MONASH University

AUSTRALIAN BREAST DEVICE REGISTRY

2019 REPORT

AUSTRALIAN Breast Device REGISTRY

Addendum: Version 1.1

A misprint on Table 5 has been corrected in this version (1.1) of the 2019 ABDR Annual Report. The misprint did not affect the total number of registered patients, procedures at patient level, and procedures at breast level, by indication for surgery reported in Table 5, or data from Table 5 displayed in Figures 5 and 6.

This corrected version (1.1) supersedes all versions of the 2019 ABDR Annual Report.

This publication was produced by the Australian Breast Device Registry (ABDR).

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Data Period

The data contained in this document were extracted from the ABDR on 18 April 2020 and pertains to data that had been submitted from the initiation of the pilot ABDR on 19 January 2012 to 31 December 2019. As the registry does not capture data in real time, there can be a lag between occurrence of an event and capture in the ABDR.

The Australian Breast Device Registry is supported by funding from the Australian Government Department of Health.

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FOREWORD

It is with great pleasure that we release the 2019 Australian Breast Device Registry (ABDR) Annual Report – the registry's fourth annual report.

The ABDR continues to increase its coverage across Australia, in contributing sites and surgeons and most importantly patients. The registry has progressed since it commenced nationally in 2015 and is now reaching a phase of consolidation and ongoing growth.

This year the format of the Annual Report follows previous years, including the separation of reconstructive and aesthetic indications for surgery, in recognition of the fact that patients with these indications for surgery follow distinct surgical pathways.

In 2019 we released the registry's second clinician and site reports. All clinicians received an individual report, and site reports were released to the top 50% high volume sites.

The ABDR is one of the first clinical registries to utilise text messaging technology to collect feedback from patients as patient reported outcome measures (PROMs) data. PROMs results have been provided separately for the aggregate response from Year-1, Year-2 and Year-5 after surgery and the response reflecting the single patient journey from Year-1 to Year-2 of the surgery for the first time. This rich dataset will further our understanding of patients' experiences of their implants and be used to monitor the performance of breast devices.

International collaboration continued to strengthen in 2019, with focus on an internationally harmonised dataset to provide the framework for international post-market surveillance of breast devices. There was significant work towards classifying breast devices undertaken in 2019 for future reporting purposes. At home and abroad there was increased research into Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL), and the registry worked closely with the Therapeutic Goods Administration (TGA) on this issue. The TGA took significant regulatory action, suspending a number of implants due to risk of BIA-ALCL, and the registry was able to assist surgeons and sites in rapid identification of patients with those implants that have been inserted since 2015.

The ABDR is grateful for the continued support of the Commonwealth Government, which in 2019 wrote to all surgeons, sites and medical indemnifiers to encourage participation in the registry. We are grateful for this cooperation for the ongoing development and success of the ABDR. Participation in the registry is voluntary, and sites, surgeons and patients are enthusiastic contributors to this important health and safety initiative, contributing on all surgeries involving breast devices. Of critical importance to the ABDR is the capture of revision and explantation information so that the characteristics of these devices are clearly identified and improve our understanding of specific breast device performance.

We thank everyone involved in developing this annual report; from the project team led by Associate Professor Ingrid Hopper, to members of the governance committees overseen by the Steering Committee Chair, Professor John McNeil, to the surgeons and sites contributing data. As always, the biggest thanks go to the patients who allow the registry to retain their data and use it to monitor device performance and quality of breast devices and surgery; and the team of ABDR for their tireless efforts in their ongoing work including producing this quality Annual Report.

Australian Society *of* Plastic Surgeons

Breast Surgeons of Australia & New Zealand

Associate Professor Elisabeth Elder, PhD, FRACS, BreastSurgANZ

Associate Professor Colin Moore, FRACS, ACCS

Associate Professor Gillian Farrell, FRACS, ASPS

ACKNOWLEDGEMENTS

The ABDR receives ongoing funding from the Australian Government Department of Health with in-kind support from Monash University. The registry is operated by the Department of Epidemiology and Preventive Medicine, Monash University, and is endorsed by major surgical societies in Australia.

We are grateful for the contributions made by the ABDR steering committee, ABDR clinical quality committee, and ABDR management committee. We acknowledge the leadership of Professor John McNeil who chairs the steering committee, and Associate Professor Ingrid Hopper who is project lead and data custodian. We would like to acknowledge the contributions of the ABDR project team (Full list on page 64) and the Registry Science and Research (RSR) team including Professor Susannah Ahern, Associate Professor Arul Earnest, Ms Breanna Pellegrini and Ms Jessy Hansen.

We also gratefully acknowledge the dedication of the steering committee members, including the clinical leads: Associate Professor Elisabeth Elder, Breast Surgeons of Australia and New Zealand Inc. (BreastSurgANZ); Associate Professor Colin Moore, Australasian College of Cosmetic Surgery (ACCS); and Associate Professor Gillian Farrell representing Australian Society of Plastic Surgeons (ASPS). We also thank Dr Amanda Craig, Therapeutic Goods Administration (TGA), Cindy Schultz Ferguson, Consumers Health Forum of Australia (CHF) representative, David Ross, Medical Technology Association of Australia (MTAA), Dr. Bernadette Aliprandi-Costa, Australian Commission on Safety and Quality in Healthcare (ACSQHC) and Dr. Supriya Budala, Australian Government Department of Health (as observer only).

Associate Professor Ingrid Hopper is supported by a National Health and Medical Research Council Fellowship which provides salary support to contribute to initiatives such as the ABDR.

This work would not have been possible without the ongoing efforts of the many surgeons, nurses and other hospital staff who contribute data to the ABDR, including surgeons who act as Principal Investigators for their sites. We would like to thank them for their commitment. We would also like to thank the patients who allow the ABDR to retain their data and recognise the importance of the ABDR.

This report was subject to critical review prior to publication. We thank the members of the committee who were involved in the peer review meeting and subsequent draft review, including individuals representing Monash University (ABDR and RSR), the three surgical societies (ACCS, ASPS, BreastSurgANZ), CHF, MTAA and the Australian Government Department of Health including the TGA. We also acknowledge our international collaborators through the International Collaboration of Breast Registry Activities (ICOBRA).

We would like to thank all surgeons and theatre staff for their generous contribution to the ABDR.

EXECUTIVE SUMMARY

This year was the biggest and busiest year for the Australian Breast Device Registry to date. The registry continues to flourish, gaining further traction with ongoing recruitment of new sites and surgeons across Australia, bringing our surgeon participation rate to over 90%.

The data contained in this report were extracted from the ABDR Database on 18 April 2020 and pertains to data that had been submitted from the initiation of the pilot ABDR on 19 January 2012 to 31 December 2019. At this point the ABDR had collected data on 49,563 patients having 55,990 procedures involving 104,012 devices. Australia-wide, 563 surgeons operating at 277 hospitals and day surgeries contributed data. The opt out rate remained low, with only 1.15% of patients choosing to opt out of participating in the ABDR. This continued increase in numbers provides strength and validity in our ability to help track and monitor the short and long-term safety of breast devices and patient health outcomes. The Patient Reported Outcome Measures (PROMs) program continued to mature. These results will further assist our understanding in how patient experience can be used to assess breast device performance.

Benefits to surgeons of contributing to the ABDR include the ability to track patients and devices inserted.

This report should be viewed in the context of important global events with regards to breast implants. Concerns regarding the rising incidence of anaplastic large cell lymphoma and its association with textured breast implants resulted in the suspension of a number of breast implants from the Australian market by the TGA in October 2019. Other regulators also acted to remove implants from their market overseas. In response, the ABDR refined its procedures for device recalls. The ABDR coded the known devices in the database by their Australian Register of Therapeutic Goods (ARTG) entry number, so that lists could then be generated to share with surgeons and public hospitals and patients could be informed. During this reporting period, the ABDR was called upon by a number of surgeons and hospital sites to provide assistance in rapidly identifying patients with the suspended implants so that they could be contacted in a timely manner and offered a surgical consultation. The ABDR website is kept up to date with important links including to the TGA website.

The structure of this report is similar to that of the previous year with separation of the reconstructive and aesthetic indications for surgery. This recognises the differences underlying the two groups in terms of patient risk profile and surgical pathways. The first registry output section of the 2019 annual report presents data on patients having reconstructive surgery; including post-cancer reconstruction, risk-reducing mastectomy and surgery to correct developmental deformity. The second registry output section of the report presents data on patients having surgery for aesthetic reasons, namely cosmetic augmentation (augmentation mammoplasty). Both sections present data on patient demographics, procedure and device details, surgical technique, complications and revision incidence.

The third section of the report presents data on registry outcomes. This includes clinician and site reporting, international collaboration, BIA-ALCL and the registry's Patient Reported Outcomes Measures (PROMs), the Breast-Q Implant Surveillance module (Breast-Q IS) which utilises five questions extracted from the larger Breast-Q tool, selected specifically to provide an early signal of potential device problems. It also lists peer reviewed papers authored by the ABDR this year, and we are very proud to have collaborated with leading researchers in the field.

The key findings and highlights from the 2019 Annual Report are presented below.

- Surgeon and site participation in the registry has been presented by state for the first time highlighting areas for ongoing engagement and recruitment.
- The total number of procedures captured by the ABDR in 2019 was 12,306 with an indication, including 3,931 reconstructive and 8,375 aesthetic procedures. The number of aesthetic procedures recorded in the registry is less than previous years, however the number of reconstructive procedures continues to increase.
- At the end of 2019, 49,563 patients had procedures captured by the ABDR, an addition of 11,960 patients in 2019.
- The ABDR 2019 data capture rate for new devices was estimated at 73% based on national supply figures provided by the TGA (up from 71% in 2018 and 63 % in 2017). The TGA supply data do not specify if devices were implanted or supplied on consignment.
- The response rate at 1-year, 2-year and 5-year PROMs follow-up after surgery was 76.0%, 73.5% and 63.2% in patients with breast reconstruction, and 59.2%, 53.4% and 44.1% in patients with breast augmentation, respectively.

INTRODUCTION

The Australian Breast Device Registry (ABDR) is a clinical quality registry (CQR) with the purpose of tracking the long-term safety and performance of breast implants and breast tissue expanders; identifying and reporting on possible trends and complications associated with breast device surgery; and identifying best surgical practice to improve patient health outcomes. The ABDR was established in 2015 with funding from the Commonwealth Department of Health[1], after a successful pilot funded by the Australasian Foundation for Plastic Surgery. This is the fourth annual report released by the ABDR in its five years of operation. The ABDR works in partnership with Australian patients, health service managers in public and private systems, theatre teams, surgeons and clinical craft groups.

The ABDR is tasked with collecting, analysing and reporting data on all breast device surgery taking place across Australia.[2] This type of surgery takes place in a wide variety of clinical settings and the ABDR captures data from public hospitals, private hospitals and private day surgeries nationwide.

REGISTRY GOVERNANCE AND STRUCTURE

Governance

As a clinical quality registry, the ABDR adheres to the Australian Commission on Safety and Quality in Health Care (ACSQHC) Framework for Australian Clinical Quality Registries (2014)[3] and Operating Principles and Technical Standards for Clinical Quality Registries (2008)[4]. It complies with all relevant standards of data security and protection, and privacy.

Steering Committee

The ABDR Governance includes a Steering Committee with broad stakeholder representation including: surgical craft groups, academic registry scientists/epidemiologists, consumers, Australian Commission on Safety and Quality in Health Care (ACSQHC), Commonwealth Department of Health (DOH) which includes the TGA and the Medical Technology Association of Australia (MTAA) (see Registry Personnel). The Steering Committee is chaired by Professor John McNeil AM and the project lead is Associate Professor Ingrid Hopper, Monash University.

Clinical Quality Committee

The ABDR Clinical Quality Committee advises the Steering Committee on clinical matters arising from ABDR data. Clinical Quality Committee members represent each of the three clinical craft groups including Australian Society of Plastic Surgeons (ASPS), the Australasian College of Cosmetic Surgery (ACCS), Breast Surgeons of Australia and New Zealand Inc. (BreastSurgANZ) and Monash University. The Clinical Quality Committee provides clinical interpretation of the data generated by the ABDR.

Management Committee

The ABDR Management Committee meets monthly to discuss and resolve issues associated with day-to-day running of the ABDR. It provides a link between operational stakeholders (sites, surgeons, patients) and advisory stakeholders (Steering Committee members).

METHODS

Surgeon recruitment

The clinical craft groups ASPS, ACCS and BreastSurgANZ endorse the registry and encourage their members to participate. When a surgeon agrees to participate, a Surgeon Participation Agreement is signed which details the surgeon's agreement to participate and a commitment to inform patients prior to surgery that their data will be collected. Once an agreement is received, the ABDR sends the surgeon an Implementation Folder containing information on the registry and arranges for a meeting with the surgeon and/or their staff to explain the ABDR processes, and education sessions targeting surgeons, practice staff and nursing staff in operating theatres. The Implementation Folder includes Patient Leaflets and Site Posters for the surgeons' consulting rooms and instructions for the surgeon on completing the Data Collection Form (Appendix 1). The surgeon ensures that the Patient Leaflet is provided to patients prior to surgery and ensures that patients are aware that their data will go into the registry.

Benefits to surgeons of contributing to the ABDR include the ability to track patients and devices inserted; the capacity to compare practice against peers in a protected environment; Continuous Medical Education (CME) points for participating in the registry; and the capacity to include on their website a logo demonstrating that they are contributing to the ABDR and their commitment to patient safety.

Site recruitment

The ABDR Project Officers recruit sites depending on the ethical and governance processes at each individual site, and guided by relevant policies and process. The ABDR Project Officers submits an application to the relevant Human Research Ethics Committee (HREC) and Research Governance Office or Medical Advisory Committee (MAC), as appropriate. To formalise participation, the Project Agreement or Clinical Trial Research Agreement is signed by both parties. Patient data are entered to the registry after the site has obtained both ethics and governance approval.

Patient recruitment

To ensure high quality data, the ABDR is a patient opt out registry. As a result of the 2010 Poly Implant Prosthèse (PIP) crisis, the Australian Senate commissioned an inquiry into the Australian Government's regulation of medical devices and subsequently recommended that the Department of Health "establish an opt out Breast Implant Registry as a priority"[5]. All patients presenting to participating hospitals with a participating surgeon should be included in the registry, and there are no exclusion criteria. The patient can, however, choose to opt out. The registry includes any person undergoing surgery that involves the insertion of a breast implant, tissue expander, repositioning of a breast implant, repositioning of a tissue expander, replacement of a breast implant, replacement of a tissue expander, removal of breast implant, and/or removal of tissue expander.

Data collection

Data are captured via the ABDR Data Collection Form – a one page, double-sided paper based form, based on a short "tick and stick" process. All data elements are defined in the ABDR data dictionary. A Data Collection Form is completed at the time of surgery for each patient undergoing breast device surgery, including patients who notify the registry prior to surgery that they wish to opt out of the registry. This decision was made on the basis of practicality; it was considered that to ask surgeons and operating theatre staff to complete the Data Collection Form on a selective basis would complicate the process and inevitably lead to mistakes.

Once the registry receives a Data Collection Form, patients are sent a Patient Explanatory Statement in the post. Patients who have not opted out two weeks after the date on which the Patient Explanatory Statement is sent will have their data included in the ABDR, although there are no timelines or restrictions for opting out and patients can withdraw at any time. Patients have several opt out options available. Patients can choose to remove their personal details including contact details, so they cannot be personally identified, but can allow their procedural data to be kept in the registry. Patients who do not want their data included in the registry and who do not wish to be contacted in the event of future revision surgeries, will have their first name, last name and date of birth retained in the ABDR database. These key personal details allow the registry to reasonably match patients for future revision surgeries and avoid contacting them again. Patients can also choose to opt out entirely, and remove both personal details and procedural details.

Following surgery, the Data Collection Form is directed to the ABDR via electronic secure transfer to the Monash Secure File Transfer as a preference, and if a site is unable to arrange this, by overnight post. The ABDR provides all materials required for the return of the forms.

Data storage and data security

Information contained within the ABDR is confidential. The Department of Epidemiology and Preventive Medicine has a strong working knowledge of privacy and confidentiality ensuring secure filing of both paper and computer files. Copies of the paper Data Collection Form are stored in a locked filing cabinet accessible only by the authorised ABDR staff. Monash Registry Database security is maintained using encryption of data, a managed and audited protocol for access, training and accreditation of personnel, role based access and authentication of data. Monash Registry Databases are housed and managed in a certified environment. No patient identifiable data are stored or transferred outside of Australia. The certification incorporates the Privacy Act (1988) and Health Records Act (2001) within its Applicability Statement.

Database

Data entry is completed manually by trained ABDR personnel, from paper Data Collection Forms forwarded by participating sites. The registry database was developed to automatically build a Product Lookup List, which enables device characteristics (texture, gel, shape) to be automatically populated in the database based on the entered device reference number, and the registry to remain up to date as new products enter the market.

Data checking and data cleaning

The ABDR Database Coordinator conducts an internal database audit twice a year, whereby a small percentage of forms is reviewed, to check the completeness and accuracy of Data Collection Forms and data entry. The ABDR database has been developed with tools to reduce data entry error, including range and reliability checks that are activated as data are entered into the registry reduce the opportunity for data errors.

Data requests

Access to data is subject to applicable privacy laws and principles, and ethics approvals. Specific measures have been put in place to maintain the confidentiality of personal identifying information in the ABDR. Patient request for access to their own information can be made by contacting the ABDR Research Manager. Patients will be required to provide sufficient proof of identity prior to the release of any data, in line with the ABDR Privacy Policy. All other requests for data must comply with the ABDR Data Access and Publications Policy.

Outcome assessment

Time-to-revision analysis using survival analysis methods[6] is conducted to investigate revision incidence rates for primary reconstructive breast implants, tissue expanders for insertion and aesthetic breast implants separately. Revision surgery includes the unplanned replacement, reposition or explant of an in situ breast device. Revision time is defined as the time from the insertion of the breast implant or tissue expanders to the first subsequent revision procedure. Crude cumulative revision incidence rates were generated using Nelson-Aalen estimates for all primary reconstructive breast implants, primary reconstructive tissue expanders and aesthetic breast implants captured by the ABDR since 2012 to 2019. Breasts without a revision procedure captured by the registry had their follow-up time censored at the date of data extraction at 18 April 2020.

REGISTRY PARTICIPATION (2012-2019)

Site Participation

The ABDR continues to engage eligible sites Australia-wide to contribute data to the registry. An **eligible** site is defined as a site currently undertaking breast device surgery as identified by Australian modification of the International statistical classification of diseases and health related problems, 10th revision (ICD-10-AM) coding data provided by the Australian Government Department of Health or as reported by external sources (internet search, surgeons or site staff).

Table 1 shows the number and classification of site engagement by facility type and state. The total number of currently eligible private sites is estimated at 237 and eligible public sites is estimated at 89. Approximately 77% of eligible private sites and 81% of the eligible public sites are located in New South Wales, Queensland and Victoria.

The list of eligible sites is dynamic and updated regularly based on information obtained from surgeons and site staff, and information gleaned from internet search engines and websites. The ABDR maintains a 'watch list' of sites identified as having the potential to undertake occasional breast device surgeries.

TABLE 1: SITE ENGAGEMENT BY STATE AT 31ST DECEMBER 2019

State/ Territory	Number of Closed/No Device Sites	Sites in Progress	Participating Private Sites	Eligible Private Sites	Participating Public Sites	Eligible Public Sites	Engagement of Eligible Private Sites*	Engagement of Eligible Public Sites*
NSW	2	18	64	75	20	29	85%	69%
VIC	1	9	48	55	23	27	87%	85%
QLD	3	7	47	52	12	16	90%	75%
WA	0	8	21	24	0	7	88%	0%
SA	0	2	18	19	4	6	95%	67%
ACT	0	2	5	6	1	2	83%	50%
TAS	0	0	4	4	1	1	100%	100%
NT	0	0	2	2	1	1	100%	100%
TOTAL	**6**	**46**	**209**	**237**	**62**	**89**	**88%**	**70%**

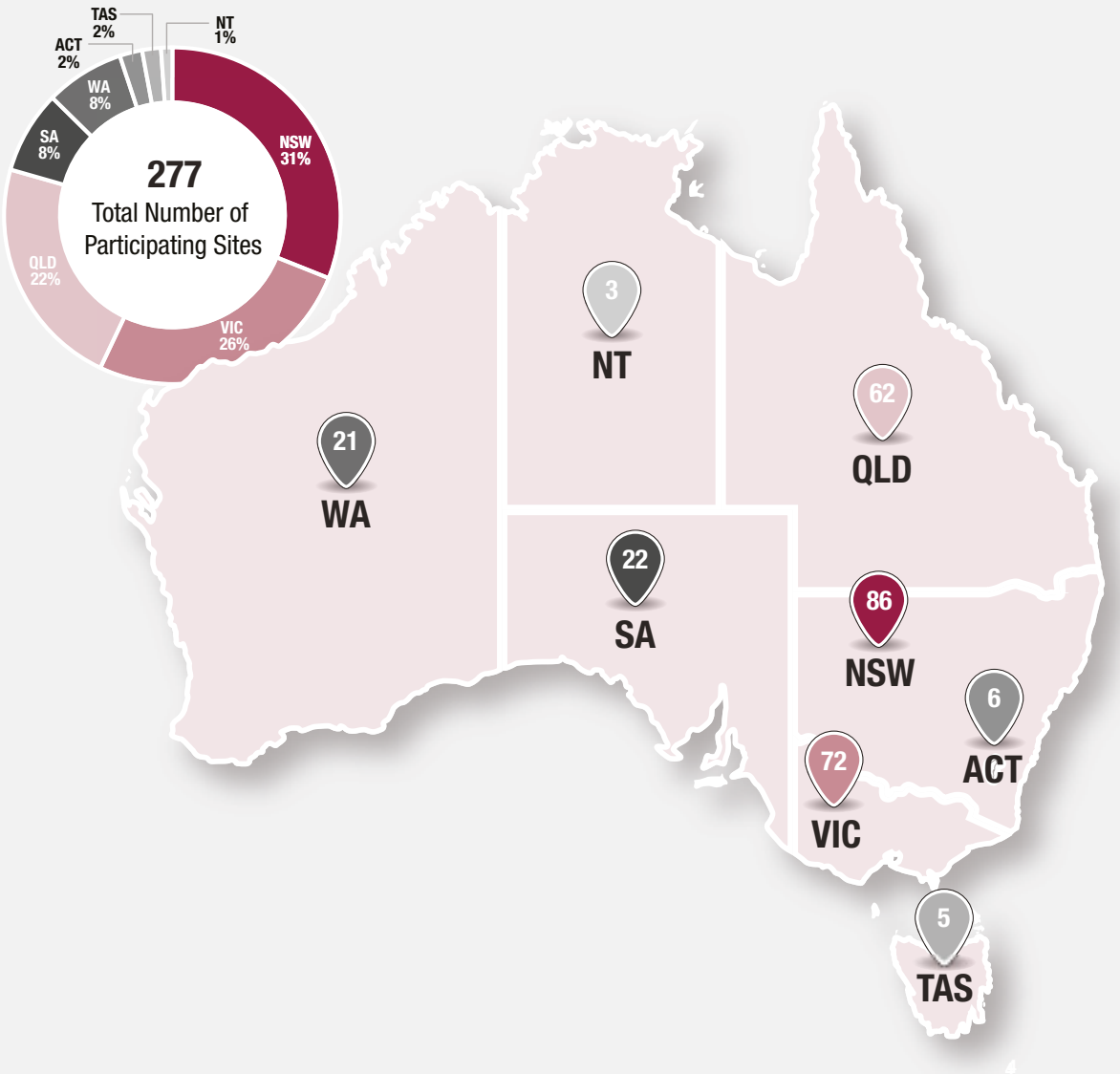
Notes: * Engagement of eligible sites is the percentage of eligible sites that are also participating sites ('implemented' and 'sites represented by surgeons contributing').

A **participating** site is defined as any site that has been granted ethics and governance approval and the data collection for the registry has commenced. As of 31 December 2019, 88% (209) of eligible private sites and 70% (62) of eligible public sites, or 83% of total eligible sites were participating in the ABDR (Table 1). The total number of participating sites throughout 2019 was 277, which included 6 sites that by the end of 2019 were classified as closed or no device sites.

† Australian modification of the International statistical classification of diseases and health related problems, 10th revision (ICD-10-AM)

Public hospitals from Western Australia are not participating, as they are prevented by state legislation. We are working together towards a solution to allow patients from Western Australia to access this important health and safety initiative. New South Wales, Victoria and Queensland continue to have the greatest number of participating sites (79%), reflecting the higher concentration of providers in these states (Figure 1). The most common reason that eligible sites are not participating is that the implementation process has not yet been completed or participating sites no longer performs the breast implant surgery.

FIGURE 1: SITE PARTICIPATION BY STATE



Private facilities comprise the majority of participating sites (77%) (Table 2). Of the 277 participating sites, 266 are actively contributing data. The remaining 11 have received ethics and governance approval but have either not contributed data in the reporting period or are considered to not routinely perform breast device surgery.

