



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

DIR : 2 - ID : 140419

Released by Theta Technologies on 26/06/1985 21:02:22

Report Information Section

Report # : 22028	Records Management # : 2010/015587	Reporter's Reference # : [Redacted]	Report Type: Final
Report Status: Closed	Sponsor's Reported Category: [Redacted]	Date of Adverse Event: §22 [Redacted]	Date of Initial Report: [Redacted]
Date of Final Report: 23/09/2010	Date of Initial TGA Action: 24/09/2010	Reviewed by DIRE: [Redacted]	Date Response Received: 27/10/2010
Date Completed: 03/11/2010	Operator at Time of Event: [Redacted]	If 'Other' Operator Selected: [Redacted]	Reporter Confidentiality: No
Source of Report: Sponsor	If 'Other' Source Selected: [Redacted]	Type of Initial Action: For IRIS Meeting	

Clinical Event Information:

This silicone gel implant was found to have ruptured [Redacted] after insertion.

CT scan showed silicone migration to be extracapsular with an extension into the [Redacted]

Patient developed §22 [Redacted].

Implant removed including §22 [Redacted] and §22 [Redacted]. Same silicone granulomatous deposits remain insitu replacement with saline implant planned.

Report sourced from specialist.

Contact: [Redacted]	Alternative Person Title: [Redacted]	Alternative Person First Name: [Redacted]	Alternative Person Surname: [Redacted]
Alternative Person Phone: [Redacted]	Alternative Person Fax: [Redacted]		

Patient Information

Sex: [Redacted]	Weight: [Redacted]	Age: [Redacted]
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Patient Focused Corrective Action Taken:
[Redacted]

Patient History:
[Redacted]

Patient Outcome/Consequences:
[Redacted]

Other Devices Involved:
[Redacted]

[Redacted]

Submitting Reporter Section

Search Reporter By Surname: s22		Reporter #: [Redacted]	
Reporter Title: Dr	First Name: s22	Surname: s22	
Position: Surgeon		Company/Institution: s22	
Address 1: s22	Address 2: [Redacted]	Town/Suburb: s22	State: s22
Country: Australia	Postcode: s22	Phone: s22	Fax: s22
Mobile: [Redacted]	Email: s22		

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

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

Device Information Section

Product Exempt: No	If No, fill out ARTG No: [Redacted]	Search Device ARTG: 128767	Device ARTG #: 128767
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: [Redacted]	

Initial Device Description:			
<input type="text" value="Silicone Gel Breast Implant"/>			
Usage of Device:	Software Version:		
<input type="text"/>	<input type="text"/>		
Model #:	Serial #:	Batch #:	Lot #:
<input type="text" value="MLPX350"/>	<input type="text" value="12920542"/>	<input type="text" value="1473870"/>	<input type="text"/>
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Access Contact Phone:	Access Contact Fax:		
<input type="text"/>	<input type="text"/>		

Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:	Address 1:	
<input type="text" value="Inamed Pty Ltd T/A Inamed Aesthetics Pty Ltd"/>	<input type="text" value="s22"/>	<input type="text"/>	
Address 2:	Town/Suburb:	State/Province:	Country:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Postcode:	Phone:	Fax:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Email:	Manufacturer Informed:	Date Aware of Adverse Event:	
<input type="text"/>	<input type="text" value="Yes"/>	<input type="text"/>	
Contact Title:	Contact First Name:	Contact Surname:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	

Supplier Information Section

Supplier Name:	Address 1:	Address 2:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Town/Suburb:	State:	Postcode:	Phone:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Fax:	Email:	Supplier Informed:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Contact Phone:	Contact Fax:		
<input type="text"/>	<input type="text"/>		

Statistics Checklist Section

Date:	Assessed By:			
Sample Received:	Sterile:	Reusable:	Single Use:	
No	No	No		
Potential Effect:	Actual Effect:	Injured Party:		
Serious Injury	Serious Injury	Patient		
Risk Frequency:	Risk Severity:	Risk Detectability:	Classification:	Exclude report from DIRE:
			Routine	

Sponsor Information Section

Search Sponsors:	Name:	Client #:	
Al	Allergan Australia Pty Limited	17	
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22	Locked Bag 1514		PYMBLE
State:	Postcode:	Phone:	Fax:
NSW	2073	s22	02 9498 0299
Email:			
s22@allergan.com			

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
Letter		19/10/2010			Overdue Sponsor Response - > 10 Days
Receipt Acknowledgement	01/10/2010				S:\DATA\IRS\PRD\POSTMAKT\INVESTIG\DIR\RN22028.DOC
Sponsor Notification	01/10/2010				S:\DATA\IRS\PRD\POSTMAKT\INVESTIG\DIR\SN22028.DOC
Completion Notification	03/11/2010				S:\DATA\IRS\PRD\POSTMAKT\INVESTIG\DIR\RC22028.DOC
Completion Notification	03/11/2010				S:\DATA\IRS\PRD\POSTMAKT\INVESTIG\DIR\SC22028.DOC

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
Mechanical		

Cause Details

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

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested
No further action	

Recall Number:

Investigation Summary:

The reported statistics for this model (MLP 350) were reviewed, the current worldwide rupture rate for this model is 0.338% and the rupture rate in Australia is 0.776%. The current worldwide silicone migration/extravasations rate for this model is 0.048% and 0.155% in Australia. Gel rupture is a known possible complication with this type of device. A warning regarding gel rupture is included in the products instructions for use. 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.

Flow Details : DIR-REQ - Device Incident Request : 30400

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
30400	DIR-REQ		Closed	theta	IRIS Coordinator	03/11/2010	Normal	0

Signature Details

Role	IRIS Investigator
User	theta - Theta Technologies
Signed At	03/11/2010 00:00:00
Comment	Automatically signed off closed DIR forms as part of data migration



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

DIR : 2 - ID : 141675

Released by Theta Technologies on 26/06/1985 21:02:22

Report Information Section			
Report #:	Records Management #:	Reporter's Reference #:	Report Type:
23328	2011/007043		Final
Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed		s22	03/05/2011
Date of Final Report:	Date of Initial TGA Action:	Reviewed by DIRE:	Date Response Received:
03/05/2011	03/05/2011		30/05/2011
Date Completed:	Operator at Time of Event:	If 'Other' Operator Selected:	Reporter Confidentiality:
09/06/2011			No
Source of Report:	If 'Other' Source Selected:	Type of Initial Action:	
Specialist		For IRIS Meeting	
Clinical Event Information:			
<p>410FM Style breast implant had been causing pain in the left breast for a few years and eventually the patient elected to have them removed and replaced to try and reduce the pain.</p> <p>At surgery the left breast implant was found to be replaced (with no history of trauma) at s22</p> <p>Removal and replacement seems to have solved the problem of burning pain.</p> <p>Report sourced from Specialist.</p>			
Contact:	Alternative Person Title:	Alternative Person First Name:	Alternative Person Surname:
Alternative Person Phone:	Alternative Person Fax:		
Patient Information			
Sex:	Weight:	Age:	
Patient Focused Corrective Action Taken:			
Patient History:			
Patient Outcome/Consequences:			
Other Devices Involved:			

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Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
<input type="text" value="§22"/>	<input type="text"/>		
Reporter Title:	First Name:	Surname:	
<input type="text" value="Dr"/>	<input type="text" value="§22"/>	<input type="text" value="§22"/>	
Position:	Company/Institution:		
<input type="text" value="Plastic Surgeon"/>	<input type="text"/>		
Address 1:	Address 2:	Town/Suburb:	State:
<input type="text" value="§22"/>	<input type="text" value="§22"/>	<input type="text" value="§22"/>	<input type="text" value="§22"/>
Country:	Postcode:	Phone:	Fax:
<input type="text" value="Australia"/>	<input type="text"/>	<input type="text" value="§22"/>	<input type="text" value="§22"/>
Mobile:	Email:		
<input type="text"/>	<input type="text" value="§22"/>		

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

As Above?:	<i>If No, fill out the following:</i>	Initial Reporter Confidential:	
<input type="text"/>		<input type="text"/>	
Search Reporter By Surname:	Initial Reporter #:		
<input type="text"/>	<input type="text"/>		
Title:	First Name:	Surname:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Position:	Company/Institution:		
<input type="text"/>	<input type="text"/>		
Address 1:	Address 2:	Town/Suburb:	State:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Postcode:	Phone:	Fax:	Mobile:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Email:	<input type="text"/>		
<input type="text"/>			

Device Information Section

Product Exempt:	<i>If No, fill out ARTG No:</i>	Search Device ARTG:	Device ARTG #:
<input type="text" value="No"/>		<input type="text" value="171475"/>	<input type="text" value="171475"/>
Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN Code:
<input type="text" value="Medical Device"/>	<input type="text" value="Included"/>	<input type="text" value="Class III"/>	<input type="text" value="36197"/>
GMDN Text:	Brand Name:		
<input type="text"/>	<input type="text"/>		

Prosthesis, internal, mammary, gel filled			
Initial Device Description:			
Breast Implant - Silicone			
Usage of Device:		Software Version:	
Model #:		Serial #:	Batch #:
5T-410mm		11535879	
Purchase Date:		Expiry Date:	Date of Implant:
Reported Device Location:		Access Contact Title:	Access Contact First Name:
Access Contact Phone:		Access Contact Fax:	
Manufacturer Information Section			
Manufacturer Name:		Manufacturer Client Id:	Address 1:
Allergan		s22	
Address 2:		Town/Suburb:	State/Province:
Postcode:		Phone:	Fax:
Email:		Manufacturer Informed:	Date Aware of Adverse Event:
		No	
Contact Title:		Contact First Name:	Contact Surname:
Supplier Information Section			
Supplier Name:		Address 1:	Address 2:
Town/Suburb:		State:	Postcode:
Fax:		Email:	
Date of Supplier Contact:		Contact Title:	Contact First Name:
Contact Phone:		Contact Fax:	

Statistics Checklist Section

Date:	Assessed By:			
<input type="text"/>	<input type="text"/>			
Sample Received:	Sterile:	Reusable:	Single Use:	
<input type="text" value="No"/>	<input type="text" value="No"/>	<input type="text" value="No"/>	<input type="text"/>	
Potential Effect:	Actual Effect:	Injured Party:		
<input type="text" value="Serious Injury"/>	<input type="text" value="Serious Injury"/>	<input type="text" value="Patient"/>		
Risk Frequency:	Risk Severity:	Risk Detectability:	Classification:	Exclude report from DIRE:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text" value="Routine"/>	<input type="text"/>

Sponsor Information Section

Search Sponsors:	Name:	Client #:	
<input type="text" value="AI"/>	<input type="text" value="Allergan Australia Pty Limited"/>	<input type="text" value="17"/>	
Attention To:	Address 1:	Address 2:	Town/Suburb:
<input type="text" value="s22"/>	<input type="text" value="Locked Bag 1514"/>	<input type="text"/>	<input type="text" value="PYMBLE"/>
State:	Postcode:	Phone:	Fax:
<input type="text" value="NSW"/>	<input type="text" value="2073"/>	<input type="text" value="s22"/>	<input type="text" value="02 9498 0292"/>
Email:			
<input type="text" value="s22@allergan.com"/>			

Investigation Information Section

Device Analysis Results:	
<input type="text"/>	
Corrective/Preventative Actions:	
<input type="text"/>	
Details of Similar Events:	
<input type="text"/>	
Number of Similar Events:	Rate of Similar Events:
<input type="text"/>	<input type="text"/>
Countries Similar Events Also Occurred:	
<input type="text"/>	
Additional Comments:	
<input type="text"/>	

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
Receipt Acknowledgement	16/05/2011				D:\TEMP\DIR\RN23328.DOC
Sponsor Notification	31/05/2011				D:\TEMP\DIR\SN23328.DOC
Completion Notification	09/06/2011				D:\TEMP\DIR\RC23328.DOC
Completion Notification	09/06/2011				D:\TEMP\DIR\SC23328.DOC

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
Mechanical		

Cause Details

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

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested
No further action	

Recall Number:

Investigation Summary:

Requested Pain and Rupture rates from sponsor. Pain rate is 0.142% (Worldwide) and Rupture Rate is 0.071% (Worldwide).

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

Flow Details : DIR-REQ - Device Incident Request : 31656

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
31656	DIR-REQ		Closed	s22	OPR Administration User	05/08/2015	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	05/08/2015 12:05:53	
Comment		



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

DIR : 2 - ID : 141267

Released by Theta Technologies on 26/06/1985 21:02:22

Report Information Section

Report #: 22910	Records Management #: 2011/002643	Reporter's Reference #: 	Report Type: Final
Report Status: Closed	Sponsor's Reported Category: 	Date of Adverse Event: §22	Date of Initial Report: 04/01/2011
Date of Final Report: 04/01/2011	Date of Initial TGA Action: 24/02/2011	Reviewed by DIRE: 	Date Response Received:
Date Completed: 03/03/2011	Operator at Time of Event: 	If 'Other' Operator Selected: 	Reporter Confidentiality: No
Source of Report: Nurse	If 'Other' Source Selected: 	Type of Initial Action: For IRIS Meeting	

Clinical Event Information:

Surgeon asked for a 410 Breast Implant.

When checking item glanced at box and proceeded to explain to scout nurse how to open item. Implanted item.

When checking notes after procedure realised it was the wrong size. Implant he wanted was a style 'Access 410' and size 410g. He initially implanted an 'Access 410 385g.

§22

Report sourced from Private Nurse.

Contact: 	Alternative Person Title: 	Alternative Person First Name: 	Alternative Person Surname:
Alternative Person Phone: 	Alternative Person Fax: 		

Patient Information

Sex: 	Weight: 	Age:
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Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname: §22		Reporter #: 	
Reporter Title: 	First Name: §22	Surname: §22	
Position: Perioperative Services Manager		Company/Institution: §22	
Address 1: §22	Address 2: 	Town/Suburb: §22	State: §22
Country: Australia	Postcode: §22	Phone: §22	Fax: §22
Mobile: 	Email: §22		

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

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

Device Information Section

Product Exempt: No	<i>If No, fill out ARTG No:</i>	Search Device ARTG: 169956	Device ARTG # : 169956
Therapeutic Licence Type: Medical Device	Product Licence Category: Included	Device Class: Class III	GMDN Code: 45417
GMDN Text: Prosthesis, mammary, internal, gel/saline-filled, inflatable		Brand Name: 	

Initial Device Description:			
<input type="text" value="Breast Implant"/>			
Usage of Device:	Software Version:		
<input type="text"/>	<input type="text"/>		
Model #:	Serial #:	Batch #:	Lot #:
<input type="text" value="Access 410"/>	<input type="text" value="71340007"/>	<input type="text" value="Lot.#: 09MSM0032"/>	<input type="text"/>
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Access Contact Phone:	Access Contact Fax:		
<input type="text"/>	<input type="text"/>		

Manufacturer Information Section

Manufacturer Name:	Manufacturer Client Id:	Address 1:	
<input type="text" value="Allergan"/>	<input type="text" value="s22"/>	<input type="text"/>	
Address 2:	Town/Suburb:	State/Province:	Country:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Postcode:	Phone:	Fax:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Email:	Manufacturer Informed:	Date Aware of Adverse Event:	
<input type="text"/>	<input type="text" value="No"/>	<input type="text"/>	
Contact Title:	Contact First Name:	Contact Surname:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	

Supplier Information Section

Supplier Name:	Address 1:	Address 2:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Town/Suburb:	State:	Postcode:	Phone:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Fax:	Email:		Supplier Informed:
<input type="text"/>	<input type="text"/>		<input type="text"/>
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Contact Phone:	Contact Fax:		
<input type="text"/>	<input type="text"/>		

Statistics Checklist Section

Date:	Assessed By:			
Sample Received:	Sterile:	Reusable:	Single Use:	
No	No	No		
Potential Effect:	Actual Effect:	Injured Party:		
Temporary Injury	Temporary Injury	Patient		
Risk Frequency:	Risk Severity:	Risk Detectability:	Classification:	Exclude report from DIRE:
			Routine	

Sponsor Information Section

Search Sponsors:	Name:	Client #:	
Al	Allergan Australia Pty Limited	17	
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22	Locked Bag 1514		PYMBLE
State:	Postcode:	Phone:	Fax:
NSW	2073	s22	02 9498 0292
Email:			
s22@allergan.com			

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
Completion Notification	03/03/2011				S:\DATA\IRS\PRD\POSTMAKT\INVESTIG\DIR\RC22910.DOC
Completion Notification	03/03/2011				S:\DATA\IRS\PRD\POSTMAKT\INVESTIG\DIR\SC22910.DOC

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
Labelling/Instructions for Use	Packaging Markings Issue	

Cause Details

Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected
Not product related		

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested
Not investigated	

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.

Flow Details : DIR-REQ - Device Incident Request : 31248

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
31248	DIR-REQ		Closed	theta	IRIS Coordinator	03/03/2011	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	22/09/2015 14:01:33	
Comment	Automatically signed off closed DIR forms as part of data migration	



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

DIR : 2 - ID : 142672

Released by Theta Technologies on 26/06/1985 21:02:22

Report Information Section

Report #: 24356	Records Management #: 2011/012923	Reporter's Reference #: 0035757/AZ	Report Type: Final
Report Status: Closed	Sponsor's Reported Category:	Date of Adverse Event: §22	Date of Initial Report: 25/07/2011
Date of Final Report: 25/07/2011	Date of Initial TGA Action: 24/08/2011	Reviewed by DIRE:	Date Response Received: 16/09/2011
Date Completed: 20/09/2011	Operator at Time of Event:	If 'Other' Operator Selected:	Reporter Confidentiality: No
Source of Report: Sponsor	If 'Other' Source Selected:	Type of Initial Action: For IRIS Meeting	

Clinical Event Information:

Implant Date: §22
 Explant Date: §22

Second implant needed to remove for §22.
 Full capsulectomy and implant removed §22.

Pathology review: §22
 §22

Reported event description to Allergan as follows:
 §22 Breast reconstruction.
 §22 Lump in right breast - found in capsule - Implant removed and replaced
 Diagnosis: Anaplastic T Cell Lymphoma. Date of event first notice: §22

Device not returned to company.

Similar events:
 Yes

Report sourced from Sponsor.

Contact:	Alternative Person Title:	Alternative Person First Name:	Alternative Person Surname:
Alternative Person Phone:	Alternative Person Fax:		

Patient Information

Sex:	Weight:	Age:
------	---------	------

Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:

Reporter #:

s22

Reporter Title:

First Name:

Surname:

Ms

s22

s22

Position:

Company/Institution:

Regulatory Affairs Officer

Allergan Australia

Address 1:

Address 2:

Town/Suburb:

State:

Allergan Australia

Level 4/810 Pacific Hwy

Gordon

NSW

Country:

Postcode:

Phone:

Fax:

Australia

2072

s22

9498 0299

Mobile:

Email:

s22 allergan.com

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:

Search Reporter By Surname:

Initial Reporter #:

Title:

First Name:

Surname:

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: 128764	Device ARTG #: 128764
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:	
Initial Device Description: Breast Implant (mfr# 0035757/AZ)			
Usage of Device:	Software Version:		
Model #: Style 410FF	Serial #:	Batch #:	Lot #:
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: Inamed Pty Ltd T/A Inamed Aesthetics Pty Ltd		Manufacturer Client Id: s22	Address 1:
Address 2:	Town/Suburb:	State/Province:	Country:
Postcode:	Phone:	Fax:	
Email:	Manufacturer Informed: No		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:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Fax: <input type="text"/>	Email: <input type="text"/>	Supplier Informed: <input type="text"/>	
Date of Supplier Contact: <input type="text"/>	Contact Title: <input type="text"/>	Contact First Name: <input type="text"/>	Contact Surname: <input type="text"/>
Contact Phone: <input type="text"/>	Contact Fax: <input type="text"/>		

Statistics Checklist Section

Date: <input type="text"/>	Assessed By: <input type="text"/>			
Sample Received: <input type="text"/>	Sterile: <input type="text"/>	Reusable: <input type="text"/>	Single Use: <input type="text"/>	
Potential Effect: <input type="text"/>	Actual Effect: <input type="text"/>	Injured Party: <input type="text"/>		
Risk Frequency: <input type="text"/>	Risk Severity: <input type="text"/>	Risk Detectability: <input type="text"/>	Classification: <input type="text"/>	Exclude report from DIRE: <input type="text"/>

Sponsor Information Section

Search Sponsors: <input type="text"/>	Name: <input type="text"/>	Client #: <input type="text"/>	
Attention To: <input type="text"/>	Address 1: <input type="text"/>	Address 2: <input type="text"/>	Town/Suburb: <input type="text"/>
State: <input type="text"/>	Postcode: <input type="text"/>	Phone: <input type="text"/>	Fax: <input type="text"/>
Email: <input type="text"/>			

Investigation Information Section

Device Analysis Results: <input type="text"/>	
Corrective/Preventative Actions: <input type="text"/>	
Details of Similar Events: <input type="text"/>	
Number of Similar Events: <input type="text"/>	Rate of Similar Events: <input type="text"/>

<input type="text"/>	<input type="text"/>
----------------------	----------------------

Countries Similar Events Also Occurred:

<input type="text"/>

Additional Comments:

<input type="text" value="7.5.12: This is a duplicate report of one of the cases presented in DIR 21041"/>
--

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
Sponsor Notification	02/09/2011				D:\TEMP\DIR\SN24356.DOC
Completion Notification	20/09/2011				D:\TEMP\DIR\RC24356.DOC
Completion Notification	20/09/2011				D:\TEMP\DIR\SC24356.DOC

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
Mechanical		

Cause Details

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

Unable to confirm complaint		
Outcome Details		
Outcome of Investigation	If Additional Outcome Detail Requested	
No further action		

Recall Number:

Investigation Summary:

The sponsor was requested to provide the rates of occurrence for similar events.

There has been one other confirmed similar incident of ALCL between 01/01/2004 to 13/09/2011 out of a distribution of 1842 devices in Australia (0.1%) and 22 727 devices worldwide.

The sponsor is currently undertaking ongoing collaboration with expert pathologists with experience in diagnosis of lymphomas to facilitate evaluation of any available tissue or cytology samples and has a strategy and communication plan in place to share all ongoing developments with the physician community and regulatory bodies.

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.

Flow Details : DIR-REQ - Device Incident Request : 32653

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
32653	DIR-REQ		Closed	s22	OPR Administration User	08/10/2015	Normal	0

Signature Details

Role	IRIS Investigator
User	s22
Signed At	08/10/2015 11:38:04
Comment	



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

DIR : 6 - ID : 151781

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

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
25941	2012/007830	0049481/AZ	Final
Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed			11/03/2012
Date of Final Report:	Date of Initial TGA Action:	Reviewed by DIRE:	Date Response Received:
11/03/2012	13/03/2012	20/03/2012	
Date Completed:	Operator at Time of Event:	If 'Other' Operator Selected:	Reporter Confidentiality:
10/11/2014			Yes
Source of Report:	If 'Other' Source Selected:	Type of Initial Action:	
Patient		For IRIS Meeting	

Clinical Event Information:

Was diagnosed in s22 with DCIS in left breast.

Surgeon A performed s22 later had s22 and s22 (Mcghan Silicone implants).

Surgeon B s22 - ? - s22 right breast ruptured (MRI).

Manufacturer contacted by Dr on removal of implant and examination of implant they have offered to pay replacement depending on result of examination valued at s22

s22

Please advice me on this as I am very concerned as to what the leakage is doing to my body.

Follow-up: Allergan Australia is in receipt of follow up information received to company on s22 from patient (Initials s22 with diagnositic Imaging results. Please find with attachment to this report.

Allergan has attempted to obtain follow-up information with Dr s22 on the 28MAY12, 8JUN12, 21JUN12. Right side device was explanted on the s22 by Dr s22. Device was returned to company and is presently undergoing Laboratory Analysis Testing.

A DIR report was submitted to the TGA on 20JUN12 relating to this case (25941).

