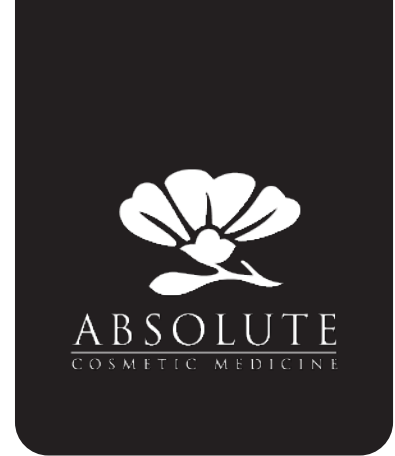


BREAST AUGMENTATION PATIENT CONSENT CHECKLIST



ONLY SIGN IF YOU FULLY AGREE AND UNDERSTAND

Before you make a decision about whether to proceed with breast implant surgery, you must ensure you are familiar with the risks associated with using these devices. The risks are reported in clinical trials, scientific literature and patient-reported outcomes. You should take the time to read through this information and take the opportunity to return to your doctor, if necessary, to discuss these further before you proceed.

You should have been given a number of options for treatment, including treatment without the use of implants, by your doctor and they should outline clear reasons why one or more of these treatment options have been recommended for you.

It is also important that you ask for help if you need assistance reading and understanding this information. In addition to this information, your doctor should also provide you with an information booklet or brochure, provided by the manufacturer of the implants to be used in your surgery, which outlines the instructions for their use.

It's important to remember that breast implants are not lifetime devices. They are associated with a range of risks that can often require further surgery to your breasts.

Health conditions that prevent the use of breast implants

If you have any of these conditions, breast implants are not suitable for you:

- An active infection such as urinary or respiratory infection
- Cancer in your breast that has not been treated
- You are pregnant or breastfeeding

Health conditions that increase risk of a poor outcome

If you have any of these conditions, consider the need for breast implants carefully:

- Chronic disease that affects healing, e.g. diabetes, autoimmune connective tissue disease
- Active smoker
- Medication that reduces immunity, e.g. steroids, chemotherapy
- Previous radiation treatment to your breast(s) and/or planned radiation treatment after surgery
- Conditions that interfere with blood clotting, e.g. haemophilia, von Willebrand disease

Health conditions that may increase risk of a poor outcome after surgery:

- Autoimmune disease, e.g. rheumatoid arthritis, lupus
- Other implanted products in the breast(s)
- Clinical diagnosis of a mental health disorder, e.g. body dysmorphic disorder, eating disorder, clinical depression

BREAST AUGMENTATION PATIENT CONSENT CHECKLIST

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Risks of breast implants

The risks of breast implant surgery may include:

Changes to your breast

- Breast pain
- Skin, nipple or areola loss of sensitivity
- Asymmetry
- Impact of weight change to size and shape of breasts
- Impact of pregnancy and breast feeding on the size, shape and position of breasts
- Infection which may require removal of implant
- Swelling
- Scarring
- Fluid collection (seroma)
- Bleeding and hematoma
- Loss of skin and nipple
- Inability to breastfeed
- Chronic pain

Changes to the implant

- Rupture, including silent rupture
- Leaking of silicone and formation of painful lumps in your breast
- Visibility and rippling of the implant
- Capsular contracture, where a hardening of tissue around the implant can cause pain, deformity and may require revision surgery or implant removal
- Mobility of the implant
- Malposition or displacement of the implant causing deformity, e.g. double bubble
- Breast implant associated anaplastic large cell lymphoma (with textured devices)

Possible association of systemic symptoms

There are some women that report a variety of systemic symptoms including joint pain, fatigue and 'brain fog', which has been labelled as breast implant illness. Whilst the causes of these symptoms remain unclear, more research is needed to further define the cause(s) and outcomes, and to determine whether these symptoms resolve following removal of implants.

Recommended follow up

By proceeding with implant surgery, you are also required to undergo regular follow up with your treating doctor for clinical and radiological assessment of your breast implants. You will require routine and regular surveillance for as long as you have breast implants.

Australian Breast Device Registry

It is strongly recommended that you register your device with the Australian Breast Device Registry. This will allow tracking of outcomes and safety and will allow notification of any important information on the safety of your breast implants to you directly. Please ask your doctor to register your device at the time of surgery.



BREAST AUGMENTATION PATIENT CONSENT CHECKLIST

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Checklist for completed clinician/patient discussion

- ☐ Health conditions that can affect breast implants
- ☐ Risks of breast implant surgery
- ☐ Risk to your breast(s)
- ☐ Risks of breast implant failure
- ☐ Risks of systemic symptoms
- ☐ Need for ongoing surveillance
- ☐ Register your device

Signature and confirmation

Patient

I _____ have had the opportunity to ask my doctor about their experience, medical degree and specialty of training and credentials. I acknowledge that I have received and read this information that has been provided to me. I have had time to discuss this information directly with my treating doctor. I have had the opportunity to ask about the benefits and risks of breast implants, given my specific health and indication for surgery. I have considered alternatives to breast implants.

Patient signature _____ Date _____

Doctor

I acknowledge that I have discussed the benefits and risks of breast implants as described above. I am satisfied that the information has been given in language that the patient can understand. I have provided the patient with the opportunity to return and ask questions, and I have addressed these questions. I have informed the patient of the need for ongoing regular surveillance of these devices and the need to report any adverse events related to breast implants and associated breast surgery.

Doctor signature _____ Date _____

