                          |                             | First Name:                 |                      |                         |  |               | Last Name:                |           |                                  | Phone:                       |            |  |
|                   |                          |                             |                             |                      |                         |  |               |                           |           |                                  |                              |            |  |
| Fax:              |                          |                             | Email:                      |                      |                         |  |               |                           |           |                                  |                              |            |  |

| 18/ | 09/2023, 12:04         |                           |             |        |             | F                     | orm Details     |             |                 | Documei  | nt 3   |
|-----|------------------------|---------------------------|-------------|--------|-------------|-----------------------|-----------------|-------------|-----------------|----------|--------|
| Ι   | Incident Locat on Deta | ails                      |             |        |             |                       |                 |             |                 |          |        |
|     | Occurred in Australia  | :                         | Organisa    | cion:  |             |                       | Address Line 1: |             | Address Line 2: |          |        |
|     | Town/Suburb:           |                           | State:      |        |             |                       | Postcode:       |             |                 |          |        |
|     |                        |                           |             |        |             |                       |                 |             |                 |          |        |
| ı   | Flow Details DIR-RE    | EQ - Device Incident Requ | uest 259093 |        |             |                       |                 |             |                 |          |        |
|     | Request Details        |                           |             |        |             |                       |                 |             |                 |          |        |
|     |                        | Туре                      | Locat on    | Status | Assigned By | Assigned To           |                 | Assigned On |                 | Priority | Attach |
| 2   | 259093                 | DIR-REQ                   |             | Closed | s22         | OPR Administration Us | ser             | 05/08/2020  |                 | Normal   | 0      |

#### Signature Details

| Role      | IRIS Investigator   |  |
|-----------|---------------------|--|
| User      | \$22                |  |
| Signed At | 05/08/2020 13:59:18 |  |
| Comment   |                     |  |

**Document 4** 

# 1

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

DIR: 44 - ID: 528946

03/09/2021 SIGNED

|   |  | Released I   | 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  |  |  |  |  |  |  |  |
| vent Descript on for Website Publication:   |  |  |  |  |  |  |  |  |  |
| 3 weeks post operatively the patient had leakage on the anastom   | osis.  |  |  |  |  |  |  |  |  |
| Clinical Event Information:   |  |  |  |  |  |  |  |  |  |
| According to the reporter, during laparoscopic hemicolectomy, the To resolve the issue the surgeon redo the surgery then, re-resect | e device was able to fire with no problem, but 3 weeks post operation and re-staple the anastomosis of the patient. There was a tissue d | rely the patient had leakage on the anastomosis.<br>amage 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

| Submitting Reporter Section                          |   |   |   |
|--|---|---|---|
| Search Reporter By Surname:                          | Reporter #:                                     |   | Preferred Contact Method:                 |
| s22  |   |   |   |
| Reporter Title:                                      | First Name:                                     | Surname:  |   |
| s22  | s22   | <b>572</b>  |   |
| Position:  |   | Company/Institut on:  |   |
| 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 Submiss on By:                                |   |
|  | @medtron c.com                                  | 113291_837 - 21/10/2021 15:42                               |   |
| In tial Reporter Section                             |   |   |   |
| As Above?:   |   |   | Initial Reporter Conf dential:            |
| No   | If No, fill out the following:                  |   | 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   |   | 522   |   |
| 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:                 |

| 18/09/2023, | 12:15 | Form Details |
|-------------|-------|--------------|
|-------------|-------|--------------|

|  |                                      |                       |                                   |                                   |                       |                     | Document 4                       |  |
|--|--------------------------------------|-----------------------|-----------------------------------|-----------------------------------|-----------------------|---------------------|----------------------------------|--|
|  |                                      | Α                     |                                   | 13/09/2017                        |                       | 0                   |                                  |  |
| Manufacturer Informat on Section       |                                      |                       |                                   |                                   |                       |                     |                                  |  |
| Manufacturer Name:                     |                                      |                       |                                   | Manufacturer Client Id:           |                       | Address 1:          |                                  |  |
| Covidien IIc                           |                                      |                       |                                   | 54968                             |                       |                     |                                  |  |
| Address 2:                             |                                      | Town/Suburb:          |                                   | State/Province:                   |                       | Country:            |                                  |  |
|  |                                      |                       |                                   |                                   |                       | ,                   |                                  |  |
| Postcode:                              |                                      | Phone:                |                                   | Fax:                              |                       | Email:              |                                  |  |
|  |                                      |                       |                                   |                                   |                       |                     |                                  |  |
| Manufacturer Informed:                 |                                      | Date Aware of Adve    | rse Event:                        | Contact Title:                    |                       | Contact First Name: |                                  |  |
| Yes                                    |                                      | 31/08/2021            | - Contact rises                   |                                   |                       |                     |                                  |  |
| Contact Surname:                       |                                      |                       |                                   |                                   |                       |                     |                                  |  |
|  |                                      |                       |                                   |                                   |                       |                     |                                  |  |
|  |                                      |                       |                                   |                                   |                       |                     |                                  |  |
| Supplier Informat on Section           |                                      |                       |                                   |                                   |                       |                     |                                  |  |
| Supplier Name:                         |                                      |                       |                                   | Address 1:                        |                       | Address 2:          |                                  |  |
|  |                                      |                       |                                   |                                   |                       |                     |                                  |  |
| Town/Suburb:                           |                                      | State:                |                                   | Country:                          |                       | Postcode:           |                                  |  |
| -1                                     |                                      |                       |                                   | _ "                               |                       |                     |                                  |  |
| Phone:                                 |                                      | Fax:                  |                                   | Email:                            |                       | Website:            |                                  |  |
|  |                                      |                       |                                   | Contact Title:                    |                       | Contact First Name: |                                  |  |
| Supplier Informed: Date of Supplier Co |                                      | Date of Supplier Col  | ntact:                            | Contact litte:                    |                       | Contact First Name  |                                  |  |
| Contract Character                     |                                      |                       | Contact Fax:                      |                                   | Contact Email:        |                     |                                  |  |
| Contact Surname: Contact Phone:        |                                      | 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 Meet                  | ing:                  | Outcome from team meeting:        |                                   |                       |                     |                                  |  |
|  |                                      |                       |                                   |                                   |                       |                     |                                  |  |
| Notes for Team meeting:                |                                      |                       |                                   |                                   |                       |                     |                                  |  |
|  |                                      |                       |                                   |                                   |                       |                     |                                  |  |
| Outcomes from Team Meeting:            |                                      |                       |                                   |                                   |                       |                     |                                  |  |
|  |                                      |                       |                                   |                                   |                       |                     |                                  |  |
| In tial Risk Analysis                  |                                      |                       |                                   |                                   |                       |                     |                                  |  |
| Background Information                 | Risk Assessment - 9                  | 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       |                                   |                                   | s22                   |                     |                                  |  |
|  | prevented with treat<br>profess onal | ment by a health      |                                   |                                   |                       |                     |                                  |  |
| 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):  |  |

## 18/09/2023, 12:15 Form Details Document 4

|                                       | 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

@medtron c.com

| 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          |                                       | No   |                                   |                               |  |  |  |  |
| In tial                                |                              | health professional  |                                       |  |                                   |                               |  |  |  |  |
|  | Assessor:                    | Manufacturer documentation:  | Incidents in last 24 months:          | Manufacturer act on:   | ESTIMATED LEVEL OF INVESTIGATION: | FINAL LEVEL OF INVESTIGATION: |  |  |  |  |
| s <u>22</u>                            |                              | Yes - manufacturer HAS<br>documented issues or<br>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: | Specific 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:     | Specific sensitivities identified:                           |                                   |                               |  |  |  |  |
|  |                              |  |                                       |  |                                   |                               |  |  |  |  |
|  |                              | 3 or more events - organisation:   | Products supplied Worldwide:          | Consultations during risk assessment:                        | Final Risk Assessment:            |                               |  |  |  |  |
|  |                              |  |                                       |  | Yes                               |                               |  |  |  |  |

| nsor/Manufacturer Information Section |                               |                   |               |  |  |  |  |
|---------------------------------------|-------------------------------|-------------------|---------------|--|--|--|--|
| Search Sponsors:                      | Name:                         |                   | Client #:     |  |  |  |  |
| 837                                   | Medtron c Australasia Pty Ltd |                   | 837           |  |  |  |  |
| Attention To:                         | Address 1:                    | Address 2:        | Town/Suburb:  |  |  |  |  |
| <mark>\$22</mark>                     | PO Box 945                    |                   | NORTH RYDE BC |  |  |  |  |
| State:                                | Postcode:                     | Phone:            | Fax:          |  |  |  |  |
| NSW                                   | 1670                          | s <mark>22</mark> |               |  |  |  |  |
| Email:                                |                               |                   |               |  |  |  |  |