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:
Female		s22 years

Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:

Reporter #:

Reporter Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Country:

Postcode:

Phone:

Fax:

Mobile:

Email:

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:

Search Reporter By Surname:

Initial Reporter #:

Title:

First Name:

Surname:

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: 126554	Device ARTG #: 126554	
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: McGhan Silicone Breast Implant		
Initial Device Description: McGhan Silicone Breast Implant				
Usage of Device: Single Use	Software Version:			
Model #:	Serial #:	Batch #:	Lot #:	
Purchase Date:	Expiry Date:	Date of Implant: s22	Date of Explant: s22	
Reported Device Location: With Supplier	Access Contact Title:	Access Contact First Name:	Access Contact Surname:	
Access Contact Phone:	Access Contact Fax:			
Manufacturer Information Section				
Manufacturer Name: Allergan		Manufacturer Client Id: s22	Address 1:	
Address 2:	Town/Suburb:	State/Province:	Country:	
Postcode:	Phone:	Fax:		
Email:		Manufacturer Informed: Yes	Date Aware of Adverse Event: 20/04/2012	
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:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Contact Phone:	Contact Fax:		
<input type="text"/>	<input type="text"/>		

Statistics Checklist Section

Date:	Assessed By:			
<input type="text" value="13/03/2012"/>	<input type="text" value="s22"/>			
Sample Received:	Sterile:	Reusable:	Single Use:	
<input type="text" value="No"/>	<input type="text" value="Yes"/>	<input type="text" value="No"/>	<input type="text" value="Yes"/>	
Potential Effect:	Actual Effect:	Injured Party:		
<input type="text" value="Serious Injury"/>	<input type="text" value="Serious Injury"/>	<input type="text" value="Patient"/>		
Risk Frequency:	Risk Severity:	Risk Detectability:	Classification:	Exclude report from DIRE:
<input type="text" value="Unlikely"/>	<input type="text" value="Serious"/>	<input type="text" value="Occasionally"/>	<input type="text" value="Routine"/>	<input type="checkbox"/>
DIRE Meeting Notes:				
<input type="text" value="Discussed at outstanding DIR meeting. Agreed to close."/>				

Sponsor Information Section

Search Sponsors:	Name:	Client #:	
<input type="text" value="Allergan"/>	<input type="text" value="Allergan Australia Pty Ltd"/>	<input type="text" value="17"/>	
Attention To:	Address 1:	Address 2:	Town/Suburb:
<input type="text" value="s22"/>	<input type="text"/>	<input type="text"/>	<input type="text" value="PYMBLE"/>
State:	Postcode:	Phone:	Fax:
<input type="text" value="NSW"/>	<input type="text" value="2073"/>	<input type="text" value="s22"/>	<input type="text" value="(02) 9498 0292"/>
Email:			
<input type="text" value="s22@allergan.com"/>			

Investigation Information Section

Device Analysis Results:	
<input type="text"/>	
Corrective/Preventative Actions:	
<input type="text"/>	
Details of Similar Events:	
<input type="text"/>	

Number of Similar Events: <input type="text"/>	Rate of Similar Events: <input type="text"/>
Countries Similar Events Also Occurred: <input type="text"/>	
Additional Comments: <input type="text"/>	

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
Questionnaire sent	04/06/2012	18/06/2012	22/06/2012		
Reporter Notification sent	04/06/2012				
Completion Letter	10/11/2014	21/11/2014			See TRIM reference R14/1153458 and email R14/1153482

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
Mechanical	Leak	

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
Reviewed, No Further Action Required	

Recall Number:

Investigation Summary:

The potential for a rupture to a breast implant is a known complication and is listed in the instructions for use document. 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.

This report has been entered into the Medical Device Incident Report Investigation Scheme (IRIS) database. The aim of the Medical Device Incident Report Investigation Scheme (IRIS) is to improve the standard of medical devices and to reduce the number and severity of incidents with devices in Australia, through voluntary cooperation between medical device users, industry and government.

I have noted that your report mentions a refund towards the cost of the device. The TGA cannot assist you with refunds, however you can contact the Australian Competition and Consumer Commission (ACCC) which may be helpful in assisting you with that issue. In addition, the TGA does not regulate clinical practice and is not able to provide clinical advice. You can contact your suregon or the Health Care Complaint Commission (HCCC) of your state for further information about this issue.

As stated earlier, the TGA will continue to monitor the rate of implant rupture associated with this device. Please do not hesitate to contact the TGA if you require any further details.

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		DIR 25941 - Questionnaire Letter		92 Form	
FILE		DIR 25941 - Questionnaire Letter_PS_contributi...		102 Form	
FILE		MCGHAN		3318 Form	
FILE		RMR Single s22		993 Form	

Flow Details : DIR-REQ - Device Incident Request : 34739

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
----	------	----------	--------	-------------	-------------	-------------	----------	--------

34739

DIR-REQ

Closed

brogac

OPR Administration User

11/11/2014

Document 5
Normal 0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	10/11/2014 15:47:43	
Comment		



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

DIR : 2 - ID : 142890

Released by Theta Technologies on 26/06/1985 21:02:22

Report Information Section			
Report #: 24585	Records Management #: 2011/014636	Reporter's Reference #: 0037204/AZ	Report Type: Final
Report Status: Closed	Sponsor's Reported Category:	Date of Adverse Event: s22	Date of Initial Report: 02/09/2011
Date of Final Report: 02/09/2011	Date of Initial TGA Action: 26/09/2011	Reviewed by DIRE:	Date Response Received:
Date Completed: 26/10/2011	Operator at Time of Event:	If 'Other' Operator Selected:	Reporter Confidentiality: No
Source of Report: Sponsor	If 'Other' Source Selected:	Type of Initial Action: For IRIS Meeting	
Clinical Event Information: Implant Date: s22 Explant Date: TBA. On 08/06/2011 HCP reports to company a female with Breast Implants inserted in s22 underwent "s22". HCP performed a Ultrasound on the s22 and confirmed a "internal rupture of left breast". There is no abnormality seen in the breast tissue on either side. s22. Explant date to be confirmed. Left side Catalog number s22 Left side Lot Number s22 Patient underwent a repair of a s22 on the s22 Patient has completely recovered from her s22. Patient presented with s22. Imaging identified as a s22. s22 Medication as follows: s22 s22 Rupture complaints received: Australia 2.65% ANZ 2.89% Worldwide 2022% Report sourced from sponsor.			
Contact:	Alternative Person Title:	Alternative Person First Name:	Alternative Person Surname:
Alternative Person Phone:	Alternative Person Fax:		

Patient Information			
Sex:	Weight:	Age:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Patient Focused Corrective Action Taken:			
<input type="text"/>			
Patient History:			
<input type="text"/>			
Patient Outcome/Consequences:			
<input type="text"/>			
Other Devices Involved:			
<input type="text"/>			
Submitting Reporter Section			
Search Reporter By Surname:	Reporter #:		
<input type="text" value="s22"/>	<input type="text"/>		
Reporter Title:	First Name:	Surname:	
<input type="text" value="Ms"/>	<input type="text" value="s22"/>	<input type="text" value="s22"/>	
Position:	Company/Institution:		
<input type="text" value="Regulatory Affairs Officer"/>	<input type="text" value="Allergan Australia"/>		
Address 1:	Address 2:	Town/Suburb:	State:
<input type="text" value="Allergan Australia"/>	<input type="text" value="Level 4/810 Pacific Hwy"/>	<input type="text" value="Gordon"/>	<input type="text" value="NSW"/>
Country:	Postcode:	Phone:	Fax:
<input type="text" value="Australia"/>	<input type="text" value="2072"/>	<input type="text" value="s22"/>	<input type="text" value="9498 0299"/>
Mobile:	Email:		
<input type="text"/>	<input type="text" value="s22@allergan.com"/>		
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:
<input type="text"/>	<input type="text"/>		<input type="text"/>
Search Reporter By Surname:	Initial Reporter #:		
<input type="text"/>	<input type="text"/>		
Title:	First Name:	Surname:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Position:	Company/Institution:		
<input type="text"/>	<input type="text"/>		
Address 1:	Address 2:	Town/Suburb:	State:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Postcode:	Phone:	Fax:	Mobile:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Email:				
<input type="text"/>				
Device Information Section				
Product Exempt:	<i>If No, fill out ARTG No:</i>	Search Device ARTG:	Device ARTG #:	
No		128767	128767	
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				
Initial Device Description:				
McGhan Breast Implant - (mfr ref: 0037204/AZ)				
Usage of Device:	Software Version:			
<input type="text"/>	<input type="text"/>			
Model #:	Serial #:	Batch #:	Lot #:	
27-110301	YW9566	<input type="text"/>	<input type="text"/>	
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Access Contact Phone:	Access Contact Fax:			
<input type="text"/>	<input type="text"/>			
Manufacturer Information Section				
Manufacturer Name:	Manufacturer Client Id:	Address 1:		
Allergan	s22	<input type="text"/>		
Address 2:	Town/Suburb:	State/Province:	Country:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Postcode:	Phone:	Fax:		
<input type="text"/>	<input type="text"/>	<input type="text"/>		
Email:	Manufacturer Informed:	Date Aware of Adverse Event:		
<input type="text"/>	Yes	<input type="text"/>		
Contact Title:	Contact First Name:	Contact Surname:		
<input type="text"/>	<input type="text"/>	<input type="text"/>		
Supplier Information Section				

Supplier Name:		Address 1:	Address 2:
Town/Suburb:		State:	Postcode:
Fax:		Email:	Supplier Informed:
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
Contact Phone:	Contact Fax:		

Statistics Checklist Section

Date:	Assessed By:		
Sample Received:	Sterile:	Reusable:	Single Use:
Potential Effect:	Actual Effect:	Injured Party:	
Risk Frequency:	Risk Severity:	Risk Detectability:	Classification:
			Exclude report from DIRE:

Sponsor Information Section

Search Sponsors:	Name:	Client #:
Attention To:	Address 1:	Address 2:
State:	Postcode:	Phone:
Email:		Fax:

Investigation Information Section

Device Analysis Results:
Corrective/Preventative Actions:

Details of Similar Events:		
<input type="text"/>		
Number of Similar Events:	Rate of Similar Events:	
<input type="text"/>	<input type="text"/>	
Countries Similar Events Also Occurred:		
<input type="text"/>		
Additional Comments:		
<input type="text" value="Diary Entry: 01/11 2011 - ARTG number updated as per final report received on 31/10/2011."/>		

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
Completion Notification	26/10/2011				D:\TEMP\DIR\SC24585.DOC

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
Mechanical		

Cause Details

Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected
Materials and chemistry		

Outcome Details	
Outcome of Investigation	If Additional Outcome Detail Requested
Not investigated	

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.

Flow Details : DIR-REQ - Device Incident Request : 32871

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
32871	DIR-REQ		Closed	theta	IRIS Coordinator	01/11/2011	Normal	0

Signature Details

Role	IRIS Investigator
User	s22
Signed At	02/10/2015 14:45:19
Comment	Automatically signed off closed DIR forms as part of data migration



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

DIR : 3 - ID : 145835

Released by Theta Technologies on 30/11/2011 15:13:57

Report Information Section

Report #: 25028	Records Management #: 2011/018537	Reporter's Reference #: 	Report Type: Final
Report Status: Closed	Sponsor's Reported Category: 	Date of Adverse Event: s22	Date of Initial Report: 07/12/2011
Date of Final Report: 07/12/2011	Date of Initial TGA Action: 09/12/2011	Reviewed by DIRE: 	Date Response Received:
Date Completed: 05/04/2012	Operator at Time of Event: 	If 'Other' Operator Selected: 	Reporter Confidentiality: No
Source of Report: Surgeon	If 'Other' Source Selected: 	Type of Initial Action: For IRIS Meeting	

Clinical Event Information:

Ruptured gel filled breast reconstruction implant.
Replaced with a new device.

Contact: 	Alternative Person Title: 	Alternative Person First Name: 	Alternative Person Surname:
Alternative Person Phone: 	Alternative Person Fax: 		

Patient Information

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

Submitting Reporter Section

Search Reporter By Surname: 	Reporter #:
---------------------------------	-----------------

<input type="text" value="s22"/>	<input type="text" value="5274"/>		
Reporter Title: <input type="text"/>	First Name: <input type="text" value="s22"/>	Surname: <input type="text" value="s22"/>	
Position: <input type="text" value="Surgeon"/>	Company/Institution: <input type="text" value="s22"/>		
Address 1: <input type="text"/>	Address 2: <input type="text"/>	Town/Suburb: <input type="text"/>	State: <input type="text"/>
Country: <input type="text" value="Australia"/>	Postcode: <input type="text"/>	Phone: <input type="text" value="Unknown"/>	Fax: <input type="text"/>
Mobile: <input type="text"/>	Email: <input type="text"/>		

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

As Above?: <input type="text" value="Yes"/>	<i>If No, fill out the following:</i>	Initial Reporter Confidential: <input type="text"/>	
Search Reporter By Surname: <input type="text"/>	Initial Reporter #: <input type="text"/>		
Title: <input type="text"/>	First Name: <input type="text"/>	Surname: <input type="text"/>	
Position: <input type="text"/>	Company/Institution: <input type="text"/>		
Address 1: <input type="text"/>	Address 2: <input type="text"/>	Town/Suburb: <input type="text"/>	State: <input type="text"/>
Postcode: <input type="text"/>	Phone: <input type="text"/>	Fax: <input type="text"/>	Mobile: <input type="text"/>
Email: <input type="text"/>			

Device Information Section

Product Exempt: <input type="text" value="No"/>	<i>If No, fill out ARTG No:</i>	Search Device ARTG: <input type="text" value="128763"/>	Device ARTG #: <input type="text" value="128763"/>
Therapeutic Licence Type: <input type="text" value="Medical Device"/>	Product Licence Category: <input type="text" value="Included"/>	Device Class: <input type="text" value="Class III"/>	GMDN Code: <input type="text" value="36197"/>
GMDN Text: <input type="text" value="Prosthesis, internal, mammary, gel filled"/>	Brand Name: <input type="text" value="McGhan Breast Prosthesis"/>		
Initial Device Description: <input type="text" value="McGhan Breast Prosthesis"/>			
Usage of Device: <input type="text"/>	Software Version: <input type="text"/>		

Single Use			
Model #:	Serial #:	Batch #:	Lot #:
410 FX			
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
01/03/2008		s22	s22
Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
With Reporter			
Access Contact Phone:	Access Contact Fax:		

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
Allergan		s22	
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:
Allergan Australia			
Town/Suburb:	State:	Postcode:	Phone:
Fax:	Email:		Supplier Informed:
			Yes
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
Contact Phone:	Contact Fax:		

Statistics Checklist Section

Date:	Assessed By:		
09/12/2011	s22		
Sample Received:	Sterile:	Reusable:	Single Use:

<input type="text" value="No"/>	<input type="text" value="Yes"/>	<input type="text" value="No"/>	<input type="text" value="Yes"/>
Potential Effect: <input type="text" value="Serious Injury"/>	Actual Effect: <input type="text" value="Temporary Injury"/>	Injured Party: <input type="text" value="Patient"/>	
Risk Frequency: <input type="text" value="Unlikely"/>	Risk Severity: <input type="text" value="Minor"/>	Risk Detectability: <input type="text" value="Likely"/>	Classification: <input type="text" value="Routine"/>
			Exclude report from DIRE: <input type="checkbox"/>

Sponsor Information Section

Search Sponsors: <input type="text" value="Allergan"/>	Name: <input type="text" value="Allergan Australia Pty Ltd"/>	Client #: <input type="text" value="17"/>
Attention To: <input type="text" value="s22"/>	Address 1: <input type="text" value="Locked Bag 1514"/>	Address 2: <input type="text"/>
State: <input type="text" value="NSW"/>	Postcode: <input type="text" value="2073"/>	Phone: <input type="text" value="s22"/>
Email: <input type="text" value="s22@Allergan.com"/>		Town/Suburb: <input type="text" value="PYMBLE"/>
		Fax: <input type="text" value="(02) 9498 0292"/>

Investigation Information Section

Device Analysis Results: <input type="text"/>	
Corrective/Preventative Actions: <input type="text"/>	
Details of Similar Events: <input type="text"/>	
Number of Similar Events: <input type="text"/>	Rate of Similar Events: <input type="text"/>
Countries Similar Events Also Occurred: <input type="text"/>	
Additional Comments: <input type="text"/>	

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
Questionnaire Sent	14/12/2011	04/01/2012	30/12/2011		
Reporter notification					Reporter didn't provide mail or phone details. Letter not sent.
Sponsor Completion	05/04/2012				R12/655148
Reporter Completion	05/04/2012				Not sent as no contact details provided - saved on TRIM file

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
No further action	

Recall Number:

Investigation Summary:

The TGA has reviewed this incident. The sponsor confirmed that rupture is a known complication for this device and advised that the current worldwide reported rupture rate for this implant is 0.2%. The product literature was reviewed and specifies rupture as a known risk for this implant. A post market review of breast implants is currently being

undertaken.


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.

Attachment(s) Details


Type	Open	Name	Size	Attached Within	Attached To
FILE		Attachement 1 (DIR 25028 Questionnaire	15	Form	
FILE		completed DIR 25028-ARTG#128763	164	Form	
FILE		CUI PID - DIR 25028	3241	Form	
FILE		DIR 25028, List of Complaints, Style 410FX, Ru...	11	Form	
FILE		RMF - DIR 25028	327	Form	

Flow Details : DIR-REQ - Device Incident Request : 33496

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
33496	DIR-REQ		Closed		OPR Administration User	05/04/2012	Normal	0

Signature Details

Role	IRIS Investigator
User	
Signed At	05/04/2012 10:25:35
Comment	



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

DIR : 4 - ID : 149385

Released by s22 on 12/12/2011 12:55:15

Report Information Section			
Report #: 25564	Records Management #: 2012/005708	Reporter's Reference #: 	Report Type: Final
Report Status: Closed	Sponsor's Reported Category: 	Date of Adverse Event: 	Date of Initial Report: 02/02/2012
Date of Final Report: 02/02/2012	Date of Initial TGA Action: 06/02/2012	Reviewed by DIRE: 14/02/2012	Date Response Received:
Date Completed: 27/08/2014	Operator at Time of Event: 	If 'Other' Operator Selected: 	Reporter Confidentiality: Yes
Source of Report: Patient	If 'Other' Source Selected: 	Type of Initial Action: For IRIS Meeting	
Clinical Event Information: Anaplastic large cell lymphoma left breast. Diagnosed s22 s22			
Contact: 	Alternative Person Title: 	Alternative Person First Name: 	Alternative Person Surname:
Alternative Person Phone: 	Alternative Person Fax: 		
Patient Information			
Sex: 	Weight: 	Age: 	
Patient Focused Corrective Action Taken: 			
Patient History: 			
Patient Outcome/Consequences: 			

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:		Reporter #:	
<input type="text"/>		<input type="text"/>	
Reporter Title:	First Name:	Surname:	
Ms	s22	s22	
Position:		Company/Institution:	
<input type="text"/>		<input type="text"/>	
Address 1:	Address 2:	Town/Suburb:	State:
s22	<input type="text"/>	s22	s22
Country:	Postcode:	Phone:	Fax:
Australia	s22	s22	<input type="text"/>
Mobile:	Email:		
<input type="text"/>	<input type="text"/>		

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

As Above?:	<i>If No, fill out the following:</i>	Initial Reporter Confidential:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Search Reporter By Surname:		Initial Reporter #:	
<input type="text"/>		<input type="text"/>	
Title:	First Name:	Surname:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Position:		Company/Institution:	
<input type="text"/>		<input type="text"/>	
Address 1:	Address 2:	Town/Suburb:	State:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Postcode:	Phone:	Fax:	Mobile:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Email:			
<input type="text"/>			

Device Information Section

Product Exempt:	<i>If No, fill out ARTG No:</i>	Search Device ARTG:	Device ARTG #:
<input type="text"/>	<input type="text"/>	128767	128767
Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN Code:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Medical Device	Included	Class III	36197
GMDN Text: Prosthesis, internal, mammary, gel filled		Brand Name: Inamed Breast Implants (allergan)	
Initial Device Description: Inamed Breast Implants (allergan)			
Usage of Device: Single Use	Software Version:		
Model #: 27-110361	Serial #: 11658256 & 11711854	Batch #:	Lot #: 1148082 & 1162438
Purchase Date: 20/02/2006	Expiry Date:	Date of Implant: s22	Date of Explant: s22
Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
Access Contact Phone:	Access Contact Fax:		

Manufacturer Information Section

Manufacturer Name: Allergan		Manufacturer Client Id: s22	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:
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
Contact Phone:	Contact Fax:		

<input type="text"/>	<input type="text"/>
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Statistics Checklist Section

Date: <input type="text" value="06/02/2012"/>	Assessed By: <input type="text" value="s22"/>			
Sample Received: <input type="text" value="No"/>	Sterile: <input type="text" value="Yes"/>	Reusable: <input type="text" value="No"/>	Single Use: <input type="text" value="Yes"/>	
Potential Effect: <input type="text" value="Death"/>	Actual Effect: <input type="text" value="Serious Injury"/>	Injured Party: <input type="text" value="Patient"/>		
Risk Frequency: <input type="text" value="Unlikely"/>	Risk Severity: <input type="text" value="Serious"/>	Risk Detectability: <input type="text" value="Rarely"/>	Classification: <input type="text" value="Routine"/>	Exclude report from DIRE: <input type="checkbox"/>

Sponsor Information Section

Search Sponsors: <input type="text" value="allergan"/>	Name: <input type="text" value="Allergan Australia Pty Ltd"/>	Client #: <input type="text" value="17"/>
Attention To: <input type="text" value="s22"/>	Address 1: <input type="text" value="Locked Bag 1514"/>	Address 2: <input type="text"/>
State: <input type="text" value="NSW"/>	Postcode: <input type="text" value="2073"/>	Phone: <input type="text"/>
Email: <input type="text" value="GO-Medical-Affairs@allergan.com"/>		Town/Suburb: <input type="text" value="PYMBLE"/>
		Fax: <input type="text"/>

Investigation Information Section

Device Analysis Results: <input type="text"/>	
Corrective/Preventative Actions: <input type="text"/>	
Details of Similar Events: <input type="text"/>	
Number of Similar Events: <input type="text"/>	Rate of Similar Events: <input type="text"/>
Countries Similar Events Also Occurred: <input type="text"/>	
Additional Comments: <input type="text"/>	

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
Reporter Notification Sent	13/03/2012				
Sponsor Questionnaire	19/07/2012	30/07/2012	24/08/2012	1) The number of reports for ALCL that Allergan Australia have received; 8. 2)The number of reports for ALCL that Allergan have received (worldwide number) including the reports in Australia; 86. 3) The number of breast implants supplied in Australia; and 92,486 from January 1, 2004 through July31, 2012. 4) The number of breast implants supplied worldwide, including the number supplied in Australia. 4,336,895 from January 1,2004 through July 31,2012	WW rate: 0.00198% Aust rate: 0.00864%

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
Other	Other	patient factors

Cause Details

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

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

Recall Number:

Investigation Summary:

At the time of this report the rate for this event is very low. The manufacturer and regulators are continuing to monitor this issue and should the rate begin to rise the issue will be re-investigated.

Flow Details : DIR-REQ - Device Incident Request : 34213

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
34213	DIR-REQ		Closed	s22	OPR Administration User	02/09/2014	Normal	0

Signature Details

Role	IRIS Investigator
User	s22
Signed At	02/09/2014 09:11:43
Comment	



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

DIR : 4 - ID : 150275

Released by s22 on 12/12/2011 12:55:15

Report Information Section

Report #: 25704	Records Management #: 2012/006412	Reporter's Reference #: 	Report Type: Final
Report Status: Closed	Sponsor's Reported Category: 	Date of Adverse Event: 	Date of Initial Report: 16/02/2012
Date of Final Report: 16/02/2012	Date of Initial TGA Action: 17/02/2012	Reviewed by DIRE: 	Date Response Received:
Date Completed: 15/05/2012	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:

Breast reconstruction post s22 Noticed deformity in the shape of the reconstructed breast s22 post op. found superior rupture with hernation of intact gel.
Replacement with a new prosthesis.

