MONASH University

# AUSTRALIAN BREAST DEVICE REGISTRY

# 2020 REPORT

AUSTRALIAN Breast Device REGISTRY

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**Data Period**

The data contained in this document were extracted from the ABDR on 18 May 2021 and pertains to data that had been submitted from the initiation of the pilot ABDR on 19 January 2012 to 31 December 2020. 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

We are delighted to present the 2020 Australian Breast Device Registry (ABDR) Annual Report, the registry's fifth.

This report further extends the ABDR's previous reports, reflecting the continued growth in clinical data and device and procedure follow up by the registry. In particular, this report includes separate explant only procedures, presents 5-year graphical trend data of ABDR procedures and devices, and includes additional device and matrix outcome revision analyses. Importantly, for the first time, we report data on Breast-Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) including summary procedure and device information, that has been consolidated from ABDR and external sources. In the future, the ABDR will be an extremely important national repository of ongoing data relating to this rare lymphoma. We thank all surgical clinicians who have provided the ABDR with specific information related to confirmed cases of BIA-ALCL, to assist us in better understanding the procedure and device profile associated with this disease.

In 2020, there have been many challenges associated with the COVID-19 pandemic. Nevertheless, the ABDR did not see an overall decrease in activity, and we again thank our colleagues who have continued to support the ABDR through completion of their data collection throughout this period.

The ABDR thanks the Commonwealth Department of Health for its continued support, ensuring the ongoing success of this important safety register. We also continue to work closely with the Therapeutic Goods Administration (TGA) to ensure that the ABDR is aligned with TGA regulatory activities. The ABDR is gaining increasing interest from researchers and industry who have research or safety questions that the ABDR can assist to answer. The ABDR also supports hundreds of women every year who contact the registry seeking breast device information and guidance. We thank all those women who support the registry through the provision of their clinical and Patient Reported Outcome (PROMs) information.

We also thank the ABDR team for their registry expertise and hard work. During 2020 the ABDR Academic Lead, Associate Professor Ingrid Hopper, and the Steering Committee Chair, Professor John McNeil, stepped down after 5 years of outstanding contribution to the registry. We thank them for their vision in establishing the ABDR and their strong leadership in managing such a nationally significant registry. As we write this foreword, we note that a number of other Steering Committee members are also retiring at the end of 2021. These include Associate Professor Elisabeth Elder, Associate Professor Colin Moore, and Cindy Shultz-Ferguson, the ABDR's consumer representative. All have provided exceptional service and guidance for the ABDR over the last five years.

We hope that you find the ABDR's 5th Annual Report interesting reading, and we commend it to you.

**Associate Professor Elisabeth Elder, PhD, FRACS, BreastSurgANZ**

**Associate Professor Colin Moore, FRACS, ACCS**

**Associate Professor Gillian Farrell, FRACS, ASPS**



# ACKNOWLEDGEMENTS

The registry continues to receive support and invaluable assistance from the Australian Government Department of Health with in-kind support from Monash University and three major surgical societies in Australia.

We are grateful for the contributions made by the ABDR steering and management committee. We acknowledge the leadership of the chair of the steering committee, who is also the ABDR academic lead and data custodian. We would like to acknowledge the contributions of the ABDR project team including Data Analysts.

We also gratefully acknowledge the dedication of the steering committee members, clinical leads including 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 Ms. Oriana Wallace, Australian Government Department of Health. We extend our gratitude to Macquarie University Working Group for sharing summary data regarding their previous BIA-ALCL research.

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.

In 2020, there have been many challenges associated with the COVID-19 pandemic. Nevertheless, the ABDR did not see an overall decrease in activity, and we again thank our colleagues who have continued to support the ABDR through completion of their data collection throughout this period.

**STEERING COMMITTEE REPRESENTATIVES**

Professor Susannah Ahern, ABDR Steering Committee Chair/ABDR Academic Lead
Australasian College of Cosmetic Surgery and Medicine (ACCSM)
Australian Commission on Safety and Quality in Health Care (ACSQHC)
Australian Society of Plastic Surgeons (ASPS)
Breast Surgeons of Australia and New Zealand (BreastSurgANZ)
Consumers Health Forum of Australia (CHF)
Australian Government Department of Health (Health)
Medical Technology Association of Australia (MTAA)
Therapeutic Goods Administration (TGA)

**CLINICAL LEADS**

Associate Professor Elisabeth Elder, Breast Surgeons of Australia and New Zealand Inc. (BreastSurgANZ)
Associate Professor Colin Moore, Australian College of Cosmetic Surgeons and Medicine (ACCSM)
Associate Professor Gillian Farrell, Australian Society of Plastic Surgeons (ASPS)

# EXECUTIVE SUMMARY

The Australian Breast Device Registry (ABDR) is overseen by a national Steering Committee that has broad stakeholder representation, and a Management Committee that comprises craft group representatives and the ABDR leadership team. Throughout 2020, 295 sites participated in the ABDR, representing an estimated 88% of total eligible sites. The overwhelming majority of breast device surgery reported to the ABDR occurs in private hospitals, which perform 99% of all cosmetic device procedures and 76% of reconstructive device procedures in Australia.

Australia-wide, **543 surgeons** operating at **295 hospitals** and day surgeries contributed data to the ABDR in 2020. As at 31 Dec 2020, the ABDR had collected data on **62,521 patients** having a total of **71,054 procedures** involving **132,205 devices.** The opt out rate remained low, with only 1% of patients choosing to opt out of participating in the ABDR. Seventy-three percent of registered patients had cosmetic device procedures, with the remainder being reconstructive device procedures (with 6.5% not stated). The majority of procedures were device insertions, although these have declined slightly over the last five years, and explants have increased slightly as a proportion of total procedures over this time. While the majority of overall procedures occurred in private hospitals, a higher proportion of explants were likely to be undertaken in public hospitals, compared with insertions and revisions.

In 2020, an additional 12,958 new patients were added to the ABDR. The number of reconstructive procedures in 2020, at **3,814**, was a slight reduction compared with 2019. Reconstructive device procedures include procedures following breast cancer, risk-reducing procedures, and procedures for developmental reasons. Over 50% of post-cancer and risk-reducing insertions had concurrent matrix use, as did 27% of these procedures where a tissue expander was used. Over 60% of implants used for reconstructive procedures in 2020 were smooth, with the remainder being textured implants. There has been a significant decline of approximately 50% in the use of textured implants for reconstructive surgery over the last 5 years.

In 2020, the most common complications associated with reconstructive procedures were capsular contracture (34%), device malposition (24%) and device rupture (18%). All-cause revision incidence at 5 years was 19% for risk-reducing procedures, 16% for post-cancer procedures, and 13% for developmental procedures. Revision incidence due to complications was 13%, 12% and 8% respectively. Polyurethane devices had a higher revision incidence compared to textured and smooth implants during this period. While device malposition and capsular contracture rates were lower for implants associated with matrix, the complications of deep wound infection, skin scarring and seroma/haematoma were higher. Overall, revision incidence was higher for reconstructive breast implants with matrix, compared to those without. The main complications reported with the use of tissue expanders for reconstructive procedures were deep wound infection, device rupture and device deflation.

In 2020, an additional **9,496** cosmetic procedures were captured by the ABDR. Over 64% of cosmetic implants in 2020 were smooth, with the remainder being textured. The proportion of textured implants has similarly declined by about 50% in the last 5 years. In 2020, the most common complications associated with cosmetic procedures were capsular contracture (36%), device rupture (23%) and device malposition (19%). All-cause revision incidence at 5 years was 5%, and revision incidence due to complications was 3%. Revision incidence was similar for the different types of devices, although was higher for polyurethane devices from 2019.

Data from the Macquarie University team included **112** confirmed breast implant associated anaplastic large cell lymphoma (BIA-ALCL) cases between 2007 and 2019. BIA-ALCL is a very rare cancer of the immune system; it is not breast cancer. It has excellent cure rates if detected early, and the device and surrounding capsule are surgically removed. There were 45 patients with a diagnosis of BIA-ALCL where associated procedure and device information had been captured in the ABDR as of 31 December 2020. Twenty-six of these procedures associated with BIA-ALCL were cosmetic surgeries, followed by post-cancer reconstruction surgery (18), benign/prophylactic surgery (4) and not stated (2) (a total of 50 devices from 45 patients). ABDR-reported cases showed variation in the duration of the implanted device, with the most common duration being 8-9 years from insertion to the BIA-ALCL diagnosis. The most common complications associated with BIA-ALCL revisions were seroma/haematoma. Of the 41 explanted devices that were identified, 25 had a textured shell and 12 had a polyurethane shell, with the device not being stated for 4 implants.

From October 2018 to December 2020, over 57,000 patients who had received a breast implant were contacted by the ABDR to complete a brief patient reported outcome measures (PROMs.) survey During this time there has been a decline in participant response rates, from 49-79% in 2018 to 35-55% in 2020. Response rates were higher for reconstructive procedures, and were lower at 5 years post implant. Overall, patients with cosmetic implants are more satisfied and experience less pain and tightening in their breasts than patients who had reconstructive device procedures. There was a 5-10% reduction in satisfaction (slightly lower for cosmetic compared to reconstructive patients), and a 3% increase in pain/tightness from year 1 to year 2.

For the first time in 2020, the ABDR reported three clinical quality indicators as 5-year trends; these included proportion of procedures with intra-operative antibiotic use; cumulative revision incidence at 60 days due to complications; and the proportion of patients who were satisfied with implants at one year.

The ABDR provided reports to a majority of participating surgeons and sites in 2020, that for the first time included 1-year comparative PROMs data. Four requests in 2020 were made for ABDR data, all being for research studies from Monash University researchers. The ABDR encourages secondary use of data from external stakeholders including researchers, clinicians, government agencies and industry.

# OVERVIEW OF THE AUSTRALIAN BREAST DEVICE REGISTRY

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, breast tissue expanders and matrices; 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 fifth annual report released by the ABDR in its six 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.[1] 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.

The ABDR is tasked with collecting, analysing and reporting data on all breast device surgery taking place across Australia.[1] 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.

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)[2] and Operating Principles and Technical Standards for Clinical Quality Registries (2008)[3]. It complies with all relevant standards of data security and protection, and privacy.

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). Steering Committee membership is provided on page 3. A Management Committee comprising clinician representatives and the ABDR team meets monthly to discuss and resolve issues associated with day-to-day running of the ABDR.

Importantly, the ABDR is endorsed by the three participating clinical craft groups, the Breast Surgeons of Australia and New Zealand Inc. (BreastSurgANZ); the Australian College of Cosmetic Surgery and Medicine (ACCSM); and the Australian Society of Plastic Surgeons (ASPS). Benefits to surgeons of contributing to the ABDR include the ability to track devices; the capacity to audit clinical practice; 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.

The ABDR has ethics approval from Human Research Ethics Committees (HREC) in each Australian State and Territory, and site governance approval is obtained at all sites before data is collected. To ensure high quality data, the ABDR is a patient opt out registry[4]. All patients 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 who present to participating hospitals with a participating surgeon are included in the registry. Patients can choose to opt out of the registry at anytime.

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 that is completed at the time of surgery. Since 2017, the ABDR has also administered a brief survey - the BREAST-Q IS module - to breast implant recipients at one, two and five years following insertion of a breast device regarding satisfaction and physical concerns related to their breasts[5-7].

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. The ABDR Database Coordinator also conducts regular queries over the database to find missing or incorrect data.

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. 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[8] is conducted to investigate revision incidence rates for primary reconstructive breast implants, cosmetic breast implants and matrices 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 to the first subsequent revision procedure.
- All-cause revision incidence considers all revisions captured by the registry, whether for complication reasons, patient preference or other unknown reasons.
- A revision due to complication is 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).

Crude cumulative revision incidence rates were generated using Nelson-Aalen estimates for all primary reconstructive and cosmetic breast implants captured by the ABDR from 2012 to 2020. Primary breasts without a revision procedure captured by the registry had their follow-up time censored at the date of data extraction (18 May 2021).

# REGISTRY PARTICIPATION (2012-2020)

## 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).

The total number of currently eligible private sites is estimated at 221 and eligible public sites is estimated at 91 (Table 1).

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 AND SITE TYPE

| State | Closed Sites | In Progress Sites | Eligible Private Sites | Participating Private sites | Engagement of Eligible Private Sites | Eligible Public Sites | Participating Public Sites | Engagement of Eligible Public Sites |
|---|---|---|---|---|---|---|---|---|
| NSW | 6 | 12 | 70 | 63 | 90% | 32 | 22 | 69% |
| VIC | 4 | 3 | 51 | 48 | 94% | 26 | 21 | 81% |
| QLD | 6 | 3 | 48 | 48 | 100% | 16 | 13 | 81% |
| WA | 1 | 5 | 22 | 21 | 95% | 5 | 0 | 0% |
| SA | 3 | 1 | 18 | 18 | 100% | 7 | 6 | 86% |
| ACT | 0 | 1 | 6 | 5 | 83% | 2 | 1 | 50% |
| TAS | 0 | 0 | 4 | 4 | 100% | 2 | 2 | 100% |
| NT | 0 | 0 | 2 | 2 | 100% | 1 | 1 | 100% |
| **Total** | **20** | **25** | **221** | **209** | **95%** | **91** | **66** | **73%** |

A **participating** site is defined as any site that has been granted ethics and governance approval and data collection for the registry has commenced. As of 31 December 2020, 95% (209) of eligible private sites and 73% (66) of eligible public sites, or 88% of total eligible sites were participating in the ABDR. **Engagement** is the proportion of eligible sites that are currently participating. The most common reason that eligible sites are not participating is that the implementation process has not yet been completed. Public hospitals from Western Australia are not participating, as they are currently prevented by state legislation.

The total number of participating sites throughout 2020 was 295, which included 20 sites that by the end of 2020 were classified as closed sites. Of the 295 sites, 77% were private and 23% were public hospitals, a consistent pattern across all jurisdictions (Figure 1).

**FIGURE 1:** SITE PARTICIPATION BY STATE AND SITE TYPE

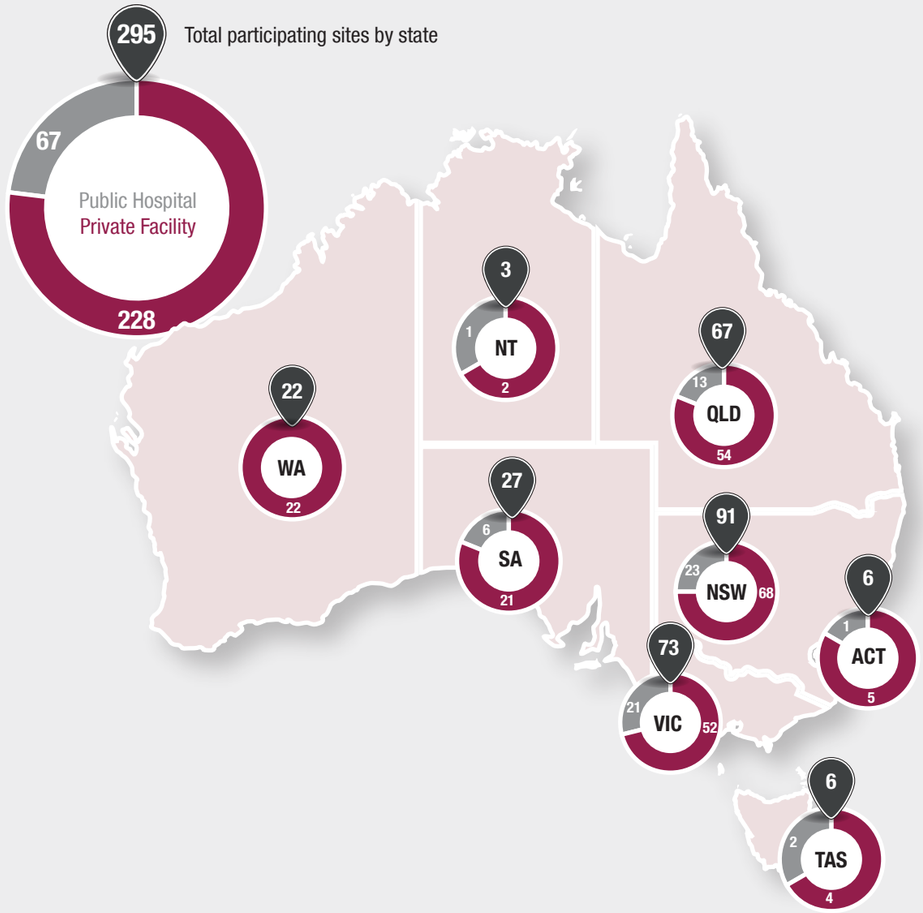


Table 2 and 3 provides the patient participation in public and private sites by site state and surgery indication. A total of 68,274 patient procedures were undertaken until 31 December 2020. Of these, **93%** (63,489) were performed in a private hospital, and **7%** (4,785) were undertaken in a public hospital. This highlights that although approximately one quarter of participating sites are public, that the vast majority of breast device procedures (both cosmetic and reconstructive) are undertaken in private hospitals. Indeed, over 99% of all cosmetic procedures were undertaken in private hospitals, as were 76% of all reconstructive procedures.

Of the procedures undertaken in private hospitals, 73% were cosmetic, 20% were reconstructive, and 7% were not stated/unknown. Of the procedures undertaken in public hospitals, 84% were reconstructive, and 16% were cosmetic/not stated. There was some variation in public/private mix for reconstructive surgery by jurisdiction.

**TABLE 2:** PATIENT PARTICIPATION IN PRIVATE SITES BY SITE STATE AND SURGERY INDICATION (2012-2020)

| State | Cosmetic | Reconstructive | Not Stated/Known | Total |
|---|---|---|---|---|
| NSW | 13,892 (30.0%) | 3,209 (24.7%) | 962 (23.1%) | 18,063 (93.5%) |
| QLD | 14,010 (30.3%) | 2,251 (17.3%) | 1,405 (33.7%) | 17,666 (93.5%) |
| VIC | 9,596 (20.7%) | 2,708 (20.8%) | 777 (18.6%) | 13,081 (90.9%) |
| WA | 5,666 (12.2%) | 2,306 (17.7%) | 694 (16.6%) | 8,666 (100.0%) |
| SA | 2,467 (5.3%) | 1,817 (14.0%) | 227 (5.4%) | 4,511 (87.0%) |
| TAS | 466 (1.0%) | 359 (2.8%) | 78 (1.9%) | 903 (83.4%) |
| ACT | 111 (0.2%) | 262 (2.0%) | 13 (0.3%) | 386 (76.0%) |
| NT | 106 (0.2%) | 91 (0.7%) | 16 (0.4%) | 213 (93.8%) |
| **Total** | **46,314** | **13,003** | **4,172** | **63,489 (93.0%)** |

**TABLE 3:** PATIENT PARTICIPATION IN PUBLIC SITES BY SITE STATE AND SURGERY INDICATION (2012-2020)

| State | Cosmetic | Reconstructive | Not Stated/Known | Total |
|---|---|---|---|---|
| NSW | 83 (24.9%) | 1,055 (26.4%) | 119 (26.1%) | 1,257 (6.5%) |
| QLD | 91 (27.2%) | 1,010 (25.3%) | 126 (27.6%) | 1,227 (6.5%) |
| VIC | 76 (22.8%) | 1,116 (27.9%) | 119 (26.1%) | 1,311 (9.1%) |
| WA | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| SA | 55 (16.5%) | 560 (14.0%) | 59 (12.9%) | 674 (13.0%) |
| TAS | 22 (6.6%) | 140 (3.5%) | 18 (3.9%) | 180 (16.6%) |
| ACT | 7 (2.1%) | 102 (2.6%) | 13 (2.9%) | 122 (24.0%) |
| NT | 0 (0.0%) | 12 (0.3%) | 2 (0.4%) | 14 (6.2%) |
| **Total** | **334** | **3,995** | **456** | **4,785 (7.0%)** |

## Surgeon Participation

At 31 December 2020, a total of 614 surgeons across the three craft groups were identified as performing breast device procedures i.e. were eligible to participate in the ABDR (Table 4). From 2012 to 2020, 543 individual surgeons participated in the ABDR including 342 plastic surgeons, 154 general surgeons and 47 cosmetic surgeons (Table 4). This totals 88% of eligible surgeons, with 93% of plastic surgeons, 87% of cosmetic surgeons and 80% of general/breast surgeons participating. Plastic surgeons are the largest participating craft group, comprising 63% of total participating surgeons (Table 4).