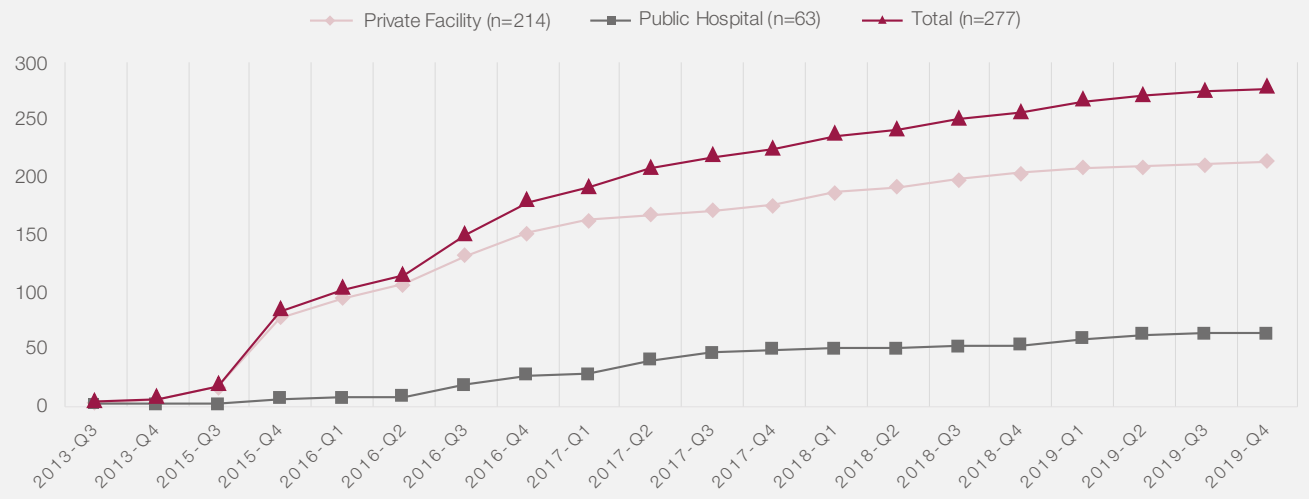
TABLE 2: SITE PARTICIPATION BY SITE TYPE

Site Type	Number of Participating Sites	%
Private Facility	214	77%
Public Hospital	63	23%
TOTAL	**277**	**100%**

Timeline of site participation

The number of participating sites continues to increase steadily since inception of the ABDR in April 2015 (Figure 2) after a pilot study was conducted involving seven sites prior to 2015, to a total of 277 sites participating at the end of 2019.

FIGURE 2: CUMULATIVE PARTICIPATING ABDR SITES BY SITE TYPE



Surgeon Participation

At 31 December 2019, a total of 626 surgeons were identified as undertaking breast device procedures (Table 3). At 31 December 2019, 563 individual surgeons were participating in the ABDR including 351 plastic surgeons, 159 general/breast surgeons and 53 cosmetic surgeons (Table 3). This totals 90% of eligible surgeons.

TABLE 3: SURGEON ENGAGEMENT BY STATE AND CRAFT GROUP

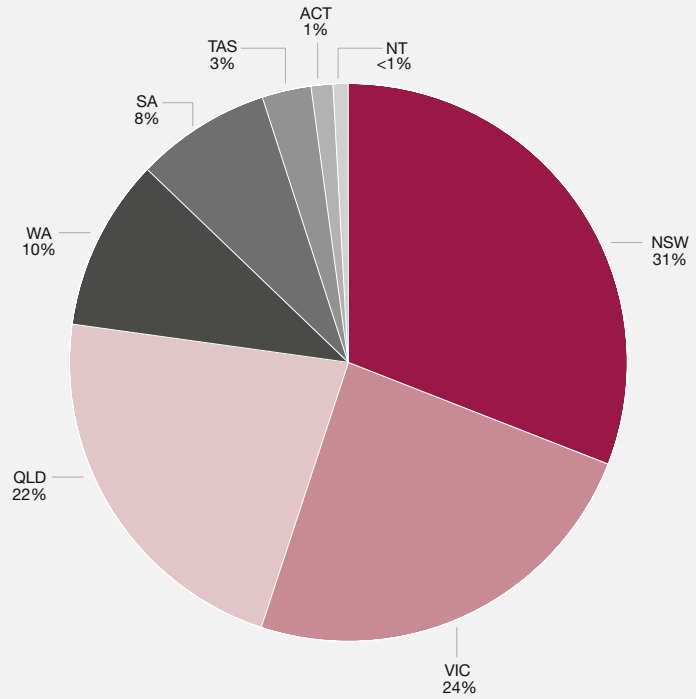
State	Participating Cosmetic Surgeons	Participating General Surgeons	Participating Plastic Surgeons	Eligible Cosmetic Surgeons	Eligible General Surgeons	Eligible Plastic Surgeons	Cosmetic Surgeons Engagement	General Surgeons Engagement	Plastic Surgeons Engagement
ACT	0	4	3	0	4	3	NA	100%	100%
NSW	27	56	91	30	71	88	90%	79%	100%
NT	0	3	2	0	3	2	NA	100%	100%
QLD	14	39	72	17	48	69	82%	81%	100%
SA	2	10	32	2	10	30	100%	100%	100%
TAS	0	3	13	0	4	12	NA	75%	100%
VIC	6	30	100	8	62	97	75%	48%	100%
WA	4	14	38	4	24	38	100%	58%	100%
SUB TOTAL	**53**	**159**	**351***	**61**	**226**	**339***	**87%**	**70%**	**100%**
TOTAL	**563**			**626**					

Notes: *The number of participating surgeons includes surgeons who contributed data to the ABDR but are now retired. These retired surgeons are not included in numbers for eligible surgeons resulting in a greater number of surgeons participating than eligible in some states. NA = Not applicable.

Participating surgeons were principally from New South Wales, Victoria, and Queensland (Figure 3). Plastic surgeons are the largest participating craft group, comprising 62% of participating surgeons (Table 3).

FIGURE 3: SURGEON PARTICIPATION BY STATE

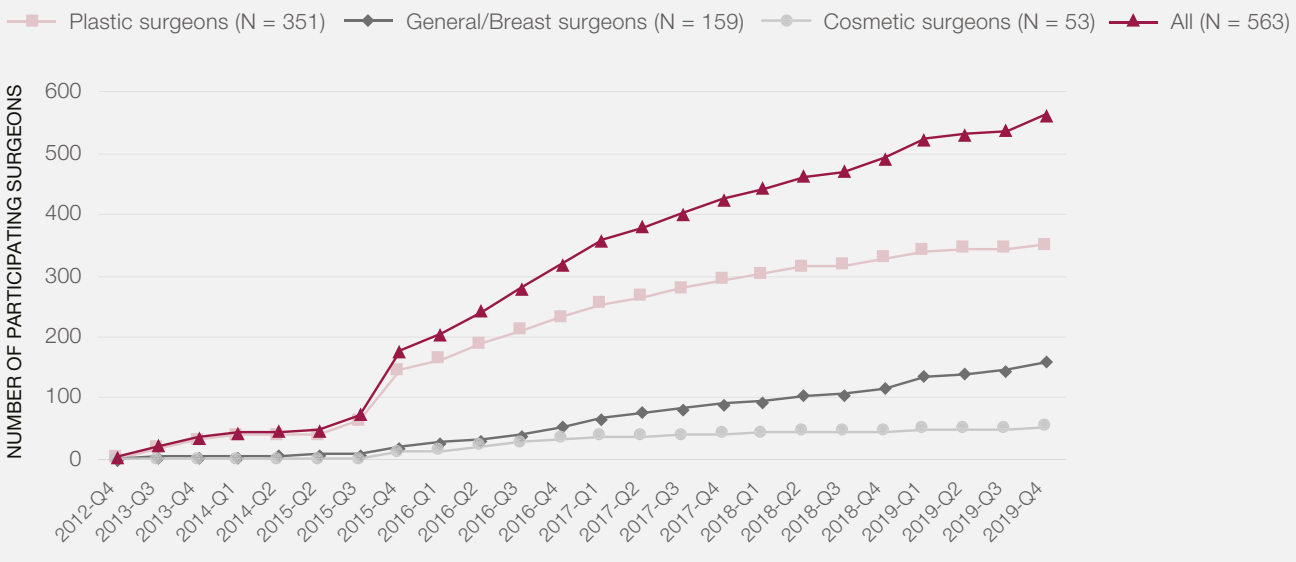
N = 563



Timeline of Surgeon Participation

Figure 4 shows the timeline for recruitment of surgeons into the pilot BDR and ABDR. Prior to April 2015, the pilot study included accredited sites with plastic surgeons and general/breast surgeons only. In 2015, the registry became an initiative of the Australian Government Department of Health and the scope was broadened to include all medical professionals performing breast device surgery. Members of the Australasian College of Cosmetic Surgery began participating in October 2015.

FIGURE 4: CUMULATIVE PARTICIPATING ABDR SURGEONS BY CRAFT GROUP



DATA QUALITY

Data Completeness

The ABDR is designed to collect information about surgical procedures involving breast implants, tissue expanders and matrix if used.

Table 4 shows a summary of the completeness of data elements captured within the ABDR database for procedures in 2017, 2018 and 2019. Noticeable improvements in data completeness for procedures in 2018 were seen and this high level of data completeness was maintained for procedures in 2019. Regular review of incoming forms, imputation of missing data where possible and prompt follow up of missing key data fields are strategies that have contributed to this. Email addresses are not provided on the hospital patient label, so attempts are being made to capture these at the time of PROMs follow-up. Explanted device characteristics are infrequently provided by surgeons, as these data are commonly not available to the explanting surgeon, however as the dataset matures, devices will be explanted with details recorded by the registry at the time of implantation.

TABLE 4: DATA COMPLETENESS

	2017	2018	2019
Patient Characteristics (Patient Level)	**13,018**	**13,424**	**12,856**
Name	100%	100%	100%
Surname	100%	100%	100%
Medicare number	88.2%	88.1%	88.7%
Date of birth	100%	100%	100%
Address	95.2%	96.5%	98.1%
Telephone	83.4%	86.0%	86.6%
Email	23.9%	21.5%	9.1%
Surgery Characteristics (Procedure Level)	**13,588**	**14,144**	**13,551**
Operation date	100%	100%	100%
Patient UR	100%	100%	100%
Hospital	100%	100%	100%
Surgeon	100%	100%	100%
Intraoperative Techniques	92.1%	89.3%	88.1%
Surgery Characteristics (Breast Level)	**25,501**	**26,223**	**25,070**
Side of breast	100%	100%	100%
Indication for surgery	96.2%	94.0%	90.7%
Surgery type (device insertion or revision)	100%	99.9%	100%
Previous radiotherapy (if indication = reconstruction)	90.0%	90.4%	90.7%
Incision site	93.5%	89.6%	88.6%
Plane	89.1%	85.4%	84.7%
Concurrent mastectomy	94.1%	92.3%	92.7%
Axillary surgery	93.9%	92.2%	92.6%
Concurrent mastopexy / reduction	94.4%	92.3%	92.7%
Concurrent flap cover	93.8%	92.1%	92.6%
Previous mastopexy / reduction	93.8%	92.1%	92.6%
Fat grafting	89.7%	90.3%	92.3%
Fat grafting volume (if fat grafting = yes)	84.8%	89.1%	92.0%
Intraoperative fill volume (if tissue expander)	67.1%	67.6%	67.5%

CONTINUED... TABLE 4: DATA COMPLETENESS

	2017	2018	2019
Revision Surgery Characteristics (Breast Level)	**5,546**	**7,736**	**8,989**
Revision surgery type	100%	100%	99.9%
Indication for revision surgery	92.8%	94.5%	95.7%
Capsulectomy	85.1%	86.1%	88.3%
Neo pocket formation	73.5%	74.8%	74.4%
Neo pocket formation details (if neo pocket formation = yes)	82.6%	81.3%	85.2%
Revision of an implant inserted overseas	84.1%	84.3%	84.8%
Breast cancer	91.7%	94.0%	95.8%
Device rupture	92.5%	93.1%	95.0%
Device deflation	91.2%	94.0%	95.7%
Capsular contracture	92.6%	94.0%	95.7%
Device malposition	91.8%	93.9%	95.8%
Skin scarring problems	91.6%	94.1%	95.8%
Deep wound infection	91.7%	94.1%	95.8%
Seroma / Haematoma	91.9%	94.1%	95.8%
Anaplastic Large Cell Lymphoma	91.7%	93.9%	95.7%
Device Characteristics (Breast Level, Inserted)	**24,795**	**24,688**	**22,140**
Breast implant/tissue expander Device ID	100%	99.9%	99.7%
Matrix used	99.2%	99.0%	99.4%
Matrix Device ID (if Matrix = yes)	99.9%	99.7%	99.3%
Device Characteristics (Breast Level, Explanted)	**5,399**	**7,562**	**8,861**
Explanted device details provided	77.1%	76.8%	84.2%

ABDR device capture rate

The ABDR received breast device (breast implant and tissue expander) supply data from the TGA in 2019 for the purpose of case ascertainment calculations. The data capture rate for implant procedures in 2019 was 73%, increased from 71% in 2018, and 63% in 2017. The TGA supply data do not account for breast devices that have been implanted versus those that have been supplied to sites on consignment, therefore the supply data provides an indication of device capture rate only.

Patient opt out rate

Patient opt out rate is 1.15% overall. This was 1.26% in 2019, 1.47% in 2018, and 1.02% in 2017.

Presentation of the report

Due to clinical differences between patients presenting for breast reconstructive surgery and cosmetic breast augmentation, the registry outputs have been presented separately for these two groups within the following two sections of this report:

- **Registry outputs: Reconstructive indications** will include procedures for post-cancer reconstruction, risk-reducing reconstruction and developmental deformity.
- **Registry outputs: Aesthetic indications** will include cosmetic augmentation only.

Records for which the indication was not stated were excluded from further analysis in this report (Table 4). Within the two registry output sections, results have been presented for two types of surgical/procedure intervention:

- **Insertion surgery** which includes insertion of a new device, either a breast implant or tissue expander in a patient who has or has not had previous breast device surgery. Also included are procedures involving the insertion of an implant following tissue expander removal and insertion of a tissue expander following implant removal.
- **Revision surgery** which includes unplanned replacement, reposition or explant of an in-situ device, either a tissue expander or breast implant. The initial device insertion may or may not have also been captured by the registry.

Patient, procedure, device numbers (2012 – 2019)

As at December 2019, **49,563 patients** were participating in the ABDR, an addition of 11,960 in 2019. A patient is considered to be participating in the ABDR from the date of their earliest ABDR recorded surgery. Due to the lag of data transfer from the surgeon to the ABDR, additional patients may have had surgery in this timeframe but are yet to be included in the database. Data from patients who chose to opt out (n= 536) are not included in the reported figures.

Table 5 presents the number of patients, number of procedures at patient level and number of procedures at breast level (excluding matrix) by indication (reason) for surgery. Indication was assigned based on a four-tier hierarchy beginning with post-cancer reconstruction, followed by risk-reducing reconstruction, developmental deformity and then cosmetic augmentation. Patients were assigned to the indication for their first procedure as recorded on the Data Collection Form submitted by surgeons and subsequently recorded in the ABDR database. When the first operation was bilateral but different procedures were undertaken on each breast, the four-tier hierarchy was applied. For example, a patient with a bilateral first procedure with post-cancer reconstruction on one side, and cosmetic augmentation on the other side would be allocated to the post-cancer reconstruction indication based on the hierarchy. The hierarchy was also used to assign indication to procedures (at patient level) when bilateral differences were seen. This hierarchy did not apply at the breast/device level.

Of the 49,563 patients in the ABDR, 73% entered the registry for cosmetic augmentation, 16% for post-cancer reconstruction, 3% for risk-reducing reconstruction, and 2% for correction of developmental deformity. Five percent entered the registry with an indication for surgery not stated on the Data Collection Form.

TABLE 5. REGISTERED PATIENTS, PROCEDURES AT PATIENT LEVEL, AND PROCEDURES AT BREAST LEVEL BY INDICATION FOR SURGERY (2012 – 2019)

	Patients*		Procedures at Patient Level **		Procedures at Breast Level ***	
	N	(%)	N	(%)	N	(%)
Reconstructive						
Post-cancer reconstruction	7,765	(15.7%)	11,158	(19.9%)	14,101	(13.6%)
Risk-reducing Reconstruction	1,703	(3.4%)	2,411	(4.3%)	6,639	(6.4%)
Developmental deformity	1,166	(2.4%)	1,343	(2.4%)	2,203	(2.1%)
Aesthetic						
Cosmetic augmentation	36,233	(73.1%)	37,852	(67.6%)	75,155	(72.3%)
Not Stated	2,696	(5.4%)	3,226	(5.8%)	5,914	(5.7%)
TOTAL	**49,563**	**(100%)**	**55,990**	**(100%)**	**104,012**	**(100%)**

Notes: Indication was assigned based on a four-tier hierarchy beginning with post-cancer reconstruction, followed by risk-reducing reconstruction, developmental deformity and then cosmetic augmentation. * Patients were assigned to the indication for their first procedure recorded in the ABDR. ** The number of procedures at patient level have been reported. *** The number of procedures at breast level have been reported.

Figures 5 and 6 show a steady rise in the number of both reconstructive and aesthetic patients and procedures captured by the ABDR over the last three years. A total of 10,634 patients had reconstructive surgery, comprising 14,912 total procedures, and utilising 22,943 breast devices in 2019. A total of 36,233 patients had aesthetic surgery comprising 37,852 total procedures and utilising 75,155 breast devices in 2019.

FIGURE 5. REGISTERED PATIENTS, PROCEDURES AND DEVICES - RECONSTRUCTIVE (2012 – 2019)

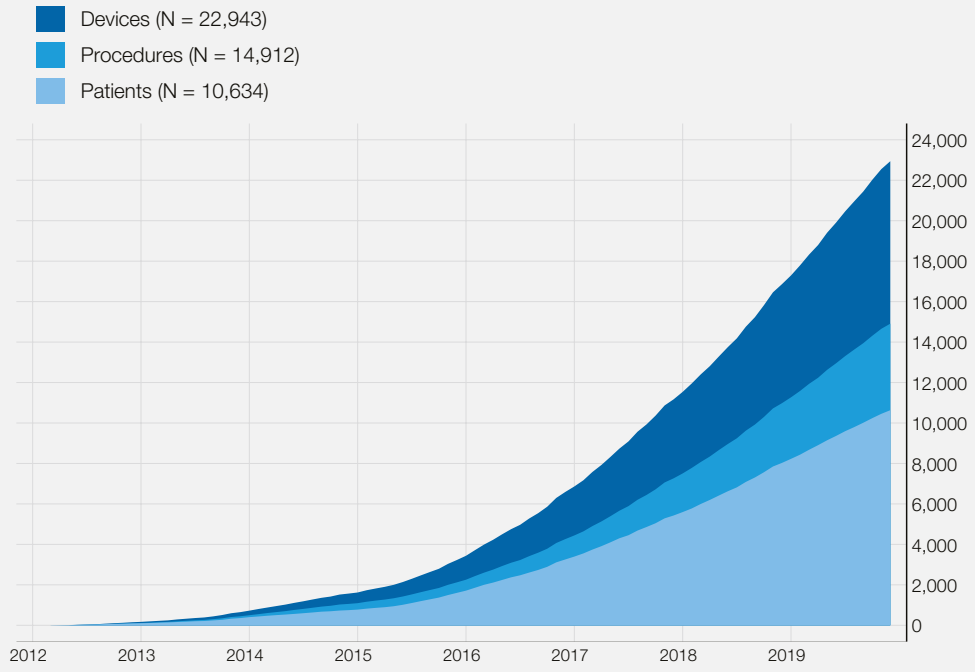
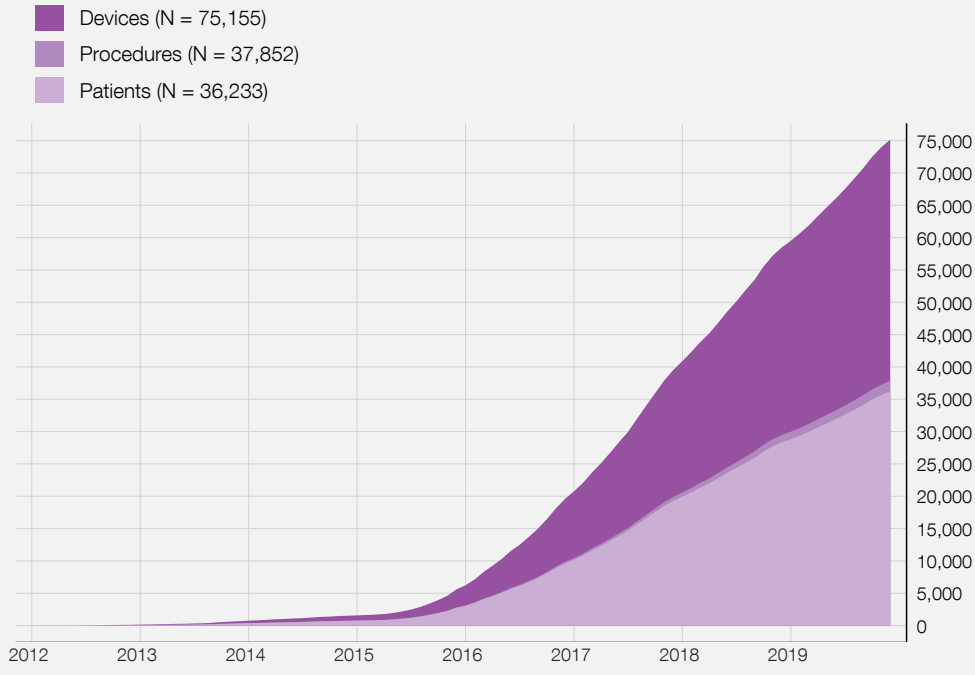
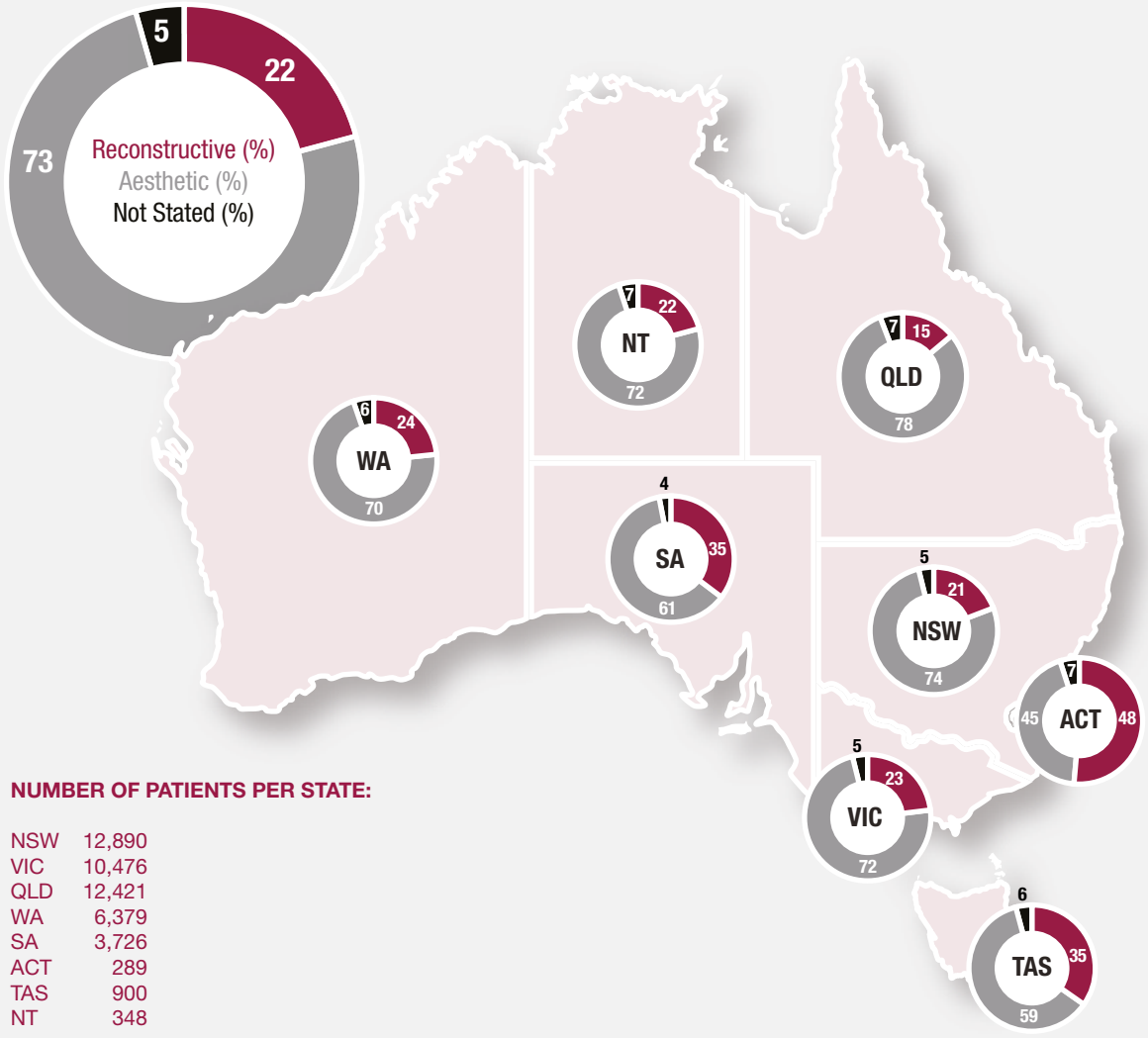


FIGURE 6. REGISTERED PATIENTS, PROCEDURES AND DEVICES - AESTHETIC (2012 – 2019)



Patient residency and indication at the time of entry to the registry are presented in Figure 7. Overall, there are 73% of patients with aesthetic indication, and 22% with reconstructive indication. Queensland has a higher number of residents who entered the registry for aesthetic breast surgery at 78%. Also, reconstructive surgery was higher for ACT residents at 48%, and South Australian and Tasmanian residents at 35%. Almost all overseas residents captured by the registry had aesthetic breast surgery in Australia.