Contact: 	Alternative Person Title: 	Alternative Person First Name: 	Alternative Person Surname:
Alternative Person Phone: 	Alternative Person Fax: 		

Patient Information

Sex: Female	Weight: s22	Age: s22 years
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Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname: s22		Reporter #: 5387	
Reporter Title: Dr	First Name: s22	Surname: s22	
Position: Surgeon		Company/Institution: s22	
Address 1: s22	Address 2:	Town/Suburb: s22	State: s22
Country: Australia	Postcode: s22	Phone: s22	Fax:
Mobile:	Email: s22		

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

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

Device Information Section

Product Exempt: []	<i>If No, fill out ARTG No:</i>	Search Device ARTG: 171387	Device ARTG #: 171387
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: Allergan Breast Implant	
Initial Device Description: Allergan Breast Implant			

Usage of Device: Single Use	Software Version: 		
Model #: 510FX	Serial #: 13206164	Batch #: 1532586	Lot #: 11
Purchase Date: 19/03/2004	Expiry Date: 	Date of Implant: s22	Date of Explant: s22
Reported Device Location: Place of use	Access Contact Title: 	Access Contact First Name: 	Access Contact Surname:
Access Contact Phone: 	Access Contact Fax: 		

Manufacturer Information Section

Manufacturer Name: Allergan	Manufacturer Client Id: s22	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: Yes
Date of Supplier Contact: 16/02/2012	Contact Title: 	Contact First Name: 	Contact Surname:
Contact Phone: 	Contact Fax: 		

Statistics Checklist Section

Date: 	Assessed By:
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<input type="text" value="17/02/2012"/>	<input type="text" value="s22"/>			
Sample Received: <input type="text" value="No"/>	Sterile: <input type="text" value="Yes"/>	Reusable: <input type="text" value="No"/>	Single Use: <input type="text" value="Yes"/>	
Potential Effect: <input type="text" value="Serious Injury"/>	Actual Effect: <input type="text" value="Serious Injury"/>	Injured Party: <input type="text" value="Patient"/>		
Risk Frequency: <input type="text" value="Rarely"/>	Risk Severity: <input type="text" value="Serious"/>	Risk Detectability: <input type="text" value="Occasionally"/>	Classification: <input type="text" value="Routine"/>	Exclude report from DIRE: <input type="checkbox"/>

Sponsor Information Section

Search Sponsors: <input type="text" value="allergan"/>	Name: <input type="text" value="Allergan Australia Pty Ltd"/>	Client #: <input type="text" value="17"/>	
Attention To: <input type="text" value="s22"/>	Address 1: <input type="text" value="Locked Bag 1514"/>	Address 2: <input type="text"/>	Town/Suburb: <input type="text" value="PYMBLE"/>
State: <input type="text" value="NSW"/>	Postcode: <input type="text" value="2073"/>	Phone: <input type="text" value="s22"/>	Fax: <input type="text" value="(02) 9498 0292"/>
Email: <input type="text" value="s22@Allergan.com"/>			

Investigation Information Section

Device Analysis Results: <input type="text"/>	
Corrective/Preventative Actions: <input type="text"/>	
Details of Similar Events: <input type="text"/>	
Number of Similar Events: <input type="text"/>	Rate of Similar Events: <input type="text"/>
Countries Similar Events Also Occurred: <input type="text"/>	
Additional Comments: <input type="text"/>	

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
asked for ww rates	01/05/2012	12/05/2012	15/05/2012		
RC	15/05/2012				R12/830742
SC	15/05/2012				R12/830737

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
No further action	

Recall Number:

Investigation Summary:

The sponsor has provided statistics that indicate the reported rate of rupture for this implant since 2006 is 0.08% in Australia and 0.17% worldwide rate.

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

Document 9

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		Request for Information DIR 25704	352	Form	
FILE		s22 050712_Final	20	Form	

Flow Details : DIR-REQ - Device Incident Request : 34406

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
34406	DIR-REQ		Closed	s22	OPR Administration User	15/05/2012	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	15/05/2012 16:21:44	
Comment		



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

DIR : 6 - ID : 153310

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

Report Information Section

Report #: 26189	Records Management #: 2012/009113	Reporter's Reference #: 	Report Type: Final
Report Status: Closed	Sponsor's Reported Category: 	Date of Adverse Event: s22	Date of Initial Report: 28/03/2012
Date of Final Report: 28/03/2012	Date of Initial TGA Action: 30/03/2012	Reviewed by DIRE: 10/04/2012	Date Response Received:
Date Completed: 21/05/2012	Operator at Time of Event: 	If 'Other' Operator Selected: 	Reporter Confidentiality: No
Source of Report: Surgeon	If 'Other' Source Selected: 	Type of Initial Action: For IRIS Meeting	

Clinical Event Information:

Bilateral rupture of implants. Unknown cause.
Significant gel migration and associated infammation of tissue affected.
New pockets created and inmplants replaced with Cereform 360 shaped gels.

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: Female	Weight: s22	Age: s22 years
Patient Focused Corrective Action Taken: 		
Patient History: 		
Patient Outcome/Consequences: 		
Other Devices Involved: 		

Submitting Reporter Section

Search Reporter By Surname: s22		Reporter #: 5440	
Reporter Title: Dr	First Name: s22	Surname: s22	
Position: Surgeon		Company/Institution: s22	
Address 1: s22	Address 2: s22	Town/Suburb: s22	State: s22
Country: Australia	Postcode: s22	Phone: s22	Fax:
Mobile:	Email: s22		

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

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

Device Information Section

Product Exempt: No	<i>If No, fill out ARTG No:</i>	Search Device ARTG: 128767	Device ARTG #: 128767
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: CUI Round Gel Breast Implants	
Initial Device Description: CUI Round Gel Breast Implants			

Usage of Device: Single Use	Software Version: 		
Model #: 340cc	Serial #: 	Batch #: 	Lot #:
Purchase Date: 01/01/1998	Expiry Date: 	Date of Implant: s22	Date of Explant: s22
Reported Device Location: Discarded	Access Contact Title: 	Access Contact First Name: 	Access Contact Surname:
Access Contact Phone: 	Access Contact Fax: 		

Manufacturer Information Section

Manufacturer Name: Allergan	Manufacturer Client Id: s22	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: 	Assessed By:
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30/03/2012		s22	
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:
Unlikely	Minor	Likely	Routine
DIRE Meeting Notes:			Exclude report from DIRE: <input type="checkbox"/>

Sponsor Information Section

Search Sponsors:	Name:	Client #:	
allerga	Allergan Australia Pty Ltd	17	
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22	Locked Bag 1514		PYMBLE
State:	Postcode:	Phone:	Fax:
NSW	2073	s22	
Email:			
s22@allergan.com			

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
Reporter Completion	21/05/2012				R12/837113
Sponsor Completion	21/05/2012				R12/836924

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	Burst	

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
No further action	

Recall Number:

Investigation Summary:

Information received from the current sponsor of this device confirmed the reported rupture rate in Australia as 0.5% (2004 - 2011).

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.

[Document 10](#)

Flow Details : DIR-REQ - Device Incident Request : 35082

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
35082	DIR-REQ		Closed	s22	OPR Administration User	21/05/2012	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	24/09/2015 11:14:53	
Comment		



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

DIR : 6 - ID : 154614

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

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
26395	2012/011251		Final
Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed		s22	18/04/2012
Date of Final Report:	Date of Initial TGA Action:	Reviewed by DIRE:	Date Response Received:
18/04/2012	18/04/2012	24/04/2012	
Date Completed:	Operator at Time of Event:	If 'Other' Operator Selected:	Reporter Confidentiality:
02/05/2012			No
Source of Report:	If 'Other' Source Selected:	Type of Initial Action:	
Patient		For IRIS Meeting	

Clinical Event Information:

In s22 Dr supplied & implanted 2 x Inamed 410 MX Breast Implants, at the time the Device Technologies were the Australian distributor. Since then Allergan have become the Australian distributor and the implants I have are now known as NATRELLE@410 Anatomical breast implant.

On or around s22 I presented to my GP with right breast pain and concern over lumps I was feeling in the breast. At the time rupture was the furthest thought, I initially assumed it was a s22

The first day the Radiologist was open again after s22. I presented there that day and the Radiologist and subsequently the Dr reporting on the Radiologist's findings concluded that my right implant had ruptured and silicone had migrated to my lymph nodes.

On being told of this situation by the Radiologist I immediately phoned Dr and I was given an appointment date of s22

I visited Dr on s22 and he referred me for an MRI which I had on s22.

The MRI concurred with the findings of the ultrasound, both reports & films can be provided should the TGA like to see them.

On s22 I visited Dr again who advised that he could perform the breast surgery to remove and replace the implants but that I would have to speak to a specialist about the lymph nodes as this was not his specialty.

Despite the fact the manufacturer of the implants and Dr himself told me the implant had a lifetime warranty I have since learnt that the warranty does not cover any surgery cost only a replacement implant. Dr has asked me to pay him s22 to explant and replace s22

Allergan state on their Australian breast implant website, in the frequently asked questions section, that their device would not need to be replaced until after the 10 year mark, this I was prepared for, but not the s22, see <http://www.natrelle.com.au/Faq.aspx>.

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

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Patient Information

Sex:	Weight:	Age:	
Female	s22	s22 months	
Patient Focused Corrective Action Taken:			
Patient History:			
Patient Outcome/Consequences:			
I am not sure of the outcome or consequence that the ruptued implant can or will cause to my health, and if there is any Dr has not made me aware of it.			
s22			
Other Devices Involved:			

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:		
s22			
Reporter Title:	First Name:	Surname:	
Ms	s22	s22	
Position:	Company/Institution:		
Address 1:	Address 2:	Town/Suburb:	State:
s22	s22	s22	s22
Country:	Postcode:	Phone:	Fax:
	s22	s22	
Mobile:	Email:		
	s22		

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

As Above?:	<i>If No, fill out the following:</i>	Initial Reporter Confidential:
Yes		
Search Reporter By Surname:	Initial Reporter #:	
Title:	First Name:	Surname:
Position:	Company/Institution:	

Address 1: <input type="text"/>	Address 2: <input type="text"/>	Town/Suburb: <input type="text"/>	State: <input type="text"/>
Postcode: <input type="text"/>	Phone: <input type="text"/>	Fax: <input type="text"/>	Mobile: <input type="text"/>
Email: <input type="text"/>			

Device Information Section

Product Exempt: <input type="text"/>	<i>If No, fill out ARTG No:</i> <input type="text"/>	Search Device ARTG: <input type="text" value="171512"/>	Device ARTG #: <input type="text" value="171512"/>
Therapeutic Licence Type: <input type="text" value="Medical Device"/>	Product Licence Category: <input type="text" value="Included"/>	Device Class: <input type="text" value="Class III"/>	GMDN Code: <input type="text" value="36197"/>
GMDN Text: <input type="text" value="Prosthesis, internal, mammary, gel filled"/>		Brand Name: <input type="text" value="Allergan / NATRELLE® 410 Anatomical breast implant"/>	
Initial Device Description: <input type="text" value="Allergan / NATRELLE® 410 Anatomical breast implant"/>			
Usage of Device: <input type="text" value="Single Use"/>	Software Version: <input type="text"/>		
Model #: <input type="text" value="410 MX"/>	Serial #: <input type="text" value="13131903"/>	Batch #: <input type="text"/>	Lot #: <input type="text" value="1520810"/>
Purchase Date: <input type="text" value="21/01/2008"/>	Expiry Date: <input type="text"/>	Date of Implant: <input type="text" value="§22"/>	Date of Explant: <input type="text"/>
Reported Device Location: <input type="text" value="With Patient"/>	Access Contact Title: <input type="text" value="Ms"/>	Access Contact First Name: <input type="text" value="§22"/>	Access Contact Surname: <input type="text" value="§22"/>
Access Contact Phone: <input type="text" value="§22"/>	Access Contact Fax: <input type="text"/>		

Manufacturer Information Section

Manufacturer Name: <input type="text" value="Allergan"/>	Manufacturer Client Id: <input type="text" value="§22"/>	Address 1: <input type="text" value="Level 4 810 Pacific Highway"/>	
Address 2: <input type="text" value="Gordon"/>	Town/Suburb: <input type="text" value="Sydney"/>	State/Province: <input type="text" value="NSW"/>	Country: <input type="text" value="Australia"/>
Postcode: <input type="text" value="2072"/>	Phone: <input type="text" value="§22"/>	Fax: <input type="text" value="9498 0290"/>	
Email: <input type="text"/>	Manufacturer Informed: <input type="text"/>	Date Aware of Adverse Event: <input type="text"/>	
Contact Title: <input type="text"/>	Contact First Name: <input type="text"/>	Contact Surname: <input type="text"/>	

Supplier Information Section

Supplier Name:		Address 1:	Address 2:	
Dr s22		s22	s22	
Town/Suburb:	State:	Postcode:	Phone:	
s22	s22	s22	s22	
Fax:	Email:	Supplier Informed:		
s22	s22	Yes		
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:	
10/04/2012	Dr	s22	s22	
Contact Phone:	Contact Fax:			
s22	s22			

Statistics Checklist Section

Date:	Assessed By:			
18/04/2012	s22			
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:	Exclude report from DIRE:
Rarely	Serious	Occasionally	Routine	<input type="checkbox"/>
DIRE Meeting Notes:				
To be reviewed				

Sponsor Information Section

Search Sponsors:	Name:	Client #:	
allergan	Allergan Australia Pty Ltd	17	
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22	Locked Bag 1514		PYMBLE
State:	Postcode:	Phone:	Fax:
NSW	2073	s22	
Email:			
s22 @Allergan.com			

Investigation Information Section

Device Analysis Results:	
<input style="width:100%;" type="text"/>	
Corrective/Preventative Actions:	
<input style="width:100%;" type="text"/>	
Details of Similar Events:	
<input style="width:100%;" type="text"/>	
Number of Similar Events:	Rate of Similar Events:
<input style="width:100%;" type="text"/>	<input style="width:100%;" type="text"/>
Countries Similar Events Also Occurred:	
<input style="width:100%;" type="text"/>	
Additional Comments:	
<input style="width:100%;" type="text"/>	

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
Reporter completion	02/05/2012	13/05/2012			
Sponsor completion	02/05/2012	13/05/2012			

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
No further action	

Recall Number:

Investigation Summary:

The TGA has investigated this case and due to rupture being a known complication associated with breast implants, no further action will occur at this stage.

As the TGA is unable to comment on warranty issues, the reporter of this event has been advised to contact the Australian Competition and Consumer Commission (ACCC) or the Australian Society of Plastic Surgeons (ASOPS) regarding her dispute over warranty and associated costs for revision surgery.

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		Device and Service Invoice 001	433	Form Item	Report Information Section / Brand Name
FILE		Device Serial Number 001	451	Form Item	Report Information Section / Brand Name
FILE		s22 Medical Imaging Report dated 100412 001	1086	Form Item	Report Information Section / Brand Name
FILE		Superscan MRI Report 130412	709	Form Item	Report Information Section / Brand Name

Flow Details : DIR-REQ - Device Incident Request : 35350

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
35350	DIR-REQ		Closed	s22	OPR Administration User	02/05/2012	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	02/05/2012 14:51:02	
Comment		



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

DIR : 6 - ID : 154766

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

Report Information Section			
Report #: 26415	Records Management #: 2012/010634	Reporter's Reference #: 	Report Type: Final
Report Status: Closed	Sponsor's Reported Category: 	Date of Adverse Event: §22	Date of Initial Report: 19/04/2012
Date of Final Report: 19/04/2012	Date of Initial TGA Action: 19/04/2012	Reviewed by DIRE: 01/05/2012	Date Response Received:
Date Completed: 11/05/2012	Operator at Time of Event: 	If 'Other' Operator Selected: 	Reporter Confidentiality: No
Source of Report: Surgeon	If 'Other' Source Selected: 	Type of Initial Action: For IRIS Meeting	
Clinical Event Information: Complete rupture of right implant. CUI 320g smooth round gel. No other details available. Implant removed. New pocket created. New implants inserted left and right. Implant date: §22 .			
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: Female	Weight: §22	Age: §22 Patient initials: §22	
Patient Focused Corrective Action Taken: 			
Patient History: No other relevant history.			
Patient Outcome/Consequences: 			
Other Devices Involved: 			

Submitting Reporter Section

Search Reporter By Surname: s22		Reporter #: 5440	
Reporter Title: Dr	First Name: s22	Surname: s22	
Position: Surgeon		Company/Institution: s22	
Address 1: s22	Address 2: s22	Town/Suburb: s22	State: s22
Country: Australia	Postcode: s22	Phone: s22	Fax:
Mobile:	Email: s22		

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

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

Device Information Section

Product Exempt:	<i>If No, fill out ARTG No:</i>	Search Device ARTG: 126554	Device ARTG #: 126554
Therapeutic Licence Type: Medical Device	Product Licence Category: Included	Device Class: Class III	GMDN Code: 36197
GMDN Text:	Brand Name:		

Prosthesis, internal, mammary, gel filled		CUI Breast Implants, 320 Smooth Shell, Round, Gel	
Initial Device Description:			
CUI Breast Implants, 320 Smooth Shell, Round, Gel			
Usage of Device:	Software Version:		
Single Use			
Model #:	Serial #:	Batch #:	Lot #:
CUI			68127
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
			s22
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:
Allergan		s22	
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: 20/04/2012	Assessed By: §22			
Sample Received: No	Sterile: Yes	Reusable: No	Single Use: Yes	
Potential Effect: Serious Injury	Actual Effect: Temporary 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: For investigation				

Sponsor Information Section

Search Sponsors: allergan	Name: Allergan Australia Pty Ltd	Client #: 17	
Attention To:	Address 1: Locked Bag 1514	Address 2:	Town/Suburb: PYMBLE
State: NSW	Postcode: 2073	Phone:	Fax:
Email: §22@allergan.com			

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
Request for information	07/05/2012	18/05/2012	07/05/2012		See TRIM R12/780609.
Reporter Notification Sent	07/05/2012				
Reporter Completion	11/05/2012				R12/784142
Sponsor Completion	11/05/2012				

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

No further action

Recall Number:

Investigation Summary:

Information received from the current sponsor of this device confirmed the reported rupture rate in Australia as 0.5% (2004 - 2011).

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.

Flow Details : DIR-REQ - Device Incident Request : 35386

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
35386	DIR-REQ		Closed	s22	OPR Administration User	11/05/2012	Normal	0

Signature Details

Role	IRIS Investigator
User	s22
Signed At	15/07/2014 09:50:48
Comment	



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

DIR : 6 - ID : 156448

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

Report Information Section			
Report #: 26691	Records Management #: 2012/012044	Reporter's Reference #: 	Report Type: Final
Report Status: Closed	Sponsor's Reported Category: 	Date of Adverse Event: 	Date of Initial Report: 11/05/2012
Date of Final Report: 11/05/2012	Date of Initial TGA Action: 14/05/2012	Reviewed by DIRE: 22/05/2012	Date Response Received:
Date Completed: 22/05/2012	Operator at Time of Event: 	If 'Other' Operator Selected: 	Reporter Confidentiality: No
Source of Report: Surgeon	If 'Other' Source Selected: 	Type of Initial Action: For IRIS Meeting	
Clinical Event Information: Complete rupture of right implant (retropectoral). Unknown cause. Implant/gel removed and new implants inserted. Implanted: s22			
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: Female	Weight: s22	Age: s22 Patient initials: s22	
Patient Focused Corrective Action Taken: 			
Patient History: Otherwise healthy.			
Patient Outcome/Consequences: 			
Other Devices Involved: 			
Submitting Reporter Section			

Search Reporter By Surname: s22		Reporter #: 5441	
Reporter Title: Dr		First Name: s22	Surname: s22
Position: Surgeon		Company/Institution: s22	
Address 1: s22	Address 2:	Town/Suburb: s22	State: s22
Country: Australia	Postcode: s22	Phone: s22	Fax:
Mobile:	Email: s22		

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

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

Device Information Section

Product Exempt: No	<i>If No, fill out ARTG No:</i>	Search Device ARTG: 126554	Device ARTG #: 126554
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: CUI Breast Implant		
Initial Device Description: CUI Breast Implant			

Usage of Device: Single Use		Software Version: 	
Model #: CUI Round Smooth Gel 290g	Serial #: 	Batch #: 	Lot #: 119681
Purchase Date: 	Expiry Date: 	Date of Implant: 	Date of Explant: s22
Reported Device Location: 	Access Contact Title: 	Access Contact First Name: 	Access Contact Surname:
Access Contact Phone: 	Access Contact Fax: 		

Manufacturer Information Section

Manufacturer Name: Allergan		Manufacturer Client Id: s22	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:
Date of Supplier Contact: 	Contact Title: 	Contact First Name: 	Contact Surname:
Contact Phone: 	Contact Fax: 		

Statistics Checklist Section

Date: 	Assessed By:
-----------	------------------

14/05/2012		s22	
Sample Received:	Sterile:	Reusable:	Single Use:
No	Yes	No	Yes
Potential Effect:	Actual Effect:	Injured Party:	
Serious Injury	Serious Injury	Patient	
Risk Frequency:	Risk Severity:	Risk Detectability:	Classification:
Rarely	Minor	Occasionally	Routine
DIRE Meeting Notes:			Exclude report from DIRE:
Invetsigate			<input type="checkbox"/>

Sponsor Information Section

Search Sponsors:	Name:	Client #:	
allergan	Allergan Australia Pty Ltd	17	
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22			
State:	Postcode:	Phone:	Fax:
		s22	
Email:			
s22@allergan.com			

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
Reporter Completion	22/05/2012	02/06/2012			R12/845844
Sponsor Completion	22/05/2012				R12/845825

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	Burst	

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
No further action	

Recall Number:

Investigation Summary:

Information received from the current sponsor of this device confirmed the reported rupture rate in Australia as 0.5% (2004 - 2011).

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

[Document 13](#)

Flow Details : DIR-REQ - Device Incident Request : 35752

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
35752	DIR-REQ		Closed	s22	OPR Administration User	22/05/2012	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	22/05/2012 16:02:43	
Comment		



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

DIR : 6 - ID : 156612

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

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
26729	2012/012044		Final
Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed		s22	15/05/2012
Date of Final Report:	Date of Initial TGA Action:	Reviewed by DIRE:	Date Response Received:
15/05/2012	15/05/2012	22/05/2012	
Date Completed:	Operator at Time of Event:	If 'Other' Operator Selected:	Reporter Confidentiality:
22/06/2012			Yes
Source of Report:	If 'Other' Source Selected:	Type of Initial Action:	
Sponsor		For IRIS Meeting	

Clinical Event Information:

On the s22, patient had a removal & replacement of bilateral breast implants. At surgery, both implants removed by Dr were found to have any outer saline rupture.

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:
Female	N/A	s22

Patient Focused Corrective Action Taken:

Patient History:

None specified

Patient Outcome/Consequences:

Implants were replaced with Mentor 350 cc implants, submammary.

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:

Reporter Title: Miss		First Name: §22	Surname: §22
Position: Plastic & Cosmetic Nurse Consultant (RN) for Dr §22		Company/Institution: Dr §22	
Address 1: §22	Address 2: §22	Town/Suburb: §22	State: §22
Country:	Postcode: §22	Phone: §22	Fax: §22
Mobile:	Email: §22		

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

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

Device Information Section

Product Exempt: No	<i>If No, fill out ARTG No:</i>	Search Device ARTG: 128762	Device ARTG #: 128762
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: McGhan Breast Implants		
Initial Device Description: McGhan Breast Implants 180 cc, Double Lumen (inner silicone/outer saline), smooth			
Usage of Device:	Software Version:		

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Model #: <input type="text" value="Unknown"/>	Serial #: <input type="text" value="Unknown"/>	Batch #: <input type="text" value="Unknown"/>	Lot #: <input type="text" value="Unknown"/>
Purchase Date: <input type="text"/>	Expiry Date: <input type="text"/>	Date of Implant: <input type="text"/>	Date of Explant: <input type="text" value="§22"/>
Reported Device Location: <input type="text" value="Discarded"/>	Access Contact Title: <input type="text"/>	Access Contact First Name: <input type="text"/>	Access Contact Surname: <input type="text"/>
Access Contact Phone: <input type="text"/>	Access Contact Fax: <input type="text"/>		

Manufacturer Information Section

Manufacturer Name: <input type="text" value="Allergan"/>		Manufacturer Client Id: <input type="text" value="§22"/>	Address 1: <input type="text" value="Unknown"/>
Address 2: <input type="text"/>	Town/Suburb: <input type="text"/>	State/Province: <input type="text" value="<>"/>	Country: <input type="text" value="Australia"/>
Postcode: <input type="text"/>	Phone: <input type="text" value="Unknown"/>	Fax: <input type="text"/>	
Email: <input type="text"/>	Manufacturer Informed: <input type="text"/>	Date Aware of Adverse Event: <input type="text"/>	
Contact Title: <input type="text"/>	Contact First Name: <input type="text"/>	Contact Surname: <input type="text"/>	

Supplier Information Section

Supplier Name: <input type="text" value="Unknown"/>		Address 1: <input type="text"/>	Address 2: <input type="text"/>
Town/Suburb: <input type="text"/>	State: <input type="text"/>	Postcode: <input type="text"/>	Phone: <input type="text"/>
Fax: <input type="text"/>	Email: <input type="text"/>	Supplier Informed: <input type="text" value="No"/>	
Date of Supplier Contact: <input type="text"/>	Contact Title: <input type="text"/>	Contact First Name: <input type="text"/>	Contact Surname: <input type="text"/>
Contact Phone: <input type="text"/>	Contact Fax: <input type="text"/>		

Statistics Checklist Section

Date: <input type="text" value="16/05/2012"/>	Assessed By: <input type="text" value="§22"/>		
Sample Received:	Sterile:	Reusable:	Single Use:

<input type="text" value="No"/>	<input type="text" value="Yes"/>	<input type="text" value="No"/>	<input type="text" value="Yes"/>
Potential Effect: <input type="text" value="Serious Injury"/>	Actual Effect: <input type="text" value="Serious Injury"/>	Injured Party: <input type="text" value="Patient"/>	
Risk Frequency: <input type="text" value="Rarely"/>	Risk Severity: <input type="text" value="Serious"/>	Risk Detectability: <input type="text" value="Occasionally"/>	Classification: <input type="text" value="Routine"/>
DIRE Meeting Notes: <input type="text" value="More information required"/>			Exclude report from DIRE: <input type="checkbox"/>

Sponsor Information Section

Search Sponsors: <input type="text" value="allergan"/>	Name: <input type="text" value="Allergan Australia Pty Ltd"/>	Client #: <input type="text" value="17"/>
Attention To: <input type="text" value="s22"/>	Address 1: <input type="text" value="Locked Bag 1514"/>	Address 2: <input type="text"/>
State: <input type="text" value="NSW"/>	Postcode: <input type="text" value="2073"/>	Town/Suburb: <input type="text" value="PYMBLE"/>
Email: <input type="text" value="s22@allergan.com"/>	Phone: <input type="text"/>	Fax: <input type="text"/>

Investigation Information Section

Device Analysis Results: <input type="text"/>	
Corrective/Preventative Actions: <input type="text"/>	
Details of Similar Events: <input type="text"/>	
Number of Similar Events: <input type="text"/>	Rate of Similar Events: <input type="text"/>
Countries Similar Events Also Occurred: <input type="text"/>	
Additional Comments: <input type="text"/>	

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
Request for Information	23/05/2012	05/06/2012	20/06/2012		
Reporter Notification	23/05/2012				
SC / RC	22/06/2012				R12/917306 / R12/917313

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
No further action	

Recall Number:

Investigation Summary:

The sponsor advised that the reported rate of rupture for this device in Australia is 0.6%.

