Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

DRAFT
Australia's Breast Implant Risk Management Framework

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TGA Consultation Hub

Contents

Glossary of definition

Term	Definition
Acellular Dermal Matrix	a soft tissue substitute that can replace or support tissues in patients undergoing breast reconstruction.
Adverse event	any unfavourable and unintended sign, symptom or disease that occurs associated with the use of a therapeutic good (such as breast implants).
Breast augmentation	a surgical procedure that involves use of breast implants to enlarge or alter breast size and shape.
Biocompatibility	compatibility of implanted medical devices (such as breast implants) to exist in harmony with tissues without causing any harmful effects.
Capsular contracture	complication of breast implant surgery where scar tissues form a tight and hard capsule around the implant.
Clinical trials	research studies to test new medical and other interventions that may improve health and wellbeing of people
Cooling off period	a period (of at least 7 days) after you give consent, during which patient can reconsider to proceed with the surgery.
Explant	removal of implanted medical device (such as breast implants) from body involving additional procedure.
Informed consent	patient's agreement to get treatment from health care professional with full knowledge of the possible consequences, risks and benefits.
Implant	medical device placed into human body either permanently or temporarily to replace or support functions of organs or tissues.
Manufacturer	a person or company responsible for design, production, packaging and labelling of a device before it is supplied
Patient Information Leaflet	a document that can be provided to consumers before a surgical procedure that can be used to inform discussions and decision have a medical device implanted.
Patient Implant Card	information provided after surgery with the specific details of the implanted medical device (such as breast implants). The card contains the name, model, batch, lot, and manufacturer's details.
Post market review	a review conducted by the TGA after a medical device has been approved to be supplied to ensure medical devices continue to be safe and perform as the manufacturer intended.
Reconstructive surgery	a procedure done for medical reasons to repair damage to the body that affects how it works or looks or that restores body parts after an injury or disease.
Sponsor	a person or company who is responsible for applying to the TGA to have their medical device included on the Australian Register of Therapeutic Goods and ensure that all products supplied in Australia continue to meet the regulatory requirements.

Purpose

Breast implant surgery for cosmetic or reconstructive purposes has become increasingly common. Like any medical device, there are risks and benefits with the use and surgical implantation of breast implants. Some known risks or complications associated with breast implants include capsular contraction, implant rupture, and breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) (see Risks of Breast Implants to learn more). Breast implants are long term implantable devices (10–15 year period), and sometimes the complications associated with the use of implants may only appear over time.

The Therapeutic Goods Administration (TGA) takes a proactive approach in monitoring the potential impacts of all types of breast implants including the newer models, to minimise implant related hazards, detect any adverse effects early, and, if required take regulatory action quickly. This draft framework outlines our processes to identify and manage risk. It contains useful information on what consumers and health care professionals can do to be vigilant. It describes the cooperative efforts that could be used by health care professionals, experts in the field, international regulators and consumer advocates in the on-going monitoring and gathering of real-world evidence.

Risk Identification

Post-market surveillance

1. Adverse event reporting

When a breast implant is first included in the Australian Register of Therapeutic Goods (ARTG) information about its safety and effectiveness is usually based on early evidence typically through clinical trials. Clinical trials provide information about many of the possible adverse events associated with a breast implant, but they cannot detect all possible adverse events as the trials do not continue for long enough to detect adverse events that manifest after a long period of time, and are not large enough, in terms of patient numbers, to detect rare complications. Clinical trials do not cover the breadth, types, and number of patients that use the implants in the real world. Even though sponsors of new implant devices must provide annual reports on complaints received and adverse event data for the first three years after inclusion of the device in the ARTG, ongoing adverse event reporting from their routine use (also known as “real world evidence”) helps in monitoring the ongoing safety of therapeutic goods outside of controlled clinical trial conditions and in identifying potential risks associated with medical devices like breast implants.

