

Poly Implant Prothèse (PIP) breast implants

Joint surgical statement on clinical guidance for patients, GPs and surgeons

The Association of Breast Surgery, the British Association of Plastic and Reconstructive Aesthetic Surgeons, the British Association of Aesthetic Plastic Surgeons, the Federation of Surgical Speciality Associations and the Royal College of Surgeons participated in the expert group convened by Professor Sir Bruce Keogh to review policy in relation to breast implants from the French company Poly Implant Prothèse (PIP). All organisations have endorsed the findings of the interim report published on 6 January 2012.

These five professional surgical organisations are now independently publishing further clinical guidance for GPs and surgeons regarding the care of patients who have received PIP breast implants.

Guidance for patients

If you have breast implants and do not have details of your implant manufacturer, you are advised to check the details of your implant with the surgeon or surgical provider responsible for your care. The surgeon or provider should have a record of the implants used (including the make and size). We would expect this information to be provided free of charge. If you are unable to access your surgeon or provider you should contact your GP for advice regarding an alternative referral.

We recommend that you discuss your options with your surgeon first of all. The decision on whether a scan will be required will only be made after consultation with a surgeon.

It is expected that the provider of the initial procedure, either private sector or the NHS, will offer the same information and where necessary implant removal and replacement without cost to you.

Guidance for GPs

The purpose of this guidance is to ensure patients who seek advice are assessed and managed in an agreed and standardised fashion, and that they have appropriate access to specialist advice.

All NHS patients who have undergone aesthetic or reconstructive surgery with PIP implants will be contacted by their local hospital. If they do not hear from their original provider they may contact their GP or their surgeon.

It is expected that private providers will follow the example of the NHS and call their patients for consultation. The first port of call for all patients who have undergone breast augmentation in the private sector is their original provider.

At present the government has decided that private patients referred to the NHS will be entitled to explantation and not re-augmentation. Patients planning re-augmentation soon after explantation should be advised of the increased risk associated with having two operations.

GPs are advised that patients should not be referred for scanning (USS/MRI) before receiving a specialist surgical opinion.

GPs consulted by patients with PIP implants are advised to assess the patient for the following signs and symptoms.

Symptoms that may be associated with rupture/gel leak:

- » localised pain and discomfort
- » axillary pain/discomfort
- » persistent burning sensation

Signs of rupture/ gel leak:

- » lumpiness of the breast
- » regional swelling of the lymph nodes/glands (lymphadenopathy) – this may be in the absence of other breast signs/symptoms
- » change in the shape of the breast
- » hardening or firmness of the breast
- » tenderness of the breast
- » swelling of the breast

GP referral pathways through the NHS

1. If breast change or lymphadenopathy raises concerns of breast disease requiring urgent investigation:

Patients with significant new breast symptoms or signs should be referred to an NHS

Rapid Access Breast Unit. This 'fast track' should **ONLY** be used when there is a **need to exclude serious breast disease**. It is not anticipated that this group of patients will be large.

2. If breast lumpiness/lymphadenopathy is felt to be related to problems with implants/gel, but signs or symptoms do NOT raise concerns of breast disease:

In cases where the practitioner has reasonable confidence that the breast lumps or lymphadenopathy are associated with the implant rupture or gel leak, or when patients report changes in shape, size or feel of the breast without raising concerns of breast disease, referral should be made to the regional plastic and reconstructive surgery breast service. **These patients do NOT require fast-track referral to the NHS Rapid Access Breast Unit.**

3. If there are no signs or symptoms:

For patients without physical signs or symptoms, we feel that there is a duty of care on the part of the original surgical providers to reduce anxieties about the long-term health consequence of these implants. For many women, reassurance and confidence will only be achieved once the implant has been removed.

In these cases referral may be made to the regional plastic and reconstructive surgery breast service.

It is understood that the government's policy explicitly offers these services without the need for specific clearance from the local commissioner (ie the primary care trust).

Guidance for all clinicians regarding scanning

Patients should not be referred for scanning (USS/MRI) before receiving a specialist surgical opinion.

