

Toolkit for the management of breast implants

April 2022

Surgical Services Taskforce

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AGENCY FOR CLINICAL INNOVATION

1 Reserve Road St Leonards NSW 2065

Locked Bag 2030, St Leonards NSW 1590

T +61 2 9464 4666

E aci-info@nsw.gov.au | aci.health.nsw.gov.au

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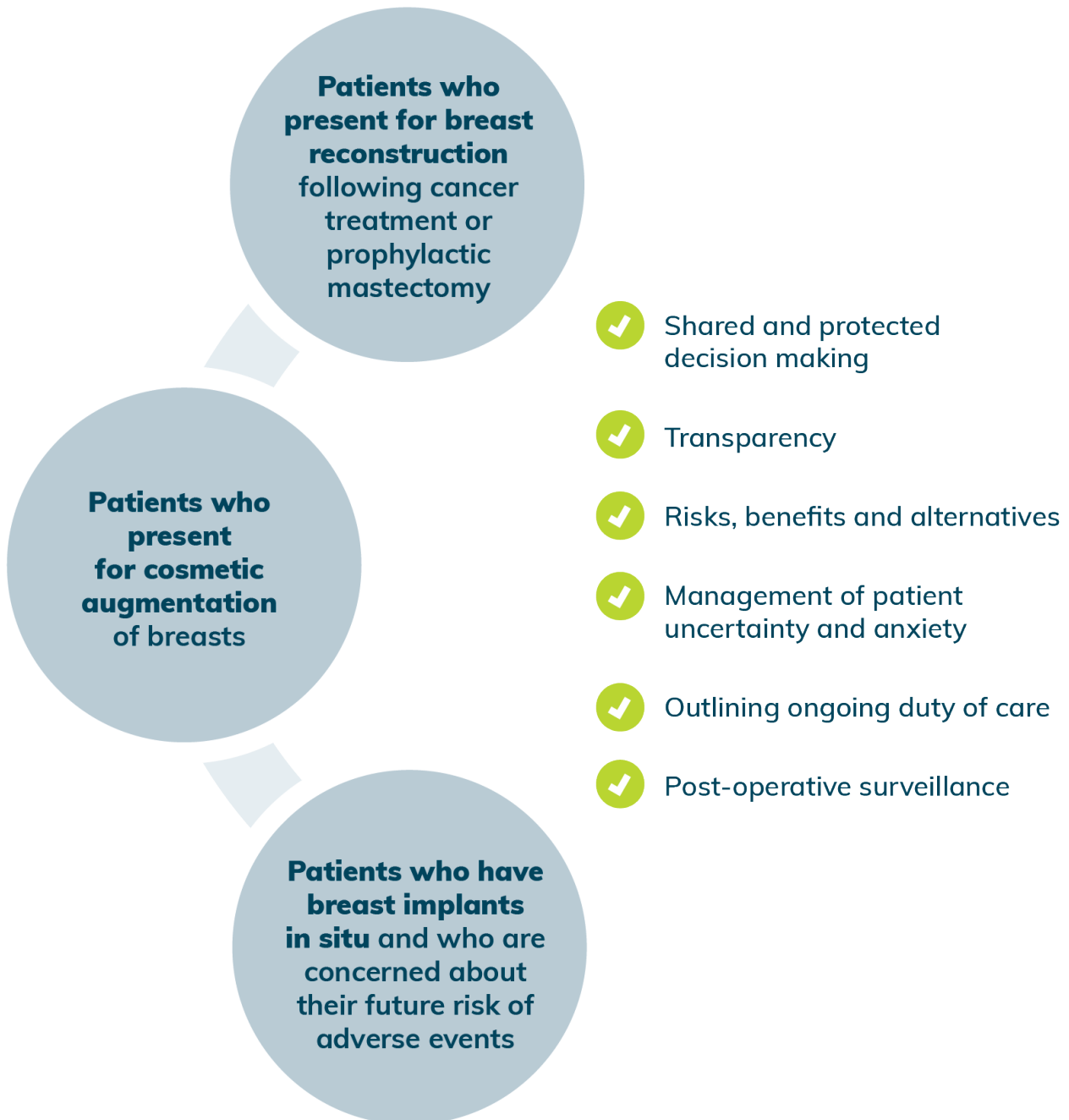
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Management of breast implants at a glance