FIGURE 7. PATIENT RESIDENCY BY INDICATION (2012 – 2019)



NUMBER OF PATIENTS PER STATE:

NSW	12,890
VIC	10,476
QLD	12,421
WA	6,379
SA	3,726
ACT	289
TAS	900
NT	348

Notes: N = 49,563 patients. This includes 252 overseas residents and 1,882 with unknown residency. Patients with unknown residency are those who have elected email as the form of correspondence.

REGISTRY OUTPUTS: RECONSTRUCTIVE INDICATIONS

Reconstructive procedure numbers

The ABDR has captured a total of 14,912 surgical procedures involving breast devices for reconstructive surgery, including post-cancer reconstruction, risk-reducing reconstruction and developmental deformity. Figure 8 shows a steady rise in the annual number of reconstructive procedures captured in each year since registry commencement. In 2019, 3,931 reconstructive procedures were captured. Of these 37% were unilateral post-cancer reconstruction, 19% were bilateral post-cancer reconstruction, 19% were bilateral with post-cancer reconstruction on one side and risk-reducing reconstruction on the other side, and 12% were bilateral risk-reducing reconstruction on both sides (Table 6).

Procedure numbers

FIGURE 8. REGISTERED PROCEDURES - RECONSTRUCTIVE (2012 – 2019)

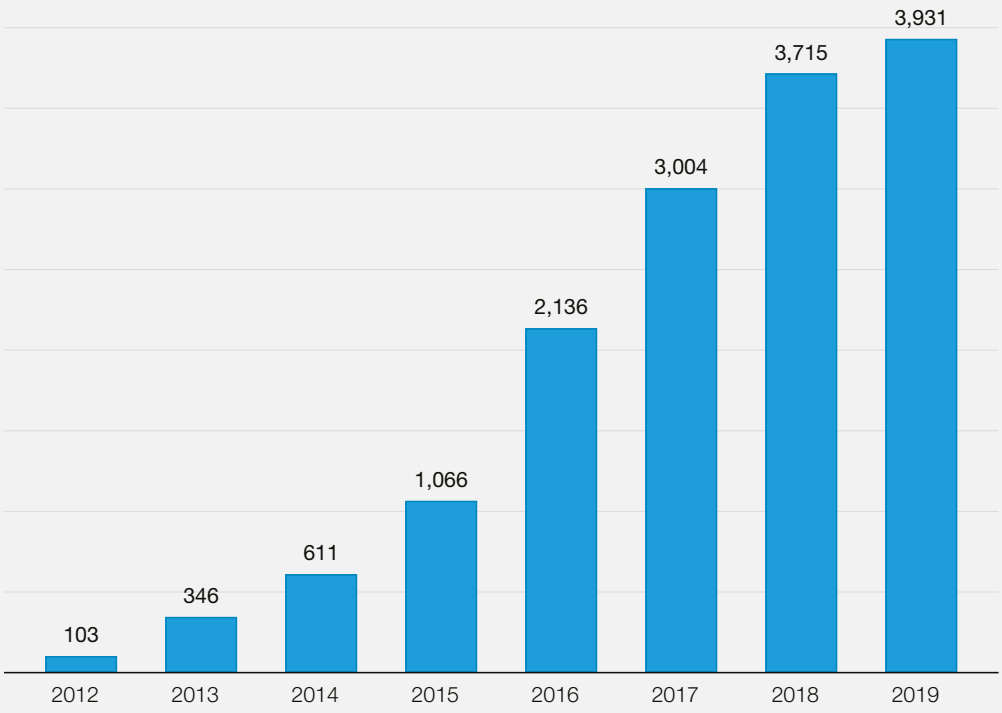


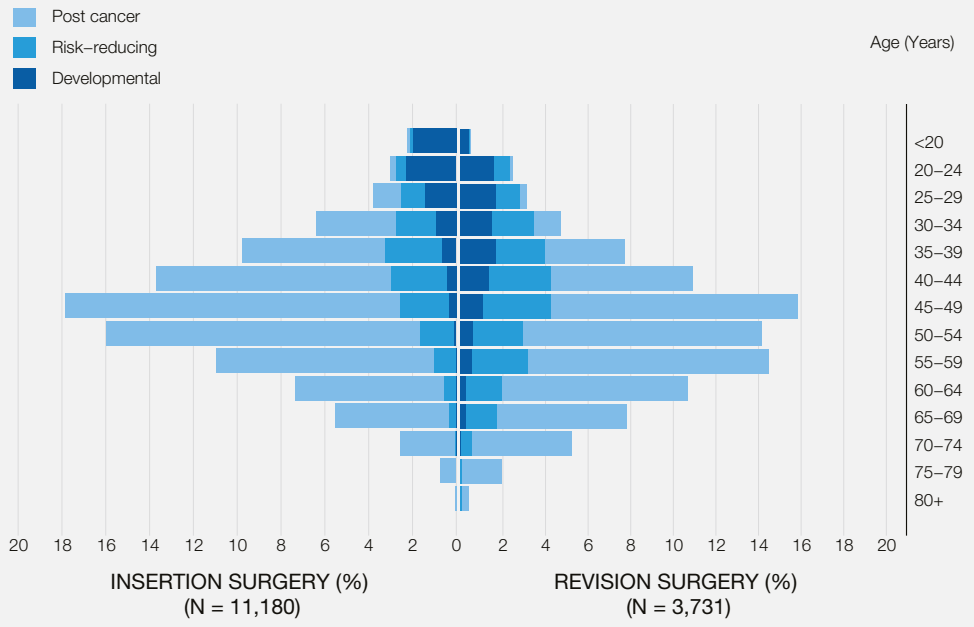
TABLE 6. PROCEDURE TYPE – RECONSTRUCTIVE

	2012-2019		2018		2019	
	N	(%)	N	(%)	N	(%)
Unilateral						
Post-cancer	5,434	(36.4%)	1,383	(37.2%)	1,435	(36.5%)
Risk-reducing	570	(3.8%)	155	(4.2%)	145	(3.7%)
Developmental	361	(2.4%)	81	(2.2%)	84	(2.1%)
Bilateral						
Post-cancer | Post-cancer	2,943	(19.7%)	720	(19.4%)	758	(19.3%)
Post-cancer | Risk-reducing	2,421	(16.2%)	628	(16.9%)	726	(18.5%)
Risk-reducing | Risk-reducing	1,807	(12.1%)	461	(12.4%)	466	(11.9%)
Developmental | Developmental	857	(5.7%)	168	(4.5%)	198	(5.0%)
Post-cancer | Augmentation	329	(2.2%)	77	(2.1%)	83	(2.1%)
Developmental | Augmentation	123	(0.8%)	23	(0.6%)	20	(0.5%)
Other	67	(0.4%)	19	(0.5%)	16	(0.4%)
TOTAL RECONSTRUCTIVE PROCEDURES	**14,912**	**(100%)**	**3,715**	**(100%)**	**3,931**	**(100%)**

Patient age at reconstructive procedures

The age distribution at the time of reconstructive procedure is shown in Table 7 and Figure 9. Age differences can be seen by the indication for procedure and whether the procedure involved device insertion or revision. In 2019, median age for post-cancer reconstruction was 50 years for insertion surgery and 56 years for revision surgery. Patient age was lower for risk-reducing reconstruction and lowest for developmental deformity. Median age for risk-reducing reconstruction was 44 years for insertion surgery and 48 years for revision surgery. The median age for procedures to correct for developmental deformity was 25 for insertion surgery and 38 years for revision surgery.

FIGURE 9. AGE DISTRIBUTION FOR RECONSTRUCTIVE PROCEDURES (2012 – 2019)



Notes: Insertion and revision procedures have been analysed independently. Both unilateral and bilateral procedures have been included. A procedure indication hierarchy has been applied for bilateral procedures with different indication and procdure type detail per breast. Procedures with unknown procedure type (insertion or revision) have not been included.

TABLE 7. SUMMARY STATISTICS FOR AGE AT TIME OF RECONSTRUCTIVE PROCEDURES

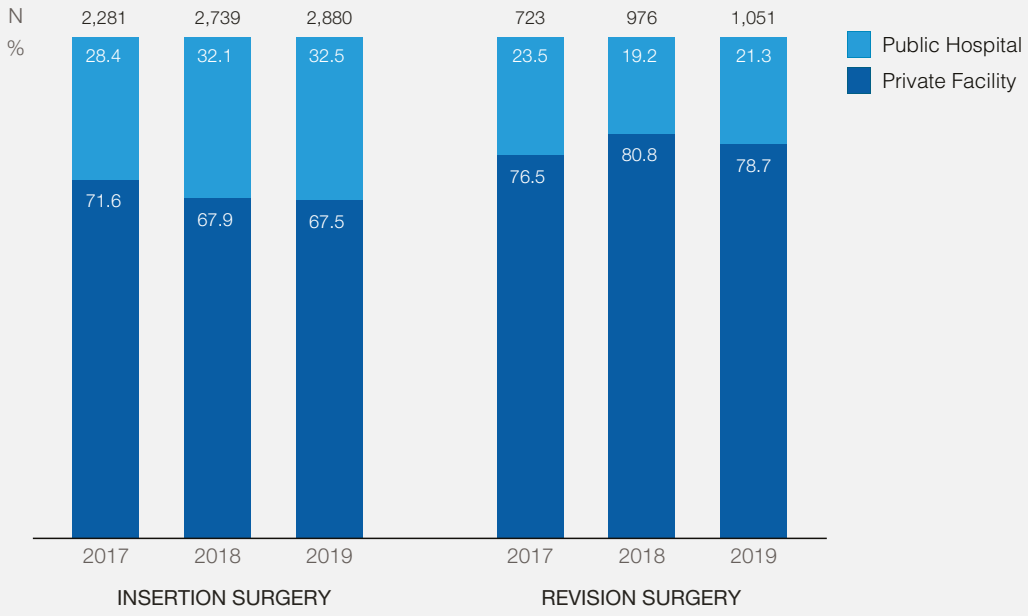
	Insertion Surgery			Revision Surgery		
	2012-2019	2018	2019	2012-2019	2018	2019
Post-cancer						
N	8,629	2,160	2,271	2,528	656	740
Mean Age (Standard deviation)	50.8 (10.6)	50.6 (11.0)	50.3 (10.9)	55.0 (10.8)	55.5 (11.1)	56.0 (10.8)
Median Age (Interquartile range)	50.3 (43.7, 57.7)	49.9 (43.1, 57.8)	49.6 (43.2, 57.2)	54.5 (47.2, 62.6)	55.3 (47.2, 63.4)	55.6 (48.1, 63.2)
Risk-reducing						
N	1,624	420	412	787	207	205
Mean Age (Standard deviation)	42.7 (11.0)	42.0 (11.0)	44.5 (10.9)	47.8 (12.7)	48.2 (12.8)	47.9 (11.8)
Median Age (Interquartile range)	42.2 (35.1, 49.8)	40.7 (34.7, 49.1)	43.7 (36.5, 51.7)	47.6 (38.6, 57.6)	48.4 (38.6, 57.9)	47.7 (39.2, 57.1)
Developmental						
N	927	159	197	416	113	106
Mean Age (Standard deviation)	27.4 (9.6)	25.1 (8.0)	28.1 (10.8)	37.2 (12.4)	38.3 (12.9)	38.3 (12.7)
Median Age (Interquartile range)	24.7 (20.2, 32.3)	22.3 (19.2, 27.9)	25.1 (20.0, 34.0)	35.9 (27.1, 45.4)	37.1 (28.2, 47.1)	37.6 (27.6, 48.2)

Notes: Insertion and revision procedures have been analysed independently. Both unilateral and bilateral procedures have been included.
A procedure indication hierarchy has been applied for bilateral procedures with different indication and procedure type details per breast.
Procedures with unknown procedure type (insertion or revision) have not been included.
The interquartile range reports observed patient age at the 25th and 75th percentiles.

Site type for reconstructive procedures

Over the last three years (2017 – 2019) the capture of procedures in public hospitals and private facilities has increased as registry participation for sites and surgeons continues to grow (Figure 10). Reconstructive procedures captured by the registry in 2017 were predominately reported in private facilities, 72% for insertion surgery and 77% for revision surgery. In 2019, 68% of reconstructive procedures involving breast device insertion were reported in private facilities and 33% in public hospitals. However, breast device revision surgery was more often reported in private facilities for reconstruction procedures. In 2019, 79% of reconstructive procedures involving breast device revision were reported in private facilities and 21% in public hospitals.

FIGURE 10. SITE TYPE FOR RECONSTRUCTIVE PROCEDURES (2017 – 2019)



Notes: Insertion and revision procedures have been analysed independently. Both unilateral and bilateral procedures have been included. A procedure indication hierarchy has been applied for bilateral procedures with different indication and procedure type details per breast. Procedures with unknown procedure type (insertion or revision) have not been included.

Reconstructive procedure techniques and elements

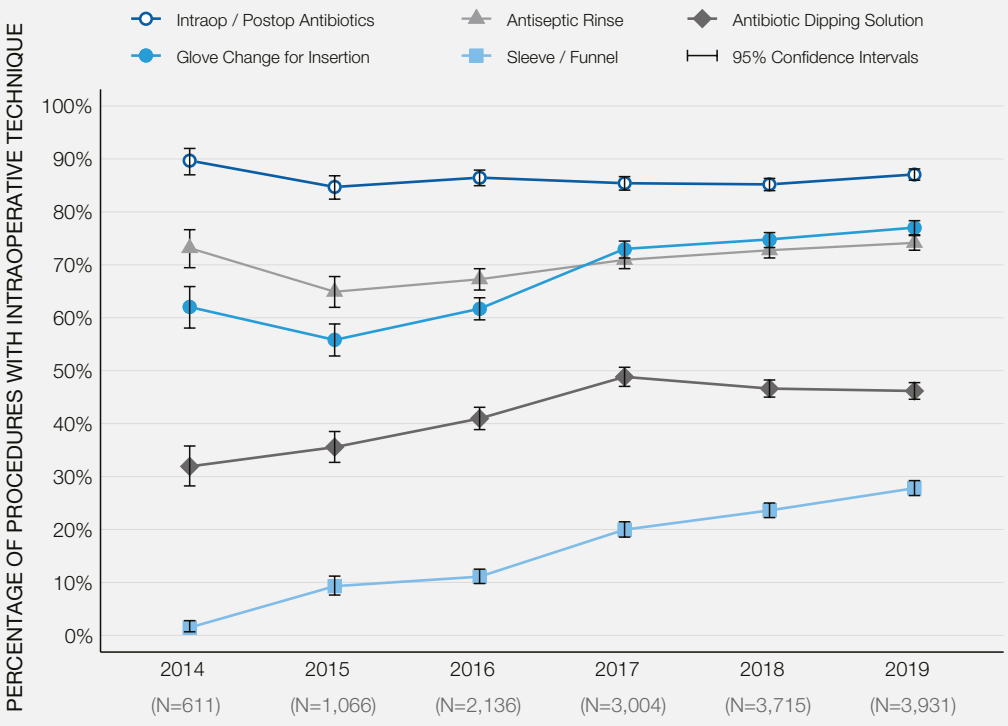
The ABDR collects data on intraoperative techniques used by contributing surgeons in order to identify current practice in surgical techniques and their association with patient outcomes. More than one intraoperative technique can be used and recorded per procedure. Table 8 and Figure 11 show the intraoperative techniques used during breast reconstruction surgery. The use of intraoperative antibiotics and postoperative antibiotics are also reported separately for 2018 and 2019. In 2019, the use of intraoperative and/or postoperative antibiotics (87%), antiseptic rinse (74%) and glove change for insertion (77%) were commonly reported during breast reconstruction. Less frequently reported intraoperative techniques included antibiotic dipping solution (46%) and sleeve/funnel (28%) in 2019.

TABLE 8. INTRAOPERATIVE TECHNIQUES – RECONSTRUCTIVE PROCEDURES

	2012-2019		2018		2019	
	N	(%)	N	(%)	N	(%)
Intraop / Postop antibiotics	12,856	(86.2%)	3,165	(85.2%)	3,423	(87.1%)
Intraoperative antibiotics	-	-	3,107	(83.6%)	3,388	(86.2%)
Postoperative antibiotics	-	-	2,769	(74.5%)	2,896	(73.7%)
Antiseptic rinse	10,658	(71.5%)	2,703	(72.8%)	2,915	(74.2%)
Glove change for insertion	10,581	(71.0%)	2,775	(74.7%)	3,028	(77.0%)
Antibiotic dipping solution	6,562	(44.0%)	1,732	(46.6%)	1,815	(46.2%)
Sleeve / Funnel	2,920	(19.6%)	877	(23.6%)	1,093	(27.8%)
Not stated	1,726	(11.6%)	486	(13.1%)	459	(11.7%)
TOTAL NO. OF PROCEDURES	**14,912**		**3,715**		**3,931**	

Notes: More than one intraoperative technique can be used and recorded per procedure. Information regarding intraoperative and postoperative antibiotics only collected separately from 2015.

FIGURE 11. INTRAOPERATIVE TECHNIQUES – RECONSTRUCTIVE PROCEDURES (2014 – 2019)



The registry reports details about other surgical elements and techniques used during each breast procedure. From 2012-2019 the most common surgical plane used during breast reconstruction surgery was sub-pectoral / dual plane at 64% when involving device insertion and 53% when involving device revision surgery (Table 9). A previous mastectomy scar or the inframammary fold were the most commonly used incision sites reported in reconstructive breast procedures during 2012 to 2019 (Table 9).

TABLE 9. SURGICAL PLANE AND INCISION SITE – RECONSTRUCTIVE PROCEDURES

	Insertion Surgery						Revision Surgery					
	2012-2019		2018		2019		2012-2019		2018		2019	
	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Plane												
Sub-pectoral/ Dual plane	11,210	(64.4%)	2,846	(67.1%)	2,686	(59.9%)	2,913	(52.6%)	716	(49.4%)	813	(51.0%)
Sub-flap	1,583	(9.1%)	357	(8.4%)	408	(9.1%)	516	(9.3%)	130	(9.0%)	130	(8.2%)
Sub-glandular/ Sub-fascial*	1,446	(8.3%)	264	(6.2%)	457	(10.2%)	707	(12.8%)	196	(13.5%)	219	(13.7%)
Other	442	(2.5%)	102	(2.4%)	242	(5.4%)	34	(0.6%)	3	(0.2%)	20	(1.3%)
Not stated	2,725	(15.7%)	675	(15.9%)	691	(15.4%)	1,366	(24.7%)	404	(27.9%)	413	(25.9%)
Incision Site												
Previous mastectomy scar	7,215	(41.5%)	1,574	(37.1%)	1,435	(32.0%)	2,192	(39.6%)	550	(38.0%)	590	(37.0%)
Inframammary	5,381	(30.9%)	1,293	(30.5%)	1,636	(36.5%)	2,334	(42.2%)	631	(43.5%)	691	(43.3%)
Areolar	1,801	(10.3%)	519	(12.2%)	568	(12.7%)	191	(3.5%)	37	(2.6%)	51	(3.2%)
Mastopexy/ reduction wound	1,495	(8.6%)	435	(10.2%)	398	(8.9%)	382	(6.9%)	101	(7.0%)	108	(6.8%)
Axillary	157	(0.9%)	58	(1.4%)	42	(0.9%)	24	(0.4%)	8	(0.6%)	3	(0.2%)
Other	807	(4.6%)	207	(4.9%)	258	(5.8%)	50	(0.9%)	13	(0.9%)	19	(1.2%)
Not stated	1,000	(5.7%)	254	(6.0%)	277	(6.2%)	491	(8.9%)	150	(10.4%)	168	(10.5%)
TOTAL	**17,406**		**4,244**		**4,484**		**5,536**		**1,449**		**1,595**	

Notes: Details are at the breast level. Insertion and revision procedures have been analysed independently. More than one incision site can be recorded. Procedures with unknown procedure type (insertion or revision) have not been included.

*This includes sub-cutaneous placement after mastectomy

Table 10 details other surgical elements reported during breast reconstruction. Concurrent mastectomy occurred in 36% of breast reconstruction procedures involving device insertion. Axillary surgery (18%) and concurrent flap cover (10%) were other surgical elements reported during breast reconstruction procedures involving device insertion. Fat grafting occurred in 14% of reconstructive revision procedures. Drains were used in 54% of reconstructive insertion procedures and in 48% of reconstructive revision procedures. The nipple was absent during 48% of reconstructive insertion procedures and during 34% of reconstructive revision procedures. Nipple sparing was another technique used during breast reconstruction procedures, 22% when involving device insertion and 16% when involving device revision surgery.

TABLE 10. OTHER SURGICAL ELEMENTS – RECONSTRUCTIVE PROCEDURES

	Insertion Surgery						Revision Surgery					
	2012-2019		2018		2019		2012-2019		2018		2019	
	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Axillary Surgery (incl. Sentinel Node Biopsy)												
Yes	3,096	(17.8%)	904	(21.3%)	1,059	(23.6%)	108	(2.0%)	36	(2.5%)	42	(2.6%)
No	11,610	(66.7%)	3,167	(74.6%)	3,305	(73.7%)	4,382	(79.2%)	1,250	(86.3%)	1,383	(86.7%)
Not stated	2,700	(15.5%)	173	(4.1%)	120	(2.7%)	1,046	(18.9%)	163	(11.2%)	170	(10.7%)
Concurrent Mastectomy												
Yes	6,245	(35.9%)	1,773	(41.8%)	2,030	(45.3%)	179	(3.2%)	58	(4.0%)	68	(4.3%)
No	8,590	(49.4%)	2,308	(54.4%)	2,339	(52.2%)	4,326	(78.1%)	1,232	(85.0%)	1,358	(85.1%)
Not stated	2,571	(14.8%)	163	(3.8%)	115	(2.6%)	1,031	(18.6%)	159	(11.0%)	169	(10.6%)
Concurrent Mastopexy/Reduction												
Yes	1,196	(6.9%)	337	(7.9%)	276	(6.2%)	359	(6.5%)	95	(6.6%)	100	(6.3%)
No	15,044	(86.4%)	3,711	(87.4%)	4,084	(91.1%)	4,536	(81.9%)	1,194	(82.4%)	1,325	(83.1%)
Not stated	1,166	(6.7%)	196	(4.6%)	124	(2.8%)	641	(11.6%)	160	(11.0%)	170	(10.7%)
Concurrent Flap Cover												
Yes	1,760	(10.1%)	421	(9.9%)	432	(9.6%)	208	(3.8%)	49	(3.4%)	51	(3.2%)
No	14,468	(83.1%)	3,630	(85.5%)	3,929	(87.6%)	4,672	(84.4%)	1,237	(85.4%)	1,374	(86.1%)
Not stated	1,178	(6.8%)	193	(4.5%)	123	(2.7%)	656	(11.8%)	163	(11.2%)	170	(10.7%)
Previous Mastopexy/Reduction												
Yes	496	(2.8%)	123	(2.9%)	130	(2.9%)	331	(6.0%)	102	(7.0%)	86	(5.4%)
No	14,119	(81.1%)	3,923	(92.4%)	4,220	(94.1%)	4,158	(75.1%)	1,180	(81.4%)	1,339	(83.9%)
Not stated	2,791	(16.0%)	198	(4.7%)	134	(3.0%)	1,047	(18.9%)	167	(11.5%)	170	(10.7%)
Fat Grafting												
Yes	823	(4.7%)	260	(6.1%)	291	(6.5%)	760	(13.7%)	188	(13.0%)	254	(15.9%)
No	14,814	(85.1%)	3,727	(87.8%)	4,051	(90.3%)	3,992	(72.1%)	1,098	(75.8%)	1,165	(73.0%)
Not stated	1,769	(10.2%)	257	(6.1%)	142	(3.2%)	784	(14.2%)	163	(11.2%)	176	(11.0%)
Drains Used												
Yes	9,441	(54.2%)	2,258	(53.2%)	2,383	(53.1%)	2,645	(47.8%)	655	(45.2%)	768	(48.2%)
No	7,965	(45.8%)	1,986	(46.8%)	2,101	(46.9%)	2,891	(52.2%)	794	(54.8%)	827	(51.8%)
Not stated	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Nipple Guard/Shield												
Yes	2,591	(14.9%)	618	(14.6%)	803	(17.9%)	1,157	(20.9%)	322	(22.2%)	332	(20.8%)
No	14,815	(85.1%)	3,626	(85.4%)	3,681	(82.1%)	4,379	(79.1%)	1,127	(77.8%)	1,263	(79.2%)
Not stated	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)	0	(0.0%)
Nipple Absent												
Yes	8,333	(47.9%)	2,172	(51.2%)	2,085	(46.5%)	1,874	(33.9%)	544	(37.5%)	589	(36.9%)
No	8,448	(48.5%)	2,072	(48.8%)	2,399	(53.5%)	3,494	(63.1%)	905	(62.5%)	1,006	(63.1%)
Not stated	625	(3.6%)	0	(0.0%)	0	(0.0%)	168	(3.0%)	0	(0.0%)	0	(0.0%)
Nipple Sparing												
Yes	3,814	(21.9%)	1,038	(24.5%)	1,294	(28.9%)	890	(16.1%)	238	(16.4%)	287	(18.0%)
No	12,967	(74.5%)	3,206	(75.5%)	3,190	(71.1%)	4,478	(80.9%)	1,211	(83.6%)	1,308	(82.0%)
Not stated	625	(3.6%)	0	(0.0%)	0	(0.0%)	168	(3.0%)	0	(0.0%)	0	(0.0%)
TOTAL	**17,406**		**4,244**		**4,484**		**5,536**		**1,449**		**1,595**	

Notes: Details are at the breast level. Insertion and revision procedures have been analysed independently. Procedures with unknown procedure type (insertion or revision) have not been included.

