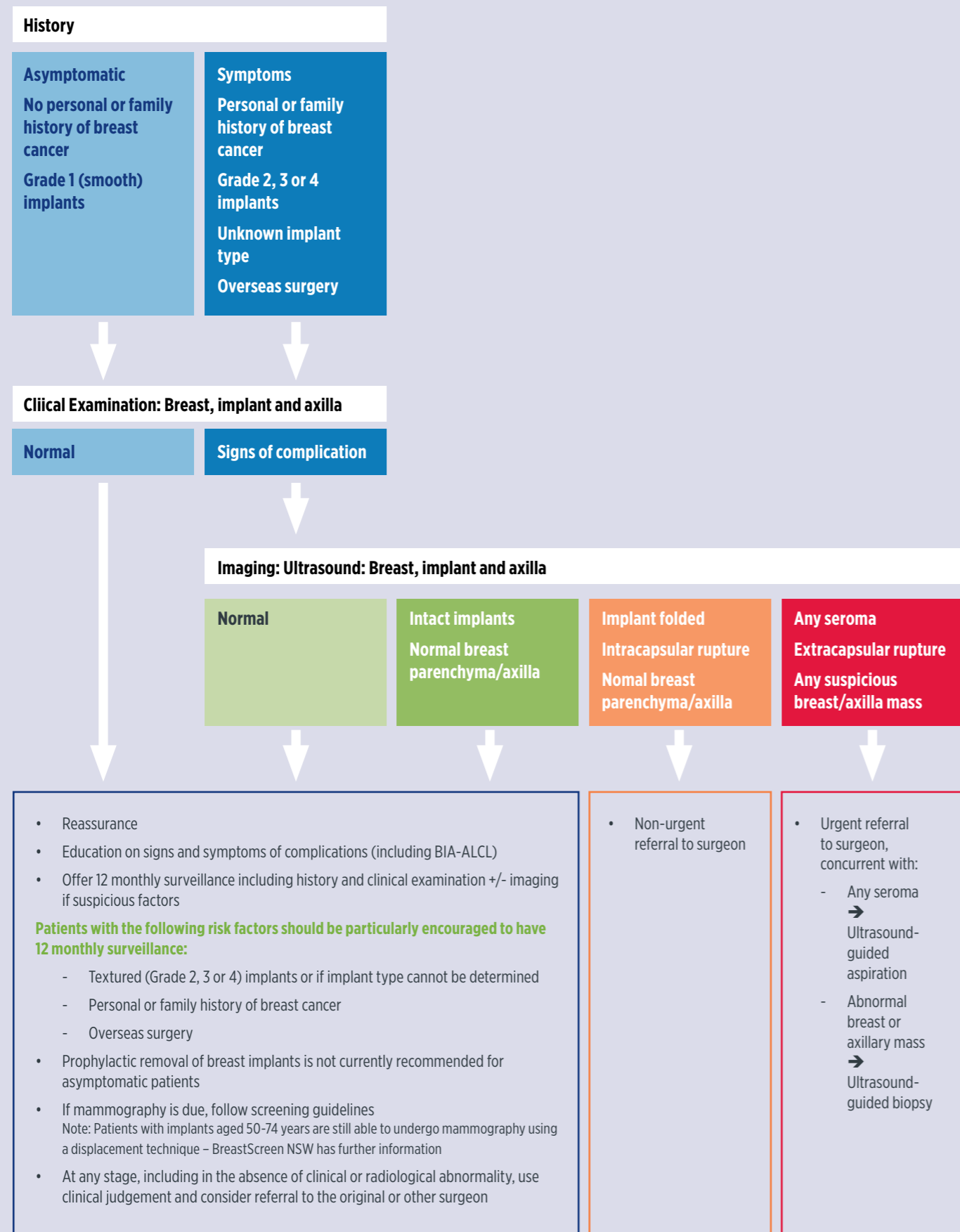


## The investigation of patients with breast implants



## Recommended management of a patient with a breast implant

January 2020



### Introduction

The purpose of this guide is to support general practitioners in the assessment and management of patients with breast implants.

This guide has been designed to supplement existing clinical guidelines, such as the Cancer Australia 'The investigation of a new breast symptom – a guide for General Practitioners'. It summarises important information relevant to general practitioners caring for patients with breast implants.

Recommendations outlined in this guide are based on 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 fields of plastic, reconstructive and breast surgery.

### Patient history

A thorough history should be taken to assess the patient's general breast health.

Below are examples of history relevant to assessing for complications associated with breast implants:

- Procedure – indication (breast cancer reconstruction/ cosmetic breast augmentation), implant type, size, placement, any patient concerns
- Risk factors – breast cancer, lymphoma, autoimmune disease
- Breast history – lactation, infection, previous surgery

- Symptoms – pain, deformity, change in size/ shape, lumps, systemic symptoms, asymptomatic

### Complications of breast implants

As with any surgery and medical device, complications can occur following the insertion of a breast implant. For example additional surgeries, breast pain, capsular contracture, rupture, infection, patient dissatisfaction, and breast implant-associated anaplastic large cell lymphoma (BIA-ALCL).