**TABLE 4:** SURGEON ENGAGEMENT BY STATE AND CRAFT GROUPS (2012-2020)

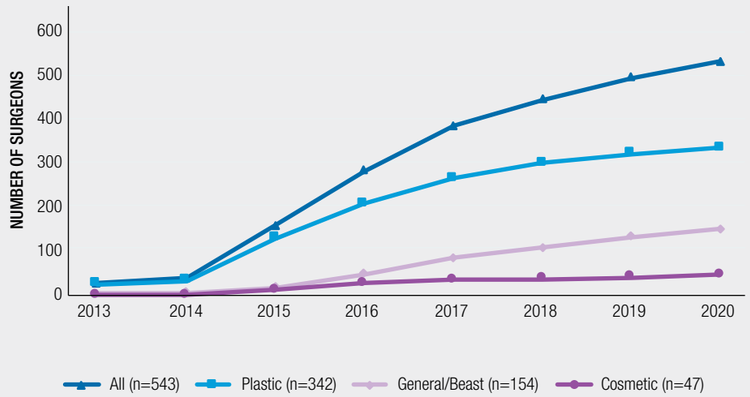
| State | Eligible Plastic surgeons | Participating Plastic surgeons | Plastic Surgeons Engagement | Eligible General/ Breasts Surgeons | Participating General/ Breasts Surgeon | General / Breasts Surgeons Engagement | Eligible Cosmetic Surgeons | Participating Cosmetic surgeons | Cosmetic Surgeons Engagement |
|---|---|---|---|---|---|---|---|---|---|
| NSW | 100 | 91 | 91% | 64 | 57 | 89% | 24 | 20 | 83% |
| VIC | 108 | 101 | 94% | 39 | 25 | 64% | 8 | 8 | 100% |
| QLD | 71 | 67 | 94% | 47 | 39 | 83% | 16 | 13 | 81% |
| WA | 41 | 37 | 90% | 19 | 13 | 68% | 4 | 4 | 100% |
| SA | 31 | 29 | 94% | 13 | 10 | 77% | 2 | 2 | 100% |
| TAS | 12 | 12 | 100% | 3 | 3 | 100% | 0 | 0 | 0% |
| ACT | 3 | 3 | 100% | 4 | 4 | 100% | 0 | 0 | 0% |
| NT | 2 | 2 | 100% | 3 | 3 | 100% | 0 | 0 | 0% |
| **Total** | **368** | **342** | **93%** | **192** | **154** | **80%** | **54** | **47** | **87%** |

**Note:** The number of participating surgeons includes surgeons who contributed data to the ABDR excluding retired surgeons.

## Timeline of Surgeon Participation

Figure 2 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 and Medicine began participating in October 2015.

**FIGURE 2:** CUMULATIVE PARTICIPATING ABDR SURGEONS BY CRAFT GROUPS




## Presentation of the Report

Due to clinical differences between patients presenting for breast reconstructive surgery and cosmetic procedures, 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: Cosmetic indications** will include cosmetic augmentation only.

Records for which the indication was not stated were excluded from further analysis in this report (Table 5). Within the two registry output sections, results have been presented for three types of surgical/procedure intervention where relevant:

- **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.
- **Revision surgery** which includes unplanned replacement or reposition procedures. The initial device insertion may or may not have also been captured by the registry. Also included are procedures involving the removal of an implant and insertion of a tissue expander.
- **Explant only surgery** which includes explant of an in-situ device without replacement, either a tissue expander or breast implant.

# REGISTRY OUTPUTS: ABDR DATA OVERVIEW

## Patient, Procedure, Device Numbers (2012 – 2020)

As at December 2020, **62,521 patients** were participating in the ABDR, an addition of **12,958** in 2020. 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=657) are not included in the reported figures.

Table 5 presents the registered patients, procedures at patient level, and procedures at breast level by indication 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 procedures. 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 procedure 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.

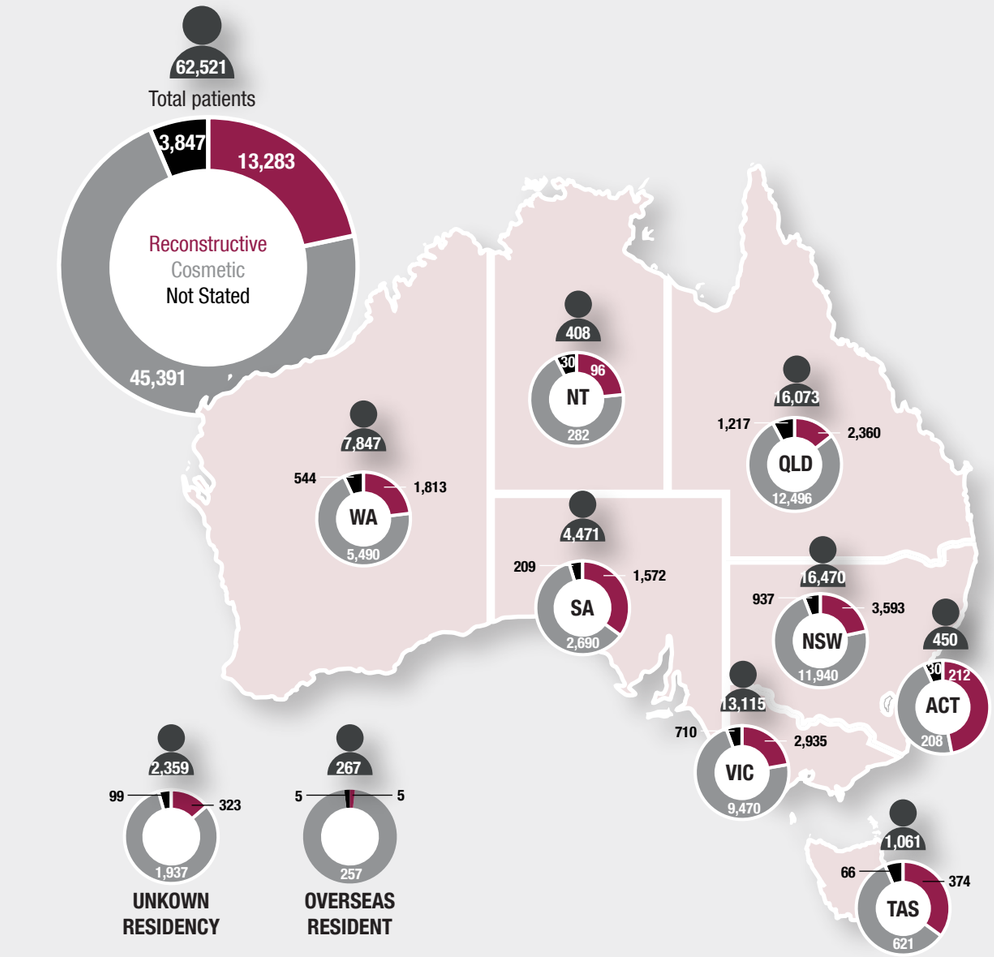
Of the 62,521 patients in the ABDR, approximately 73% entered the registry for cosmetic procedures, 16% for post-cancer reconstruction, 3% for risk-reducing reconstruction, and 2% for correction of developmental deformity. Six percent entered the registry with an indication for surgery not stated on the Data Collection Form (Table 5).

**TABLE 5.** REGISTERED PATIENTS, PROCEDURES AT PATIENT LEVEL, AND PROCEDURES AT BREAST LEVEL BY INDICATION FOR SURGERY (2012 – 2020)

| | Patients | | Procedures at Patient Level | | Procedures at Breast Level | |
|---|---|---|---|---|---|---|
| | N | (%) | N | (%) | N | (%) |
| **Reconstructive** | | | | | | |
| Post-cancer reconstruction | 9,776 | (15.6%) | 14,208 | (20.0%) | 17,981 | (13.6%) |
| Risk-reducing reconstruction | 2,089 | (3.3%) | 3,018 | (4.2%) | 8,472 | (6.4%) |
| Developmental deformity | 1,418 | (2.3%) | 1,634 | (2.3%) | 2,719 | (2.1%) |
| **Total reconstructive** | **13,283** | **(21.2%)** | **18,860** | **(26.5%)** | **29,172** | **(22.1%)** |
| **Total cosmetic** | **45,391** | **(72.6%)** | **47,539** | **(66.9%)** | **94,448** | **(71.4%)** |
| Not stated | 3,847 | (6.2%) | 4,655 | (6.6%) | 8,585 | (6.5%) |
| **Total** | **62,521** | **(100%)** | **71,054** | **(100%)** | **132,205** | **(100%)** |

Patient residency and indication at the time of entry to the registry are presented in Figure 3. Queensland has the highest proportion of its patients having cosmetic surgery, and New South Wales has the highest proportion of its patients having reconstructive surgery. Approximately 4% (2,359 patients) have unknown residency.

**FIGURE 3.** PATIENT RESIDENCY BY INDICATION (2012 – 2020)




Notes: N = 62,521 patients. This includes 267 overseas residents and 2,359 with unknown residency.

Figures 4 and 5 show a steady rise in the number of both reconstructive and cosmetic patients and procedures captured by the ABDR over the last five years. A total of **13,283 patients** had **reconstructive** surgery, comprising **18,860 total procedures**, and utilising **29,172 breast devices** from 2012-2020. A total of **45,391 patients** had **cosmetic** surgery comprising **47,539 total procedures** and utilising **94,448 breast devices** from 2012-2020.

**FIGURE 4.** REGISTERED PATIENTS, PROCEDURES AND DEVICES (2012 – 2020) - RECONSTRUCTIVE

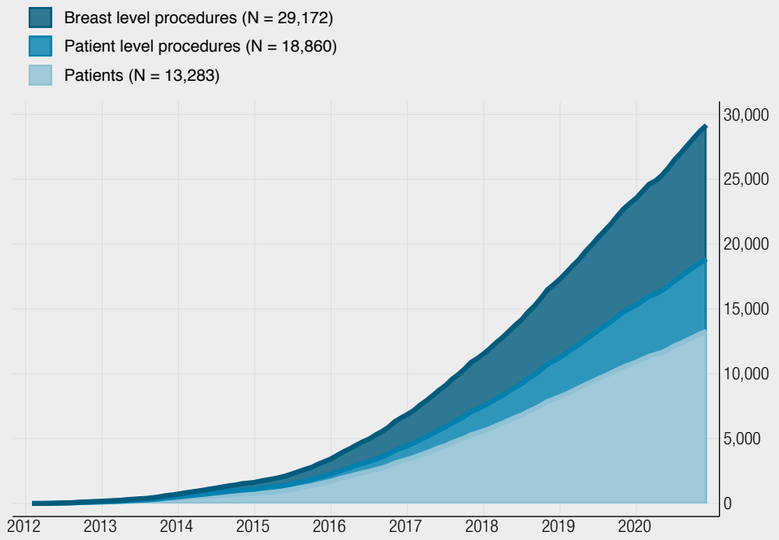
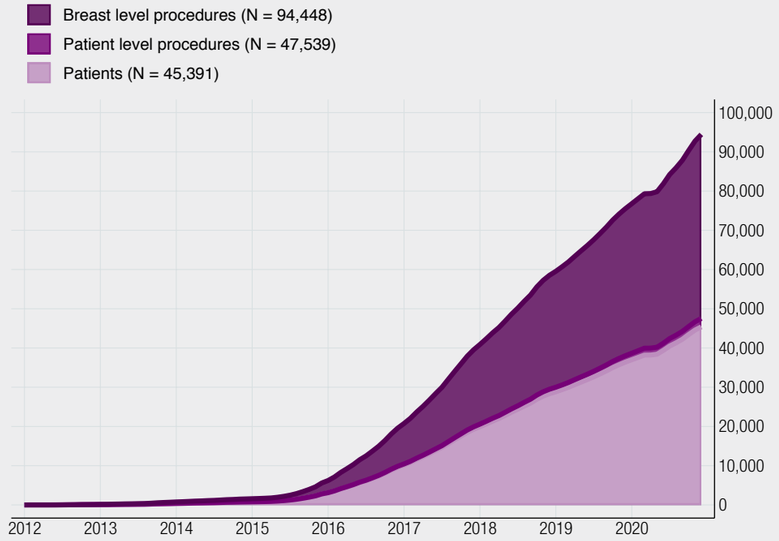



**FIGURE 5.** REGISTERED PATIENTS, PROCEDURES AND DEVICES (2012 – 2020) - COSMETIC

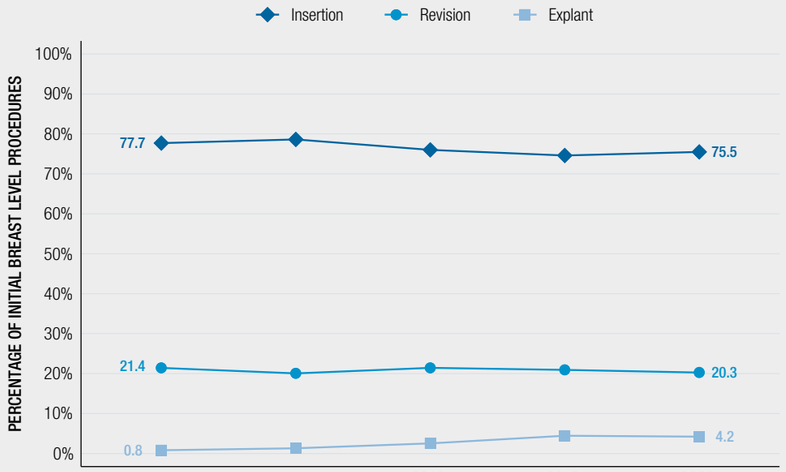





## Insertion, Revision and Explant Procedures (2012-2020)

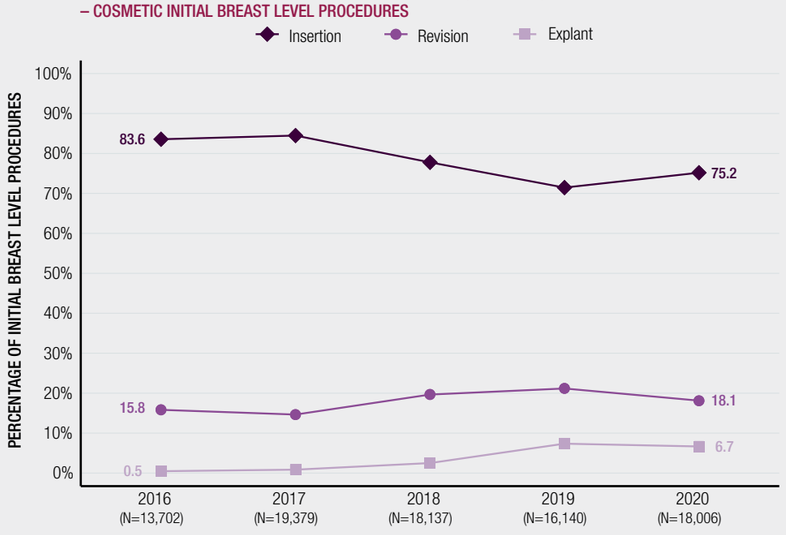
Figure 6 and Figure 7 shows the number of implant insertion, revision and explant surgery procedures over a 5-year period for both reconstructive and cosmetic initial breast level procedures. There was a 2% and 8% decrease in the proportion of initial insertion procedures for reconstructive and cosmetic procedures, respectively, from 2016 to 2020. There is increasing trend of explant procedures over the same period, with the proportion of total initial procedures for device explant rising for the reconstructive cohort (1% to 4%) and cosmetic cohort (1% to 7%) from 2016 to 2020.

**FIGURE 6:** INSERTION, REVISION AND EXPLANT SURGERY PROCEDURES OVER TIME (2016-2020) – RECONSTRUCTIVE INITIAL BREAST LEVEL PROCEDURES




Notes: Data at the breast level for the first (initial) procedure captured by the registry.
Procedures with unknown procedure type (insertion, revision or explant) have not been included.

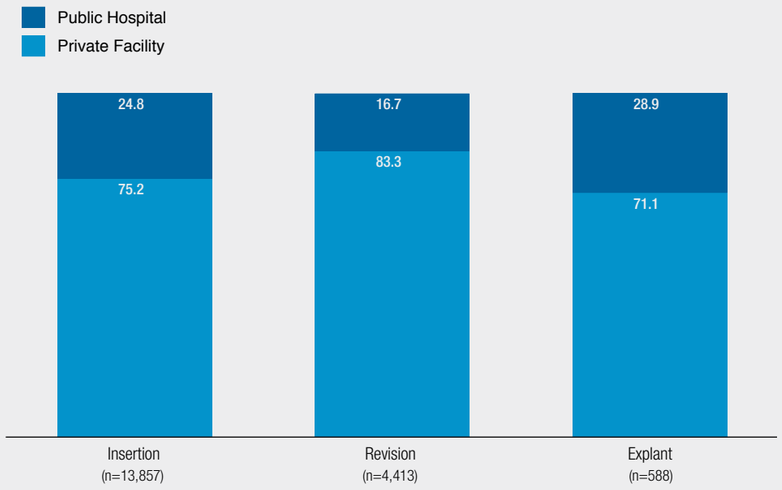
**FIGURE 7:** INSERTION, REVISION AND EXPLANT SURGERY OVER TIME (2016-2020) – COSMETIC INITIAL BREAST LEVEL PROCEDURES




Notes: Data at the breast level for the first (initial) procedure captured by the registry.
Procedures with unknown procedure type (insertion, revision or explant) have not been included.

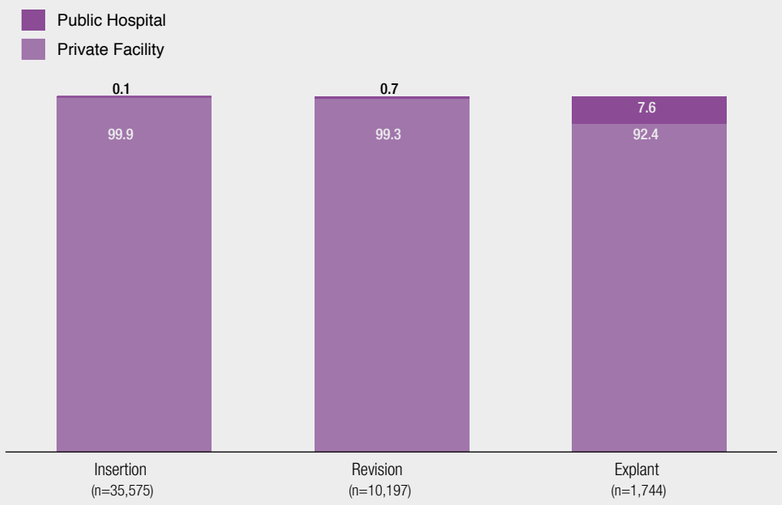
Of the reconstructive procedures, approximately 83% of revisions, 75% of insertions and 71% of explants were undertaken in private hospitals (Figure 8). Of the cosmetic procedures, approximately 99-100% of insertions and revisions were undertaken in private hospitals, as were 92% of explants (Figure 9). Overall, while the majority of surgeries were undertaken in private hospitals, a higher proportion of explants were likely to be undertaken in public hospitals compared with insertions and revisions.