Patients and health professionals are strongly encouraged to report a problem or side effect and share any problems associated with medical devices, they are experiencing or are aware of. Reports can be submitted online and when submitting, include as much information as possible, including implant/explant dates, model, and serial numbers. These reports help us to monitor the performance and safety of medical devices.

2. Post-market reviews

All medical devices are required to comply with the Essential Principles (EPs). The EPs consider the long-term safety, performance, design, and construction of devices and focus on ensuring the benefits of the devices outweigh the risks. Manufacturers must hold evidence that their devices meet all the relevant EPs before gaining approval to supply their devices in Australia.

We (the TGA) conduct post-market reviews of medical devices to ensure the devices continue to meet the EPs and conditions of inclusion of the device in the ARTG. We receive information from a range of sources for example clinical experiences, scientific publications, information or action taken by other medical device regulators, and our own monitoring processes. We may select a device for an in-depth post-market review based on these signals or identification of any safety or performance issue for similar devices that are included in the ARTG.

When we undertake a post-market review, any aspect of a medical device may be reviewed. This includes the documents and any related information held by the sponsor, the clinical evidence reports, the manufacturers’ processes and procedures, ingredients or materials used, risk assessment documents, and design of the device. If an issue is identified, we will work with the sponsor to implement the appropriate regulatory or non-regulatory actions. Actions can include requiring design changes, recalling a product, suspension, or cancellation of the device from the ARTG, and imposing conditions for continued inclusion in the ARTG.

Gathering intelligence from registries and the healthcare sector

The Australian Government established the Australian Breast Device Registry (ABDR) to track the long-term safety and performance of breast implants and help safeguard health outcomes for patients using implants for reconstructive and cosmetic purposes. Since then, the registry has been collecting, analysing, and publishing annual reports on all breast device procedures undertaken in public and private hospitals, and day surgeries. The ABDR complies with State, Territory, and Commonwealth privacy laws, and the data is stored in a highly secure database. It complies with the clinical quality registry standards established by the Australian Commission on Safety and Quality in Health Care Operating Principles.

The TGA, and the Breast Implant Expert Working Group, support the ABDR as the repository of information relating to breast implants.

The Breast Implant Expert Working Group advises us on clinical and other matters relating to breast implant and tissue expander medical devices. The working group includes reconstructive surgeons, cosmetic surgeons, breast-cancer surgeons, epidemiologists, data analysts, public health practitioners, and consumer representatives.

Working with healthcare professionals

1. Adverse events reports

Health professionals can report problems with breast implants to TGA's Incident Reporting and Investigation Scheme (IRIS). All surgeries, including primary implants, revision, and explants involving breast implants and meshes can be reported to the ABDR. Each report contributes to the on-going risk identification and management of these products.

2. Keeping track of latest information published on BIA-ALCL

We have been monitoring issues related to BIA-ALCL since 2011 when an association between breast implants and ALCL was first identified. It is important for healthcare professionals to keep abreast of the latest information on BIA-ALCL and breast implants, including the most up-to-date risk rates.

A review of BIA-ALCL cases reported to us indicated differing risk rates for breast implants with differing surface textures. The data available in 2023 indicated that polyurethane-coated implants have an estimated risk of 1 in 1,800 and macro-textured implants have an estimated risk of 1 in 2,400. These kinds of breast implant are no longer included in the ARTG; however, they may remain implanted in some people.

In contrast, the data available in 2023, indicates that micro-textured implants have an estimated risk of 1 in 18,000 and there are no confirmed cases of BIA-ALCL in individuals in Australia who have a known history of only smooth breast implants. Both these kinds of breast implants are still available for supply in Australia.

Medical experts do not recommend removal of breast implants if there are no symptoms of BIA-ALCL or even if the breast implant is no longer supplied in Australia. This is because BIA-ALCL is a rare cancer, and the risk of undergoing surgery could be higher than the risk of developing BIA-ALCL.