| Investigat on Information Sect on - Submitted by Sponsor/Manufa   | cturer   |  | Document 4   |  |  |  |
|---|--|--|--|--|--|--|
| Device Analysis Results:  |  | Details of Similar Events:   |  |  |  |  |
| not established. The deployed staples did not hold the tissue and the staple line of a There was not enough informat on to make any determination not established.  A device history review was performed and the lot number was a thoroughly reviewed to ensure that products are released meeting manufacture. The device history review determined that there Action.  A medical assessment was performed. The medical assessment of Further action was not required because there was insufficient in | following complaint(s) were investigated: as reported that: nexpected content leak occurred along the staple line. ere was not enough informat on to make any determination based on insuff cient evidence. The most likely root cause was stablished. deployed staples did not hold the tissue and the staple line opened up ere was not enough informat on to make any determination based on insuff cient evidence. The most likely root cause was stablished.  vice history review was performed and the lot number was not prov ded. However, records from each manufacturing lot are bughtly reviewed to ensure that products are released meeting all Medtron c quality release specifical ons at the time of uffacture. The device history review determined that there was insufficient information to conduct the specific Investigat on an edical assessment was performed. The medical assessment results were inconclusive.  The device history review determined that there was insufficient information.  In the device history review determined that there was insufficient information to conduct the specific Investigat on the conduct the specific Investigation of the conduct of the products are released meeting all Medtron c quality release specificat ons at the time of uffacture. The device history review determined that there was insufficient information to conduct the specific Investigation of the conduct of the product of the |  |  |  |  |  |
| Addit onal Details (use for tables):  |  | CAPA# Reference:   |  |  |  |  |
|   | A  | Risk Assessment  |  |  |  |  |
| E   | A  | Frequency:   | Severity:  |  |  |  |
|   |  | Rating:  |  |  |  |  |
| Type Cause and Outcome:   | Number of Similar Events:  | Expected Rate:   | Actual Rate:   |  |  |  |
| Countries Similar Events Also Occurred:   |  |  |  |  |  |  |
| Indonesia Ireland Israel Italy Korea, Republic Of Kuwa t Latvia Le  | azil Bulgaria Canada Canary Islands Chile China Colombia Costa Rica<br>ebanon Luxembourg Macao Malaysia Montenegro Netherlands New<br>lovenia South Afr ca Spain Sweden Sw tzerland Thailand Turkey Ukr  | a Croatia Cyprus Czech Republ c Denmark Finland France Germany Gre<br>Zealand North Macedonia Norway Pakistan Panama Paraguay Peru Pola<br>'aineUn ted Arab Emirates Un ted Kingdom Un ted States Viet Nam | ece Guadeloupe Guatemala Hong Kong Hungary Iceland India<br>nd Portugal Puerto R co Qatar Reunion RomaniaRussian |  |  |  |
| 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-oper   | ned 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 Ev            | vidence for Level 2                |                         |   |             |                    |              |                         |                   |          |                  |  |           |
|--------------------------|------------------------------------|-------------------------|---|-------------|--------------------|--------------|-------------------------|-------------------|----------|------------------|--|-----------|
| Details of Sou           | rce                                |                         |   |             |                    |              |                         |                   |          |                  |  |           |
| Sources of Ev            | dence                              |                         |   | If 'Other   | rs' please specify | here         |                         | Expected Sourcing | Date     | D                | ate of Ev dence Received                 |           |
|                          |                                    |                         |   |             |                    |              |                         |                   |          |                  |  |           |
|                          |                                    |                         |   |             |                    |              |                         |                   |          |                  |  |           |
| Evidence                 |                                    |                         |   |             |                    |              |                         |                   |          |                  |  |           |
| Investigat on            | Quest ons (Level 1 and Level 2):   |                         |   |             |                    |              |                         |                   |          |                  |  |           |
|                          |                                    |                         |   |             |                    |              |                         |                   |          |                  |  |           |
| Potential Risks          | 5                                  |                         |   |             |                    |              |                         |                   |          |                  |  |           |
| Delays in res            | ponse by product manufacturers:    |                         | Delays in response by incident              | reporters:  |                    | De           | lays in analysis w thi  | n the TGA:        |          | Delays in report | ing by other sources (e.g. clin cal regi | istries): |
|                          |                                    |                         |   |             |                    |              |                         |                   |          |                  |  |           |
| Other Risks (            | (wh ch need to be specified):      |                         |   |             |                    |              |                         |                   |          |                  |  |           |
|                          |                                    |                         |   |             |                    |              |                         |                   |          |                  |  |           |
| Next Steps for           | r Level 1 & Level 2 Investigat ons |                         |   |             |                    |              |                         |                   |          |                  |  |           |
| Next Steps fo            | or Level 1 Investigat on:          |                         |   |             |                    | Ne           | xt Steps for Level 2 I  | Investigat on:    |          |                  |  |           |
|                          |                                    |                         |   |             |                    |              |                         |                   |          |                  |  |           |
| Clair FBIT to b          | ania and Camarana dan an ambana    | Note that the Forell    | adduces and attend to one will one attended |             | 'Sthe Dete D       |              | and Ciled in leading De | to Forestad       |          |                  |  |           |
|                          | egin a new Correspondence entry.   | . Note that the Email a | daress specified fiere will receiv          | е а поштсац | on ii the Date Re  | eceived is i | not filled in by the Da | ate Expected.     |          |                  |  |           |
| Corresponden<br>Include? | ce and Chronology Details  Heading | Type L1                 | Type L2                                     | Email       |                    | Sent         | Expected                | Received          | Response |                  | Notes                                    |           |
| include:                 | rieading                           | туре Ст                 | Type LZ                                     | Liliali     |                    | Seric        | Expected                | Received          | Response |                  | Notes                                    |           |
|                          |                                    |                         |   |             |                    |              |                         |                   |          |                  |  |           |
|                          |                                    |                         |   |             |                    |              |                         |                   |          |                  |  |           |
| List of Problen          | n Observed Codes - Cl ck [N] to b  | eain enterina informat  | t on.                                       |             |                    |              |                         |                   |          |                  |  |           |
| Problem Obse             |                                    |                         |   |             |                    |              |                         |                   |          |                  |  |           |
|                          | rved (Level 1)                     | Problem Observed        | i (Level 2)                                 | Problem O   | bserved (Level 3   | ) If 'Ot     | her' Selected           |                   |          |                  |  |           |
| Insufficient In          |                                    |                         | ,   |             | •                  |              |                         |                   |          |                  |  |           |
|                          |                                    |                         |   |             |                    |              |                         |                   |          |                  |  |           |
| Clinical signs           | symptoms and conditions            |                         |   |             |                    |              |                         |                   |          |                  |  |           |
| Details                  |                                    |                         |   |             |                    |              |                         |                   |          |                  |  |           |
| Level 1                  |                                    | Level 2                 |   |             | Level 3            |              |                         |                   |          |                  |  |           |
| Gastrointestin           | al System                          |                         |   |             |                    |              |                         |                   |          |                  |  |           |
|                          |                                    |                         |   |             |                    |              |                         |                   |          |                  |  |           |
| Health Impac             | f                                  |                         |   |             |                    |              |                         |                   |          |                  |  |           |
| Details                  |                                    |                         |   |             |                    |              |                         |                   |          |                  |  |           |
| Level 1                  |                                    | Level 2                 |   |             | Level 3            |              |                         |                   |          |                  |  |           |
| Surgical Interv          | vention                            | Add tional Si           | urgery                                      |             | 207013             |              |                         |                   |          |                  |  |           |
| J                        |                                    |                         | <u> </u>                                    |             |                    |              |                         |                   |          |                  |  |           |
| Investigation            | Findinge                           |                         |   |             |                    |              |                         |                   |          |                  |  |           |
| _                        | _                                  |                         |   |             |                    |              |                         |                   |          |                  |  |           |
| Finding Details          | 5                                  |                         |   |             |                    |              |                         |                   |          |                  |  |           |

|            | ,                        |                      |                            |                               |                           |           |                 |                               |              |                          |             |             |        |
|------------|--------------------------|----------------------|----------------------------|-------------------------------|---------------------------|-----------|-----------------|-------------------------------|--------------|--------------------------|-------------|-------------|--------|
| Investiga  | ion Findings (Level 1)   | I                    | nvestigat on Findings      | s (Level 2)                   | Investigation Findings 3) | (Level    | If 'Other' Sel  | cted                          |              |                          |             | Docum       | nent 4 |
| No Findin  | gs Available             |                      |                            |                               |                           |           |                 |                               |              |                          |             |             |        |
|            |                          |                      |                            |                               |                           |           |                 |                               |              |                          |             |             |        |
| Investiga  | tion Conclusion          |                      |                            |                               |                           |           |                 |                               |              |                          |             |             |        |
| Conclus o  | n Details                |                      |                            |                               |                           |           |                 |                               |              |                          |             |             |        |
| Investiga  | ion Conclus on (L1)      |                      | Investigation Co           | onclusion (L2)                | If Add tions              | ıl Conclu | ıs on Detail Re | uested                        |              |                          |             |             |        |
| Cause No   | Established              |                      |                            |                               |                           |           |                 |                               |              |                          |             |             |        |
|            |                          |                      |                            |                               |                           |           |                 |                               |              |                          |             |             |        |
| Investiga  | tion Outcomes            |                      |                            |                               |                           |           |                 |                               |              |                          |             |             |        |
| Outcome    |                          |                      |                            |                               |                           |           |                 |                               |              |                          |             |             |        |
|            | of Investigation (L1)    |                      | Outcome of Inv             | estigat on (L2)               | If Add tions              | ıl Conclu | ıs on Detail Re | uested                        |              |                          |             |             |        |
|            | for Trending Purposes    | Only                 |                            |                               |                           |           |                 |                               |              |                          |             |             |        |
|            |                          | ,                    |                            |                               |                           |           |                 |                               |              |                          |             |             |        |
|            |                          |                      |                            |                               |                           |           |                 |                               |              |                          |             |             |        |
|            | tion Summary             |                      |                            |                               |                           |           |                 |                               |              |                          |             |             |        |
| Latest Ir  | vestigat on (DII) where  | this DIR is the Prin | nary DIR: Latest I         | nvestigat on (DII) where this | DIR is a Related DIR:     | Invest    | tigator:        |                               | Peer Rev     | riew:                    |             |             |        |
| Investig   | ator's Notes:            |                      |                            |                               |                           | Summ      | nary Findings:  |                               | No           |                          | Recall 1    | lumher:     |        |
|            |                          |                      |                            |                               |                           |           |                 | tion will occur at this time, | , however t  | the TGA will continue to |             |             |        |
|            |                          |                      |                            |                               |                           | the ra    | ate and pattern | of occurrence and may re      | e-open the   | file as appropriate.     |             |             |        |
| Device L   | ookup                    |                      |                            |                               |                           |           |                 |                               |              |                          |             |             |        |
| This secti | on is used to match info | rmat on prov ded v   | ia UDIR forms to AR        | rG information. You can selec | t a Brand/Name from in    | format o  | on prov ded in  | he 'Other Devices Involved    | d' table bel | ow or enter information  | n manually. |             |        |
| Other De   | evice (Entered):         | Brand                | Name:                      | Manufacture                   | er Name:                  |           | Device ARTG     | <b>#</b> :                    |              |                          |             |             |        |
|            |                          |                      |                            |                               |                           |           |                 |                               |              |                          |             |             |        |
| Other Dev  | rices                    |                      |                            |                               |                           |           |                 |                               |              |                          |             |             |        |
| Device AR  |                          | Manufacti            | urer Name:                 | Sponsor/S                     | unnlier:                  |           | G               | MDN / UMDN Text:              |              | Trade/Brand Name:        |             | Serial #:   |        |
| Device 711 | 10.110.                  | Tunaracc             | arer rume.                 | эропзогуз                     | иррпет.                   |           |                 | ibity offibit fext.           |              | ridde, Brand Name.       |             | Serial # .  |        |
| Model Nur  | nher:                    | Batch #:             |                            | Lot #:                        |                           |           | F               | piry Date:                    |              |                          |             |             |        |
| Ploder Nul | inder.                   | Baten #.             |                            | Εστ #.                        |                           |           | -               | tpiry Date.                   |              |                          |             |             |        |
|            |                          |                      |                            |                               |                           |           |                 |                               |              |                          |             |             |        |
| Related D  | IR Information - Cl ck N | lew to begin enteri  | ng informat on.            |                               |                           |           |                 |                               |              |                          |             |             |        |
| Rec No     |                          |                      |                            |                               |                           |           |                 |                               |              |                          |             |             |        |
| 1          |                          |                      |                            |                               |                           |           |                 |                               |              |                          |             |             |        |
| Samples    | Record - Click [N] to be | gin entering inform  | ation. <b>Note:</b> Sample | # Generated on Save.          |                           |           |                 |                               |              |                          |             |             |        |
| Rec No     | Details                  | Sample Details       |                            |                               | Add t onal D              | etails    |                 |                               |              |                          |             |             |        |
| 1          | Date Entered:            | LIMS #:              | Sample Requested:          | Sample Received:              | Manufacture               |           | GM              | DN:                           | Dev ce F     | Descript on:             | Brand Name: | Serial Numl | ber:   |
|            |                          | -                    |                            |                               |                           |           |                 |                               | +            | • • • •                  |             |             |        |
|            |                          |                      |                            |                               |                           |           |                 |                               |              |                          |             |             |        |

|           | Reason for Testing:       | # Samples from Reporter: | # Samples from Sponsor: | outcome of TGA's Testing:                  | Lot Number:                |             | Batch Number:                  | Model Number: | ١      | Vers on Number:               | Document 4 |
|-----------|---------------------------|--------------------------|-------------------------|--|----------------------------|-------------|--------------------------------|---------------|--------|-------------------------------|------------|
|           |                           |                          |                         |  |                            |             |                                |               |        |                               |            |
|           |                           |                          |                         |  | Who sent the dev ce        | to the TGA  | <b>:</b>                       |               | ١      | Why does the TGA have the sar | nple?:     |
|           |                           |                          |                         |  |                            |             |                                |               |        |                               |            |
|           |                           |                          |                         |  |                            |             |                                |               |        |                               |            |
| Additio   | nal Patients              |                          |                         |  |                            |             |                                |               |        |                               |            |
| Cl ck [N  | 1) to begin entering info | rmation.                 |                         |  |                            |             |                                |               |        |                               |            |
| Patient   | Details                   |                          |                         |  |                            |             |                                |               |        |                               |            |
| Sex:      |                           |                          |                         | Weight:                                    |                            | Age:        |                                |               |        |                               |            |
|           |                           |                          |                         |  |                            |             |                                |               |        |                               |            |
| Patient I | Focused Corrective Act o  | n Taken:                 |                         |  |                            | Patient His | story:                         |               |        |                               |            |
|           |                           |                          |                         |  |                            |             |                                |               |        |                               |            |
| Injured   | - Extent of Injury:       |                          |                         | Was dev ce directly linked to death?:      |                            | Was devic   | e directly linked to permanent | disabiltiy?:  | Conse  | quence:                       |            |
|           |                           |                          |                         |  |                            |             |                                |               |        |                               |            |
| Other C   | onsequence:               |                          |                         | Describe any test (Lab, xray, etc.):       |                            | Add tional  | Event Descript on:             |               | Med ca | al Problem Device Used For:   |            |
|           |                           |                          |                         |  |                            |             |                                |               |        |                               |            |
|           |                           |                          |                         |  |                            |             |                                |               |        |                               |            |
|           |                           |                          |                         |  |                            |             |                                |               |        |                               |            |
| Additio   | nal Device Information    |                          |                         |  |                            |             |                                |               |        |                               |            |
| Where     | did you get this dev ce   | from?:                   | How relia               | ant is the affected person on correct/safe | e operation of this device | :?:         |                                |               |        |                               |            |
|           | ,                         |                          |                         |  |                            |             |                                |               |        |                               |            |
| Any ot    | her relevant information  | to aid assessing/inv     | estigating the inc      | cident?:                                   |                            |             |                                |               |        |                               |            |
|           |                           |                          |                         |  |                            |             |                                |               |        |                               |            |
| Similar   | Events                    |                          |                         |  |                            |             |                                |               |        |                               |            |
| Simila    | r events - how many tim   | ies?:                    | Date of R               | lecent Report:                             |                            |             | Event Reported To:             |               | Rep    | porter Reference Number:      |            |
|           |                           |                          |                         |  |                            |             |                                |               |        |                               |            |
| Dev ce    | Access - Alternate Dev c  | e Contact Informat o     | on Provided             |  |                            |             |                                |               |        |                               |            |
| Title:    |                           |                          | First Nam               | ne:  |                            |             | Last Name:                     |               | Pho    | one:                          |            |
|           |                           |                          |                         |  |                            |             |                                |               |        |                               |            |
| Fax:      |                           |                          | Email:                  |  |                            |             |                                |               |        |                               |            |
|           |                           |                          |                         |  |                            |             |                                |               |        |                               |            |
| Inciden   | t Locat on Details        |                          |                         |  |                            |             |                                |               |        |                               |            |
| Occurr    | red in Australia:         |                          | Organisat               | tion:                                      |                            |             | Address Line 1:                |               | Add    | dress Line 2:                 |            |
|           |                           |                          |                         |  |                            |             |                                |               |        |                               |            |
| Town/     | Town/Suburb: State:       |                          |                         |  |                            | Postcode:   |                                |               |        |                               |            |