**FIGURE 8.** SITE TYPE BY PROCEDURE INTERVENTION TYPE (2012-2020) – RECONSTRUCTIVE PROCEDURES




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

**FIGURE 9.** SITE TYPE BY PROCEDURE INTERVENTION TYPE (2012-2020) – COSMETIC PROCEDURES



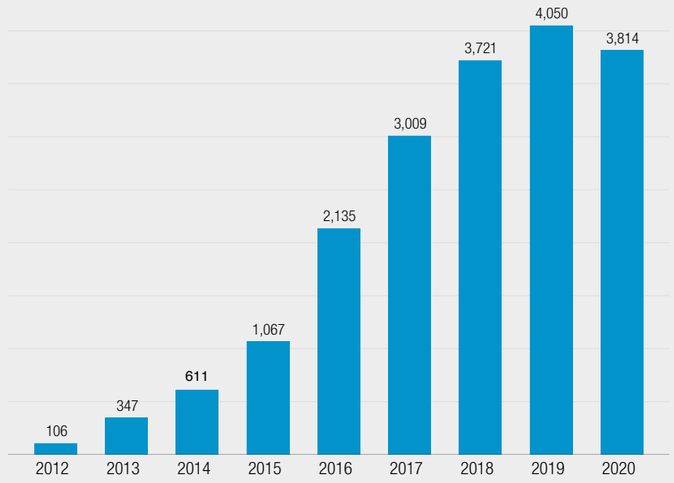

Notes: Insertion, revision and explant procedures for any indication have been analysed independently.
Both unilateral and bilateral procedures are included.
Procedures with unknown type (insertion, revision, explant) have not been included.

# REGISTRY OUTPUTS: RECONSTRUCTIVE INDICATIONS

## Reconstructive Procedure Numbers

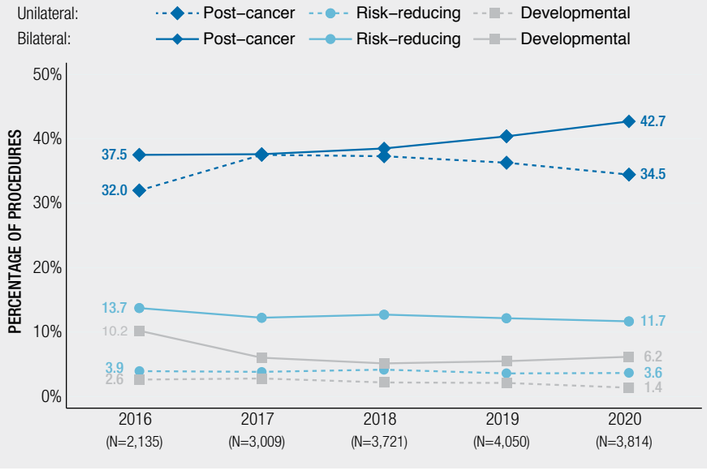
The ABDR has captured a total of **18,860 surgical procedures** involving breast devices for reconstructive surgery, including post-cancer reconstruction, risk-reducing reconstruction and developmental deformity. Figure 10 shows a steady rise in the annual number of reconstructive procedures captured in each year since registry commencement except for 2020. In 2020, **3,814** reconstructive procedures were captured as opposed to 4,050 in 2019. This may reflect some impact of the COVID-19 pandemic on elective surgery.

**FIGURE 10.** REGISTERED PROCEDURES (2012 – 2020) – RECONSTRUCTIVE PROCEDURES




Over time, the proportion of bilateral and unilateral post-cancer reconstruction procedures have slightly increased, while the proportion of bilateral and unilateral procedures for risk-reducing and developmental indications have slightly decreased (Figure 11).

**FIGURE 11.** INDICATION FOR SURGERY (2016-2020) – RECONSTRUCTIVE PROCEDURES

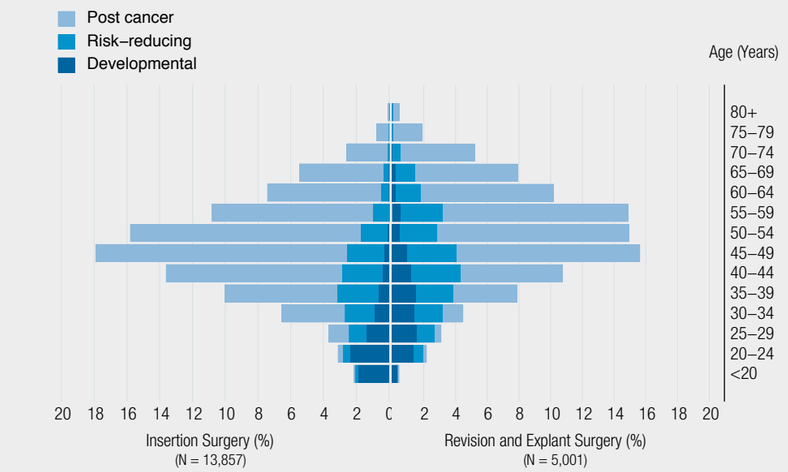



Note: A procedure indication hierarchy has been applied for bilateral procedures with different indication and procedure type details per breast.

## Patient Age at Reconstructive Procedures

The age distribution at the time of reconstructive procedure is shown in Table 6 and Figure 12. Age differences can be seen by the indication for procedure and whether the procedure involved device insertion, revision or explant. In 2012-2020, the median age for post-cancer reconstruction was approximately 50 years for insertion surgery, 54 years for revision surgery and 55 years for explant surgery. Patient age was lower for risk-reducing reconstruction and lowest for developmental deformity.

**FIGURE 12.** AGE DISTRIBUTION AT TIME OF PROCEDURE (2012 – 2020) – RECONSTRUCTIVE PROCEDURES




Notes: Insertion and revision (including explant) 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, revision or explant) have not been included.

**TABLE 6.** SUMMARY STATISTICS FOR AGE AT TIME OF PROCEDURE (2012-2020) – RECONSTRUCTIVE PROCEDURES

| | Insertion | | Revision | | Explant | |
|---|---|---|---|---|---|---|
| | N | Median (IQR) | N | Median (IQR) | N | Median (IQR) |
| Post-cancer | 10,743 | 50.1 (43.5, 57.8) | 3,062 | 54.3 (47.1, 62.4) | 401 | 55.3 (48.5, 63.0) |
| Risk-reducing | 1,978 | 42.2 (35.2, 49.9) | 897 | 47.5 (39.1, 57.5) | 143 | 43.7 (35.6, 55.3) |
| Developmental | 1,136 | 24.6 (20.3, 32.1) | 454 | 35.8 (27.3, 44.9) | 44 | 37.6 (27.4, 45.5) |
| **Total Procedures** | **13,857** | | **4,413** | | **588** | |

Notes: Insertion, revision and explant only 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, revision or explant) have not been included. The interquartile range (IQR) reports observed patient age at the 25th and 75th percentiles.

## Reconstructive Procedure Aseptic Techniques

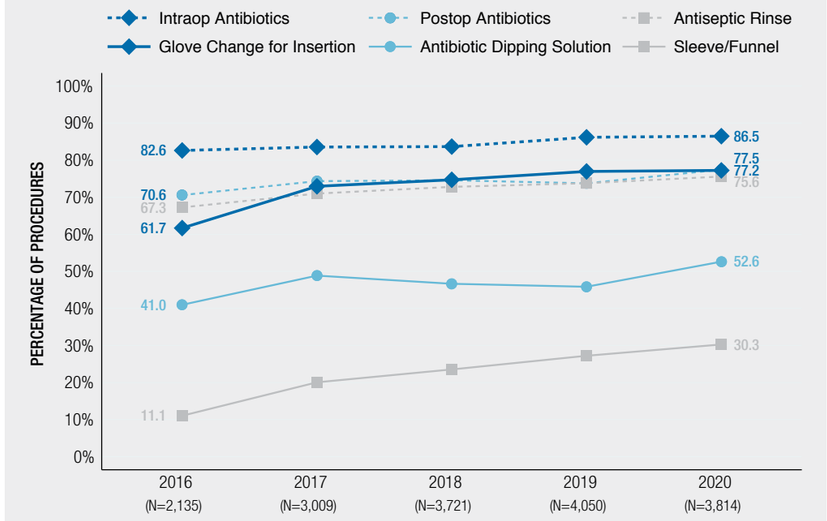
The ABDR collects data on intra-operative aseptic techniques used by contributing surgeons. More than one intra-operative technique can be used and recorded per procedure. Table 7 and Figure 13 show the intraoperative techniques used during breast reconstruction surgery. The use of intra-operative antibiotics and post-operative antibiotics are reported together for 2012-2020 as these data were not collected separately until 2015. Overall, the use of a range of aseptic techniques has increased during this period.

**TABLE 7.** INTRAOPERATIVE TECHNIQUES (2012-2020) – RECONSTRUCTIVE PROCEDURES

| | 2012-2020 | |
|---|---|---|
| | N | (%) |
| Intra-op / Post-op antibiotics | 16,317 | (86.5%) |
| Antiseptic rinse | 13,629 | (72.3%) |
| Glove change for insertion | 13,630 | (72.3%) |
| Antibiotic dipping solution | 8,621 | (45.7%) |
| Sleeve / Funnel | 4,087 | (21.7%) |
| Not stated | 2,177 | (11.5%) |
| **Total Number of Procedures** | **18,860** | |

Notes: More than one intraoperative technique can be used and recorded per procedure, row percentages are shown.

**FIGURE 13.** INTRAOPERATIVE TECHNIQUES (2016 – 2020) – RECONSTRUCTIVE PROCEDURES




Note: Information regarding intraoperative and postoperative antibiotics have been collected separately since 2015.

The registry reports details about other surgical elements and techniques used during each breast procedure. These are summarised in Table 8.

**TABLE 8.** SURGICAL ELEMENTS (2012-2020) – RECONSTRUCTIVE BREAST LEVEL PROCEDURES

| | Insertion | | Revision | | Explant | |
|---|---|---|---|---|---|---|
| | N | (%) | N | (%) | N | (%) |
| **Incision site*** | | | | | | |
| Previous mastectomy scar | 8,415 | (38.8%) | 2,565 | (38.8%) | 286 | (33.1%) |
| Inframammary | 7,086 | (32.7%) | 2,980 | (45.0%) | 235 | (27.2%) |
| Areola | 2,316 | (10.7%) | 232 | (3.5%) | 20 | (2.3%) |
| Mastopexy/ reduction scar | 1,906 | (8.8%) | 419 | (6.3%) | 84 | (9.7%) |
| Axillary | 178 | (0.8%) | 22 | (0.3%) | 7 | (0.8%) |
| Other | 1,056 | (4.9%) | 70 | (1.1%) | 10 | (1.2%) |
| Not stated | 1,306 | (6.0%) | 505 | (7.6%) | 243 | (28.2%) |
| **Surgical plane** | | | | | | |
| Sub-pectoral/ Dual plane | 13,561 | (62.5%) | 3,629 | (54.9%) | - | - |
| Sub-flap | 1,918 | (8.8%) | 629 | (9.5%) | - | - |
| Sub-glandular/ sub-fascial** | 2,072 | (9.6%) | 863 | (13.0%) | - | - |
| Other | 763 | (3.5%) | 62 | (0.9%) | - | - |
| Not stated | 3,377 | (15.6%) | 1,433 | (21.7%) | - | - |
| **Axillary surgery** | | | | | | |
| Yes | 4,217 | (19.4%) | 175 | (2.6%) | 12 | (1.4%) |
| **Concurrent mastectomy** | | | | | | |
| Yes | 8,278 | (38.2%) | 265 | (4.0%) | 26 | (3.0%) |
| **Concurrent mastopexy** | | | | | | |
| Yes | 1,458 | (6.7%) | 406 | (6.1%) | 83 | (9.6%) |
| **Flap cover** | | | | | | |
| Yes | 2,114 | (9.7%) | 253 | (3.8%) | 63 | (7.3%) |
| **Previous mastopexy** | | | | | | |
| Yes | 640 | (3.0%) | 398 | (6.0%) | 35 | (4.1%) |
| **Fat grafting** | | | | | | |
| Yes | 1,099 | (5.1%) | 946 | (14.3%) | 38 | (4.4%) |
| **Drain use** | | | | | | |
| Yes | 11,819 | (54.5%) | 3,118 | (47.1%) | 381 | (44.1%) |
| **Nipple guard** | | | | | | |
| Yes | 3,439 | (15.9%) | 1,470 | (22.2%) | 34 | (3.9%) |
| **Nipple absent** | | | | | | |
| Yes | 10,167 | (46.9%) | 2,417 | (36.5%) | 202 | (23.4%) |
| **Nipple sparing** | | | | | | |
| Yes | 5,197 | (24.0%) | 1,202 | (18.2%) | 83 | (9.6%) |
| **Total Procedures** | **21,691** | | **6,616** | | **863** | |

Notes: Details are at the breast procedure level. Insertion, revision and explant only procedures have been analysed independently.
Procedures with unknown procedure type (insertion, revision or explant) have not been included.
*More than one incision site can be recorded, row percentages are shown.
**This includes sub-cutaneous placement after mastectomy.

## Matrix Use in Reconstructive Breast Level Procedures

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 9 reports matrix usage during reconstructive surgery involving breast implants and tissue expanders. Matrix was used during 53% of direct-to-implant insertions for post-cancer reconstruction, 55% of risk-reducing reconstructions and 0.1% of surgeries for developmental deformity. Additionally, matrix usage during reconstructive procedures involving the insertion of tissue expanders was 27% for both post-cancer and risk-reducing reconstructions. Matrix was not used in the procedures involving tissue expanders for developmental reconstruction.

**TABLE 9.** MATRIX USE (2012-2020) – RECONSTRUCTIVE BREAST LEVEL PROCEDURES

| | Total number of procedures (N) | Number of procedures with matrix use (N) | Proportion of procedures with matrix use (%) |
|---|---|---|---|
| **BREAST IMPLANTS** | | | |
| **Direct to implant insertion** | | | |
| Post-cancer | 3,288 | 1,754 | (53.3%) |
| Risk-reducing | 2,172 | 1,194 | (55.0%) |
| Developmental | 1,679 | 1 | (0.1%) |
| **Total** | **7,139** | **2,949** | **(41.3%)** |
| **Two-stage insertion*** | | | |
| Post-cancer | 5,386 | 131 | (2.4%) |
| Risk-reducing | 1,903 | 43 | (2.3%) |
| Developmental | 146 | 0 | (0.0%) |
| **Total** | **7,435** | **174** | **(2.3%)** |
| **Revision (not explant)** | | | |
| Post-cancer | 3,738 | 312 | (8.3%) |
| Risk-reducing | 1,823 | 163 | (8.9%) |
| Developmental | 722 | 20 | (2.8%) |
| **Total** | **6,283** | **495** | **(7.9%)** |
| **TISSUE EXPANDER** | | | |
| **Insertion** | | | |
| Post-cancer | 4,793 | 1,280 | (26.7%) |
| Risk-reducing | 2,219 | 607 | (27.4%) |
| Developmental | 105 | 0 | (0.0%) |
| **Total** | **7,117** | **1,887** | **(26.5%)** |
| **Revision (not explant)** | | | |
| Post-cancer | 271 | 27 | (10.0%) |
| Risk-reducing | 62 | 4 | (6.5%) |
| Developmental | 0 | 0 | (0.0%) |
| **Total** | **333** | **31** | **(9.3%)** |
| **Total Procedures** | **28,307** | **5,536** | **(19.6%)** |

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



## Device Characteristics for Breast Reconstruction

The registry captures information about breast devices (breast implants, tissue expanders and matrices) used during procedures in Australia. Table 10 provides information regarding device shell/texture, shape, and fill characteristics for breast implants and tissue expanders used for breast reconstruction during an insertion procedure or a replacement revision procedure. Of the reconstructive breast implants used, 62% were textured, 36% were smooth and 2% polyurethane. More than half of the breast reconstructive implants were shaped/anatomical (52%) followed by round implants (47%). In terms of device fill for reconstructive breast implants, 97.5% were silicone filled, 1.5% silicone/saline filled and <1% with saline.

The majority of tissue expanders were textured, with less than 1% having a smooth shell. In addition, the majority of tissue expanders were shaped/anatomical with less than 1% being round. More than 90% of tissue expanders were silicone filled and 8% filled with carbon dioxide.

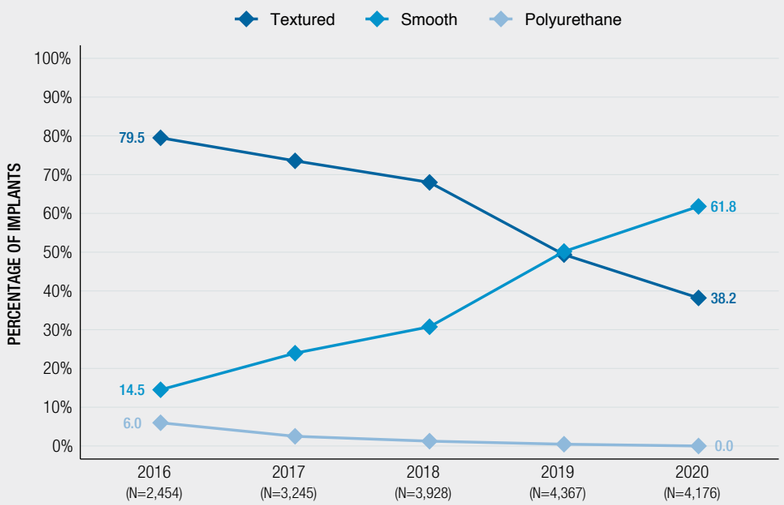
**TABLE 10.** DEVICE CHARACTERISTICS (2012-2020) – RECONSTRUCTIVE BREAST DEVICES

| | Implant | | Tissue Expander | |
|---|---|---|---|---|
| | N | (%) | N | (%) |
| **Shell/ Texture** | | | | |
| Textured | 12,766 | (62.3%) | 7,601 | (99.6%) |
| Smooth | 7,299 | (35.6%) | 11 | (0.1%) |
| Polyurethane | 381 | (1.9%) | - | - |
| Not stated | 38 | (0.2%) | 16 | (0.2%) |
| **Shape** | | | | |
| Round | 9,703 | (47.4%) | 16 | (0.2%) |
| Shaped/anatomical | 10,738 | (52.4%) | 7,596 | (99.6%) |
| Not stated | 43 | (0.2%) | 16 | (0.2%) |
| **Fill** | | | | |
| Silicone | 19,982 | (97.5%) | - | - |
| Saline | 163 | (0.8%) | 6,973 | (91.4%) |
| Silicone/ Saline | 301 | (1.5%) | - | - |
| Carbon dioxide | | | 639 | (8.4%) |
| Not stated | 38 | (0.2%) | 16 | (0.2%) |
| **Total Devices** | **20,484** | **100** | **7,628** | **100** |

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

Figure 14 and Figure 15 provide the trends in device shell/texture and shape use from 2016 to 2020. For the reconstructive cohort, from 2016 to 2020 there has been a substantial decrease in use of textured implants from 80% to 38% and polyurethane implants from 6% to 0%. This trend reflects the changes in use of textured implants preceding and since the TGA action to suspend some textured implants in 2019. Over the same period, the use of smooth implants have increased from 15% to 62%.

