



Australian Government

Department of Health and Ageing

CHIEF MEDICAL OFFICER'S FACT SHEET

Silicone gel filled Breast Implants

Health consequences

All silicone gel filled breast implants are considered high risk medical devices

- They have a limited lifespan - the risk of rupture increases with time, with an estimate of 10-15% rupturing by 10 years.
- A rupture may not present with any clinical signs or symptoms.
- MRI is the best imaging method to detect rupture. No imaging test currently can predict rupture.
- Silicone from ruptured breast implants may migrate, resulting in swollen and sometimes sore lymph nodes.
- There is no evidence of increased risk of breast cancer or connective tissue diseases.
- There is a possible link between all silicone breast implants and a specific but rare cancer called Anaplastic Large Cell Lymphoma (ALCL), however any risk appears very small.

PIP breast implants

- Testing by the Therapeutic Goods Administration (TGA) has not identified a specific serious safety concern with PIP breast implants. There is also no scientific evidence that there are any chemicals in PIP implants that are likely to cause harm to a woman or her unborn or breast-fed children.
- Unless women with PIP breast implants have medical complications associated with the implant (such as evidence that your breast implant has ruptured), there is no medical reason for having them routinely removed.
- It has been suggested that PIP breast implants are more likely to rupture than other silicone gel filled breast implants. The information we have cannot confirm or exclude this possibility but the number of reported ruptures in Australia to date is within an expected range.
- There is no evidence that the risk of ALCL in the breast for PIP breast implants is greater than for all silicone gel filled breast implants. No cases of ALCL in the breast in women with PIP breast implants have been reported in Australia or the UK.
- Some consumers with PIP breast implants have reported experiencing systemic symptoms such as fatigue, hair loss and headaches. While there is no published evidence that silicone gel filled breast implants cause connective tissue disease, the TGA is attempting to collect further information on these individual reports. As systemic or general symptoms can be experienced as part of many different health conditions, it is important that women experiencing these symptoms visit their medical practitioners for a specific review.

Explantation surgery (surgery to remove breast implants)

All silicone gel filled breast implants

- Surgery for ruptured breast implants is not urgent, unless there are signs of breast tissue reaction.
- As with all surgery, there are risks associated with anaesthesia. In healthy people, as expected in the majority of women with breast implants, the risk of death associated with anaesthesia is approximately 1/100,000.
- Local complications are common.
- If replacement with new implants is undertaken, there is a likely increased risk of delayed local complications such as contracture, rupture, implant removal and reoperation associated with the second and subsequent surgeries compared to the primary or initial surgery. If necessary, reoperation may be required earlier following revision surgery than primary augmentation surgery.

Medicare rebate

- Medicare rebates are available for the cost of medical services related to managing PIP breast implants concerns including GP and surgeon consultations, diagnostic tests and surgery and related anaesthetic services to remove and replace implants when clinically indicated.
- A Medicare rebate is available for Magnetic Resonance Imaging (MRI) to assess the structural integrity of known or suspected PIP breast implants for a 12 month period, until 12 March 2013.

Further information

- For women with implants: the most appropriate person from which to obtain the best available information is your GP or the surgeon who did your implant. Since January 2012 the Department of Health and Ageing and the TGA have been liaising closely with key medical organisations and taking advice from an Expert Committee including surgical experts from the Royal Australasian College of Surgeons, the Australian Society of Plastic Surgeons and the Australasian College of Cosmetic Surgeons. This group will continue to meet to examine any new information and these organisations will continue to inform their members of any new development.
- TGA website: The TGA has a wealth of information on its website which is updated every week – visit www.tga.gov.au
- HealthInsite has a topic page on Breast Implants, with links to information about issues associated with their use including links to videos produced by the Australasian College of Cosmetic Surgery – visit www.healthinsite.gov.au

What is available under Medicare to help with the cost of testing or removal?

Women who have a PIP implant (or where evidence suggests they may have a PIP implant) can receive a Medicare rebate to access a MRI scan to see if their PIP implant is structurally sound until 12 March 2013.

In Australia, prior to and since January 2012, Medicare rebates have continued to be available to any woman whose doctor decided on clinical grounds to remove any implant (for example because it was ruptured). These rebates contribute to the cost of the private surgeon, anaesthetist, any surgical assistant and the cost of an ultrasound and any relevant medical or surgical consultations related to the initial surgery.

Where it has been established there is a valid clinical reason for a breast implant removal and the woman cannot afford private surgery, she can be referred to a public hospital.

Under the Medicare arrangements, clinical grounds for removal include both physical and psychological reasons (such as significant anxiety).

Medicare pays rebates as follows:

Consultations – Women who have had breast implants are encouraged to consult with their medical practitioner(s) regarding the need for clinical follow-up or radiological investigation. Normal Medicare arrangements are available for these consultations.

Investigations – If considered medically necessary, from 12 March 2012, women with a PIP implant can access a Medicare rebate for a PIP MRI service to assess the state of the implant. This referral, from either a specialist, consultant physician or a GP must state that the patient is known or suspected of having a PIP branded implant and note on the referral if the patient has symptoms of a rupture. The MRI scan will be undertaken by a specialist radiologist at an accredited diagnostic imaging provider with a breast coil. Medicare rebates are also available for investigation by ultrasound.

Management – including removal and replacement where the clinician (surgeon) believes there is a physical (eg rupture) and/or psychological (eg significant anxiety) consequences of the prostheses remaining in place.

MBS rebates contribute to the medical costs, including those of the surgeon, anaesthetist and any surgical assistants.

Under the usual Medicare benefits arrangements, the cost of prostheses, or implants, are not covered. Patients with private health insurance should contact their insurer to ascertain if their policy would cover the cost of the implant, private hospital accommodation and hospital theatre costs.

Women should be aware that to be entitled to Medicare benefits, breast enlargement (augmentation) for cosmetic purposes cannot be the primary reason for the surgical procedure. However, the circumstances of the original implant, such as if it was for cosmetic reasons, do not affect eligibility for MBS rebates if removal and replacement is clinically indicated.