Email Message

From:	scanneddocument [SMTP:scanneddocument@tga.gov.au]
To:	[redacted]@tga.gov.au]
Cc:	
Sent:	22/05/2012 at 9:31 AM
Received:	22/05/2012 at 9:32 AM
Subject:	Scan Data from PRN101230
Attachments:	img-5220931-0001.pdf

Number of Images: 6
Attachment File Type: PDF

Device Name: ApeosPort-II 4000
Device Location:

- img-5220931-0001.pdf

2012/011679

Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Request for additional information – breast implant

The Therapeutic Goods Administration wishes to gather accurate details about reports of problems detected with breast implants. **It would be very helpful to the TGA if, in addition to completing and returning this questionnaire, you would also provide copies of all related reports of investigations (such as ultrasound, MRI, culture of fluids, etc) and copies of any related letters you have sent to any referring doctor. Please retain the same patient identifiers as in the questionnaire but otherwise de-identify the documents before sending to TGA.**

The questions in this column relate to the implant about which you have identified a problem.	Has an implant also been removed from the contralateral breast to that described in the left hand column? Yes ☒ No ☐ If 'Yes', please answer the questions in this column.

Patient Identifier

Initials or medical record number	[redacted]
Age OR date of birth	
TGA device incident report number	26634

Site of implant:

Concerning the problem you have reported about an implant in this person:

Site of implantation	Rt ☒ Lt ☐
Date of implantation	04/04/2007
Date of explantation	04/04/2012

Reasons for removal of the contralateral implant

Was the reason to remove this contralateral implant ***solely*** because of the problems identified with the implant in the other breast?

Yes ☒ No ☐ Patient wanted intact PIP implant removed

If NO, please answer the following questions.

Did the patient complain of symptoms or have clinical signs referable to this contralateral implant? Yes ☒ No ☐

If YES, please describe: intercostal nerve neuralgia (chronic)

The questions in this column relate to the implant about which you have identified a problem.	The questions in this column relate to the other implant.

Brand and model of implant: PIP. CS-UH 475cc

Batch number of implant if known: ~~52~~ 35105

Serial number: 167

Investigations:

Was ultrasound reported as indicating rupture?

Yes ☐ No ☒ Not performed ☐

Was MRI reported as indicating rupture?

Yes ☐ No ☐ Not performed ☒

Reasons for removal of the implant

Capsular contraction[1]? I ☐ II ☐ III ☐ IV ☐

Device rupture	☐	Device migration	☒
Device malposition	☐	Haematoma	☐
Seroma	☐		

PIP implant, ic Rupture not suspected pre-op

Silicone extravasation (gel bleed):

intra-capsule	☐	extra-capsule	☐
distant	☐		

On examination:

Was there evidence of capsular contraction?

If YES, please indicate Grade[1]:

I ☐ II ☐ III ☐ IV ☐

Investigations:

Was ultrasound of this contralateral implant reported as indicating rupture?

Yes ☐ No ☒ Not performed ☐

Was MRI of this contralateral implant reported as indicating rupture?

Yes ☐ No ☐ Not performed ☒

[1] Capsular Contraction definitions – "Baker grades" – as in the US FDA Breast Implant Consumer Handbook – 2011

Grade I – breast is normally soft and looks natural

Grade II – breast is a little firm but looks normal

Grade III – breast is firm and looks abnormal

Grade IV – breast is hard, painful and looks abnormal

The questions in this column relate to the implant about which you have identified a problem.	The questions in this column relate to the other implant.
Explanted implant – findings on removal:	**Explanted contralateral implant – findings on removal:**
At the time of operative removal, was rupture confirmed?	At the time of operative removal, was rupture confirmed? Yes ☐ No ☒
Yes ☒ No ☐	If rupture had occurred, was the rupture:
If rupture had occurred, was the rupture:	Intracapsular ☐ Extracapsular ☐
Intracapsular ☒ Extracapsular ☐	At the time of removal, was there any evidence of gel bleed[2] from the intact implant?: Yes ☐ No ☐
If not ruptured at the time of removal, was there any evidence of gel bleed[2] of fluid from the intact implant?: Yes ☐ No ☐	If there was evidence of gel bleed, please briefly describe your observations of the state and condition of the removed implant:
If there was evidence of gel bleed, please briefly describe your observations of the state and condition of the removed implant:	
Was ultrasound reported as indicating gel bleed or another problem other than rupture? Yes ☐ No ☒	Was ultrasound reported as indicating gel bleed or another problem other than rupture?
If YES, please describe:	Yes ☐ No ☒ Not performed ☐
	If YES, please describe:
Was MRI reported as indicating gel bleed or another problem other than rupture? Yes ☐ No ☐ N/A	Was MRI reported as indicating gel bleed or another problem other than rupture? Yes ☐ No ☐ Not performed ☒

[2] Gel bleed – a passage of the silicone fluid through the shell of an intact prosthesis, which may or may not have been accompanied by clinical signs or complications, such as pain or lymphadenopathy, and which may or may not have been identified on ultrasound or MRI.

The questions in this column relate to the implant about which you have identified a problem.	The questions in this column relate to the other implant.
If YES, please describe:	If YES, please describe:
Were there any immediately local or more remote apparent clinical consequences to the gel bleed? Yes ☐ No ☒	Were there any immediately local or more remote apparent clinical consequences to the gel bleed of this contralateral implant? Yes ☐ No ☒
If YES, please describe:	If YES, please describe:
At the time of removal, had the appearance of the implant changed in any way other than as described in the answer to the question about gel bleed? Yes ☒ No ☐	At the time of removal, had the appearance of the implant changed in any way other than as described in the answer to the question about gel bleed? Yes ☐ No ☒
If YES, please describe the altered appearance: 3mm rear edge of implant. See photo. Implant yellowed. Gel still cohesive	If YES, please describe the altered appearance:
At the time of removal, were there any immediately local or more remote unusual or abnormal clinical findings other than those described in answer to the question about gel bleed? Yes ☐ No ☒	At the time of removal, were there any immediately local or more remote unusual or abnormal clinical findings other than those described in answer to the question about gel bleed? Yes ☐ No ☒
If YES, please describe:	If YES, please describe:

The questions in this column relate to the implant about which you have identified a problem.	The questions in this column relate to the other implant.
Was any material sent for laboratory investigation? Yes ☒ No ☐ If YES please describe the material, the tests ordered and the name of the laboratory. (If results have been received, please attach a copy). IGA Laboratory Chemical Cd analysis	Was any material from this contralateral implant sent for laboratory investigation? Yes ☒ No ☐ If YES, please describe the material, the tests ordered and the name of the laboratory. (If results have been received, please attach a copy). none

Name of Reporter	h J. Pouw	Signature:	[redacted]
Address of reporter	[redacted]		
Telephone number	[redacted]	Date: 10.5.12	

Please return this form to the Therapeutic Goods Administration

Postal address:

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Fax: 02 6232 8392

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