3. Awareness of Breast Implant Illness/Systemic Symptoms associated with Breast Implants

Breast Implant Illness (BII) refers to a range of symptoms that some individuals experience after cosmetic augmentation or breast reconstruction. The condition may also be referred to as "systemic symptoms associated with breast implants" (SSBI).

The symptoms are diverse, including fatigue, brain fog, memory loss, rashes, hair loss, joint pain and muscle pain. While current scientific evidence is limited, ongoing studies are underway to shed light on its development and to better understand any potential association with breast implants.[1] [2] Symptoms are not restricted to particular device types. BII can affect patients with any type of breast implant, including silicone, saline, smooth, textured or tear-drop, regardless of whether the implants are ruptured, leaking or intact.

Until further research can define the relationship between breast implants and BII, it is important for patients to recognise and be aware of the associated symptoms. We encourage patients and health care professionals to report any adverse events associated with breast implants.

4. Awareness of the use of mesh devices and their potential symptoms

Meshes made up of biological or synthetic matrices[2] are increasingly being used to support breast implants or expanders during breast reconstruction or augmentation. The mesh is used to create a sling within the chest to cradle the breast implant, which are both inserted at the same time.[3]

Biological meshes, also referred to as acellular dermal matrix (ADM), are derived from human or animal tissue. The reported benefits of biological meshes are rapid host revascularisation and cell repopulation. However, they are more expensive than synthetic matrices and can pose increased infection risks.[4]

Synthetic meshes are either absorbable (generally made from a plastic-like material like polyglactin) or non-absorbable (e.g., titanium-coated polypropylene models). Absorbable models of mesh are intended to degrade slowly, while non-absorbable mesh remain implanted with the breast implant. While synthetic meshes have reportedly been linked to lower explantation rates and infections, and their long terms effects require further studies and research.[5]

Similar to breast implants, we encourage patients and health care professionals to report any adverse events associated with meshes.

[1] A. Kaderbhai et al, (2021). Breast implants: A guide for general practice. Australian Journal of General Practice, Vol 50, Issue 7.
[2] Magnusson MR, Deva AK et al. (2019) Breast implant illness: A way forward. Plast Reconstr Surg 74S–81S.
[3] Logan Ellis. et al. (2016). Biological and synthetic mesh use in breast reconstructive surgery: a literature review . World J Surg Onc 14, 121.
[4] Choi YS et al. (2023). Comparing Complications of Biologic and Synthetic Mesh in Breast Reconstruction: A Systematic Review and Network Meta-Analysis. Arch Plast Surg. 6;50(1):3-9.
[5] E. Guimier et al. (2022). Pharmacological Approaches for Prevention of Breast Implant Capsular Contracture. Journal of Surgical Research. Vol 280: 129-150.

Working with consumers

Improving awareness and informed consent

No surgery is risk-free but understanding the possible complications can help patients and surgeons make better decisions and identify risks associated with breast implants.

We have a guidance and resource page that provides information on things to consider before having a breast implant surgery. It includes information such as asking health professionals about their training and experience, knowing if the implant is included on the ARTG, knowing about the potential side effects and knowing the symptoms of breast implant associated cancer.

We have required medical device manufacturers to provide patient implant cards and patient information leaflets to patients when receiving or considering having an implant as part of their health care (see Risk Management- Introduction of patient information materials).

Alignment, communication, and collaboration with international regulators

We communicate regularly with other international regulators to monitor safety concerns related to breast implants. Alerts issued by other regulators are considered by us and regulatory action is taken if required.

In September 2022, we issued a Safety Alert about reports of squamous cell carcinoma (SCC) and various lymphomas located in the capsule or scar tissue around breast implants following a safety communication issued by the US Food and Drug Administration (FDA). The reports of cancers in the capsule around breast implants are different to BIA-ALCL. Like other regulators, we continue to monitor the occurrence of disease in people with breast implants in Australia.

