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

DIR 129 - ID : 410720

27/07/2018
SIGNED
Print

Released by Theta Technologies on 21/08/2018 17:03:32

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
52764	E18-329403	WIR01	Final

ARTG: 280883

Document Container URL

Report Information Section

Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed		s22	27/07/2018
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by Team:**	**Date Response Received:**
15/08/2018	27/07/2018		23/08/2018
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
23/08/2018	Doctor		No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Sponsor		Trend data only	

Event Description for Website Publication:

Filter tip broke off.

Clinical Event Information:

s22

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

Patient Information

Sex:	Weight:	Age:	
s22		s22	

Patient Focused Corrective Action Taken:

Patient History:

s22

Describe any test (Lab, xray, etc.):	Patient Outcome/Consequences:		Injured - Extent of Injury:
	s22		
Other Consequence:	**Other medical devices currently using/implanted:**	**Additional Event Description:**	**Medical Problem Device Used For:**

Additional Patients Added:

0

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22	s22		
Reporter Title:	**First Name:**	**Surname:**	

s22 s22

Position:

Company/Institution:

s22

Diverse Devices

Address 1: Address 2: Town/Suburb: State:

s22 Darlinghurst New South Wales

Country: Postcode: Phone: Fax:

Australia 2010 s22

Mobile: Email: Are you happy for the device company to contact you about the incident?: Last External Submission By:

s22 Diverse_62078 - 15/08/2018 15:08

Initial Reporter Section

As Above?: *If No, fill out the following:* Initial Reporter Confidential:

s22

Device Information Section

Product Exempt: *If No, fill out ARTG No:* Search Device ARTG: Device ARTG #:

No 280883 280883

Therapeutic Licence Type: Product Licence Category: Device Class: GMDN / UMDN Code:

Medical Device Included Class III 44841

GMDN / UMDN Text: Brand Name: Initial Device Description: Usage of Device:

Emboli capture guidewire Distal Protection Filter - Emboli capture guidewire Distal Protection Filter - Emboli capture guidewire Single Use

Software Version: Model #: Serial #: Batch #:

p290705s p290705s

Lot #: Purchase Date: Expiry Date: Date of Implant:

DS17003 26/07/2018 12/12/2019 26/07/2018

Date of Explant: Reported Device Location: Access Contact Title: Access Contact First Name:

26/07/2018 With Supplier s22 s22

Access Contact Surname: Access Contact Phone: Access Contact Fax:

s22 04991202324

Manufacturer Information Section

Manufacturer Name:

Gardia Medical Ltd

Manufacturer Client Id:

s22

s22

Address 2:

Ceasarea industrial park

Town/Suburb:

s22

State/Province:

Postcode:

3088900

Phone:

s22

Fax:

Email:

s22

Manufacturer Informed:

Yes

Date Aware of Adverse Event:

27/07/2018

Contact Title:

s22

Contact First Name:

2

Contact Surname:

s22

Supplier Information Section

Supplier Name:

s22

Address 1:

Address 2:

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:
30/09/2016	27/07/2018	Closed

Problems Observed:

Material; Material Separation;

Report Status

For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:
Yes	Yes	No	Event determined to be an isolated one	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:	Assessed By:	Licence Status:	Status Reason:	Status Effective Date:
23/08/2018	s22	Active		30/09/2016
Injured Party:	**Potential Effect:**	**Actual Effect:**	**Found Prior To Use:**	**Sample Received:**
Patient	Serious Injury	No Injury	No	No
Sterile:	**Invasive Device:**	**Single Use:**	**Human Origin:**	**Genetically Modified:**
Yes	Yes	Yes	No	No
Reusable:	**Risk Frequency:**	**Risk Severity:**	**Risk Rating:**	**Further Review Needed:**
No	Rarely	Minor	Minor Risk	

Risk Assessment Notes:

Additional Risk Assesments Required:

Sponsor/Manufacturer Information Section

Search Sponsors:	Name:	Client #:
62078	Diverse Devices Pty Ltd	62078
Attention To:	**Address 1:**	**Address 2:**	**Town/Suburb:**
s22 [redacted]			

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results:

This is the first time such an incident of filter tearing was reported to Gardia.
An investigation was conducted as following:
DHR, Lot release data and all applicable documentation were examined and found to be adequate. The lot underwent all required tests and inspections, and had passed them successfully.

Upon the return of the device, a thorough investigation was conducted:

As was reported by the customer, the physician applied excessive force while trying to retrieve the filter, and so the investigation focused on the attempt to reenact the described above scenario, under the assumption that the application of excessive force during the filter retrieval, resulted in the filter tearing.

Reenactment method:
The system was prepared in accordance with the IFU instructions and the filter was deployed (see image 1). A cotton ball soaked with water was placed inside the open filter (simulating the debris caught after the catheterization procedure) (see figure 2).

Then, an attempt was made to retrieve the filter, using an excessive force (measured by a manual force gauge). Following the application of a force equal to 23.7 N, the filer tore (see image 3).

In addition to the used device, a set of images taken during procedure were received from the customer. While performing a comparison between the outcome of both the actual procedure (A) and the reenactment (B), it is clear that a high level of similarity exists (see image 4).