Device characteristics for breast reconstruction

The registry captures information about breast devices used during procedures in Australia. Information is collected about breast implants, tissue expanders and matrices. Table 11 and 12 provide device shell, fill and shape characteristics for breast implants and tissue expanders used for breast reconstruction during an insertion procedure or a revision procedure. One device previously classified as textured was reclassified to smooth in accordance with their listing on the Australian Register of Therapeutic Goods in 2018. In 2019, an increase in use of smooth implants was seen, and 48% of the breast implants used in registry participants for breast reconstruction were silicone implants with smooth shell and round shape, while 41% were silicone implants with textured shell and anatomical shape, and 8% were silicone implants with textured shell and round shape (Table 11). This reflects the TGA action to suspend some textured implants. Of the tissue expanders used in 2019 for breast reconstruction, 90% were saline expanders with textured shell and anatomical shape, and 9% were carbon dioxide expanders with textured shell and anatomical shape (Table 12).

TABLE 11. DEVICE CHARACTERISTICS – RECONSTRUCTIVE BREAST IMPLANTS

	2012-2019		2018		2019	
	N	(%)	N	(%)	N	(%)
Silicone Implants						
Textured | Anatomical	8,735	(54.1%)	2,156	(54.9%)	1,721	(40.5%)
Textured | Round	2,120	(13.1%)	432	(11.0%)	332	(7.8%)
Smooth | Round	4,510	(27.9%)	1,189	(30.3%)	2,024	(47.6%)
Smooth | Anatomical	27	(0.2%)	0	(0.0%)	27	(0.6%)
Polyurethane | Anatomical	290	(1.8%)	44	(1.1%)	15	(0.4%)
Polyurethane | Round	90	(0.6%)	5	(0.1%)	5	(0.1%)
Saline Implants						
Textured | Anatomical	12	(0.1%)	5	(0.1%)	0	(0.0%)
Textured | Round	5	(<0.05%)	3	(0.1%)	0	(0.0%)
Smooth | Round	91	(0.6%)	18	(0.5%)	53	(1.3%)
Silicone/Saline Implants						
Textured | Anatomical	239	(1.5%)	71	(1.8%)	60	(1.4%)
Textured | Round	9	(0.1%)	2	(0.1%)	5	(0.1%)
Not Stated	25	(0.2%)	2	(0.1%)	12	(0.3%)
TOTAL	**16,153**	**(100%)**	**3,927**	**(100%)**	**4,254**	**(100%)**

Notes: Device characteristics are reported for all new devices during an insertion procedure or a replacement revision procedure.

TABLE 12. DEVICE CHARACTERISTICS – RECONSTRUCTIVE TISSUE EXPANDERS

	2012-2019		2018		2019	
	N	(%)	N	(%)	N	(%)
Saline Expanders						
Textured | Anatomical	5,402	(88.9%)	1,326	(85.6%)	1,390	(90.0%)
Textured | Round	7	(0.1%)	0	(0.0%)	0	(0.0%)
Smooth | Anatomical	2	(<0.05%)	0	(0.0%)	0	(0.0%)
Smooth | Round	10	(0.2%)	2	(0.1%)	5	(0.3%)
Carbon Dioxide Expanders						
Textured | Anatomical	639	(10.5%)	217	(14.0%)	139	(9.0%)
Not Stated	15	(0.3%)	4	(0.3%)	11	(0.7%)
TOTAL	**6,075**	**(100%)**	**1549**	**(100%)**	**1545**	**(100%)**

Notes: Device characteristics are reported for all new devices during an insertion procedure or a replacement revision procedure.

Matrices are most commonly used during reconstructive surgery. The registry captures the use of matrices when used concurrently with a tissue expander or breast implant. Table 13 reports matrix usage during reconstructive surgery involving breast implants and tissue expanders. In 2019 a matrix was used during 60% of direct-to-implant insertions for post-cancer reconstruction and 63% for risk-reducing reconstruction. For patients undergoing surgery for developmental deformity, matrices were only used at the time of revision surgery (1% in 2019). Additionally, in 2019 matrix usage during reconstructive procedures involving the insertion of tissue expanders was 27% for post-cancer and 28% for risk-reducing reconstruction.

TABLE 13. MATRIX USE IN PROCEDURES AT BREAST LEVEL IN BREAST RECONSTRUCTION SURGERY

	2012-2019		2018		2019	
	Total Number of Procedures (N)	Number of Procedures with Matrix (% Matrix Use)	Total Number of Procedures (N)	Number of Procedures With Matrix (% Matrix Use)	Total Number of Procedures (N)	Number of Procedures with Matrix (% Matrix Use)
BREAST IMPLANTS						
Direct-to-implant Insertion Surgery						
Post-cancer reconstruction	2,405	1,188 (49.4%)	633	329 (52.0%)	726	434 (59.8%)
Risk-reducing reconstruction	1,662	871 (52.4%)	448	258 (57.6%)	459	290 (63.2%)
Developmental deformity	1,345	1 (0.1%)	235	1 (0.4%)	303	0 (0.0%)
Two-stage Insertion Surgery*						
Post-cancer reconstruction	4,490	101 (2.2%)	1,044	19 (1.8%)	1,087	25 (2.3%)
Risk-reducing reconstruction	1,557	37 (2.4%)	388	5 (1.3%)	417	10 (2.4%)
Developmental deformity	117	0 (0.0%)	17	0 (0.0%)	14	0 (0.0%)
Revision Surgery						
Post-cancer reconstruction	2,988	226 (7.6%)	775	59 (7.6%)	899	65 (7.2%)
Risk-reducing reconstruction	1,552	123 (7.9%)	397	33 (8.3%)	440	31 (7.0%)
Developmental deformity	646	14 (2.2%)	177	5 (2.8%)	161	1 (0.6%)
TISSUE EXPANDERS						
Insertion Surgery						
Post-cancer reconstruction	3,929	971 (24.7%)	1,005	249 (24.8%)	982	262 (26.7%)
Risk-reducing reconstruction	1,811	460 (25.4%)	465	113 (24.3%)	475	134 (28.2%)
Developmental deformity	90	0 (0.0%)	9	0 (0.0%)	21	0 (0.0%)
Revision Surgery						
Post-cancer reconstruction	288	18 (6.3%)	79	4 (5.1%)	75	6 (8.0%)
Risk-reducing reconstruction	57	3 (5.3%)	18	1 (5.6%)	18	0 (0.0%)
Developmental deformity	5	0 (0.0%)	3	0 (0.0%)	2	0 (0.0%)
Not Stated	1		0		0	
TOTAL NUMBER OF PROCEDURES (breast level)	**22,943**		**5,693**		**6,079**	

Notes: Matrix includes acellular dermal and synthetic matrices.

**"Two-stage" refers to use of matrix at the time of definitive implant surgery, i.e. when the TE is removed and implant is inserted.

Complications and revision incidence – Breast implants for reconstruction

The registry collects details of issues and complications that are found at the time of a revision procedure involving breast devices. Revision surgery includes the unplanned replacement, reposition or explant of an in-situ breast device. Table 14 reports issues identified during reconstructive breast implant revision procedures. Multiple issues can be recorded at the time of revision surgery, and issues are either identified as a reason for the revision or found incidentally during the revision procedure. Table 14 reports the issues identified at all reconstructive breast implant revisions, including revisions for breasts where the insertion of the initial implant may or may not have also been captured by the registry. A more detailed revision and complication analysis follows for the primary breast implants for which the revision details can be linked to the initial inserted implant. In 2019, capsular contracture was the most common issue identified and reported at 37% of reconstructive breast implant revisions, followed by device malposition reported at 27% of revisions and device rupture reported at 16% of revisions. One reconstructive implant revision procedure in 2016 was recorded to include both seroma/haematoma and BIA-ALCL Breast Implant Associated. Refer also to the BIA-ALCL reports in the Registry Outcomes section for information relating to cases of Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL).

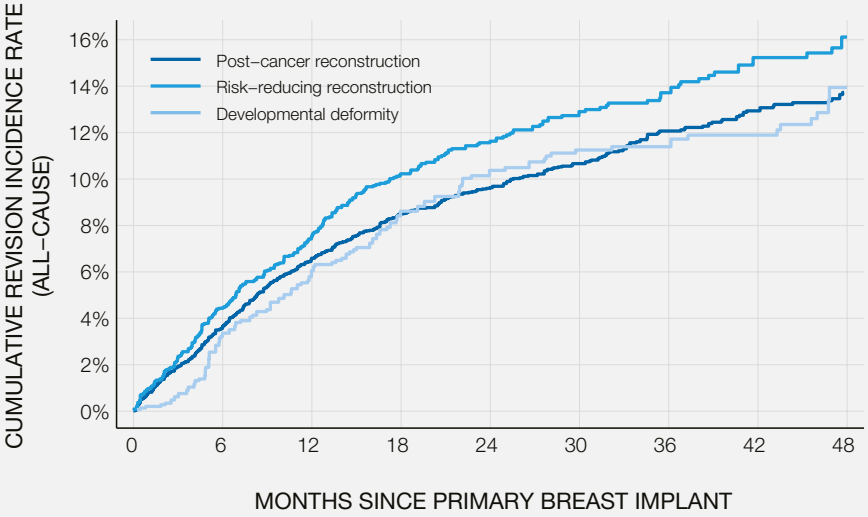
TABLE 14. ISSUES IDENTIFIED AT REVISION PROCEDURE –RECONSTRUCTIVE BREAST IMPLANTS

Complications and Issues Identified at Revision (N.B. Not complication rates)	2012-2019		2018		2019	
	N	(%)	N	(%)	N	(%)
Capsular contracture	2,008	(38.9%)	523	(39.3%)	558	(37.2%)
Device malposition	1,637	(31.7%)	438	(32.9%)	411	(27.4%)
Device rupture	786	(15.2%)	221	(16.6%)	240	(16.0%)
Device deflation	372	(7.2%)	96	(7.2%)	90	(6.0%)
Skin scarring problems	358	(6.9%)	114	(8.6%)	86	(5.7%)
Seroma/Haematoma	218	(4.2%)	58	(4.4%)	57	(3.8%)
Deep wound infection	144	(2.8%)	47	(3.5%)	34	(2.3%)
TOTAL REVISION PROCEDURES	**5,157**		**1,331**		**1,499**	

Notes: Listed in order of frequency are issues identified during reconstructive breast implant revision procedures. Multiple issues can be recorded at the time of revision surgery and issues were either identified as a reason for revision or found incidentally during the revision procedure. The crude percentage attached to each issue identified at revision is an observational proportion that has not accounted for censoring and patient follow-up time so cannot be interpreted as a complication rate.

Figure 12 provides an all-cause revision incidence curve for the three reconstructive indications. All-cause revision incidence rates at time intervals after the date of implant insertion are also reported in Table 15. All-cause revision incidence considers all revisions captured by the registry, whether for complication reasons, patient preference or other unknown reasons. In this case, breasts without a revision procedure captured by the registry had their follow-up time censored at the date of data extraction (18 April, 2020). At 12 months after the date of primary implant insertion, 6.6% of implants for post-cancer reconstruction were revised for the first time, 7.5% of implants for risk-reducing reconstruction and 6.1% of primary implants used for developmental deformity were revised for the first time.

FIGURE 12. ALL-CAUSE REVISION INCIDENCE – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS

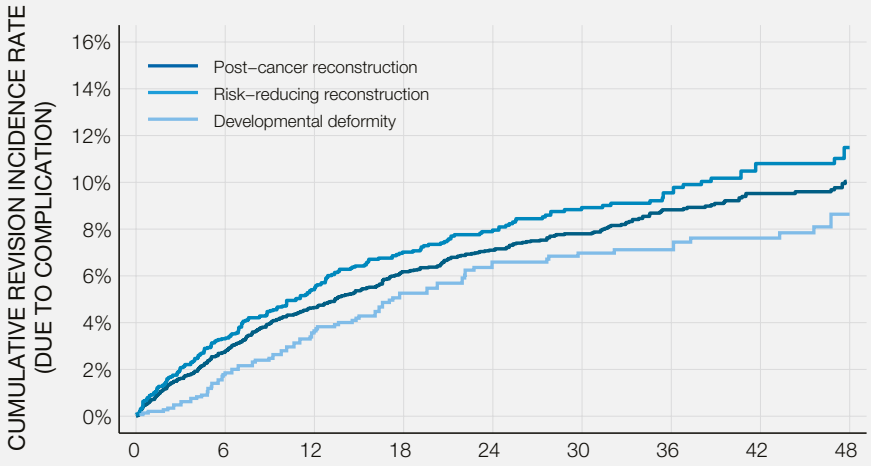


NUMBER AT RISK

6,736	6,183	5,117	4,198	3,432	2,679	2,043	1,496	1,085	Post–cancer
3,161	2,836	2,356	1,889	1,502	1,155	866	607	415	Risk–reducing
1,452	1,330	1,145	990	866	747	614	476	328	Developmental

Figure 13 provides revision incidence due to complication curves for the three reconstructive indications. Revision incidence rates due to complication are also reported in Table 15. Revision incidence due to complication considers all revisions captured by the registry that occurred due to complication. A revision due to complication in this case was defined as revisions that stated complication as the reason for revision and/or an issue was identified at revision (issues included any of device rupture, device deflation, capsular contracture, device malposition, skin scarring problems, deep wound infection, seroma/haematoma and BIA-ALCL. Breasts without a revision procedure due to complication captured by the registry had their follow-up time censored at either the date of a revision procedure that occurred due to other reasons or the date of data extraction (18 April, 2020) if no revision was captured. At 12 months after the date of primary implant insertion, revision incidence due to complication was 4.7% for post-cancer reconstruction implants, 5.4% for risk-reducing reconstruction implants and 3.7% for primary implants inserted for developmental deformity.

FIGURE 13. REVISION INCIDENCE DUE TO COMPLICATION – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS

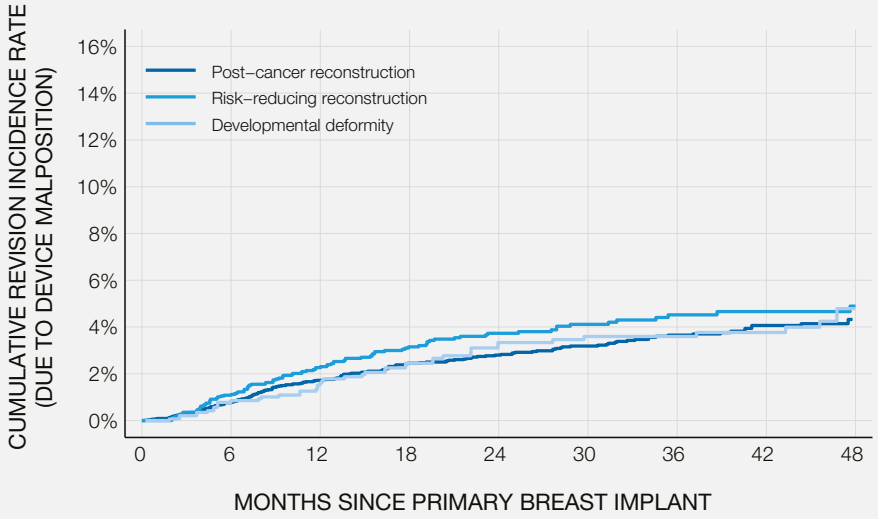


NUMBER AT RISK

6,736	6,183	5,117	4,198	3,432	2,679	2,043	1,496	1,085	Post–cancer
3,161	2,836	2,356	1,889	1,502	1,155	866	607	415	Risk–reducing
1,452	1,330	1,145	990	866	747	614	476	328	Developmental

Revision incidence curves and rates for reconstructive primary breast implants were produced for revisions due to device malposition, capsular contracture and device rupture/deflation (Figures 14-16 and Table 15). Breasts without a revision procedure due to these issues were censored at either the date of a revision procedure that occurred due to other reasons or the date of data extraction (18 April, 2020) if no revision was captured. Revision incidence due to device malposition for reconstructive breast implants was 1.9% at 12 months and 4.6% at 48 months following the date of primary implant insertion. Revision incidence due to capsular contracture was 1.3% at 12 months and 4.3% at 48 months following the date of primary implant insertion. Revision incidence due to device rupture/deflation for reconstructive breast implants was 0.2% at 12 months and 0.6% at 48 months following the date of primary implant insertion.

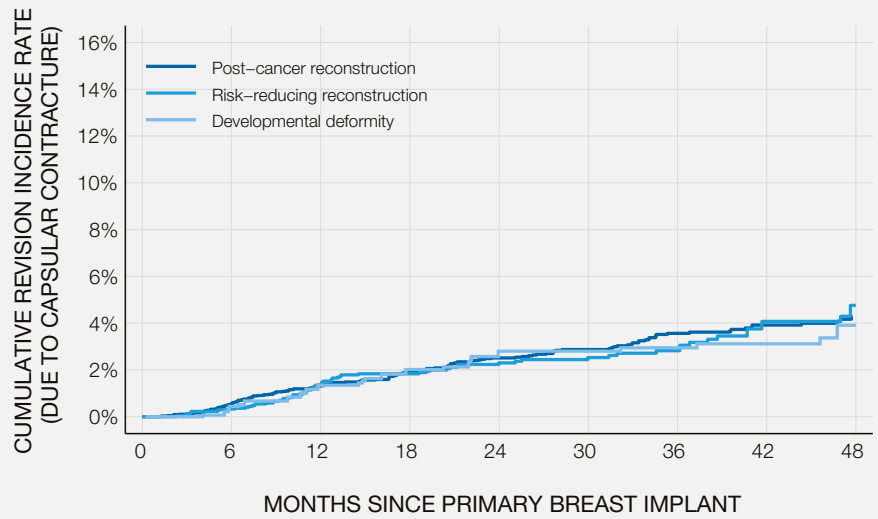
FIGURE 14. REVISION INCIDENCE DUE TO DEVICE MALPOSITION – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS



NUMBER AT RISK

6,736	6,183	5,117	4,198	3,432	2,679	2,043	1,496	1,085	Post–cancer
3,161	2,836	2,356	1,889	1,502	1,155	866	607	415	Risk–reducing
1,452	1,330	1,145	990	866	747	614	476	328	Developmental

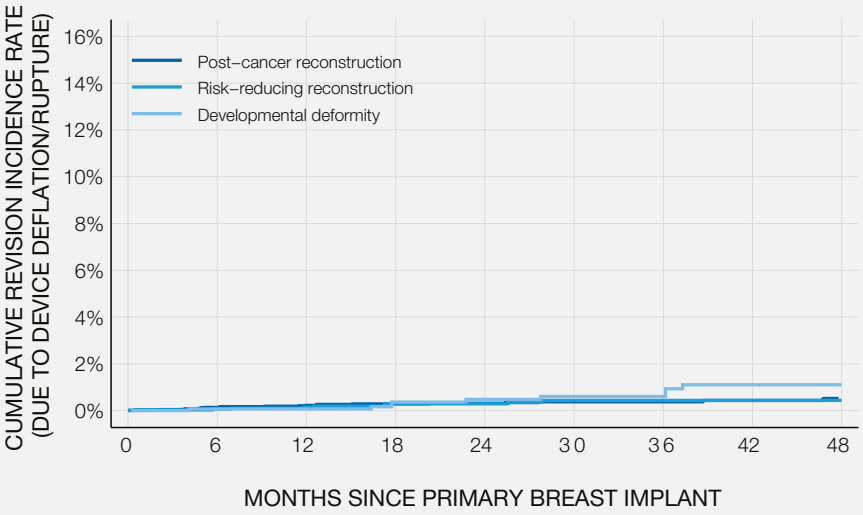
FIGURE 15. REVISION INCIDENCE DUE TO CAPSULAR CONTRACTURE – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS



NUMBER AT RISK

6,736	6,183	5,117	4,198	3,432	2,679	2,043	1,496	1,085	Post–cancer
3,161	2,836	2,356	1,889	1,502	1,155	866	607	415	Risk–reducing
1,452	1,330	1,145	990	866	747	614	476	328	Developmental

FIGURE 16. REVISION INCIDENCE DUE TO DEVICE DEFLATION/RUPTURE – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS



Number at risk

6,736	6,183	5,117	4,198	3,432	2,679	2,043	1,496	1,085	Post–cancer
3,161	2,836	2,356	1,889	1,502	1,155	866	607	415	Risk–reducing
1,452	1,330	1,145	990	866	747	614	476	328	Developmental

TABLE 15. REVISION INCIDENCE: RECONSTRUCTIVE PRIMARY BREAST IMPLANTS

	N Primary Breast Implants	N Revised	Revision Incidence (95% Confidence Interval)			
			12 months	24 months	36 months	48 months
All-cause revision						
Post-cancer	6,736	647	6.6% (6.0, 7.3)	9.6% (8.8, 10.5)	12.1% (11.1, 13.1)	13.7% (12.6, 15.0)
Risk-reducing	3,161	352	7.5% (6.6, 8.6)	11.6% (10.4, 13.1)	13.7% (12.2, 15.4)	16.1% (14.2, 18.3)
Developmental	1,452	144	6.1% (4.9, 7.5)	10.4% (8.7, 12.4)	11.4% (9.6, 13.6)	14.0% (11.7, 16.7)
TOTAL	**11,349**	**1,143**	**6.8% (6.3, 7.3)**	**10.3% (9.7, 11.0)**	**12.4% (11.7, 13.2)**	**14.4% (13.5, 15.4)**
Revision due to complication						
Post-cancer	6,736	470	4.7% (4.1, 5.2)	7.1% (6.4, 7.9)	8.8% (8.0, 9.8)	10.0% (9.1, 11.1)
Risk-reducing	3,161	243	5.4% (4.6, 6.3)	8.0% (6.9, 9.1)	9.6% (8.3, 11.0)	11.5% (9.9, 13.4)
Developmental	1,452	90	3.7% (2.8, 4.9)	6.6% (5.3, 8.3)	7.1% (5.7, 8.9)	8.6% (6.9, 10.8)
TOTAL	**11,349**	**803**	**4.7% (4.3, 5.2)**	**7.3% (6.7, 7.9)**	**8.8% (8.1, 9.5)**	**10.2% (9.4, 11.1)**
Revision due to device malposition						
Post-cancer	6,736	187	1.7% (1.4, 2.1)	2.8% (2.4, 3.3)	3.7% (3.1, 4.3)	4.3% (3.7, 5.1)
Risk-reducing	3,161	104	2.3% (1.8, 2.9)	3.7% (3.0, 4.6)	4.5% (3.7, 5.6)	4.9% (3.9, 6.1)
Developmental	1,452	45	1.6% (1.1, 2.5)	3.3% (2.4, 4.6)	3.6% (2.6, 4.9)	4.8% (3.5, 6.6)
TOTAL	**11,349**	**336**	**1.9% (1.6, 2.1)**	**3.1% (2.8, 3.5)**	**3.9% (3.5, 4.4)**	**4.6% (4.0, 5.2)**
Revision due to capsular contracture						
Post-cancer	6,736	175	1.3% (1.1, 1.7)	2.5% (2.1, 3.0)	3.6% (3.0, 4.2)	4.3% (3.6, 5.1)
Risk-reducing	3,161	76	1.4% (1.0, 1.9)	2.3% (1.8, 3.0)	2.8% (2.2, 3.7)	4.8% (3.6, 6.3)
Developmental	1,452	37	1.4% (0.8, 2.2)	2.8% (2.0, 4.0)	3.0% (2.1, 4.2)	3.9% (2.7, 5.6)
TOTAL	**11,349**	**288**	**1.3% (1.1, 1.6)**	**2.5% (2.2, 2.9)**	**3.3% (2.9, 3.7)**	**4.3% (3.8, 4.9)**
Revision due to device deflation/rupture						
Post-cancer	6,736	22	0.2% (0.1, 0.4)	0.3% (0.2, 0.5)	0.4% (0.2, 0.6)	0.5% (0.3, 0.9)
Risk-reducing	3,161	10	0.1% (0.1, 0.4)	0.3% (0.1, 0.6)	0.4% (0.2, 0.9)	0.4% (0.2, 0.9)
Developmental	1,452	10	0.1% (0.0, 0.5)	0.5% (0.2, 1.2)	0.6% (0.3, 1.4)	1.1% (0.6, 2.2)
TOTAL	**11,349**	**42**	**0.2% (0.1, 0.3)**	**0.3% (0.2, 0.5)**	**0.4% (0.3, 0.6)**	**0.6% (0.4, 0.9)**

Notes: Revision incidence is based on reconstructive primary breast implants inserted from 2012 to 2019. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary implant insertion date to the first revision procedure.