This toolkit has been developed to inform surgeons who insert breast implants of best practice when caring for patients with breast implants or considering implants. It was developed in response to a safety alert regarding anaplastic large cell lymphoma.¹



Acknowledgement of contributors

The Surgical Services Taskforce acknowledges the efforts of the following subject matter experts in developing this toolkit:

- Professor Mark Ashton, University of Melbourne
- Dr. Nalini Bhola, Statewide Clinical Director, BreastScreen NSW
- Professor Anand Deva, Macquarie University
- Associate Professor James French, Westmead Breast Cancer Institute, University of Sydney
- Associate Professor Bruno Giuffre, Radiology, Royal North Shore Hospital, University of Sydney
- Associate Professor Mark Magnusson, Griffith University
- Associate Professor Sanjay Warriar, University of Sydney, Royal Prince Alfred Academic Institute

Collaboration with regulatory bodies

Professors Deva, Ashton and Associate Professors Magnusson and Warriar were nominated to be on the breast implant expert working group for the Therapeutic Goods Administration (TGA). The proposal for a breast implant toolkit was first presented to the TGA expert panel meeting and progressed to the TGA consumer forum in October 2019. The Australian Commission on Safety and Quality in Health Care were also consulted as part of the engagement process. The toolkit was then adopted by the Agency for Clinical Innovation (ACI) and presented to the expert panel working on breast implants convened by the Office of the Chief Health Officer, NSW Health. The toolkit was further refined with input from the Surgical Services Taskforce.

Introduction

The TGA issued a safety alert in 2020 regarding an association between breast implants and anaplastic large cell lymphoma.¹ Global regulatory action has taken place to address the safety of breast implants. Guidance is needed about best practice for the clinical use of these devices, both for reconstruction following mastectomy and for cosmetic augmentation.

This toolkit was developed by drawing from clinician groups who are directly involved in the surgical deployment of breast implants and associated devices.

Input was also sought from other related clinical groups including pathology, radiology, consumer advocates, patients who have experienced adverse events related to breast implants and government authorities involved in the administration and regulation of these devices.

This toolkit considers three specific clinical scenarios:

1. Patients who present for breast reconstruction following cancer treatment or prophylactic mastectomy.
2. Patients who present for cosmetic augmentation of breasts.
3. Patients who have breast implants in situ and who are concerned about their future risk of adverse events.

The founding principles that shape these guidelines are:

- Empowerment of patients and encouragement of shared and protected decision making with, where possible, multiple time points for discussion
- Transparency in potential personal and commercial conflicts of interest
- Education of patients on risks, benefits and alternatives of breast reconstruction procedures
- Management of patient uncertainty and anxiety
- Providing options and choice for a variety of treatments
- Outlining ongoing duty of care and post-operative surveillance

NSW Health has published the [Consent to Medical and Healthcare Treatment Manual](#) on informed consent procedures relating to healthcare treatment.² This is a supporting document for this toolkit.

Where possible, patients should be encouraged to attend consultations with a support person or persons, to ensure that there are multiple opportunities to process information and to provide advocacy and support.

It is also important that any complications or adverse events associated with breast implant procedures are recorded and reported appropriately. This includes compliance with [Policy Directive PD2020_047: Incident Management, the Therapeutic Goods Administration online module for adverse event reporting](#) and local hospital or facility policies.^{3, 4}

Method

A team of healthcare professionals, technical experts and lay representatives were consulted and undertook the drafting of the clinical scenarios and supported best practice as determined by clinical consensus.

Where required, opinions were sought from relevant specialists (e.g. radiology, regulatory scientists) in relation to these devices. This group was supported by the ACI and the Surgical Services Taskforce, who assisted to harmonise the guidelines with existing NSW Health directives and structure the toolkit in line with other ACI initiatives. The use of prophylactic antibiotics in breast implant surgery was further investigated by performing a literature search. Finally, input was sought from health consumers to ensure that their concerns were addressed and that the language and recommendations were aligned to an appropriate level of health literacy.