**Document 4** 

Flow Details DIR-REQ - Device Incident Request 318468

Request Details

| 18/09/2023. 12:15 | Form Details   | Document 4 |
|-------------------|----------------|------------|
| 10/03/2023, 12.13 | I UIII Details | Document 7 |

| ID     | Туре    | 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      | \$22                |  |
| Signed At | 25/10/2021 19:04:18 |  |
| Comment   |                     |  |



Document 5

08/03/2022 SIGNED

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

| Report #:   | Records Management #:   | Reporter's Reference #:  | Report Type:   |
|---|---|--|--|
| 76781   |   | 0704894000   | Final  |
| ARTG: 293808  | <u>Document Container URL</u>   |  |  |
| 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 detach   | ed.   |  |  |
| Clinical Event Information:   |   |  |  |
| According to the reporter, during a laparoscop c high anterior resec<br>with the anastomosis. One week post operative, the patient was un | t on, the stapler was difficult to remove after firing and when t wa<br>well and was taken back to the theatre. The anastomosis was not | s removed, the anvil detached. The anvil was removed and the surger<br>intact. Patient died from multiple organ failure due to sepsis secondar | on d d a leak test and sigmo doscopy. The surgeon was satisfied y 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 ->                                | t->;  |  |  |
| 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 -> -> ;<br>Surgical Intervent on -> Addit onal Surgery ->   |   |  |  |
| Patient Informat on   |   |  |  |
| Sex:  | Weight:   | Age:   |  |
| s22   |   | SV   |  |
| Patient Focused Corrective Act on Taken:  |   | Patient History:   |  |
|   |   |  |  |
| Patient Outcome/Consequences:   |   | Additional Event Descript on:  |  |
| Patient passed away.  |   |  |  |
| Describe any test (Lab, xray, etc.):  | Injured - Extent of Injury:   | Other med cal devices currently using/implanted:   | Med cal Problem Dev ce Used For:   |

18/09/2023, 12:28 Form Details **Document 5** Add tional Patients Added: Submitting Reporter Section Search Reporter By Surname: Reporter #: Preferred Contact Method: Reporter Title: First Name: Surname: Company/Inst tution: Position: Medtron c Australasia Pty Ltd. Address 1: Address 2: Town/Suburb: State: 2 Alma Road, Macquarie Park, NSW, 2113 Macquarie Park NSW Country: Postcode: Phone: Fax: Australia 2113 Mobile: Email: Last External Submission By: 114395\_837 - 07/07/2022 14:50 @medtronic.com In tial Reporter Section As Above?: Initial Reporter Confidential: If No, fill out the following: 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: State: Adelaide SA Postcode: Country: Phone: Fax: Allow the dev ce company Mobile: Email: to contact you about the incident: Dev ce Information Sect on Product Exempt (Note: If not exempt, enter ARTG No): Search Device ARTG: Device ARTG #: Therapeut c Licence Type: 293808 293808 Med cal Device Product Licence Category: Device Class: GMDN / UMDN Code: GMDN / UMDN Text: Included Class IIb 59875 Intraluminal circular stapler, single-use Brand Name: In tial Device Description: Usage of Device: Software Version:

EEA - Intraluminal circular stapler, single-use EEA - Intraluminal circular stapler, single-use Batch #: Model #: Serial #: Lot #: TRIEEA28MT P1L0118

Date of Implant: Date of Explant: Expiry Date: Place of Implantation: Reported Dev ce Locat on: Access Contact Ttle:

Access Contact First Name: Access Contact Surname: Access Contact Phone: Access Contact Fax:

Purchase Date:

Date of Inital Procedure:

|  |                        |                         |  |   |                       |                                  | Document 5  |  |
|--|------------------------|-------------------------|--|---|-----------------------|----------------------------------|---|--|
| Access Contact Email: Licence Status:      |                        | 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 IIc                               |                        | T                       |  | 54968   |                       | Country                          |   |  |
| Address 2:                                 |                        | Town/Suburb:            |  | State/Province:                                 |                       | Country:                         |   |  |
| Postcode:                                  |                        | Phone:                  |  | Fax:  |                       | Email:                           |   |  |
| rosicoue.                                  |                        | Filone.                 |  | rax.  |                       | Liliali.                         |   |  |
| Manufacturer Informed:                     |                        | Date Aware of Adve      | rse Event:                                   | Contact T tle:                                  |                       | Contact First Name               |   |  |
| Yes  |                        | 03/03/2022              | Too Eventi                                   | Contact Files                                   |                       | Contact First Hame               | •   |  |
| Contact Surname:                           |                        | 03/03/2022              |  |   |                       |                                  |   |  |
|  |                        |                         |  |   |                       |                                  |   |  |
|  |                        |                         |  |   |                       |                                  |   |  |
| Supplier Informat on Section               |                        |                         |  |   |                       |                                  |   |  |
| Supplier Name:                             |                        |                         |  | Address 1:                                      |                       | Address 2:                       |   |  |
|  |                        |                         |  |   |                       |                                  |   |  |
| Town/Suburb:                               |                        | State:                  |  | Country:  |                       | Postcode:                        |   |  |
| -  |                        | _                       |  |   |                       |                                  |   |  |
| Phone:                                     |                        | Fax:                    |  | Email:  |                       | Website:                         |   |  |
| Constitution to forward.                   |                        | Data of Constitution Co | -tt-   | Contract Tables                                 |                       | Contract Signat Name             |   |  |
| Supplier Informed:                         |                        | Date of Supplier Co     | ntact:                                       | Contact T tle:                                  |                       | Contact First Name               | :   |  |
| Contact Surname:                           |                        | Contact Phone:          |  | Contact Fax:                                    |                       | Contact Email:                   |   |  |
| Contact Sumanie.                           |                        | Contact Frione.         |  | Contact rax.                                    |                       | Contact Linaii.                  |   |  |
|  |                        |                         |  |   |                       |                                  |   |  |
|  |                        |                         |  |   |                       |                                  |   |  |
| 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 & I   | m)                               | Routine   |  |
| Team Review                                |                        |                         |  |   |                       |                                  |   |  |
| Reviewed by Team:                          | Reason Sent To Meetin  | ng:                     | Outcome from team meeting:                   |   |                       |                                  |   |  |
|  | Death                  |                         | Post-market Review is recommended            |   |                       |                                  |   |  |
| Notes for Team meeting:                    |                        |                         |  |   |                       |                                  |   |  |
|  | team meeting because o | of death. Should we as  | sk whether or not the dev ce was returned an | d why they haven't conducted any analysis if th | e dev ce was returned | ?                                |   |  |
| Outcomes from Team Meeting:                |                        |                         |  |   |                       |                                  |   |  |
| Closed as this is a known procedural compl | lication.              |                         |  |   |                       |                                  |   |  |
| In tial Risk Analysis                      |                        |                         |  |   |                       |                                  |   |  |
| Background Information                     | Risk Assessment - Se   | ection 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                   |                                  | 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               |                                  | No recalls for similar inc dents in<br>Australia                |  |
| Incidents in last 36 months: IVD status:   |                        |                         | EXCEPTION TO INVESTIGATION LEVEL:            |   | Found Prior To Use:   | Is AE covered by current recall: |   |  |

|  |                   |                           |                            |              |                               |           |   | No               |                       | Document 5                          |
|--|-------------------|---------------------------|----------------------------|--------------|-------------------------------|-----------|---|------------------|-----------------------|-------------------------------------|
| Incidents Worldw de:   |                   | Number of poten           | tial contributing factors: |              |                               |           |   | Reusable:        |                       | Similar events (past 6 months):     |
|  |                   | No                        |                            |              |                               |           |   | Yes              |                       | 0 inc dents                         |
| Products supplied the las  | st 12 months:     | Specific factors in       | dentified:                 | ESTIMATED    | LEVEL OF PRIORITY:            | FINAL     | LEVEL OF PRIORITY:                        |                  |                       | 3 or more events - batch/model:     |
|  |                   |                           |                            | Expedite     |                               | Routi     | ne  |                  |                       |                                     |
| Products supplied last 24  | 1 months:         | Number of poten           | tial sens tivities:        | EXCEPTION    | TO PRIORITY LEVEL:            |           |   |                  |                       | 3 or more events - health district: |
|  |                   |                           | ntial sens tivities (up to | Sent to tea  | m meeting.                    |           |   |                  |                       |                                     |
| Products supplied last 36  | 5 months:         | 3)<br>Specific sens tivit | ies dentified:             |              |                               |           |   |                  |                       | 3 or more events - organisation:    |
| Troduces supplied last so  | , monens.         |                           | igh acu ty clinical        |              |                               |           |   |                  |                       | 5 of more events organisation.      |
|  |                   | environments              | ligit acu ty clittical     |              |                               |           |   |                  |                       |                                     |
| Products supplied World  | w de:             | Consultations dur         | ring risk assessment:      | Final Risk A | ssessment:                    |           |   |                  |                       |                                     |
|  |                   | I did none of the         | above incidents            | Yes          |                               |           |   |                  |                       |                                     |
| Additional Risk Analysis Cl ck 'N' to start a new ris Analysis Details Update Device Details?: |                   |                           | Risk Assessment - Se       | ction A      | Risk Assessment - Section     | on B      | Risk Assessment - Section C               | Risk Assessm     | ient - Section D      |                                     |
| •  | Date:             |                           | Sever ty:                  |              | Incidents in the last 12 mon  |           | Manufacturer analysis:                    |                  |                       |                                     |
| Copy Data From:  | Date.             |                           | Sever ty.                  |              | incidents in the last 12 mon  |           | Plantifacturer arialysis.                 |                  |                       |                                     |
| Copy Data From.  |                   |                           |                            |              |                               |           |   |                  |                       |                                     |
|  | Assessor:         |                           | Manufacturer documenta     | tion:        | Incidents in last 24 months:  |           | Manufacturer act on:                      | ESTIMATED LEV    | /EL OF INVESTIGATION: | FINAL LEVEL OF INVESTIGATION:       |
|  |                   |                           |                            |              |                               |           |   |                  |                       |                                     |
|  | Injured Party:    |                           | Device Recalls:            |              | Incidents in last 36 months:  |           | IVD status:                               | EXCEPTION TO     | INVESTIGATION LEVEL:  |                                     |
|  |                   |                           |                            |              |                               |           |   |                  |                       |                                     |
|  | Found Prior To Us | e:                        | Is AE covered by current   | recall:      | Incidents Worldwide:          |           | Number of potential contributing factors: |                  |                       |                                     |
|  | Reusable:         |                           | Similar events (past 6 m   | onths):      | Products supplied the last 1. | 2 months: | Specific factors dentified:               | ESTIMATED LEV    | /EL OF PRIORITY:      | FINAL LEVEL OF PRIORITY:            |
|  |                   |                           | 3 or more events - batch   | /model:      | Products supplied last 24 mg  | onths:    | Number of potential sensitiv ties:        | EXCEPTION TO     | PRIORITY LEVEL:       |                                     |
|  |                   |                           | 3 or more events - health  | n distr ct:  | Products supplied last 36 me  | onths:    | Specific sensitiv ties identified:        |                  |                       |                                     |
|  |                   |                           | 3 or more events - organ   | isat on:     | Products supplied Worldw de   | e:        | Consultat ons during risk assessment:     | Final Risk Asses | ssment:               |                                     |
| Sponsor/Manufacturer In  | formation 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:   |                   |                           |                            |              |                               |           |   |                  |                       |                                     |