In patients without signs or symptoms of rupture, scanning should only be used to assist decision making where the patient is uncertain of whether to have the implant removed or where rupture is identified. For all patients who have already decided to undergo explantation, scanning is unnecessary.

Caution is urged in interpreting ultrasound or MRI imaging information, owing to the available evidence offering conflicting advice about false positive and negative detection rates for implant rupture and leaks.

Guidance for surgeons

Surgeons and hospital specialists reviewing patients with PIP implants should carefully assess the patient for the possibility of rupture or gel leak.

For patients who have evidence of implant rupture/gel leak

Patients should be advised of the surgical implications of implant removal/exchange. If it is felt that the risk–benefit ratio favours removal or exchange, then this procedure should be strongly advised.

For patients without symptoms or signs of leak or rupture

If a patient requests it, removal should be offered in cases where the surgeon considers that the benefits outweigh the risks. If a patient is unable to come to a decision immediately, arrangements should be made for regular review and follow-up. We understand that the current offer to remove and/or replace PIP implants is not time-limited and can be reviewed at future follow-up appointments.

Surgical procedure

Surgeons removing an implant should do so using conventional techniques. Where possible the implant should be removed or exchanged through the original incision.

In cases with a **soft ‘quiet’ capsule without evidence of silicone impregnation/ local inflammation or contracture** the capsule and immediate pericapsular tissues should be biopsied, but a capsulectomy will usually be unnecessary.

In cases of **extensive capsular thickening/inflammation/contracture** a complete capsulectomy should be performed. The capsule and biopsies from areas of pericapsular thickening should be sent for histology.

In patients **with breast cancer who have undergone implant-based breast reconstruction**, any suggestion of capsular thickening should prompt consideration of full capsulectomy and excision biopsy of areas of thickening. All specimens must be sent for histology.

Patients with extensive lymphadenopathy or extensive parenchymal swelling and lumpiness should be discussed in a breast multi-disciplinary meeting. Where lymph node removal may be clinically indicated, it should only be carried out in patients who are fully informed about the risks of additional axillary surgery.

Specific considerations for PIP-related explantation

Reports have suggested that in cases of PIP implant rupture/leak the inflammatory reaction may be more intense than usual, making a conventional capsulectomy more difficult. Washing or wiping the cavity with diluted aqueous povidone-iodine (PVPI) topical antiseptic solution or aqueous chlorhexidine appears to help dislodge and remove residues of the silicone gel from the surface of the cavity.

In cases of extreme contamination where re-augmentation had been planned, a decision to defer replacement should be considered. Surgeons are advised to discuss this possibility with patients in advance.

Dealing with the implant

A ruptured implant should be discarded unless arrangements for examination have been made with the Medicines and Healthcare products Regulatory Agency.

We would advise surgeons to collect all available data at the time of consultation and surgery. Further advice regarding data collection will be made available shortly by the relevant surgical organisations.

Implant replacement

Patients from the private sector who have been unable to secure help from their original provider will be eligible for help from the NHS. The government has offered implant removal but implants will not be replaced in these patients. Surgeons are advised to make this clear at the initial consultation.

We would encourage all surgeons and surgical providers responsible for breast augmentations using PIP implants to undertake replacement surgery without making a charge to the patients.

Professional conduct

It is expected that all surgeons will offer advice and care based on these guidelines. We hope and expect that a compassionate and caring attitude will be shown to all patients.

Future monitoring

Patients who have undergone explantation following rupture/gel leak of PIP implants should be advised to attend annual follow-up for at least two years.

Patients who underwent a 'clean' explantation or re-implantation should be advised about normal follow-up procedures.

Where a patient decides, after consultation with specialist, not to have their PIP implants removed, they should be followed up on an annual basis. In the case of NHS patients this review would normally be carried out by the GP; private patients should be followed up by the surgeon or provider responsible for the original implantation. Patients with PIP implants should be made aware of the signs and symptoms of implant rupture and gel bleed.

This guidance may change after consultation with relevant parties.