Evidence informed	Based on literature search. Literature search of MEDLINE for the terms breast implant, antibiotics, prophylaxis were performed in October 2019, October 2020 and March 2022.
Collaboration	Surgical Services Taskforce Office of the Chief Health Officer Professor Mark Ashton, University of Melbourne Dr. Nalini Bhola, Statewide Clinical Director, BreastScreen NSW Professor Anand Deva, Macquarie University Associate Professor James French, Westmead Breast Cancer Institute, University of Sydney Associate Professor Bruno Giuffre, Radiology, Royal North Shore Hospital, University of Sydney

	Associate Professor Mark Magnusson, Griffith University Associate Professor Sanjay Warriar, University of Sydney, Royal Price Alfred Academic Institute
Currency	Review in 5 years
Updates	<ul style="list-style-type: none"> • First published March 2022. • Point 7, Operative procedure, Implant-based breast reconstruction section was updated in April 2022 to reflect <i>Therapeutic guidelines: Surgical antibiotic prophylaxis for specific procedures</i>.⁵

Implant-based breast reconstruction

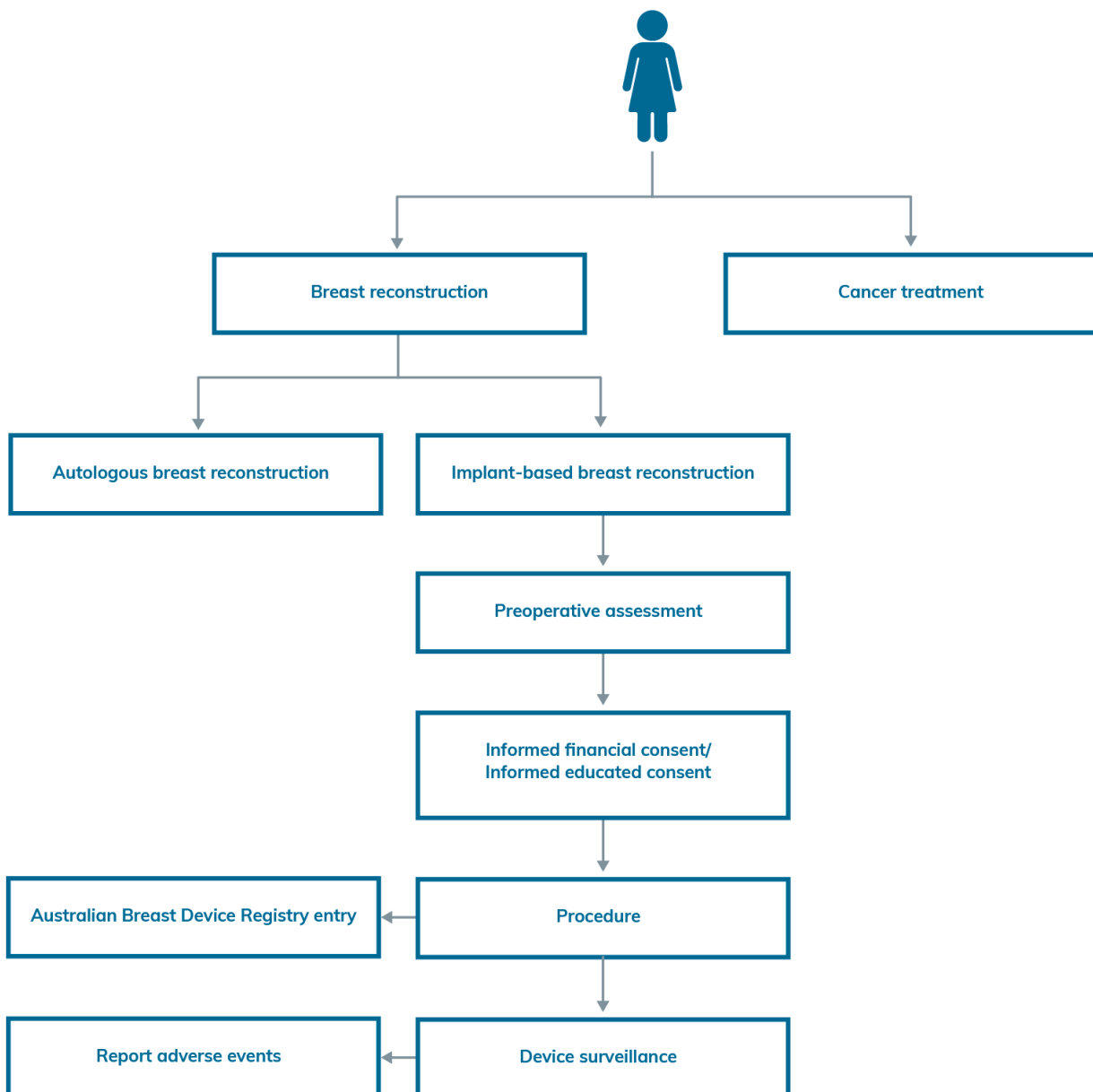
Breast implants, and associated devices such as supporting mesh and dermal matrices, may be indicated for reconstruction of all or part of a breast following mastectomy.