|  | acturer  |   |                           |  |  |
|--|--|---|---------------------------|--|--|
| Device Analysis Results:   |  | Corrective/Preventative Actions:        |                           |  |  |
| not established.  The anvil disengaged either fully or partially from the device.  | at on based on insufficient evidence. The most likely root cause was at on based on insufficient evidence. The most likely root cause was results were inconclusive. |   |                           |  |  |
| Details of Similar Events:   |  | Add tional Details (use for tables):    |                           |  |  |
| Australia:  2 similar events from 3993 un ts (0.05009%) sold in CY2019; 2 similar events from 2977 un ts (0.06718%) sold in CY2019; 1 similar events from 3517 un ts (0.02843%) sold in CY2021; 1 similar events from 1580 un ts (0.06329%) sold in CY2022 (1 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 of product reported per subject event.  CAPA# Reference:  Risk Assessment  Frequency: | ·<br>);  |   |                           |  |  |
|  |  |   |                           |  |  |
| Rating:  |  | Type Cause and Outcome:                 | Number of Similar Events: |  |  |
| Expected Rate:   | Actual Rate:   |   |                           |  |  |
| Countries Similar Events Also Occurred:  |  |   |                           |  |  |
|  | , Netherlands, New Zealand, Spain, Sweden, Switzerland, United King  | dom & 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 Ev                 | /idence for Level 2             |                            |                                |                   |                     |              |                        |                   |          |                |                              |                    |      |
|-------------------------------|---------------------------------|----------------------------|--------------------------------|-------------------|---------------------|--------------|------------------------|-------------------|----------|----------------|------------------------------|--------------------|------|
| Details of Sour               | rce                             |                            |                                |                   |                     |              |                        |                   |          |                |                              |                    |      |
| Sources of Ev                 | dence                           |                            |                                | If 'Othe          | ers' please specify | here         |                        | Expected Sourcing | Date     | ı              | Date of Ev dence Received    |                    |      |
|                               |                                 |                            |                                |                   |                     |              |                        |                   |          |                |                              |                    |      |
|                               |                                 |                            |                                |                   |                     |              |                        |                   |          |                |                              |                    |      |
| Evidence                      |                                 |                            |                                |                   |                     |              |                        |                   |          |                |                              |                    |      |
| Investigat on                 | Quest ons (Level 1 and Level 2) | ):                         |                                |                   |                     |              |                        |                   |          |                |                              |                    |      |
|                               |                                 |                            |                                |                   |                     |              |                        |                   |          |                |                              |                    |      |
| Potential Risks               | 5                               |                            |                                |                   |                     |              |                        |                   |          |                |                              |                    |      |
| Delays in res                 | ponse by product manufacturers  | s: De                      | lays in response by inciden    | it reporters:     |                     | Dela         | ys in analysis w thi   | in the TGA:       |          | Delays in repo | rting by other sources (e.g. | clin cal registrie | es): |
|                               |                                 |                            |                                |                   |                     |              |                        |                   |          |                |                              |                    |      |
| Other Risks (                 | wh ch need to be specified):    |                            |                                |                   |                     |              |                        |                   |          |                |                              |                    |      |
|                               |                                 |                            |                                |                   |                     |              |                        |                   |          |                |                              |                    |      |
| Next Steps for                | Level 1 & Level 2 Investigat on | S                          |                                |                   |                     |              |                        |                   |          |                |                              |                    |      |
| Next Steps fo                 | or Level 1 Investigat on:       |                            |                                |                   |                     | Next         | Steps for Level 2      | Investigat on:    |          |                |                              |                    |      |
|                               |                                 |                            |                                |                   |                     |              |                        |                   |          |                |                              |                    |      |
| Clair FNT to b                | anin a nau Camaanandanaa ank    | Note that the Freeil add   | was an acifical base will was  | ii.a a makifi aak | vian if the Date De | animad in ma | at filled in butter D  | aka Evraakad      |          |                |                              |                    |      |
|                               | egin a new Correspondence entr  | y. Note that the Email add | ress specified fiere will rece | eive a notincat   | ion ii the Date Re  | cerved is no | ot filled iff by the D | ate Expected.     |          |                |                              |                    |      |
| Include?                      | Heading                         | Type L1                    | Type L2                        | Email             | S                   | ent          | Expected               | Received          | Response |                | Notes                        |                    |      |
| meidde.                       | ricading                        | Type L1                    | 1790 22                        | Eman              |                     | ·Circ        | Expected               | Received          | Кезропзе |                | Notes                        |                    |      |
| List of Problem Problem Obser | n Observed Codes - Cl ck [N] to | begin entering informat or | 1.                             |                   |                     |              |                        |                   |          |                |                              |                    |      |
| Problem Obser                 |                                 | Problem Observed (L        | evel 2)                        | Problem C         | Observed (Level 3)  | ) If 'Oth    | er' Selected           |                   |          |                |                              |                    |      |
| Mechan cal Pro                |                                 | Retract on Problem         |                                |                   | (                   | ,            |                        |                   |          |                |                              |                    |      |
| Mechan cal Pro                | oblem                           | Detachment of Devic        | e or dev ce Component          |                   |                     |              |                        |                   |          |                |                              |                    |      |
|                               |                                 |                            | •                              |                   |                     |              |                        |                   |          |                |                              |                    |      |
| Clinical signs                | symptoms and conditions         |                            |                                |                   |                     |              |                        |                   |          |                |                              |                    |      |
| Details                       |                                 |                            |                                |                   |                     |              |                        |                   |          |                |                              |                    |      |
| Level 1                       |                                 | Level 2                    |                                |                   | Level 3             |              |                        |                   |          |                |                              |                    |      |
| Infections                    |                                 | Sepsis                     |                                |                   |                     |              |                        |                   |          |                |                              |                    |      |
| General Disord                | ders                            | Multiple Organ             | Dysfunct on Syndrome           |                   |                     |              |                        |                   |          |                |                              |                    |      |
|                               |                                 |                            |                                |                   |                     |              |                        |                   |          |                |                              |                    |      |
| Health Impact                 | t                               |                            |                                |                   |                     |              |                        |                   |          |                |                              |                    |      |
| Details                       |                                 |                            |                                |                   |                     |              |                        |                   |          |                |                              |                    |      |
| Level 1                       |                                 | Level 2                    |                                |                   | Level 3             |              |                        |                   |          |                |                              |                    |      |
| Surgical Interv               | vention                         | Add tional Surg            | ery                            |                   |                     |              |                        |                   |          |                |                              |                    |      |
| Death                         |                                 |                            |                                |                   |                     |              |                        |                   |          |                |                              |                    |      |

| Patient Fotused Corrective Act on Taken:   Limix #:   Sample Requested:   Sample Received:   Sample Recei    | Document 5     |
|--|----------------|
| Additional Patients  Cl ck [N] to begin entering information.  Patient Details  Sex:   | Serial Number: |
| Additional Patients  Cl ck [N] to begin entering information.  Patient Details  Sex:   |                |
| Additional Patients  Cl ck [N] to begin entering information.  Patient Details  Sex: Weight: Age: Age: Age: Age: Age: Age: Age: Age  |                |
| Clck [N] to begin entering information.  Patient Details  Sex: Weight: Age: Common Age: Co | imple?:        |
| Cl ck [N] to begin entering information.  Patient Details  Sex: Weight: Age: Graph of the control of the contro |                |
| Patient Details  Sex: Meight: Age: Meight: A |                |
|  |                |
| Patient Focused Corrective Act on Taken: Patient History:  |                |
| 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 disability?: 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:  |                |
| THE. THIS NAME.  |                |
| Fax: Email:  |                |
|  |                |
| Incident Location Details  Occurred in Australia:  Address Line 1:  Address Line 1:  |                |
| Occurred in Australia: Organisation: Address Line 1: Address Line 2:   |                |
| Town/Suburb: State: Postcode:  |                |

Flow Details DIR-REQ - Device Incident Request 335428

Document 5

Request Details

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

**Document 5** 

#### Signature Details

| Role      | IRIS Investigator   |  |
|-----------|---------------------|--|
| User      | \$22                |  |
| Signed At | 19/07/2022 14:12:18 |  |
| Comment   |                     |  |



# 1

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

DIR: 46 - ID: 547498

17/10/2022 SIGNED

|  |  |   | Released by 522 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:                                |  |   |  |
| in permanent colostomy bag for the patient. Further bowe   | I needed to be resected due to the circular staple line dehis<br>distal and proximal donuts were both intact. A second proce | cence and t us unknown there will be enough bowel to rejoin. But during | there is a high potential that the bowel cannot be re-anastomosed resulting the first surgery, the dev ce that was used was funct oned as expected, no These were to close rectal stump and create colostomy. Another operat on is |
| 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:  |  |
| 522  |  | 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:   |

|  |   |  | Document 6                                |
|--|---|--|---|
| Add tional Patients Added:                           |   |  |   |
| 0  |   |  |   |
| Cubarities Basedon Cartina                           |   |  |   |
| Submitting Reporter Section                          |   |  |   |
| Search Reporter By Surname:                          | Reporter #:                                     |  | Preferred Contact Method:                 |
| \$22   |   |  |   |
| Reporter Title:                                      | First Name:                                     | Surname:   |   |
| s22  | s22   | \$22   |   |
| Position:  |   | Company/Institut on:   |   |
| 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 Submiss on By:                                   |   |
| 1.00.00  |   | 113291_837 - 02/02/2023 12:45                                  |   |
|  | @medtron c.com                                  | 113291_637 - 02/02/2023 12:45                                  |   |
| In tial Reporter Section                             |   |  |   |
| As Above?:   | If No, fill out the following:                  |  | Initial Reporter Conf dential:            |
| No   | I No, III out the following.                    |  | Yes                                       |
| Search Reporter By Surname:                          | In tial Reporter #:                             |  | Preferred Contact Method:                 |
|  |   |  |   |
| Title:   | First Name:                                     | Surname:   |   |
|  |   |  |   |
| Position:  |   | Company/Institut on:   |   |
|  |   |  |   |
| Address 1:   | Address 2:                                      | S4/F Town/Suburb:  | State:                                    |
| Add 633 11   | Audi das 2.1                                    |  |   |
| S4/F   | Courter   | SA7F   | s4  |
| Postcode:  | Country:  | Phone:   | Fax:                                      |
| s47  |   | SA/F   | s47F                                      |
| Mobile:  | Email:  | Allow the device company<br>to contact you about the inc dent: |   |
|  | s47F  |  |   |
| Daving Information Control                           |   |  |   |
| 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 Device 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 #:                                    |
| TRIEEA28XT   |   |  | 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:                       |

