

Email Message

From: scanneddocument [SMTP:scanneddocument@tga.gov.au]
To: [REDACTED]@tga.gov.au
Cc:
Sent: 16/02/2012 at 7:55 AM
Received: 16/02/2012 at 7:55 AM
Subject: user report

Attachments: img-2160655-0001.pdf

Number of Images: 2
Attachment File Type: PDF

Device Name: ApeosPort-II 4000
Device Location:

- img-2160655-0001.pdf

C Problem Description

Please provide all available details
If you do not have enough space please add information onto another sheet of paper or into the body of your email.

10. Add a brief description of the problem. Include what led to, or contributed to the problem.

P I P Implants Removal & Replacement
with new implants.

11. Add a brief description of the consequences or outcome of the problem.

Please add sketches and pictures if necessary and/or available

12. Patient Information

[Redacted Patient Information]

D Reporter

Please provide all available details

13. Do you want your identity to remain confidential?

If YES your name & contact details will not be disclosed to manufacturers or suppliers without your permission. TGA will contact you if more information is needed.

A report without contact details cannot be processed.

YES NO

Name	Position / Occupation
DR. WJ Pow	Surgeon
Department, Institution & Address	Phone
[Redacted]	[Redacted]
email	

E Initial Reporter

Please provide all available details

14. Do they want their identity to remain confidential?

If YES their name & contact details will not be disclosed to manufacturers or suppliers without their permission. TGA will contact them if more information is needed.

If YES or NO add contact details below

YES NO

Name	Position / Occupation
[Redacted]	[Redacted]
Department, Institution & Address	Phone
[Redacted]	()
[Redacted]	Fax
[Redacted]	()
email	

F TGA Feedback

Please provide all available details

15. Who can TGA or Medsafe contact for more information regarding this incident?

Reporter Initial Reporter Other Appropriate Person Phone & Fax

Name	Name	Name	Phone & Fax
DR. WJ Pow	[Redacted]	[Redacted]	[Redacted]

G How to submit

Post, Fax or email your completed form to:

Australian Reporters TGA	<input checked="" type="checkbox"/> Post to Reply Paid 100 Medical Device IRIS TGA, PO Box 100 Woden ACT 2606 AUSTRALIA	<input type="checkbox"/> email / intranet iris@tga.gov.au http://www.tga.gov.au/safety/problem-device-report-user.htm	<input type="checkbox"/> Fax to (02) 6203 1713	<input type="checkbox"/> Phone FREE HOTLINE 1800 809 361
	<input checked="" type="checkbox"/> Post to Product Safety Team, MEDSAFE Ministry of Health Deloitte House 10 Brandon Street PO Box 5013 Wellington NEW ZEALAND	<input type="checkbox"/> email / intranet devices@moh.govt.nz	<input type="checkbox"/> Fax to (04) 819 6806	<input type="checkbox"/> Phone (04) 819 6800