In some cases, there is a period of tissue expansion, usually between six weeks and six months, where soft tissue is prepared prior to the deployment of a permanent implant device. The more immediate priority for such patients is the clinicopathological staging and treatment of the cancer prior to reconstruction planning.

Discussion around options for reconstruction may be constrained by time as well as the impact of the cancer diagnosis.

Figure 1 outlines steps that are recommended for pre, intra and post-operative management of implant-based breast reconstruction.

Figure 1: Steps for implant-based breast reconstruction



Preoperative work up

1. Outline all options for breast reconstruction with the patient, including:
 - a. autologous
 - b. combined autologous with implant
 - c. tissue expander (+/- supporting mesh, acellular dermal matrix) with implant
 - d. direct to implant (+/- supporting mesh, acellular dermis matrix).
2. For implant-based reconstruction, outline options for the use of tissue expanders, as well as other associated mesh or acellular dermal matrices and definitive implant(s).
3. Discuss the risks for each implantable device clearly and supported by use of an adverse event checklist, including likely frequency of each complication.
4. Discuss specific risks related to the patient, including any comorbidities, specific anatomy and related cancer treatment, that may impact on the outcome.
5. Present clinical credentials and experience clearly, including the clinicians' track record of patient outcomes.
6. For implant or tissue expander, discuss the range of options and make recommendations supported by sound clinical reasoning.
7. Clear declaration of any industry or personal conflicts related to the device(s).
8. Complete an informed educated consent checklist (see [Appendix 1](#) for an example of this).
9. Obtain informed financial consent.
10. Outline immediate postoperative care plan for the patient.
11. Discuss plans for ongoing and long-term surveillance.
12. Offer a second consultation or telephone conversation, time permitting, prior to undergoing procedure.

Operative procedure

1. The reconstructive procedure must be performed in a fully licensed and accredited facility with established access to high dependency care, if required.
2. Prophylactic intravenous antibiotics are administered at least 10 minutes prior to skin incision.⁶⁻⁹
3. Use thorough skin preparation.¹⁰
4. Apply infection control mechanisms, including steps to prevent bacterial contamination: pocket irrigation, haemostasis, layered closure and sterile surgical technique are essential.^{11, 12}
5. Use drains, where required, aiming to remove these as early as practicable.¹³
6. Provide clear postoperative instructions on wound and drain management.

7. Provide postoperative antibiotic prophylaxis in accordance with [National guidelines](#).⁵ Prophylaxis beyond 24 hours, even in the presence of a drain, is not indicated.⁵
8. Entry of the device/s onto the [Australian Breast Device Registry](#).¹⁴
9. Provide the implant card to the patient with encouragement to enter details to their My Health Record or assist in entering this with administrative support.
10. Document device details in the surgical report or patient notes according to local protocols.
11. Include device details in the patient discharge summary.
12. Communicate operative information, implant information and clinical history to the patient's primary care provider.

Postoperative care

1. Schedule inspection of the surgical site by the treating surgeon (for example at one week, two weeks and six weeks post-operatively).
2. Provide clear, written instructions to the patient as to what to look for in the immediate postoperative period and a contact number in the case of an emergency.
3. Provide a written program of clinical and radiological cancer and implant surveillance to the patient at six to eight weeks post-operatively.¹⁵
4. Discuss signs and symptoms that should prompt medical review by either treating doctor or general practitioner, including provision of a written information sheet.

