



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

DIR : 6 - ID : 155966

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

Report Information Section

Report #: 26634	Records Management #: 2012/011679	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: No
Source of Report: Surgeon	If 'Other' Source Selected:	Type of Initial Action:	
Clinical Event Information: Ruptured implants right breast implant only (MRI). Patient had PIP ruptured implant.			
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:	Weight:	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	Company/Institution:
Position: Cosmetic Plastic Surgeon	Address 1: [REDACTED]	Address 2: [REDACTED]	Town/Suburb: [REDACTED]	State: [REDACTED]	
Country: [REDACTED]	Postcode: [REDACTED]	Phone: [REDACTED]	Mobile: [REDACTED]	Fax: [REDACTED]	
	Email: drpouw@[REDACTED].[REDACTED].[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
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Search Reporter By Surname:	Initial Reporter #:		
Title: [REDACTED]	First Name: [REDACTED]	Surname: [REDACTED]	
Position:	Company/Institution:		
Address 1:	Address 2:	Town/Suburb:	State:
Postcode:	Phone:	Fax:	Mobile:
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 #:
 185 (l) & 1467 (r) 53705 (l) & 35105 (r)
 Purchase Date: Expiry Date: Date of Implant: Date of Explant:
 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:
 Date of Supplier Contact: Contact Title: Contact First Name: No
 Contact Phone: Contact Fax: Contact Surname:

Statistics Checklist Section

Date: Assessed By:
 08/05/2012
 Sample Received: Sterile: Reusable: Single Use:
 No Yes No Yes
 Potential Effect: Actual Effect: Injured Party:
 Serious Injury Not Known Patient
 Risk Frequency: Risk Severity: Risk Detectability: Classification: Exclude report from DIRE:
 Rarely Serious Occasionally Routine

Sponsor Information Section

Search Sponsors: Name: Client #:
 medical vision Medical Vision Australia Pty Ltd :29703
 Attention To: Address 1: Address 2: Town/Suburb:
 99 King William Street KENT TOWN
 State: Postcode: Phone: Fax:
 SA 5067 (08) 8132 0300 (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 #
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Related DIR Information - Click **New** to begin entering information.

Incident Details

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

Correspondence Type	Date Sent	Date Response Expected	Date Received	Sponsor's Response	Investigator's Notes
Additional Information Form Sent	08/05/2012	19/05/2012			
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 : 35670

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority
35670	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