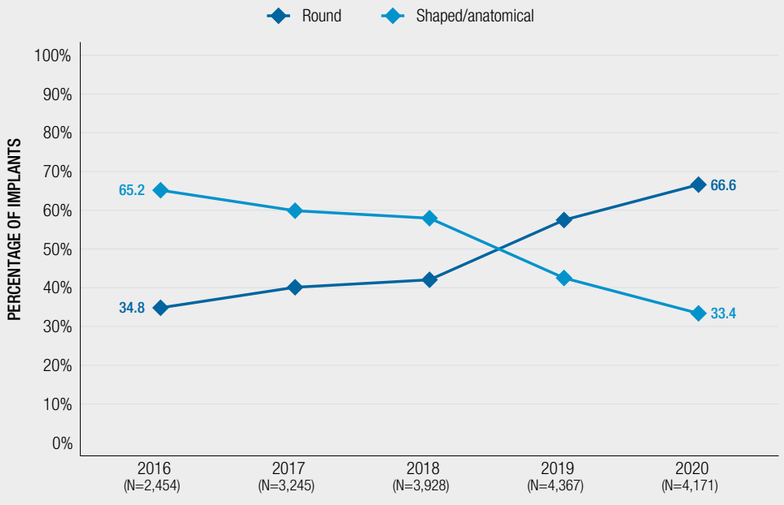
**FIGURE 14.** DEVICE SHELL (2016-2020) – RECONSTRUCTIVE IMPLANTS




Notes: Device texture is reported for new implants during an insertion procedure or a replacement revision procedure. Implants with an unknown shell type have not been included.

Shaped/anatomical implant use has reduced from approximately 65% to 33%, reflective of the fact that textured implants are generally shaped/anatomical.

**FIGURE 15.** DEVICE SHAPE (2016-2020) – RECONSTRUCTIVE IMPLANTS




Notes: Device shape is reported for new implants during an insertion procedure or a replacement revision procedure. Implants with an unknown shape have not been included.



## 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 11 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. 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. In 2020, capsular contracture was the most common issue identified and reported at approximately 34% of reconstructive breast implant revisions, followed by device malposition reported at 24% of revisions and device rupture reported at 18% of revisions. This pattern has remained relatively stable over time.

**TABLE 11.** ISSUES IDENTIFIED AT REVISION PROCEDURE – RECONSTRUCTIVE BREAST IMPLANTS

| Complications and issues identified at revision (N.B. Not complication rates) | 2012-2020 | | 2020 | |
|---|---|---|---|---|
| | N | (%) | N | (%) |
| Capsular contracture | 2,578 | (38.0%) | 541 | (34.4%) |
| Device malposition | 2,024 | (29.8%) | 369 | (23.5%) |
| Device rupture | 1,075 | (15.8%) | 282 | (17.9%) |
| Device deflation | 485 | (7.1%) | 107 | (6.8%) |
| Skin scarring problems | 482 | (7.1%) | 122 | (7.8%) |
| Seroma/ haematoma | 283 | (4.2%) | 65 | (4.1%) |
| Deep wound infection | 187 | (2.8%) | 42 | (2.7%) |
| **Total Revision Procedures** | **6,789** | | **1,572** | |

Notes: Listed in order of frequency are issues identified during reconstructive breast implant revision (including explant) 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 16 provides an all-cause revision incidence curve for the three reconstructive indications. At 5-year after the date of primary implant insertion, 16% of implants for post-cancer reconstruction were revised, 19% of implants for risk-reducing reconstruction and 13% of primary implants used for developmental deformity were revised.

**FIGURE 16.** ALL-CAUSE REVISION INCIDENCE BY INDICATION – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS

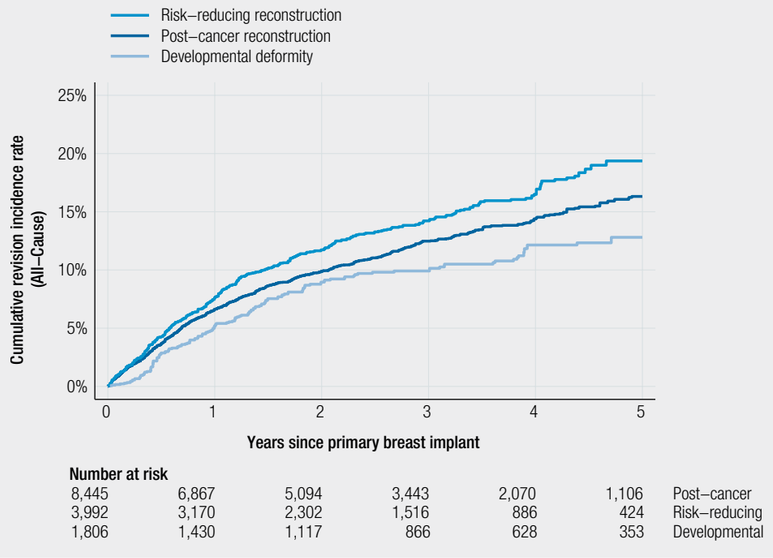
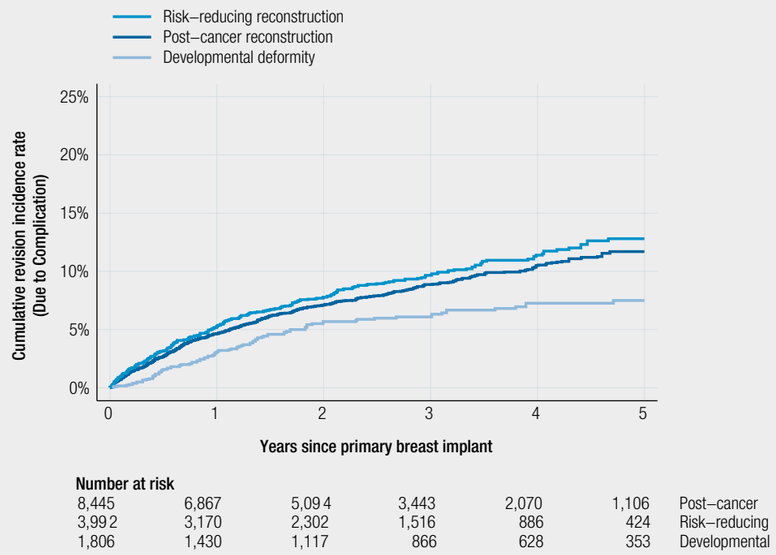


Figure 17 provides revision incidence due to complication curves for the three reconstructive indications. At 5-year after the date of primary implant insertion, revision incidence due to complication was 12% for post-cancer reconstruction implants, 13% for risk-reducing reconstruction implants and 8% for primary implants inserted for developmental deformity.

**FIGURE 17.** REVISION INCIDENCE DUE TO COMPLICATION BY INDICATION – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS




Revision incidence rates for reconstructive procedures due to different complications issues identified at time intervals after the date of implant insertion are reported in Table 12. The most common complications requiring revision were device malposition (approximately 5% at 5 years) and capsular contracture (approximately 5% at 5 years). Other complications had a lower 5-year incidence.

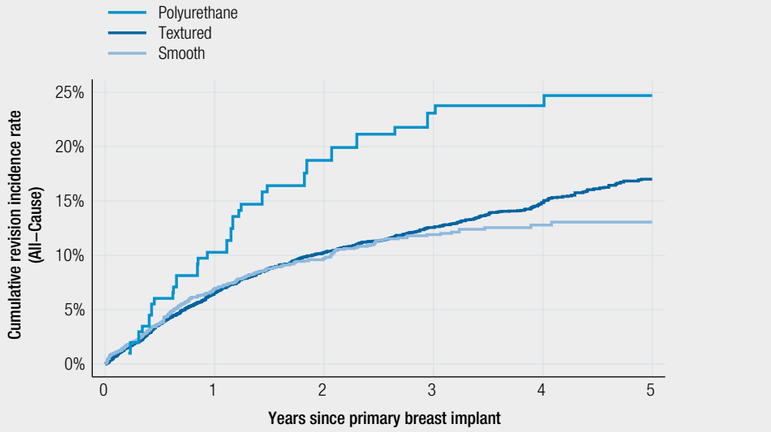
**TABLE 12.** REVISION INCIDENCE BY SPECIFIC COMPLICATION – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS

| | N | N | Revision Incidence | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Primary Breast Implants | Revised | 1 Year | | 2 Years | | 3 Years | | 4 Years | | 5 Years | |
| | | | N | RI | N | RI | N | RI | N | RI | N | RI |
| **Revision due to device malposition** | | | | | | | | | | | | |
| Post-cancer | 8,445 | 271 | 6,867 | 1.7% | 5,094 | 2.8% | 3,443 | 3.8% | 2,070 | 4.5% | 1,106 | 4.8% |
| Risk-reducing | 3,992 | 147 | 3,170 | 2.2% | 2,302 | 3.6% | 1,516 | 4.7% | 886 | 4.9% | 424 | 5.4% |
| Developmental | 1,806 | 53 | 1,430 | 1.4% | 1,117 | 3.0% | 866 | 3.2% | 628 | 4.0% | 353 | 4.3% |
| **Total** | **14,243** | **471** | **11,467** | **1.8%** | **8,513** | **3.1%** | **5,825** | **3.9%** | **3,584** | **4.6%** | **1,883** | **4.9%** |
| **Revision due to capsular contracture** | | | | | | | | | | | | |
| Post-cancer | 8,445 | 264 | 6,867 | 1.3% | 5,094 | 2.5% | 3,443 | 3.5% | 2,070 | 4.4% | 1,106 | 5.0% |
| Risk-reducing | 3,992 | 117 | 3,170 | 1.2% | 2,302 | 2.2% | 1,516 | 2.9% | 886 | 4.3% | 424 | 5.5% |
| Developmental | 1,806 | 44 | 1,430 | 1.1% | 1,117 | 2.4% | 866 | 2.5% | 628 | 3.3% | 353 | 3.3% |
| **Total** | **14,243** | **425** | **11,467** | **1.3%** | **8,513** | **2.4%** | **5,825** | **3.2%** | **3,584** | **4.2%** | **1,883** | **4.9%** |
| **Revision due to device deflation/rupture** | | | | | | | | | | | | |
| Post-cancer | 8,445 | 45 | 6,867 | 0.2% | 5,094 | 0.3% | 3,443 | 0.4% | 2,070 | 0.7% | 1,106 | 1.0% |
| Risk-reducing | 3,992 | 16 | 3,170 | 0.2% | 2,302 | 0.4% | 1,516 | 0.5% | 886 | 0.5% | 424 | 0.5% |
| Developmental | 1,806 | 11 | 1,430 | 0.1% | 1,117 | 0.4% | 866 | 0.5% | 628 | 0.9% | 353 | 0.9% |
| **Total** | **14,243** | **72** | **11,467** | **0.2%** | **8,513** | **0.4%** | **5,825** | **0.5%** | **3,584** | **0.7%** | **1,883** | **0.8%** |
| **Revision due to skin scarring** | | | | | | | | | | | | |
| Post-cancer | 8,445 | 87 | 6,867 | 0.7% | 5,094 | 0.9% | 3,443 | 1.2% | 2,070 | 1.4% | 1,106 | 1.4% |
| Risk-reducing | 3,992 | 57 | 3,170 | 1.1% | 2,302 | 1.3% | 1,516 | 1.6% | 886 | 1.8% | 424 | 1.8% |
| Developmental | 1,806 | 8 | 1,430 | 0.1% | 1,117 | 0.5% | 866 | 0.5% | 628 | 0.7% | 353 | 0.7% |
| **Total** | **14,243** | **152** | **11,467** | **0.7%** | **8,513** | **1.0%** | **5,825** | **1.2%** | **3,584** | **1.4%** | **1,883** | **1.4%** |
| **Revision due to seroma/haematoma** | | | | | | | | | | | | |
| Post-cancer | 8,445 | 53 | 6,867 | 0.6% | 5,094 | 0.6% | 3,443 | 0.7% | 2,070 | 0.7% | 1,106 | 0.7% |
| Risk-reducing | 3,992 | 38 | 3,170 | 0.8% | 2,302 | 0.9% | 1,516 | 1.0% | 886 | 1.1% | 424 | 1.3% |
| Developmental | 1,806 | 7 | 1,430 | 0.4% | 1,117 | 0.4% | 866 | 0.4% | 628 | 0.4% | 353 | 0.4% |
| **Total** | **14,243** | **98** | **11,467** | **0.6%** | **8,513** | **0.7%** | **5,825** | **0.7%** | **3,584** | **0.8%** | **1,883** | **0.8%** |
| **Revision due to deep wound infection** | | | | | | | | | | | | |
| Post-cancer | 8,445 | 92 | 6,867 | 1.0% | 5,094 | 1.1% | 3,443 | 1.1% | 2,070 | 1.2% | 1,106 | 1.2% |
| Risk-reducing | 3,992 | 41 | 3,170 | 1.0% | 2,302 | 1.0% | 1,516 | 1.1% | 886 | 1.1% | 424 | 1.1% |
| Developmental | 1,806 | 7 | 1,430 | 0.4% | 1,117 | 0.4% | 866 | 0.4% | 628 | 0.4% | 353 | 0.4% |
| **Total** | **14,243** | **140** | **11,467** | **0.9%** | **8,513** | **1.0%** | **5,825** | **1.0%** | **3,584** | **1.1%** | **1,883** | **1.1%** |

Notes: Revision incidence is based on reconstructive primary breast implants inserted from 2012 to 2020. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary implant insertion date to the first revision procedure. Time to revision was censored at data extract date for non-revised implants.

Figure 18 provides the all-cause revision incidence for reconstructive implants by shell characteristics. The all-cause revision incidence rate at five-years since primary implant insertion was approximately 25% for polyurethane implants, 17% for textured implants and 13% for smooth implants. The higher incidence of all-cause revisions for polyurethane implants at five-years may be due to women having these devices removed following TGA device recall in 2019.

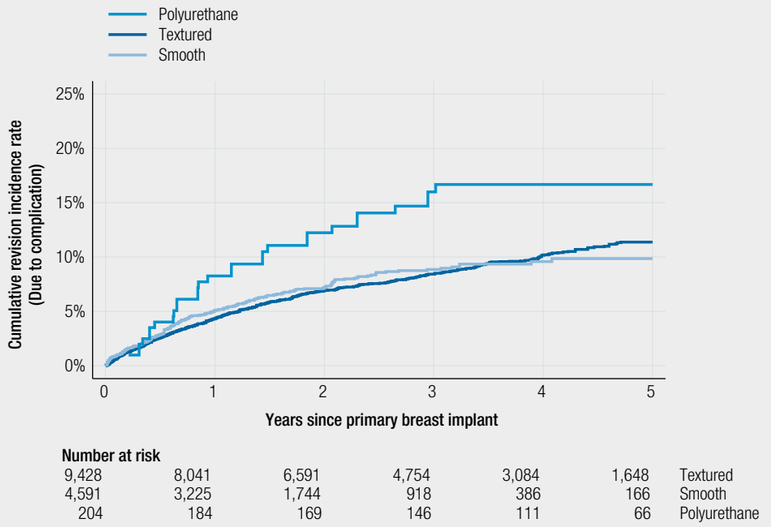
**FIGURE 18.** ALL-CAUSE REVISION INCIDENCE BY SHELL – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS




Note: Implants with an unknown shell have not been included.

Figure 19 provides the revision incidence due to complications for reconstructive primary implants by shell characteristics. The revision due to complication incidence rate at five-years since primary implant insertion was 17% for polyurethane implants, 11% for textured implants and 10% for smooth implants.

**FIGURE 19.** REVISION INCIDENCE DUE TO COMPLICATION BY SHELL – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS




Note: Implants with an unknown shell have not been included.

Table 13 shows the revision incidence rate for different complications identified for reconstructive primary breast implants by shell type. The highest proportion of specific complications was device malposition for polyurethane implants, which had an 8.4% 5-year incidence, compared with devices having textured and smooth shells that had an average of approximately 5% incidence at 5 years. Polyurethane implants also had a higher 5-year incidence of device deflation/rupture (2.3%), compared with textured and smooth implants (<1%), and a higher 5-year incidence of seroma/haematoma and skin scarring.

**TABLE 13.** REVISION INCIDENCE FROM SPECIFIC COMPLICATIONS BY DEVICE SHELL – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS

| | N | N | Revision Incidence | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Primary Breast Implants | Revised | 1 Year | | 2 Years | | 3 Years | | 4 Years | | 5 Years | |
| | | | N | RI | N | RI | N | RI | N | RI | N | RI |
| **Revision due to device malposition** | | | | | | | | | | | | |
| Textured | 9,428 | 303 | 8,041 | 1.6% | 6,591 | 2.7% | 4,754 | 3.4% | 3,084 | 4.1% | 1,648 | 4.5% |
| Smooth | 4,591 | 153 | 3,225 | 2.3% | 1,744 | 3.9% | 918 | 4.9% | 386 | 5.0% | 166 | 5.3% |
| Polyurethane | 204 | 15 | 184 | 4.0% | 169 | 5.2% | 146 | 8.4% | 111 | 8.4% | 66 | 8.4% |
| **Total** | **14,223** | **471** | **11,450** | **1.8%** | **8,504** | **3.1%** | **5,818** | **3.9%** | **3,581** | **4.6%** | **1,880** | **4.9%** |
| **Revision due to capsular contracture** | | | | | | | | | | | | |
| Textured | 9,428 | 350 | 8,041 | 1.4% | 6,591 | 2.8% | 4,754 | 3.5% | 3,084 | 4.6% | 1,648 | 5.3% |
| Smooth | 4,591 | 66 | 3,225 | 1.0% | 1,744 | 1.5% | 918 | 2.1% | 386 | 2.8% | 166 | 3.0% |
| Polyurethane | 204 | 9 | 184 | 2.6% | 169 | 3.2% | 146 | 4.4% | 111 | 5.1% | 66 | 5.1% |
| **Total** | **14,223** | **425** | **11,450** | **1.3%** | **8,504** | **2.4%** | **5,818** | **3.2%** | **3,581** | **4.2%** | **1,880** | **4.9%** |
| **Revision due to device deflation/rupture** | | | | | | | | | | | | |
| Textured | 9,428 | 53 | 8,041 | 0.2% | 6,591 | 0.3% | 4,754 | 0.4% | 3,084 | 0.6% | 1,648 | 0.8% |
| Smooth | 4,591 | 15 | 3,225 | 0.2% | 1,744 | 0.4% | 918 | 0.4% | 386 | 0.6% | 166 | 0.6% |
| Polyurethane | 204 | 4 | 184 | 0.5% | 169 | 1.6% | 146 | 2.3% | 111 | 2.3% | 66 | 2.3% |
| **Total** | 14,223 | 72 | 11,450 | 0.2% | 8,504 | 0.4% | 5,818 | 0.5% | 3,581 | 0.7% | 1,880 | 0.8% |
| **Revision due to skin scarring** | | | | | | | | | | | | |
| Textured | 9,428 | 91 | 8,041 | 0.6% | 6,591 | 0.8% | 4,754 | 1.0% | 3,084 | 1.2% | 1,648 | 1.2% |
| Smooth | 4,591 | 57 | 3,225 | 1.0% | 1,744 | 1.3% | 918 | 1.7% | 386 | 1.8% | 166 | 1.8% |
| Polyurethane | 204 | 4 | 184 | 1.0% | 169 | 1.6% | 146 | 1.6% | 111 | 2.3% | 66 | 2.3% |
| **Total** | **14,223** | **152** | **11,450** | **0.7%** | **8,504** | **1.0%** | **5,818** | **1.2%** | **3,581** | **1.4%** | **1,880** | **1.4%** |
| **Revision due to seroma/haematoma** | | | | | | | | | | | | |
| Textured | 9,428 | 60 | 8,041 | 0.5% | 6,591 | 0.6% | 4,754 | 0.7% | 3,084 | 0.7% | 1,648 | 0.8% |
| Smooth | 4,591 | 30 | 3,225 | 0.7% | 1,744 | 0.7% | 918 | 0.7% | 386 | 0.7% | 166 | 0.7% |
| Polyurethane | 204 | 8 | 184 | 3.1% | 169 | 3.1% | 146 | 4.3% | 111 | 4.3% | 66 | 4.3% |
| **Total** | **14,223** | **98** | **11,450** | **0.6%** | **8,504** | **0.7%** | **5,818** | **0.7%** | **3,581** | **0.8%** | **1,880** | **0.8%** |
| **Revision due to deep wound infection** | | | | | | | | | | | | |
| Textured | 9,428 | 92 | 8,041 | 0.9% | 6,591 | 1.0% | 4,754 | 1.0% | 3,084 | 1.1% | 1,648 | 1.1% |
| Smooth | 4,591 | 46 | 3,225 | 1.0% | 1,744 | 1.0% | 918 | 1.1% | 386 | 1.1% | 166 | 1.1% |
| Polyurethane | 204 | 2 | 184 | 0.5% | 169 | 0.5% | 146 | 0.5% | 111 | 1.2% | 66 | 1.2% |
| **Total** | **14,223** | **140** | **11,450** | **0.9%** | **8,504** | **1.0%** | **5,818** | **1.0%** | **3,581** | **1.1%** | **1,880** | **1.1%** |

Notes: Revision incidence is based on reconstructive primary breast implants inserted from 2012 to 2020. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary implant insertion date to the first revision procedure. Time to revision was censored at data extract date for non-revised implants. Implants with an unknown device shell have not been included.

