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

DIR : 26 - ID : 410720

27/07/2018
UNSIGNED

Released by s22 on 17/11/2016 14:13:04

Print

Report Informat on Sect on

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
52764		WIR01	
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Triage		s22	27/07/2018
Date of Final Report:	**Date of In tial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
27/07/2018	27/07/2018		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Conf dentiality:**
			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Act on:**	

Event Descript on 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:**	

Patient Information

s22 [redacted]	Weight:	s22 [redacted]

Patient Focused Corrective Action Taken:

Patient History:

s22 [redacted]

Patient Outcome/Consequences:

s22 [redacted]

Other Dev ces Involved:

Subm tting Reporter Section

s22 [redacted]

In tial Reporter Sect on

As Above?:	*If No, fill out the following:*	Initial Reporter Conf dential:
Yes		
Search Reporter By Surname:	**In tial Reporter #:**	
T tle:	**First Name:**	**Surname:**
Position:		**Company/Institution:**
Address 1:	**Address 2:**	**Town/Suburb:** **State:**

Postcode: | Phone: | Fax: | Mobile:

Email:

Device Informat on Sect on

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

Therapeut c L cence Type: | Product Licence Category: | Device Class: | GMDN / UMDN Code:

GMDN / UMDN Text: | Brand Name: s22

Initial Device Descript on: Distal protection filter

Usage of Device: | Software Version:

Model #:	Serial #:	Batch #:	Lot #:
	p290705s		DS17003

Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
26/07/2018	12/12/2019	26/07/2018	26/07/2018

Manufacturer Information Section

Manufacturer Name: s22 | Manufacturer Client Id: | Address 1: s22

Address 2: | Town/Suburb: | State/Province: | Country: Israel

Postcode: s22 | Phone: s22 | Fax:

Email: | Manufacturer Informed: | Date Aware of Adverse Event:

Contact T tle: | Contact First Name: | Contact Surname:

Supplier Information Section

Supplier Name: s22 | Address 1: s22 | Address 2:

Town/Suburb:	State:	Postcode:	Phone:
s22	NSW	2065	s22

Fax: | Email: info@diversedevices.com.au | Supplier Informed: Yes

Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
26/07/2018	s22	s22	s22

Contact Phone: s22 | Contact Fax:

Statist cs Checklist Sect on

Date:	Assessed By:	For webs te publicat on:	Ready for Publicat on:	Exclude report from DIRE:
27/07/2018			No	☐
Sample Received:	**Sterile:**	**Reusable:**	**Single Use:**	**Potential Effect:**
	Yes	No	Yes	
Actual Effect:	**Injured Party:**		**Found Pr or To Use:**	**Risk Frequency:**
Risk Sever ty:	**Risk Detectability:**	**Classification:**	**Investigated:**	**Date of DIRE Meeting:**

DIRE Meeting Notes:

Sponsor Information Section

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

Investigation Informat on Sect on

Dev ce Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:	Additional Details (use for tables):
	

Number of Similar Events:	Rate of Similar Events:

Countries Similar Events Also Occurred:

Add t onal Comments:

Device Lookup

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

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

Other Devices

Dev ce ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text
	Abbott	abbott	Iron man wire			

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

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

Sample Details

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

Correspondence Information Sect on. Note that the Correspondence Recipient will receive a notif cation if the Date Received is not filled in by the Date Expected.

Correspondence Details

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

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

Type Details

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected

Investigation Problem Causes

Cause Details			
Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	

Investigation Outcomes

Outcome Details		
Outcome of Investigat on	If Add t onal Outcome Detail Requested	

Recall Number:

Investigat on Summary:

Flow Details DIR-REQ - Device Incident Request 145098

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Prior ty	Attach
145098	DIR-REQ		Triage	theta	IRIS Coordinator	27/07/2018	Normal	0

Signature Details

Role	IRIS Investigator	
User		
Signed At		
Comment		