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.

Document 14

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		DIR 26729 - Request for Information	82	Form	
FILE		s22 053112_Final	18	Form	

Flow Details : DIR-REQ - Device Incident Request : 35790

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
35790	DIR-REQ		Closed	s22	OPR Administration User	22/06/2012	Normal	0

Signature Details

Role	IRIS Investigator
User	s22
Signed At	22/06/2012 11:05:20
Comment	



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

DIR : 6 - ID : 156618

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

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
26731	2012/012907		Final
Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed		s22	15/05/2012
Date of Final Report:	Date of Initial TGA Action:	Reviewed by DIRE:	Date Response Received:
16/05/2012	16/05/2012	22/05/2012	
Date Completed:	Operator at Time of Event:	If 'Other' Operator Selected:	Reporter Confidentiality:
06/05/2013			Yes
Source of Report:	If 'Other' Source Selected:	Type of Initial Action:	
Surgeon		For IRIS Meeting	

Clinical Event Information:

On the s22, patient had removal of bilateral breast implants, at surgery Dr noted that the implant from the right breast was intact, however the left had an intracapsular rupture. Findings also confirmed by breast ultrasound.

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:
Female		s22

Patient Focused Corrective Action Taken:

--

Patient History:

s22

Patient Outcome/Consequences:

Bilateral breast implants were removed.

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:

Reporter #:

Reporter Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Country:

Postcode:

Phone:

Fax:

Mobile:

Email:

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:

Search Reporter By Surname:

Initial Reporter #:

Title:

First Name:

Surname:

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 #:

Therapeutic Licence Type:

Product Licence Category:

Device Class:

GMDN Code:

GMDN Text: Prosthesis, internal, mammary, gel filled		Brand Name: McGhan Breast Implants	
Initial Device Description: McGhan Breast Implants, 220cc, round, smooth			
Usage of Device: Single Use	Software Version: 		
Model #: Unknown	Serial #: Unknown	Batch #: Unknown	Lot #: Unknown
Purchase Date: 	Expiry Date: 	Date of Implant: 	Date of Explant: s22
Reported Device Location: Discarded	Access Contact Title: 	Access Contact First Name: 	Access Contact Surname:
Access Contact Phone: 	Access Contact Fax: 		

Manufacturer Information Section

Manufacturer Name: Allergan		Manufacturer Client Id: s22	Address 1: Unknown
Address 2: 	Town/Suburb: 	State/Province: <>	Country: Australia
Postcode: 	Phone: 	Fax: 	
Email: 	Manufacturer Informed: 		Date Aware of Adverse Event:
Contact Title: 	Contact First Name: 	Contact Surname: 	

Supplier Information Section

Supplier Name: Unknown		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:			
16/05/2012	§22			
Sample Received:	Sterile:	Reusable:	Single Use:	
No	Yes	No	Yes	
Potential Effect:	Actual Effect:	Injured Party:		
Serious Injury	Serious Injury	Patient		
Risk Frequency:	Risk Severity:	Risk Detectability:	Classification:	Exclude report from DIRE:
Rarely	Serious	Occasionally	Routine	<input type="checkbox"/>
DIRE Meeting Notes:				
More information required				

Sponsor Information Section

Search Sponsors:	Name:	Client #:	
allergan	Allergan Australia Pty Ltd	17	
Attention To:	Address 1:	Address 2:	Town/Suburb:
§22	Locked Bag 1514		PYMBLE
State:	Postcode:	Phone:	Fax:
NSW	2073	§22	(02) 9498 0299
Email:			
§22@allergan.com			

Investigation Information Section

Device Analysis Results:	
Corrective/Preventative Actions:	
Details of Similar Events:	
Number of Similar Events:	Rate of Similar Events:
36 (Australia) 160 (WW)	0.74% (Aus) 0.15% (WW)
Countries Similar Events Also Occurred:	
Agrentina, Belgium, Brazil, China, Colombia, Denmark, Ecuador, France, Germany, Ireland, Mexico, Netherlands, Peru, Philippines, Poland, Slovakia, Spain, Sweden, UK, USA, Venezuela.	
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
Reporter Notification Letter	25/05/2012				
Questionnaire Letter	18/04/2013	01/05/2013	02/05/2013		Extension to 03/05/2013 granted.
Response from sponsor	06/05/2013	17/05/2013			Questionnaire response
RC letter	06/05/2013	17/05/2013			
SC letter	06/05/2013	17/05/2013			

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
Not investigated	

Recall Number:

Investigation Summary:

Information received from the current sponsor of this device confirmed the reported rupture rate in Australia as 0.74% (2004 - 2013) and 0.15% Worldwide. Rupture is a known complication of silicone breast implant surgery.

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

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		DIR 26731 - questionnaire letter	93	Form	
FILE		s22 042213_final	19	Form	

Flow Details : DIR-REQ - Device Incident Request : 35795

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
35795	DIR-REQ		Closed	s22	OPR Administration User	06/05/2013	Normal	0

Signature Details

Role	IRIS Investigator
User	s22
Signed At	06/05/2013 09:24:33
Comment	



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

DIR : 6 - ID : 157241

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

Report Information Section

Report #: 26834	Records Management #: 2012/012750	Reporter's Reference #: 	Report Type: Final
Report Status: Closed	Sponsor's Reported Category: 	Date of Adverse Event: s22	Date of Initial Report: 15/05/2012
Date of Final Report: 15/05/2012	Date of Initial TGA Action: 23/05/2012	Reviewed by DIRE: 29/05/2012	Date Response Received:
Date Completed: 06/05/2013	Operator at Time of Event: 	If 'Other' Operator Selected: 	Reporter Confidentiality: No
Source of Report: Surgeon	If 'Other' Source Selected: 	Type of Initial Action: For IRIS Meeting	

Clinical Event Information:

Ruptured left breast implant.
Pale yellow discolouration with rupture of implant and intracapsular silicon.

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: Female	Weight: 	Age: s22
----------------	-------------	-------------

Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:	Reporter #:
-----------------------------	-------------

s22	5369		
Reporter Title: Dr	First Name: s22	Surname: s22	
Position: Plastic Surgeon	Company/Institution:		
Address 1: s22	Address 2:	Town/Suburb: s22	State: s22
Country: Australia	Postcode: s22	Phone: s22	Fax:
Mobile:	Email: s22		

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

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

Device Information Section

Product Exempt:	<i>If No, fill out ARTG No:</i>	Search Device ARTG: 128767	Device ARTG #: 128767
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: McGhan Breast Implants		
Initial Device Description: McGhan Breast Implants			
Usage of Device:	Software Version:		

<input type="text" value="Single Use"/>			
Model #:	Serial #:	Batch #:	Lot #:
<input type="text" value="MHP"/>	<input type="text" value="11562071 & 11550109"/>	<input type="text"/>	<input type="text" value="1119857 & 1117977"/>
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
<input type="text"/>	<input type="text"/>	<input type="text" value="§22"/>	<input type="text" value="§22"/>
Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
<input type="text" value="Place of use"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Access Contact Phone:	Access Contact Fax:		
<input type="text"/>	<input type="text"/>		

Manufacturer Information Section

Manufacturer Name:		Manufacturer Client Id:	Address 1:
<input type="text" value="Allergan"/>		<input type="text" value="§22"/>	<input type="text"/>
Address 2:	Town/Suburb:	State/Province:	Country:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Postcode:	Phone:	Fax:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Email:	Manufacturer Informed:		Date Aware of Adverse Event:
<input type="text"/>	<input type="text"/>		<input type="text"/>
Contact Title:	Contact First Name:	Contact Surname:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	

Supplier Information Section

Supplier Name:		Address 1:	Address 2:
<input type="text"/>		<input type="text"/>	<input type="text"/>
Town/Suburb:	State:	Postcode:	Phone:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Fax:	Email:		Supplier Informed:
<input type="text"/>	<input type="text"/>		<input type="text"/>
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Contact Phone:	Contact Fax:		
<input type="text"/>	<input type="text"/>		

Statistics Checklist Section

Date:	Assessed By:		
<input type="text" value="23/05/2012"/>	<input type="text" value="§22"/>		
Sample Received:	Sterile:	Reusable:	Single Use:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

<input type="text" value="No"/>	<input type="text" value="Yes"/>	<input type="text" value="No"/>	<input type="text" value="Yes"/>
Potential Effect: <input type="text" value="Serious Injury"/>	Actual Effect: <input type="text" value="Serious Injury"/>	Injured Party: <input type="text" value="Patient"/>	
Risk Frequency: <input type="text" value="Rarely"/>	Risk Severity: <input type="text" value="Serious"/>	Risk Detectability: <input type="text" value="Occasionally"/>	Classification: <input type="text" value="Routine"/>
DIRE Meeting Notes: <input type="text"/>			Exclude report from DIRE: <input type="checkbox"/>

Sponsor Information Section

Search Sponsors: <input type="text" value="allergan"/>	Name: <input type="text" value="Allergan Australia Pty Ltd"/>	Client #: <input type="text" value="17"/>
Attention To: <input type="text" value="s22"/>	Address 1: <input type="text" value="Locked Bag 1514"/>	Address 2: <input type="text"/>
State: <input type="text" value="ACT"/>	Postcode: <input type="text" value="2073"/>	Town/Suburb: <input type="text" value="PYMBLE"/>
Email: <input type="text" value="s22@Allergan.com"/>	Phone: <input type="text" value="s22"/>	Fax: <input type="text"/>

Investigation Information Section

Device Analysis Results: <input type="text"/>	
Corrective/Preventative Actions: <input type="text"/>	
Details of Similar Events: <input type="text"/>	
Number of Similar Events: <input type="text" value="3 (Aus) 74 (WW)"/>	Rate of Similar Events: <input type="text" value="2.63% (Aus) 0.14%(WW)"/>
Countries Similar Events Also Occurred: <input type="text" value="Brazil, Columbia, Costa Rica, Ecuador, France, Israel, Italy, Mexico, Norway, Spain, & UK"/>	
Additional Comments: <input type="text"/>	

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
asked for rupture stats	04/06/2012	15/06/2012			
RC letter	06/05/2013	17/05/2013			
SC letter	06/05/2013	17/05/2013			

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
No further action	

Recall Number:

Investigation Summary:

The implant was not returned to the manufacturer and as a result no physical device analysis was able to be undertaken. Rupture is a known complication of silicone breast implant surgery. 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.

Similar events - 3 (Aus) 74 (WW)

Flow Details : DIR-REQ - Device Incident Request : 35935

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
35935	DIR-REQ		Closed	s22	OPR Administration User	28/05/2013	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	06/05/2013 13:31:10	
Comment		



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

25/05/2012

SIGNED

DIR : 20 - ID : 157483

Released by s22 on 25/06/2015 15:11:06

Report Information Section

Report #: 26861	Records Management #: 2012/012952	Reporter's Reference #: 681173	Report Type: Final
Report Status: Closed	Sponsor's Reported Category: Death / Serious Injury	Date of Adverse Event: s22	Date of Initial Report: 04/08/2011
Date of Final Report: 06/06/2014	Date of Initial TGA Action: 25/05/2012	Reviewed by DIRE:	Date Response Received: 27/05/2014
Date Completed: 11/06/2014	Operator at Time of Event: Patient	If 'Other' Operator Selected:	Reporter Confidentiality: No
Source of Report: Sponsor	If 'Other' Source Selected:	Type of Initial Action: Trend data only	

Event Description for Website Publication:

The healthcare professional informed the Technical Consultant that the explant procedure is only a precaution and Anaplastic Large Cell Lymphoma (ALCL) has not been diagnosed.

Clinical Event Information:

The healthcare professional reported to an Allergan Technical Consultant that information regarding this case has been reported to another physician and that he is liaising with him only. An explant date was not been confirmed. The healthcare professional informed the Allergan Technical Consultant that the explant procedure is only a precaution and Anaplastic Large Cell Lymphoma (ALCL) has not been diagnosed. The patients original implants were implanted by another healthcare professional on an unspecified date and were described as 410 range FF. Size and serial numbers not known therefore Allergan Australia are unable to confirm the ARTG #. No other information is available.

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: Female	Weight: NI	Age: NI
Patient Focused Corrective Action Taken: NI		
Patient History: NI		

Patient Outcome/Consequences:

NI

Other Devices Involved:

NI

Submitting Reporter Section

Search Reporter By Surname:

§22

Reporter #:

5166 - §22 - Regulatory Affairs Officer - Allergan Australia

Reporter Title:

Miss

First Name:

§22

Surname:

§22

Position:

§22

Company/Institution:

Allergan Australia

Address 1:

Allergan Australia

Address 2:

Level 4/810 Pacific Hwy

Town/Suburb:

Gordon

State:

NSW

Country:

Australia

Postcode:

2072

Phone:

1800 252 224

Fax:

02 9498 0299

Mobile:

Email:

GO-Medical-Affairs@allergan.com

Last External Submission By:

Initial Reporter Section

As Above?:

No

If No, fill out the following:

Initial Reporter Confidential:

Yes

Search Reporter By Surname:

§22

Initial Reporter #:

5557 - §22

Title:

Dr

First Name:

§22

Surname:

§22

Position:

Company/Institution:

§22

Address 1:

§22

Address 2:

Town/Suburb:

§22

State:

§22

Postcode:

§22

Phone:

§22

Fax:

§22

Mobile:

Email:

§22

Device Information Section			
Product Exempt: No	If No, fill out ARTG No:	Search Device ARTG: 128763	Device ARTG #: 128763
Therapeutic Licence Type: Medical Device	Product Licence Category: Included	Device Class: Class III	GMDN / UMDN Code: 36197
GMDN / UMDN Text: Prosthesis, internal, mammary, gel filled		Brand Name: Style 410 Cohesive Silicone Gel Filled Breast Implant	
Initial Device Description: Style 410 Cohesive Silicone Gel Filled Breast Implant			
Usage of Device: Single Use	Software Version: N/A		
Model #: UNK (Full height/Full projection)	Serial #: NI	Batch #: N/A	Lot #: NI
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
Reported Device Location: Insitu	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
Access Contact Phone:	Access Contact Fax:		
Manufacturer Information Section			
Manufacturer Name: Allergan	Manufacturer Client Id: s22	Address 1: Marlow International Parkway	
Address 2:	Town/Suburb: Marlow	State/Province: Bucks	Country: United Kingdom
Postcode: SL7 1YL	Phone: 1800 252 224	Fax: 02 9498 0299	
Email: GO-Medical-Affairs@allergan.com	Manufacturer Informed: Yes	Date Aware of Adverse Event: 27/07/2011	
Contact Title: Miss	Contact First Name: s22	Contact Surname: s22	
Supplier Information Section			

Supplier Name:		Address 1:		Address 2:	
<input type="text"/>		<input type="text"/>		<input type="text"/>	
Town/Suburb:		State:		Postcode:	
<input type="text"/>		<input type="text"/>		<input type="text"/>	
Fax:		Email:		Supplier Informed:	
<input type="text"/>		<input type="text"/>		<input type="text"/>	
Date of Supplier Contact:		Contact Title:		Contact First Name:	
<input type="text"/>		<input type="text"/>		<input type="text"/>	
Contact Phone:		Contact Fax:			
<input type="text"/>		<input type="text"/>			

Statistics Checklist Section

Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
<input type="text" value="11/06/2014"/>	<input type="text" value="§22"/>	<input type="text" value="Yes"/>	<input type="text" value="Yes"/>	<input checked="" type="checkbox"/>
Sample Received:	Sterile:	Reusable:	Single Use:	Potential Effect:
<input type="text" value="No"/>	<input type="text" value="Yes"/>	<input type="text" value="No"/>	<input type="text" value="Yes"/>	<input type="text" value="Temporary Injury"/>
Actual Effect:	Injured Party:			Risk Frequency:
<input type="text" value="Not Known"/>	<input type="text" value="Patient"/>			<input type="text" value="Unlikely"/>
Risk Severity:	Risk Detectability:	Classification:	Investigated:	Date of DIRE Meeting:
<input type="text" value="Minor"/>	<input type="text" value="Unlikely"/>	<input type="text" value="Not Investigated"/>	<input type="text"/>	<input type="text"/>
DIRE Meeting Notes:				
<input type="text"/>				

Sponsor Information Section

Search Sponsors:	Name:	Client #:	
<input type="text" value="Allergan"/>	<input type="text" value="Allergan Australia Pty Ltd"/>	<input type="text" value="17"/>	
Attention To:	Address 1:	Address 2:	Town/Suburb:
<input type="text" value="§22"/>	<input type="text" value="Locked Bag 1514"/>	<input type="text"/>	<input type="text" value="PYMBLE"/>
State:	Postcode:	Phone:	Fax:
<input type="text" value="NSW"/>	<input type="text" value="2073"/>	<input type="text" value="§22"/>	<input type="text" value="(02) 9498 0299"/>
Email:			
<input type="text" value="GO-Medical-Affairs@allergan.com"/>			

Investigation Information Section

Device Analysis Results:

The reporting health professional stated that the device(s) would be explanted though this was never confirmed. The device(s) has not returned to Allergan for analysis.

Corrective/Preventative Actions:

The AE Term Code "No complaint against the device" has been assigned to this record in the Company Safety Database. No corrective action is deemed necessary.

Details of Similar Events:

N/A Allergan have assigned the AE Term Code "No complaint against the device".

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

N/A

Additional Comments:

Repeated attempts to obtain further information about this patient have been made to the reporting health professional with no success to date. Follow up information was requested via email and telephone, by an Allergan Sales Representative and Allergan Medical Affairs.

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 #:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text

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

Incident Details

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

Samples Record - Click **[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 Section. Note that the Correspondence Recipient will receive a notification 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
Request for final report		09/05/2013	22/05/2013			This was not recorded on my spreadsheet and Have sent another letter out.
Request for final report		27/05/2014	10/06/2014			
Request for ARTG#		10/06/2014				

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

Type Details			
Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected	
Other	Other	Explant as precaution	

Investigation Problem Causes

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

Investigation Outcomes

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

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.

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		0039586_ Follow Up IRIS Report	114	Form	

Flow Details : DIR-REQ - Device Incident Request : 35968

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
35968	DIR-REQ		Closed	s22	OPR Administration User	11/06/2014	Normal	0

Signature Details

Role	IRIS Investigator
User	s22
Signed At	11/06/2014 09:59:43
Comment	



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

25/07/2012

SIGNED

DIR : 20 - ID : 161530

Released by s22 on 25/06/2015 15:11:06

Report Information Section

Report #: 27494	Records Management #: 2012/016549	Reporter's Reference #: 0050980/AZ	Report Type: Final
Report Status: Closed	Sponsor's Reported Category: Other	Date of Adverse Event: s22	Date of Initial Report: 29/05/2012
Date of Final Report: 02/04/2013	Date of Initial TGA Action: 25/07/2012	Reviewed by DIRE: 09/04/2013	Date Response Received:
Date Completed: 05/06/2013	Operator at Time of Event: Patient	If 'Other' Operator Selected:	Reporter Confidentiality: No
Source of Report: Sponsor	If 'Other' Source Selected:	Type of Initial Action: For IRIS Meeting	

Event Description for Website Publication:

The patient had the LHS implant explanted and biopsies were taken and the histopathology report provided. Confirmed that there is no evidence of left breast involvement by lymphoma.

Clinical Event Information:

The patient had the LHS implant explanted in s22 and biopsies were taken and the histopathology report provided. Confirmed that there is no evidence of left breast involvement by lymphoma.

No further information to report.

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: Female	Weight:	Age: s22
----------------	---------	-------------

Patient Focused Corrective Action Taken:

Patient History:

Right breast cancer in s22 . *s22 bilateral breast augmentation with silicone implants. *ALK negative anaplastic larger cell lymphoma involving capsule around implant of right breast diagnosed in s22 *s22

Patient Outcome/Consequences:

On s22 further information was received from Dr s22 rooms regarding this patient.

On s22 the patient was reviewed by s22 Haematology Registrar to s22

On s22 the patient was reviewed by Dr s22 , Radiation Oncologist (s22) who confirmed that the patient has been well and that clinical examination was unremarkable.

Letters from both of these reviews were provided to Allergan Australia and have been attached to this report in full.

Other Devices Involved:

N/A.

Submitting Reporter Section

Search Reporter By Surname:		Reporter #:	
<input type="text" value="Allergan"/>		<input type="text" value="5166 - s22 - Regulatory Affairs Officer - Allergan Australia"/>	
Reporter Title:	First Name:	Surname:	
<input type="text" value="Ms"/>	<input type="text" value="s22"/>	<input type="text" value="s22"/>	
Position:		Company/Institution:	
<input type="text" value="Regulatory Affairs Officer"/>		<input type="text" value="Allergan Australia"/>	
Address 1:	Address 2:	Town/Suburb:	State:
<input type="text" value="Allergan Australia"/>	<input type="text" value="Level 4/810 Pacific Hwy"/>	<input type="text" value="Gordon"/>	<input type="text" value="New South Wales"/>
Country:	Postcode:	Phone:	Fax:
<input type="text" value="Australia"/>	<input type="text" value="2072"/>	<input type="text" value="s22"/>	<input type="text" value="9498 0299"/>
Mobile:	Email:	Last External Submission By:	
<input type="text"/>	<input type="text" value="GO-Medical-Affairs@allergan.com"/>	<input type="text"/>	

Initial Reporter Section

As Above?:	If No, fill out the following:		Initial Reporter Confidential:
<input type="text" value="No"/>	<input type="text"/>		<input type="text" value="No"/>
Search Reporter By Surname:		Initial Reporter #:	
<input type="text"/>		<input type="text"/>	
Title:	First Name:	Surname:	
<input type="text" value="Dr"/>	<input type="text" value="s22"/>	<input type="text" value="s22"/>	
Position:		Company/Institution:	
<input type="text"/>		<input type="text"/>	

Plastic and reconstruction Surgeon			
Address 1:	Address 2:	Town/Suburb:	State:
§22		§22	§22
Postcode:	Phone:	Fax:	Mobile:
§22	§22	§22	
Email:			

Device Information Section

Product Exempt:	If No, fill out ARTG No:	Search Device ARTG:	Device ARTG #:
		128764	128764
Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN / UMDN Code:
Medical Device	Included	Class III	36197
GMDN / UMDN Text:	Brand Name:		
Prosthesis, internal, mammary, gel filled	Style 410 Cohesive Silicone Gel Filled Breast Implant		
Initial Device Description:			
Style 410 Cohesive Silicone Gel Filled Breast Implant			
Usage of Device:	Software Version:		
Single Use			
Model #:	Serial #:	Batch #:	Lot #:
27-MM110-215	RC2012		185091
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
		§22	§22
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:	
Allergan	§22		
Address 2:	Town/Suburb:	State/Province:	Country:
Postcode:	Phone:	Fax:	

Email:		Manufacturer Informed:	Date Aware of Adverse Event:
<input type="text"/>		Yes	21/05/2012
Contact Title:	Contact First Name:	Contact Surname:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Supplier Information Section			
Supplier Name:		Address 1:	Address 2:
<input type="text"/>		<input type="text"/>	<input type="text"/>
Town/Suburb:	State:	Postcode:	Phone:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Fax:	Email:	Supplier Informed:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Contact Phone:	Contact Fax:		
<input type="text"/>	<input type="text"/>		

Statistics Checklist Section				
Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
04/04/2013	s22	No		<input type="checkbox"/>
Sample Received:	Sterile:	Reusable:	Single Use:	Potential Effect:
No	Yes	No	Yes	Serious Injury
Actual Effect:	Injured Party:			Risk Frequency:
Serious Injury	Patient			Unlikely
Risk Severity:	Risk Detectability:	Classification:	Investigated:	Date of DIRE Meeting:
Minor	Occasionally	Routine		
DIRE Meeting Notes:				
Check to see if right implant reported then close				

Sponsor Information Section		
Search Sponsors:	Name:	Client #:
<input type="text"/>	<input type="text"/>	<input type="text"/>

Allergan	Allergan Australia Pty Ltd	17	
Attention To:	Address 1:	Address 2:	Town/Suburb:
s22	Locked Bag 1514		PYMBLE
State:	Postcode:	Phone:	Fax:
NSW	2073	s22	02 9498 0299
Email:			
GO-Medical-Affairs@allergan.com			

Investigation Information Section

Device Analysis Results:

Devices were not returned for testing.