## Complications and Revision Incidence – Device with Matrix Use at Revision Procedure

The registry collects details of issues and complications that are found at the time of a revision procedure for primary implants inserted with matrix use. Revision surgery includes the unplanned replacement, reposition or explant of an in-situ breast device. Table 14 reports the issues identified at revision procedure of devices with and without matrix use accompanying insertion of primary reconstructive breast implants. 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. While device malposition and capsular contracture were lower for implants inserted with matrix (25.5% vs 30.5%; 22.1 vs 25.6%), all other complications were higher – particularly deep wound infection (18.7% vs 5.6%), skin scarring (11.9% vs 8.9%) and seroma/haematoma (11.4% vs 3.8%).

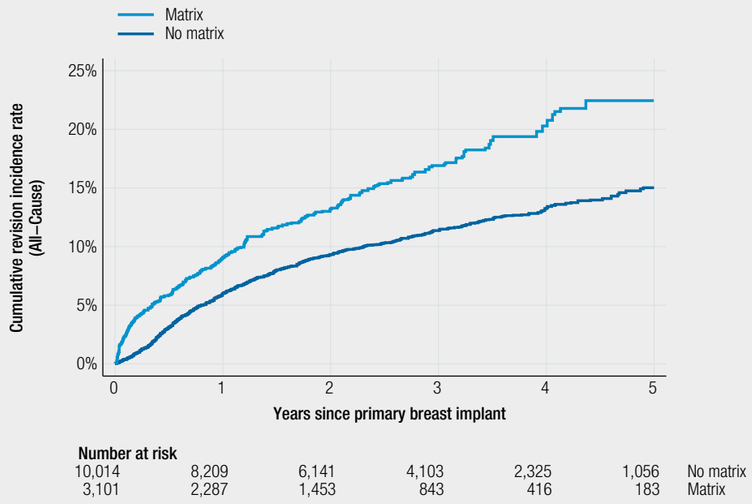
**TABLE 14.** ISSUES IDENTIFIED AT REVISION PROCEDURE OF IMPLANTS INSERTED WITH AND WITHOUT MATRIX – RECONSTRUCTIVE BREAST IMPLANTS

| Complications and issues identified at revision (N.B. Not complication rates) | Primary implant (without Matrix use at insertion) revisions | | Primary implant (with Matrix use at insertion) revisions | |
|---|---|---|---|---|
| | N | (%) | N | (%) |
| Device malposition | 319 | (30.5%) | 105 | (25.5%) |
| Capsular contracture | 268 | (25.6%) | 91 | (22.1%) |
| Skin scarring problems | 93 | (8.9%) | 49 | (11.9%) |
| Deep wound infection | 59 | (5.6%) | 77 | (18.7%) |
| Seroma/Haematoma | 40 | (3.8%) | 47 | (11.4%) |
| Device rupture | 40 | (3.8%) | 8 | (1.9%) |
| Device deflation | 24 | (2.3%) | 6 | (1.5%) |
| **Total Revision Procedures** | **1,047** | | **411** | |

Notes: Listed in order of frequency are issues identified during reconstructive primary breast implant revision (including explant) 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. Revision procedures of primary implant procedures with unknown matrix use at insertion have not been included.

Figure 20 provides an all-cause revision incidence curve for reconstructive primary breast implants by matrix use. At five-years after insertion, 22% of the implants with matrix and 15% without matrix use had been revised.

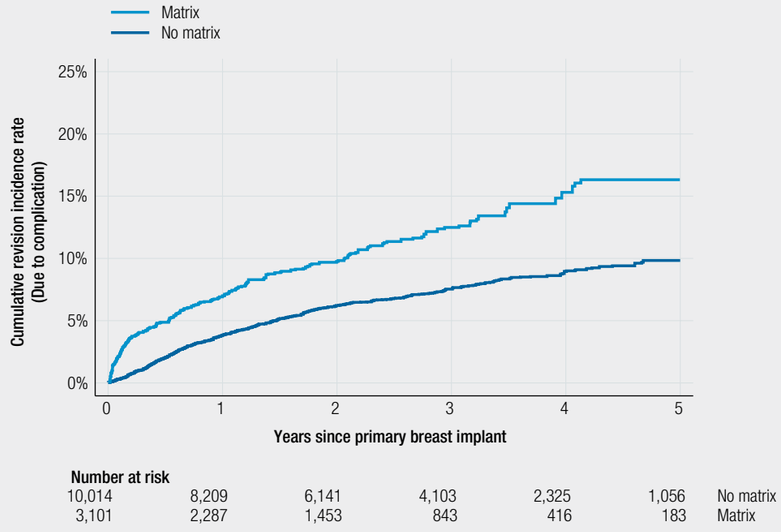
**FIGURE 20.** ALL-CAUSE REVISION INCIDENCE BY MATRIX USE – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS




Note: Implants with unknown matrix use have not been included.

Figure 21 provides a revision due to complication incidence curve for reconstructive primary breast implants by matrix use. At five-years after insertion 16% of the implants with matrix use and 9% without matrix use had been revised due to complications.

**FIGURE 21.** REVISION DUE TO COMPLICATION INCIDENCE BY MATRIX USE – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS




Note: Implants with unknown matrix use have not been included.

Revision incidence rates due to specific complications identified at time intervals following primary implant insertion with and without matrix use are reported in Table 15. All of the specific complications had a higher incidence rate for implants associated with matrix compared to implants alone, except for device deflation/rupture which had a lower incidence for implants inserted with matrix. The highest revision incidence overall was 6.8% at 5-years due to capsular contracture and 6.5% at 5-years for malposition of devices associated with matrix.

**TABLE 15.** REVISION INCIDENCE BY MATRIX USE – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS

| | N | N | Revision Incidence | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Primary Breast Implants | Revised | 1 Year | | 2 Years | | 3 Years | | 4 Years | | 5 Years | |
| | | | N | RI | N | RI | N | RI | N | RI | N | RI |
| **Revision due to device malposition** | | | | | | | | | | | | |
| No matrix | 10,014 | 319 | 8,209 | 1.8% | 6,141 | 3.0% | 4,103 | 3.7% | 2,325 | 4.3% | 1,056 | 4.5% |
| Matrix | 3,101 | 105 | 2,287 | 1.9% | 1,453 | 3.1% | 843 | 5.0% | 416 | 5.5% | 183 | 6.5% |
| **Total** | **13,115** | **424** | **10,496** | **1.8%** | **7,594** | **3.1%** | **4,946** | **3.9%** | **2,741** | **4.6%** | **1,239** | **4.8%** |
| **Revision due to capsular contracture** | | | | | | | | | | | | |
| No matrix | 10,014 | 268 | 8,209 | 1.1% | 6,141 | 2.2% | 4,103 | 2.8% | 2,325 | 3.5% | 1,056 | 4.0% |
| Matrix | 3,101 | 91 | 2,287 | 1.4% | 1,453 | 2.7% | 843 | 4.0% | 416 | 6.1% | 183 | 6.8% |
| **Total** | **13,115** | **359** | **10,496** | **1.2%** | **7,594** | **2.3%** | **4,946** | **3.1%** | **2,741** | **4.0%** | **1,239** | **4.5%** |
| **Revision due to device deflation/rupture** | | | | | | | | | | | | |
| No matrix | 10,014 | 52 | 8,209 | 0.2% | 6,141 | 0.3% | 4,103 | 0.4% | 2,325 | 0.6% | 1,056 | 0.9% |
| Matrix | 3,101 | 12 | 2,287 | 0.2% | 1,453 | 0.4% | 843 | 0.4% | 416 | 0.5% | 183 | 0.5% |
| **Total** | **13,115** | **64** | **10,496** | **0.2%** | **7,594** | **0.4%** | **4,946** | **0.4%** | **2,741** | **0.6%** | **1,239** | **0.9%** |
| **Revision due to skin scarring** | | | | | | | | | | | | |
| No matrix | 10,014 | 93 | 8,209 | 0.5% | 6,141 | 0.8% | 4,103 | 1.1% | 2,325 | 1.3% | 1,056 | 1.3% |
| Matrix | 3,101 | 49 | 2,287 | 1.4% | 1,453 | 1.5% | 843 | 1.8% | 416 | 2.0% | 183 | 2.0% |
| **Total** | **13,115** | **142** | **10,496** | **0.7%** | **7,594** | **1.0%** | **4,946** | **1.2%** | **2,741** | **1.4%** | **1,239** | **1.4%** |
| **Revision due to seroma/haematoma** | | | | | | | | | | | | |
| No matrix | 10,014 | 40 | 8,209 | 0.3% | 6,141 | 0.4% | 4,103 | 0.4% | 2,325 | 0.5% | 1,056 | 0.5% |
| Matrix | 3,101 | 47 | 2,287 | 1.4% | 1,453 | 1.5% | 843 | 1.7% | 416 | 2.0% | 183 | 2.0% |
| **Total** | **13,115** | **87** | **10,496** | **0.6%** | **7,594** | **0.7%** | **4,946** | **0.7%** | **2,741** | **0.8%** | **1,239** | **0.8%** |
| **Revision due to deep wound infection** | | | | | | | | | | | | |
| No matrix | 10,014 | 59 | 8,209 | 0.5% | 6,141 | 0.6% | 4,103 | 0.6% | 2,325 | 0.7% | 1,056 | 0.7% |
| Matrix | 3,101 | 77 | 2,287 | 2.3% | 1,453 | 2.6% | 843 | 2.7% | 416 | 2.7% | 183 | 2.7% |
| **Total** | **13,115** | **136** | **10,496** | **1.0%** | **7,594** | **1.1%** | **4,946** | **1.1%** | **2,741** | **1.2%** | **1,239** | **1.2%** |

Notes: Revision incidence is based on reconstructive primary breast implants inserted from 2012 to 2020. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary implant insertion date to the first revision procedure. Time to revision was censored at data extract date for non-revised implants. Implants with an unknown matrix use have not been included.

## Complication and Revision – Tissue Expanders for Reconstruction

The registry also collects details of 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. In 2020, device deflation/rupture was the most common issue reported for 40% of reconstructive tissue expander revisions, followed by ddeep wound infection at approximately 28%.

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

| Complications and issues identified at revision (N.B. not complication rates) | 2012-2020 | | 2020 | |
|---|---|---|---|---|
| | N | (%) | N | (%) |
| Device deflation/rupture | 166 | (35.2%) | 48 | (39.7%) |
| Deep wound infection | 107 | (22.7%) | 34 | (28.1%) |
| Seroma/haematoma | 67 | (14.2%) | 12 | (9.9%) |
| Capsular contracture | 59 | (12.5%) | 10 | (8.3%) |
| Skin scarring problems | 45 | (9.5%) | 10 | (8.3%) |
| Device malposition | 45 | (9.5%) | 9 | (7.4%) |
| **Total Revision Procedures** | **472** | | **121** | |

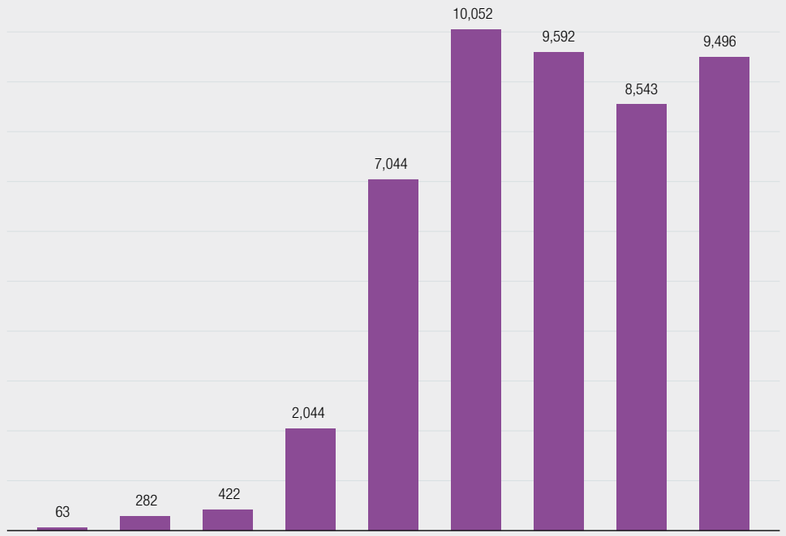
Notes: Listed in order of frequency are issues identified during unplanned reconstructive tissue expander revision (including explant) procedures. Multiple issues can be recorded at the time of revision surgery and issues were either identified as a reason for revision or found incidentally during the 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.

# REGISTRY OUTPUTS: COSMETIC INDICATIONS

## Cosmetic Procedure Numbers

The ABDR has captured a total of **47,538** surgical procedures involving breast devices for cosmetic indication (reasons). The cosmetic procedures captured include procedures for cosmetic procedure only, reported either unilaterally or bilaterally. Figure 22 shows that 2017 reported the greatest number of cosmetic implants, followed by 2018. In 2020, **9,496** cosmetic procedures were captured.

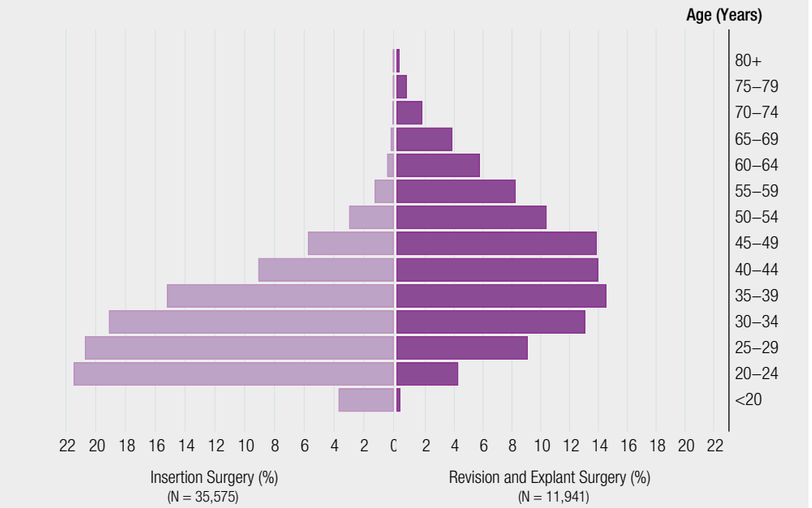
**FIGURE 22.** REGISTERED PROCEDURES (2012 – 2020) – COSMETIC PROCEDURES



## Patient Age at Cosmetic Procedures

The age distribution at the time of cosmetic procedure is shown in Table 17 and Figure 23. Overall, the median age at cosmetic procedures was 31 years for insertion surgery, 43 years for revision surgery and 44 years for explant surgery.

**FIGURE 23.** AGE DISTRIBUTION AT TIME OF PROCEDURE (2012 – 2020) – COSMETIC PROCEDURES




Notes: Insertion and revision (including explant) 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, revision or explant) have not been included.

**TABLE 17.** SUMMARY STATISTICS FOR AGE AT TIME OF PROCEDURE (2012-2020) – COSMETIC PROCEDURES

| | Insertion | | Revision | | Explant | |
|---|---|---|---|---|---|---|
| | N | Median (IQR) | N | Median (IQR) | N | Median (IQR) |
| **Cosmetic** | 35,575 | 31.0 (25.0, 38.1) | 10,197 | 43.1 (34.5, 52.1) | 1,744 | 43.5 (33.8, 55.8) |

Notes: Insertion, revision and explant only 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, revision or explant) have not been included. The interquartile range (IQR) reports observed patient age at the 25th and 75th percentiles.

## Cosmetic Aseptic Procedure Techniques

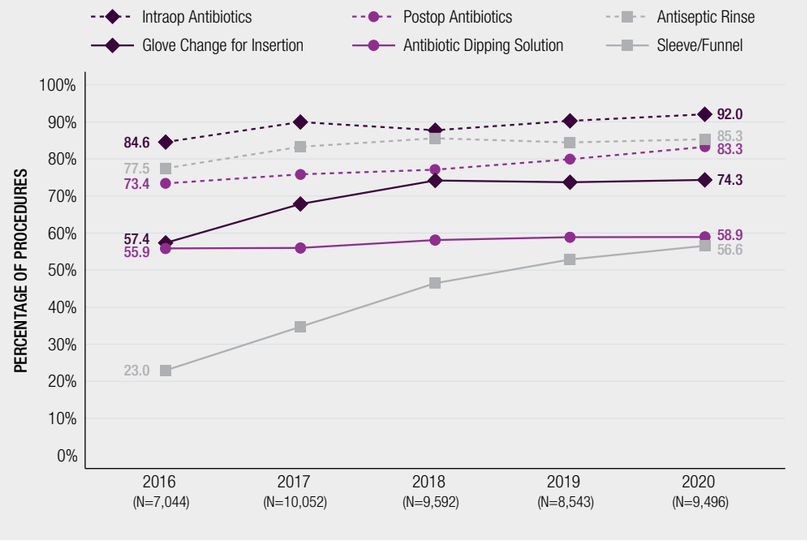
Table 18 and Figure 24 show the intraoperative techniques used during cosmetic procedures. More than one intraoperative technique can be used and recorded during a procedure. Overall, the use of intraoperative and/or post-operative antibiotics (90%), antiseptic rinse (83%) and glove change for insertion (70%) were commonly reported for cosmetic procedures and have increased over time.

**TABLE 18.** INTRAOPERATIVE TECHNIQUES (2012-2020) – COSMETIC PROCEDURES

| | 2012-2020 | |
|---|---|---|
| | N | (%) |
| Intra-op / Post-op antibiotics | 42,994 | (90.4%) |
| Antiseptic rinse | 39,502 | (83.1%) |
| Glove change for insertion | 33,019 | (69.5%) |
| Antibiotic dipping solution | 27,212 | (57.2%) |
| Sleeve / Funnel | 19,906 | (41.9%) |
| Not stated | 3,010 | (6.3%) |
| **Total Number of Procedures** | **47,538** | |

Notes: More than one intraoperative technique can be used and recorded per procedure, row percentages are shown.

**FIGURE 24.** INTRAOPERATIVE TECHNIQUES (2016 – 2020) – COSMETIC PROCEDURES




Note: Information regarding intraoperative and postoperative antibiotics have been collected separately since 2015.

Surgical characteristics of cosmetic procedures are presented in Table 19.