Complication and revision incidence – Tissue expanders for reconstruction

The registry also collects details of issues and complications found at the time of unplanned revision procedures involving tissue expanders. Table 16 reports issues identified during reconstructive tissue expander revision procedures. Multiple issues can be recorded at the time of revision surgery and issues were either identified as a reason for the revision or found incidentally during the revision procedure. Table 16 reports the issues identified at all unplanned reconstructive tissue expander revisions, including revisions for breasts where the insertion of the initial tissue expander may or may not have also been captured by the registry. A more detailed revision analysis follows for the primary tissue expanders for which the revision details can be linked to the initial inserted tissue expander. In 2019, deep wound infection was the most common issue reported at 20% of reconstructive tissue expander revisions followed by device rupture/deflation at 19%, seroma/haematoma at 17%, skin scarring problems at 5% and capsular contracture at 4% of unplanned reconstructive tissue expander revisions. None of the BIA-ALCL cases was reported in the seroma/haematoma.

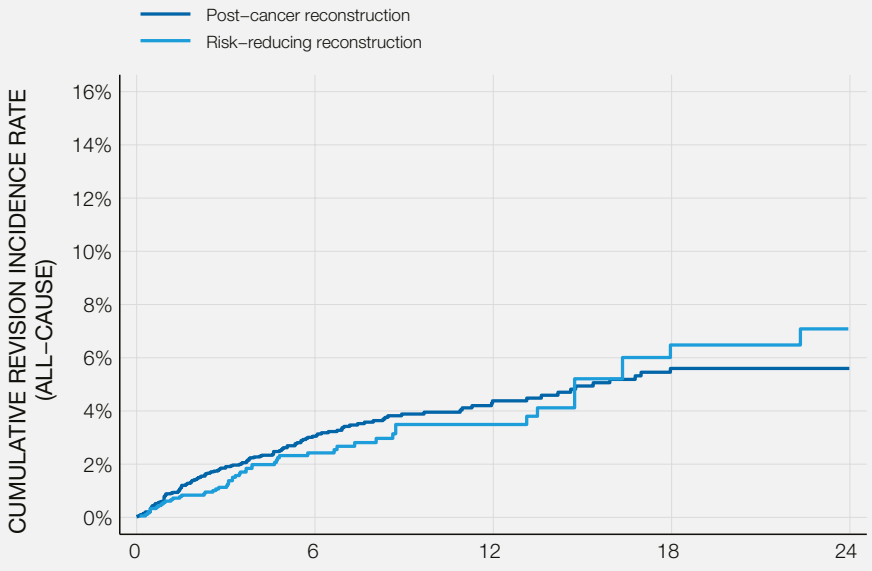
TABLE 16. ISSUES IDENTIFIED AT REVISION PROCEDURE – RECONSTRUCTIVE TISSUE EXPANDERS

Complications and Issues Identified at Revision (N.B. Not complication rates)	2012-2019		2018		2019	
	N	(%)	N	(%)	N	(%)
Deep wound infection	74	(21.2%)	18	(18.2%)	19	(20.0%)
Capsular contracture	48	(13.8%)	18	(18.2%)	4	(4.2%)
Device rupture/deflation	70	(20.1%)	21	(21.2%)	18	(18.9%)
Seroma/Haematoma	55	(15.8%)	15	(15.2%)	16	(16.8%)
Device malposition	35	(10.0%)	8	(8.1%)	3	(3.2%)
Skin scarring problems	34	(9.7%)	16	(16.2%)	5	(5.3%)
TOTAL REVISION PROCEDURES	**349**		**99**		**95**	

Notes: Listed in order of frequency are issues identified during unplanned reconstructive tissue expander revision procedures. Multiple issues can be recorded at the time of revision surgery and issues were either identified as a reason for revision or found incidentally during the revision procedure. The crude percentage attached to each issue identified at revision is an observational proportion that has not accounted for censoring and patient follow-up time so cannot be interpreted as a complication rate.

Figure 17 provides an all-cause revision incidence curve for post-cancer and risk-reducing reconstruction. All-cause revision incidence rates at time intervals after the date of tissue expander insertion are also reported in Table 17. All-cause revision incidence considers all revisions captured by the registry, whether for complication reasons, patient preference or other unknown reasons. In this case, breasts without a revision procedure captured by the registry had their follow-up time censored at the date of data extraction (18 April, 2020). At 12 months after the date of primary tissue expander insertion, 4.4% of tissue expanders for post-cancer reconstruction were revised for the first time; and 3.5% of tissue expanders for risk-reducing reconstruction were revised for the first time.

FIGURE 17. ALL-CAUSE REVISION INCIDENCE – RECONSTRUCTIVE PRIMARY TISSUE EXPANDERS



NUMBER AT RISK

3,852	2,337	1,093	696	525	Post–cancer
1,802	906	363	212	153	Risk–reducing

Figure 18 provides revision incidence due to complication curves for post-cancer and risk-reducing reconstruction. Revision incidence rates due to complication are also reported in Table 17. Revision incidence due to complication considers all revisions captured by the registry that occurred due to complication. A revision due to complication in this case was defined as revisions that stated complication as the reason for revision and/or an issue was identified at revision (issues included any of device rupture, device deflation, capsular contracture, device malposition, skin scarring problems, deep wound infection, seroma/haematoma and BIA-ALCL). Breasts without a revision procedure due to complication captured by the registry had their follow-up time censored at either the date of a revision procedure that occurred due to other reasons or the date of data extraction (18 April, 2020) if no revision was captured. At 12 months after the date of primary tissue expander insertion, revision incidence due to complication was 3.1% for post-cancer reconstruction and 2.8% for risk-reducing reconstruction.

FIGURE 18. REVISION INCIDENCE DUE TO COMPLICATION – RECONSTRUCTIVE PRIMARY TISSUE EXPANDERS

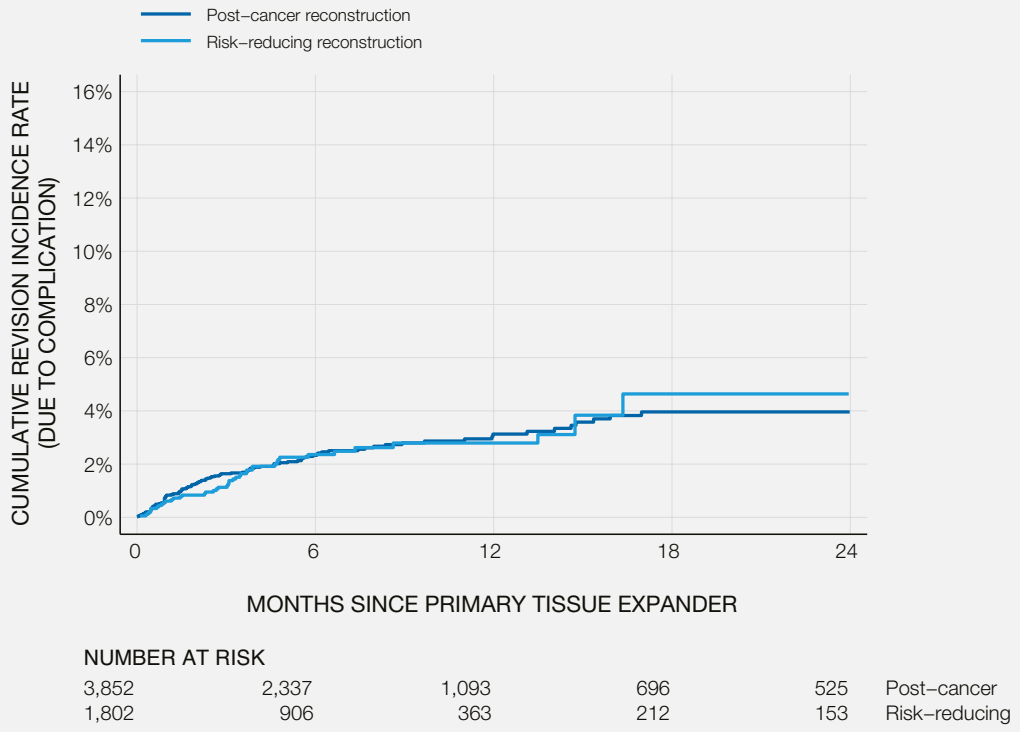


TABLE 17. REVISION INCIDENCE: RECONSTRUCTIVE PRIMARY TISSUE EXPANDERS

	N Primary Tissue Expanders	N Revised	Revision Incidence (95% Confidence Interval)			
			6 Months	12 Months	18 Months	24 Months
All-cause revision						
Post-cancer	3,852	143	3.1% (2.5, 3.7)	4.4% (3.6, 5.3)	5.6% (4.6, 6.8)	5.6% (4.6, 6.8)
Risk-reducing	1,802	56	2.4% (1.8, 3.4)	3.5% (2.5, 4.8)	6.5% (4.5, 9.3)	7.1% (4.9, 10.3)
TOTAL	**5,654**	**199**	**2.9% (2.4, 3.4)**	**4.1% (3.5, 4.9)**	**5.8% (4.8, 6.9)**	**5.9% (4.9, 7.1)**
Revision due to complication						
Post-cancer	3,852	104	2.3% (1.9, 2.9)	3.1% (2.5, 3.9)	4.0% (3.1, 5.0)	4.0% (3.1, 5.0)
Risk-reducing	1,802	46	2.4% (1.7, 3.3)	2.8% (2.0, 3.9)	4.6% (3.1, 6.9)	4.6% (3.1, 6.9)
TOTAL	**5,654**	**150**	**2.3% (2.0, 2.8)**	**3.0% (2.5, 3.7)**	**4.1% (3.4, 5.0)**	**4.1% (3.4, 5.0)**

Notes: Revision incidence is based on reconstructive primary tissue expanders inserted from 2012 to 2019. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary tissue expander insertion date to the first revision procedure.

REGISTRY OUTPUTS: AESTHETIC INDICATIONS

Aesthetic procedure numbers

The ABDR has captured a total of 37,852 surgical procedures involving breast devices with aesthetic indication (reasons). The aesthetic procedures captured include procedures for cosmetic augmentation only, reported either unilaterally or bilaterally. Figure 19 shows a rise in the annual number of aesthetic procedures captured in each year since registry commencement until 2017, and then a reduction in the number of procedures in 2018 and 2019. In 2019, 8,375 aesthetic procedures were captured, 98% were bilateral cosmetic augmentations and 2% were unilateral cosmetic augmentation (Table 18).

FIGURE 19. REGISTERED PROCEDURES – AESTHETIC (2012 – 2019)

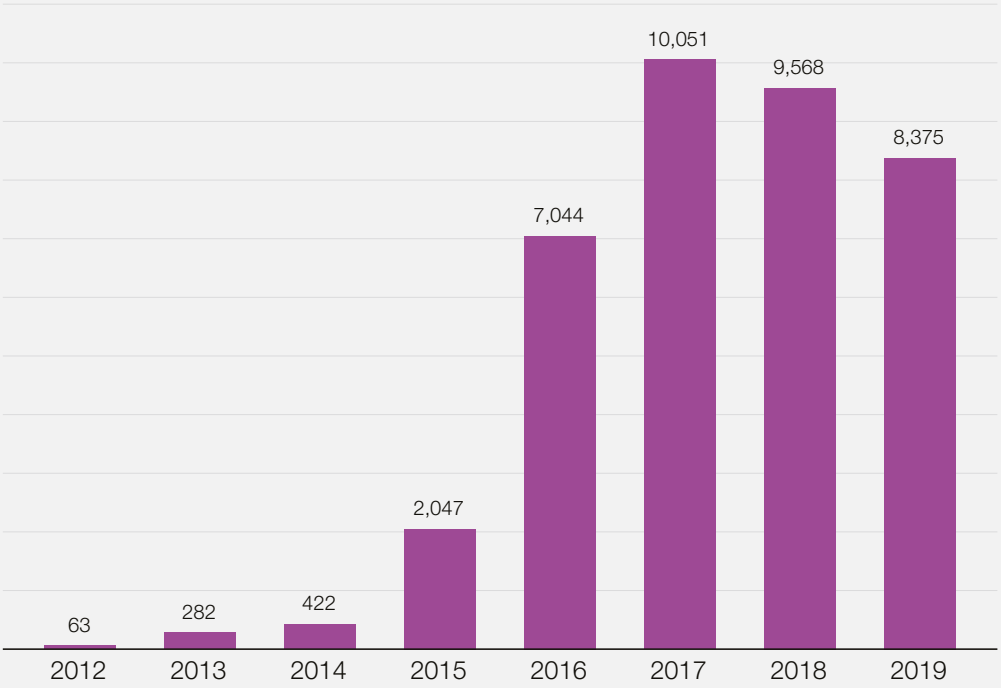


TABLE 18. PROCEDURE TYPE – AESTHETIC

	2012-2019		2018		2019	
	N	(%)	N	(%)	N	(%)
Cosmetic Augmentation						
Bilateral	36,830	(97.3%)	9,279	(97.0%)	8,180	(97.7%)
Unilateral	1,022	(2.7%)	289	(3.0%)	195	(2.3%)
TOTAL AESTHETIC PROCEDURES	**37,852**	**(100%)**	**9,568**	**(100%)**	**8,375**	**(100%)**

Patient age at aesthetic procedures

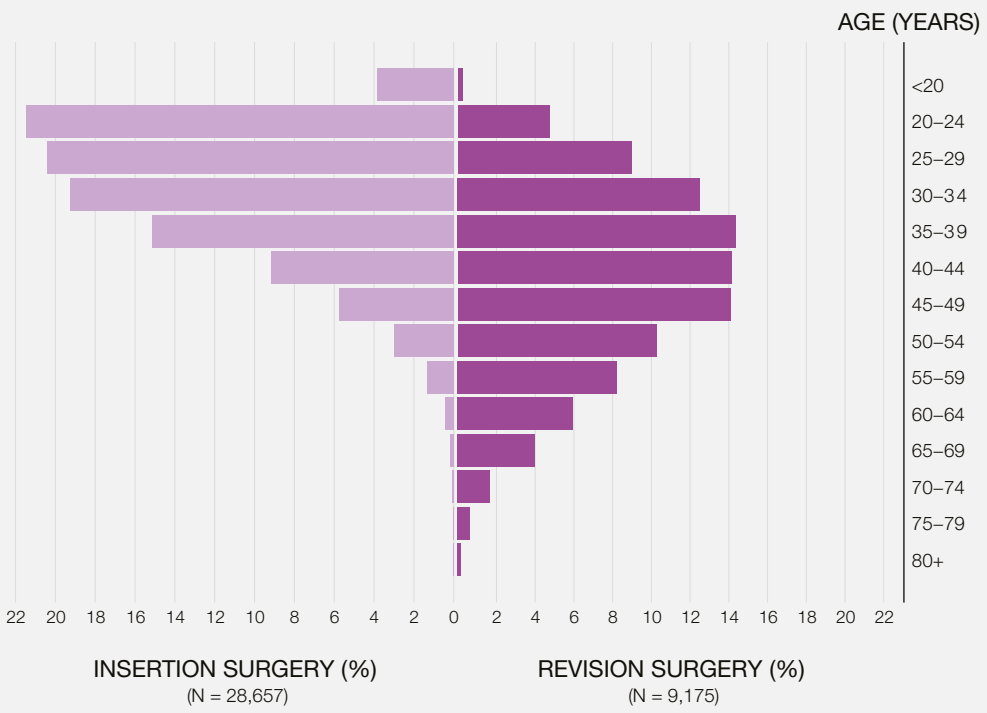
The age distribution at the time of aesthetic procedure is shown in Table 19 and Figure 20. A difference can be seen by whether the procedure involved device insertion or revision. In 2019, the median age at cosmetic augmentation was 31 years for insertion surgery and 44 years for revision surgery.

TABLE 19. SUMMARY STATISTICS FOR PATIENT AGE AT TIME OF AESTHETIC PROCEDURES

	Insertion Surgery			Revision Surgery		
	2012-2019	2018	2019	2012-2019	2018	2019
Cosmetic						
N	28,657	7,034	5,667	9,175	2,529	2,708
Mean Age (Standard deviation)	32.5 (9.3)	32.4 (9.3)	32.8 (9.6)	44.1 (12.6)	44.4 (12.5)	44.6 (12.8)
Median Age (Interquartile range)	31.1 (24.9, 38.2)	31.1 (24.9, 38.1)	31.3 (25.3, 38.5)	43.2 (34.5, 52.6)	43.3 (34.9, 53.1)	43.7 (34.6, 53.5)

Notes: Insertion and revision procedures have been analysed independently. Both unilateral and bilateral procedures have been included. Procedures with unknown procedure type (insertion or revision) have not been included. The interquartile range reports observed patient age at the 25th and 75th percentiles.

FIGURE 20. AGE DISTRIBUTION FOR AESTHETIC PROCEDURES (2012 – 2019)



Notes: Insertion and revision procedures have been analysed independently. Both unilateral and bilateral procedures have been included. Procedures with unknown procedure type (insertion or revision) have not been included.

Aesthetic procedure techniques and elements

Table 20 and Figure 21 show the intraoperative techniques used during aesthetic procedures. More than one intraoperative technique can be used and recorded during a procedure. The use of intraoperative antibiotics and postoperative antibiotics are also reported separately for 2018 and 2019. In 2019, the use of intraoperative and/or postoperative antibiotics (91%), antiseptic rinse (84%) and glove change for insertion (74%) were commonly reported for aesthetic procedures. Less frequently reported intraoperative techniques included antibiotic dipping solution (59%) and sleeve/funnel (53%).

TABLE 20.INTRAOPERATIVE TECHNIQUES – AESTHETIC PROCEDURES

	2012-2019		2018		2019	
	N	(%)	N	(%)	N	(%)
Intra-op / Post-op antibiotics	33,992	(89.8%)	8,546	(89.3%)	7,638	(91.2%)
Intraoperative antibiotics	-	-	8,392	(87.7%)	7,559	(90.3%)
Postoperative antibiotics	-	-	7,374	(77.1%)	6,698	(80.0%)
Antiseptic rinse	31,228	(82.5%)	8,184	(85.5%)	7,063	(84.3%)
Glove change for insertion	25,810	(68.2%)	7,092	(74.1%)	6,170	(73.7%)
Antibiotic dipping solution	21,489	(56.8%)	5,550	(58.0%)	4,929	(58.9%)
Sleeve / Funnel	14,462	(38.2%)	4,458	(46.6%)	4,441	(53.0%)
Not stated	2,464	(6.5%)	637	(6.7%)	500	(6.0%)
TOTAL NO. OF PROCEDURES	**37,852**		**9,568**		**8,375**	

Notes: More than one intraoperative technique can be used and recorded per procedure.

FIGURE 21. INTRAOPERATIVE TECHNIQUES – AESTHETIC PROCEDURES (2014 – 2019)

From 2012-2019, the most common surgical plane used during aesthetic procedures was dual plane, which was used in 82% of device insertions, and 65% of device revisions (Table 21). The inframammary fold was the most commonly used incision site reported for cosmetic augmentations during 2012 to 2019 (Table 21). Table 22 details other surgical elements reported during aesthetic breast procedures. Concurrent mastopexy/ reduction occurred in 11% of cosmetic augmentations involving device insertion and 17% involving device revision. Drains were used in 11% of cosmetic augmentations involving device insertion and in 35% involving device revision. A nipple guard or shield was used in 77% of cosmetic augmentations involving device insertion and in 55% involving device revision.

TABLE 21. SURGICAL PLANE AND INCISION SITE – AESTHETIC PROCEDURES

	Insertion Surgery						Revision Surgery					
	2012-2019		2018		2019		2012-2019		2018		2019	
	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Plane												
Dual plane	46,939	(82.1%)	11,571	(82.4%)	9,540	(84.4%)	11,354	(65.1%)	3,142	(65.5%)	3,481	(66.3%)
Sub-glandular/ Sub-fascial	6,443	(11.3%)	1,392	(9.9%)	1,206	(10.7%)	3,430	(19.7%)	883	(18.4%)	1,063	(20.2%)
Other	199	(0.3%)	20	(0.1%)	33	(0.3%)	62	(0.4%)	13	(0.3%)	15	(0.3%)
Not stated	3,617	(6.3%)	1,057	(7.5%)	520	(4.6%)	2,593	(14.9%)	758	(15.8%)	695	(13.2%)
Incision Site												
Inframammary	48,985	(85.6%)	11,743	(83.6%)	9,716	(86.0%)	12,918	(74.1%)	3,534	(73.7%)	3,755	(71.5%)
Mastopexy/ reduction wound	3,898	(6.8%)	1,008	(7.2%)	787	(7.0%)	2,465	(14.1%)	675	(14.1%)	855	(16.3%)
Areolar	585	(1.0%)	161	(1.1%)	83	(0.7%)	387	(2.2%)	100	(2.1%)	101	(1.9%)
Axillary	212	(0.4%)	66	(0.5%)	29	(0.3%)	47	(0.3%)	14	(0.3%)	7	(0.1%)
Other	113	(0.2%)	18	(0.1%)	27	(0.2%)	98	(0.6%)	18	(0.4%)	37	(0.7%)
Not stated	3,680	(6.4%)	1,147	(8.2%)	731	(6.5%)	1,613	(9.2%)	504	(10.5%)	507	(9.6%)
TOTAL	**57,198**		**14,040**		**11,299**		**17,439**		**4,796**		**5,254**	

Notes: Details are at breast level. Insertion and revision procedures have been analysed independently. More than one incision site can be recorded. Procedures with unknown procedure type (insertion or revision) have not been included.

TABLE 22. OTHER SURGICAL ELEMENTS – AESTHETIC PROCEDURES

	Insertion Surgery						Revision Surgery					
	2012-2019		2018		2019		2012-2019		2018		2019	
	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)	N	(%)
Concurrent Mastopexy/Reduction												
Yes	6,142	(10.7%)	1,574	(11.2%)	1,398	(12.4%)	2,891	(16.6%)	760	(15.8%)	1,055	(20.1%)
No	47,809	(83.6%)	11,791	(84.0%)	9,738	(86.2%)	12,827	(73.6%)	3,607	(75.2%)	3,877	(73.8%)
Not stated	3,247	(5.7%)	675	(4.8%)	163	(1.4%)	1,721	(9.9%)	429	(8.9%)	322	(6.1%)
Previous Mastopexy/Reduction												
Yes	603	(1.1%)	125	(0.9%)	197	(1.7%)	1,052	(6.0%)	339	(7.1%)	290	(5.5%)
No	52,132	(91.1%)	13,201	(94.0%)	10,939	(96.8%)	13,920	(79.8%)	4,023	(83.9%)	4,639	(88.3%)
Not stated	4,463	(7.8%)	714	(5.1%)	163	(1.4%)	2,467	(14.1%)	434	(9.0%)	325	(6.2%)
Fat grafting												
Yes	898	(1.6%)	169	(1.2%)	590	(5.2%)	396	(2.3%)	117	(2.4%)	190	(3.6%)
No	49,654	(86.8%)	12,817	(91.3%)	10,464	(92.6%)	14,760	(84.6%)	4,170	(86.9%)	4,726	(90.0%)
Not stated	6,646	(11.6%)	1,054	(7.5%)	245	(2.2%)	2,283	(13.1%)	509	(10.6%)	338	(6.4%)
Drains used												
Yes	6,272	(11.0%)	1,197	(8.5%)	783	(6.9%)	6,051	(34.7%)	1,574	(32.8%)	1,739	(33.1%)
No	50,926	(89.0%)	12,843	(91.5%)	10,516	(93.1%)	11,386	(65.3%)	3,220	(67.1%)	3,515	(66.9%)
Not stated	0	(0.0%)	0	(0.0%)	0	(0.0%)	2	(<0.05%)	2	(<0.05%)	0	(0.0%)
Nipple guard/shield												
Yes	44,017	(77.0%)	11,684	(83.2%)	9,668	(85.6%)	9,552	(54.8%)	2,790	(58.2%)	2,896	(55.1%)
No	13,181	(23.0%)	2,356	(16.8%)	1,631	(14.4%)	7,885	(45.2%)	2,004	(41.8%)	2,358	(44.9%)
Not stated	0	(0.0%)	0	(0.0%)	0	(0.0%)	2	(<0.05%)	2	(<0.05%)	0	(0.0%)
TOTAL	**57,198**		**14,040**		**11,299**		**17,439**		**4,796**		**5,254**	

Notes: Details are at breast/device level. Insertion and revision procedures have been analysed independently. Procedures with unknown procedure type (insertion or revision) have not been included.