Cosmetic breast augmentation

While not generally performed within the NSW public health system, the use of breast implants for cosmetic augmentation remains one of the most commonly performed cosmetic surgical procedures worldwide.¹⁶

In order to provide a complete picture of the use of breast implant devices, guidance around cosmetic breast augmentation is included in this document. This may also have relevance for general practitioners and public hospitals, as patients can present for an assessment and treatment of adverse events following cosmetic surgical treatment.¹⁷

There is considerable variation in the clinical delivery of cosmetic breast augmentation. Credentials, training, certification of practitioners and accreditation of facilities where these procedures are undertaken are not strictly regulated outside of the public health system.

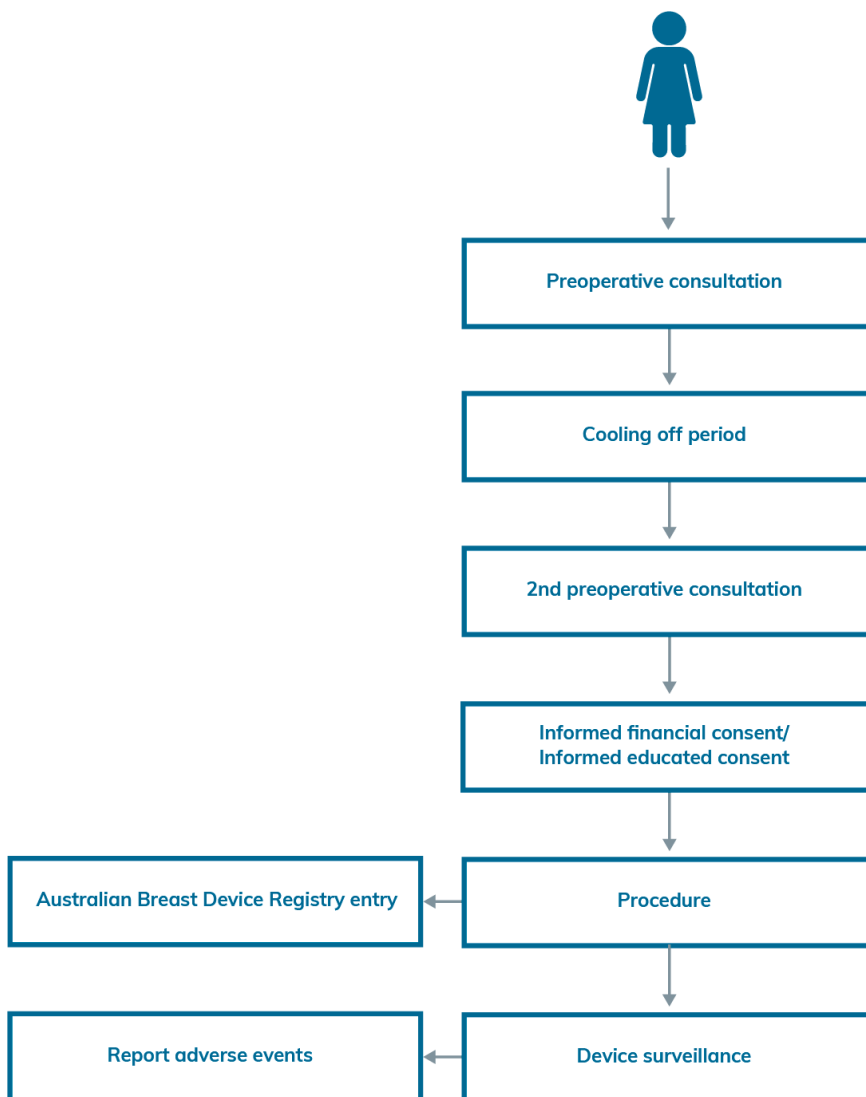
In June 2016, the [Private Health Facilities Regulation 2017](#) was amended to reflect the requirement that all cosmetic surgical procedures (including cosmetic breast augmentation) be undertaken in licensed facilities.¹⁸

In 2018, NSW Health conducted a [review of the regulation of cosmetic procedures](#).¹⁹ This included recommendations with respect to clearer titling of health practitioners and cooling off periods prior to elective cosmetic surgery. This toolkit seeks to expand on best clinical practice to ensure that patients presenting for cosmetic breast augmentation are given sufficient information and time before they decide to proceed with this elective procedure.