**TABLE 19.** SURGICAL ELEMENTS (2012-2020) – COSMETIC BREAST LEVEL PROCEDURES

| | Insertion | | Revision | | Explant | |
|---|---|---|---|---|---|---|
| | N | (%) | N | (%) | N | (%) |
| **Incision site*** | | | | | | |
| Inframammary | 60,432 | (85.1%) | 14,939 | (77.1%) | 1,775 | (51.7%) |
| Mastopexy/ reduction incision | 5,270 | (7.4%) | 2,471 | (12.8%) | 914 | (26.6%) |
| Areola | 702 | (1.0%) | 435 | (2.2%) | 44 | (1.3%) |
| Axillary | 228 | (0.3%) | 51 | (0.3%) | 10 | (0.3%) |
| Other | 125 | (0.2%) | 116 | (0.6%) | 23 | (0.7%) |
| Not stated | 4,587 | (6.5%) | 1,473 | (7.6%) | 675 | (19.7%) |
| **Surgical plane** | | | | | | |
| Sub-pectoral/ Dual plane | 58,562 | (82.5%) | 13,103 | (67.6%) | - | - |
| Sub-glandular/ sub-fascial | 7,918 | (11.2%) | 3,788 | (19.6%) | - | - |
| Other | 314 | (0.4%) | 71 | (0.4%) | - | - |
| Not stated | 4,217 | (5.9%) | 2,410 | (12.4%) | - | - |
| **Concurrent mastopexy/reduction** | | | | | | |
| Yes | 8,192 | (11.5%) | 3,060 | (15.8%) | 1,064 | (31.0%) |
| **Previous mastopexy/reduction** | | | | | | |
| Yes | 771 | (1.1%) | 1,192 | (6.2%) | 172 | (5.0%) |
| **Fat grafting** | | | | | | |
| Yes | 1,747 | (2.5%) | 543 | (2.8%) | 136 | (4.0%) |
| **Drain use** | | | | | | |
| Yes | 7,102 | (10.0%) | 6,320 | (32.6%) | 1,567 | (45.7%) |
| **Nipple guard/shield** | | | | | | |
| Yes | 55,682 | (78.4%) | 11,951 | (61.7%) | 590 | (17.2%) |
| **Total Procedures** | **71,011** | | **19,372** | | **3,432** | |

Details are at the breast procedure level. Insertion, revision and explant only procedures have been analysed independently. Procedures with unknown procedure type (insertion, revision or explant) have not been included. *More than one incision site can be recorded, row percentages are shown.

## Device Characteristics for Cosmetic Implants

Table 20 provides device shell, shape and fill characteristics for breast implants inserted for cosmetic procedures during an insertion procedure or a replacement revision procedure. Of the total implants, 54% were textured, 42% were smooth implants and 4% were polyurethane devices. The majority of breast implants were round (70%), followed by shaped/anatomical (29%). Regarding implant fill, 99% were silicone implants.

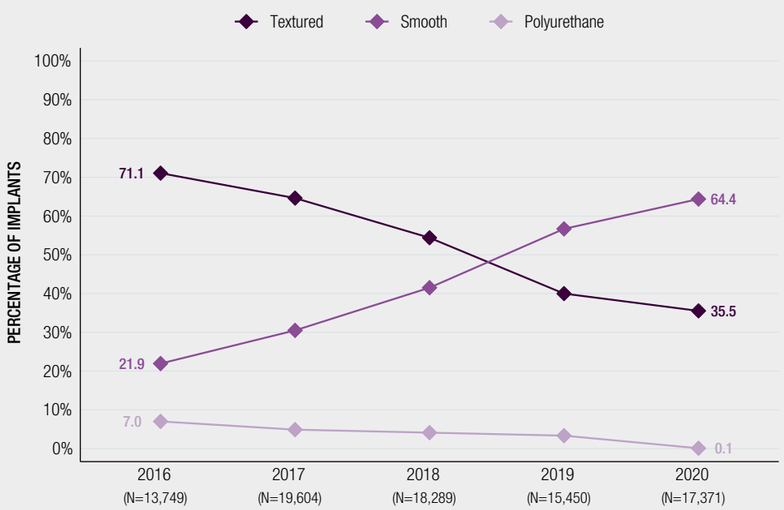
**TABLE 20.** DEVICE CHARACTERISTICS (2012-2020) – COSMETIC BREAST IMPLANTS

| | Implant | |
|---|---|---|
| | N | (%) |
| **Shell/ Texture** | | |
| Textured | 48,835 | (54.3%) |
| Smooth | 37,465 | (41.6%) |
| Polyurethane | 3,604 | (4.0%) |
| Not stated | 107 | (0.1%) |
| **Shape** | | |
| Round | 63,467 | (70.5%) |
| Shaped/anatomical | 26,405 | (29.3%) |
| Not stated | 139 | (0.2%) |
| **Fill** | | |
| Silicone | 89,073 | (99.0%) |
| Saline | 807 | (0.9%) |
| Silicone/ Saline | 14 | (0.0%) |
| Not stated | 117 | (0.1%) |
| **Total Devices** | **90,011** | **(100.0%)** |

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

Figure 25 and Figure 26 shows the trend in use of breast implants by shell and shape over time. The number of textured implant has reduced by half from from approximately 71% of devices in 2016 to 36% in 2020, and the number of smooth devices has increased from approximately 22% of devices in 2016 to 64% in 2020.

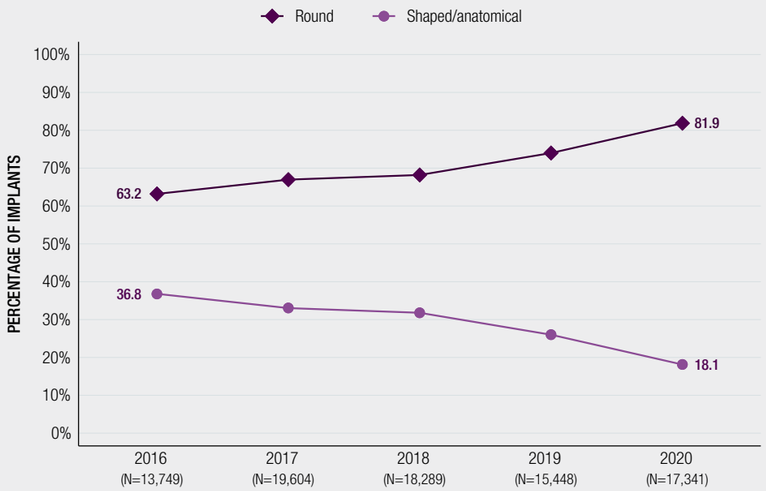
**FIGURE 25.** DEVICE SHELL (2016-2020) – COSMETIC IMPLANTS




Notes: Device texture is reported for new implants during an insertion procedure or a replacement revision procedure. Implants with an unknown shell type have not been included.

This change is associated with the increased use of round breast implants from approximately 63% in 2016 to 82% in 2020, and concurrent decrease in the use of shaped/ anatomical implants from 37% to 18% in 2020.

**FIGURE 26.** DEVICE SHAPE (2016-2020) – COSMETIC IMPLANTS




Notes: Device shape is reported for new implants during an insertion procedure or a replacement revision procedure. Implants with an unknown shape have not been included.



## Complications and Revision Incidence – Cosmetic 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 21 reports the complications identified at all revisions of cosmetic breast implants, including revisions for breasts where the insertion of the initial implant may or may not have also been captured by the registry. In 2020, capsular contracture was the most common issue identified at approximately 36% of cosmetic implant revisions, followed by device rupture (23%) and device malposition (19%).

**TABLE 21.** ISSUES IDENTIFIED AT REVISION PROCEDURE – COSMETIC BREAST IMPLANTS

| Complications and issues identified at revision (N.B. Not complication rates) | 2012-2020 | | 2020 | |
|---|---|---|---|---|
| | N | (%) | N | (%) |
| Capsular contracture | 8,774 | (38.9%) | 1,828 | (35.6%) |
| Device malposition | 4,919 | (21.8%) | 978 | (19.0%) |
| Device rupture | 4,890 | (21.7%) | 1,190 | (23.2%) |
| Device deflation | 2,210 | (9.8%) | 532 | (10.4%) |
| Seroma/ haematoma | 620 | (2.7%) | 134 | (2.6%) |
| Skin scarring problems | 608 | (2.7%) | 109 | (2.1%) |
| Deep wound infection | 152 | (0.7%) | 27 | (0.5%) |
| **Total Number of Implant Revision Procedures** | **22,582** | | **5,137** | |

Notes: Listed in order of frequency are issues identified during reconstructive breast implant revision (including explant) 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 27 provides an all-cause revision incidence curve for cosmetic procedures. At 5-years, 5% of cosmetic breast implants were revised after insertion.

**FIGURE 27.** ALL-CAUSE REVISION INCIDENCE – COSMETIC PRIMARY BREAST IMPLANTS

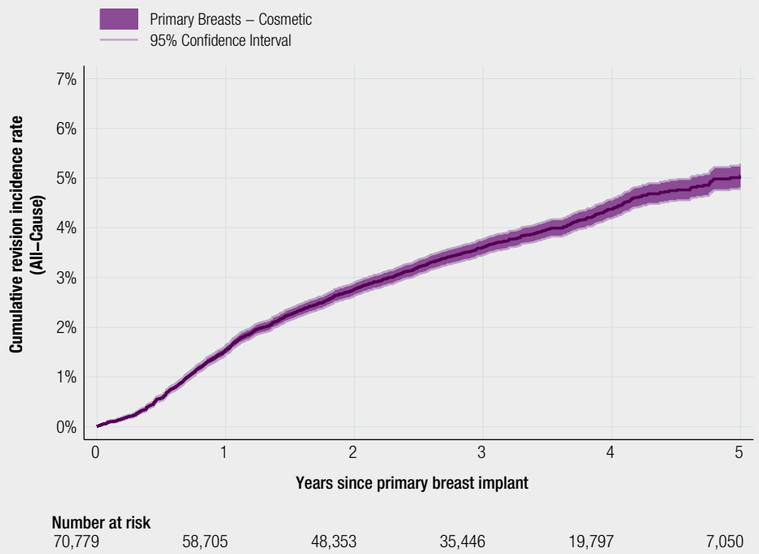
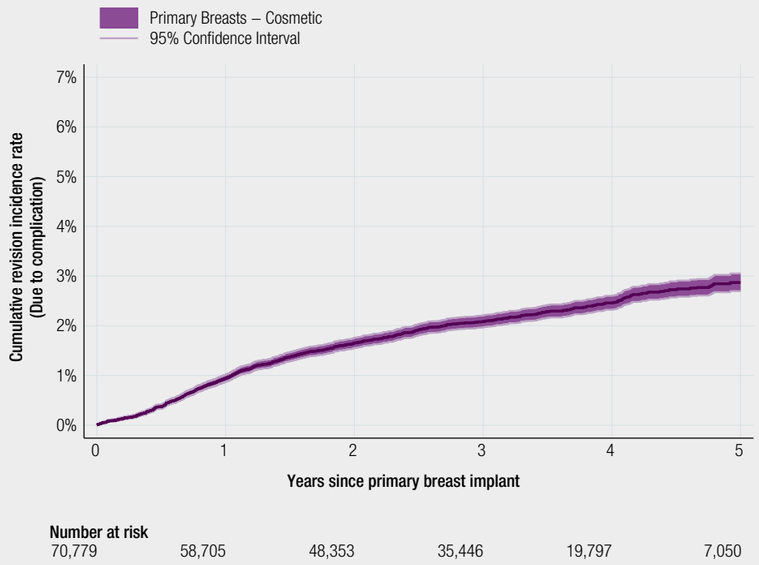



Figure 28 provides a revision incidence curve due to complication for cosmetic procedures. At 5-years after insertion, 3% of cosmetic implants were revised due to complications.

**FIGURE 28.** REVISION INCIDENCE DUE TO COMPLICATION – COSMETIC PRIMARY BREAST IMPLANTS




Revision incidence rates due to specific complications are reported in Table 22. At five-years since primary breast implant insertion, 1.4% of the implants were revised due to device malposition, 1.1% due to capsular contracture, and less than 1% of the implants were revised for other issues, such as device deflation/rupture, skin scarring problem, seroma/haematoma and deep wound infection.

**TABLE 22.** REVISION INCIDENCE – COSMETIC PRIMARY BREAST IMPLANTS

| | N | N | Revision Incidence | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Primary Breast Implants | Revised | 1 Year | | 2 Years | | 3 Years | | 4 Years | | 5 Years | |
| | | | N | RI | N | RI | N | RI | N | RI | N | RI |
| Revision due to device malposition | 70,779 | 698 | 58,705 | 0.5% | 48,353 | 0.9% | 35,446 | 1.1% | 19,797 | 1.3% | 7,050 | 1.4% |
| Revision due to capsular contracture | 70,779 | 504 | 58,705 | 0.3% | 48,353 | 0.6% | 35,446 | 0.7% | 19,797 | 0.9% | 7,050 | 1.1% |
| Revision due to device deflation/rupture | 70,779 | 123 | 58,705 | 0.0% | 48,353 | 0.1% | 35,446 | 0.2% | 19,797 | 0.2% | 7,050 | 0.3% |
| Revision due to skin scarring | 70,779 | 85 | 58,705 | 0.1% | 48,353 | 0.1% | 35,446 | 0.1% | 19,797 | 0.2% | 7,050 | 0.2% |
| Revision due to seroma/haematoma | 70,779 | 83 | 58,705 | 0.1% | 48,353 | 0.1% | 35,446 | 0.1% | 19,797 | 0.1% | 7,050 | 0.1% |
| Revision due to deep wound infection | 70,779 | 28 | 58,705 | 0.0% | 48,353 | 0.0% | 35,446 | 0.0% | 19,797 | 0.0% | 7,050 | 0.0% |

Notes: Revision incidence is based on reconstructive primary breast implants inserted from 2012 to 2020. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary implant insertion date to the first revision procedure. Time to revision was censored at data extract date for non-revised implants. 95% Confidence interval not provided for ease of presentation.

## Revision Incidence by Device Characteristics

Figure 29 and Figure 30 provide all-cause revision incidence and revision incidence due to complication by device shell type for primary cosmetic breast implants. The revision incidence rates are fairly similar for the three device shell types, except for an increase in polyurethane revisions at 4-5 years post insertion. Given that this rate is higher for all-cause revision (Figure 29) rather than revision due to complications (Figure 30), this may be related to women seeking a pre-emptive removal of devices following a TGA recall of these devices in 2019.

**FIGURE 29.** ALL-CAUSE REVISION INCIDENCE BY SHELL – COSMETIC PRIMARY BREAST IMPLANTS

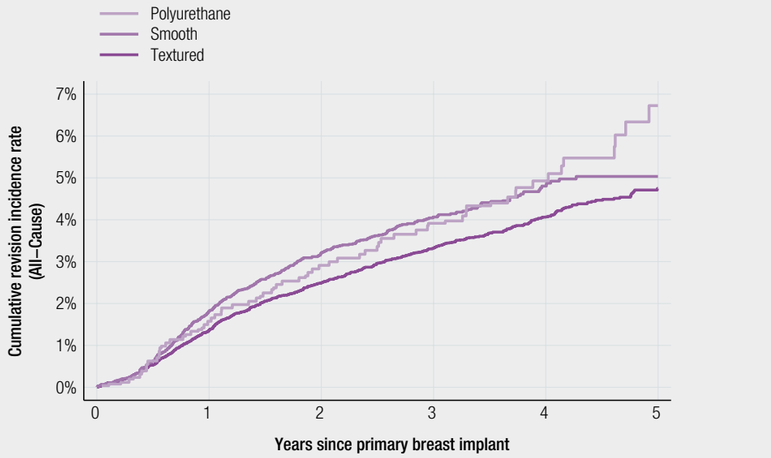
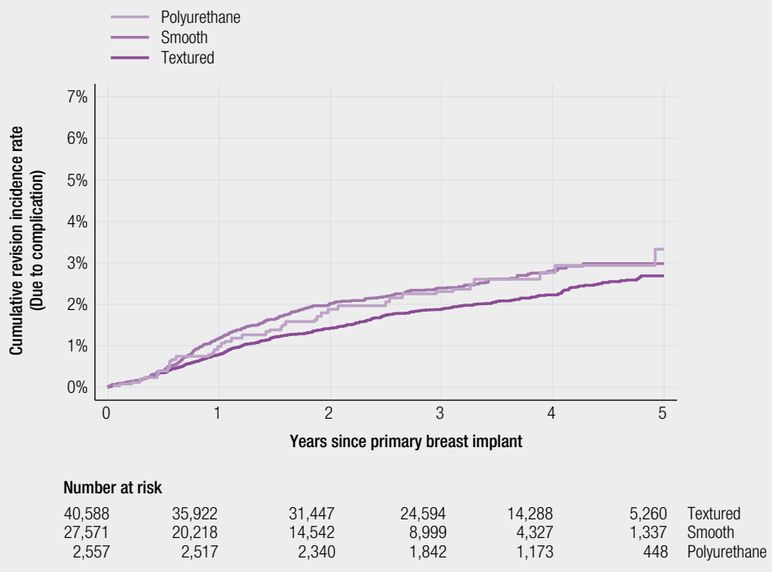



**FIGURE 30.** REVISION INCIDENCE DUE TO COMPLICATION BY SHELL – COSMETIC PRIMARY BREAST IMPLANTS






Revision incidence for specific complications after primary implant insertion by device shell are reported in Table 23. At five-years after primary implant insertion, revision incidence remains low (<2%) for all device types for specific complications.

