Breast Implant Information PIP Breast Implants

There has been some reporting in the media about a French brand of breast implant which may contain a silicone gel that is different to the gel approved by regulatory authorities.

The stories are about the Poly Implant Prothese (PIP) brand of breast implant. This issue only affects people with this PIP brand of implant.

This brand was implanted in about 5000 cases in Australia between 2000 and April 2010. A small number of PIP implants may have been used in 1998 and 1999.

Breast implant operations performed before 1998 or after April 2010 in Australia, are not affected. Saline implants are also not affected.

What are PIP Breast Implants?

PIP breast implants are implants pre-filled with silicone based gel manufactured by the French company, Poly Implant Prothese (PIP).

When were PIP breast implants supplied in Australia?

PIP breast implants were available in Australia between 1998 and April 2010 after which they were recalled.

Why were PIP implants recalled?

The implants were recalled following concerns by the French medical device regulatory authority (AFSSAPS) that there may be an increased incidence of ruptures and concerns that they contained unapproved ingredients.

Is there evidence to suggest that PIP implants used in Australia leak, break or rupture at a higher rate than other implants?

Based on current numbers of implant ruptures reported to the Therapeutic Goods Administration, there is no evidence that more PIP silicone gel breast implants used in Australia have ruptured than would be expected from published studies on other brands of breast implant.

What are the risks if the implant does rupture break or leak?

There are two types of ways that breast implants can rupture, break or leak with both usually having no symptoms (known as asymptomatic). A rupture of a breast implant is either:

- intra capsular with the gel confined to within the fibrous capsule that the body naturally forms around the implant or
- extra capsular where the gel has extended into the breast or other localised tissues.

Localised inflammation causing lumps and/or discomfort may occur typically with extra capsular rupture. Implanting surgeons should discuss the risks of rupture and other potential complications of breast implant surgery with patients prior to any operation.

How often do breast implants rupture?

There is no evidence that the PIP implant has a higher rate of breaking or leaking. Currently the US Food and Drug Administration evidence shows that about 10% of all types of silicone implants break or leak within 10 years of being implanted.

There is currently no evidence that the gel in the PIP implants causes cancer, and testing of the gel in the implants in Britain and France has confirmed this.

There is no need for routine removal of PIP breast implants.

Can PIP implants cause cancer?

There is no evidence that breast implants, including PIP implants, are associated with a higher risk of breast cancer.

The TGA has received no reports of the rare tumour Anaplastic Large Cell Lymphoma (ALCL) from Australians who have received PIP implants. However, the TGA has received reports of six patients who have been diagnosed with ALCL all of whom received other brands of breast implants (filled either with silicone gel or saline).

What are the health impacts if any of PIP breast implants, including if they rupture, for the babies of breastfeeding mothers?

No toxic chemicals have been found in PIP breast implants (whether intact or ruptured) that are likely to affect the production of breast milk (lactation) in a woman with either ruptured or intact breast implants, or have any effect on the health of breast-fed babies.

What are the health impacts if any of PIP breast implants, including if they rupture, for the developing babies of pregnant women?

No toxic chemicals have been identified in PIP breast implants that are likely to have any effect on a growing foetus or on the outcomes of a pregnancy.

How can a PIP breast implant be identified?

Australian implant patients are usually given a card after their surgery which will have the details including the brand of the implant. The card will state if Poly Implant Prothèse (PIP) have been used.

The surgeon who performed the implantation will be able to confirm if PIP implants have been used.

What if the surgeon's name is not known?

Patients GP's may also have the information on file or seek a referral to a surgeon.

What if the surgery was performed overseas?

Check any paperwork from the surgeon regarding the brand implanted. If there is no information, seek advice from a GP.

What is the current advice on PIP implants?

Current advice from the Therapeutic Goods Administration and clinical experts is that there is no evidence that more PIP silicone gel breast implants used in Australia have ruptured than would be expected from published studies on other brands of breast implant.

However as a precautionary measure it is recommended that an appointment is made to have a clinical evaluation with a surgeon.

Why isn't the TGA recommending that PIP implants be removed?

The Australian Government's advice remains that removal of PIP breast implants in the absence of evidence of rupture is not routinely required. The results of scientific testing to date have not shown that the risks of these implants outweigh the risk of surgery. However, patients with PIP implants or who are unsure about the brand of their breast implants should consult their general practitioner or surgeon for individual clinical assessment and advice.

