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

05/02/2019
UNSIGNED

DIR : 31 - ID : 418731

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

Print

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
55668			

ARTG:

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Triage		s22	05/02/2019
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
05/02/2019	05/02/2019		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	

Event Description for Website Publication:

s22 [redacted]

Clinical Event Information:

s22 [redacted]

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

Patient Information

s22 [redacted]

Patient Focused Corrective Action Taken:

Patient History:

s22 [redacted]

Patient Outcome/Consequences:

s22 [redacted]

Additional Event Description:

s22 [redacted]

Describe any test (Lab, xray, etc.):	Injured - Extent of Injury:	Was device directly linked to permanent disabiltiy?:	Other medical devices currently using/implanted:
	Permanent Disability	Yes	
Medical Problem Device Used For:	**Additional Patients Added:**		
s22 [redacted]	0		

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		Preferred Contact Method:
s22			Email
Reporter Title:	**First Name:**	**Surname:**	
s22	s22	s22 [redacted]	

Form Details

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Country:

Australia

Postcode:

Phone:

s22

Fax:

Mobile:

Email:

s22

Are you happy for the device company to contact you about the incident?:

Last External Submission By:

Initial Reporter Section

As Above?:

No

If No, fill out the following:

Initial Reporter Confidential:

No

Search Reporter By Surname:

Initial Reporter #:

Preferred Contact Method:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Country:

Australia

Phone:

Fax:

Mobile:

Email:

Allow the device company to contact you about the incident:

Device Information Section

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

No

Search Device ARTG:

Device ARTG #:

Therapeutic Licence Type:

Product Licence Category:

Device Class:

GMDN / UMDN Code:

GMDN / UMDN Text:

Brand Name:

WIRION EPD SYSTEM

Initial Device Description:

DISTAL EMBOLIC PROTECTION SYSTEM

Usage of Device:

Software Version:

Model #:

Serial #:

Batch #:

Lot #:

Purchase Date:

25/07/2018

Expiry Date:

Date of Implant:

Date of Explant:

Place of Implantation:

Reported Device Location:

With Manufacturer

Access Contact Title:

Access Contact First Name:

Access Contact Surname:

Access Contact Phone:

Access Contact Fax:

Access Contact Email:

Additional Devices Added:

0

Manufacturer Information Section

Manufacturer Name:

Gardia Medical Devices

Manufacturer Client Id:

Address 1:

Address 2:

Town/Suburb:

State/Province:

Country:

Australia

Postcode:

Phone:

Fax:

Email:

Manufacturer Informed:

Date Aware of Adverse Event:

Contact Title:

Contact First Name:

Contact Surname:

Form Details

Supplier Information Section

Supplier Name:		**Address 1:**	**Address 2:**
Diverse Medical			
Town/Suburb:	**State:**	**Country:**	**Postcode:**
Phone:	**Fax:**	**Email:**	**Website:**
Supplier Informed:	**Date of Supplier Contact:**	**Contact Title:**	**Contact First Name:**
Yes	01/08/2018	s22	s22
Contact Surname:	**Contact Phone:**	**Contact Fax:**	**Contact Email:**
s22	s22		s22

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

Licence Start Date:	**Date of Initial TGA Action:**	**Report Status:**
	05/02/2019	Triage

Problems Observed:

Report Status

For website publication:	**Ready for Publication:**	**Investigated:**	**Investigation Reason:**	**Team Assignment:**
	No			Unassigned

Report Priority:
Not Investigated

Team Review

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

Team Meeting Notes:

DPRC Review

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

Meeting Notes:

Initial Risk Analysis

Date:	**Assessor:**	**Licence Status:**	**Status Reason:**	**Status Effective Date:**
05/02/2019				
Injured Party:	**Potential Effect:**	**Actual Effect:**	**Found Prior To Use:**	**Sample Received:**
				No
Sterile:	**Invasive Device:**	**Single Use:**	**Human Origin:**	**Genetically Modified:**
Reusable:	**Risk Frequency:**	**Risk Severity:**	**Risk Rating:**	**Further Review Needed:**
				Team Review

Risk Assessment Notes:

Final Risk Assessment:

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

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:		Client #:
Attention To:	Address 1:	Address 2:	Town/Suburb:
State:	Postcode:	Phone:	Fax:
Email:			

Investigation Information Section - Submitted by Sponsor/Manufacturer

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

Risk Assessment

Frequency:	Severity:
Rating:	

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

Countries Similar Events Also Occurred:

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

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

Correspondence and Chronology Details

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

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

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	

Investigation Outcomes

Outcome Details			
Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested	

Investigation Summary

Investigation Type:	Latest Investigation (DII) where this DIR is the Primary DIR:	Latest Investigation (DII) where this DIR is a Related DIR:	Investigator:	Extension Number:
Investigator's Notes:		**Summary Findings:**		**Recall Number:**

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

Device Lookup

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

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

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

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

Rec No	
1	

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

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

Additional Patients

Click [N] to begin entering information.

Patient Details

Sex:	Weight:	Age:	

Patient Focused Corrective Action Taken:	Patient History:

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

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

Additional Device Information

Where did you get this device from?: Hospital

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

Any other relevant information to aid assessing/investigating the incident?: Yes, medical reports and summaries

Similar Events

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

Device Access - Alternate Device Contact Information Provided

Title:	First Name:	Last Name:	Phone:

Fax:	Email:

Incident Location Details

Occurred in Australia:	Organisation:	Address Line 1:	Address Line 2:
Yes			

Town/Suburb:	State:	Postcode:

Flow Details DIR-REQ - Device Incident Request 160829

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
160829	DIR-REQ		Triage	theta	IRIS Coordinator	05/02/2019	Normal	0

Signature Details

Role	IRIS Investigator	
User		
Signed At		
Comment		