**TABLE 23.** REVISION INCIDENCE BY DEVICE SHELL – COSMETIC PRIMARY BREAST IMPLANTS

| | N | N | Revision Incidence | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Primary Breast Implants | Revised | 1 Year | | 2 Years | | 3 Years | | 4 Years | | 5 Years | |
| | | | N | RI | N | RI | N | RI | N | RI | N | RI |
| **Revision due to device malposition** | | | | | | | | | | | | |
| Textured | 40,588 | 326 | 35,922 | 0.3% | 31,447 | 0.6% | 24,594 | 0.8% | 14,288 | 0.9% | 5,260 | 1.1% |
| Smooth | 27,571 | 332 | 20,218 | 0.8% | 14,542 | 1.3% | 8,999 | 1.5% | 4,327 | 1.8% | 1,337 | 1.8% |
| Polyurethane | 2,557 | 40 | 2,517 | 0.7% | 2,340 | 1.2% | 1,842 | 1.5% | 1,173 | 1.7% | 448 | 1.7% |
| **Total** | **70,716** | **698** | **58,657** | **0.5%** | **48,329** | **0.9%** | **35,435** | **1.1%** | **19,788** | **1.3%** | **7,045** | **1.4%** |
| **Revision due to capsular contracture** | | | | | | | | | | | | |
| Textured | 40,588 | 330 | 35,922 | 0.3% | 31,447 | 0.5% | 24,594 | 0.8% | 14,288 | 0.9% | 5,260 | 1.1% |
| Smooth | 27,571 | 147 | 20,218 | 0.3% | 14,542 | 0.6% | 8,999 | 0.7% | 4,327 | 0.8% | 1,337 | 0.9% |
| Polyurethane | 2,557 | 25 | 2,517 | 0.2% | 2,340 | 0.5% | 1,842 | 0.7% | 1,173 | 1.0% | 448 | 1.5% |
| **Total** | **70,716** | **502** | **58,657** | **0.3%** | **48,329** | **0.6%** | **35,435** | **0.7%** | **19,788** | **0.9%** | **7,045** | **1.1%** |
| **Revision due to device deflation/rupture** | | | | | | | | | | | | |
| Textured | 40,588 | 88 | 35,922 | 0.1% | 31,447 | 0.1% | 24,594 | 0.2% | 14,288 | 0.2% | 5,260 | 0.4% |
| Smooth | 27,571 | 31 | 20,218 | 0.0% | 14,542 | 0.1% | 8,999 | 0.1% | 4,327 | 0.2% | 1,337 | 0.3% |
| Polyurethane | 2,557 | 4 | 2,517 | 0.0% | 2,340 | 0.1% | 1,842 | 0.1% | 1,173 | 0.1% | 448 | 0.2% |
| **Total** | **70,716** | **123** | **58,657** | **0.0%** | **48,329** | **0.1%** | **35,435** | **0.2%** | **19,788** | **0.2%** | **7,045** | **0.3%** |
| **Revision due to skin scarring** | | | | | | | | | | | | |
| Textured | 40,588 | 47 | 35,922 | 0.1% | 31,447 | 0.1% | 24,594 | 0.1% | 14,288 | 0.1% | 5,260 | 0.2% |
| Smooth | 27,571 | 37 | 20,218 | 0.1% | 14,542 | 0.1% | 8,999 | 0.2% | 4,327 | 0.2% | 1,337 | 0.2% |
| Polyurethane | 2,557 | 1 | 2,517 | 0.0% | 2,340 | 0.0% | 1,842 | 0.0% | 1,173 | 0.0% | 448 | 0.0% |
| **Total** | **70,716** | **85** | **58,657** | **0.1%** | **48,329** | **0.1%** | **35,435** | **0.1%** | **19,788** | **0.2%** | **7,045** | **0.2%** |
| **Revision due to seroma/haematoma** | | | | | | | | | | | | |
| Textured | 40,588 | 53 | 35,922 | 0.1% | 31,447 | 0.1% | 24,594 | 0.1% | 14,288 | 0.2% | 5,260 | 0.2% |
| Smooth | 27,571 | 22 | 20,218 | 0.1% | 14,542 | 0.1% | 8,999 | 0.1% | 4,327 | 0.1% | 1,337 | 0.1% |
| Polyurethane | 2,557 | 7 | 2,517 | 0.2% | 2,340 | 0.2% | 1,842 | 0.3% | 1,173 | 0.3% | 448 | 0.3% |
| **Total** | **70,716** | **82** | **58,657** | **0.1%** | **48,329** | **0.1%** | **35,435** | **0.1%** | **19,788** | **0.1%** | **7,045** | **0.1%** |
| **Revision due to deep wound infection** | | | | | | | | | | | | |
| Textured | 40,588 | 21 | 35,922 | 0.1% | 31,447 | 0.1% | 24,594 | 0.1% | 14,288 | 0.1% | 5,260 | 0.1% |
| Smooth | 27,571 | 7 | 20,218 | 0.0% | 14,542 | 0.0% | 8,999 | 0.0% | 4,327 | 0.0% | 1,337 | 0.0% |
| Polyurethane | 2,557 | 0 | 2,517 | 0.0% | 2,340 | 0.0% | 1,842 | 0.0% | 1,173 | 0.0% | 448 | 0.0% |
| **Total** | **70,716** | **28** | **58,657** | **0.0%** | **48,329** | **0.0%** | **35,435** | **0.0%** | **19,788** | **0.0%** | **7,045** | **0.0%** |

Notes: Revision incidence is based on cosmetic primary breast implants inserted from 2012 to 2020. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary implant insertion date to the first revision procedure. Time to revision was censored at data extract date for non-revised implants. Implants with an unknown device shell have not been included.

# REGISTRY OUTCOMES

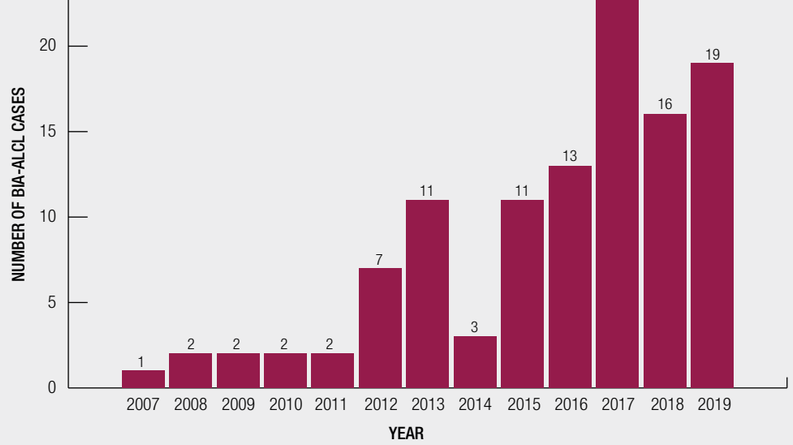
## Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

Breast Implant Associated- Anaplastic Large Cell Lymphoma (BIA-ALCL) is a very rare cancer of the immune system; it is not breast cancer. It has excellent cure rates if detected early, and the device and surrounding capsule are surgically removed. In 2015 the ABDR included a database field related to BIA-ALCL as a reason for revision. Since that time, 45 BIA-ALCL cases have been reported to the ABDR. Surgeons may also notify the Therapeutic Goods Administration (TGA) of BIA-ALCL cases. Additionally from 2007 until November 2019 Dr Anand Deva and his research team at Macquarie University undertook a research study in relation to BIA-ALCL, where they received a number of reports of BIA-ALCL from surgeons and the TGA. Clinicians and researchers from both the ABDR and the Macquarie Research team are members of the TGA's expert advisory panel regarding BIA-ALCL, (this is now called the TGA Breast Implant Expert Working Group).

The data presented in this report is in two parts; (1) Data from de-identified summary data provided to the ABDR by Macquarie University including reports from the TGA, and (2) Data from cases reported directly to the ABDR. These latter cases may overlap with some of those reported from the Macquarie group, and include additional information regarding operation category, associated complications and explant information.

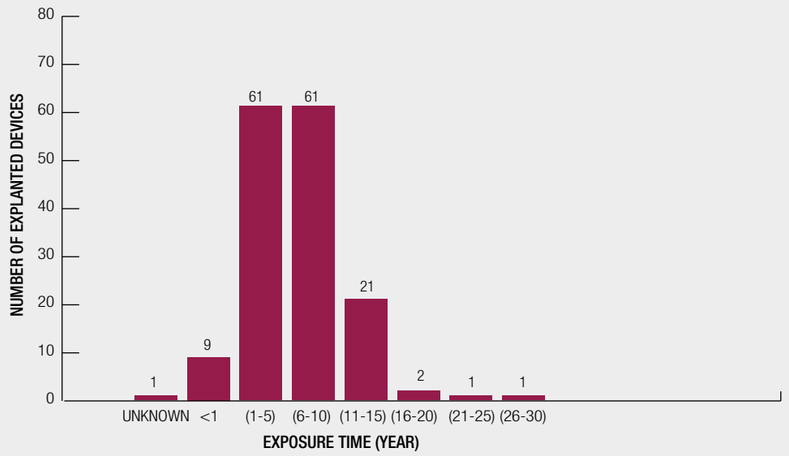
Data from the Macquarie University team included **112 confirmed BIA-ALCL cases** between the years of 2007 to 2019, with the highest number of cases reported in 2017 (Figure 31).

**FIGURE 31.** BIA-ALCL CASES REPORTED IN AUSTRALIA 2007-2019: MACQUARIE UNIVERSITY (N=112)



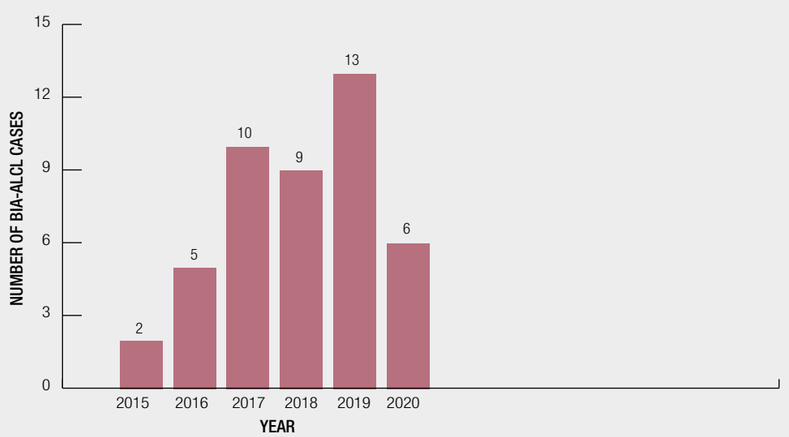
A total of 157 devices relating to these reports were explanted, with the majority (127 of 157; 81%) being in situ for up to 10 years, and the remainder beyond 10 years (Figure 32).

**FIGURE 32.** NUMBER OF YEARS IMPLANT IN SITU IN AUSTRALIA 2007-2019: MACQUARIE UNIVERSITY (N=157)




BIA-ALCL cases reported directly to the ABDR from 2015 to 2020 comprised **45** women (Figure 33) and **50** breast devices (Table 24).

**FIGURE 33.** BIA-ALCL CASES REPORTED BY YEAR (ABDR 2015-2020; N=45)




Twenty-six of these cases (52%) were from cosmetic procedures (Table 24).

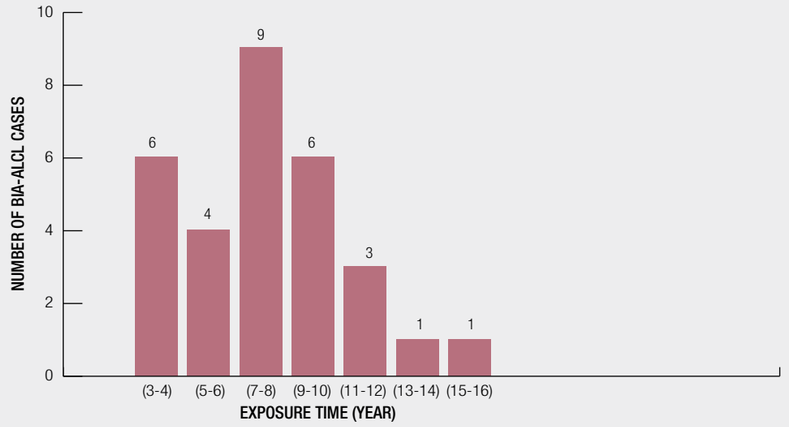
**TABLE 24.** BIA-ALCL CASES BY OPERATION INDICATION (ABDR DATA AS AT DECEMBER 2020)

| OPERATION CATEGORY | NUMBER OF BIA-ALCL CASES |
|---|---|
| Cosmetic augmentation | 26 |
| Reconstruction post cancer | 18 |
| Reconstruction benign/prophylactic | 4 |
| Reconstruction not otherwise specified | 1 |
| Not stated | 1 |
| **Total** | **50** |

In forty-seven (94%) of cases, a diagnosis of BIA-ALCL was the reason for revision, in two cases BIA-ALCL was found incidentally, and 1 was not stated. Concurrent complications were recorded in 19 of the cases. The most common complication was seroma/haematoma (13 cases), followed by capsular contracture (3), device malposition (2), and skin scarring.

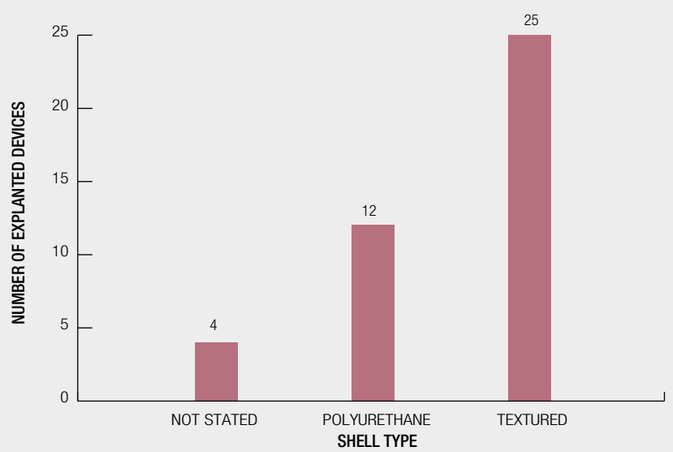
Thirty cases reported the number of years the implant was in situ which ranged from 3 to 16 years, with a mode of 7 years (Figure 34).

**FIGURE 34.** NUMBER OF YEARS IMPLANT IN SITU: ABDR 2015-2020 (N=30)




Device characteristics were recorded for the 41 explanted devices reported, with textured shell 25 (61%), polyurethane shell 12 (29%), and 4 (10%) being not stated (Figure 35).

**FIGURE 35.** EXPLANTED DEVICES BY SHELL TYPE (ABDR 2015-2020) (N=41)




The TGA encourages surgeons to report all cases of BIA-ALCL to the ABDR so that it becomes the national repository of BIA-ALCL device-related information. The ABDR has also applied for data linkage with state-based and national cancer registries to ascertain the complete number of BIA-ALCL cases reported in Australia.

## Data Requests

The ABDR experienced a further increase of enquiries from patients during this reporting period. Over 100 patients emailed and another 230 called the registry directly, with the majority seeking their device details or information regarding health concerns including device recalls, Breast Implant Associated- Anaplastic Large Cell Lymphoma (BIA-ALCL) and Breast Implant Illness.

Nine requests for patient data were received from surgeons including three from public sites. Lists of patients were only generated if the request was made by the surgeon directly, or by an appropriately delegated hospital Quality Manager.

The ABDR also encourages the secondary uses of its data for research and related purposes. A total of four research data access requests were approved for the ABDR in 2020.

| Date of approval | Name/Organisation | Title of the Project |
|---|---|---|
| 09/03/2021 | Sheymonti Hoque/ Monash University | Assessing and comparing patient outcomes and revision rates of direct-to-implant and two-stage reconstruction with or without acellular dermal matrix. |
| 09/03/2020 | Swarna Vishwanath/ Monash University | Surgical Techniques used in Breast Device Surgery: Preliminary results from the Australian Breast Device Registry |
| 16/04/2020 | Randi Thisakya Jayasinghe/ Monash University | Patient Reported Outcome Measures after Breast Augmentation – Using the BREAST-Q IS. |
| 20/07/2020 | Michelle Merenda/ Monash University | Does the BREAST-Q IS PROM predict re-operation in the Australian Breast Device Registry? |

## Patient Reported Outcome Measures

From October 2018 to December 2020, a total of 47,789 patients who had received cosmetic procedures were contacted and 9,506 who had received breast reconstruction were contacted (total of 57,295 patients). Response rates were calculated from the patients who were followed-up and either provided complete responses to the PROMs questions, a partial response, were not eligible to be included, or chose to opt out of follow-up.

Table 25 provides summary of the PROMs response figures from 2018 to 2020. Key findings are:

- From 2018 to 2020, the total number of patients contacted has significantly increased, from 9,970 in 2018 to 23,610 in 2020
- Overall response rates have declined over this time
- Response rates for reconstructive procedures are higher than for cosmetic procedures
- Response rates are lower at 5-years post-implant, compared to at 1 or 2 years
- Response rates for the majority of women contacted in 2020 are less than 50%

These factors should be taken into consideration when interpreting the PROMs results below.

**TABLE 25.** PROMS RESPONSES AT YEAR 1, YEAR 2 AND YEAR 5 POST-OPERATIVE RECONSTRUCTIVE AND COSMETIC PATIENTS FROM 2018 TO 2020

| Follow-up year | 2018 Reconstruction | | 2018 Cosmetic | | 2019 Reconstruction | | 2019 Cosmetic | | 2020 Reconstruction | | 2020 Cosmetic | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Total Contacted N = 1,290 | Total Responded 77.2 % | Total Contacted N = 8,680 | Total Responded 60% | Total Contacted N = 3,630 | Total Responded 75.2 % | Total Contacted N = 20,085 | Total Responded 59% | Total Contacted N = 4,586 | Total Responded 52.8% | Total Contacted N = 19,024 | Total Responded 41.6% |
| Year 1 | 686 | 78.6% | 5,037 | 62.5% | 1,874 | 76.5% | 9,290 | 60.7% | 2,118 | 54.5% | 7,811 | 42.5% |
| Year 2 | 538 | 74.0% | 3,509 | 56.6% | 1,486 | 75.2% | 10,059 | 56.9 % | 1,932 | 54.5% | 9,237 | 42.3% |
| Year 5 | 79 | 74.7% | 134 | 49.3% | 270 | 66.0% | 452 | 51.3% | 536 | 40.1% | 1,976 | 34.5% |
| **Total no.** | **Total 9,970 contacted** | | | | **Total 23,715 contacted** | | | | **Total 23,610 contacted** | | | |

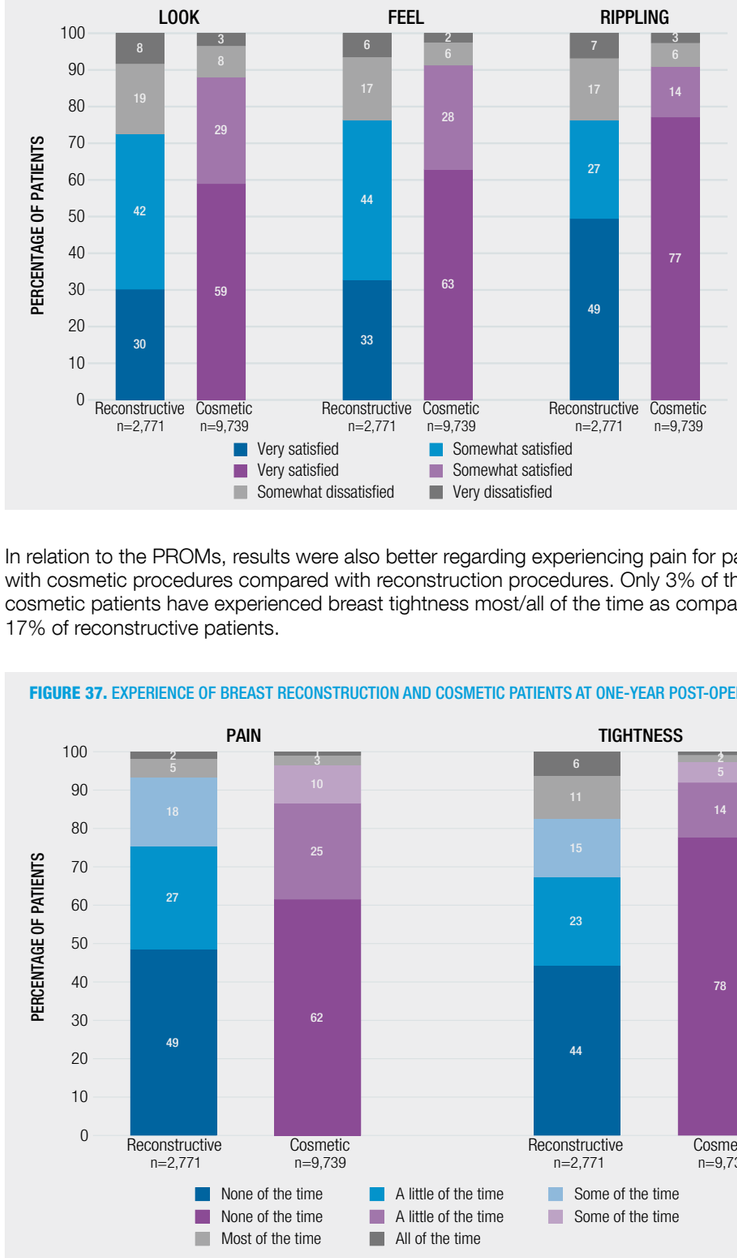
Note: PROMs contacts made in 2020 are made for patients who have had surgery one, two or five years since the inception of the surgery. There is no data eligible yet for procedures in 2020.

## PROMs Results

The analysis of the PROMs data comprised patients who provided complete responses to the PROMs questions. The results of the Breast-Q IS for patients with breast reconstruction compared with cosmetic implants at one-year post operation, are shown below in Figures 36-37.

At one-year post-operation, a minority of patients with cosmetic implants (11% or less) were very or somewhat dissatisfied with implant look, feel and rippling, whereas about 25% of the patients with breast reconstruction were dissatisfied with implant look, feel and rippling.

