



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

DIR : 6 - ID : 155967

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

Report Information Section

Report #: 26635	Records Management #: 2012/011678	Reporter's Reference #: 	Report Type: Final
Report Status: Closed	Sponsor's Reported Category: 	Date of Adverse Event: 	Date of Initial Report: 23/04/2012
Date of Final Report: 23/04/2012	Date of Initial TGA Action: 07/05/2012	Reviewed by DIRE: 	Date Response Received:
Date Completed: 23/05/2013	Operator at Time of Event: 	If 'Other' Operator Selected: 	Reporter Confidentiality: Yes
Source of Report: Surgeon	If 'Other' Source Selected: 	Type of Initial Action: 	
Clinical Event Information: Right PIP implatn ruptured. Patient had pain in breast (right) implant ruptured. One implant sent to TGA.			
Number of Incidents in Report: 1	Contact: 	Alternative Person Title: 	Alternative Person First Name:
Alternative Person Surname: 	Alternative Person Phone: 	Alternative Person Fax: 	

Patient Information

Sex: [REDACTED]	Weight: [REDACTED]	Age: [REDACTED]
Patient Focused Corrective Action Taken: 		
Patient History: 		
Patient Outcome/Consequences: 		
Other Devices Involved: 		

Submitting Reporter Section

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

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

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

Device Information Section

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

Usage of Device: Single Use	Software Version:		
Model #:	Serial #:	Batch #:	Lot #:
Purchase Date:	Expiry Date:	Date of Implant: 01/01/2002	Date of Explant: 18/04/2012
Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
Access Contact Phone:	Access Contact Fax:		

Manufacturer Information Section

Manufacturer Name: Poly Implant Protheses (Pip) SA	Manufacturer Client Id: 29265	Address 1:	
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: 08/05/2012	Assessed By:			
Sample Received: No	Sterile: Yes	Reusable: No	Single Use: Yes	
Potential Effect: Serious Injury	Actual Effect: Serious Injury	Injured Party: Patient		
Risk Frequency: Rarely	Risk Severity: Serious	Risk Detectability: Occasionally	Classification: Routine	Exclude report from DIRE: <input type="checkbox"/>
DIRE Meeting Notes:				

Sponsor Information Section

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

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
Additional Info form sent	08/05/2012				
Reporter Notification Sent	17/05/2012				
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 : 35671

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority
35671	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