Corrective/Preventative Actions:

N/A.

Details of Similar Events:

Yes, for ARTG 128764 worldwide:

	Event Count:	Event Rate:
Capsular contracture	1,100	0.3560%
Lump/nodule	19	0.0061%
Lymphoma - ALCL	7	0.0023%
Cellulitis	4	0.0013%

Sales: 309,007.

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Argentina, Australia, Austria, Belgium, Brazil, Canada, Chile, China, Colombia, Costa Rica, Czech Republic, Ecuador, France, Germany, Greece, Honduras, Hungary, Israel, Italy, Mexico, Netherlands, New Zealand, Poland, Portugal, Russia, Slovenia, South Africa, Spain, Sweden, Switzerland, Ukraine, United Kingdom, United States of America.

Additional Comments:

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	

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

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

Samples Record - Click **[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 Section. Note that the Correspondence Recipient will receive a notification 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
Email requesting similar event info as it does not appear on final or previous reports		14/03/2013		19/04/2013		
Request for information		16/04/2013	29/04/2013			
41JA letter sent		06/05/2013	20/05/2013	08/05/2013		
Email to Sponsor		05/06/2013				R13/435284 Email with Sponsor Complete Letter
Sponsor Complete Letter		05/06/2013				Attached

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

Type Details

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

Investigation Problem Causes

Cause Details			
Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected	
Unable to confirm complaint	Investigation did not reveal a root cause		

Investigation Outcomes

Outcome Details		
Outcome of Investigation	If Additional Outcome Detail Requested	
Reviewed, No Further Action Required		

Recall Number:

Investigation Summary:

The TGA has investigated this complaint.

Advice received from the Sponsor and medical reports confirm that no Lymphoma was detected in the left breast. Lymphoma was detected around the right breast implant and the patient underwent treatment.

Both implants have been explanted. The reported rate for Lymphoma - ALCL is 0.0023%

No further investigation will occur at this time however TGA will continue to monitor the pattern and rate of occurrence and may re-open the file as appropriate.

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		0050980 - Haematology Report	53	Form	
FILE		IRIS - FORM - MDIR03 - 3rd followup	134	Form	

FILE		0050980 redacted 23NOV12 - letter	62	Form
FILE		0050980_FUP IRIS FORM_24DEC2012	53	Form
FILE		MDM Discussion Summary	63	Form
FILE		DIR 27494_Final IRIS report_14MAR2013	112	Form
FILE		0050980_redacted Final from HCP_06MAR2013	112	Form
FILE		s22 031313_ARTG_final	19	Form
FILE		DIR 27494_FINAL IRIS Report_02APR2013	112	Form
FILE		0050980_redacted fup_20MAR13	138	Form
FILE		DIR 27494_follow up IRIS report_28MAR2013	113	Form
FILE		_ DIR 27494 - 41JA letter [SEC=UNCLASSIFIED] A...	184	Form
FILE		0050980	54	Form
FILE		DIR 27494 - Sponsor Complete Letter	262	Form

Flow Details : DIR-REQ - Device Incident Request : 36805

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
36805	DIR-REQ		Closed	s22	OPR Administration User	05/06/2013	Normal	0

Signature Details

Role	IRIS Investigator
User	s22
Signed At	05/06/2013 09:29:36

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

DIR : 20 - ID : 162021

Document 19

01/08/2012

SIGNED

Released by s22 on 25/06/2015 15:11:06

Report Information Section

Report #: 27612	Records Management #: 2012/017026	Reporter's Reference #: 0052817/AZ	Report Type: Final
Report Status: Closed	Sponsor's Reported Category: Other	Date of Adverse Event: s22	Date of Initial Report: 27/07/2012
Date of Final Report: 09/06/2013	Date of Initial TGA Action: 01/08/2012	Reviewed by DIRE: 18/06/2013	Date Response Received:
Date Completed: 27/10/2014	Operator at Time of Event:	If 'Other' Operator Selected:	Reporter Confidentiality: No
Source of Report: Sponsor	If 'Other' Source Selected:	Type of Initial Action: For IRIS Meeting	

Event Description for Website Publication:

Report received reporting a patient with breast implants with a "possible suspicious of s22 to Anaplastic Large Cell Lymphoma".

Clinical Event Information:

Initial report received to company on s22 from HCP reporting a female patient with BREAST implants with a "possible suspicious of s22 to Anaplastic Large Cell Lymphoma", not confirmed by pathology.

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: Female	Weight:	Age: s22 ears	
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Patient Focused Corrective Action Taken:

Explant surgery on s22

Patient History:

Unknown.

Patient Outcome/Consequences:

Unknown.

Other Devices Involved:

N/A.

Submitting Reporter Section

Search Reporter By Surname:

§22

Reporter #:

Reporter Title:

First Name:

§22

Surname:

§22

Position:

Company/Institution:

Allergan Australia

Address 1:

Level 4

Address 2:

810 Pacific Highway

Town/Suburb:

Gordon

State:

NSW

Country:

Australia

Postcode:

2073

Phone:

§22

Fax:

02 9498 0299

Mobile:

Email:

§22 @allergan.com

Last External Submission By:

Initial Reporter Section

As Above?:

No

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Title:

Dr

First Name:

§22

Surname:

§22

Position:

Company/Institution:

§22

Address 1:

§22

Address 2:

Town/Suburb:

§22

State:

§22

Postcode:

Phone:

§22

Fax:

Mobile:

Email:

Device Information Section

Product Exempt: No	If No, fill out ARTG No:	Search Device ARTG: 128764	Device ARTG #: 128764
Therapeutic Licence Type: Medical Device	Product Licence Category: Included	Device Class: Class III	GMDN / UMDN Code: 36197
GMDN / UMDN Text: Prosthesis, internal, mammary, gel filled		Brand Name: Style 410 Cohesive Silicone Gel Filled Breast Implant	
Initial Device Description: Style 410 Cohesive Silicone Gel Filled Breast Implant			
Usage of Device: Single Use	Software Version:		
Model #: 27-FF130-425	Serial #: Right: II6794	Batch #:	Lot #: Right: 253777
Purchase Date:	Expiry Date:	Date of Implant: s22	Date of Explant: s22
Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
Access Contact Phone:	Access Contact Fax:		

Manufacturer Information Section

Manufacturer Name: Allergan	Manufacturer Client Id: s22	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:
<input type="text"/>		<input type="text"/>	<input type="text"/>
Town/Suburb:	State:	Postcode:	Phone:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Fax:	Email:		Supplier Informed:
<input type="text"/>	<input type="text"/>		<input type="text"/>
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Contact Phone:	Contact Fax:		
<input type="text"/>	<input type="text"/>		

Statistics Checklist Section

Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
<input type="text" value="12/06/2013"/>	<input type="text" value="s22"/>	<input type="text" value="Yes"/>	<input type="text" value="Yes"/>	<input type="checkbox"/>
Sample Received:	Sterile:	Reusable:	Single Use:	Potential Effect:
<input type="text" value="No"/>	<input type="text" value="Yes"/>	<input type="text" value="No"/>	<input type="text" value="Yes"/>	<input type="text" value="Death"/>
Actual Effect:	Injured Party:			Risk Frequency:
<input type="text" value="Serious Injury"/>	<input type="text" value="Patient"/>			<input type="text" value="Unlikely"/>
Risk Severity:	Risk Detectability:	Classification:	Investigated:	Date of DIRE Meeting:
<input type="text" value="Serious"/>	<input type="text" value="Occasionally"/>	<input type="text" value="Routine"/>	<input type="text"/>	<input type="text"/>
DIRE Meeting Notes:				
<input type="text" value="Investigate"/>				

Sponsor Information Section

Search Sponsors:	Name:	Client #:
<input type="text" value="Allergan"/>	<input type="text" value="Allergan Australia Pty Ltd"/>	<input type="text" value="17"/>
Attention To:	Address 1:	Address 2:
<input type="text" value="s22"/>	<input type="text" value="Locked Bag 1514"/>	<input type="text"/>
State:	Postcode:	Phone:
<input type="text" value="NSW"/>	<input type="text" value="2073"/>	<input type="text" value="1800 252224"/>
Email:		Fax:
<input type="text" value="GO-Medical-Affairs@allergan.com"/>		<input type="text" value="02 9498 0299"/>

Investigation Information Section

Device Analysis Results:

Device analysis was not possible since the device was not returned to Allergan. Pathology results and results of inspection by the Pathologist were previously submitted to TGA on 27JUL2012.

Corrective/Preventative Actions:

Seroma is an expected event clearly documented in the product Directions for Use. Lymphoma - ALCL is not an expected event with Allergan Breast Implants and is not listed in product Directions for Use.

Allergan are committed to patient safety and perform regular signal detection on all adverse events reported to the Company. To date no new trend has been identified specific to the events in this report. In addition, Allergan conducts an annual review of Anaplastic Large Cell Lymphoma (ALCL) diagnosed in patients with breast implants - the last review was made available to TGA on 25JAN2013, sent via email.

Allergan will continue to gather, closely monitor and thoroughly investigate all sources of breast implant safety and performance data and act out of an abundance of caution to protect patients should adverse trends and/or events of significance can be identified.

Details of Similar Events:

None reported for model # 27 FF130 425.

Style 410 Breast Implant Cat# 27 FF130 425 Similar Incidents for PRID 894565*
Received Worldwide through May 29, 2013

Lymphoma - ALCL

Aus Events: 1, Aus Rate: 0.74%, WW Events**: 1, WW Rate: 0.09%.

Seroma

Aus Events: 1, Aus Rate: 0.74%, WW Events**: 1, WW Rate: 0.09%.

Sales:

Aus***: 136.

WW†: 1,160.

*There are no other similar incidents to PR 894565. The above events do not include non device related (NDR) events.

**Worldwide events includes Australia.

***Australia sales are from January 1, 2007 through April 30, 2013. Country specific sales are not available prior to 2007. May 2013 sales are not available at the time of this report.

†Worldwide sales include Australia. The sales date range is from January 1, 2004 through February 28, 2013. Sales prior to 2004 are not available. May 2013 sales are not available at the time of this report

Report Date: 05/30/2013.

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Additional Comments:

Allergan have attempted to obtain the following information from the reporting health professional without success to date;
Patient history – previous cancers? Any chronic conditions?
Surgery type Aug/Recon/Revision? And if applicable previous implant and expander history (with dates & details)
Placement – sub muscular or sub glandular?

ALCL Primary / Secondary to other site?
 How did the ALCL present? Just Seroma? Was there Capsular Contracture?
 Treatment of ALCL – details of Tx and dates
 Patient outcome

Should Allergan receive any additional information regarding this event this will be provided to TGA in a timely report.

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): <input type="text"/>	Brand Name: <input type="text"/>	Manufacturer Name: <input type="text"/>	Device ARTG #: <input type="text"/>
---	-------------------------------------	--	--

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text

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

Incident Details

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

Samples Record - Click **[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 Section. Note that the Correspondence Recipient will receive a notification 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

Request for final report		20/05/2013	03/06/2013				
Questionnaire letter		18/07/2013	31/07/2013	24/07/2013			
Email requesting updated IFU		30/05/2014	10/06/2014			TRIM R14/745524	
Fololowup email re IFU update		22/07/2014	02/08/2014			TRIM R14/907187	
Email sponsor completion letter		27/10/2014	07/11/2014			TRIM R14/1123411	

List of Problem Type Codes Click **[N]** to begin entering information.

Type Details			
Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected	
Incompatibility	Patient Device Incompatibility		

Investigation Problem Causes

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

Investigation Outcomes







Outcome Details		
Outcome of Investigation	If Additional Outcome Detail Requested	
Reviewed, No Further Action Required		

Recall Number:

Investigation Summary:

Review of the updated Instructions For Use (IFU), provided by the sponsor, shows the IFU has been updated accordingly, to include information regarding potential risk of contracting ALCL from breast implants. The sponsor advises that the updated IFU has not yet been implemented within the device packs being shipped to ANZ, this is scheduled for later in the year. No further investigation will occur at this time; however the TGA will continue to monitor and may re-open the file as appropriate.

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		s22 053013_final	19	Form	
FILE		0052817_Final IRIS Report	116	Form	
FILE		0052817_AE incidence report	19	Form	
FILE		0052817_redacted laboratory results	227	Form	
FILE		DIR 27612 - questionnaire letter - Allergan Re...	110	Form	
FILE		L3441 Natrelle rev 3 18.12.2013 DRAFT	483	Form	

Flow Details : DIR-REQ - Device Incident Request : 36954

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
36954	DIR-REQ		Closed	s22	OPR Administration User	27/10/2014	Normal	1

Signature Details

Role	IRIS Investigator
------	-------------------

User	s22	
Signed At	27/10/2014 15:28:10	
Comment		



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

DIR : 20 - ID : 163040

Document 20

14/08/2012

SIGNED

Released by s22 on 25/06/2015 15:11:06

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
27916	2012/017870		Final
Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed			08/08/2012
Date of Final Report:	Date of Initial TGA Action:	Reviewed by DIRE:	Date Response Received:
08/08/2012	14/08/2012	21/08/2012	
Date Completed:	Operator at Time of Event:	If 'Other' Operator Selected:	Reporter Confidentiality:
22/08/2012	Healthcare Professional		
Source of Report:	If 'Other' Source Selected:	Type of Initial Action:	
Surgeon		For IRIS Meeting	

Event Description for Website Publication:

At surgery one was found to be ruptured and the both were found to be rotated and one was found to be flipped over.

A capsule modification had to be made on the ruptured right side where the front and back wall of the implant had bridged together through the ruptured gel.

Clinical Event Information:

At surgery to upsize the implants one was found to be ruptured and the both were found to be rotated and one was found to be flipped over.

A capsule modification had to be made on the ruptured right side where the front and back wall of the implant had bridged together through the ruptured gel.

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:	
Female	s22	s22	

Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:

s22

Reporter #:

Reporter Title:

Dr

First Name:

s22

Surname:

s22

Position:

Plastic Surgeon

Company/Institution:

Address 1:

s22

Address 2:

s22

Town/Suburb:

s22

State:

s22

Country:

Postcode:

Phone:

s22

Fax:

s22

Mobile:

Email:

s22

Last External Submission By:

Initial Reporter Section

As Above?:

Yes

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Phone:

Fax:

Mobile:

Email:

Device Information Section			
Product Exempt:	<i>If No, fill out ARTG No:</i>	Search Device ARTG:	Device ARTG #:
No		175420	175420
Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN / UMDN Code:
Medical Device	Included	Class III	36197
GMDN / UMDN Text:	Brand Name:		
Prosthesis, internal, mammary, gel filled	Allergan Breast Implant		
Initial Device Description:			
Breast Implants			
Usage of Device:	Software Version:		
Single Use			
Model #:	Serial #:	Batch #:	Lot #:
410 FM	L: YM2070 & R: YR2031		L: 54915 & R: 58529
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
28/09/2000		S22	S22
Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
Discarded			
Access Contact Phone:	Access Contact Fax:		
Manufacturer Information Section			
Manufacturer Name:		Manufacturer Client Id:	Address 1:
Allergan		S22	
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:
<input type="text"/>		<input type="text"/>	<input type="text"/>
Town/Suburb:	State:	Postcode:	Phone:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Fax:	Email:		Supplier Informed:
<input type="text"/>	<input type="text"/>		<input type="text"/>
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Contact Phone:	Contact Fax:		
<input type="text"/>	<input type="text"/>		

Statistics Checklist Section

Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
<input type="text" value="14/08/2012"/>	<input type="text" value="s22"/>	<input type="text" value="Yes"/>	<input type="text" value="Yes"/>	<input type="checkbox"/>
Sample Received:	Sterile:	Reusable:	Single Use:	Potential Effect:
<input type="text" value="No"/>	<input type="text" value="Yes"/>	<input type="text" value="No"/>	<input type="text" value="Yes"/>	<input type="text" value="Serious Injury"/>
Actual Effect:	Injured Party:			Risk Frequency:
<input type="text" value="Temporary Injury"/>	<input type="text" value="Patient"/>			<input type="text" value="Rarely"/>
Risk Severity:	Risk Detectability:	Classification:	Investigated:	Date of DIRE Meeting:
<input type="text" value="Minor"/>	<input type="text" value="Occasionally"/>	<input type="text" value="Routine"/>	<input type="text"/>	<input type="text"/>
DIRE Meeting Notes:				
<input type="text" value="If sample available obtain. If not close - No sample available"/>				

Sponsor Information Section

Search Sponsors:	Name:	Client #:
<input type="text" value="allergan"/>	<input type="text" value="Allergan Australia Pty Ltd"/>	<input type="text" value="17"/>
Attention To:	Address 1:	Address 2:
<input type="text" value="s22"/>	<input type="text" value="Locked Bag 1514"/>	<input type="text"/>
State:	Postcode:	Phone:
<input type="text" value="NSW"/>	<input type="text" value="2073"/>	<input type="text" value="s22"/>
		Fax:
		<input type="text" value="02 9498 0292"/>

Email:

s22 @allergan.com

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:

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

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

Incident Details

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

Samples Record - Click **[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 Section. Note that the Correspondence Recipient will receive a notification 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
Completion letter		22/08/2012				
Reporters Completion letter		22/08/2012				

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

Type Details

Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected
Material	Burst	
Mechanical	Unintended Movement	

Investigation Problem Causes

Cause Details

Cause of Problem (Level 1)	Cause of Problem (Level 2)	If 'Other' Cause Selected
Not product related	Event related to patient condition or anatomy	
Not product related	User error caused or contributed to event	

Investigation Outcomes

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested

Not investigated Document 20

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.

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		SM578343	126	Form	

Flow Details : DIR-REQ - Device Incident Request : 37285

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
37285	DIR-REQ		Closed	s22	OPR Administration User	22/08/2012	Normal	0

Signature Details

Role	IRIS Investigator
User	s22
Signed At	22/08/2012 11:26:47
Comment	



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

28/09/2012

SIGNED

DIR : 20 - ID : 166597

Released by s22 on 25/06/2015 15:11:06

Report Information Section

Report #: 28760	Records Management #: 2012/024747	Reporter's Reference #: Allergan Ref # 919156	Report Type: Final
Report Status: Closed	Sponsor's Reported Category:	Date of Adverse Event: s22	Date of Initial Report: 28/09/2012
Date of Final Report: 28/09/2012	Date of Initial TGA Action: 28/09/2012	Reviewed by DIRE: 09/10/2012	Date Response Received:
Date Completed: 24/01/2013	Operator at Time of Event:	If 'Other' Operator Selected:	Reporter Confidentiality: Yes
Source of Report: Nurse	If 'Other' Source Selected:	Type of Initial Action: For IRIS Meeting	

Event Description for Website Publication:

Left intracapsular implant rupture found at time of surgery.

Clinical Event Information:

Left intracapsular implant rupture found at time of surgery.

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

Patient Information

Sex:	Weight:	Age:	
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Patient Focused Corrective Action Taken:

Patient History:

N/A

Patient Outcome/Consequences:

Patient had removal and replacement of bilateral implants or s22 At surgery Dr found there was a left intracapsular rupture of the existing implants. Implants replaced.

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:

Reporter #:

s22

Reporter Title:

First Name:

Surname:

Miss

s22

s22

Position:

Company/Institution:

Plastic & Cosmetic Nurse Consultant (RN)

s22

Address 1:

Address 2:

Town/Suburb:

State:

s22

s22

s22

s22

Country:

Postcode:

Phone:

Fax:

s22

s22

s22

Mobile:

Email:

Last External Submission By:

s22

Initial Reporter Section

As Above?:

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Phone:

Fax:

Mobile:

Email:

Device Information Section			
Product Exempt: <input type="text"/>	If No, fill out ARTG No: <input type="text"/>	Search Device ARTG: <input type="text" value="171512"/>	Device ARTG #: <input type="text" value="171512"/>
Therapeutic Licence Type: <input type="text" value="Medical Device"/>	Product Licence Category: <input type="text" value="Included"/>	Device Class: <input type="text" value="Class III"/>	GMDN / UMDN Code: <input type="text" value="36197"/>
GMDN / UMDN Text: <input type="text" value="Prosthesis, internal, mammary, gel filled"/>		Brand Name: <input type="text" value="INAMED Breast Implant"/>	
Initial Device Description: <input type="text" value="INAMED Breast Implant"/>			
Usage of Device: <input type="text" value="Single Use"/>	Software Version: <input type="text"/>		
Model #: <input type="text" value="410 FX"/>	Serial #: <input type="text" value="12968071"/>	Batch #: <input type="text"/>	Lot #: <input type="text" value="1485420"/>
Purchase Date: <input type="text" value="20/11/2007"/>	Expiry Date: <input type="text"/>	Date of Implant: <input type="text" value="s22"/>	Date of Explant: <input type="text" value="s22"/>
Reported Device Location: <input type="text" value="With Supplier"/>	Access Contact Title: <input type="text"/>	Access Contact First Name: <input type="text"/>	Access Contact Surname: <input type="text"/>
Access Contact Phone: <input type="text"/>	Access Contact Fax: <input type="text"/>		
Manufacturer Information Section			
Manufacturer Name: <input type="text" value="Allergan"/>		Manufacturer Client Id: <input type="text" value="s22"/>	Address 1: <input type="text" value="Level 4, 810 Pacific Highway"/>
Address 2: <input type="text"/>	Town/Suburb: <input type="text" value="Gordon"/>	State/Province: <input type="text" value="NSW"/>	Country: <input type="text" value="Australia"/>
Postcode: <input type="text" value="2072"/>	Phone: <input type="text" value="1800252224"/>	Fax: <input type="text" value="02 94980184"/>	
Email: <input type="text"/>	Manufacturer Informed: <input type="text"/>		Date Aware of Adverse Event: <input type="text"/>
Contact Title: <input type="text"/>	Contact First Name: <input type="text"/>	Contact Surname: <input type="text"/>	
Supplier Information Section			

Supplier Name: Same as above		Address 1:		Address 2:	
Town/Suburb:		State:		Postcode:	
Fax:		Email:		Supplier Informed: Yes	
Date of Supplier Contact: 27/09/2012		Contact Title: Mrs		Contact First Name: §22	
Contact Phone: 1800 252 224		Contact Fax:		Contact Surname: §22	

Statistics Checklist Section

Date: 02/10/2012	Assessed By: §22	For website publication: Yes	Ready for Publication: Yes	Exclude report from DIRE: <input type="checkbox"/>
Sample Received: No	Sterile: Yes	Reusable: No	Single Use: Yes	Potential Effect: Serious Injury
Actual Effect: Temporary Injury	Injured Party: Patient			Risk Frequency: Sometimes
Risk Severity: Serious	Risk Detectability: Occasionally	Classification: Routine	Investigated:	Date of DIRE Meeting:
DIRE Meeting Notes: Investigate §22				

Sponsor Information Section

Search Sponsors: allergan	Name: Allergan Australia Pty Ltd	Client #: 17	
Attention To: §22	Address 1: Locked Bag 1514	Address 2:	Town/Suburb: PYMBLE
State: NSW	Postcode: 2073	Phone: §22	Fax: (02) 9498 0299
Email: §22@allergan.com			

Investigation Information Section

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Number of Similar Events: <input type="text" value="483"/>	Rate of Similar Events: <input type="text" value="0.74%"/>
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Countries Similar Events Also Occurred:

Additional Comments:

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): <input type="text"/>	Brand Name: <input type="text"/>	Manufacturer Name: <input type="text"/>	Device ARTG #: <input type="text"/>
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Other Devices							
Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text	

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

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

Samples Record - Click **[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 Section. Note that the Correspondence Recipient will receive a notification 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	
Questionnaire sent		13/12/2012	02/01/2013	31/12/2012		See TRIM R13/30515.	
Report Notification Sent		13/12/2012					
SC letter		24/01/2013	04/02/2013				
RC letter		24/01/2013	04/02/2013				

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

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

Investigation Problem Causes

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

Investigation Outcomes

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

Recall Number:

Investigation Summary:

Rupture is a known complication of silicone filled breast implants.

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.