All patients should understand that breast implants are not lifetime devices. They can result in adverse events, which may require further surgical intervention.

Figure 2 outlines steps that are recommended for pre, intra and post-operative management of cosmetic breast augmentation.

Figure 2: Steps for cosmetic breast augmentation



Preoperative work up

1. Present clinical credentials and experience clearly, including track record of performing implant-associated cosmetic augmentation procedures.
2. A minimum of 45 minutes direct face-to-face consultation between the patient and clinician performing the procedure (including patient support persons where appropriate).
3. While telehealth consultations may be offered for patients who are in regional or remote areas, these should not be used a substitute for face-to-face consultation.
4. A thorough clinical assessment of both breasts and axillae and preoperative ultrasound examination and mammography of both breasts and axillae is recommended for all women aged 35 years and older. For women under 35 years of age, a preoperative ultrasound examination of both breasts and axillae in addition to a clinical assessment is recommended.
5. Outline the options for various types of breast implants including shaped, textured or smooth and the options for placement of these implants either above or below the pectoralis major muscle. The clinician should provide the patient with a list of benefits and risks for each option that is offered.

6. Clearly discuss and document the risks associated with breast implants and the need for further surgery as a result of breast parenchymal changes, pregnancy and weight changes.
7. Outline the specific risks related to the patient including any comorbidities, or consideration relating to anatomy and asymmetry.
8. Perform preoperative sizing.
9. Present and discuss the surgeon's operative outcomes and timeframe of achieving these results.
10. Declare any industry or personal conflicts related to the device(s) recommended.
11. Complete an informed educated consent checklist (see [Appendix 1](#) for an example of this).
12. Obtain informed financial consent.
13. Outline immediate postoperative care plan for the patient.
14. Ensure a minimum cooling off period of one week is completed.
15. Ensure a second face-to-face consultation prior to proceeding with surgery, preferably one week prior to the surgical date, to review information again, discuss any radiological findings and confirm treatment plan.

Operative procedure

1. The breast augmentation procedure must be performed in a fully licensed accredited facility.
2. A qualified anaesthetist and appropriately qualified support staff must be present in the operating theatre and appropriately qualified staff must care for the patient in recovery and the postoperative ward.
3. Prophylactic intravenous antibiotics are administered at least 10 minutes prior to skin incision.^{6, 7}
4. Use thorough skin preparation.¹⁰
5. Apply infection control mechanisms, including steps to prevent bacterial contamination: nipple shields, pocket irrigation, good haemostasis, layered closure and sterile surgical technique are essential.^{11, 12}
6. Provide clear postoperative instructions on wound management and physical activity following surgery.
7. Entry of the device/s onto the [Australian Breast Device Registry](#).¹⁴
8. Provide the implant card to the patient with encouragement to enter details to their My Health Record or assist in entering this with administrative support.
9. Include device details in the patient discharge summary.
10. Communicate operative information, implant information and clinical history to the patient's primary care provider.

Postoperative care

1. Schedule an inspection of the surgical site by the treating surgeon (for example at one week, two weeks and six weeks post-operatively).
2. Provide clear, written instructions to the patient as to what to look for in the immediate postoperative period and a contact number in case of emergency.
3. Provide a written program of clinical and radiological cancer and implant surveillance to the patient at six to eight weeks post-operatively.¹⁵
4. Discuss signs and symptoms that should prompt medical review by either treating doctor or general practitioner, including provision of a written information sheet.
5. Schedule a regular surveillance check at one year postoperatively and then at regular intervals at the discretion of the clinician and patient thereafter. It is recommended that patients are seen at least every two years until 10 years and then yearly thereafter, as adverse event rates accumulate significantly following this.
6. Initiate and incorporate an ongoing screening and surveillance program for breast cancer at an appropriate age. Patients should be instructed to inform imaging staff of the presence of implants to ensure that appropriate care and projections are taken.