Risk Communication – using channels of communications

TGA's breast implant hub & working groups

Our breast implant hub contains information about the risks and benefits and breast implant associated cancer to support people with concerns about their implants or those considering implants.

The Breast Implant Expert and Consumer working Groups was established in 2016 following reports of breast implant associated anaplastic large cell lymphoma (BIA-ALCL). The Working Groups provided advice including on the development and content of the TGA's breast implant hub. Some of these include safety communications and guidance to support consumers with lived experience and health professionals. The Women's Health Product Working Group is another working group at the TGA that offers advice on women's health products and acts as a two-way channel of communication.

Recall actions, safety alerts etc.

Recall actions and safety alerts are a set of market actions that are undertaken via the Uniform Recall Procedure for Therapeutic Goods (URPTG) to manage breast implants already supplied in the Australian market when issues, deficiencies, or defects are identified. We coordinate the recall action, advising the sponsor or manufacturer of the appropriate procedures to undertake to correct their problem. If necessary, we have the legislative powers to mandate the recall of medical devices, including breast implants, under the *Therapeutic Goods Act 1989*.

Social media

We have several social media platforms, including Facebook/Meta, Instagram, Twitter/X, YouTube and LinkedIn. We use these platforms to get important messages, such as the latest updates on breast implants and associated complications, out to consumers, healthcare professionals, researchers and other groups. Consumers can use these platforms to find TGA-related information and tips on the safety of medicines and medical devices (including breast implants), while health professionals can use them to follow the latest news and guidance on the regulation of health products.

Working with other stakeholders and promoting relevant publications

We work with breast implant experts, Cancer Council Australia and Breast Cancer Network Australia to ensure all Australians who are affected by breast cancer receive the best care, treatment, and support.

Cancer Council Australia is a non-for-profit that advises various groups, including the government, and has built a support network to identify cancer-related issues. Cancer Council Australia develops independent cancer control policies and undertakes research, patient support and education programs.

The Breast Cancer Network Australia is a consumer group that inform consumers on issues related to breast implants through their advocacy, connection and information. BCNA provide trusted resources to those affected by breast cancer through their online network and an active online peer-to-peer support community, offering people affected by breast cancer with a safe space to connect with others, share stories or ask for advice.

NSW Health has published information about breast implants and BIA-ALCL. The website contains a toolkit for the management of breast implants and guides patients on the complications associated with breast implants and the steps to take to find out what type of implant they may have received.

Risk Management

TGA

1. Appropriate regulatory requirements for new breast implant models

a. Classification of medical devices

Breast implant devices, including tissue expanders and mesh, are implanted devices that are regulated as Class III high risk medical devices. Class III devices require rigorous and stringent assessments and the highest level of scientific and clinical evidence to be provided when applying to be included in the ARTG. These devices are monitored and examined thoroughly over the life cycle of the device, compared to devices classified as lower risk.

b. Compliance with Essential Principles

The Australian medical devices regulatory system is among the most stringent in the world. Manufacturers of medical devices are required to hold evidence against the relevant EPs, which consider:

- the long-term safety,
- performance,
- design, and
- construction of devices.

The EPs focus on ensuring that the benefits of the device outweigh the risks. Manufacturers are responsible for generating, collating, assessing, and maintaining scientific and engineering evidence that demonstrate that their devices meet all the relevant EPs before TGA approves the supply of the device in Australia and for the duration of supply in Australia.

For example, EP 1 requires a medical device to be designed and produced in a way so that the device does not compromise the safety of a patient, and that any risks associated with the use of the device are acceptable when weighed against the intended benefits. EP 14 states every medical device requires clinical evidence, appropriate for the use and classification of the device, demonstrating that the device complies with the applicable provisions of the EPs.

c. Clinical evidence guidelines for sponsors and manufacturers

We have issued clinical evidence guidelines for the medical devices. The guidelines are intended to be a common reference point for both industry and the regulator – assisting sponsors and manufacturers to collect, compile, and present clinical evidence to meet their regulatory requirements. These guidelines describe the clinical evidence that should be submitted to us when completing an application for inclusion on the ARTG and upon request during a post-market review or investigation into an adverse event.

