Email Message

From:	scanneddocument [SMTP:scanneddocument@tga.gov.au]
To:	[redacted]@tga.gov.au]
Cc:	
Sent:	8/05/2012 at 8:05 AM
Received:	8/05/2012 at 8:06 AM
Subject:	DIR 26634
Attachments:	img-5080805-0001.pdf

Number of Images: 2
Attachment File Type: PDF

Device Name: ApeosPort-II 4000
Device Location:

- img-5080805-0001.pdf

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Authors initials . [redacted] Left & right implants

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

Document 8

2012/011679

26634

Users Medical Device Incident Report *eg Doctors, Nurses, Patients, Public*

What should be reported? A medical device is any material instrument, apparatus, machine, implement, contrivance, implant etc (including any component, part or accessory) which is used in health care and includes in-vitro diagnostics.
Typical problems include deficiencies in labelling, instructions or packaging, defective components, performance failures, poor construction or design. Suggestions for rectifying the problem or improving product performance would be appreciated.

What should you do with the device? **Please keep the device and its associated packaging until you are contacted by the TGA/Medsafe.** To send the device please follow the instructions in this link
http://www.tga.gov.au/industry/problem-device-samples-testing.htm

What happens to your report? The report will be investigated and discussed with the manufacturer/supplier. You may be contacted for further information. The report may also be reported to other Health Authorities. If action is considered necessary it may involve any of the following:

1. Recall - removal of goods from sale or use, or their correction, for reasons relating to safety, performance or quality.
2. Safety Alert – information relating to the correct use of the device to inform those responsible for the device, or affected by the problem.
3. Report in a TGA News Bulletin (a communication produced by the TGA and distributed in Australia and New Zealand to convey information on medical devices) or other appropriate journal(s).

Medical device manufacturers or suppliers should use form # MDIR03
http://www.tga.gov.au/safety/problem-device-report-industry.htm

A Product Identification — *Please provide all available details* — Date of Report: 23. 4. 2012

1. Brand/Trade Name: PIP
2. Device Description *(eg Urinary Catheter)*: Breast Implants
3. Device Identification

Model	Serial Number	Batch Number	Lot Number	Software (Version)
Round	185 - Left 167 - Right		53705 - L 35105 - R	

4. Relevant Dates

Purchase *(Approximate)*	Expiry	If Device is Implantable *(eg pacemaker, venous port etc)* Date of Implant	Date of Explant
[illegible]07		4-[illegible]07	4. 4. 2012

5. Manufacturer's name address & telephone: ~~MEDEAL~~
6. Supplier's name address and telephone: MEDICAL VISION
35 North Terrace
Hackney
S. Australia 5069.

B Reporting the Problem — *Please provide all available details*

7. Has the supplier been informed of the problem? ☐ YES ☒ NO

If YES Date Contacted	If YES add contact details Name	Phone / Fax
		( )

8. Where is the device now? ☐ Place of use ☐ With Reporter ☐ With Supplier ☐ With Patient

Please Do Not discard the device or related consumables & packaging

Contacts for access to device

Name	Phone / Fax
	( )

9. Is this device supplied sterile? ☐ YES ☒ NO
Is this device reusable? ☐ YES ☒ NO
Is this device single use? ☒ YES ☐ NO

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.

Ruptured Implants Right breast Implant only (MRI)

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

Please add sketches and pictures if necessary and/or available

Pt had PIP ruptured Implant

12. Patient Information

[redacted]

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: DR. WJ Pauw — Position / Occupation: Surgeon

Department, Institution & Address: [redacted] — Phone: [redacted]

Fax: [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: [redacted] — Position / Occupation:

Department, Institution & Address: — Phone: [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: [redacted]	Name: DR. Pauw	Name:	Phone: [redacted]

G How to submit — Post, Fax or email your completed form to:

	✉ Post to		🖱 email / intranet	🖷 Fax to	☎ Phone
Australian Reporters **TGA**	**Reply Paid 100** Medical Device IRIS TGA, PO Box 100 Woden ACT 2606 AUSTRALIA	**Courier delivery:** TGA 136 Narrabundah Ln, Symonston ACT 2609, AUSTRALIA	iris@tga.gov.au http://www.tga.gov.au/safety/problem-device-report-user.htm	(02) 6203 1713	**FREE HOTLINE** **1800 809 361**
New Zealand Reporters **MEDSAFE**	✉ Post to		🖱 email / intranet	🖷 Fax to	☎ Phone
	Product Safety Team, MEDSAFE Ministry of Health Deloitte House 10 Brandon Street PO Box 5013 Wellington NEW ZEALAND		devices@moh.govt.nz	(04) 819 6806	(04) 819 6800