Similar events - 483 / 64930 units sold in Australia since 2004 (0.74%)

Flow Details : DIR-REQ - Device Incident Request : 38336

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
38336	DIR-REQ		Closed	s22	OPR Administration User	24/01/2013	Normal	0

Signature Details

Role	IRIS Investigator
User	s22
Signed At	24/01/2013 12:48:23
Comment	



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

DIR : 20 - ID : 166626

Document 22

28/09/2012

SIGNED

Released by §22 on 25/06/2015 15:11:06

Report Information Section

Report #: 28766	Records Management #: 2012/024748	Reporter's Reference #: Allergan Ref# 896502/900004	Report Type: Final
Report Status: Closed	Sponsor's Reported Category:	Date of Adverse Event: §22	Date of Initial Report: 28/09/2012
Date of Final Report: 02/10/2012	Date of Initial TGA Action: 02/10/2012	Reviewed by DIRE: 09/10/2012	Date Response Received:
Date Completed: 24/01/2013	Operator at Time of Event:	If 'Other' Operator Selected:	Reporter Confidentiality: Yes
Source of Report: Nurse	If 'Other' Source Selected:	Type of Initial Action: For IRIS Meeting	

Event Description for Website Publication:

Breast MRI confirmed intracapsular rupture of the right breast.

Clinical Event Information:

Breast MRI confirmed intracapsular rupture of the right breast.

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

Patient Information

Sex: Female	Weight:	Age: §22 rs	
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Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

s22 : Pt had removal & replacement of bilateral implants. At surgery s22 found RIGHT intracapsular rupture of the implant, the left implant was intact. Implants were replaced. Document 22

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname: Reporter #:

Reporter Title: First Name: Surname:

Position: Company/Institution:

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

Country: Postcode: Phone: Fax:

Mobile: Email: Last External Submission By:

Initial Reporter Section

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

Search Reporter By Surname: Initial Reporter #:

Title: First Name: Surname:

Position: Company/Institution:

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

Postcode: Phone: Fax: Mobile:

Email:

Device Information Section

Product Exempt: <input type="text"/>	<i>If No, fill out ARTG No:</i> <input type="text"/>	Search Device ARTG: <input type="text" value="126554"/>	Device ARTG #: <input type="text" value="126554"/>
Therapeutic Licence Type: <input type="text" value="Medical Device"/>	Product Licence Category: <input type="text" value="Included"/>	Device Class: <input type="text" value="Class III"/>	GMDN / UMDN Code: <input type="text" value="36197"/>
GMDN / UMDN Text: <input type="text" value="Prosthesis, internal, mammary, gel filled"/>		Brand Name: <input type="text" value="INAMED Breast Implant"/>	
Initial Device Description: <input type="text" value="Breast Implant"/>			
Usage of Device: <input type="text" value="Single Use"/>	Software Version: <input type="text"/>		
Model #: <input type="text" value="230 MLP"/>	Serial #: <input type="text" value="AHB 794"/>	Batch #: <input type="text"/>	Lot #: <input type="text"/>
Purchase Date: <input type="text"/>	Expiry Date: <input type="text"/>	Date of Implant: <input type="text" value="s22"/>	Date of Explant: <input type="text"/>
Reported Device Location: <input type="text" value="With Supplier"/>	Access Contact Title: <input type="text"/>	Access Contact First Name: <input type="text"/>	Access Contact Surname: <input type="text"/>
Access Contact Phone: <input type="text"/>	Access Contact Fax: <input type="text"/>		

Manufacturer Information Section

Manufacturer Name: <input type="text" value="Allergan"/>	Manufacturer Client Id: <input type="text" value="s22"/>	Address 1: <input type="text" value="Level 4, 810 Pacific Highway"/>	
Address 2: <input type="text"/>	Town/Suburb: <input type="text" value="Gordon"/>	State/Province: <input type="text" value="NSW"/>	Country: <input type="text" value="Australia"/>
Postcode: <input type="text" value="2072"/>	Phone: <input type="text" value="1800 252224"/>	Fax: <input type="text"/>	
Email: <input type="text"/>	Manufacturer Informed: <input type="text"/>	Date Aware of Adverse Event: <input type="text"/>	
Contact Title: <input type="text"/>	Contact First Name: <input type="text"/>	Contact Surname: <input type="text"/>	

Supplier Information Section

Supplier Name: Same as above		Address 1: 		Address 2: 	
Town/Suburb: 		State: 		Postcode: 	
Fax: 		Email: 		Supplier Informed: Yes	
Date of Supplier Contact: 11/07/2012		Contact Title: Mrs		Contact First Name: s22	
Contact Phone: 94980111		Contact Fax: 		Contact Surname: s22	

Statistics Checklist Section

Date: 02/10/2012	Assessed By: s22	For website publication: Yes	Ready for Publication: Yes	Exclude report from DIRE: <input type="checkbox"/>
Sample Received: No	Sterile: Yes	Reusable: No	Single Use: Yes	Potential Effect: Serious Injury
Actual Effect: Temporary Injury	Injured Party: Patient			Risk Frequency: Sometimes
Risk Severity: Serious	Risk Detectability: Likely	Classification: Routine	Investigated: 	Date of DIRE Meeting:
DIRE Meeting Notes: Investigation s22				

Sponsor Information Section

Search Sponsors: allergan	Name: Allergan Australia Pty Ltd	Client #: 17	
Attention To: s22	Address 1: Locked Bag 1514	Address 2: 	Town/Suburb: PYMBLE
State: NSW	Postcode: 2073	Phone: s22	Fax: 02 9498 0299
Email: s22@allergan.com			

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:

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

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

Incident Details

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

Samples Record - Click **[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 Section. Note that the Correspondence Recipient will receive a notification 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
Questionnaire sent		13/12/2012	02/01/2013	31/12/2012		See TRIM R13/30519.
Report Notification Sent		13/12/2012				
SC		24/01/2013	04/02/2013			
RC		24/01/2013	04/02/2013			

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

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

Investigation Problem Causes

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

Investigation Outcomes

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

Recall Number:

Investigation Summary:

Rupture is a known complication of silicone filled breast implants.

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.

Similar events - 483 / 64930 units sold in Australia since 2004 (0.74%)

Flow Details : DIR-REQ - Device Incident Request : 38345

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
38345	DIR-REQ		Closed	s22	OPR Administration User	24/01/2013	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	24/01/2013 12:06:42	
Comment		



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

24/10/2012

SIGNED

DIR : 20 - ID : 168251

Released by s22 on 25/06/2015 15:11:06

Report Information Section

Report #: 29009	Records Management #: 2012/023090	Reporter's Reference #: 	Report Type: Final
Report Status: Closed	Sponsor's Reported Category: 	Date of Adverse Event: 	Date of Initial Report: 07/11/2012
Date of Final Report: 07/11/2012	Date of Initial TGA Action: 07/11/2012	Reviewed by DIRE: 	Date Response Received:
Date Completed: 17/06/2014	Operator at Time of Event: 	If 'Other' Operator Selected: 	Reporter Confidentiality: No
Source of Report: Surgeon	If 'Other' Source Selected: 	Type of Initial Action: For IRIS Meeting	

Event Description for Website Publication:

Leakage - bilateral implants.

Granuloma developed (extensive).
Deformity of shape.

Clinical Event Information:

Leakage - bilateral implants.

Granuloma developed (extensive).
Deformity of shape.

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: Female	Weight: 	Age: s22 ears	
Patient Focused Corrective Action Taken: 			

Patient History:

Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:

Reporter #:

Reporter Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Country:

Postcode:

Phone:

Fax:

Mobile:

Email:

Last External Submission By:

Initial Reporter Section

As Above?:

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Title:

First Name:

Surname:

Position:

Company/Institution:

Address 1:

Address 2:

Town/Suburb:

State:

Postcode:

Phone:

Fax:

Mobile:

Email:			
Device Information Section			
Product Exempt:	<i>If No, fill out ARTG No:</i>	Search Device ARTG:	Device ARTG #:
No		128764	128764
Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN / UMDN Code:
Medical Device	Included	Class III	36197
GMDN / UMDN Text:	Brand Name:		
Prosthesis, internal, mammary, gel filled	Allergan Breast Implant		
Initial Device Description:			
Allergan Breast Implants			
Usage of Device:	Software Version:		
Single Use			
Model #:	Serial #:	Batch #:	Lot #:
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
		S22	S22
Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
Place of use			
Access Contact Phone:	Access Contact Fax:		
Manufacturer Information Section			
Manufacturer Name:	Manufacturer Client Id:	Address 1:	
Allergan	S22		
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:
<input type="text"/>		<input type="text"/>	<input type="text"/>
Town/Suburb:	State:	Postcode:	Phone:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Fax:	Email:		Supplier Informed:
<input type="text"/>	<input type="text"/>		No <input type="text"/>
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Contact Phone:	Contact Fax:		
<input type="text"/>	<input type="text"/>		

Statistics Checklist Section				
Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
<input type="text" value="08/11/2012"/>	<input type="text" value="§22"/>	<input type="text" value="Yes"/>	<input type="text" value="Yes"/>	<input type="checkbox"/>
Sample Received:	Sterile:	Reusable:	Single Use:	Potential Effect:
<input type="text" value="No"/>	<input type="text" value="Yes"/>	<input type="text" value="No"/>	<input type="text" value="Yes"/>	<input type="text" value="Serious Injury"/>
Actual Effect:	Injured Party:			Risk Frequency:
<input type="text" value="Temporary Injury"/>	<input type="text" value="Patient"/>			<input type="text" value="Sometimes"/>
Risk Severity:	Risk Detectability:	Classification:	Investigated:	Date of DIRE Meeting:
<input type="text" value="Serious"/>	<input type="text" value="Likely"/>	<input type="text" value="Routine"/>	<input type="text"/>	<input type="text"/>
DIRE Meeting Notes:				
<input type="text"/>				

Sponsor Information Section			
Search Sponsors:	Name:	Client #:	
<input type="text" value="allergan"/>	<input type="text" value="Allergan Australia Pty Ltd"/>	<input type="text" value="17"/>	
Attention To:	Address 1:	Address 2:	Town/Suburb:
<input type="text" value="§22"/>	<input type="text" value="Locked Bag 1514"/>	<input type="text"/>	<input type="text" value="PYMBLE"/>
State:	Postcode:	Phone:	Fax:
<input type="text" value="NSW"/>	<input type="text" value="2073"/>	<input type="text" value="§22"/>	<input type="text" value="(02) 9498 0299"/>

Email: <input style="width:95%;" type="text" value="GO-Medical-Affairs@allergan.com"/>	
Investigation Information Section	
Device Analysis Results: <input style="width:95%;" type="text"/>	
Corrective/Preventative Actions: <input style="width:95%;" type="text"/>	
Details of Similar Events: <input style="width:95%;" type="text"/>	
Number of Similar Events: <input style="width:95%;" type="text"/>	Rate of Similar Events: <input style="width:95%;" type="text"/>
Countries Similar Events Also Occurred: <input style="width:95%;" type="text"/>	
Additional Comments: <input style="width:95%;" type="text"/>	

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): <input style="width:95%;" type="text"/>	Brand Name: <input style="width:95%;" type="text"/>	Manufacturer Name: <input style="width:95%;" type="text"/>	Device ARTG #: <input style="width:95%;" type="text"/>	
---	---	--	--	--

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text	

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

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

Samples Record - Click **[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 Section. Note that the Correspondence Recipient will receive a notification 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
Questionnaire letter sent		05/03/2013	18/03/2013	19/03/2013		
Followup request- - further question		09/08/2013	20/08/2013			R13/609601
Sponsor response				22/08/2013		TRIM R14/792515
Sponsor Completion Letter		17/06/2014				
Reporter completion letter		17/06/2014				

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

Type Details

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

Investigation Problem Causes

Cause Details

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

Investigation Outcomes

Outcome Details	
Outcome of Investigation	If Additional Outcome Detail Requested
Reviewed, No Further Action Required	

Recall Number:

Investigation Summary:

The sponsor has provided reported rates of these types of adverse events: rupture 0.4455%; post-operative deformation: 0.0236%; and nodule/lump: 0.0101%. The adverse events reported are known to occur with these types of devices.

The sponsor has advised that granuloma had not been an adverse event term captured in their database and hence they were unable to provide specific data and rates for granuloma formation. However, the sponsor also advised that: "Prior to this response, it had already been determined that the need for such a code exists and it will added during the next update of the database. We will then be able to trend off this specific code going forward."


No further action is warranted at this stage. The TGA will continue to monitor the adverse event rates.

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		DIR 29009 incident report	19	Form	
FILE		DIR 29009 - questionnaire letter completed	95	Form	

Flow Details : DIR-REQ - Device Incident Request : 38712

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
38712	DIR-REQ		Closed		OPR Administration User	17/06/2014	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	12/10/2015 09:23:40	
Comment		



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

DIR : 20 - ID : 169016

Document 24

05/11/2012

SIGNED

Released by §22 on 25/06/2015 15:11:06

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
29137	2012/022827	0054582/AZ	Final
Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed	Death / Serious Injury	§22	13/09/2012
Date of Final Report:	Date of Initial TGA Action:	Reviewed by DIRE:	Date Response Received:
11/07/2013	05/11/2012	23/07/2013	
Date Completed:	Operator at Time of Event:	If 'Other' Operator Selected:	Reporter Confidentiality:
12/08/2013	Patient		No
Source of Report:	If 'Other' Source Selected:	Type of Initial Action:	
Sponsor		For IRIS Meeting	

Event Description for Website Publication:

During review of the Global Literature, an article entitled, "Breast Implant associated Anaplastic Large Cell Lymphoma: A case report and reconstructive option." was identified. Patient had bilateral augmentation. §22 later, she presented with RHS seroma, resolving with conservative management several weeks later. After another §22 she presented with RHS seroma and had 2 revision surgeries. §22 year the patient had bilateral replacement of implants and the device referenced in this report was implanted to the RHS. The patient re-presented again on several occasions with right breast seromas which were treated with multiple aspirations. About §22 later, the patient presented with another seroma - this was aspirated (300mL), cytology workup on the fluid identified ALCL. §22 later, the patient had bilateral explantation, bilateral capsulectomy, drainage of large serous fluid collection and replacement of implants. Left breast was negative for malignancy, RHS capsule showed evidence of ALCL (neoplastic cells), ALK1 was negative.

Clinical Event Information:

On §22 during review of the Global Literature, Allergan HQ identified an article entitled, "Breast Implant associated Anaplastic Large Cell Lymphoma: A case report and reconstructive option." This case was initially reported to Allergan by Dr on 27AUG2012 and reported to TGA on 13SEP2012 following confirmation that the involved implant was an Allergan device. Patient (DOB §22) had bilateral augmentation in §22 (Allergan Implants). In §22 she presented with RHS seroma, resolving with conservative management §22 later. In §22 she presented with RHS seroma and had 2 revision surgeries. In §22 the patient had bilateral replacement of implants (Allergan Implants) and the device referenced in this report was implanted to the RHS. The patient re-presented again on several occasions with right breast seromas which were treated with multiple aspirations. On §22 the patient presented with another seroma - this was aspirated (300mL), cytology workup on the fluid identified ALCL (cytology report previously reported to TGA). On §22 the patient had bilateral explantation, bilateral capsulectomy, drainage of large serous fluid collection and replacement of implants (Allergan Implants). Left breast was negative for malignancy, RHS capsule showed evidence of ALCL (neoplastic cells), ALK1 was negative.

Additional information is received on 15/07/2014:

On 8th June 2014 Allergan received written correspondence from the patient that stated; "I can no longer work full time since radiation treatment which resulted in the diagnosis of psoriatic arthritis - a chronic and debilitating condition that I experience primarily in my spine and right side of my torso."

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:	
Female		s22	
Patient Focused Corrective Action Taken:			
Explant surgery on s22 with replacement of implant. 36Gy in 20 fractions of s22			
Patient History:			
None reported.			
Patient Outcome/Consequences:			
s22 post capsulectomy and exchange of implants both breasts had healed with no evidence of seroma recurrence and with an excellent aesthetic result. The patient finished s22 and follow up is ongoing.			
Other Devices Involved:			
See Section VII - device information is being requested from Dr s22 for the other RHS device (implanted in s22 associated with the recurrent seromas.			
Submitting Reporter Section			
Search Reporter By Surname:	Reporter #:		
s22	5166 - s22 - Regulatory Affairs Officer - Allergan Australia		
Reporter Title:	First Name:	Surname:	
Ms	s22	s22	
Position:	Company/Institution:		
Regulatory Affairs Officer	Allergan Australia		
Address 1:	Address 2:	Town/Suburb:	State:
Allergan Australia	Level 4/810 Pacific Hwy	Gordon	New South Wales
Country:	Postcode:	Phone:	Fax:
Australia	2072	s22	9498 0299
Mobile:	Email:	Last External Submission By:	
	s22@allergan.com		
Initial Reporter Section			
As Above?:	If No, fill out the following:		Initial Reporter Confidential:
No			No
Search Reporter By Surname:	Initial Reporter #:		
Title:	First Name:	Surname:	

Mr	§22	§22		
Position:		Company/Institution:		
		§22		
Address 1:	Address 2:	Town/Suburb:	State:	
§22	§22	§22	§2	
Postcode:	Phone:	Fax:	Mobile:	
§22	§22	§22		
Email:				

Device Information Section

Product Exempt:	<i>If No, fill out ARTG No:</i>	Search Device ARTG:	Device ARTG #:
No		175422	175422
Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN / UMDN Code:
Medical Device	Included	Class III	36197
GMDN / UMDN Text:	Brand Name:		
Prosthesis, internal, mammary, gel filled	Natrele INSPIRA Truform 1 gel, Textured, Single Lumen Breast implants		
Initial Device Description:			
Natrele INSPIRA Truform 1 gel, Textured, Single Lumen Breast implants			
Usage of Device:	Software Version:		
Single Use			
Model #:	Serial #:	Batch #:	Lot #:
N-TRM275	16402266		2067491
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
		§22	§22
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:	
Allergan	§22		
Address 2:	Town/Suburb:	State/Province:	Country:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Postcode: <input type="text"/>	Phone: <input type="text"/>	Fax: <input type="text"/>	
Email: <input type="text"/>	Manufacturer Informed: Yes <input type="text"/>		Date Aware of Adverse Event: <input type="text" value="18/06/2013"/>
Contact Title: <input type="text"/>	Contact First Name: <input type="text"/>	Contact Surname: <input type="text"/>	
Supplier Information Section			
Supplier Name: <input type="text"/>		Address 1: <input type="text"/>	Address 2: <input type="text"/>
Town/Suburb: <input type="text"/>	State: <input type="text"/>	Postcode: <input type="text"/>	Phone: <input type="text"/>
Fax: <input type="text"/>	Email: <input type="text"/>		Supplier Informed: <input type="text"/>
Date of Supplier Contact: <input type="text"/>	Contact Title: <input type="text"/>	Contact First Name: <input type="text"/>	Contact Surname: <input type="text"/>
Contact Phone: <input type="text"/>	Contact Fax: <input type="text"/>		

Statistics Checklist Section				
Date: <input type="text" value="15/07/2013"/>	Assessed By: <input type="text" value="s22"/>	For website publication: <input type="text" value="No"/>	Ready for Publication: <input type="text"/>	Exclude report from DIRE: <input type="checkbox"/>
Sample Received: <input type="text" value="No"/>	Sterile: <input type="text" value="No"/>	Reusable: <input type="text" value="No"/>	Single Use: <input type="text" value="Yes"/>	Potential Effect: <input type="text" value="Death"/>
Actual Effect: <input type="text" value="Serious Injury"/>	Injured Party: <input type="text" value="Patient"/>			Risk Frequency: <input type="text" value="Unlikely"/>
Risk Severity: <input type="text" value="Serious"/>	Risk Detectability: <input type="text" value="Unlikely"/>	Classification: <input type="text" value="Routine"/>	Investigated: <input type="text"/>	Date of DIRE Meeting: <input type="text"/>
DIRE Meeting Notes: <input type="text" value="investigate"/>				

Sponsor Information Section

Search Sponsors: Allergan	Name: Allergan Australia Pty Ltd	Client #: 17
Attention To: s22	Address 1: Locked Bag 1514	Address 2:
State: NSW	Postcode: 2073	Town/Suburb: PYMBLE
Email: GO-Medical-Affairs@allergan.com	Phone: 1800 252 224	Fax: 02 9498 0299

Investigation Information Section

Device Analysis Results:

No analysis on this device was possible as it was not returned to Allergan.

Corrective/Preventative Actions:

The adverse event of "seroma" is clearly described in the product labeling. Anaplastic large-cell lymphoma (ALCL) is not an expected event (not listed in the product Instructions for Use) associated with use of Allergan Breast Implants.

Allergan are committed to patient safety and perform regular signal detection on adverse events reported to the Company. No new trend has been identified specific to the events in this report with the associated device. Numbers and incidence rates of seroma and ALCL with model # N-TRM275 will be provided in a follow up and final IRIS report. Follow up is also continuing with Dr s22 and any additional information will be reported to TGA.

Allergan conducts an annual review of ALCL diagnosed in patients with breast implants - the last review was made available to TGA on 25JAN2013, sent via email. Allergan will continue to gather, closely monitor and thoroughly investigate all sources of breast implant safety and performance data and act out of an abundance of caution to protect patients should adverse trends and/or events of significance can be identified.

Details of Similar Events:

No, not for this specific model #.

Inspira Textured Silicone Breast Implant Cat# N-TRM275 Similar Incidents for PRID 910509* Received Worldwide through July 7, 2013:

Seroma - AUS Events: 2, AUS Rate: 2.53%, WW Events**: 2, WW Rate: 0.04%.

Lymphoma - ALCL - AUS Events: 1, AUS Rate: 1.27%, WW Events**: 1, WW Rate: 0.02%.

Sales: AUS***: 79, WW†: 5,543.

*The above events do not include non device related (NDR) events. PR 910509 accounts for the Lymphoma -ALCL event and 1 seroma event. There are no events for this catalog number outside of Australia.

**Worldwide events includes Australia.

***Australia sales are from date first distributed of October 1, 2010 to May 31, 2013. June and July 2013 sales are not available at the time of this report.

†Worldwide sales include Australia. The sales date range is from date first distributed of November 1, 2009 through May 31, 2013. June and July 2013 sales are not available at the time of this report.

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Australia. There are no similar events for this device model # outside of Australia in our complaints database.

Additional Comments:

A request for follow up was sent to the health professional via email on 28JUN2013. No further information has been received to date. Section VII of this IRIS Report has been completed and this constitutes the final IRIS Report from Allergan Australia for this case.

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): <input type="text"/>	Brand Name: <input type="text"/>	Manufacturer Name: <input type="text"/>	Device ARTG #: <input type="text"/>
---	-------------------------------------	--	--

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text

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

Incident Details

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

Samples Record - Click **[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 Section. Note that the Correspondence Recipient will receive a notification 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

Completion letter		12/08/2013					
thank you email		16/07/2014					

List of Problem Type Codes Click **[N]** to begin entering information.

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

Investigation Problem Causes

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

Investigation Outcomes

Outcome Details		
Outcome of Investigation	If Additional Outcome Detail Requested	
Reviewed, No Further Action Required		

Recall Number:

Investigation Summary:

This report will be closed at this time however; the TGA will continue to monitor this type of issue.

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		0054582_article_18JUN2013	244	Form	
FILE		0054582 Follow up IRIS Report	119	Form	

FILE		0054582_Final IRIS Report	115	Form	Document 24
FILE		0054582_AE incidence rate report_10JUL2013	19	Form	

Flow Details : DIR-REQ - Device Incident Request : 38888

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
38888	DIR-REQ		Closed	s22	OPR Administration User	16/07/2014	Normal	2

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	16/07/2014 10:56:01	
Comment		



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

07/11/2012

SIGNED

DIR : 20 - ID : 169223

Released by s22 on 25/06/2015 15:11:06

Report Information Section

Report #: 29173	Records Management #: 2012/022967	Reporter's Reference #: 	Report Type: Final
Report Status: Closed	Sponsor's Reported Category: 	Date of Adverse Event: 	Date of Initial Report: 05/11/2012
Date of Final Report: 05/11/2012	Date of Initial TGA Action: 07/11/2012	Reviewed by DIRE: 13/11/2012	Date Response Received:
Date Completed: 03/12/2012	Operator at Time of Event: 	If 'Other' Operator Selected: 	Reporter Confidentiality: Yes
Source of Report: Other	If 'Other' Source Selected: Practice Manager	Type of Initial Action: For IRIS Meeting	

Event Description for Website Publication:

Ultrasound suggests possible rupture of right breast prosthesis.

The next day revised breast augmentation. Right rupture. Left intact prosthesis. Bilateral partial capsulectomies.

Clinical Event Information:

s22 Ultrasound suggests possible rupture of right breast prosthesis.

s22 Revised breast augmentation. Right rupture. Left intact prosthesis. Bilateral partial capsulectomies.