In 2023, we updated the breast implant clinical evidence guidance chapter. The document describes the clinical evidence that should be provided for breast implants filled with saline, silicone gel, or alternative filler intended for breast augmentation or breast reconstruction, and tissue expanders which are used in breast reconstruction.

d. Requirements for full biocompatibility testing

To improve implant biocompatibility, breast implant surface modifications have been studied by our laboratories to test whether implants on the Australian market are correctly classified for surface roughness in accordance with ISO 14607:2018. For example, silicone material is commonly used in breast implants for cosmetic and oncologic surgical indications owing to their inertness and being nontoxic (i.e., improved biocompatibility). However, certain breast implant surfaces have been linked with complications, including capsular contracture and anaplastic large cell lymphoma, over time. Novel implant surfaces and modifications of existing ones can directly impact cell-surface interactions and enhance biocompatibility and integration.

We will continue to monitor and evaluate biocompatibility of breast implants through the clinical evidence supplied by manufacturers when applying to us to first supply the implant in Australia. We continue to test and monitor surface modifications and textures to remain vigilant on emerging complications.

e. Taking regulatory actions where required

i. TGA investigations & laboratory testing

We request information and evidence from sponsors when conducting post-market investigations, including post-market reviews and device incident report investigations. When reviewing the information provided by the breast implant sponsors and manufacturers, we assess the evidence for compliance with the Essential Principles, in association with our guidance documents, and international standards.

For example, in response to an increase in adverse events and emerging reports of BIA-ALCL, we have conducted laboratory analysis of breast implants and sponsors of the breast implant devices supplied in Australia were asked for documentation about their manufacturing processes, risk management strategies, clinical evidence, and biological safety assessments and samples for our laboratory analysis.

A detailed report of the laboratory analysis was published on 26 September 2019. The study found that the sponsors correctly classified surface roughness in almost all cases, in accordance with the international standard (ISO 14607:2018). The standard classifies implants as smooth, micro or macro-textured based on surface roughness. Overall, this study found that it may be appropriate to consider surface texturing methods in the classification standard as similar implants have similar characteristics. This has contributed to the ongoing work to revise ISO 14607.

ii. New conditions for breast implants

New conditions for breast implants were imposed following our review and investigations. The conditions required by us for breast implants allow improved post market surveillance of the devices by increasing the data that is collected. The data collected helps with analysing adverse event trends and allows early insights on the use and effects of the implants. If a sponsor does not comply with the new conditions, we can take further regulatory action. These conditions are:

- reporting all BIA-ALCL to the TGA within 10 working days of becoming aware of the adverse event

- providing a report on supply, adverse events and complaints received to the TGA every six months to support greater vigilance through increased data collection.
- including the risk of BIA-ALCL in the instructions for use of all breast implant and tissue expander devices to promote clinicians' awareness,
- all patients who have a breast implant, mesh and/or tissue expander device(s) implanted must be given a patient information leaflet and patient implant card, to support informed choices and traceability of the implanted device(s). Patient information leaflets must contain warnings and risks associated with the product.
- Information relating to the ABDR must also be included in the patient information leaflet, to support on-going reporting and monitoring.

iii. Suspension/cancellation of breast implant devices

TGA investigations, including post-market reviews and device incident reporting, can identify potential issues and non-conformities with the EPs. We will work with sponsors to implement appropriate correction actions to manage and mitigate the risks associated with the device. Some of the corrective actions available to us include product recall, imposing of conditions (as outlined above), amendments to Instructions for Use, and suspension or cancellation of the device from the ARTG.

f. Identifying, with the Expert Working Group and the ABDR, signal detection and regulatory actions

We work with the ABDR to improve the safety of breast devices, including breast implants, tissue expanders and mesh/matrix, at the device level and for reconstructive or cosmetic procedures. Factors such as shape, size or fill of implants and their impact on device performance and potential emergence of signals may be studied.

