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

DIR : 6 - ID : 153308

Released by Theta Technologies on 01/03/2012 12:04:11

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
26188	2012/009112		Final
Report Status:	**Sponsor's Reported Category:**	**Date of Adverse Event:**	**Date of Initial Report:**
Closed			23/03/2012
Date of Final Report:	**Date of Initial TGA Action:**	**Reviewed by DIRE:**	**Date Response Received:**
23/03/2012	30/03/2012		
Date Completed:	**Operator at Time of Event:**	**If 'Other' Operator Selected:**	**Reporter Confidentiality:**
23/05/2013			No
Source of Report:	**If 'Other' Source Selected:**	**Type of Initial Action:**	
Surgeon			

Clinical Event Information:

PIP Implants.

Patient worried as she had PIP implants.

Left breast rupture.

Implants recieved at the TGA.

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

Patient Information

Sex:	Weight:	Age:
[redacted]		

Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
pouw	5383		
Reporter Title:	**First Name:**	**Surname:**	
Dr	William	Pouw	
Position:		**Company/Institution:**	
Cosmetic Plastic Surgeon			
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
[redacted]		[redacted]	[redacted]
Country:	**Postcode:**	**Phone:**	**Fax:**
[redacted]	[redacted]	[redacted]	[redacted]
Mobile:	**Email:**		
	drpouw@[redacted]		

Initial Reporter Section - in the final release this will connect to the existing list of reporters in IRIS

As Above?:	*If No, fill out the following:*		Initial Reporter Confidential:
No			Yes
Search Reporter By Surname:	**Initial Reporter #:**		
Title:	**First Name:**	**Surname:**	
[redacted]			
Position:		**Company/Institution:**	
Address 1:	**Address 2:**	**Town/Suburb:**	**State:**
Postcode:	**Phone:**	**Fax:**	**Mobile:**
Email:			

Device Information Section

Product Exempt:	*If No, fill out ARTG No:*	Search Device ARTG:	Device ARTG #:
No		114902	114902
Therapeutic Licence Type:	**Product Licence Category:**	**Device Class:**	**GMDN Code:**
Medical Device	Included	Class III	36197
GMDN Text:		**Brand Name:**	
Prosthesis, internal, mammary, gel filled		PIP Breast Implant	

Initial Device Description:

PIP Breast Implant

Usage of Device:	Software Version:		
Single Use			
Model #:	Serial #:	Batch #:	Lot #:
	268 (f) & 046 (l)		12705 (r) & 03604 (l)
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
		14/09/2006	22/03/2012
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:
Poly Implant Protheses (Pip) SA		29265	
Address 2:	Town/Suburb:	State/Province:	Country:
Postcode:	Phone:	Fax:	
Email:		Manufacturer Informed:	Date Aware of Adverse Event:
Contact Title:	Contact First Name:	Contact Surname:	

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
Town/Suburb:	State:	Postcode:	Phone:
Fax:	Email:		Supplier Informed:
			No
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
Contact Phone:	Contact Fax:		

Statistics Checklist Section

Date:	Assessed By:		
30/03/2012	[redacted]		
Sample Received:	Sterile:	Reusable:	Single Use:
No	Yes	No	Yes
Potential Effect:	Actual Effect:	Injured Party:	
Serious Injury	Temporary Injury	Patient	
Risk Frequency:	Risk Severity:	Risk Detectability:	Classification:
Rarely	Serious	Occasionally	Routine

Exclude report from DIRE: ☐

DIRE Meeting Notes:

Sponsor Information Section

Search Sponsors:	Name:		Client #:
medical vision	Medical Vision Australia Pty Ltd		29703
Attention To:	Address 1:	Address 2:	Town/Suburb:
[redacted]	99 King William Street		KENT TOWN
State:	Postcode:	Phone:	Fax:
SA	5067	(08) 8132 0300	(08) 8132 0311
Email:			
[redacted]			

Investigation Information Section

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events: Rate of Similar Events:

Countries Similar Events Also Occurred:

Additional Comments:

Note: As in other places, on the production system the ARTG # text box will be replaced with a link to the register

Other Devices

Search Device ARTG	Device ARTG No	Product Name	Serial #

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

Incident Details

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

Samples Record - Click **New** to begin entering information.

Sample Details

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

Correspondence Details

Correspondence Type	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes
Additinal Info Request	30/03/2012				
Reporter Notification Sent	03/04/2012				
Reporter Completion Letter	23/05/2013				

List of Problem Type Codes - Click **New** to begin entering information.

Type Details

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

Cause Details

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

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested
TGA Publication	Refer to other TGA office - Laboratory testing

Recall Number:

Investigation Summary:

The information provided in this report has been used to assist the broader TGA investigation of PIP breast implants.

As of April 17 2013, the TGA had received 498 confirmed and unconfirmed reports of rupture of PIP breast implants from surgeons, patients and the Australian supplier. Approximately 13,000 PIP silicone gel breast implants were supplied in Australia between 1998 and 2010.

The TGA has performed and reported on an extensive range of tests on the chemical properties, physical properties and the biological safety of the gels and shells of PIP breast implants. The TGA tested silicone material from both new and explanted devices. Testing undertaken by TGA has not found evidence that the risks involved with the use of PIP breast implants are any greater than those for any other brand of silicone gel-filled breast implants.

Complete details regarding the test results and the findings of the TGA investigation can be found in the TGA website (http://www.tga.gov.au/safety/alerts-device-breast-implants-pip.htm). For your convenience a copy of the most up to date information regarding this investigation has been attached to this letter. Additional detail on PIP implants can be found in the Department of Health, Chief Medical Officer report into PIP implants. This document can be found via the Department of Health and Aging website (http://www.health.gov.au/internet/publications/publishing.nsf/Content/PIP-breast-implants-report-CMO-toc).

Flow Details : DIR-REQ - Device Incident Request : 35081

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority
35081	DIR-REQ		Closed	theta	OPR Administration User	23/05/2013	Normal

Signature Details

Role	IRIS Investigator
User	theta - Theta Technologies
Signed At	23/05/2013 16:17:32
Comment	Automatically signed off as part of bulk update