The Australian Government is communicating about this issue as a precautionary measure, given the publicity generated by overseas activity.

Some other countries are recommending routine removal - why is Australian advice different?

Australia has taken a very considered and comprehensive approach to considering the available evidence associated with PIP implants and has undertaken a range of tests and gathered expert evidence to support responsible Government decision making.

Although a few countries have taken a different approach, the advice given by the Australian Government is similar to many other countries including the European Commission and is based on careful assessment of the currently available best evidence.

Surgery to remove implants is associated with risk and at the current time, the risk of this surgery where there is no evidence of rupture appears to outweigh any benefit, although decisions for individual patients are best made after consultation with their doctors.

Who pays for the consultation with the GP or surgeon?

Usual Medicare arrangements will apply. There may be some “gap” payments.

How much will it cost?

As doctors determine their own fees, the cost of surgery may vary considerably.

Medicare will pay a rebate for surgery to remove and replace breast implants when it is medically necessary to do so. The Medicare subsidy for the most common procedure to remove and replace both implants is $750.

In addition, the anaesthetist will charge fees for which there are Medicare rebates. Medicare also provides rebates for diagnostic tests such as MRI and consultation with GPs and surgeons before the surgery.

Medicare does not cover the cost of replacement prostheses or the cost of hospital accommodation. Private health insurance should subsidise these costs for those with insurance.

As medical fees can vary considerably it is recommended that specific information is obtained from the surgeon about the costs of surgery. Doctors are obliged to provide informed financial consent and it is recommended that concerns are discussed with the doctor or by obtaining a second opinion.

Are saline implants involved?
Saline implants are not part of this issue.

**Are breast implants safe?**

Personal circumstances and the risks associated with implants and surgery should be discussed with the surgeon during the surgical consent process.

**If an implant has ruptured or is leaking, what are the symptoms?**

Leaking or rupturing can occur without symptoms. It is advised that if there are any concerns to see a surgeon and have scans as necessary.

**Why were these implants allowed to be used in Australia?**

Before including breast implants manufactured by a French company, Poly Implant Prothese (PIP), on the Australian Register of Therapeutic Goods, the Therapeutic Goods Administration (TGA) inspected the manufacturing facility in France. A number of deficiencies were identified, satisfactorily addressed by the company, and ongoing Australian marketing approval required continued oversight by a European ‘notified body’. This notified body, TUV Rheinland, continued to provide oversight of manufacturing on behalf of European regulators and the TGA.

In April 2010, acting on updated advice from French regulatory authorities, the TGA took prompt regulatory action to ensure that PIP breast implants were withdrawn from the Australian market. On 6 April 2010, the TGA published advice on its website that consumers with the PIP silicone gel implants who have concerns should contact their treating breast implant physician for advice and follow-up.

Since that time, TGA has continued to conduct scientific tests on available samples of PIP implants, to consult with Australian and international experts (including with scientific, clinical and consumer representatives), to monitor the emerging Australian and international evidence, and to maintain regular and ongoing communication with international regulators including the FDA and European authorities.

**What is the Australian Government doing?**

The Australia regulator, the Therapeutic Goods Administration (TGA) continues to thoroughly gather evidence about the safety of these devices, including by:

1. Conducting scientific tests on available samples of PIP implants, including explanted devices;
2. Consulting with Australian and international experts (including with scientific, clinical and consumer representatives), to monitor the emerging Australian and international evidence;
3. Working closely with international regulators including the FDA and European authorities;
4. Regularly updating its public advice as new evidence emerges.

The TGA wrote to all implanting surgeons on Monday 9 January 2012, suggesting that they contact their patients.

The Australian Government also set up a free call Breast Implant Information Line in January 2012; however this service has now closed. Anyone concerned about their breast implants can access information on [The Department of Health’s website](http://www.health.gov.au/pip).

Additionally, those who have had breast implants and are concerned may wish to see their surgeon for advice regarding the need for clinical follow up or radiological investigation.

A Clinical Advisory Committee (CMO CAC) was convened by the Chief Medical Officer (9 January 2012) to provide him with regular and frequent advice on clinical measures, risks and benefits, and communication strategies in response to health concerns related to PIP breast implants. The committee includes senior representatives of relevant clinical and consumer groups.