The ABDR and the TGA's Breast Implant Expert Working Group agree there is a lack of data on capsular contracture as it does not necessarily result in surgical intervention, where data is usually captured. The ABDR are re-implementing Patient Reported Outcome Measures (PROMs) at pre-determined intervals, which will help collect information on most common complications, such as capsular contracture.

g. Engage with and align with international standards – International Organization of Standardization (ISO) and American Society for testing and Materials (ASTM)

We actively participate in international forums to develop appropriate standards. It chairs the international working group revising ISO 14607, which specifies particular requirements for breast implants. A 3-letter code is expected to be used in the updated standard to classify breast implant textures, to note the type of surface texturing technique used and include both surface area ratio and categories for surface roughness measurements.

The ISO committee is redrafting the standard to clarify the biological evaluation of breast implants and also the characterisation and quantification of surface particulates. Our work together with the Dutch National Institute for Public Health and the Environment (RIVM) regarding particulates may be used to redraft the new standards, with input from others on the ISO committee.

2. Introduction of patient information materials

From 1 December 2021, all patients receiving implantable medical devices, including breast implants, expanding devices and mesh, are supplied with patient information materials (patient information leaflet and patient implant card).

The patient information leaflets can be used by the patient and the health professional as one of the many information sources to inform discussions about using a breast implant device. The leaflets aim to provide important information about risks, warnings, precautions, expected device lifetime, monitoring and maintenance of the device, to assist with making informed decisions.

The patient implant card provides specific details about the breast implant that has been implanted. The information in the cards can be used by health practitioners and consumers after a surgical procedure to identify the device and improve tracking of the device if there are safety issues.

3. Unique Device Identification system

We have established a Unique Device Identification (UDI) system for medical devices. The UDI contains the device and device production information as a series of characters applied to the medical device label or packaging and patient implant card. We are also building a publicly available Australian UDI Database (AusUDID) that will enable public access and search for specific device information (e.g., ARTG ID, device model numbers, serial/lot/batch numbers, expiry information).

The Australian UDI system is beneficial to consumers, healthcare professionals, researchers, the medical device industry, and other regulators as it will make it easier to find information about the devices in the ARTG. This will in turn improve post-market surveillance of the device as important information can be obtained quickly.

Health Professionals

1. Report to ABDR

The Australian Breast Device Registry allows surgeons and healthcare operators to contribute to the continued safety and quality of breast device surgery in Australia. Data entered into the simple Data Collection Form (DCF) will help the collection of a powerful and important dataset. ABDR reports will provide surgeons with data on their own patients as well as aggregated state and/or national level data. Information such as patient numbers, reasons for surgery, plane of implantation, number of primary versus revision surgeries, as well as complications such as device rupture and capsular contracture can be captured and can contribute to early signal detection and treatment.

Surgeons are encouraged to complete this form to contribute to the ABDR. The more surgeons and healthcare professionals that participate in the ABDR, the more reliable, powerful and important the ABDR becomes.

2. Report adverse events to TGA

In conjunction with reporting to the ABDR, health professionals should report problems with breast implants to us. Your report will contribute to our monitoring of these products. For

more information see the TGA Incident Reporting and Investigation Scheme (IRIS). Each report contributes to the on-going risk identification and management of these products.

3. Obtain informed consent for breast implant surgery

a. Informed consent guidelines

It is important that patients are informed and aware of the risks associated with breast implant surgery, prior to consenting to it. Health professionals have a duty to provide the patient with enough information to enable them to understand the nature, effects and risks associated with breast implants. This will help patients to manage their health and recognise when things are not right and report their experience.

