



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration
Australian Medical Device
Incident Report Investigation Scheme

DR Timothy Cooper
Hollywood Medical Centre
Suite 44
85 Monash Ave
Nedlands WA 6009

Dear DR Cooper

**DEVICE INCIDENT REPORT DIR 23973 - IMGHC-TX-R - Prosthesis, internal,
mammary, gel filled/Poly Implant Prosthesis (Pip) SA**

We have now completed our evaluation of the incident you reported to the Therapeutic Goods Administration concerning the above device.

A copy of the Incident Report Investigation Scheme (IRIS) database entry, complete with closing recommendations is attached for your information.

In addition to the closing of this report the TGA requests:

- 1. Are you able to send a copy of your paper once it has been published**
- 2. Upon contacting your colleagues re the PIP implants could you ask that they forward a summation or number of issues that they have had with this device to IRIS for our database.**

Thank you for your support of the Medical Device Incident Report Investigation Scheme. Should you have any further queries concerning this report please do not hesitate to contact me here in Canberra on (02) 6232 8987.

Yours sincerely

Sharon Hughes

Incident Report and Investigation Scheme
Market Vigilance and Monitoring Section
Therapeutic Goods Administration

18/07/2011

DIR/23973 IMGHC-TX-R - Prosthesis, internal, mammary,
gel filled/Poly Implant Protheses (Pip) SA

Reporter#

Exempt/Not on Artg: N
Syst/Artg No:ARTG/114902
Ecri Code: 36197 Prosthesis, internal, mammary, gel
filled
Device: PIP Breast Implant
Model No: N/A
Batch No:
Serial No: N/A
Manufacturer:Poly Implant Protheses (Pip) SA 29265
FRA

Sponsor: Medical Vision Australia Pty Ltd 29703
35 North Terrace
HACKNEY SA 5069 AU

Contact: Stan Radic Phone: 08 8132 0300 Fax:

Description: I am a plastic surgeon in Perth and became
aware of the PIP implant problem in April
2010. I had done a number of breast
augmentations using PIP implants from 2005 to
2007.

Essentially, the findings are that I have 131
patients who had PIP implants. Of these, I
have had a 20% failure rate for a mean implant
time of 4.5 years. This is clearly
unacceptably high compared to the world
literature for implants and I wanted to bring
this to your attention. I did present my
findings at the latest ASPS conference in the
Gold Coast and am now undertaking to make you
aware of the problem.

I am also intending to publish a paper but
would like to try to get hold of the results
of other colleagues who have implanted PIPs in
Australia. I understand there are some 4,500
women who have had PIPs in Australia.

Report sourced from specialist.

Recommendation:

This report is part of a recall issued on
3/4/2010 - recall reference number: RC-2010-
RN-00338-3. This product has also been removed
from the Australian Register of Therapeutic
Goods. This report has been logged into the
IRIS database for trending purposes. No
further investigation will occur at this time,
however the TGA will continue to monitor the
rate and pattern of occurrence and may re-open
the file as appropriate.

Dates

Received: 14/07/2011
Entered: 18/07/2011
Completed: 18/07/2011

***** End Of DIR/ 23973 *****