|                                  |                         |                     |                                    |                               |                    |                      | Document 6  |
|----------------------------------|-------------------------|---------------------|------------------------------------|-------------------------------|--------------------|----------------------|---|
| Access Contact Email:            |                         | Licence Status:     |                                    | Status Effective Date:        |                    | Addit onal Devices A | Added:  |
|                                  |                         | Α                   |                                    | 13/09/2017                    |                    | 0                    |   |
| Manufacturer Informat on Section |                         |                     |                                    |                               |                    |                      |   |
| Manufacturer Name:               |                         |                     |                                    | Manufacturer Client Id:       |                    | Address 1:           |   |
| Covidien IIc                     |                         |                     |                                    | 54968                         |                    | Address 1.           |   |
| Address 2:                       |                         | Town/Suburb:        |                                    | State/Province:               |                    | Country:             |   |
|                                  |                         | ,                   |                                    |                               |                    | ,.                   |   |
| Postcode:                        | de: Phone:              |                     |                                    | Fax:                          |                    | Email:               |   |
|                                  |                         |                     |                                    |                               |                    |                      |   |
| Manufacturer Informed:           |                         | Date Aware of Adv   | erse 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:                      |                         | Fax:                |                                    | Email:                        |                    | Website:             |   |
|                                  |                         |                     |                                    |                               |                    |                      |   |
| Supplier Informed: Date          |                         | Date of Supplier Co | ontact:                            | Contact Title:                |                    | Contact First Name:  | :   |
|                                  |                         |                     |                                    |                               |                    |                      |   |
| Contact Surname: Contact Phone:  |                         | 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  | g:                  | Outcome from team meeting:         |                               |                    |                      |   |
|                                  |                         |                     |                                    |                               |                    |                      |   |
| Notes for Team meeting:          |                         |                     |                                    |                               |                    |                      |   |
|                                  |                         |                     |                                    |                               |                    |                      |   |
| Outcomes from Team Meeting:      |                         |                     |                                    |                               |                    |                      |   |
|                                  |                         |                     |                                    |                               |                    |                      |   |
| In tial Risk Analysis            |                         |                     |                                    |                               |                    |                      |   |
| Background Information           | Risk Assessment - Se    | ction 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 imp   | pairment            |                                    | 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     | Level 1 Investigat on (to complete | Screening only                | Patient            |                      | 0. No recalls for similar inc dents in                          |
| Incidents in last 36 months      | returned for analysis)  |                     | screening)                         |                               | Found Prior To Use |                      | Australia  Is AE covered by current recall:                     |

|  |  |                     |                                 | The dev ce                   | e was not returned - Low rat | te  |                                       | No                |                      | Document 6                          |
|--|--|---------------------|---------------------------------|------------------------------|------------------------------|---|---------------------------------------|-------------------|----------------------|-------------------------------------|
| Incidents Worldw de:   |  | Number of poten     | itial contributing factors:     |                              |                              |   |                                       | Reusable:         |                      | Similar events (past 6 months):     |
|  |  | No                  |                                 |                              |                              |   |                                       | No                |                      | 0 inc dents                         |
| Products supplied the la   | st 12 months:                                | Specific factors in | dentified:                      | ESTIMATE                     | LEVEL OF PRIORITY:           | FINAL                                     | LEVEL OF PRIORITY:                    |                   |                      | 3 or more events - batch/model:     |
|  |  |                     |                                 | Routine                      |                              | Routi                                     | ne                                    |                   |                      |                                     |
| Products supplied last 2   | 4 months:                                    | Number of poten     | itial sens tivities:            | EXCEPTION TO PRIORITY LEVEL: |                              |   |                                       |                   |                      | 3 or more events - health district: |
|  |  | No                  |                                 |                              |                              |   |                                       |                   |                      |                                     |
| Products supplied last 3   | 6 months:                                    | Specific sens tivi  | ties dentified:                 |                              |                              |   |                                       |                   |                      | 3 or more events - organisation:    |
|  |  |                     |                                 |                              |                              |   |                                       |                   |                      |                                     |
| Products supplied World  | dw de:                                       | Consultations du    | ring risk assessment:           | Final Risk A                 | Assessment:                  |   |                                       |                   |                      |                                     |
|  |  | I did none of the   | e above incidents               | Yes                          |                              |   |                                       |                   |                      |                                     |
| Additional Risk Analysi<br>Cl ck 'N' to start a new ri<br>Analysis Details |  | st Sect on          |                                 |                              |                              |   |                                       |                   |                      |                                     |
| Jpdate Device Details?:  | Background In                                | formation           | Risk Assessment - Se            | ction A                      | Risk Assessment - Sec        | ction B                                   | Risk Assessment - Section C           | Risk Assessm      | ent - Section D      |                                     |
|  | Date: Sever t                                |                     | Sever ty:                       |                              | Incidents in the last 12 m   |   | Manufacturer analysis:                |                   |                      |                                     |
| Copy Data From:  | Date.  |                     | Sever ty.                       |                              | incidents in the last 12 ii  | nonais.                                   | Plantiaccurer analysis.               |                   |                      |                                     |
| Lopy Data From.  |  |                     |                                 |                              |                              |   |                                       |                   |                      |                                     |
|  | Assessor:                                    |                     | Manufacturer documenta          | ition:                       | Incidents in last 24 mont    | ths:                                      | Manufacturer act on:                  | ESTIMATED LEV     | EL OF INVESTIGATION: | FINAL LEVEL OF INVESTIGATION:       |
|  |  |                     |                                 |                              |                              |   |                                       |                   |                      |                                     |
|  | Injured Party:                               |                     | Device Recalls:                 |                              | Incidents in last 36 mont    | ths:                                      | IVD status:                           | EXCEPTION TO      | INVESTIGATION LEVEL: |                                     |
|  |  |                     |                                 |                              |                              |   |                                       |                   |                      |                                     |
|  | Found Prior To Use: Is AE covered by current |                     | it recall: Incidents Worldwide: |                              |                              | Number of potential contributing factors: |                                       |                   |                      |                                     |
|  |  |                     |                                 |                              |                              |   |                                       |                   |                      |                                     |
|  | Reusable:                                    |                     | Similar events (past 6 m        | onths):                      | Products supplied the las    | st 12 months:                             | Specific factors dentified:           | ESTIMATED LEV     | 'EL OF PRIORITY:     | FINAL LEVEL OF PRIORITY:            |
|  |  |                     |                                 |                              |                              |   |                                       |                   |                      |                                     |
|  |  |                     | 3 or more events - batch        | /model:                      | Products supplied last 24    | 1 months:                                 | Number of potential sensitiv ties:    | EXCEPTION TO      | PRIORITY LEVEL:      |                                     |
|  |  |                     |                                 |                              |                              |   |                                       |                   |                      |                                     |
|  |  |                     | 3 or more events - healt        | h distr ct:                  | Products supplied last 36    | months:                                   | Specific sensitiv ties identified:    |                   |                      |                                     |
|  |  |                     |                                 |                              |                              |   |                                       |                   |                      |                                     |
|  |  |                     | 3 or more events - organ        | vicat on:                    | Products supplied Worldw     | w do:                                     | Consultat ons during risk assessment: | Final Pick Accord | cmont:               |                                     |
|  |  |                     | 5 of more events organ          | iisat oii.                   | Troducts supplied Worldv     | w ue.                                     | Consultations during risk assessment. | Tillal Risk Asses | Silient.             |                                     |
|  |  |                     |                                 |                              |                              |   |                                       |                   |                      |                                     |
| Sponsor/Manufacturer Ir  | nformation 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:   |  |                     |                                 |                              |                              |   |                                       |                   |                      |                                     |
|  |  |                     |                                 |                              |                              |   |                                       |                   |                      |                                     |

Form Details

| Sources | Ωf | Evidence | for I | 01/01/2 |  |
|---------|----|----------|-------|---------|--|

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

| Evidence                     | 0                                   |                       |                             |                     |                      |            |                        |               |          |  |            |
|------------------------------|-------------------------------------|-----------------------|-----------------------------|---------------------|----------------------|------------|------------------------|---------------|----------|--|------------|
| Investigat or                | n Quest ons (Level 1 and Level 2):  |                       |                             |                     |                      |            |                        |               |          |  |            |
| Potential Risk               | KS                                  |                       |                             |                     |                      |            |                        |               |          |  |            |
| Delays in res                | sponse by product manufacturers:    |                       | Delays in response by inc   | ident reporters:    |                      | Dela       | ays in analysis w thir | n the TGA:    |          | Delays in reporting by other sources (e.g. clin cal re | gistries): |
|                              |                                     |                       |                             |                     |                      |            |                        |               |          |  |            |
| Other Risks                  | (wh ch need to be specified):       |                       |                             |                     |                      |            |                        |               |          |  |            |
| Next Steps fo                | or Level 1 & Level 2 Investigat ons |                       |                             |                     |                      |            |                        |               |          |  |            |
|                              | for Level 1 Investigat on:          |                       |                             |                     |                      | Nex        | t Steps for Level 2 I  | nvestigat on: |          |  |            |
|                              |                                     |                       |                             |                     |                      |            |                        |               |          |  |            |
| Cl ck <b>[N]</b> to b        | pegin a new Correspondence entry.   | Note that the Email a | address specified here will | receive a notificat | ion if the Date Rece | eived is n | ot filled in by the Da | ite Expected. |          |  |            |
|                              | nce and Chronology Details          |                       |                             |                     |                      |            | ., ., ., .             |               |          |  |            |
| Include?                     | Heading                             | Type L1               | Type L2                     | Email               | Ser                  | nt         | Expected               | Received      | Response | Notes  |            |
|                              |                                     |                       |                             |                     |                      |            |                        |               |          |  |            |
| Problem Obse<br>Problem Obse | erved Details erved (Level 1)       | Problem Observed      | i (Level 2)                 | Problem (           | Observed (Level 3)   | If 'Oth    | ner' Selected          |               |          |  |            |
| Problem Obse                 | erved (Level 1)                     | Problem Observed      | i (Level 2)                 |                     |                      | If 'Oth    | ner' Selected          |               |          |  |            |
| Mechan cal Pr                | roblem                              | Leak / Splash         |                             | Fluid Leak          |                      |            |                        |               |          |  |            |
| Clinical sign                | s symptoms and conditions           |                       |                             |                     |                      |            |                        |               |          |  |            |
| Details                      | s symptoms and conditions           |                       |                             |                     |                      |            |                        |               |          |  |            |
| Level 1                      |                                     | Level 2               |                             |                     | Level 3              |            |                        |               |          |  |            |
| Gastrointestir               | nal System                          | Rectal Anas           | tomotic Leakage             |                     |                      |            |                        |               |          |  |            |
|                              |                                     |                       |                             |                     |                      |            |                        |               |          |  |            |
| Health Impac                 | et                                  |                       |                             |                     |                      |            |                        |               |          |  |            |
| Details                      |                                     |                       |                             |                     |                      |            |                        |               |          |  |            |
| Level 1                      |                                     | Level 2               |                             |                     | Level 3              |            |                        |               |          |  |            |
| Surgical Inter               | rvention                            | Add tional S          | urgery                      |                     |                      |            |                        |               |          |  |            |
| Inventinati                  | Findings                            |                       |                             |                     |                      |            |                        |               |          |  |            |
| Investigation                |                                     |                       |                             |                     |                      |            |                        |               |          |  |            |
| Finding Detail Investigation | Findings (Level 1)                  | Investigat on Find    | ings (Level 2)              | Investigat          | ion Findings (Level  | If 'Oth    | ner' Selected          |               |          |  |            |
| No Findings A                |                                     | 3                     | - ` '                       | 3)                  | 3- (                 |            |                        |               |          |  |            |
| NO FINAINGS A                | wanaule                             |                       |                             |                     |                      |            |                        |               |          |  |            |