Device characteristics for cosmetic augmentation

Table 23 provides device shell, fill and shape characteristics for breast implants inserted for cosmetic augmentation during an insertion procedure or a replacement revision procedure. In 2019, 56% of the breast implants inserted in registry participants for cosmetic augmentation were silicone implants with smooth shell and round shape, 24% were silicone implants with textured shell and anatomical shape and 16% were silicone implants with textured shell and round shape.

TABLE 23. DEVICE CHARACTERISTICS – AESTHETIC BREAST IMPLANTS

	2012-2019		2018		2019	
	N	(%)	N	(%)	N	(%)
Silicone Implants						
Textured | Anatomical	20,615	(28.5%)	5,275	(28.9%)	3,574	(23.5%)
Textured | Round	21,870	(30.3%)	4,620	(25.3%)	2,485	(16.4%)
Textured | Not stated	2	(<0.05%)	0	(0.0%)	2	(<0.05%)
Smooth | Round	25,377	(35.1%)	7,454	(40.8%)	8,445	(55.6%)
Smooth | Anatomical	5	(<0.05%)	0	(0.0%)	5	(<0.05%)
Polyurethane | Anatomical	2,590	(3.6%)	535	(2.9%)	392	(2.6%)
Polyurethane | Round	992	(1.4%)	215	(1.2%)	118	(0.8%)
Saline Implants						
Textured | Round	17	(<0.05%)	10	(0.1%)	0	(0.0%)
Smooth | Round	709	(1.0%)	130	(0.7%)	124	(0.8%)
Silicone/Saline Implants						
Textured | Anatomical	4	(<0.05%)	2	(<0.05%)	1	(<0.05%)
Textured | Round	2	(<0.05%)	0	(0.0%)	0	(0.0%)
Not Stated	79	(0.1%)	10	(0.1%)	50	(0.3%)
TOTAL	**72,262**	**(100%)**	**18,251**	**100%**	**15,196**	**100%**

Notes: Device characteristics are reported for all new devices during an insertion procedure or a replacement revision procedure.

Matrix was used infrequently in aesthetic breast surgery (Table 24).

TABLE 24. MATRIX USE IN PROCEDURES AT BREAST LEVEL IN AESTHETIC BREAST SURGERY

	2012-2019		2018		2019	
	Total Number of Procedures (N)	Number of Procedures with Matrix (% Matrix Use)	Total Number of Procedures (N)	Number of Procedures with Matrix (% Matrix Use)	Total Number of Procedures (N)	Number of Procedures with Matrix (% Matrix Use)
Breast augmentation surgery	56,834	28 (<0.05%)	13,952	4 (<0.05%)	11,216	9 (<0.1%)
Two-stage insertion surgery	332	5 (1.5%)	82	0 (0.0%)	74	1 (1.4%)
Revision surgery (breast augmentation)	17,324	234 (1.4%)	4,776	59 (1.2%)	5,167	62 (1.2%)
TOTAL NUMBER OF PROCEDURES (breast level)*	**74,490**		**18,810**		**16,457**	

Notes: Matrix includes acellular dermal and synthetic matrices.
*The breast level aesthetic procedures captured include procedures for cosmetic augmentation only, reported unilaterally or bilaterally, and also excludes tissue expander and unknown procedure types.

Complications and revision incidence – Aesthetic breast implants

The registry collects details of complications and issues that are found at the time of a revision procedure involving breast devices, either identified as a reason for the revision or found incidentally during the revision procedure. Multiple issues can be recorded at revision surgery. Table 25 reports the issues identified at all aesthetic revisions of breast implants, including revisions for breasts where the insertion of the initial implant may or may not have also been captured by the registry. A more detailed revision and complication analysis follows for the primary breast implants for which the revision details can be linked to the initial inserted implant. In 2019, capsular contracture was the most common issue identified estimated at 37% of aesthetic breast implants revisions, followed by device malposition at 19% of revisions, device rupture at 23% of revisions and device deflation at 9% of revisions. Eight aesthetic breast implant revision procedures (two in 2017, two in 2018 and four in 2019) were reported to include both seroma/hematoma and BIA-ALCL. Refer also to the BIA-ALCL reports in the Registry Outcomes section for information relating to cases of Anaplastic Large Cell Lymphoma.

TABLE 25. ISSUES IDENTIFIED AT REVISION PROCEDURE – AESTHETIC BREAST IMPLANTS

Complications and Issues Identified at Revision (N.B. Not ComplicationRates)	2012-2019		2018		2019	
	N	(%)	N	(%)	N	(%)
Capsular contracture	6,881	(39.7%)	1,996	(41.8%)	1,897	(36.7%)
Device malposition	3,916	(22.6%)	1,244	(26.0%)	995	(19.3%)
Device rupture	3,673	(21.2%)	1,028	(21.5%)	1,192	(23.1%)
Device deflation	1,668	(9.6%)	491	(10.3%)	470	(9.1%)
Skin scarring problems	491	(2.8%)	128	(2.7%)	114	(2.2%)
Seroma/Haematoma	483	(2.8%)	133	(2.8%)	142	(2.7%)
Deep wound infection	122	(0.7%)	35	(0.7%)	27	(0.5%)
TOTAL REVISION PROCEDURES	**17,324**		**4,776**		**5,167**	

Notes: Listed in order of frequency are issues identified during aesthetic breast implant revision procedures. Multiple issues can be recorded per revision and issues were either identified as a reason for revision or found incidentally during the revision procedure. The crude percentage attached to each issue identified at revision is an observational proportion that has not accounted for censoring and patient follow-up time so cannot be interpreted as a complication rate.

Figure 22 provides an all-cause revision incidence curve for cosmetic augmentation. All-cause revision incidence rates at time intervals after the date of breast implant insertion are also reported in Table 26. All-cause revision incidence considers all revisions captured by the registry, whether for complication, patient preference or other unknown reasons. In this case, breasts without a revision procedure captured by the registry had their follow-up time censored at the date of data extraction (18 April, 2020). At 12 months after the date of primary breast implant insertion, 1.6% of cosmetic augmentations were revised for the first time; and 4.4% were revised for the first time at 48 months after the implant insertion.

FIGURE 22. ALL-CAUSE REVISION INCIDENCE – AESTHETIC PRIMARY BREAST IMPLANTS

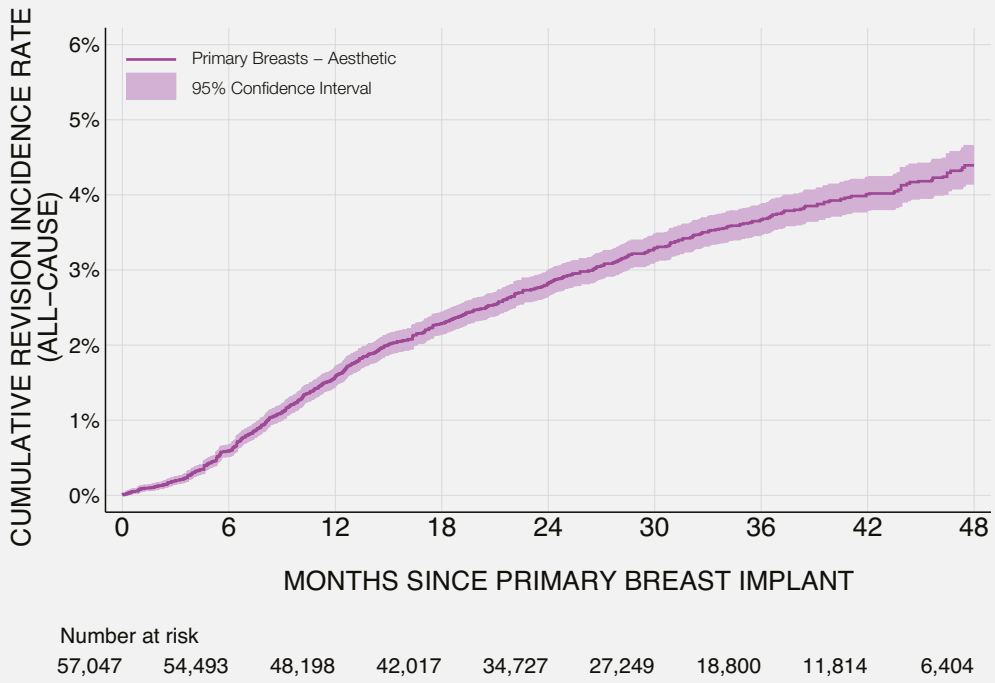
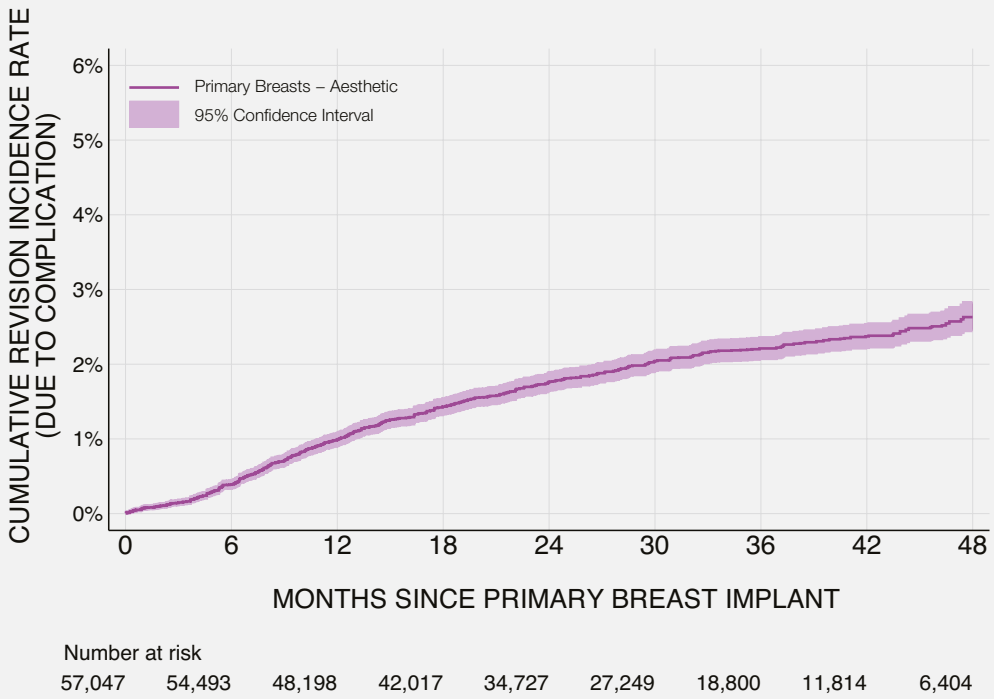


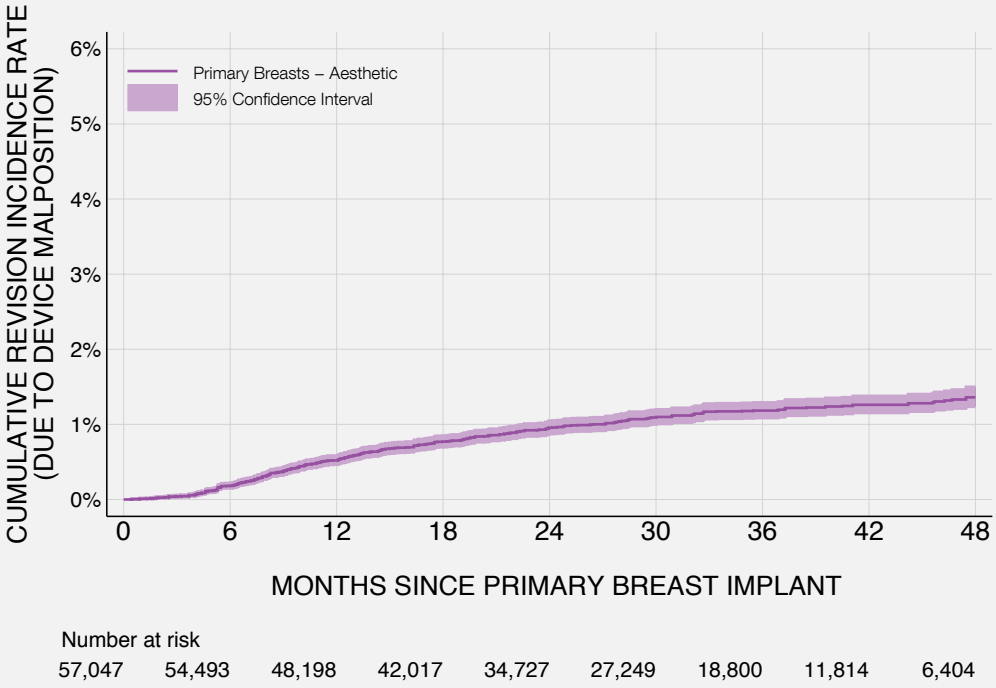
Figure 23 provides revision incidence due to complication curves for cosmetic augmentation. Revision incidence rates due to complication are also reported in Table 26. A revision due to complication in this case was defined as revisions that stated complication as the reason for revision and/or an issue was identified at revision (issues included any of device rupture, device deflation, capsular contracture, device malposition, skin scarring problems, deep wound infection, seroma/haematoma and BIA-ALCL). Breasts without a revision procedure due to complication captured by the registry had their follow-up time censored at either the date of a revision procedure that occurred due to other reasons or the date of data extraction (18 April, 2020) if no revision was captured. Revision incidence due to complication for cosmetic augmentation was 1.0% at 12 months after the date of primary implant insertion and 2.6% at 48 months after implant insertion.

FIGURE 23. REVISION INCIDENCE DUE TO COMPLICATION – AESTHETIC PRIMARY BREAST IMPLANTS



Revision incidence curves and rates for aesthetic primary breast implants were produced for revisions due to device malposition, capsular contracture and device rupture/deflation (Figures 24-26 and Table 26). Breasts without a revision procedure due to these issues were censored at either the date of a revision procedure that occurred due to other reasons or the date of data extraction (18 April, 2020) if no revision was captured. Revision incidence due to device malposition for breast implants inserted for cosmetic augmentation was 1.4% at 48 months following the date of primary implant insertion. Revision incidence due to capsular contracture for breast implants for cosmetic augmentation was 1.0% at 48 months following primary insertion. Revision incidence due to device deflation/rupture for breast implants inserted for cosmetic augmentation was 0.2% at 48 months following the date of primary insertion.

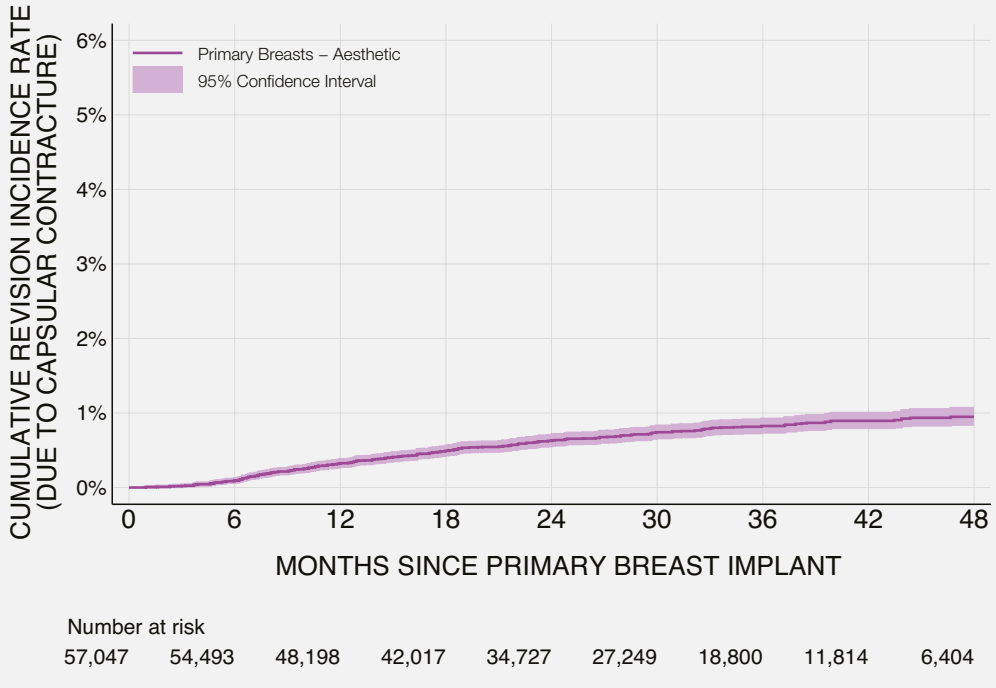
FIGURE 24. REVISION INCIDENCE DUE TO DEVICE MALPOSITION – AESTHETIC PRIMARY BREAST IMPLANTS



Number at risk

57,047	54,493	48,198	42,017	34,727	27,249	18,800	11,814	6,404

FIGURE 25. REVISION INCIDENCE DUE TO CAPSULAR CONTRACTURE – AESTHETIC PRIMARY BREAST IMPLANTS



Number at risk

57,047	54,493	48,198	42,017	34,727	27,249	18,800	11,814	6,404

FIGURE 26. REVISION INCIDENCE DUE TO DEVICE DEFLATION/RUPTURE – AESTHETIC PRIMARY BREAST IMPLANTS

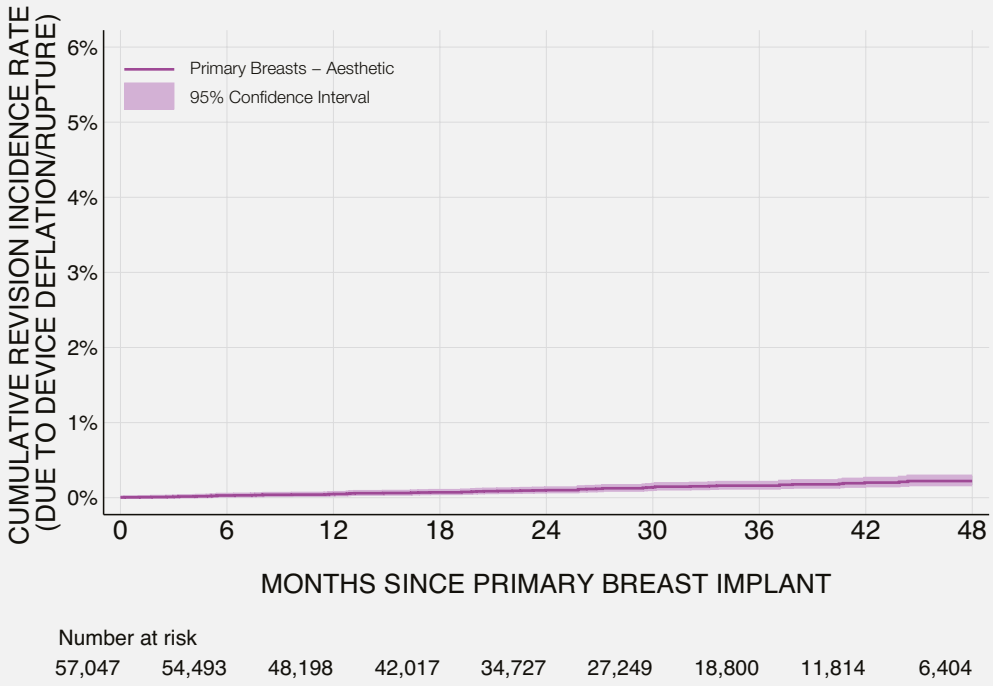


TABLE 26. REVISION INCIDENCE: AESTHETIC PRIMARY BREAST IMPLANTS

	N Primary Breast Implants	N Revised	Revision Incidence (95% Confidence Interval)			
			12 months	24 months	36 months	48 months
All-cause revision	57,047	1,716	1.6% (1.5, 1.7)	2.8% (2.7, 3.0)	3.7% (3.5, 3.9)	4.4% (4.2, 4.7)
Revision due to complication	57,047	1,043	1.0% (0.9, 1.1)	1.8% (1.7, 1.9)	2.2% (2.1, 2.4)	2.6% (2.5, 2.8)
Revision due to device malposition	57,047	550	0.5% (0.5, 0.6)	1.0% (0.9, 1.1)	1.2% (1.1, 1.3)	1.4% (1.2, 1.5)
Revision due to capsular contracture	57,047	381	0.3% (0.3, 0.4)	0.6% (0.6, 0.7)	0.8% (0.7, 0.9)	1.0% (0.9, 1.1)
Revision due to device deflation/rupture	57,047	77	0.1% (0.0, 0.1)	0.1% (0.1, 0.1)	0.2% (0.1, 0.2)	0.2% (0.2, 0.3)

Notes: Revision incidence is based on aesthetic primary breast implants inserted from 2012 to 2019. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary implant insertion date to the first revision procedure.

REGISTRY OUTCOMES

Surgeon and Site Reporting

Surgeon

The ABDR released its first round of surgeon reports in 2019. These individualised activity-based reports was sent to all surgeons who had contributed breast procedure data to the ABDR in the period to 31 December 2018 and reported data on the number of patients submitted, the number and type of procedures completed (broken down by site) and the completeness of submitted data, comparing the individual surgeon total to the ABDR aggregate total. The surgeon reports will not provide benchmarked outcome data provided as the issue of qualified privilege remains unresolved[7]. As the registry matures, surgeons will be invited to opt-in to receive reports benchmarking their performance.[8]

Site

The first 2018 site reports was released in 2019 to the top 50% of contributing sites. These site reports included a descriptive overview of each site's number of surgeries and use of intraoperative techniques.

Data Requests

We saw an increase in the number of calls from patients directly to the registry in response to the TGA device recall in 2019. Most calls were received directly from patients, with a smaller number coming as enquiries through the PROMs program, both as written responses and through telephone contact with patients. Two requests were received from surgeons and six requests from public hospitals for their patient data. Lists of patients were only generated if they requested by the surgeon directly or an appropriately delegated hospital Quality Manager.

International Minimum Dataset and Data Definitions

The ABDR continued to collaborate with the International Collaboration Of Breast Registry Activities (ICOBRA)[9], and an international minimum dataset and data definitions were agreed upon and accepted for publication[10]. The ICOBRA dataset and definitions were formatted into a pilot ABDR Data Collection Form and have been reviewed and tested by Australian clinicians, and release of the Australian revised dataset is planned.

BIA-ALCL Reports

The ABDR is one of three reporting channels for new cases of breast implant associated anaplastic large cell lymphoma (BIA-ALCL), including the TGA and Macquarie University research group. All new cases reported to any group are redacted to remove patient and surgeon identifying information and cross-referenced to ensure the TGA has a full record of all Australian cases.

At the end of 2019, 107 cases of BIA-ALCL in Australian women had been reported to the TGA.[11] The ABDR had received direct reports on 43 cases of confirmed BIA-ALCL at the end of 2019.

The ABDR sits on the TGA expert advisory panel on BIA-ALCL that was convened in November 2016. The panel was convened to provide ongoing advice and monitoring of the association between breast implants and BIA-ALCL. The panel consists of representative cancer epidemiologists, data analysts, plastic surgeons, cosmetic surgeons, breast-cancer surgeons, consumers and public-health practitioners.

Patient Reported Outcome Measures

The ABDR implemented registry-wide Patient Reported Outcome Measures (PROMs) in 2017 following a successful pilot.[12] Patients are contacted by text message at different time periods after their procedure (1, 2 and 5 years) and invited to answer the five questions BREAST-Q Implant Surveillance module (BREAST-Q IS) relating to their breast device. Patients who had not responded to the initial text message were followed up with a reminder text message and then contacted by an alternative method such as phone, email or regular post.

From October 2017 to December 2019, a total of 28,520 patients who had received breast augmentation were contacted and 5,045 who had received breast reconstruction were contacted. The total response rate was calculated from the patients who were followed-up and either provided complete responses to the PROMs questions, provided a partial response to the PROMs question, were not eligible to be included or chose to opt out of follow-up. Table 27 provides summary of the PROMs response figures. The patients with breast reconstruction had a higher response rate than patients with breast augmentation.