It is also important that health professionals explain to patients that breast implants are not intended to be lifelong devices and most breast implants will need replacement or removal within 10-15 years.

Some of the complications and adverse outcomes of breast implants include additional surgeries, capsular contraction, breast pain, changes in nipple and breast sensation and infections. In very rare circumstances, breast implants can lead to serious complications such as BIA-ALCL. The NSW Health and Australian Commission on Safety and Quality in Health Care has published more information confirming informed consent is a professional requirement for health providers.

b. cooling off period between informed consent and breast implant procedures

The Australian Commission on Safety and Quality in Health Care (ACSQHC) is working on reforms to the cosmetic surgery sector to ensure doctors providing cosmetic surgeries are appropriately qualified and work to the highest safety standards expected in Australia. The National Safety and Quality Cosmetic Surgery Standards (NSQHS) is proposed to be expanded to include informed consent and opportunities for cooling off period.

4. Refer to clinical guidelines: recommended management of a patient with breast implant

NSW Health has published a clinical guide to support general practitioners in the assessment and management of patients with breast implants. Recommendations outlined in this guide are based on the best practice, expert consensus and available evidence at the time of publishing. This guide has been developed in collaboration with representatives of NSW RACGP and clinical specialists in the field of plastic, reconstructive and breast surgery.

5. Maintaining latest standards and credentialing status

The National Safety and Quality Health Service Standards are developed by the ACSQHC in collaboration with the Australian government, states and territories, the private sector, clinical experts, patients, and carers. Out of eight NSQHS standards, two of them play an important role in risk identification for the safety of breast implants. *Clinical Governance* describes the clinical governance, and safety and quality systems that are required to maintain and improve the reliability, safety, and quality of health care, and improve health outcomes for patients with breast implants. *Partnering with Consumers*, describes the systems and strategies to create a person-centred health system by including patients in shared decision making, to ensure patients are partners in their own care, and that consumers are involved in the development and design of quality health care.

The ACSQHC is developing a cosmetic surgery national licensing framework and safety and quality standards to ensure the doctors providing cosmetic surgeries are appropriately qualified and work to the highest health safety standards expected in Australia. Extensive consultation is planned with consumers, clinicians, services, regulators, peak representative organisations, and other key stakeholders throughout the project.

6. Maintain credentialing status

We work with the ACSQHC to support health professionals to provide safe and high-quality health care that is informed, supported, and organised. Credentialing by health service organisations is a process used to verify the qualifications and experience of a clinician within a specific health care setting and role to confirm suitability to practise in a competent and ethical manner. In 2015, the ACSQHC released guidance on the Credentialing health practitioners and defining their scope of clinical practice.

7. Better patient doctor communication on breast implant illness/systemic symptoms associated with breast implants

Although the current scientific evidence continues to evaluate a possible association between breast implants and BII, it is important for health professionals to acknowledge and manage patients who present with related symptoms.

Open, transparent communication fosters patient comfort in discussing their symptoms and concerns. Some recommendations for managing patients with BII include patient counselling and education (such as a discussion of symptoms and the risk-benefit profile of treatment options), clinical and laboratory assessment of symptoms and specialist referral if required.[6] Consideration of individual medical backgrounds, family history and other underlying factors is key to understanding and managing patients' symptoms.

[6] McGuire P et al. (2022). A Practical Guide to Managing Patients With Systemic Symptoms and Breast Implants. Aesthet Surg J. 2022 Mar 15;42(4):397-407.

Consumers

1. Be observant and have regular examinations

Women with breast implants should continue to routinely monitor their breast implants and consult their surgeon if they have any concerns. There is information available on self-examination of breast on Breast Cancer Network Australia and Breast Screen NSW.

2. Ask questions

We have published a fact sheet on *Five questions to ask your health professional before you get a medical implant* to help with your conversation with your doctor.