**Document 6** 

| Conclus   | n Details               |                             |                           |                    |                          |                 |                    |   |              |                         |                       | Docum        | nent 6 |
|-----------|-------------------------|-----------------------------|---------------------------|--------------------|--------------------------|-----------------|--------------------|---|--------------|-------------------------|-----------------------|--------------|--------|
| Investiga | tion Conclus on (L1)    |                             | Investigation C           | Conclusion (L2)    |                          | If Add tional ( | Conclus on Detail  | Requested   |              |                         |                       |              |        |
| Cause No  | t Established           |                             |                           |                    |                          |                 |                    |   |              |                         |                       |              |        |
| Outcome   |                         |                             |                           |                    |                          |                 |                    |   |              |                         |                       |              |        |
|           | of Investigation (L1)   |                             | Outcome of In             | vestigat on (L2)   |                          | If Add tional ( | Conclus on Detail  | Requested   |              |                         |                       |              |        |
| Reviewed  | , for Trending Purposes | Only                        |                           |                    |                          |                 |                    |   |              |                         |                       |              |        |
| Investiga | ation Summary           |                             |                           |                    |                          |                 |                    |   |              |                         |                       |              |        |
| Latest Ir | nvestigat on (DII) wher | e this DIR is the Prim      | ary DIR: Latest           | Investigat on (DI  | I) where this DIR is a R | elated DIR:     | Investigator:      |   | Peer Rev     | iew:                    |                       |              |        |
|           |                         |                             |                           |                    |                          |                 |                    |   | No           |                         |                       |              |        |
| Investig  | ator's Notes:           |                             |                           |                    |                          |                 | Summary Finding    | s:  |              |                         | Recall N              | lumber:      |        |
|           |                         |                             |                           |                    |                          |                 | No further invest  | igation will occur at this time<br>ern of occurrence and may re | ; however,   | the TGA will continue t | o monitor             |              |        |
| Other De  | evice (Entered):        | Brand N                     | lame:                     | RTG information. \ | Manufacturer Name:       | Name from infoi | Device ART         |   | d' table bel |                         | n manually.           |              |        |
| Device AF | RTG No:                 | Manufactu                   | rer Name:                 |                    | Sponsor/Supplier:        |                 |                    | GMDN / UMDN Text:   |              | Trade/Brand Name:       |                       | Serial #:    |        |
| Model Nu  | mber:                   | Batch #:                    |                           |                    | Lot #:                   |                 |                    | Expiry Date:  |              |                         |                       |              |        |
| Related D | IR Information - Cl ck  | <b>New</b> to begin enterin | g informat on.            |                    |                          |                 |                    |   |              |                         |                       |              |        |
| Rec No    |                         |                             |                           |                    |                          |                 |                    |   |              |                         |                       |              |        |
| 1         |                         |                             |                           |                    |                          |                 |                    |   |              |                         |                       |              |        |
|           | Record - Click [N] to b |                             | tion. <b>Note:</b> Sample | e # Generated on   |                          |                 |                    |   |              |                         |                       |              |        |
| Rec No    | Details                 | Sample Details              |                           |                    |                          | Add t onal Deta | ails               |   |              |                         |                       |              |        |
|           | Date Entered:           | LIMS #:                     | Sample Requested          | d: Sample Receiv   | ed:                      | Manufacturer:   |                    | GMDN:   | Dev ce D     | escript on:             | Brand Name:           | Serial Num   | ber:   |
|           |                         |                             |                           |                    |                          |                 |                    |   |              |                         |                       |              |        |
| 1         | Reason for Testing:     | # Samples from<br>Reporter: | # Samples from Sponsor:   | Outcome of TG      | A's Testing:             | Lot Number:     | E                  | Batch Number:   | Model Nu     | ımber:                  | Vers on Number:       |              |        |
|           |                         |                             |                           |                    |                          | Who sent the d  | dev ce to the TGA? | :   |              |                         | Why does the TGA have | the sample?: |        |
|           |                         |                             |                           |                    |                          |                 |                    |   |              |                         | ,                     |              |        |

Document 6

| Cl ck [N] to begin en   | tering information.        |                         |                         |                                   |                 |              |   |             |                             |          |        |
|-------------------------|----------------------------|-------------------------|-------------------------|-----------------------------------|-----------------|--------------|---|-------------|-----------------------------|----------|--------|
| Patient Details         |                            |                         |                         |                                   |                 |              |   |             |                             |          |        |
| Sex:                    |                            |                         | Weight:                 |                                   | Ag              | ge:          |   |             |                             |          |        |
|                         |                            |                         |                         |                                   |                 |              |   |             |                             |          |        |
| Patient Focused Corre   | ective Act on Taken:       |                         |                         |                                   | Pa              | itient Histo | ry:                                       |             |                             |          |        |
|                         |                            |                         |                         |                                   |                 |              |   |             |                             |          |        |
| Injured - Extent of Inj | jury:                      |                         | Was dev ce directly     | linked to death?:                 | Wa              | as device o  | directly linked to permanent disabiltiy?: | C           | Consequence:                |          |        |
|                         |                            |                         |                         |                                   |                 |              |   |             |                             |          |        |
| Other Consequence:      |                            |                         | Describe any test (L    | ab, xray, etc.):                  | Ac              | dd tional Ev | vent Descript on:                         | N           | 1ed cal Problem Device Used | For:     |        |
|                         |                            |                         |                         |                                   |                 |              |   |             |                             |          |        |
|                         |                            |                         |                         |                                   |                 |              |   |             |                             |          |        |
|                         |                            |                         |                         |                                   |                 |              |   |             |                             |          |        |
| Additional Device Inf   | formation                  |                         |                         |                                   |                 |              |   |             |                             |          |        |
| Where did you get the   | his dev ce from?:          | How reli                | iant is the affected pe | rson on correct/safe operation of | f this device?: |              |   |             |                             |          |        |
|                         |                            |                         |                         |                                   |                 |              |   |             |                             |          |        |
| Any other relevant in   | nformation to aid assessir | ng/investigating the in | ncident?:               |                                   |                 |              |   |             |                             |          |        |
|                         |                            |                         |                         |                                   |                 |              |   |             |                             |          |        |
| Similar Events          |                            |                         |                         |                                   |                 |              |   |             |                             |          |        |
| Similar events - how    | v many times?:             | Date of                 | Recent Report:          |                                   |                 |              | Event Reported To:                        |             | Reporter Reference Number   | er:      |        |
|                         |                            | . 5                     |                         |                                   |                 |              |   |             |                             |          |        |
|                         | nate Dev ce Contact Infor  |                         |                         |                                   |                 |              | Look November                             |             | Discourse                   |          |        |
| Title:                  |                            | First Na                | me:                     |                                   |                 |              | Last Name:                                |             | Phone:                      |          |        |
| Fax:                    |                            | Email:                  |                         |                                   |                 |              |   |             |                             |          |        |
|                         |                            |                         |                         |                                   |                 |              |   |             |                             |          |        |
| Incident Locat on Det   | tails                      |                         |                         |                                   |                 |              |   |             |                             |          |        |
| Occurred in Australia   | a:                         | Organisa                | ation:                  |                                   |                 |              | Address Line 1:                           |             | Address Line 2:             |          |        |
|                         |                            |                         |                         |                                   |                 |              |   |             |                             |          |        |
| Town/Suburb:            |                            | State:                  |                         |                                   |                 |              | Postcode:                                 |             |                             |          |        |
|                         |                            |                         |                         |                                   |                 |              |   |             |                             |          |        |
|                         |                            |                         |                         |                                   |                 |              |   |             |                             |          |        |
| Flow Details DIR-RE     | EQ - Device Incident Req   | uest 352894             |                         |                                   |                 |              |   |             |                             |          |        |
|                         |                            |                         |                         |                                   |                 |              |   |             |                             |          |        |
| Request Details         |                            |                         |                         |                                   |                 |              |   |             |                             |          |        |
| ID                      | Туре                       | Locat on                | Status                  | Assigned By                       | Assigned To     | )            |   | Assigned On |                             | Priority | Attach |
| 352894                  | DIR-REQ                    |                         | Closed                  | s <mark>22</mark>                 | OPR Admini      | istration U  | ser                                       | 09/02/2023  |                             | Normal   | 0      |

**Additional Patients** 

| Role      | IRIS Investigator   | Document 6 |
|-----------|---------------------|------------|
| User      | \$ <mark>22</mark>  |            |
| Signed At | 09/02/2023 15:47:26 |            |
| Comment   |                     |            |



Add tional Dationto Addodu

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

DIR: 46 - ID: 564527

|   |                              | Released   | by <b>322</b> 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:                                       |                              |  |  |
|   |                              | Surgical was intervent on needed to prevent a permanent impairmer erat on was extended by 2.5 hours. The surgeon had to make a large |  |
| 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 | e ->                         |  |  |
| 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:         |
|   |                              |  |  |

Form Details

AUU LIVIIAI FALICIILS AUUCU.

0

Submitting Reporter Section

| Search Reporter By Surname:                          | Reporter #:                                     |   | Preferred Contact Method:                 |
|--|---|---|---|
| s22  |   |   |   |
| Reporter Title:                                      | First Name:                                     | Surname:  |   |
| s22  | <b>522</b>                                      | s22   |   |
| Position:  |   | Company/Inst tution:  |   |
| s22  |   | Medtron c 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:                                |   |
|  | v@medtronic.com                                 | 113291_837 - 04/07/2023 16:39                               |   |
| In tial Reporter Section                             |   |   |   |
| As Above?:   | If No, fill out the following:                  |   | Initial Reporter Confidential:            |
| No   | 1 Ho, III out the following:                    |   | Yes                                       |
| Search Reporter By Surname:                          | In tial Reporter #:                             |   | Preferred Contact Method:                 |
|  |   |   |   |
| Title:   | First Name:                                     | Surname:  |   |
|  |   |   |   |
| Position:  |   | Company/Inst tution:  |   |
|  |   | 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 dev ce company to contact you about the inc dent: |   |
|  |   |   |   |
| Dev ce Information Sect on                           |   |   |   |
| Product Exempt (Note: If not exempt, enter ARTG No): | Search Device ARTG:                             | Device ARTG #:  | Therapeut c Licence Type:                 |
| No   | 293808  | 293808  | Med cal Device                            |
| Product Licence Category:                            | Device Class:                                   | GMDN / UMDN Code:   | GMDN / UMDN Text:                         |
| Included   | Class IIb                                       | 59875   | Intraluminal circular stapler, single-use |
| Brand Name:  | In tial 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 Inital Procedure:                            | Place of Implantat on:                          | Reported Dev ce Locat on:                                   | Access Contact T tle:                     |
|  |   |   |   |
| Access Contact First Name:                           | Access Contact Surname:                         | Access Contact Phone:                                       | Access Contact Fax:                       |
|  |   |   |   |

Form Details

| 18/09/2023, 12:44 | Form Details |
|-------------------|--------------|
|-------------------|--------------|

| Access Contact Email:            |                                       | Licence Status:      |   | Status Effective Date:                               |                    | Add t onal Devices A | Added: Document 7                                |
|----------------------------------|---------------------------------------|----------------------|---|--|--------------------|----------------------|--|
|                                  |                                       | A                    |   | 13/09/2017   |                    | 0                    |  |
| Manufacturer Informat on Section |                                       |                      |   |  |                    |                      |  |
| Manufacturer Name:               |                                       |                      |   | Manufacturer Client Id:                              |                    | Address 1:           |  |
| Covidien IIc                     |                                       |                      |   | 54968  |                    |                      |  |
| Address 2:                       |                                       | Town/Suburb:         |   | State/Province:                                      |                    | Country:             |  |
|                                  |                                       |                      |   |  |                    |                      |  |
| Postcode:                        |                                       | Phone:               |   | Fax:   |                    | Email:               |  |
|                                  |                                       |                      |   |  |                    |                      |  |
| Manufacturer Informed:           |                                       | Date Aware of Adver  | rse 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 Cor | ntact:  | Contact Title:                                       |                    | Contact First Name:  |  |
| Contract Commonwell              |                                       | Contrat Phone        |   | Contract Form  |                    | Contact Foreille     |  |
| 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 Meetin                 | ng:                  | Outcome from team meeting:                    |  |                    |                      |  |
|                                  |                                       |                      | _   |  |                    |                      |  |
| Notes for Team meeting:          |                                       |                      |   |  |                    |                      |  |
|                                  |                                       |                      |   |  |                    |                      |  |
| Outcomes from Team Meeting:      |                                       |                      |   |  |                    |                      |  |
|                                  |                                       |                      |   |  |                    |                      |  |
| In tial Risk Analysis            |                                       |                      |   |  |                    |                      |  |
| Background Information           | Risk Assessment - S                   | ection 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 v               |                      |   | Yes  | s22                |                      | Unknown - updated informat on from               |
|                                  | prevented with treatr<br>profess onal | ment by a health     |   |  |                    |                      | 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            |                      | No recalls for similar inc dents in<br>Australia |
| Incidents in last 36 months:     | IVD status:                           |                      | EXCEPTION TO INVESTIGATION LEVEL:             |  | Found Prior To Use | :                    | Is AE covered by current recall:                 |
|                                  |                                       |                      |   |  |                    |                      | 1  |