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: 	
----------	-------------	----------	--

Patient Focused Corrective Action Taken:

--

Patient History:

Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname: §22		Reporter #: 4991 - §22 - Practice Manager - §22	
Reporter Title: §22	First Name: §22	Surname: §22	
Position: Practice Manager		Company/Institution: §22	
Address 1: §22	Address 2: §22	Town/Suburb: §22	State: §22
Country: Australia	Postcode: §22	Phone: §22	Fax: §22
Mobile: §22	Email: §22		Last External Submission By: §22

Initial Reporter Section

As Above?: No	If No, fill out the following:		Initial Reporter Confidential: §22
Search Reporter By Surname: §22		Initial Reporter #: 5344 - §22 Surgeon - §22	
Title: Mr	First Name: §22	Surname: §22	
Position: Surgeon		Company/Institution: §22	
Address 1: §22	Address 2: §22	Town/Suburb: §22	State: §22
Postcode: §22	Phone: §22	Fax: §22	Mobile: §22
Email: §22			

s22			
Device Information Section			
Product Exempt: No	If No, fill out ARTG No:	Search Device ARTG: 128764	Device ARTG #: 128764
Therapeutic Licence Type: Medical Device	Product Licence Category: Included	Device Class: Class III	GMDN / UMDN Code: 36197
GMDN / UMDN Text: Prosthesis, internal, mammary, gel filled		Brand Name: McGhan Breast Implant	
Initial Device Description: McGhan Breast Prosthesis			
Usage of Device:	Software Version:		
Model #: 110-360	Serial #: 2V5057	Batch #: 27-110361	Lot #: 120248
Purchase Date:	Expiry Date:	Date of Implant: s22	Date of Explant: s22
Reported Device Location: With Supplier	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
Access Contact Phone:	Access Contact Fax:		
Manufacturer Information Section			
Manufacturer Name: Allergan	Manufacturer Client Id: s22	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:
<input type="text"/>		<input type="text"/>	<input type="text"/>
Town/Suburb:	State:	Postcode:	Phone:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Fax:	Email:		Supplier Informed:
<input type="text"/>	<input type="text"/>		<input type="text"/>
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Contact Phone:	Contact Fax:		
<input type="text"/>	<input type="text"/>		

Statistics Checklist Section				
Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
<input type="text" value="08/11/2012"/>	<input type="text" value="§22"/>	<input type="text" value="Yes"/>	<input type="text" value="Yes"/>	<input type="checkbox"/>
Sample Received:	Sterile:	Reusable:	Single Use:	Potential Effect:
<input type="text" value="No"/>	<input type="text" value="Yes"/>	<input type="text" value="No"/>	<input type="text" value="Yes"/>	<input type="text" value="Temporary Injury"/>
Actual Effect:	Injured Party:			Risk Frequency:
<input type="text" value="Temporary Injury"/>	<input type="text" value="Patient"/>			<input type="text" value="Sometimes"/>
Risk Severity:	Risk Detectability:	Classification:	Investigated:	Date of DIRE Meeting:
<input type="text" value="Serious"/>	<input type="text" value="Likely"/>	<input type="text" value="Routine"/>	<input type="text"/>	<input type="text"/>
DIRE Meeting Notes:				
<input type="text" value="Not investigated"/>				

Sponsor Information Section			
Search Sponsors:	Name:	Client #:	
<input type="text" value="allergan"/>	<input type="text" value="Allergan Australia Pty Ltd"/>	<input type="text" value="17"/>	
Attention To:	Address 1:	Address 2:	Town/Suburb:
<input type="text" value="§22"/>	<input type="text" value="Locked Bag 1514"/>	<input type="text"/>	<input type="text" value="PYMBLE"/>
State:	Postcode:	Phone:	Fax:
<input type="text" value="NSW"/>	<input type="text" value="2073"/>	<input type="text" value="§22"/>	<input type="text" value="(02) 9498 0292"/>

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:

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): <input type="text"/>	Brand Name: <input type="text"/>	Manufacturer Name: <input type="text"/>	Device ARTG #: <input type="text"/>
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Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text

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

Incident Details

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

Samples Record - Click **[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 Section. Note that the Correspondence Recipient will receive a notification 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
Completion letter sends		03/12/2012				

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

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

Investigation Problem Causes

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

Investigation Outcomes

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

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.

Flow Details : DIR-REQ - Device Incident Request : 38944

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
38944	DIR-REQ		Closed	s22	OPR Administration User	03/12/2012	Normal	0

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	03/12/2012 13:22:02	
Comment		



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

DIR : 20 - ID : 170266

Document 26

20/11/2012

SIGNED

Released by §22 on 25/06/2015 15:11:06

Report Information Section

Report #: 29355	Records Management #: 2013/001991	Reporter's Reference #: 	Report Type: Final
Report Status: Closed	Sponsor's Reported Category: 	Date of Adverse Event: §22	Date of Initial Report: 20/11/2012
Date of Final Report: 20/11/2012	Date of Initial TGA Action: 21/11/2012	Reviewed by DIRE: 27/11/2012	Date Response Received:
Date Completed: 23/04/2013	Operator at Time of Event: 	If 'Other' Operator Selected: 	Reporter Confidentiality: No
Source of Report: Patient	If 'Other' Source Selected: 	Type of Initial Action: For IRIS Meeting	

Event Description for Website Publication:

I have had a breast implant rupture. §22
§22

Clinical Event Information:

I have had a rupture in §22 §22
§22

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

Patient Information

Sex: 	Weight: §22	Age: §22 ths	
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Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

s22

I have recently tested positive for s22 test and have s22. I am being tested for connective tissue disorders such as s22 and or s22. I do not think this is a coincidence.

There is no outcome at this stage. I want this recorded as an issue on the register as I will not stop trying to prove silicone is toxic I know I am right and one day it will be proven and I hope I have a hand in this.

Connective tissue disorders have been reported many times in research for breast implant rupture even in USA FDA approval of gummy bear implant findings they just did not have enough to show causal link.

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname: s22		Reporter #: 	
Reporter Title: Ms	First Name: s22	Surname: s22	
Position: Public servant	Company/Institution: 		
Address 1: s22	Address 2: 	Town/Suburb: s22	State: s22
Country: 	Postcode: s22	Phone: s22	Fax:
Mobile: 	Email: s22	Last External Submission By: 	

Initial Reporter Section

As Above?: 	<i>If No, fill out the following:</i>	Initial Reporter Confidential:
Search Reporter By Surname: 	Initial Reporter #: 	
Title: 	First Name: 	Surname:
Position: 	Company/Institution: 	

Address 1: <input type="text"/>	Address 2: <input type="text"/>	Town/Suburb: <input type="text"/>	State: <input type="text"/>
Postcode: <input type="text"/>	Phone: <input type="text"/>	Fax: <input type="text"/>	Mobile: <input type="text"/>
Email: <input type="text"/>			
Device Information Section			
Product Exempt: <input type="text"/>	<i>If No, fill out ARTG No:</i> <input type="text"/>	Search Device ARTG: <input type="text"/>	Device ARTG #: <input type="text"/>
No		128764	128764
Therapeutic Licence Type: <input type="text"/>	Product Licence Category: <input type="text"/>	Device Class: <input type="text"/>	GMDN / UMDN Code: <input type="text"/>
Medical Device	Included	Class III	36197
GMDN / UMDN Text: <input type="text"/>	Brand Name: <input type="text"/>		
Prosthesis, internal, mammary, gel filled	McGhan Breast Implant		
Initial Device Description: <input type="text"/>			
Breast Implant Textured Gel			
Usage of Device: <input type="text"/>	Software Version: <input type="text"/>		
Single Use			
Model #: <input type="text"/>	Serial #: <input type="text"/>	Batch #: <input type="text"/>	Lot #: <input type="text"/>
Textured Gel	L#SNXG 6721; R# SNXZ 5240		
Purchase Date: <input type="text"/>	Expiry Date: <input type="text"/>	Date of Implant: <input type="text"/>	Date of Explant: <input type="text"/>
01/01/1999		s22	s22
Reported Device Location: <input type="text"/>	Access Contact Title: <input type="text"/>	Access Contact First Name: <input type="text"/>	Access Contact Surname: <input type="text"/>
Discarded			
Access Contact Phone: <input type="text"/>	Access Contact Fax: <input type="text"/>		
Manufacturer Information Section			
Manufacturer Name: <input type="text"/>		Manufacturer Client Id: <input type="text"/>	Address 1: <input type="text"/>
Allergan		s22	
Address 2: <input type="text"/>	Town/Suburb: <input type="text"/>	State/Province: <input type="text"/>	Country: <input type="text"/>
		<>	Australia
Postcode: <input type="text"/>	Phone: <input type="text"/>	Fax: <input type="text"/>	

Email:		Manufacturer Informed:		Date Aware of Adverse Event:
<input type="text"/>		<input type="text"/>		<input type="text"/>
Contact Title:	Contact First Name:	Contact Surname:		
<input type="text"/>	<input type="text"/>	<input type="text"/>		
Supplier Information Section				
Supplier Name:		Address 1:	Address 2:	
<input type="text" value="Mcghan Implants"/>		<input type="text"/>	<input type="text"/>	
Town/Suburb:	State:	Postcode:	Phone:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Fax:	Email:		Supplier Informed:	
<input type="text"/>	<input type="text"/>		<input type="text" value="No"/>	
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Contact Phone:	Contact Fax:			
<input type="text"/>	<input type="text"/>			

Statistics Checklist Section				
Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
<input type="text" value="21/11/2012"/>	<input type="text" value="s22"/>	<input type="text" value="Yes"/>	<input type="text" value="Yes"/>	<input type="checkbox"/>
Sample Received:	Sterile:	Reusable:	Single Use:	Potential Effect:
<input type="text" value="No"/>	<input type="text" value="Yes"/>	<input type="text" value="No"/>	<input type="text" value="Yes"/>	<input type="text" value="Serious Injury"/>
Actual Effect:	Injured Party:			Risk Frequency:
<input type="text" value="Serious Injury"/>	<input type="text" value="Patient"/>			<input type="text" value="Sometimes"/>
Risk Severity:	Risk Detectability:	Classification:	Investigated:	Date of DIRE Meeting:
<input type="text" value="Serious"/>	<input type="text" value="Likely"/>	<input type="text" value="Routine"/>	<input type="text"/>	<input type="text"/>
DIRE Meeting Notes:				
<input type="text" value="Investigate"/>				

Sponsor Information Section		
Search Sponsors:	Name:	Client #:
<input type="text" value="allergan"/>	<input type="text" value="Allergan Australia Pty Ltd"/>	<input type="text" value="17"/>

Attention To: s22	Address 1: Locked Bag 1514	Address 2:	Town/Suburb: PYMBLE
State: NSW	Postcode: 2073	Phone: s22	Fax: (02) 9498 0299
Email: s22@allergan.com			

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:

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 #:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Other Devices

Device ARTG No	Manufacturer Name	Sponsor/Supplier	Trade/Brand Name	Serial #	Model Number	GMDN / UMDN Text

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

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

Samples Record - Click **[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 Section. Note that the Correspondence Recipient will receive a notification 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	
Questionnaire letter sent		07/02/2013	20/02/2013	21/02/2013			
Reporter notification sent		07/02/2013					
Sponsor completion letter		23/04/2013				TRIM R13/339319	
Reporter completion letter		23/04/2013				TRIM R13/339462	

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

Type Details			
Type of Problem (Level 1)	Type of Problem (Level 2)	If 'Other' Type Selected	
Material	Burst		
Other	Other	Mutliple systemic symptoms	

Investigation Problem Causes

Cause Details

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

Investigation Outcomes



Outcome Details	
Outcome of Investigation	If Additional Outcome Detail Requested
Reviewed, No Further Action Required	

Recall Number:

Investigation Summary:

In response to this adverse event report, an investigation was undertaken. As part of this investigation additional information was requested from the sponsor. The device incident described in the report was noted as a known potential failure mode; the rate for similar incidents in Australia between January 2004 to February 2013 was reported as 1.4%. The sponsor states that they are continuing to follow-up the clinical details of this adverse event and that their investigation is ongoing.

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		DIR 29355 response letter	97	Form	
FILE		s22 020813_Final	19	Form	

Flow Details : DIR-REQ - Device Incident Request : 39162

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
39162	DIR-REQ		Closed	s22	OPR Administration User	23/04/2013	Normal	0

Signature Details

Role	IRIS Investigator	IRIS Investigator	
User	s22	s22	
Signed At	27/06/2014 14:26:25	23/04/2013 15:11:42	
Comment			



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

21/12/2012

SIGNED

DIR : 20 - ID : 231854

Released by s22 on 25/06/2015 15:11:06

Report Information Section

Report #: 29691	Records Management #: 2012/025151	Reporter's Reference #: 	Report Type: Final
Report Status: Closed	Sponsor's Reported Category: 	Date of Adverse Event: 	Date of Initial Report: 20/12/2012
Date of Final Report: 20/12/2012	Date of Initial TGA Action: 21/12/2012	Reviewed by DIRE: 15/01/2013	Date Response Received:
Date Completed: 25/02/2013	Operator at Time of Event: 	If 'Other' Operator Selected: 	Reporter Confidentiality: Yes
Source of Report: Surgeon	If 'Other' Source Selected: 	Type of Initial Action: For IRIS Meeting	

Event Description for Website Publication:

U/S - rupture.

Rev Augment.
Right intact device.
Left ruptured/Total Capsulectomy Bilateral.

Clinical Event Information:

U/S - rupture.

Rev Augment.
Right intact device.
Left ruptured/Total Capsulectomy Bilateral.

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: Female	Weight: 	Age: 	
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Patient Focused Corrective Action Taken:

Patient History:

Patient Outcome/Consequences:

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:

s22

Reporter #:

4991 - s22 - Practice Manager - s22

Reporter Title:

First Name:

s22

Surname:

s22

Position:

Practice Manager

Company/Institution:

s22

Address 1:

s22

Address 2:

Town/Suburb:

s22

State:

s22

Country:

Australia

Postcode:

s22

Phone:

s22

Fax:

s22

Mobile:

Email:

s22

Last External Submission By:

Initial Reporter Section

As Above?:

No

If No, fill out the following:

Initial Reporter Confidential:

Yes

Search Reporter By Surname:

s22

Initial Reporter #:

5344 - s22 - Surgeon - s22

Title:

Mr

First Name:

s22

Surname:

s22

Position:

Surgeon

Company/Institution:

s22

Address 1:

s22

Address 2:

Town/Suburb:

s22

State:

s22

Postcode:

Phone:

Fax:

Mobile:

s22	s22	s22	
Email:			
s22			
Device Information Section			
Product Exempt:	<i>If No, fill out ARTG No:</i>	Search Device ARTG:	Device ARTG #:
No		128763	128763
Therapeutic Licence Type:	Product Licence Category:	Device Class:	GMDN / UMDN Code:
Medical Device	Included	Class III	36197
GMDN / UMDN Text:	Brand Name:		
Prosthesis, internal, mammary, gel filled	INAMED Breast Implant		
Initial Device Description:			
INAMED Breast Implant			
Usage of Device:	Software Version:		
Single Use			
Model #:	Serial #:	Batch #:	Lot #:
ST -410FF 535G/ST - FF140-535	IH6152		249405
Purchase Date:	Expiry Date:	Date of Implant:	Date of Explant:
		s22	s22
Reported Device Location:	Access Contact Title:	Access Contact First Name:	Access Contact Surname:
Discarded			
Access Contact Phone:	Access Contact Fax:		
Manufacturer Information Section			
Manufacturer Name:	Manufacturer Client Id:	Address 1:	
Allergan	s22		
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:
<input type="text"/>		<input type="text"/>	<input type="text"/>
Town/Suburb:	State:	Postcode:	Phone:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Fax:	Email:		Supplier Informed:
<input type="text"/>	<input type="text"/>		<input type="text" value="No"/>
Date of Supplier Contact:	Contact Title:	Contact First Name:	Contact Surname:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Contact Phone:	Contact Fax:		
<input type="text"/>	<input type="text"/>		

Statistics Checklist Section				
Date:	Assessed By:	For website publication:	Ready for Publication:	Exclude report from DIRE:
<input type="text" value="24/12/2012"/>	<input type="text" value="s22"/>	<input type="text" value="Yes"/>	<input type="text" value="Yes"/>	<input checked="" type="checkbox"/>
Sample Received:	Sterile:	Reusable:	Single Use:	Potential Effect:
<input type="text" value="No"/>	<input type="text" value="Yes"/>	<input type="text" value="No"/>	<input type="text" value="Yes"/>	<input type="text" value="Serious Injury"/>
Actual Effect:	Injured Party:			Risk Frequency:
<input type="text" value="Temporary Injury"/>	<input type="text" value="Patient"/>			<input type="text" value="Sometimes"/>
Risk Severity:	Risk Detectability:	Classification:	Investigated:	Date of DIRE Meeting:
<input type="text" value="Serious"/>	<input type="text" value="Likely"/>	<input type="text" value="Routine"/>	<input type="text"/>	<input type="text"/>
DIRE Meeting Notes:				
<input type="text" value="More information required"/>				

Sponsor Information Section			
Search Sponsors:	Name:	Client #:	
<input type="text" value="allergan"/>	<input type="text" value="Allergan Australia Pty Ltd"/>	<input type="text" value="17"/>	
Attention To:	Address 1:	Address 2:	Town/Suburb:
<input type="text" value="s22"/>	<input type="text" value="Locked Bag 1514"/>	<input type="text"/>	<input type="text" value="PYMBLE"/>
State:	Postcode:	Phone:	Fax:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

NSW	2073	s22	(02) 9498 0299
Email:			
s22@allergan.com			
Investigation Information Section			
Device Analysis Results:			
Corrective/Preventative Actions:			
Details of Similar Events:			
Australia 40 similar event from 7151 sales = 0.55%			
Number of Similar Events:		Rate of Similar Events:	
40 (Aus)		0.55%	
Countries Similar Events Also Occurred:			
Additional Comments:			

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	

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

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

--	--	--	--	--	--

Samples Record - Click **[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 Section. Note that the Correspondence Recipient will receive a notification 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
RN		24/12/2012	04/01/2013			
Request for information		30/01/2013	10/02/2013			Requested ARTG #
Request for information		30/01/2013	10/02/2013			Requesting rates for rupture on ARTG 128763
RC letter		25/02/2013	08/03/2013			
SC letter		25/02/2013	08/03/2013			

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

Type Details

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

Investigation Problem Causes

Cause Details

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

Investigation Outcomes

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

Recall Number:

Investigation Summary:

The device was discarded after explantation and thus the manufacturer was unable to undertake any physical analysis of the implant. Rupture is a known complication associated with silicone breast implants. 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.

Similar events - 40 from 7151 sold in Australia = 0.55%

Flow Details : DIR-REQ - Device Incident Request : 39686

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
39686	DIR-REQ		Closed	s22	OPR Administration User	25/02/2013	Normal	0

Signature Details

Role	IRIS Investigator
User	s22
Signed At	21/06/2013 16:10:07
Comment	



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

DIR : 20 - ID : 231946

Document 28

21/12/2012

SIGNED

Released by s22 on 25/06/2015 15:11:06

Report Information Section

Report #:	Records Management #:	Reporter's Reference #:	Report Type:
29701	2012/025220		Final
Report Status:	Sponsor's Reported Category:	Date of Adverse Event:	Date of Initial Report:
Closed			21/12/2012
Date of Final Report:	Date of Initial TGA Action:	Reviewed by DIRE:	Date Response Received:
21/12/2012	24/12/2012	15/01/2013	
Date Completed:	Operator at Time of Event:	If 'Other' Operator Selected:	Reporter Confidentiality:
15/01/2013			Yes
Source of Report:	If 'Other' Source Selected:	Type of Initial Action:	
Nurse		For IRIS Meeting	

Event Description for Website Publication:

Pt informed doctor that she gradually noticed the left breast was larger, no pain, which gradually subsided but remained bigger. ? leak, patient had an MRI.

Patient had removal & replacement of bilateral breast implants. At surgery it was found there was a left intracapsular rupture, with the right implant intact. Supported by an MRI which was performed.

Clinical Event Information:

s22 Pt informed doctor that she gradually noticed the left breast was larger, no pain, which gradually subsided but remained bigger. ? leak, patient had an MRI.

s22 Patient had removal & replacement of bilateral breast implants. At surgery it was found there was a left intracapsular rupture, with the right implant intact. Supported by an MRI which was performed on 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:	
Female		s22 ears	

Patient Focused Corrective Action Taken:

--

Patient History:

Patient Outcome/Consequences:

§22 Patient had removal & replacement of bilateral breast implants. At surgery it was found there was a left intracapsular rupture, with the right implant intact. Supported by an MRI which was performed on §22.

Other Devices Involved:

Submitting Reporter Section

Search Reporter By Surname:

 §22

Reporter #:

Reporter Title:

 Miss

First Name:

 §22

Surname:

 §22

Position:

 Plastic & Cosmetic Nurse Consultant (RN)

Company/Institution:

 §22

Address 1:

 §22

Address 2:

 §22

Town/Suburb:

 §22

State:

 §22

Country:

Postcode:

 §22

Phone:

 §22

Fax:

 §22

Mobile:

Email:

 §22

Last External Submission By:

Initial Reporter Section

As Above?:

If No, fill out the following:

Initial Reporter Confidential:

Search Reporter By Surname:

Initial Reporter #:

Title:

First Name:

Surname:

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: 151739	Device ARTG #: 151739
Therapeutic Licence Type: Medical Device	Product Licence Category: Included	Device Class: Class III	GMDN / UMDN Code: 36197
GMDN / UMDN Text: Prosthesis, internal, mammary, gel filled		Brand Name: Natrele Inspira	
Initial Device Description: Textured, round, soft-touch breast implant			
Usage of Device: Single Use	Software Version:		
Model #: TSF 415	Serial #: 14427984	Batch #:	Lot #: 1747248
Purchase Date:	Expiry Date:	Date of Implant: §22	Date of Explant: §22
Reported Device Location: With Supplier	Access Contact Title: Mrs	Access Contact First Name: §22	Access Contact Surname: §22
Access Contact Phone: §22	Access Contact Fax:		

Manufacturer Information Section

Manufacturer Name: Allergan	Manufacturer Client Id: §22	Address 1: Level 4, 810 Pacific Highway	
Address 2:	Town/Suburb: Gordon	State/Province: NSW	Country: Australia
Postcode: 2072	Phone: §22	Fax: + 61 2 9498 0184	
Email: www.allergan.com.au	Manufacturer Informed:	Date Aware of Adverse Event:	
Contact Title:	Contact First Name:	Contact Surname:	

Supplier Information Section			
Supplier Name: Same as above 'manufacturers'		Address 1: 	Address 2:
Town/Suburb: 	State: 	Postcode: 	Phone:
Fax: 	Email: 		Supplier Informed: Yes
Date of Supplier Contact: 20/11/2012	Contact Title: Mrs	Contact First Name: §22	Contact Surname: §22
Contact Phone: §22	Contact Fax: 		

Statistics Checklist Section				
Date: 24/12/2012	Assessed By: §22	For website publication: Yes	Ready for Publication: Yes	Exclude report from DIRE: <input type="checkbox"/>
Sample Received: No	Sterile: Yes	Reusable: No	Single Use: Yes	Potential Effect: Serious Injury
Actual Effect: Temporary Injury	Injured Party: Patient			Risk Frequency: Sometimes
Risk Severity: Serious	Risk Detectability: Occasionally	Classification: Routine	Investigated: 	Date of DIRE Meeting:
DIRE Meeting Notes: More information required				

Sponsor Information Section			
Search Sponsors: allergan	Name: Allergan Australia Pty Ltd	Client #: 17	
Attention To: §22	Address 1: Locked Bag 1514	Address 2: 	Town/Suburb: PYMBLE
State: 	Postcode: 	Phone: 	Fax:

Email:

Investigation Information Section

Device Analysis Results:

Corrective/Preventative Actions:

Details of Similar Events:

Australia	16	11,647	0.137%
Worldwide	299	94,138	0.318%

Number of Similar Events:

Rate of Similar Events:

Countries Similar Events Also Occurred:

Additional Comments:

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

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

Incident Details

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

Samples Record - Click **[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 Section. Note that the Correspondence Recipient will receive a notification 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
RN letter		24/12/2012	04/01/2013			
Questionnaire		24/12/2012	04/01/2013			
RC		15/01/2013	26/01/2013			
SC		15/01/2013	26/01/2013			

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

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

Investigation Problem Causes

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

Investigation Outcomes

Outcome Details

Outcome of Investigation	If Additional Outcome Detail Requested	
Reviewed, No Further Action Required		

Recall Number:

Investigation Summary:

Rupture is a known complication of breast implant surgery. 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.

