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## **PIP IMPLANT UPDATE**

*TGA Completes Preliminary Safety Tests on PIP Implants*

The Australian regulatory body responsible for the safety of medical devices, the Therapeutic Goods Administration (TGA), has released three public statements regarding PIP implants. The latest TGA message is copied below and is available from their website [www.tga.gov.au](http://www.tga.gov.au):

Consumer information

2 July 2010

Testing on Australian samples of implants supplied by the French manufacturer Poly Implant Prothese (PIP) has been undertaken by TGA to provide assurance to Australian patients that their breast implants meet relevant safety and quality requirements.

The results of TGA testing to date indicate that the PIP breast implants supplied in Australia conform to the relevant international standards for this type of product including those for gel cytotoxicity and shell strength.

The TGA is conducting further tests on the gel and is continuing to liaise with French Authorities investigating the incident.

The TGA has not received any additional reports of product failure associated with these implants in Australia since its May 2010 update.

Some breast augmentation and reconstruction patients have registered their implants on the Breast Implant Registry (BIR); an opt-in quality assurance activity and patient safety database with Commonwealth Government endorsement. Those patients with PIP implants were contacted by ASPS at the time of the PIP recall in April 2010.

An independent investigation by a member of Australian Society of Plastic Surgeons (ASPS) estimates that approximately 4500 women in Australia were given PIP implants during the period 2004 to 2010.

Australian Society of Plastic Surgeons President, Mr Peter Callan, and the Breast Implant Registry Committee have issued a guidance for women with PIP breast implants. The guidance is consistent with other medical organisations around the world.

"Patients with PIP implants are urged to see their surgeon and undergo an ultrasound or similar test within the next six months to check for rupture. If there is evidence of rupture then both implants should probably be removed," Peter Callan said.



To find a Plastic Surgeon go to the ASPS website. You can register your breast implants on the Breast Implant Registry – your surgeon will provide ASPS with the clinical information.

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