|  |                     |                        |                          | The most I   | ikely root cause was traced to | o the user.   |                                       | No                 |                      | Document /                          |
|--|---------------------|------------------------|--------------------------|--------------|--------------------------------|---------------|---------------------------------------|--------------------|----------------------|-------------------------------------|
| ncidents Worldw de:                                  |                     | Number of potential    | contributing factors:    |              | ,                              |               |                                       | Reusable:          |                      | Similar events (past 6 months):     |
|  |                     | No                     |                          |              |                                |               |                                       | No                 |                      | 0 inc dents                         |
| oducts supplied the las                              | st 12 months:       | Specific factors ident | tified:                  | ESTIMATED    | LEVEL OF PRIORITY:             | FINAL         | LEVEL OF PRIORITY:                    |                    |                      | 3 or more events - batch/model:     |
|  |                     |                        |                          | Routine      |                                | Routi         | ne                                    |                    |                      | No                                  |
| oducts supplied last 24                              | 1 months:           | Number of potential    | sens tivities:           |              | TO PRIORITY LEVEL:             |               |                                       |                    |                      | 3 or more events - health district: |
|  |                     | No                     |                          | The most I   | ikely root cause was traced to | o the user.   |                                       |                    |                      | No                                  |
| oducts supplied last 36                              | months:             | Specific sens tivities | dentified:               |              |                                |               |                                       |                    |                      | 3 or more events - organisation:    |
|  |                     |                        |                          |              |                                |               |                                       |                    |                      | No                                  |
| oducts supplied Worldv                               | w de:               | Consultations during   | risk assessment:         | Final Risk A | assessment:                    |               |                                       |                    |                      |                                     |
|  |                     | I did none of the ab   | ove incidents            | Yes          |                                |               |                                       |                    |                      |                                     |
| dditional Risk Analysis<br>ck 'N' to start a new ris |                     |                        |                          |              |                                |               |                                       |                    |                      |                                     |
| alysis Details                                       | Statist cs Checklis | st Sect on             |                          |              |                                |               |                                       |                    |                      |                                     |
| date Device Details?:                                | Background Info     | formation              | Risk Assessment - Sec    | ction A      | Risk Assessment - Secti        | ion B         | Risk Assessment - Section C           | Risk Assessme      | ent - Section D      |                                     |
|  | Date:               |                        | Sever ty:                |              | Incidents in the last 12 mo    |               | Manufacturer analysis:                | 11.01171.000001111 |                      |                                     |
| ny Data Eromy  | Date.               | 3                      | sever ty.                |              | incidents in the last 12 ino   | niciis.       | rianulacturer analysis.               |                    |                      |                                     |
| by Data From:  |                     |                        |                          |              |                                |               |                                       |                    |                      |                                     |
|  | Assessor:           | M                      | Manufacturer documenta   | ition:       | Incidents in last 24 months    | s:            | Manufacturer act on:                  | ESTIMATED LEVE     | EL OF INVESTIGATION: | FINAL LEVEL OF INVESTIGATION:       |
|  |                     |                        |                          |              |                                |               |                                       |                    |                      |                                     |
|  | Injured Party:      | С                      | Device Recalls:          |              | Incidents in last 36 months    | s:            | IVD status:                           | EXCEPTION TO I     | NVESTIGATION LEVEL:  |                                     |
|  |                     |                        |                          |              |                                |               |                                       |                    |                      |                                     |
|  | Found Prior To Use  | e: Is                  | s AE covered by current  | recall:      | Incidents Worldwide:           |               | Number of potential contributing      |                    |                      |                                     |
|  |                     |                        |                          |              |                                |               | factors:                              |                    |                      |                                     |
|  | Reusable:           | c                      | limilar avanta (nast 6 m | onths).      | Dradusts supplied the last     | 12 months     | Charific factors, dentified           | ESTIMATED LEVE     | EL OE DRIORITY       | FINAL LEVEL OF PRIORITY:            |
|  | Reusable.           | 3                      | Similar events (past 6 m | onins).      | Products supplied the last     | 12 IIIOIIUIS. | Specific factors dentified:           | ESTIMATED LEVE     | EL OF PRIORITI.      | FINAL LEVEL OF PRIORITY.            |
|  |                     |                        |                          |              |                                |               |                                       |                    |                      |                                     |
|  |                     | 3                      | 3 or more events - batch | /model:      | Products supplied last 24 n    | months:       | Number of potential sensitiv ties:    | EXCEPTION TO P     | RIORITY LEVEL:       |                                     |
|  |                     |                        |                          |              |                                |               |                                       |                    |                      |                                     |
|  |                     | 3                      | or more events - healtl  | h distr ct:  | Products supplied last 36 n    | months:       | Specific sensitiv ties identified:    |                    |                      |                                     |
|  |                     |                        |                          |              |                                |               |                                       |                    |                      |                                     |
|  |                     | 3                      | or more events - organ   | nisat on:    | Products supplied Worldw       | de:           | Consultat ons during risk assessment: | Final Risk Assess  | ment:                |                                     |
|  |                     |                        |                          |              |                                |               |                                       |                    |                      |                                     |
|  |                     |                        |                          |              |                                |               |                                       |                    |                      |                                     |
| onsor/Manufacturer Inf                               | formation Section   |                        |                          |              |                                |               |                                       |                    |                      |                                     |
| earch Sponsors:                                      |                     |                        | Name:                    |              |                                |               |                                       |                    | Client #:            |                                     |
| 37   |                     |                        | Medtron c Australasia    | Pty Ltd      |                                |               |                                       |                    | 837                  |                                     |
|  |                     |                        | Address 1:               |              |                                | Address 2     | :                                     |                    | Town/Suburb:         |                                     |
| tention To:  |                     |                        | PO Box 945               |              |                                |               |                                       |                    | NORTH RYDE BC        |                                     |
| tention To:  |                     |                        | FO DOX 343               |              |                                |               |                                       |                    |                      |                                     |
| ttention To:   |                     |                        | Postcode:                |              |                                | Phone:        |                                       |                    | Fax:                 |                                     |

Focus of Level 2 Investigation

Details of Focus

Essential Principles

If 'Other' Selected

Level 3

Health Impact
Details
Level 1

Surgical Intervention

Level 2

Prolonged surgery

**Document 7** Investigation Findings Finding Details Investigation Findings (Level 1) Investigation Findings (Level If 'Other' Selected Investigat on Findings (Level 2) Usage Problem Identified Root cause was likely traced to the user Investigation Conclusion Conclus on Details Investigation Conclusion (L2) If Add tional Conclus on Detail Requested Investigation Conclus on (L1) Cause Traced to User **Investigation Outcomes** Outcome Details Outcome of Investigation (L1) If Add tional Conclus on Detail Requested Outcome of Investigat on (L2) 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: Device ARTG #: Manufacturer Name: Other Devices Device ARTG No: Manufacturer Name: GMDN / UMDN Text: Trade/Brand Name: Serial #: Sponsor/Supplier: Model Number: Batch #: Lot #: Expiry Date: Related DIR Information -  $\operatorname{Cl}$  ck  $\operatorname{\textbf{New}}$  to begin entering informat on. Rec No Samples Record - Click [N] to begin entering information. Note: Sample # Generated on Save. Rec No Details Sample Details Add t onal Details

| 3/09/202  | 23, 12:44                                      |                             |                         |                                      |                              |             | Form Details               |                       |                             | Document 7     |
|-----------|--|-----------------------------|-------------------------|--------------------------------------|------------------------------|-------------|----------------------------|-----------------------|-----------------------------|----------------|
|           | Date Entered:                                  | LIMS #:                     | Sample Requested        | : Sample Received:                   | Manufacturer:                |             | GMDN:                      | Dev ce Descript on:   | Brand Name:                 | Serial Number: |
|           |  |                             |                         |                                      |                              |             |                            |                       |                             |                |
| 1         | Reason for Testing:                            | # Samples from<br>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       | e the sample?: |
|           |  |                             |                         |                                      |                              |             |                            |                       |                             |                |
|           | nal Patients<br>I to begin entering info       | rmation.                    |                         |                                      |                              |             |                            |                       |                             |                |
| Patient D | Details  |                             |                         |                                      |                              |             |                            |                       |                             |                |
| Sex:      |  |                             | We                      | ight:                                |                              | Age:        |                            |                       |                             |                |
|           |  |                             |                         |                                      |                              |             |                            |                       |                             |                |
| Patient F | ocused Corrective Act o                        | n Taken:                    |                         |                                      |                              | Patient His | story:                     |                       |                             |                |
| Injured - | Extent of Injury:                              |                             | Wa                      | s dev ce directly linked to death?:  |                              | Was dovice  | e directly linked to perr  | nanont disabiltiv2    | Consequence:                |                |
| Injureu   | Extent of Injury.                              |                             | vva                     | s dev ce directly linked to death:   |                              | was devic   | e directly liliked to peri | nanent disability : . | consequence.                |                |
| Other Co  | nsequence:                                     |                             | Des                     | scribe any test (Lab, xray, etc.):   |                              | Add tional  | Event Descript on:         |                       | Med cal Problem Device Used | For:           |
|           |  |                             |                         |                                      |                              |             |                            |                       |                             |                |
|           |  |                             |                         |                                      |                              |             |                            |                       |                             |                |
| A 1 114   | 18 1 16 6                                      |                             |                         |                                      |                              |             |                            |                       |                             |                |
|           | nal Device Information did you get this dev ce | from?                       | How rollant i           | s the affected person on correct/cat | fo appration of this dovice. | ٠.          |                            |                       |                             |                |
| where     | aid you get this device                        | irom?:                      | now reliant i           | s the affected person on correct/saf | re operation of this device? | f:          |                            |                       |                             |                |
| Any oth   | ner relevant information                       | to aid assessing/inv        | vestigating the incide  | nt?:                                 |                              |             |                            |                       |                             |                |
| Similar E | Events   |                             |                         |                                      |                              |             |                            |                       |                             |                |
| Similar   | events - how many tim                          | nes?:                       | Date of Rece            | nt Report:                           |                              |             | Event Reported To:         |                       | Reporter Reference Numb     | er:            |
|           |  |                             |                         |                                      |                              |             |                            |                       |                             |                |
|           | access - Alternate Devi                        | e Contact Informat          |                         |                                      |                              |             |                            |                       |                             |                |
| Title:    |  |                             | First Name:             |                                      |                              |             | Last Name:                 |                       | Phone:                      |                |
| Fax:      |  |                             | Email:                  |                                      |                              |             |                            |                       |                             |                |
|           |  |                             |                         |                                      |                              |             |                            |                       |                             |                |
| Incident  | Locat on Details                               |                             |                         |                                      |                              |             |                            |                       |                             |                |
| Occurre   | ed in Australia:                               |                             | Organisation            | :                                    |                              |             | Address Line 1:            |                       | Address Line 2:             |                |
|           |  |                             |                         |                                      |                              |             |                            |                       |                             |                |

Postcode:

State:

Town/Suburb:

#### Request Details

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

**Document 7** 

#### Signature Details

| Role      | IRIS Investigator   |  |
|-----------|---------------------|--|
| User      | \$22                |  |
| Signed At | 05/07/2023 16:06:44 |  |
| Comment   |                     |  |