Similar events - Aus (16/11,647 - 0.137%) WW (299/94,138 - 0.318%)

Flow Details : DIR-REQ - Device Incident Request : 39702

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
39702	DIR-REQ		Closed	s22	OPR Administration User	15/01/2013	Normal	2

Signature Details

Role	IRIS Investigator	
User	s22	
Signed At	15/01/2013 16:14:58	
Comment		



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

DIR : 41 - ID : 511957

Released by s22 on 19/11/2020 14:40:19

Report #: <input type="text" value="66372"/>	Records Management #: <input type="text"/>	Reporter's Reference #: <input type="text" value="2286679"/>	Report Type: <input type="text" value="Final"/>
ARTG: 220900	Document Container URL		

Report Information Section

Report Status: <input type="text" value="Closed"/>	Sponsor's Reported Category: <input type="text" value="Death / Serious Injury"/>	Date of Adverse Event: <input type="text"/>	Date of Initial Report: <input type="text" value="05/11/2020"/>
Date of Final Report: <input type="text" value="15/12/2020"/>	Date of Initial TGA Action: <input type="text" value="05/11/2020"/>	Reviewed by Team: <input type="text"/>	Date Response Received: <input type="text"/>
Date Completed: <input type="text" value="14/01/2021"/>	Operator at Time of Event: <input type="text" value="Healthcare Professional"/>	If 'Other' Operator Selected: <input type="text"/>	Reporter consents to contact by sponsor: <input type="text" value="N/A"/>
Source of Report: <input type="text" value="Sponsor"/>	If 'Other' Source Selected: <input type="text"/>	Type of Initial Action: <input type="text" value="Trend data only"/>	

Event Description for Website Publication:

Clinical Event Information:

Patient reported, her breast implants " just didn't feel right, so I decided to the explanted," s22, s22 and s22 " [INFECTION (unknown onset) s22 for the left side. The patient also reported " s22

The device has been explanted and not replaced.

---Summary of histopathology report dated s22 received from HCP:

Microscopic Description:

s22

Number of Incidents in Report: <input type="text" value="1"/>	Contact: <input type="text"/>	Alternative Person Title: <input type="text"/>	Alternative Person First Name: <input type="text"/>
Alternative Person Surname: <input type="text"/>	Alternative Person Phone: <input type="text"/>	Alternative Person Fax: <input type="text"/>	Alternative Person Email: <input type="text"/>

Recorded Problems Observed

Recorded Problems Observed:

Clinical Signs, Symptoms and Conditions

Recorded Clinical Signs, Symptoms and Conditions:

Health Impact

Recorded Health Impacts:

Patient Information

Sex: <input type="text" value="Female"/>	Weight: <input type="text"/>	Age: <input type="text" value="s22"/>
---	---------------------------------	--

Patient Focused Corrective Action Taken:

Explant procedure and no replacement of the devices

Patient Outcome/Consequences:

Describe any test (Lab, xray, etc.):

Medical Problem Device Used For:

Injured - Extent of Injury:

Serious Injury

Additional Patients Added:

0

Patient History:

Additional Event Description:

Consequence:

Required surgical intervention

Other medical devices currently using/implanted:

Submitting Reporter Section

Search Reporter By Surname:

§22

Reporter Title:

Mrs

Position:

Product Surveillance Manager APAC

Address 1:

Level 4, 810 Pacific Highway

Country:

Australia

Mobile:

Reporter #:

First Name:

§22

Address 2:

Postcode:

2072

Email:

§22 @allergan.com

Surname:

§22

Company/Institution:

Allergan

Town/Suburb:

Gordon

Phone:

§22

Last External Submission By:

101076_17 - 15/12/2020 09:48

Preferred Contact Method:

Initial Reporter Section

As Above?:

Search Reporter By Surname:

§22

Title:

Dr

Position:

Explanting surgeon

Address 1:

Postcode:

Mobile:

If No, fill out the following:

Initial Reporter #:

First Name:

§22

Address 2:

Country:

Email:

Surname:

§22

Company/Institution:

Town/Suburb:

Phone:

Allow the device company to contact you about the incident:

Initial Reporter Confidential:

Preferred Contact Method:

Device Information Section

Product Exempt (Note: If not exempt, enter ARTG No):

No

Product Licence Category:

Included

Brand Name:

BRST Round Textured Cohesive gel filled - Prosthesis, internal, mammary, gel filled

Model #:

Search Device ARTG:

220900

Device Class:

Class III

Initial Device Description:

BRST Round Textured Cohesive gel filled - Prosthesis, internal, mammary, gel filled

Serial #:

Device ARTG #:

220900

GMDN / UMDN Code:

36197

Usage of Device:

Single Use

Batch #:

Therapeutic Licence Type:

Medical Device

GMDN / UMDN Text:

Prosthesis, internal, mammary, gel filled

Software Version:

na

Lot #:

CHP-345	23423939
Purchase Date:	Expiry Date:
Date of Inital Procedure:	Place of Implantation:
Access Contact First Name:	Access Contact Surname:
Access Contact Email:	Licence Status:
	A

Date of Implant:
Reported Device Location:
Access Contact Phone:
Status Effective Date:
07/03/2014

3239454
Date of Explant:
Access Contact Title:
Access Contact Fax:
Additional Devices Added:
0

Manufacturer Information Section

Manufacturer Name:	Allergan
Address 2:	Town/Suburb:
Postcode:	Phone:
Manufacturer Informed:	Date Aware of Adverse Event:
Yes	27/10/2020
Contact Surname:	

Manufacturer Client Id:
State/Province:
Fax:
Contact Title:

Address 1:
Country:
Email:
Contact First Name:

Supplier Information Section

Supplier Name:	State:
Town/Suburb:	Phone:
Supplier Informed:	Date of Supplier Contact:
Contact Surname:	Contact Phone:

Address 1:
Country:
Email:
Contact Title:
Contact Fax:

Address 2:
Postcode:
Website:
Contact First Name:
Contact Email:

Report Status					
For website publication:	Ready for Publication:	Investigated:	Investigation Reason:	Team Assignment:	Team Priority:
Yes	Yes	No	Known complication	Unassigned	Not Investigated

Team Review		
Reviewed by Team:	Reason Sent To Meeting:	Outcome from team meeting:
Notes for Team meeting:		
Outcomes from Team Meeting:		

DPRC Review		
Reviewed by DPRC:	DPRC Reason Sent To Meeting:	Outcome from DPRC Meeting:

Meeting Notes:					
Initial Risk Analysis					
Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D	
Date: 05/11/2020	Severity: 6 - Ongoing minor impairment	Incidents in the last 12 months:	Manufacturer analysis:	Assessor: S22	Manufacturer documentation:
Incidents in last 24 months:	Manufacturer action:	ESTIMATED LEVEL OF INVESTIGATION: Screening only	FINAL LEVEL OF INVESTIGATION: Screening only	Injured Party: Patient	Device Recalls:
Incidents in last 36 months:	IVD status:	EXCEPTION TO INVESTIGATION LEVEL: Similar events based on lymphadenopathy		Found Prior To Use: No	Is AE covered by current recall:
Incidents Worldwide:	Number of potential contributing factors: No			Reusable: No	Similar events (past 6 months): 0 incidents
Products supplied the last 12 months:	Specific factors identified:	ESTIMATED LEVEL OF PRIORITY: Routine	FINAL LEVEL OF PRIORITY: Routine		3 or more events - batch/model:
Products supplied last 24 months:	Number of potential sensitivities: Yes - some potential sensitivities (up to 3)	EXCEPTION TO PRIORITY LEVEL:			3 or more events - health district:
Products supplied last 36 months:	Specific sensitivities identified: Device is difficult to substitute				3 or more events - organisation:
Products supplied Worldwide:	Consultations during risk assessment: I did none of the above incidents	Final Risk Assessment: No			

Additional Risk Analysis

Click 'N' to start a new risk analysis


Analysis Details	Statistics Checklist Section				
Update Device Details?: Yes	Background Information	Risk Assessment - Section A	Risk Assessment - Section B	Risk Assessment - Section C	Risk Assessment - Section D
Copy Data From: Initial	Date: 14/01/2021	Severity: 6 - Ongoing minor impairment	Incidents in the last 12 months:	Manufacturer analysis: Yes	
	Assessor: S22	Manufacturer documentation: Unknown - updated information from the manufacturer is required	Incidents in last 24 months:	Manufacturer action: Unable to take action (device was not returned for analysis)	ESTIMATED LEVEL OF INVESTIGATION: Level 2 Investigation (for a single DIR)
	Injured Party: Patient	Device Recalls: 2. Recalls for similar incidents in Australia have occurred more than 12 months up to 3 years ago	Incidents in last 36 months:	IVD status:	FINAL LEVEL OF INVESTIGATION: Screening only
	Found Prior To Use: No	Is AE covered by current recall: Yes	Incidents Worldwide:	EXCEPTION TO INVESTIGATION LEVEL: Known complication	
	Reusable: No	Similar events (past 6 months): 0 incidents	Products supplied the last 12 months:	Number of potential contributing factors: Yes - some potential factors (up to 3)	
		3 or more events - batch/model:	Products supplied last 24 months:	Specific factors identified: Compatibility of device - patient characteristics, Use of device - fit for purpose	ESTIMATED LEVEL OF PRIORITY: Routine
		3 or more events - health district:	Products supplied last 36 months:	Number of potential sensitivities: Yes - some potential sensitivities (up to 3)	FINAL LEVEL OF PRIORITY: Routine
				Specific sensitivities identified:	EXCEPTION TO PRIORITY LEVEL:

		Device is difficult to substitute, Investigations/actions by other regulators	
3 or more events - organisation:	Products supplied Worldwide:	Consultations during risk assessment:	Final Risk Assessment:
		I discussed issues with one of the team leaders	Yes

Sponsor/Manufacturer Information Section

Search Sponsors: 17	Name: Allergan Australia Pty Ltd	Client #: 17
Attention To: §22	Address 1: Locked Bag 1004	Address 2:
State: NSW	Postcode: 2072	Town/Suburb: Gordon
Email: §22 @allergan.com	Phone: 	Fax:

Investigation Information Section - Submitted by Sponsor/Manufacturer

Device Analysis Results: Primary cause assessment: Not possible as the device was not returned Lab analysis was not possible as the device was not returned to Allergan. --DHR The review of the documentation associated to the manufacturing process indicates that all devices with work order 3239454 were released in accordance with Allergan Medical's procedures, and no anomalies were found in the documents related to the reported event.	Corrective/Preventative Actions: None. The event is not a new or novel event, and based on the severity of the individual occurrence, no CAPA required at this time. Additional actions will be taken if an outlying trend is noticed as part of the aggregate trending based on severity and frequency
Details of Similar Events: Period: Nov 2017 to Oct 2020 DEPRESSION: Australia: 2 similar events, out of 4962 devices distributed= 0.040% Worldwide: 0 similar events, out of 10964 devices distributed= NIL LYMPHADENOPHATY Australia: 1 similar events, out of 4962 devices distributed= 0.020% Worldwide: 0 similar events, out of 10964 devices distributed= NIL INFECTION (unknown onset)-NDR Australia: 2 similar events, out of 4962 devices distributed= 0.040% Worldwide: 0 similar events, out of 10964 devices distributed= NIL	Additional Details (use for tables): 
CAPA# Reference: <input type="text"/>	
Risk Assessment	
Frequency: <input type="text"/> Severity: <input type="text"/> Rating: <input type="text"/> Expected Rate: <input type="text"/> Actual Rate: <input type="text"/>	Type Cause and Outcome: <input type="text"/> Number of Similar Events: <input type="text"/>
Countries Similar Events Also Occurred: DEPRESSION: Australia LYMPHADENOPHATY: Australia INFECTION (unknown onset)-NDR: Australia	
Completed Actions: <input type="text"/>	Planned Actions and Proposed Timelines: <input type="text"/>
Additional Comments: Report closed 14 January 2021	

Reason for Level 1 Investigation

Details of Reasons

Reason for Level 1 Investigation

Focus of Level 2 Investigation

Details of Focus

Essential Principles

If 'Other' Selected

Sources of Evidence for Level 2

Details of Source

Sources of Evidence

If 'Others' please specify here

Expected Sourcing Date

Date of Evidence Received

Evidence

Investigation Questions (Level 1 and Level 2):

Potential Risks

Delays in response by product manufacturers:

Delays in response by incident reporters:

Delays in analysis within the TGA:

Delays in reporting by other sources (e.g. clinical registries):

Other Risks (which need to be specified):

Next Steps for Level 1 & Level 2 Investigations

Next Steps for Level 1 Investigation:

Next Steps for Level 2 Investigation:

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 and Chronology Details

Include?	Heading	Type L1	Type L2	Email	Sent	Expected	Received	Response	Notes

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

Appropriate Term/Code Not Available

Lymphadenopathy

Clinical signs symptoms and conditions

Details

Level 1

Level 2

Level 3

Infections

Bacterial Infection

Immune System	Autoimmune Disorder		
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Health Impact

Details

Level 1	Level 2	Level 3
Surgical Intervention	Device Explanation	

Investigation Findings

Finding Details

Investigation Findings (Level 1)	Investigation Findings (Level 2)	Investigation Findings (Level 3)	If 'Other' Selected
No Findings Available			

Investigation Conclusion

Conclusion Details

Investigation Conclusion (L1)	Investigation Conclusion (L2)	If Additional Conclusion Detail Requested
Cause Not Established		

Investigation Outcomes

Outcome Details

Outcome of Investigation (L1)	Outcome of Investigation (L2)	If Additional Conclusion Detail Requested
Reviewed, for Trending Purposes Only		

Investigation Summary

Latest Investigation (DII) where this DIR is the Primary DIR: <input type="text"/>	Latest Investigation (DII) where this DIR is a Related DIR: <input type="text"/>	Investigator: <input type="text"/>	Peer Review: <input type="text" value="No"/>
Investigator's Notes: <input type="text"/>		Summary Findings: <input type="text" value="No further investigation will occur at this time. The TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate."/>	
			Recall Number: <input type="text" value="RC-2020-RN-00186-1"/>

Note: Letter generation buttons disabled if report not ready for website publication or risk analysis not completed.

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): <input type="text"/>	Brand Name: <input type="text"/>	Manufacturer Name: <input type="text"/>	Device ARTG #: <input type="text"/>
---	-------------------------------------	--	--

Other Devices

Device ARTG No:	Manufacturer Name:	Sponsor/Supplier:	GMDN / UMDN Text:	Trade/Brand Name:	Serial #:
Model Number:	Batch #:	Lot #:	Expiry Date:		

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.

Rec No	Details	Sample Details			Additional Details				
1	Date Entered:	LIMS #:	Sample Requested:	Sample Received:	Manufacturer:	GMDN:	Device Description:	Brand Name:	Serial Number:
	Reason for Testing:	# Samples from Reporter:	# Samples from Sponsor:	Outcome of TGA's Testing:	Lot Number:	Batch Number:	Model Number:	Version Number:	
						Who sent the device to the TGA?:		Why does the TGA have the sample?:	

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 disability?:	Consequence:
Other Consequence:	Describe any test (Lab, xray, etc.):	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 - Alternate Device Contact Information Provided

Title:

First Name:

Last Name:

Phone:

Fax:

Email:

Incident Location Details

Occurred in Australia:	Organisation:
<input type="text"/>	<input type="text"/>
Town/Suburb:	State:
<input type="text"/>	<input type="text"/>


Address Line 1:	Address Line 2:
<input type="text"/>	<input type="text"/>
Postcode:	
<input type="text"/>	

Attachment(s) Details

Type	Open	Name	Size	Attached Within	Attached To
FILE		TGA Recall Notice & Hazard Alert - RC-2020-RN-...	277	Form	

Flow Details : DIR-REQ - Device Incident Request : 285815

Request Details

ID	Type	Location	Status	Assigned By	Assigned To	Assigned On	Priority	Attach
285815	DIR-REQ		Closed		OPR Administration User	14/01/2021	Normal	0

Signature Details

Role	IRIS Investigator
User	
Signed At	14/01/2021 10:50:29
Comment	



Australian Government

Department of Health
Therapeutic Goods Administration

**URGENT PRODUCT DEFECT CORRECTION; AND
IMPLANT HAZARD ALERT***

LEVEL: Hospital

CLASS: Class II

REFERENCE: RC-2020-RN-00186-1

DATE AGREED: 28/02/2020

PRODUCT: Allergan Breast Implants

BRST Round Microcell Textured Cohesive gel filled
ARTG 220900

BRST Round Microcell Textured Responsive gel filled
ARTG 218869

BRST Round Smooth Responsive gel filled
ARTG 220696

NATRELLE INSPIRA Truform 2 gel, Smooth, Single Lumen
ARTG 175426

NATRELLE INSPIRA, Truform 1 gel, Smooth, Single Lumen
ARTG 175421

NATRELLE Truform1 Gel, Smooth Single Lumen
ARTG 171393

SPONSOR: Allergan Australia Pty Ltd

PHONE: 02 9498 0290 - Allergan Customer Service

REASON: As an outcome of the TGA post market review of breast implants and breast tissue expanders supplied in Australia, Allergan Australia are required to update their Instructions For Use (IFU) and issue a hazard alert pertaining to the risk of Breast Implant Associated-Anaplastic Large Cell Lymphoma (BIA-ALCL).

PROPOSED CUSTOMER ACTIONS: Hazard Alert Instructions:
Implanting surgeons are alerted to this issue and requested to review the relevant literature in the context of their particular patients on a case-by-case basis.

Product Defect Correction Instructions:
Allergan is advising customers that a boxed warning regarding BIA-ALCL will be placed on the product packaging.

The sponsor is expected to dispatch letters to all affected customers within two working days of the agreed date. **Please do not contact the sponsor for further information unless you believe that you have the goods under recall and have not received a recall letter.**

Product Distribution: 177 surgeons nationally

Product export status: Unknown

This issue was first identified by the Sponsor

*For further details about Recall Actions, please refer to <http://tga.gov.au/safety/recalls-about.htm>



Australian Government

Department of Health

Therapeutic Goods Administration

Recall Action Notification

Macro Textured Breast Implants & Tissue Expanders

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Important information on the System for Australian Recall Actions

The TGA publishes information about therapeutic goods supplied in the Australian market that have been subject to a recall action in a publicly searchable database.

Recall action means action taken by the responsible entity (being the person who is responsible for taking the recall action) to resolve a problem with therapeutic goods supplied in the Australian market that have, or may potentially have, deficiencies relating to safety, quality, efficacy (performance) or presentation.

- Recall actions include: the permanent removal of therapeutic goods from supply in the market, the taking of corrective action in relation to therapeutic goods (such as repair, modification, adjustment or relabelling) and, in the case of medical devices that have been implanted into patients, the issuing of a hazard alert containing information for health practitioners on how to manage patients.
- More information about Australian recall actions is available at <http://tga.gov.au/safety/recalls-about.htm>
- If you are taking a medicine, using a medical device or have had a medical device implanted into you, that is the subject to a recall action, and you have any concerns you should seek advice from a health professional. <http://www.healthdirect.org.au/>

About the release of this information

While reasonable care is taken to ensure that the information is an accurate record of recall actions that responsible entities have reported to the TGA or of which the TGA has become aware, the TGA does not guarantee or warrant the accuracy, reliability, completeness or currency of the information or its usefulness in achieving any purpose.

To the fullest extent permitted by law, including but not limited to section 61A of the Therapeutic Goods Act 1989, the TGA will not be liable for any loss, damage, cost or expense incurred in or arising by reason of any person relying on this information.

The information contained in the SARA database is released under s 61(5C) of the Therapeutic Goods Act 1989.

Copyright restrictions apply to the System of Australian Recall actions (SARA) <http://tga.gov.au/about/website-copyright.htm>.

Recall detail

Type of Productⁱ	Medical Device
TGA Recall Referenceⁱⁱ	RC-2019-RN-01116-1
Product Name/Descriptionⁱⁱⁱ	<p>Macro Textured Breast Implants & Tissue Expanders</p> <p>Natrelle Products:</p> <p>INSPIRA Truform 1 gel, Textured, Single Lumen INSPIRA Truform 2 gel, Textured Single Lumen Truform 1 gel, Textured, Single Lumen Truform 3 gel, Textured Single Lumen Soft Touch, Truform 2 gel, Textured, Single Lumen Truform Dual gel, Textured Single Lumen Saline-filled, Textured Double Lumen Gel/Saline Tissue Expanders - Skin expander</p> <p>ARTGs: 175422, 175425, 175420, 171512, 171475, 171387, 171388, 169956, 175797</p>
Recall Action Level^{iv}	Hospital
Recall Action Classification^v	Class I
Recall Action Commencement Date^{vi}	30/07/2019
Responsible Entity^{vii}	Allergan Australia Pty Ltd
Reason / Issue^{viii}	<p>Allergan is taking this action as a precautionary measure, following notification of recently updated global safety information concerning the uncommon incidence of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL).</p> <p>Recent evaluation suggests there is an increased risk of BIA-ALCL in individuals with highly textured (macro-textured) implants in comparison with those having less textured (micro-textured) or smooth implants. BIA-ALCL is a type of non-Hodgkin lymphoma that may develop many months or years after a breast implant procedure. It is not a cancer of the breast tissue. BIA-ALCL usually presents as an accumulation of fluid (known as seroma fluid) between the implant and the surrounding tissue. Whilst the specific mechanism is unknown, possible risk factors for the disease include the high surface area of the macro-textured implants, genetic factors, and long-term inflammation around the implant, possibly triggered by factors such as bacterial infection.</p>
Recall Action^{ix}	Hazard Alert

System for Australian Recall Actions

Recall Action Instructions^x	<p>Hazard Alert Instructions:</p> <p>Implanting surgeons are alerted to this issue and requested to review the relevant literature in the context of their particular patients on a case-by-case basis.</p> <p>The TGA does not provide clinical advice as part of its mandate under the Therapeutic Goods Act 1989, however the TGA website does contain information for health professionals and consumers regarding this matter.</p> <p>Furthermore, the TGA has been advised that removal or replacement of macro-textured breast implants or tissue expanders in asymptomatic patients is not recommended.</p> <p>Recall Instructions:</p> <p>Customers are requested to inspect all breast implant stock and quarantine any affected inventory. Following receipt of a completed Customer Acknowledgement Form (provided with the Customer Letter), the distributor, Device Technologies, will arrange collection of affected product.</p> <p>This action has been closed out on 09/02/2021.</p>
Contact Information^{xi}	02 9975 5755 - Device Technologies (distributor)

Footnotes

ⁱ Type of Product: Medicine, Medical Device, or Biological

ⁱⁱ TGA Recall Reference: Unique number given by the TGA

ⁱⁱⁱ Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference for the kind of medical devices. Includes all necessary information such as affected: catalogue / model and / or batch / serial numbers.

^{iv} Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the risk and the channels through which the goods have been distributed. The recall action levels are / Wholesale / Hospital / Retail / Consumer.

- **Wholesale** - includes wholesalers and state purchasing authorities.
- **Hospital** - includes nursing homes and institutions, hospital pharmacists, ambulance services, blood and tissue banks and laboratories as well as wholesale as appropriate.
- **Retail** - includes retail pharmacists, medical, dental and other health care professionals as well as wholesale and hospital as appropriate.
- **Consumer** - includes patients and consumers, as well as wholesale, hospital and retail levels as appropriate.

^v Recall Action Classification^{**}: Recall actions of therapeutic goods are classified based on the potential risk the deficiency poses to patients / consumers. They are classified as Class I, Class II or Class III.

- **Class I** - A situation in which there is a reasonable probability that the use of, or exposure to, the deficient therapeutic good(s) will cause serious adverse health consequences or death.
- **Class II** - A situation in which use of, or exposure to, the deficient therapeutic good(s) may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote.
- **Class III** - A situation in which use of, or exposure to, the deficient therapeutic good(s) is not likely to cause adverse health consequences.

^{vi} Recall Action Commencement Date: The date the recall strategy and communication was agreed by the TGA.

^{vii} Responsible Entity: Sponsor / Supplier / Importer responsible for the recall actions.

System for Australian Recall Actions

viii Reason / Issue: Reason for the recall action.

ix Recall Action^{**}: Recall action is an action taken to resolve a problem with a therapeutic good already supplied in the market for which there are issues or deficiencies in relation to safety, quality, efficacy (performance) or presentation.

There are four distinct recall actions – recall, product defect correction, hazard alert and product defect alert.

- **Recall** - The permanent removal of an affected therapeutic good from supply or use in the market.
- **Product defect correction** - Repair, modification, adjustment or re-labelling of a therapeutic good. The corrective action may take place at the user's premises or any other agreed location.
- **Hazard alert** - Information issued to healthcare professionals about issues or deficiencies relating to an implanted medical device or biological product and advice about the ongoing management of patients.
- **Product defect alert** - Information issued to raise awareness about issues or deficiencies for a therapeutic good where a recall action will result in interruption of patient treatment or a medicine shortage, including advice to reduce potential risks of using affected goods.

x Recall Action Instructions: What customers with affected goods should do.

xi Contact Information: Who the customer should contact for additional information and clarification regarding the recall action.

^{**} These definitions are applicable to the 2017 URPTG (Implemented from Jan 15 2018). Recall Action types and Recall Action Classifications prior to 15 Jan 2018 can be found at:

<https://www.tga.gov.au/sites/default/files/recalls-urptg-170412.pdf>