**Will Medicare cover the cost of radiological investigation?**

The Government established access to one Medicare rebated MRI scan until 12 March 2013 to check the implants of those who have (or think they have) a PIP breast implant. If any symptoms of implant rupture develop, they will also be able to receive a Medicare rebate for MRI, regardless of whether or not their previous MRI was normal.

If a GP or Specialist refers a patient for an MRI, the form must state that the patient has or is suspected of having a PIP branded implant. If there are symptoms of a rupture, the GP or Specialist must also note this on the referral.

**Where can the MRI scan be performed?**

The MRI scans can be performed on any MRI machine that has a dedicated breast coil and is accredited to provider Diagnostic Imaging Services. When making an appointment to have an MRI scan, check the provider has a dedicated breast coil, as not all MRI providers have dedicated breast coils. The MRI scan must also be provided by a specialist radiologist.

MRI providers will be able to provide detailed information regarding the scan and what the use of a breast coil involves.

It is important to note that a request form for a diagnostic imaging service can be taken to any accredited diagnostic imaging provider.
Patients are not compelled to take the request for the service to the provider stated on the referral form. Both private imaging practices and many public hospitals provide diagnostic imaging Medicare services. This should be discussed with a GP or Specialist when referral is received.

**Can the MRI scan be bulk billed?**

Medicare rebates apply to the new PIP MRI items. The schedule fee for the PIP MRI services has been set at $500 per item.

The Government encourages bulk billing, but it is up to the provider to choose whether or not they bulk bill. There are bulk billing incentives for diagnostic imaging services, including the MRI services. Medical practitioners, including radiologists, are free to set their own value on the services they provide. While the Government is responsible for setting the schedule fee on which Medicare benefits are based, there is nothing to prevent radiologists or any other medical practitioner setting fees that exceed those in the schedule. In these circumstances, the gap between the fee charged and the Medicare rebate will need to be paid.

**What is the eligibility for Medicare rebates if the MRI scan was performed prior to 12 March 2012?**

The authority to allow the payments for the MRI items came into effect on 12 March 2012. MRI's provided prior to this date will not be eligible to receive Medicare rebates.

**What is the eligibility for Medicare rebates if the implant surgery was performed overseas?**

If the patient holds a Medicare card, then a Medicare rebate is available. The country where the implant surgery was undertaken does not affect the eligibility to access Medicare rebates, however, as for all Medicare funded services; it would need to be clinically relevant.

**Will the Australian Government be funding any ongoing medical treatment required as a result of receiving a PIP implant?**

Normal Medicare benefits arrangements will apply, so patients can receive Medicare benefits if they wish to consult a medical practitioner. Medicare benefits will also be payable where removal of an implant and replacement of an implant is undertaken on the basis of a clinical need. Medicare does not cover the cost of breast prostheses, private hospital accommodation and theatre costs - these may be subsidised by private health insurance.

**Does Medicare cover the cost of a replacement implant?**

No, Medicare does not pay for prostheses, including breast prostheses. Patients with private health insurance should contact their insurer to ascertain if their policy would cover the cost of the implant.

**Is there any compensation available?**

'The Department' is not aware of any basis for compensation payable by the Commonwealth. Individuals should take their own legal advice as to any legal entitlements they may have.

**Can the treatment be free of charge?**

Patients may elect to be treated through the public hospital system. A medical practitioner can arrange referral of the patient to the nearest appropriate public hospital or to a specialist who performs implant procedures in the public hospital system. The hospital staff or the specialist can advise the best course of action for the patient, which may include surgical treatment. The availability and funding of breast implant procedures in the public hospital system may vary as public hospital services are funded by the states and territories.

**How to report a problem/adverse event (i.e. implant rupture etc) to the TGA?**

Information on how to report a problem and the forms are contained on the [TGA's website](https://www.tga.gov.au/form/report-medical-device-adverse-event-medical-device-user). An implant is a medical device and patients, relatives or clinicians should use this form to report any actual and suspected problems with a medical device which has, or may present, a health hazard.

Online forms are available for reporting medical device adverse events. Medical device users are encouraged to complete the [online reporting form](http://www.tga.gov.au/safety/problem-device-report-user.htm) alternatively, a word or PDF copy of the form can be downloaded.

Issues experienced in completing the online medical device adverse event reporting form should be directed via email to iris@tga.gov.au or phone 1800 809 361.

**What happens to your report?**

The report will be investigated and you may be contacted by the TGA for further information.