The breast implant associated cancer (BIA-ALCL): Information for consumers contains a number of questions that might be useful when thinking about getting a breast implant. Other resources includes; What you need to know about BIA-ALCL and breast implants that have been 'recalled' or are no longer available.

3. Be informed before consenting to surgery

Patients have ethical and legal rights to make informed consent about their health. Before giving consent, patients should ensure that the health professional:

- explains the treatment choices
- explains any risks or likelihood of the risks, and
- checks that patients understand the purpose of the procedure they are consenting to.

Patients who are considering breast implants should be made aware of the benefits and risks of the different types of implants for their clinical circumstance. They should also be provided with educational material to read and consider prior to implantation. After implantation, patients should be provided with written details about the name and type of implant and the procedure performed. They should give the patient the breast implant manufacturer's labelling, patient information leaflet, and the patient-specific implant card.

Being actively involved in your health care and working in partnership with healthcare provider can ensure the care you receive is the most appropriate for your circumstances. The Australian Commission on safety and Quality in Health Care and NSW government has published important information for consumers regarding consent to medical treatment including patients who are from culturally and linguistically diverse (CALD) background.

4. Request and read patient information material

Health information can be complex. The medical device patient implant cards, and information leaflets, help patients have informed conversations with their health professional before having breast implant surgery. We have published a fact sheet for consumers that explains what medical implants are and why it is important to request a patient information leaflet and implant card. BCNA has published resources for patients including a breast reconstruction decision aid.

5. Report concerns and adverse events

If you have received breast implants, medical experts do not recommend the implants be removed if you do not have any signs or symptoms of concern. We monitor the occurrence of the disease in Australia and communicates with other international regulators and experts in Australia.

We strongly encourage you to report all problems associated with medical devices, including breast implants. These reports help us to monitor their performance and safety.

Patients can visit the 'Report a problem or side effect' webpage to complete the online form and share any problems they may be experiencing and include as much information as they can, including implant/explant dates, model, and serial numbers.

6. Consent to be included in the ABDR

A national registry, the ABDR, collects information on breast device surgery. This includes surgical procedures involving a breast implant, tissue expander or dermal mesh. The registry tracks, monitors and reports on the safety, performance, and quality of breast devices to health authorities, such as the TGA.

Patients can participate in this data collection by asking your surgeon. If the surgeon is contributing, you will be automatically included. The ABDR complies with State, Territory and Commonwealth privacy laws and will not release patient identifiable information to any person or organisation, other than to your surgeon and to state/national government databases containing details on operations performed in hospitals, to ensure that information on the registry is accurate and complete.

Glossary of terms

Acronyms	Elaboration
ABDR	Australian Breast Device Registry
ACSQHC	Australian Commission on Safety and Quality in Health Care
ACMD	Advisory Committee for Medical Devices
ADM	Acellular Dermal Matrix
ARTG	Australian Register of Therapeutic Goods
BIA-ALCL	Breast Implant Associated – Anaplastic Large Cell Lymphoma
BI-EWG	Breast Implant Expert Working Group
BCNA	Breast Cancer Network Australia
BII	Breast Implant Illness
CALD	Culturally and Linguistically Diverse
DCF	Data Collection Form
EP	Essential Principles
FDA	Food and Drug Administration
IRIS	Incident Reporting and Investigation Scheme
ISO	International organization for Standardization
NSW RACGP	New South Wales Royal Australian College of General Practitioners
NSQHS	National Safety and Quality Health Service
PICs	Patient Implant Cards
PILs	Patient Information Leaflets
PROMs	Patient Reported Outcome Measures
RIVM	Dutch: *Rijksinstituut voor Volksgezondheid en Milieu*
SCC	Squamous Cell Carcinoma
SSBI	Systemic symptoms associated with Breast Implants
TGA	Therapeutic Goods Administration
UDI	Unique Device Identification
URPTG	Uniform Recall Procedure for Therapeutic Goods

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

Reference/Publication #