### Relative frequency of complications

Complication	Frequency of complication	
Capsular contracture	41.0%	Most Common ↓ Least Common
Device malposition	27.7%	
Device rupture	20.5%	
Seroma/haematoma	3.1%	
Deep wound infection	1.3%	
BIA-ALCL	0.4%	

Based on complications identified at both reconstructive and aesthetic revision procedures for 5,886 patients recorded in the Australian Breast Devices Registry, 2018

Reference: Hopper I, Parker E, Pelligrini B et al. The Australian Breast Device Registry 2018 Annual Report. Monash University, Department of Epidemiology and Preventive Medicine, October 2019

## Clinical examination

Refer to the Cancer Australia [‘The investigation of a new breast symptom – a guide for General Practitioners’](#) for how to conduct a thorough examination.

It is important to examine the breast, implant and axilla for signs of:

- Capsular contracture\*
- Deformity – rupture, rotation, displacement (double bubble), visibility/rippling, deflation (saline filled implants), folding, lowering/drooping of breast tissue
- Breast pain
- Breast lump
- Breast swelling
- Lymphadenopathy
- Nipple changes
- Skin rash

Baker classification of capsular contracture*	
Baker Grade 1	Implant is soft and not palpable and/or visible
Baker Grade 1B	Post-reconstruction only. Implant is soft but visible as the skin envelope is thinner
Baker Grade 2	Implant is palpable but no visible deformity
Baker Grade 3	Implant is hard, palpable with some minor visibility (e.g. puckering, rippling, change in shape) Ultrasound usually shows infolding.
Baker Grade 4	Implant is very hard, painful with significant deformity of breast and/or malposition. Ultrasound shows significant folding and/or rupture

Reference: Spear SL, Baker JL, Jr. Classification of capsular contracture after prosthetic breast reconstruction. *Plastic and Reconstructive Surgery*. 1995; 96(5):1119-1123; discussion 1124

## BIA-ALCL

Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is a rare T cell non-Hodgkin lymphoma that develops around breast implants and typically presents as breast or axillary swelling or pain, and occasionally a mass, on average 7-8 years after original insertion.

If diagnosed early, surgical removal of the implant and capsule is curative.

For more information on BIA-ALCL, go to the [Therapeutic Goods Administration Breast Implant Hub](#).

## Breast implant type

Implants can be classified according to:

- Brand/manufacturer
- Contents – silicone/saline
- Shape – round/anatomic
- Surface (Grading) – Grade 1 (smooth) – Grade 4 (textured)

All breast implants have the potential to result in complications. The normal lifespan of a breast implant is 10 – 15 years and the majority of patients require revision surgery at some point.

Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is a rare complication of breast implants and has been associated with higher grade (grade 2, 3 and 4) textured implants. As at January 2020, no reported cases of BIA-ALCL have occurred in patients with a history of only smooth (grade 1) implants.

Where possible, determining which type of implant a patient has provides helpful information to guide further investigation and follow-up. It also allows better interpretation of information released by the Therapeutic Goods Administration (TGA) in relation to particular types of products, available on the [Breast Implant Hub](#).

## Options to determine the implant type

1. Patient implant card
2. Contact the original surgeon
3. Contact the Australian Breast Device Registry (ABDR) if surgery was from 2015 onwards\*: 03 9903 0205 or 1800 998 722 or abdr@monash.edu or at <https://www.abdr.org.au/contact-us/>
4. Contact the Breast Implant Registry (BIR) if surgery was prior to 2015\*: Australian Society of Plastic Surgeons (ASPS) at 02 9437 9200 or bir@plasticsurgery.org.au
5. Contact hospital medical records department

\*Both the ABDR and BIR require patients to consent to their information being held therefore not all patients will have a record.

If the implant type is unable to be determined, patients should be reassured that regular self-examination and 12 monthly surveillance by a health practitioner to assess for any breast changes is the recommended management.

## Risk of BIA-ALCL

Compared to other complications, BIA-ALCL is rare.

Implant grade	Example implant type	Estimated risk*
4	Silimed Polyurethane	1 in 2000 – 2500
3	Allergan Biocell	1 in 2500 – 3000
2 – 3	Nagor Textured	1 in 5000 – 6000
2	Mentor Siltex	1 in 15000 – 36000

\*Based on sales data and implant exposure of Australian BIA-ALCL cases.

Reference: Loch-Wilkinson A, Beath KJ, Magnusson MR et al. Breast implant-associated anaplastic large cell lymphoma: a longitudinal study of implant and other related risks. *Aesthetic Surgery Journal*. 2019. S3333, <https://doi.org/10.1093/asj/s3333>

### Disclosures:

One member of the NSW Breast Implant Expert Panel involved in the development of this guideline is an advisor and educator for Mentor (Johnson & Johnson), Allergan, Sientra, and Motiva. No other individuals declared potential conflicts of interest with respect to the development of this guideline.