Assessment of patients with breast implants in situ

In September 2019, the TGA announced that a number of breast implants were to be suspended and/or cancelled due to the potential risk of a rare cancer associated with textured devices known as breast implant-associated anaplastic large cell lymphoma.¹

This action has prompted many women to seek a medical review of their implants. This toolkit provides a framework for assessment of these patients. To date, there is no proven benefit in recommending removal of implants that have normal clinical or radiological examination.²⁰

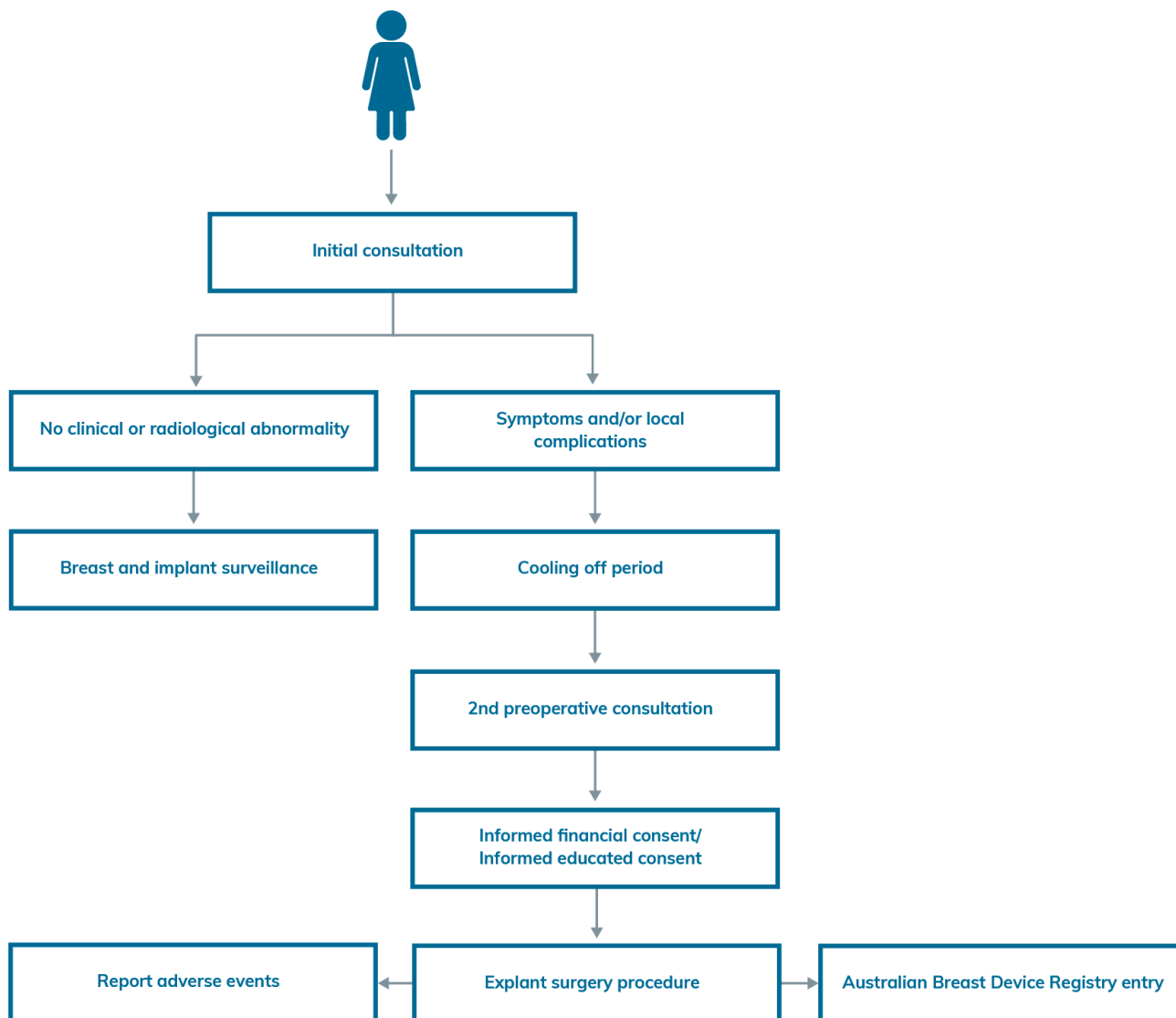
The recommended course of action for people who have no local complications related to their breast implants is to continue with a regular surveillance program.

The clinician plays an important role in completing a comprehensive assessment and providing the patient with information and advice, in relation to breast implant-associated cancer risk.