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

06/05/2014 SIGNED

**Document 8** 

DIR: 20 - ID: 275697

|  |  | Released by 🦸   | 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 Publicat   | ion:   |   |  |
|  | it developed peritonitis due to a suspected ana<br>the lateral sides of the anastomosis there was  |   | g their bowels. The surgeon had to re-operate on   |
| Clinical Event Information:  |  |   |  |
| using a Covidien size 28 stapler. The complete. As the procedure was done peritonitis due to a suspected anasto sides of the anastomosis there was a | operation went well and the anastomosis leak<br>e entirely laparoscopically, no reinforcement of<br>motic leak after the first attempt at opening he | tests using dye and air demonstrated no leak,<br>the staple line with sutures occurred. On day<br>er bowels. The surgeon had to re-operate on t<br>surgeon noted thatthe bowel was well vascula | vith reconstruction via end-to-end anastomosis  The anastomotic donuts were noted to be 6 post-operatively, the patient developed he patient and noted that on one of the lateral rized and there was no tissue tension. The patient |
| Number of Incidents in Report:   | Contact:   | Alternative Person Title:   | Alternative Person First Name:   |
| 1  |  |   |  |
| Alternative Person Surname:  | Alternative Person Phone:  | Alternative Person Fax:   |  |
| atient Information   |  |   |  |
| Sex:   | Weight:  | Age:  |  |
| Patient Focused Corrective Action Take   | en:  |   |  |
|  |  |   |  |

| Patient History:              |                                  |  | Document 8                     |
|-------------------------------|----------------------------------|--|--------------------------------|
| Patient Outcome/Consequences: |                                  |  |                                |
| Other Devices Involved:       |                                  |  |                                |
| Submitting Reporter Section   |                                  |  |                                |
| Search Reporter By Surname:   | Reporter #:                      |  |                                |
| Reporter Title:               | First Name:                      | Surname:                                 |                                |
| s22                           | s22                              | s22                                      |                                |
| Position:                     |                                  | Company/Institution:                     |                                |
| <del>\$22</del>               |                                  | 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@cov | vidien.com                               |                                |
| Initial Reporter Section      |                                  |  |                                |
| As Above?:                    | If No, fill out the following:   |  | Initial Reporter Confidential: |
| No                            | If No, IIII out the following.   |  | Yes                            |
| Search Reporter By Surname:   | Initial Reporter #:              |  |                                |
| S22 Title:                    | First Name:                      | Surname:                                 |                                |
| nue.                          |                                  |  |                                |
| Position:                     | \$22                             | S22                                      |                                |
|                               |                                  | Company/Institution:                     |                                |
| Consultant                    | Address 2                        | Shepparton Private Hospital Town/Suburb: | Chahai                         |
| Address 1:                    | Address 2:                       |  | State:                         |
| 20 Fitzgerald St Postcode:    | Phone                            | 20 Fitzgerald St                         | VIC                            |
|                               | Phone:                           | Fax:                                     | Mobile:                        |
| 3630                          |                                  |  |                                |

| Email:                               |                           |                                 | Document o                   |
|--------------------------------------|---------------------------|---------------------------------|------------------------------|
| Device Information Section           |                           |                                 |                              |
| Product Exempt:                      | If No, fill out ARTG No:  | Search Device ARTG:             | Device ARTG #:               |
| No                                   | II NO, IIII GUE ARTO NO.  | 178517                          | 178517                       |
| Therapeutic Licence Type:            | Product Licence Category: | Device Class:                   | GMDN / UMDN Code:            |
| Medical Device                       | Included                  | Class IIb                       | 45183                        |
| GMDN / UMDN Text:                    |                           | Brand Name:                     |                              |
| Applier, surgical staple, cutting    |                           | DST EEA 28MM Single-Use Stapler | r                            |
| Initial Device Description:          |                           |                                 |                              |
| DST EEA 28MM Single-Use Stapler      |                           |                                 |                              |
| Usage of Device:                     | Software Version:         |                                 |                              |
| Single Use                           |                           |                                 |                              |
| Model #:                             | Serial #:                 | Batch #:                        | Lot #:                       |
| EEA28                                |                           |                                 | 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:                   |                           | Manufacturer Client Id:         | Address 1:                   |
| Covidien IIc                         |                           | 54968                           | 15 Hampshire Street          |
| Address 2:                           | Town/Suburb:              | State/Province:                 | Country:                     |
|                                      | Mansfield                 | MA                              | United States                |
| Postcode:                            | Phone:                    | Fax:                            |                              |
| 02048                                | s22                       |                                 |                              |
| Email:                               |                           | Manufacturer Informed:          | Date Aware of Adverse Event: |
| australia-regulatory-affairs@covidio | en.com                    | Yes                             | 08/04/2014                   |
| Contact Title:                       | Contact First Name:       | Contact Surname:                |                              |
| s22                                  |                           | s22                             |                              |

| Supplier Information Section | on  |                                  |                     |                             | Document                 |
|------------------------------|---|----------------------------------|---------------------|-----------------------------|--------------------------|
| Supplier Name:               |   |                                  | Address 1: Add      |                             | Address 2:               |
| Town/Suburb:                 | State:  |                                  | Postcode:           |                             | Phone:                   |
| Fax:                         | Email:  |                                  |                     |                             | Supplier Informed:       |
| Date of Supplier Contact:    | Contact Title:  |                                  | Contact First Nan   | ne:                         | Contact Surname:         |
| Contact Phone:               | Contact Fax:  |                                  |                     |                             |                          |
| tatistics Checklist Section  |   |                                  |                     |                             |                          |
| Date:                        | Assessed By:  | For website publicat             | tion:               | Ready for Publication:      | Exclude report from DIRE |
| 31/03/2015                   | s22   | 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:                  |                     | Date of DIRE Meeting:       |                          |
| Serious                      | Unlikely  | Not Investigated                 |                     |                             |                          |
| DIRE Meeting Notes:          |   |                                  |                     |                             |                          |
|                              | sessed due to age of the report, as<br>ing trend in this type of event. | s the final report was not submi | itted by the sponso | or. A search of the IRIS da | tabase                   |
| ponsor Information Section   | on  |                                  |                     |                             |                          |
| Search Sponsors:             | Name  | e:                               |                     |                             | Client #:                |
| Covidien                     | Covi  | dien Pty Ltd                     |                     |                             | 283                      |
| Attention To:                | Addre   | ess 1:                           | Address 2:          |                             | Town/Suburb:             |
| s22                          | Lock  | ed Bag 2020                      |                     |                             | LANE COVE DC             |
| State:                       | Posto   | ode:                             | Phone:              |                             | Fax:                     |
| NSW                          | 2066  | 5                                | s22                 |                             | s22                      |

| 3/09/2023, 12:59                         |   |                            |                |                |           |           | F      | orm Deta | ails              |                         |                                   |
|--|---|----------------------------|----------------|----------------|-----------|-----------|--------|----------|-------------------|-------------------------|-----------------------------------|
| Email:                                   |   |                            |                |                |           |           |        |          |                   |                         | Document 8                        |
| Australia.Regulat                        | covidien.com                            |                            |                |                |           |           |        |          |                   |                         |                                   |
| Investigation Infor                      | mation Secti                            | on                         |                |                |           |           |        |          |                   |                         |                                   |
| Device Analysis Re                       | esults:                                 |                            |                |                |           |           |        |          |                   |                         |                                   |
| Corrective/Preven                        | tative Action                           | s:                         |                |                |           |           |        |          |                   |                         |                                   |
| Details of Similar                       | Events:                                 |                            |                |                |           |           |        |          |                   |                         |                                   |
| Number of Similar                        | r Events:                               |                            |                |                |           |           |        | Rate of  | Similar Events:   |                         |                                   |
| Countries Similar                        | Countries Similar Events Also Occurred: |                            |                |                |           |           |        |          |                   |                         |                                   |
|  |   |                            |                |                |           |           |        |          |                   |                         |                                   |
| Additional Comme                         | ents:                                   |                            |                |                |           |           |        |          |                   |                         |                                   |
| DIR closed -31/0                         | 3/2015                                  |                            |                |                |           |           |        |          |                   |                         |                                   |
| Device Lookup                            |   |                            |                |                |           |           |        |          |                   |                         |                                   |
| This section is used below or enter info | d to match ir                           | nformation provided values | ia UDIR fo     | orms to ARTG i | nformatio | on. You c | can se | lect a B | rand/Name from ir | formation provided in t | he 'Other Devices Involved' table |
| Other Device (Ent                        | ered):                                  | Brand Name:                |                | Manufacturer   | r Name:   |           | Devi   | ce ARTO  | 3 #:              |                         |                                   |
|  |   |                            |                |                |           |           |        |          |                   |                         |                                   |
| Other Devices                            |   |                            |                |                |           |           |        |          |                   |                         |                                   |
| Device ARTG No                           | Manufactu<br>Name                       | urer Sponsor/              | Supplier       | Trade/Bran     | ıd Name   | Serial a  | #      |          | Model Number      | GMDN / UMDN<br>Text     |                                   |
|  |   |                            |                |                |           |           |        |          |                   |                         |                                   |
| Related DIR Inform                       | nation - Click                          | <b>New</b> to begin enteri | ng informa     | ation.         |           |           |        |          |                   |                         |                                   |
| Incident Details                         |   |                            |                |                |           |           |        |          |                   |                         |                                   |
| DIR #                                    |   | Brand Name                 | Report<br>Name | ter First      | Reporte   | er Surnar | me     | Compa    | ny/Institution    |                         |                                   |
|  |   |                            |                |                |           |           |        |          |                   |                         |                                   |

|   |                                  |                     |                       |                                 |           |                      |            |              |                               |        | Document 8 |
|---|----------------------------------|---------------------|-----------------------|---------------------------------|-----------|----------------------|------------|--------------|-------------------------------|--------|------------|
| Samples Record - (                              | Click <b>[N]</b> to begin e      | ntering information | 1.                    |                                 |           |                      |            |              |                               |        |            |
| Sample Details                                  |                                  |                     |                       |                                 |           |                      |            |              |                               |        |            |
| Sample #  | Sample Reques                    | ted Sample Re       |                       | Samples froorter                | rom       | # Samples<br>Sponsor | from       | Outcome of   | TGA's Testing                 |        |            |
|   |                                  |                     |                       |                                 |           |                      |            |              |                               |        |            |
| Correspondence In                               | formation Section. I             | Note that the Corre | espondence Recip      | oient will r                    | eceive a  | notification i       | the Date R | eceived is n | ot filled in by the Date Expe | ected. |            |
| Correspondence De                               | etails                           |                     |                       |                                 |           |                      |            |              |                               |        |            |
| Correspondence<br>Type                          | Correspondence recipient (email) | Date Sent           | Date Resp<br>Expected | oonse                           | Date R    | Received             | Sponsor's  | Response     | Investigator's Notes          |        |            |
|   |                                  |                     |                       |                                 |           |                      |            |              |                               |        |            |
| List of Problem Typ                             | e Codes - Click [N]              | to begin entering   | information.          |                                 |           |                      |            |              |                               |        |            |
| Type Details                                    |                                  |                     |                       |                                 |           |                      |            |              |                               |        |            |
| Type of Problem (L                              | evel 1)                          | Type of Problem     | (Level 2)             | vel 2) If 'Other' Type Selected |           |                      |            |              |                               |        |            |
| Usability Use of Device Issu                    |                                  | ue                  |                       |                                 |           |                      |            |              |                               |        |            |
|   |                                  |                     |                       |                                 |           |                      |            |              |                               |        |            |
| Investigation Prob                              | olem Causes                      |                     |                       |                                 |           |                      |            |              |                               |        |            |
| Cause Details                                   |                                  |                     |                       |                                 |           |                      |            |              |                               |        |            |
| Cause of Problem (                              | (Level 1)                        | Cause of Problem    | (Level 2)             | If 'C                           | Other' Ca | use Selected         |            |              |                               |        |            |
| Unable to confirm complaint Device not returned |                                  |                     |                       |                                 |           |                      |            |              |                               |        |            |
|   |                                  |                     |                       |                                 |           |                      |            |              |                               |        |            |
| Investigation Outo                              | comes                            |                     |                       |                                 |           |                      |            |              |                               |        |            |
| Outcome Details                                 |                                  |                     |                       |                                 |           |                      |            |              |                               |        |            |
| Outcome of Investigation If Additional Outcom   |                                  |                     | itcome De             | etail Req                       | uested    |                      |            |              |                               |        |            |
| Reviewed, for Tren                              | ding Purposes Only               |                     |                       |                                 |           |                      |            |              |                               |        |            |
|   |                                  |                     |                       |                                 |           |                      |            |              |                               |        |            |
| Recall Number:                                  |                                  |                     |                       |                                 |           |                      |            |              |                               |        |            |
| Investigation Sum                               | ımary:                           |                     |                       |                                 |           |                      |            |              |                               |        |            |

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.

**Document 8** 

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

## **Request Details**

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

### **Signature Details**

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