Corrective/Preventative Actions:

To summarize - this is the first time such an incident occurred. The only possible explanation is the use of excessive force by the physician, as it was shown in the reenactment of the incident, allowing for the conclusion that a user error caused the device malfunction.
The Device IFU include warning regarding the use of excessive force:

CAUTION: Use caution when advancing or retracting the Retrieval Catheter through a deployed stent as this may cause Filter Unit/stent entanglement or stent dislocation.
WARNING: Do not pull excessively on the guide wire or the Retrieval Catheter.
NOTE: If any resistance is met during retraction of the guide wire and Filter Unit, slightly advance the guide wire and rotate the Retrieval Catheter before continuing to retract.
NOTE: If there is any resistance at the guiding catheter or sheath, retract the guide catheter or sheath and Retrieval Catheter together.

To summarize - this is the first time such an incident occurred. The only possible explanation is the use of excessive force by the physician, as it was shown in the reenactment of the incident, allowing for the conclusion that a user error caused the device malfunction.
The Device IFU include warning regarding the use of excessive force:

CAUTION: Use caution when advancing or retracting the Retrieval Catheter through a deployed stent as this may cause Filter Unit/stent entanglement or stent dislocation.
WARNING: Do not pull excessively on the guide wire or the Retrieval Catheter.
NOTE: If any resistance is met during retraction of the guide wire and Filter Unit, slightly advance the guide wire and rotate the Retrieval Catheter before continuing to retract.
NOTE: If there is any resistance at the guiding catheter or sheath, retract the guide catheter or sheath and Retrieval Catheter together.

Details of Similar Events:

None.

Additional Details (use for tables):

CAPA# Reference:

Risk Assessment

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

Countries Similar Events Also Occurred:

N/A

Completed Actions:	Planned Actions and Proposed Timelines:

Additional Comments:

Report closed on 23 August 2018

Device Lookup

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

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

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text
158014	Abbott Vascular	Abbott Vascular Division of Abbott Australasia Pty Ltd	Hi-Torque Ironman Guide Wire - Catheter guide wire			Catheter guide wire

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.

Details	Sample Details			Additional Details		
Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	Serial Number:	Model Number:
Sample #:						

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 Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes
■	Email to sponsor				27/07/2018				Email mentioning that they have used the incorrect form. They used the user report form instead of submitting a report via their online sponsor portal.
☐	Call to sponsor				31/07/2018				s22 a call in relation to one of s22 emails mentioning the report stays in 'Draft' mode. I had to leave a message and asked him to call me back.
■	Information required				15/08/2018	22/08/2018			Good Afternoon s22 The TGA have received this report as a final however, the Details of Similar Event information is not in the required format. Following is the guidance on how this information should be provided. Please also note that the similar event information should be based on the 'Clinical Event Information' and the ARTG number provided in the report, not based on the cause of the event. · Guidance on how to provide 'Details of Similar Events' · If there have been other similar events reported to either the sponsor or the manufacturer enter the number or rate. · The number should include the number sold for example 12 of 3,000 units sold over two years in Australia or 25 of 5 million units sold over five years worldwide. · The rate should preferably be provided in the form of an incidence rate, for example: 0.4%. · If none, write "0" or "Nil". Please update the Details of Similar Event information by 22/08/2018. Kind Regards, s22

Chronology

Chronology Details			
Heading:	Chronology Event (L1):	Email:	Expected:
Include?:	Chronology Event (L2):	Sent:	Received:
Notes:		Summary:	
TRIM Reference:	TRIM Container or Document?:	URL:	Comment:

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	
Material	Material Separation			

Investigation Findings

Finding Details				
Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected	
No Device Problem Found				

Investigation Conclusion

Conclusion Details			
Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested	
Cause Traced to User	Unintended Use Error Caused or Contributed to Event		

Investigation Outcomes

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

Latest Investigation where this DIR is the Primary DIR:	Latest Investigation where this DIR is a Related DIR:	Recall Number:

Investigation Summary:

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.

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.):	Other medical devices currently using/implanted:	Additional Event Description:
Medical Problem Device Used For:			

Additional Device Information

Where did you get this device from?:

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

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

Similar Events

Similar events - how many times?:

Date of Recent Report:

Event Reported To:

Reporter Reference Number:

Device Access - Details for where the device is, if not with the reporter.

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:

Organisation:

Address Line 1:

Address Line 2:

Town/Suburb:

State:

Postcode:

Report Generation

Completion Letters

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		DIR 52764- Original web report	122	Form	
FILE		image002	2	Form Item	Report Information Section / Brand Name
FILE		image004	3	Form Item	Report Information Section / Brand Name
FILE		image006	6	Form Item	Report Information Section / Brand Name
FILE		image008	6	Form Item	Report Information Section / Brand Name
FILE		image010	6	Form Item	Report Information Section / Brand Name

Flow Details : DIR-REQ - Device Incident Request : 145098

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
145098	DIR-REQ		Closed	hazels	OPR Administration User	23/08/2018	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22 [redacted]	
Signed At	23/08/2018 13:37:33	
Comment		