It is acknowledged that some patients with ongoing concerns about their breast implants may wish to have their implants and/or surrounding capsules removed. In these instances, a clear discussion about the risks compared with benefits of implant and/or capsule removal should be undertaken. The decision to proceed with surgery in these patients should also be made only after at least two clinical consultations, separated by at least a one-week time interval.

Figure 3 outlines steps recommended for patients with breast implants in situ, including consultation and pre, intra and post-operative management of explant surgery, if the patient proceeds to explant surgery.

Figure 3: Steps for patients with breast implants insitu



Consultation

1. Complete a thorough patient history, history of the implant procedure and identification of the patient’s implant type (where possible).¹⁷
2. Identify any personal or family risk of breast cancer or lymphoma.
3. Document any history of change to the breast in the period since surgery.
4. Review previous pathology and radiology results.
5. Perform a thorough physical examination of implants, breast and draining lymph nodes. Any abnormality warrants further radiological and/or pathological investigation.
6. Consideration should be given to ultrasound examination of the implants to check integrity and exclude any seroma or mass. Any abnormality on ultrasound examination should prompt further imaging with breast MRI and/or biopsy or seroma aspiration to explore pathology.¹⁷

7. While the treatment of breast implant complications is beyond the scope of this toolkit, if clinical and radiological examination detects implant-associated complications or breast pathology, consider surgical intervention.
8. Should no concerns or issues be identified through this assessment process, conduct regular surveillance and patient education.
9. Should a patient still wish to proceed with explant surgery to remove breast implants, discuss the risks and benefits of implant removal, partial capsulectomy and total capsulectomy. The future risk of breast implant-associated anaplastic large cell lymphoma should also be discussed with respect to removal of part, or all, of the capsule around the implant.

Preoperative work up: Explant surgery

These additional steps are recommended for patients proceeding to explant surgery:

1. Present clinical credentials and experience clearly, including track record performing breast explant procedures.
2. Present and discuss the surgeons' individual operative outcomes and timeframe of achieving these results.
3. Declare any industry or personal conflicts related to the device(s).
4. Complete an informed educated consent checklist (see [Appendix 1](#) for an example of this).
5. Obtain informed financial consent.
6. Outline the immediate postoperative care plan for the patient.
7. Ensure a minimum cooling off period of one week is completed.
8. Ensure a second face-to-face consultation prior to proceeding with surgery, preferably one week prior to the surgical date, to review information again and confirm treatment plans.

Operative procedure: Explant surgery

1. The explant surgery procedure must be performed in a fully licensed accredited facility.
2. A qualified anaesthetist and appropriately qualified support staff must be present in the operating theatre. Appropriately qualified staff must care for the patient in recovery and the postoperative ward.
3. Use thorough skin preparation.¹⁰
4. Apply infection control mechanisms, including steps to prevent bacterial contamination: pocket irrigation, good haemostasis, layered closure and sterile surgical technique are essential.^{11, 12}
5. Provide clear postoperative instructions on wound management and physical activity following surgery.
6. Use drains, where indicated.
7. Use postoperative compression garments, where indicated.
8. Samples must be sent for pathological examination and culture.
9. Send samples and implants to research laboratory, where the patient is enrolled in a prospective study and has provided consent.
10. Provide patient with clear postoperative instructions on wound management and activity following surgery.

11. Enter explanted device details onto the [Australian Breast Device Registry](#).¹⁴
12. Communicate operative and clinical history to the patient's primary care physician.

Postoperative care: Explant surgery

1. Schedule an inspection of the surgical site by the treating surgeon (for example at one week, two weeks and six weeks post-operatively).
2. Provide clear, written instructions to the patient as to what to look for in the immediate postoperative period and a contact number in case of emergency.
3. Discuss signs and symptoms that should prompt medical review by either treating doctor or general practitioner, including provision of a written information sheet.
4. Consider obtaining a baseline mammogram +/- breast ultrasound one year after explant surgery and review.

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Appendix 1: Patient consent checklist

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 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.

Underlying health conditions that impact breast implants

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

Risks of breast implants

The risks of breast implant surgery may include:

1. 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

2. 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)

3. 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.

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 and 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 and date