



**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**

**Australian Medical Device**  
**Incident Report Investigation Scheme**

Dr William Pouw  
Cosmetic Plastic Surgeon

File Reference: 2012/009112

[REDACTED]  
[REDACTED]

Dear Dr Pouw,

**DEVICE INCIDENT REPORT DIR 26188 - PIP Breast Implant**

Thank you for your recent correspondence concerning a problem experienced with the above device.

The information you provided has been entered into the Medical Device Incident Report investigation (IRIS) Database, where it will be evaluated against any previous incidents with the same or similar devices. A copy of the Device Incident Report (DIR) is attached for your reference.

We have also commenced an investigation into your complaint and contacted the product sponsor requesting details of any similar reports.

This process may take some time, but be assured we will advise you of the final outcome of our investigations. However, should you have any questions or further information, please contact me on [REDACTED]

Thank you for your support of the Medical Device Incident Report Investigation Scheme.

Yours sincerely

[REDACTED]

Incident Report and Investigation Scheme  
Device Vigilance and Monitoring  
Office of Product Review  
Therapeutic Goods Administration

03/04/2012

DIR 26188 - PIP Breast Implant

Reporter Reference #:

Date of Adverse Event:

Date of Final Report:  
23/03/2012

ARTG #:

Brand Name:  
PIP Breast Implant

Device Class:

Model #:

Serial #:  
268 (f) & 046 (l)

Software Version:

Batch #:

Lot #:  
12705 (r) & 03604 (l)

Manufacturer:

Sponsor:

Medical Vision Australia Pty Ltd  
99 King William Street  
KENT TOWN SA 5067

Contact Name:

[REDACTED]

Phone:  
(08) 8132 0300

Reporter:

Dr William Pouw  
Cosmetic Plastic Surgeon

Confidential: No

Phone: [REDACTED]  
Fax: [REDACTED]

Email:

drpouw [REDACTED]

Date of Implant:

14/09/2006

Date of Explant:

22/03/2012

Clinical Event Information:

PIP implants.

Patient worried as she had PIP implants.

Left breast rupture.

Implants recieved at the TGA.

Patient Outcome/Consequences:

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End of DIR 26188

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