TABLE 27. PROMS RESPONSES AT YEAR 1, YEAR 2 AND YEAR 5 POST-OPERATIVE

Follow-Up Year	Augmentation			Reconstruction		
	N	(%)	Total Contacted	N	(%)	Total Contacted
Year 1	8,683	(59.2%)	14,658	2,012	(76.0%)	2,646
Year 2	7,120	(53.4%)	13,329	1,508	(73.5%)	2,051
Year 5	235	(44.1%)	533	220	(63.2%)	348

Patient opt out rate of PROMs follow-up was similar at 0.6% for both breast augmentation patients and reconstruction patients.

The analysis of the PROMs data included all patients who provided complete responses to the PROMs questions. The results of the Breast-Q IS with aggregate data for patients with breast reconstruction are shown in Figures 27-28. Aggregate data are snapshot data and do not reflect the trajectory of individual patients.

A minority of patients with breast reconstruction experienced pain and tightness most or all of the time. Overall, for patients with breast augmentation, satisfaction with look, feel and rippling was generally high, although with a small proportion of patients who were either dissatisfied or very dissatisfied. Over 50% of patients with breast augmentation experienced no pain or tightness in Year-5.

FIGURE 27: SATISFACTION LEVEL OF BREAST RECONSTRUCTION PATIENTS AT 1, 2 AND 5 YEARS POST-OPERATIVE

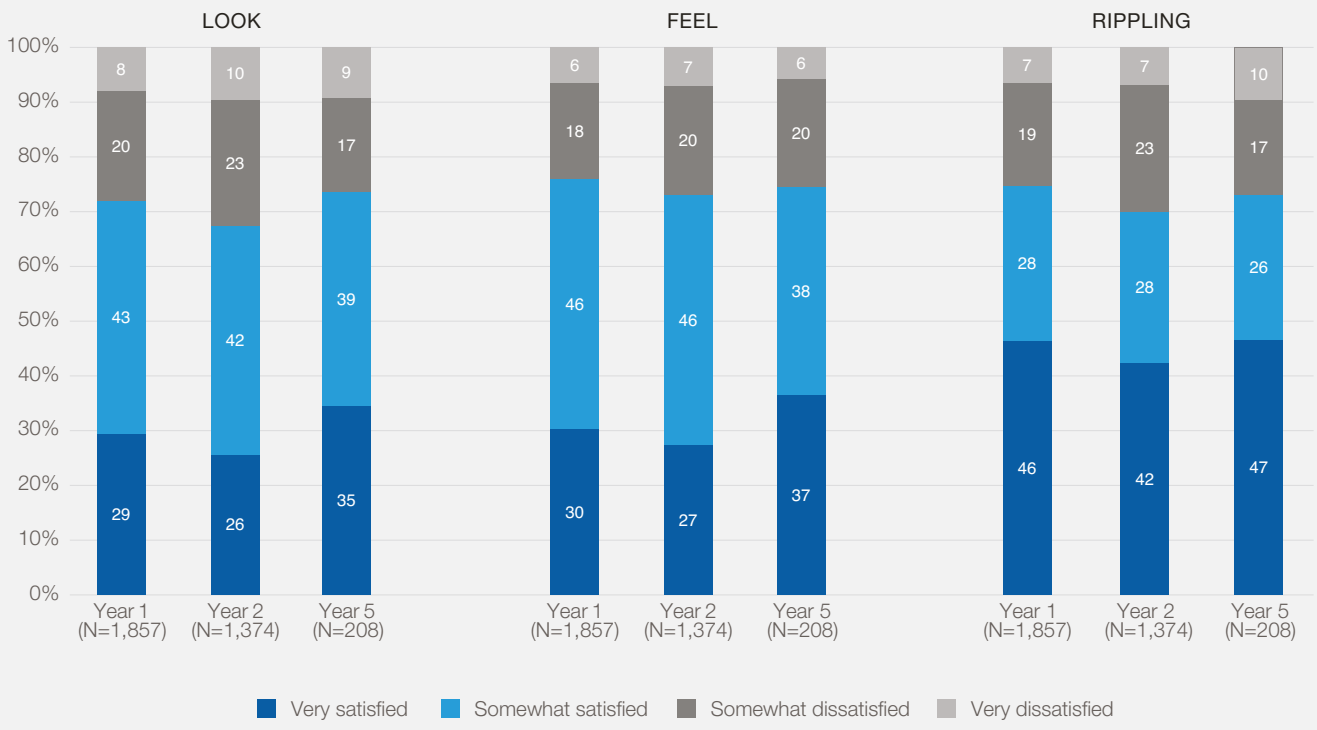
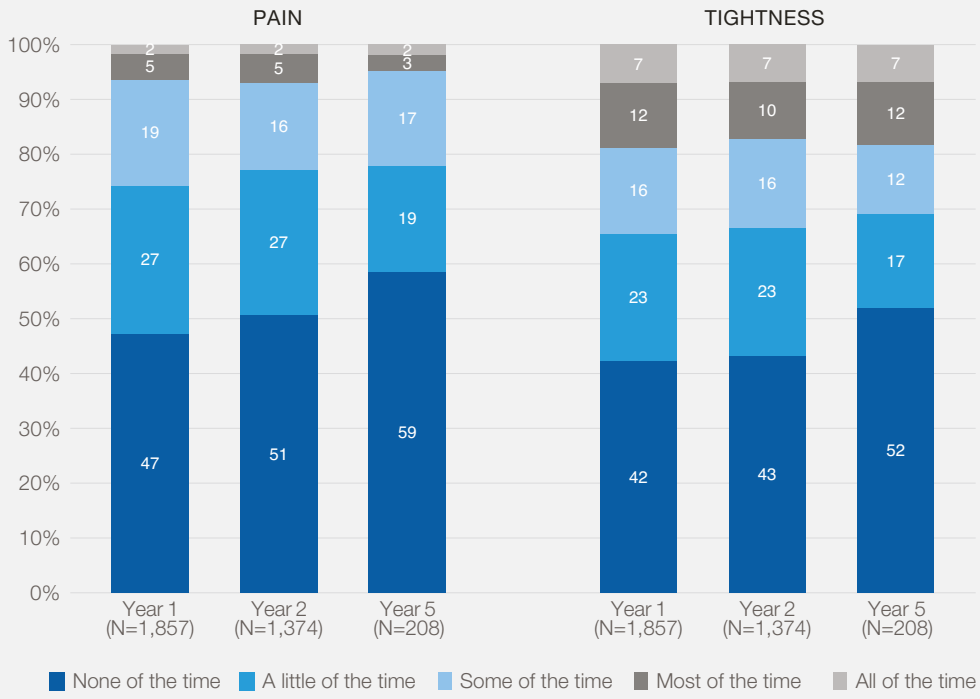


FIGURE 28: EXPERIENCE OF BREAST RECONSTRUCTION PATIENTS AT 1, 2 AND 5 YEARS POST-OPERATIVE



The results of the Breast-Q IS with linked data from patients who answered both Year-1 and Year-2 surveys are shown in Figures 29-30, showing the patient journey over time. Overall, for patients with breast reconstruction, satisfaction with look, feel and rippling decreased slightly from Year-1 to Year-2. The trend of experiencing no pain increased by 3% and tightness decreased by 2% from Year-1 to Year-2.

FIGURE 29: SATISFACTION LEVEL OF BREAST RECONSTRUCTION PATIENTS AT 1 AND 2 YEARS POST-OPERATIVE

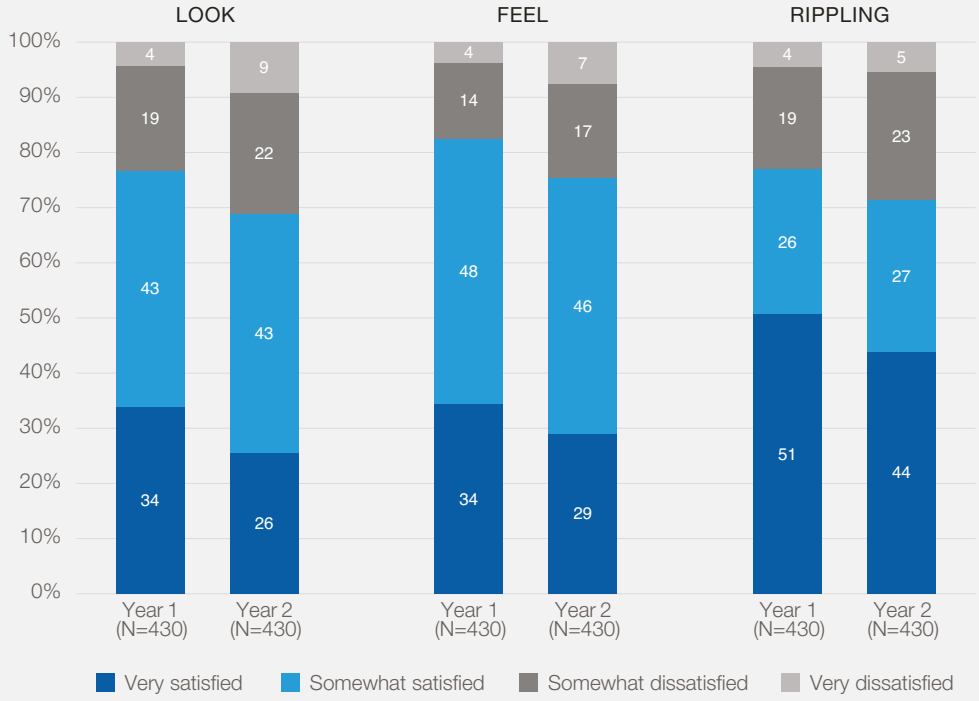
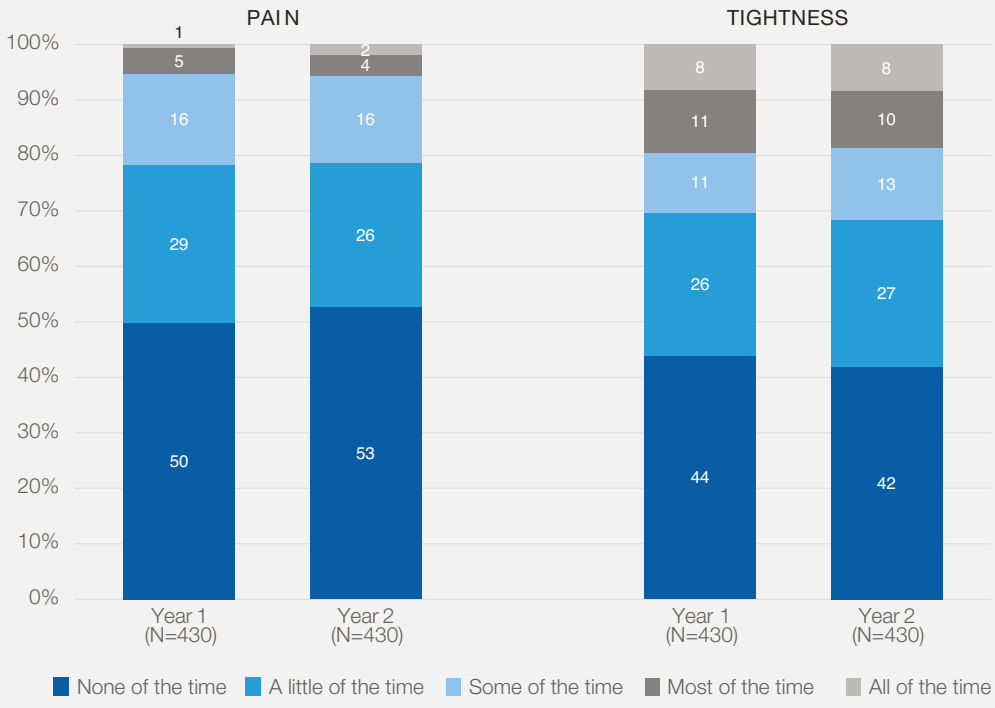


FIGURE 30: EXPERIENCE OF BREAST RECONSTRUCTION PATIENTS AT 1 AND 2 YEARS POST-OPERATIVE



The results of the Breast-Q IS with aggregate data for breast augmentation patients are shown in Figures 31-32. Aggregate data are snapshot data and do not reflect the trajectory of individual patients. Overall, for patients with breast augmentation, satisfaction with look, feel and rippling were high for approximately three-quarters, with about one-quarter reporting dissatisfaction at each of the time points (1, 2 and 5 years). Note that the number of responses at Year-5 is small. Few patients with breast augmentation experienced pain and tightness most or all of the time. Over 60% and 70% of patients with breast augmentation experienced no pain and no tightness in all years.

FIGURE 31: SATISFACTION LEVEL OF BREAST AUGMENTATION PATIENTS AT 1, 2 AND 5 YEARS POST-OPERATIVE

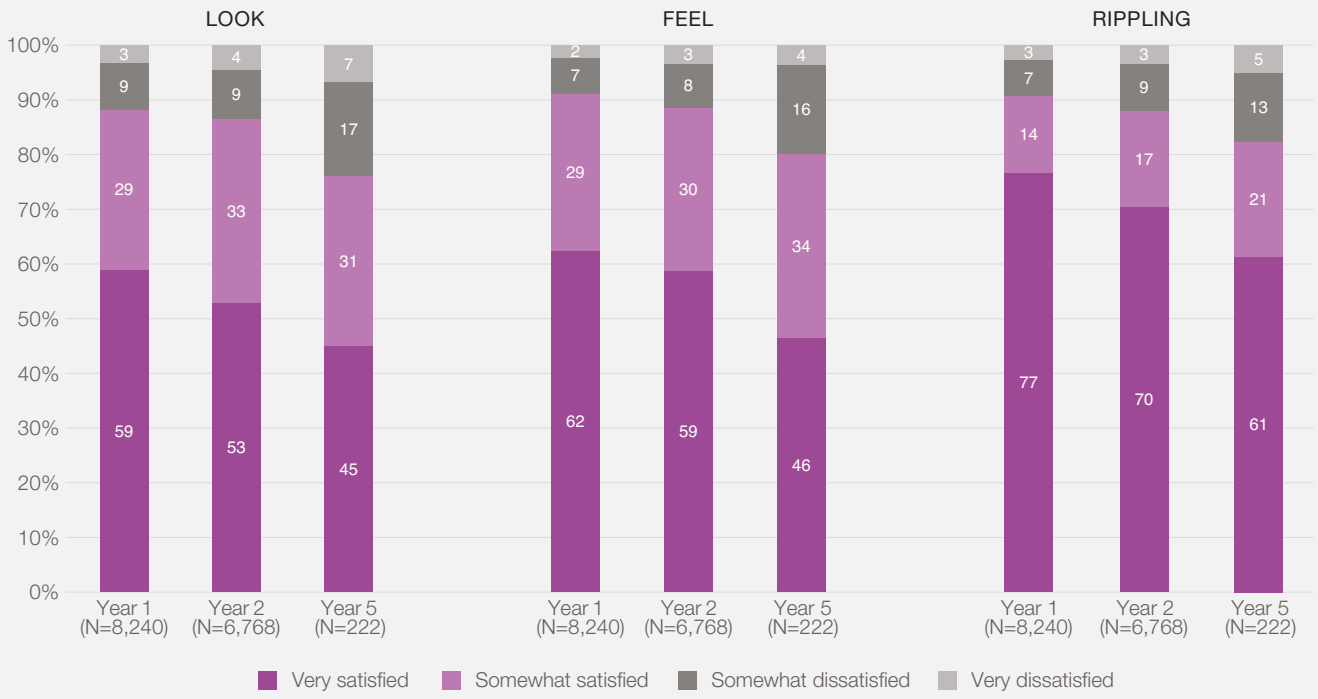
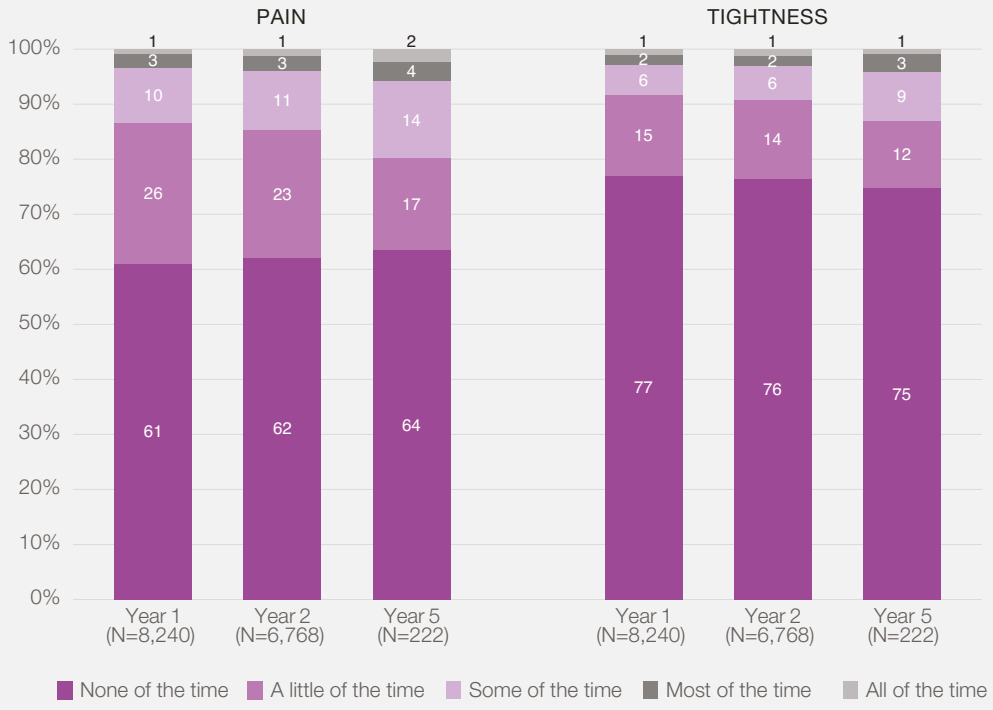


FIGURE 32: EXPERIENCE OF BREAST AUGMENTATION PATIENTS AT 1, 2 AND 5 YEARS POST-OPERATIVE



The results of the Breast-Q IS with linked data from patients who answered both Year-1 and Year-2 surveys are shown in Figures 33-34, showing the patient journey over time. Overall, for patients with breast augmentation, satisfaction with look, feel and rippling decreased slightly from Year-1 to Year-2. The trend of experiencing no pain or tightness from Year-1 to Year-2 decreased slightly.

FIGURE 33: SATISFACTION LEVEL OF BREAST AUGMENTATION PATIENTS AT 1 AND 2 YEARS POST-OPERATIVE

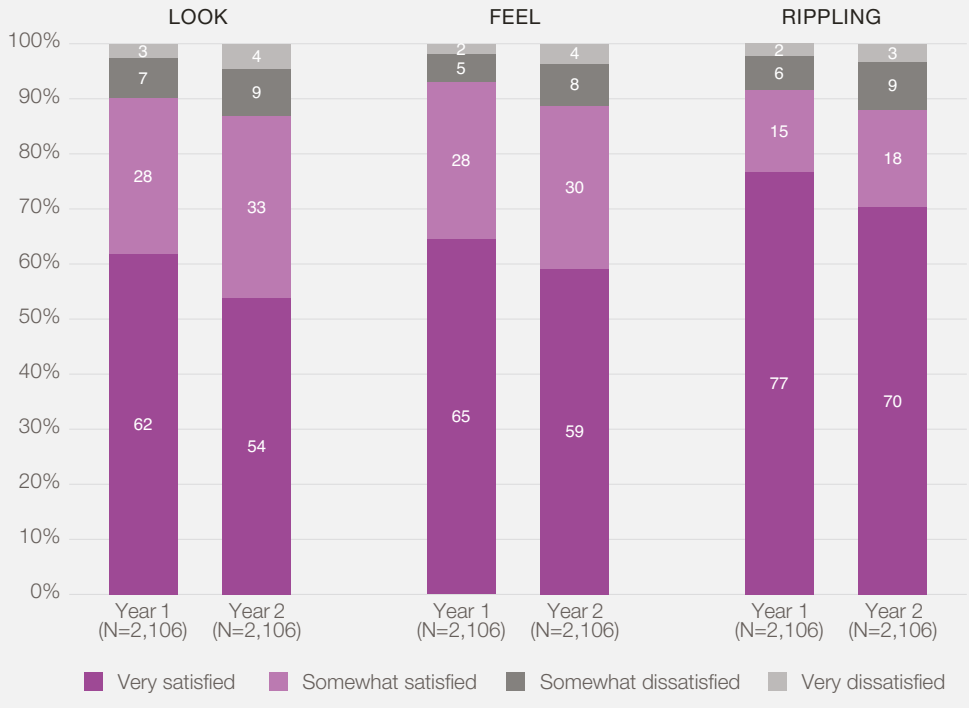
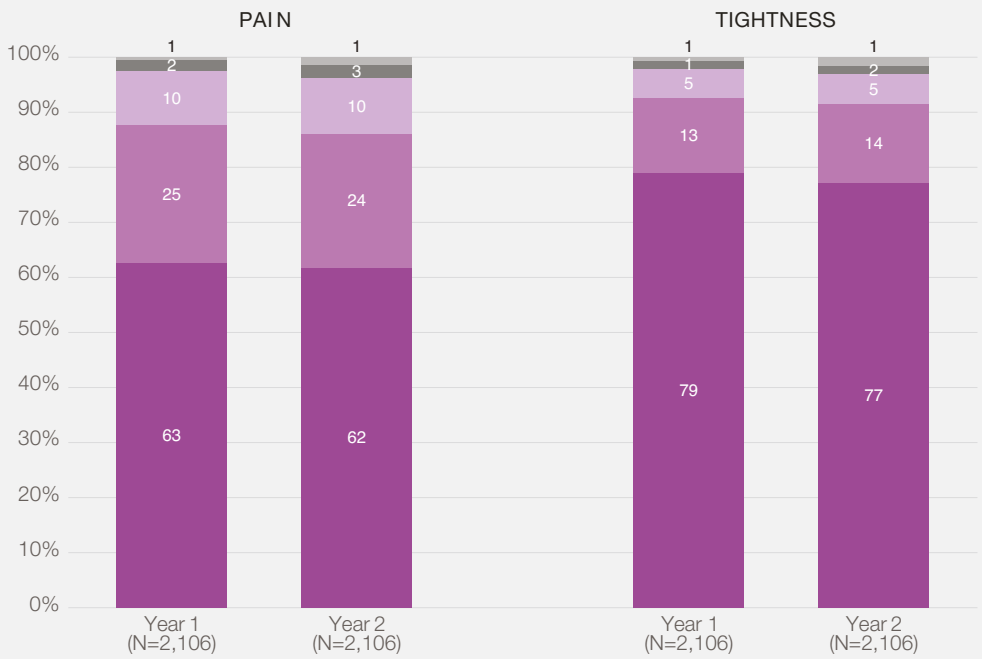


FIGURE 34: EXPERIENCE OF BREAST AUGMENTATION PATIENTS AT 1 AND 2 YEARS POST-OPERATIVE



FUTURE INITIATIVES

As the Australian Breast Device Registry moves towards maturity, the data are becoming more valuable for breast device safety monitoring. We are undertaking further work on testing and refining algorithms to identify outlier devices in collaboration with the TGA. We are also developing other methods to analyse device performance including using patient reported outcome measures as a potential early safety signal. We anticipate that these data will be informative for regulators as well as industry to understand breast device performance.

We anticipate that data from the ABDR will become increasingly important for auditing and quality improvement in healthcare. We plan to provide more detailed reports back to surgeons including their use of surgical techniques. The Commonwealth Government's Draft National Clinical Quality Registry Strategy sets out a pathway for clinical quality registries in the future. We continue to work with relevant stakeholders to ensure that the ABDR data are appropriately protected, so surgeons can review their own performance and opt in benchmarked reports can be provided in due course.

We continue to engage our stakeholders to ensure all Australians are offered the opportunity to have their breast device data recorded on the ABDR at the time of breast device surgery. We plan a consumer engagement strategy to raise awareness about the registry and educate consumers to seek out a surgeon who contributes to the ABDR.

In line with the ICOBRA harmonised dataset, ABDR expects to release an updated dataset in 2021 reflecting elements of the ICOBRA set[10] adapted to our local environment. Ethics approval for this significant development will be obtained over 2020. This will ensure that the data produced by the ABDR can be combined with that of other ICOBRA registries including Netherlands, Sweden, UK and US.

Work is underway on the first combined annual report examining breast devices across these countries. Aggregate non-identifiable data will be analysed in the same manner by each of the countries, and it is planned that these analyses will be compared and combined into a larger report. This will be the first time an international report on breast device surgery will be created, and will establish the foundation for further international reports in the future. As part of efforts to establish the capacity of comparing breast devices between countries, we are working with ICOBRA registries, medical device regulators and representatives of industry on an international device library. This will ensure that when analyses of devices are undertaken in different countries devices will be compared to like devices. This includes consistent coding of characteristics such as surface texture, shape and fill. We are also working with regulators internationally to establish surface texture standards that can be utilised by registries.

