

Email Message

From: scanneddocument [SMTP:scanneddocument@tga.gov.au]
To: [REDACTED]@tga.gov.au
Cc:
Sent: 30/03/2012 at 7:41 AM
Received: 30/03/2012 at 7:42 AM
Subject: user report

Attachments: img-3300641-0001.pdf

Number of Images: 2
Attachment File Type: PDF

Device Name: ApeosPort-II 4000
Device Location:

- img-3300641-0001.pdf



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		<i>Please provide all available details</i>				Date of Report:	26. 3. 2012.
1.	Brand/Trade Name	PIP					
2.	Device Description <small>(eg Urinary Catheter)</small>	Breast Implants					
3.	Device Identification	Model	Serial Number	Batch Number	Lot Number	Software (Version)	
		PIP	lost file 10 years ago	lost file	lost file		
4.	Relevant Dates	Purchase <small>(Approximate)</small>	Expiry	If Device is Implantable (eg pacemaker, venous port etc)		Date of Implant	Date of Explant
	<i>over 10 years file not available</i>			10 years ago?	22/3/2012.		
5.	Manufacturer's name address & telephone						
6.	Supplier's name address and telephone	PIP MEDICAL VISION 35 NORTH TERRACE HACKNEY S.A					
B Reporting the Problem		<i>Please provide all available details</i>					
7.	Has the supplier been informed of the problem?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	If YES Date Contacted	If YES add contact details		Name Phone / Fax	
						()	
8.	Where is the device now?	<input type="checkbox"/> Place of use <input type="checkbox"/> With Reporter <input type="checkbox"/> With Supplier <input type="checkbox"/> 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?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	Is this device reusable?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	Is this device single use?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> 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.

PIP Implants

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

Please add sketches and pictures if necessary and/or available

Worried about Ruptured Implant

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.

<input type="checkbox"/> YES	Name	Position / Occupation
<input checked="" type="checkbox"/> NO	Dr. WJ Poow	Surgeon
	Department, Institution & Address	Phone
	[Redacted]	[Redacted]
email	[Redacted]	[Redacted]

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

<input checked="" type="checkbox"/> YES	Name	Position / Occupation
<input type="checkbox"/> NO	[Redacted]	[Redacted]
		Phone
		()
		Fax
		()
email	[Redacted]	[Redacted]

F TGA Feedback

Please provide all available details

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

<input type="checkbox"/> Reporter	<input type="checkbox"/> Initial Reporter	<input type="checkbox"/> Other Appropriate Person	Phone & Fax
Name	Name	Name	Phone
Dr. Poow	[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 Courier delivery: TGA 136 Narrabundah Ln, Symonston ACT 2609, AUSTRALIA	<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