We have been fortunate to receive funding from the Australian Government Department of Health for the ABDR to date, but to ensure our long-term viability, more diverse sources of funding are required. We are exploring alternative funding models with the Commonwealth, and look forward to engaging with stakeholders to find an appropriate model.

The ABDR continues to work with other research collaborators on the crucially important issue of breast implant associated anaplastic large cell lymphoma. We welcome further research collaborations. The dataset is sufficiently mature that it can be used to address important clinical questions, and we look forward to opportunities to collaborate with clinicians and trainees, as well as other researchers.

The ABDR looks forward to another active year ahead, working with clinicians, hospitals, patients and other stakeholders to safeguard the health of all Australians choosing breast devices.

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Spronk PE, Begum H, Vishwanath S, Crosbie A, Earnest A, Elder E, Lumenta DB, Marinac-Dabic D, Moore CC, Mureau MA, Perks G, Pusic AL, Stark B, von Fritschen U, Klein H, Cooter RD, Rakhorst HA, Hopper I. Toward International Harmonization of Breast Implant Registries: International Collaboration of Breast Registry Activities Global Common Data Set. Plastic and Reconstructive Surgery. 2020 August. Volume 146 – Issue 2 – p 255-267. doi: 10.1097/PRS.0000000000006969

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PRESENTATIONS 2019

As part of our continued efforts to remain engaged with our contributors and patients, a number of ABDR presentations were conducted at a variety of research, health education and advocate forums, which included peri-operative nurse in-services and training seminars, specialised surgical educational events, Pink Hope, Breast Cancer Network Australia and Think Pink.

GLOSSARY

ABDR	Australian Breast Device Registry
ACCS	Australasian College of Cosmetic Surgery
ACSQHC	Australian Commission on Safety and Quality in Health Care
ASPS	Australian Society of Plastic Surgeons
BIA-ALCL	Breast Implant Associated-Anaplastic Large Cell Lymphoma
BREAST-Q IS	BREAST-Q Implant Surveillance module
BreastSurgANZ	Breast Surgeons of Australia and New Zealand Inc.
Contributing site	Any site that is currently contributing data to the ABDR
DBIR	Dutch Breast Implant Registry
DOH	Department of Health
Direct-to-implant	A breast reconstruction procedure whereby an implant is inserted at the time of the mastectomy
Eligible site	A site undertaking breast device surgery as identified by ICD-10-AM code data
HREC	Human Research Ethics Committee
ICD-10-AM	Australian Modification of the International statistical Classification of Diseases and health related problems, 10th revision
ICOBRA	International Collaboration of Breast Registry Activities
IQR	Interquartile range: Quartiles divide a rank-ordered dataset into four equal parts. The values that divide each part are called the first, second and third quartiles. First, second and third quartiles correspond to the observation at the 25th, 50th and 75th percentiles, respectively. The observation from the 25th percentile to the 75th percentile is referred as the interquartile range. An observation at the 50th percentile corresponds to the median value in the dataset.
Insertion surgery	Includes procedures that involve insertion of a new device, either a tissue expander or breast implant in a patient who has or has not had previous breast device surgery. Also included are tissue expander-to-implant exchanges and implant-to-tissue expander exchange
MTAA	Medical Technology Association of Australia
Primary implant breast	A breast for which the initial insertion of a breast implant has been captured by the ABDR
Primary tissue expander breast	A breast for which the initial insertion of a tissue expander has been captured by the ABDR
Revision surgery	A procedure involving unplanned replacement, reposition or explant of an in-situ device, either a tissue expander or breast implant. The initial device insertion may or may not have also been captured by the registry
Two-stage implant	A breast reconstruction procedure whereby the initial device insertion is a tissue expander, which is exchanged to a breast implant in a subsequent procedure
TGA	Therapeutic Goods Administration

REGISTRY PERSONNEL

Steering Committee Representatives

Australasian College of Cosmetic Surgery (ACCS) – **www.accs.org.au**

Australian Commission on Safety and Quality in Health Care (ACSQHC) – **www.safetyandquality.gov.au**

Australian Society of Plastic Surgeons (ASPS) – **www.plasticsurgery.org.au**

Breast Surgeons of Australia and New Zealand (BreastSurgANZ) – **www.breastsurganz.com**

Consumers Health Forum of Australia (CHF) – **https://chf.org.au/**

Australian Government Department of Health (Health) – **www.health.gov.au (observer only)**

Medical Technology Association of Australia (MTAA) – **www.mtaa.org.au**

Therapeutic Goods Administration (TGA) – **www.tga.gov.au**

Clinical Leads

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Associate Professor Colin Moore, Australian College of Cosmetic Surgeons (ACCS)

Associate Professor Gillian Farrell, Australian Society of Plastic Surgeons (ASPS)

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Professor John McNeil, ABDR Steering Committee Chair

Associate Professor Ingrid Hopper, ABDR Project Lead and ABDR Data Custodian

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Saeid Kalbasi, ABDR Database Coordinator

Trisha Nichols, Communications Officer

Ying Khu, Research Officer

Judith Hankin, Research Officer

Sally McInnes, Administrative Assistant

Leonardo Morandini, Data Entry

Uma Symons, Data Entry

Millie Coad, Data Entry

Hazel Loo, Telephone follow-up

Renee Conroy, Telephone Follow-up

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Couturaud, Benoit (France)

Crosbie, Andy (United Kingdom)

del Mar Vaquero, Maria (Spain)

Klein, Howard (New Zealand)

Lumenta, David (Austria)

Marinac Dabic, Danica (United States)

Montón, Javier (Spain)

Mureau, Marc (Netherlands)

Perks, Graeme (United Kingdom)

Pusic, Andrea (United States)

Rakhorst, Hinne (Netherlands)

Roe, Alison (United Kingdom)

Rosenkrantz Hølmich, Lisbet (Denmark)

Sommers, Katie (United States)

Spronk, Pauline (Netherlands)

Stark, Birgit (Sweden)

Von Fritschen, Uwe (Germany)

LIST OF FIGURES

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APPENDIX 1– DATA COLLECTION FORM

AUSTRALIAN BREAST DEVICE REGISTRY FORM

AFFIX **PATIENT** STICKER or complete details below:

Patient UR # : ☐☐☐☐☐☐☐☐☐☐

Medicare # : ☐☐☐☐☐☐☐☐☐☐

Surname : _____

First name: _____ Middle Name: _____

Birth Date: ☐☐ / ☐☐ / ☐☐☐☐ (dd/mm/yyyy)

Address : _____

_____ State: ☐☐☐ P/code: ☐☐☐☐

Telephone : ☐☐ - ☐☐☐☐☐☐☐☐ Home: ☐ Business: ☐

Mobile : ☐☐☐☐☐☐☐☐☐☐

Email : _____

OPERATION DATE: (dd/mm/yy) ☐☐ / ☐☐ / ☐☐

SITE DETAILS:

Site Name: _____

Suburb: _____ State: _____

Surgeon name: _____

Is this patient a medical tourist to Australia? Yes ☐ No ☐

RETURN FORM:

Australian Breast Device Registry,
Monash University, DEPM,
553 St Kilda Road, Melbourne 3004
email: abdr@monash.edu **fax:** (03) 9903 0277
contact phone: (03) 9903 0205

AFFIX **RIGHT DEVICE** STICKER
[COMPLETE IF NO DEVICE STICKER]

Manufacturer: _____
Distributor: _____
Reference no: _____
Serial no: _____

AFFIX **LEFT DEVICE** STICKER
[COMPLETE IF NO DEVICE STICKER]

Manufacturer: _____
Distributor: _____
Reference no: _____
Serial no: _____

AFFIX **MESH/DERMAL SHEET** STICKER
[COMPLETE IF NO DEVICE STICKER]

MESH/DERMAL SHEET: Yes ☐ No ☐

Manufacturer: _____
Reference no: _____
Serial no: _____

AFFIX **MESH/DERMAL SHEET** STICKER
[COMPLETE IF NO DEVICE STICKER]

MESH/DERMAL SHEET: Yes ☐ No ☐

Manufacturer: _____
Reference no: _____
Serial no: _____

PATIENT HISTORY:

RIGHT BREAST

☐ Tick if Same Bilateral

Category of operation

- ☐ Cosmetic augmentation
- ☐ Reconstruction - post cancer
- ☐ Reconstruction - benign / prophylactic
- ☐ Congenital deformity

Operation type

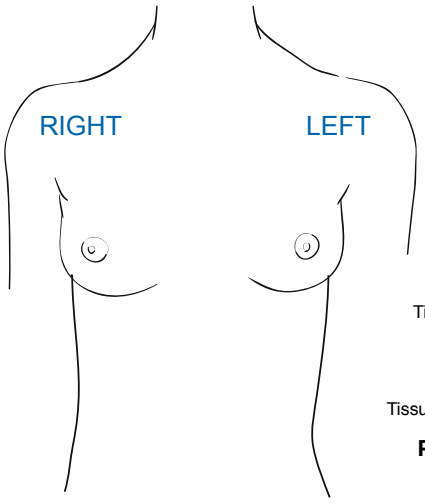
Initial (new device)

- ☐ Tissue Expander insertion
- ☐ First Implant insertion
- ☐ Tissue Expander removal & Implant insertion

Revision of in situ device

- ☐ Implant revision, removal or replacement
- ☐ Tissue Expander revision, removal, replacement

Previous Radiotherapy ☐ Yes ☐ No



BREAST **LEFT**

Category of operation

- Cosmetic augmentation ☐
- Reconstruction - post cancer ☐
- Reconstruction - benign / prophylactic ☐
- Congenital deformity ☐

Operation type

Initial (new device)

- Tissue Expander insertion ☐
- First Implant insertion ☐
- Tissue Expander removal & Implant insertion ☐

Revision of in situ device

- Implant revision, removal or replacement ☐
- Tissue Expander revision, removal, replacement ☐

Previous Radiotherapy ☐ Yes ☐ No

PLEASE COMPLETE OVER PAGE

ABDR_Data Collection Form_v1.0_20150310

ELEMENTS OF OPERATION

RIGHT BREAST

☐ Tick if Same Bilateral

Incision site
- ☐ Axillary
- ☐ Areolar
- ☐ Infra-mammary
- ☐ Previous mastectomy scar
- ☐ Mastopexy/reduction wound
- ☐ .....

Plane
- ☐ Sub-glandular / Sub-fascial
- ☐ Sub-pectoral
- ☐ Sub-flap

Concurrent Mastectomy..... ☐ Yes ☐ No
Axillary surgery incl. sentinel node biopsy ..... ☐ Yes ☐ No
Concurrent Mastopexy / Reduction ..... ☐ Yes ☐ No
Concurrent Flap cover ..... ☐ Yes ☐ No
Previous Mastopexy/Reduction ..... ☐ Yes ☐ No

Fat grafting ☐ Yes Volume.....mLs ☐ No

IF TISSUE EXPANDER, Intra Operative fill volume: .....mLs

BREAST LEFT

Plane
- Subglandular / Sub-fascial ☐
- Sub-pectoral ☐
- Sub-flap ☐

Incision site
- Axillary ☐
- Areolar ☐
- Infra-mammary ☐
- Previous mastectomy scar ☐
- Mastopexy/reduction wound ☐
- ..... ☐

☐ Yes ☐ No ..... **Concurrent Mastectomy**
☐ Yes ☐ No ..... **Axillary surgery incl. sentinel node biopsy**
☐ Yes ☐ No ..... **Concurrent Mastopexy / Reduction**
☐ Yes ☐ No ..... **Concurrent Flap cover**
☐ Yes ☐ No ..... **Previous Mastopexy/Reduction**

Fat grafting ☐ Yes Volume.....mLs ☐ No

IF TISSUE EXPANDER, Intra Operative fill volume: .....mLs

INTRAOPERATIVE TECHNIQUES

☐ Intra-op prophylactic antibiotic ☐ Antibiotic dipping solution ☐ Post-op antibiotic
☐ Glove change for insertion ☐ Sleeve/funnel ☐ Antiseptic rinse .....

RIGHT BREAST

☐ Tick if Same Bilateral

- ☐ Nipple absent
- ☐ Nipple sparing
- ☐ Occlusive nipple shield
- ☐ Drain used

BREAST LEFT

- Occlusive nipple shield ☐
- Drain used ☐
- Nipple absent ☐
- Nipple sparing ☐

FOR REVISION SURGERY ONLY

RIGHT BREAST

☐ Tick if Same Bilateral

Revision Type:
☐ Replacement ☐ Reposition existing implant ☐ Explant only

Capsulectomy ..... ☐ Full ☐ Partial ☐ None

Neo pocket formation ... ☐ Yes ☐ No ☐ Subglandular ☐ Submuscular

Explanted device: Ref.No. / Manufacturer: .....
Shell: ..... Fill: ..... Vol: ..... Date of Insert: ...../...../.....
☐ Round ☐ Anatomical ☐ Indeterminate

Reason for Revision

☐ Tick if Same Bilateral

☐ Complication ☐ Asymptomatic ☐ Patient Preference

Is the operation removing an implant inserted overseas ☐ Yes ☐ No

Details : .....

Device rupture?

☐ Tick if Same Bilateral

☐ Yes, reason for revision ☐ Yes, found incidentally ☐ No

If yes, please indicate whether silicone extravasation was found:
☐ Intracapsular ☐ Extracapsular ☐ Distant

BREAST LEFT

Revision Type:
Replacement ☐ Reposition existing implant ☐ Explant only ☐

Capsulectomy ..... Full ☐ Partial ☐ None ☐

Neo pocket formation ... Yes ☐ No ☐ Subglandular ☐ Submuscular ☐

Explanted device: Ref.No. / Manufacturer: .....
Shell: ..... Fill: ..... Vol: ..... Date of Insert: ...../...../.....
Round ☐ Anatomical ☐ Indeterminate ☐

Reason for Revision

Complication ☐ Asymptomatic ☐ Patient Preference ☐

Is the operation removing an implant inserted overseas Yes ☐ No ☐

Details : .....

Device rupture?

Yes, reason for revision ☐ Yes, found incidentally ☐ No ☐

If yes, please indicate whether silicone extravasation was found:
Intracapsular ☐ Extracapsular ☐ Distant ☐

Yes, reason for revision	Yes, found incidentally	No	Issue identified at revision	No	Yes, found incidentally	Yes, reason for revision
☐	☐	☐	Device deflation	☐	☐	☐
☐	☐	☐	Capsular contracture	☐	☐	☐
☐	☐	☐	Device malposition	☐	☐	☐
☐	☐	☐	Skin scarring problems	☐	☐	☐
☐	☐	☐	Deep wound infection	☐	☐	☐
☐	☐	☐	Seroma/Haematoma	☐	☐	☐
☐	☐	☐	Breast cancer	☐	☐	☐
☐	☐	☐	Anaplastic Large Cell Lymphoma	☐	☐	☐

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APPENDIX 2 – LIST OF PARTICIPATING SITES AS AT DECEMBER 2019

State	Site Name
ACT	Calvary Bruce Private Hospital
ACT	Calvary Bruce Public Hospital
ACT	Calvary John James Hospital
ACT	Canberra Private Hospital
ACT	National Capital Private Hospital
NSW	Aesthetic Day Surgery
NSW	Artarmon Day Surgery
NSW	Auburn Hospital
NSW	Bankstown-Lidcombe Hospital
NSW	Baringa Private Hospital
NSW	Bondi Junction Private Hospital
NSW	Brisbane Waters Private Hospital
NSW	Calvary Mater Newcastle
NSW	Calvary Riverina Hospital, Wagga Wagga
NSW	Campbelltown Private Hospital
NSW	Castlecrag Private Hospital
NSW	Charlestown Private Hospital
NSW	Concord Repatriation General Hospital
NSW	Crows Nest Day Surgery
NSW	Double Bay Day Hospital
NSW	East Sydney Private Hospital
NSW	Gosford Hospital
NSW	Gosford Private Hospital
NSW	Holroyd Private Hospital
NSW	Hunter Valley Private Hospital
NSW	Hunters Hill Private Hospital
NSW	Hurstville Private Hospital
NSW	Kareena Private Hospital
NSW	Kingsway Day Surgery
NSW	Lake Macquarie Private Hospital
NSW	Lakeview Private Hospital (formerly known as Hospital for Specialist Surgery)
NSW	Lingard Private Hospital
NSW	Liverpool Hospital
NSW	Macquarie St Day Surgery
NSW	Macquarie University Hospital
NSW	Maitland Private Hospital
NSW	Mater Hospital, North Sydney
NSW	Mount Druitt Hospital
NSW	Nepean Hospital
NSW	Nepean Private Hospital
NSW	North Shore Private Hospital
NSW	North Shore Specialist Day Hospital

State	Site Name
NSW	Northern Beaches Hospital
NSW	Norwest Private Hospital
NSW	Nowra Private Hospital
NSW	Pittwater Day Surgery
NSW	Port Macquarie Private Hospital
NSW	Prince of Wales Hospital
NSW	Prince of Wales Private Hospital
NSW	Riverina Day Surgery
NSW	Royal Hospital for Women, Sydney
NSW	Royal North Shore Hospital
NSW	San Day Surgery Hornsby
NSW	Shellharbour Private Hospital
NSW	Southern Highlands Private Hospital
NSW	St George Hospital
NSW	St George Private Hospital
NSW	St Luke's Private Hospital
NSW	St Vincent's Private Community Hospital Griffith
NSW	St Vincent's Hospital, Sydney
NSW	St Vincent's Private Hospital, Sydney
NSW	Strathfield Private Hospital
NSW	Surry Hills Day Hospital
NSW	Sydney Adventist Hospital
NSW	Sydney Children's Hospital (Inc Royal Alexandra Hospital for Children)
NSW	Sydney Day Hospital
NSW	Sydney Southwest Private Hospital
NSW	Sydney Surgical Centre
NSW	Tamara Private Hospital
NSW	The Tweed Hospital
NSW	Wagga Wagga Rural Referral Hospital
NSW	Waratah Private Hospital
NSW	Warners Bay Private Hospital
NSW	Westmead Hospital
NSW	Westmead Private Hospital
NSW	Wollongong Day Surgery
NSW	Wollongong Private Hospital
NT	Darwin Day Surgery
NT	Darwin Private Hospital
NT	Royal Darwin Hospital
QLD	Brisbane Day Hospital
QLD	Brisbane Private Hospital
QLD	Caboolture Private Hospital
QLD	Cairns Day Surgery

State	Site Name
QLD	Cairns Private Hospital
QLD	Canossa Private Hospital
QLD	Far North Day Hospital (Cairns Central Day Hospital)
QLD	Gold Coast Private Hospital
QLD	Gold Coast University Hospital
QLD	Greenslopes Private Hospital
QLD	Hillcrest Rockhampton Private Hospital
QLD	Ipswich Day Hospital
QLD	John Flynn Private Hospital
QLD	Kawana Private Hospital
QLD	Mater Hospital Brisbane
QLD	Lady Cilento Children's Hospital
QLD	Mater Hospital Brisbane
QLD	Mater Hospital Pimlico
QLD	Mater Private Hospital Brisbane
QLD	Mater Private Hospital Springfield
QLD	Mater Women's and Children's Hospital Hyde Park
QLD	Mercy Health Gladstone - Mater Misericordiae Hospital Gladstone
QLD	Mercy Health Mackay - Mater Misericordiae Hospital Mackay
QLD	Mercy Health Rockhampton - Mater Misericordiae Hospital Rockhampton
QLD	Miami Day Hospital
QLD	Montserrat - North Lakes Day Hospital
QLD	Montserrat - Samford Road Day Hospital
QLD	Noosa Hospital
QLD	North West Private Hospital (QLD)
QLD	Pacific Day Surgery
QLD	Pacific Private Day Hospital
QLD	Pindara Day Procedure Centre
QLD	Pindara Private Hospital
QLD	Princess Alexandra Hospital
QLD	Redland Hospital
QLD	Renaissant Aesthetic Health
QLD	Robina Hospital
QLD	Royal Brisbane and Women's Hospital
QLD	South Bank Day Hospital
QLD	Spring Hill Specialist Day Hospital
QLD	St Andrew's Private Hospital Ipswich
QLD	St Andrew's Toowoomba Hospital
QLD	St Vincent's Private Hospital - Holy Spirit Northside

State	Site Name
QLD	Sunshine Coast Day Surgery
QLD	Sunshine Coast University Private Hospital
QLD	Toowoomba Surgicentre
QLD	UnitingCare - Buderim Private Hospital
QLD	UnitingCare - St Andrew's War Memorial Hospital
QLD	UnitingCare - St Stephen's Hospital
QLD	UnitingCare - The Wesley Hospital
SA	Adelaide Day Surgery
SA	Ashford Hospital
SA	Burnside Hospital (War Memorial)
SA	Calvary North Adelaide Hospital
SA	Calvary Wakefield Hospital
SA	Calvary Wakefield Surgicentre
SA	Flinders Medical Centre
SA	Flinders Private Hospital
SA	Glenelg Community Hospital
SA	Hamilton House Day Surgery
SA	Noarlunga Hospital
SA	North Adelaide Day Surgery
SA	Norwood Day Surgery
SA	St Andrew's Hospital (SA)
SA	Stirling Hospital
SA	The Memorial Hospital
SA	The Queen Elizabeth Hospital
SA	Waverley House Plastic Surgery Centre
SA	Western Hospital (SA)
SA	Women's and Children's Hospital (SA)
TAS	Calvary Health Care Tasmania St John's Campus
TAS	Calvary Health Care Tasmania St Vincent's Campus
TAS	Hobart Private Hospital
TAS	Launceston General Hospital
TAS	North Tas Day Hospital
TAS	Royal Hobart Hospital
VIC	Austin Hospital
VIC	Austin TSC (Repatriation) Hospital
VIC	Ballarat Base Hospital
VIC	Beleura Private Hospital
VIC	Bendigo Day Surgery
VIC	Bendigo Hospital
VIC	Box Hill Hospital
VIC	Cabrini Hospital – Brighton
VIC	Cabrini Hospital – Malvern

State	Site Name
VIC	Casey Hospital
VIC	Corymbia House
VIC	Dandenong Hospital
VIC	Epworth Cliveden
VIC	Epworth Eastern (Box Hill)
VIC	Epworth Freemasons
VIC	Epworth Geelong
VIC	Epworth Hawthorn
VIC	Epworth Richmond
VIC	Footscray Hospital
VIC	Frances Perry House
VIC	Frankston Hospital
VIC	Glenferrie Private Hospital
VIC	Holmesglen Private Hospital
VIC	John Fawkner Private Hospital
VIC	Knox Private Hospital
VIC	Linacre Private Hospital
VIC	Maroondah Hospital
VIC	Maryvale Private Hospital
VIC	Masada Private Hospital
VIC	Melbourne Private Hospital
VIC	Mitcham Private Hospital
VIC	Monash House Private Hospital
VIC	Moorabbin Hospital
VIC	Mulgrave Private Hospital (Previously The Valley Private Hospital)
VIC	Northpark Private Hospital
VIC	Peninsula Private Hospital (VIC)
VIC	Peter MacCallum Cancer Centre
VIC	Ringwood Private Hospital
VIC	Shepparton Private Hospital
VIC	SJOG Ballarat
VIC	SJOG Bendigo
VIC	SJOG Berwick
VIC	SJOG Geelong
VIC	SJOG Warrnambool
VIC	South West Healthcare-Warrnambool Base Hospital
VIC	St Kilda Day Hospital
VIC	St Vincent's Private Hospital - East Melbourne
VIC	St Vincent's Private Hospital - Fitzroy
VIC	St Vincent's Private Hospital - Kew
VIC	St Vincent's Private Hospital - Werribee
VIC	Stonnington Day Surgery

State	Site Name
VIC	Sunshine Hospital
VIC	The Alfred Hospital
VIC	The Avenue Hospital
VIC	The Bays Hospital
VIC	The Royal Melbourne Hospital
VIC	The Royal Women's Hospital
VIC	University Hospital Geelong
VIC	Victorian Cosmetic Institute Day Surgery(VCI)
VIC	Warringal Private Hospital
VIC	Waverley Private Hospital
VIC	Western Private Hospital
VIC	Williamstown Hospital
VIC	Windsor Private Hospital
WA	Bethesda Hospital
WA	Bunbury Day Surgery
WA	Cambridge Day Surgery
WA	Colin Street Day Surgery
WA	Concept Fertility Centre and Day Hospital
WA	Glengarry Private Hospital
WA	Hollywood Private Hospital
WA	Joondalup Health Campus
WA	Mount Hospital
WA	Peel Health Campus
WA	SJOG Bunbury
WA	SJOG Midland Public and Private Hospital (previously Swan District Hospital)
WA	SJOG Mt Lawley
WA	SJOG Murdoch
WA	SJOG Subiaco
WA	SJOG Wembley Day Surgery
WA	Subiaco Private Hospital
WA	Waikiki Private Hospital
WA	West Leederville Private Hospital

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