**FIGURE 36.** SATISFACTION LEVEL OF BREAST RECONSTRUCTION AND COSMETIC PATIENTS AT ONE-YEAR POST-OPERATION




In relation to the PROMs, results were also better regarding experiencing pain for patients with cosmetic procedures compared with reconstruction procedures. Only 3% of the cosmetic patients have experienced breast tightness most/all of the time as compared to 17% of reconstructive patients.

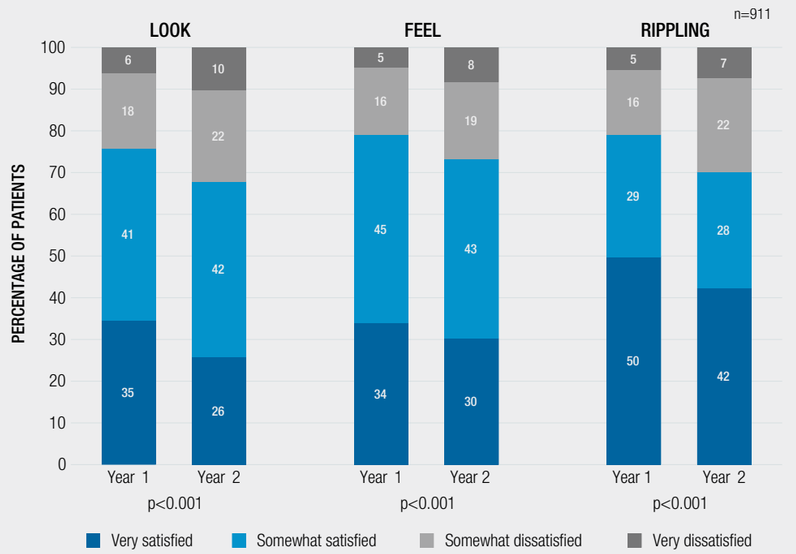
**FIGURE 37.** EXPERIENCE OF BREAST RECONSTRUCTION AND COSMETIC PATIENTS AT ONE-YEAR POST-OPERATION






The results of the Breast-Q IS with linked data from **reconstruction** patients who answered both Year-1 and Year-2 surveys are shown in Figures 38-39, showing the patient journey over a period of time. Overall, for patients with breast reconstruction, satisfaction decreased by 9% for look, 4% for feel and 8% for rippling, that reflected a slightly decreasing trend from Year-1 to Year-2.

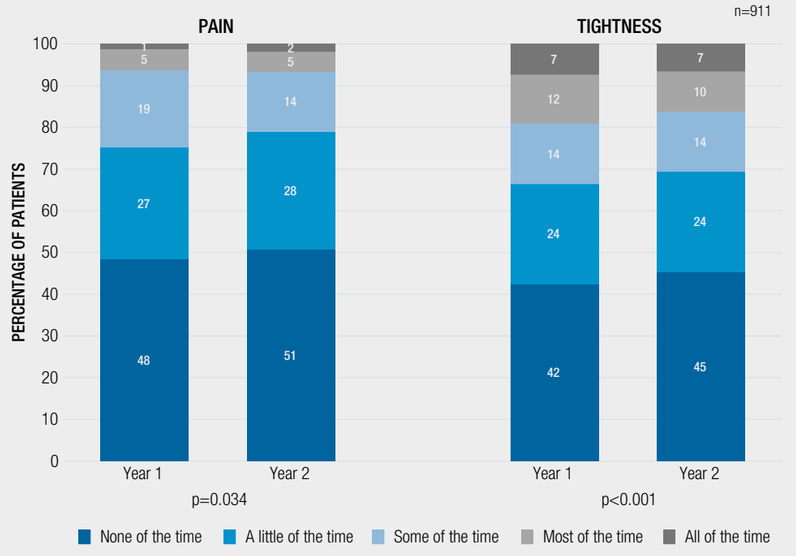
**FIGURE 38.** SATISFACTION LEVEL OF BREAST RECONSTRUCTION PATIENTS AT ONE- AND TWO-YEARS POST-OPERATION




Notes: P-value from asymptotic tests for symmetry between year one and year two presented for all linked PROMs figures

However, the proportion of patients experiencing pain and tightness 'None of the time' increased by 3% from Year-1 to Year-2.

**FIGURE 39.** EXPERIENCE OF BREAST RECONSTRUCTION PATIENTS AT ONE- AND TWO-YEARS POST-OPERATION



The results of the Breast-Q IS with linked data from cosmetic procedures who answered both Year-1 and Year-2 surveys are shown in Figures 40-41. Overall, for these women, satisfaction with look, feel and rippling were high, however there was an increase in the proportion of women dissatisfied by 2% for look, 3% for feel and 4% for rippling from Year 1 to Year 2. There is a very slight increase in proportion of women reporting pain most/all of the time by 2% for pain and by 1% for tightness from Year-1 to Year-2.

**FIGURE 40.** SATISFACTION LEVEL OF BREAST COSMETIC PATIENTS AT ONE- AND TWO-YEARS POST-OPERATION

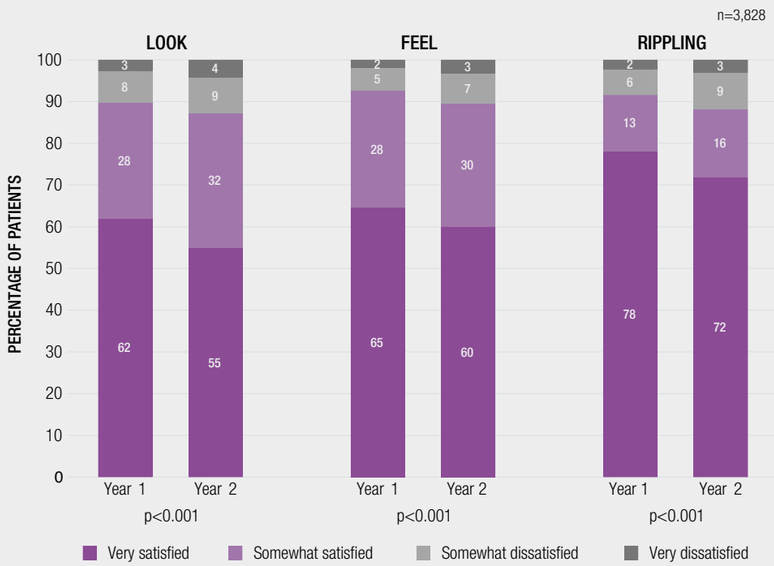
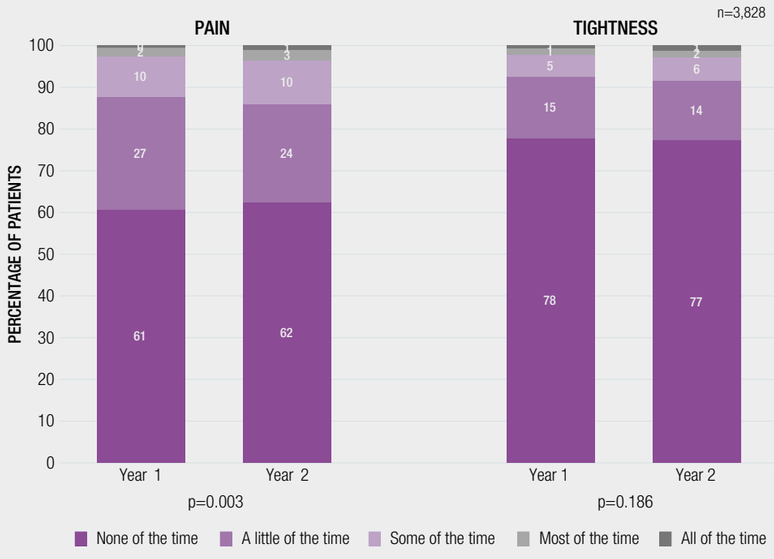



**FIGURE 41.** EXPERIENCE OF BREAST COSMETIC PATIENTS AT ONE- AND TWO-YEARS POST-OPERATION




## Surgeon and Site Reporting

The ABDR generated its second round of surgeon reports in 2020. These individualised activity-based reports were distributed to all surgeons who had contributed breast procedure data to the ABDR in the period to 31 December 2019. The second round of site reports were also released in 2020 to the top 50% of sites contributing data in 2019. For the first time, these reports presented 1-year PROMs data to participating surgeons/sites.

# CLINICAL QUALITY INDICATORS

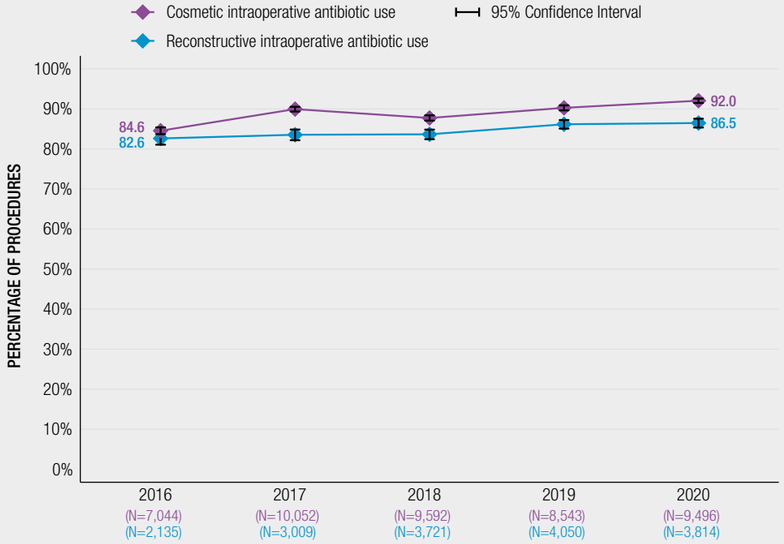
A scoping review was conducted to determine potential breast device quality indicators and consensus on the final 3 quality indicators, namely pre-operative intravenous (IV) antibiotics, reoperation due to short-term complications, and patient reported outcome measures, was obtained using a modified Delphi approach[9]. The Delphi panel comprised participants from various countries and representation from surgical specialty groups including breast and general surgeons, plastic and reconstructive surgeons, cosmetic surgeons, a breast-care nurse, a consumer, a devices regulator, and a biostatistician. The 3 endorsed quality indicator measures enables breast device registries to standardize benchmarking of care for patients undergoing breast device surgery. These are reported for the first time in the ABDR Annual Report, as trends over the last 5 years.

Clinicians use the term 'pre-operative antibiotics' interchangeably with 'intra-operative antibiotics' use, i.e. the use of antibiotics provided intravenously, orally or intramuscular immediately before incision, during or within 3 hours after surgery. Therefore, intra-operative antibiotic use has been reported in the CQI findings below.

## CQI 1: Intra-operative antibiotics use

Intra-operative antibiotics provided before skin incision to reduce complications post-surgery are presented in Figure 42. There has been an increasing use of intra-operative antibiotic use for both reconstructive and cosmetic groups from 2016 to 2020.

**FIGURE 42.** PROPORTION OF PROCEDURES WITH INTRA-OPERATIVE ANTIBIOTIC USE

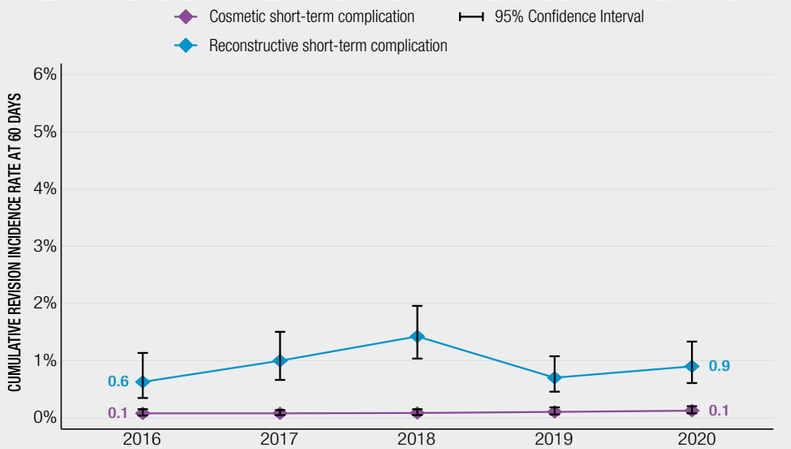



Note: Data at the procedure level.

## CQI 2: Reoperation due to short-term complication

The reoperation rate at 60 days post-operation due to short-term complications for the reconstructive and cosmetic cohorts are provided in Figure 43. The short-term complications include infection, capsular contracture, device malposition, device rupture/deflation, seroma/hematoma, and implant loss. Although implant loss is not directly captured in the Data Collection Form, it is defined as implant explantation (without replacement) for reasons other than patient preference. The revision incidence rate at 60 days post-operation due to short-term complications is very low with a slight fluctuating trend for reconstructive procedures, and has been consistently low over time for the cosmetic group at 0.1%.

**FIGURE 43.** CUMULATIVE REVISION INCIDENCE RATE AT 60 DAYS POST-OPERATION DUE TO SHORT-TERM COMPLICATIONS




Note: Data at the breast device level for primary breast implants.

## CQI 3: Patient reported outcome measures

The CQI PROMs results for patient satisfaction with implant look, feel and rippling at one-year post-operation for reconstructive and cosmetic patients are provided from Figure 44-46 . There has been slight decrease (3%) in the proportion of patient satisfaction for both groups over time. This trend is similar for satisfaction with implant feel and rippling.

**FIGURE 44.** PROPORTION OF PATIENTS VERY OR SOMEWHAT SATISFIED WITH IMPLANT LOOK ONE-YEAR POST-OPERATION

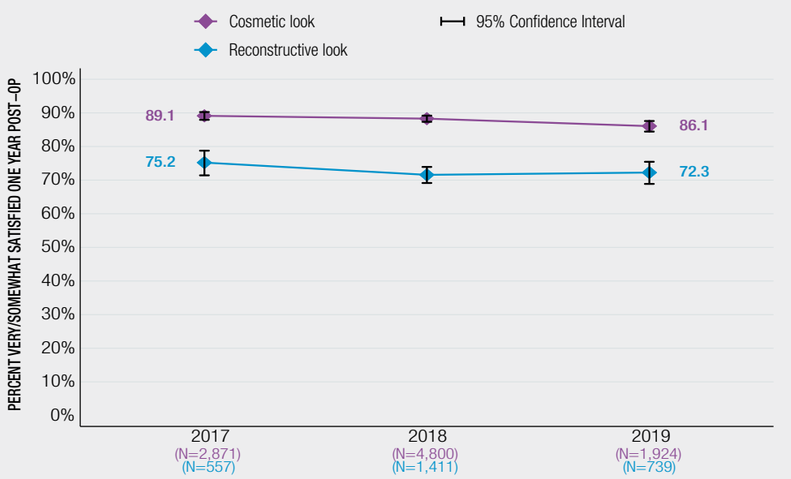


**FIGURE 45.** PROPORTION OF PATIENTS VERY OR SOMEWHAT SATISFIED WITH IMPLANT FEEL ONE-YEAR POST-OPERATION

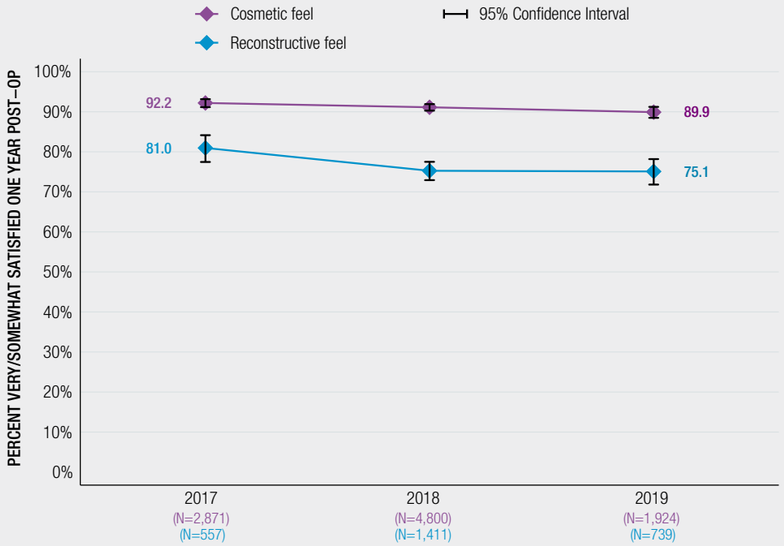



**FIGURE 46.** PROPORTION OF PATIENTS VERY OR SOMEWHAT SATISFIED WITH IMPLANT RIPPLING ONE-YEAR POST-OPERATION

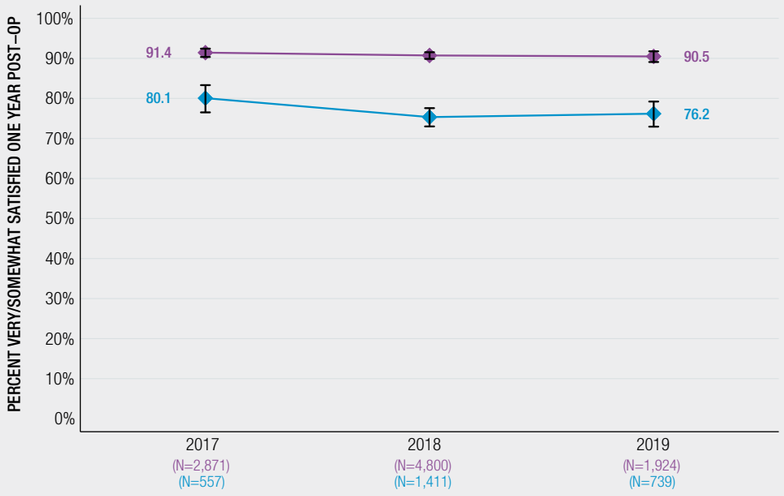





Figure 47 and 48 show the proportion of patients with low symptom frequency (reported as none or little of the time) for PROMS pain and tightness one-year post-operation for reconstructive and cosmetic patients. This has remained steady over time, and is higher for cosmetic procedures compared with reconstruction procedures.

The proportion of cosmetic patients reporting little or no breast tightness also remained relatively stable over time, although was also lower for reconstructive procedures.

**FIGURE 47.** PROPORTION OF PATIENTS WITH LOW FREQUENCY (NONE/A LITTLE OF THE TIME) PAIN ONE-YEAR POST-OPERATION

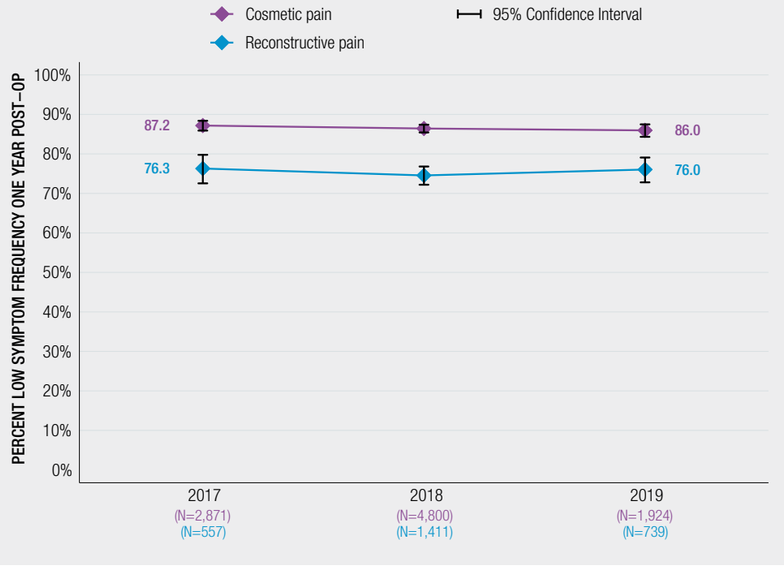
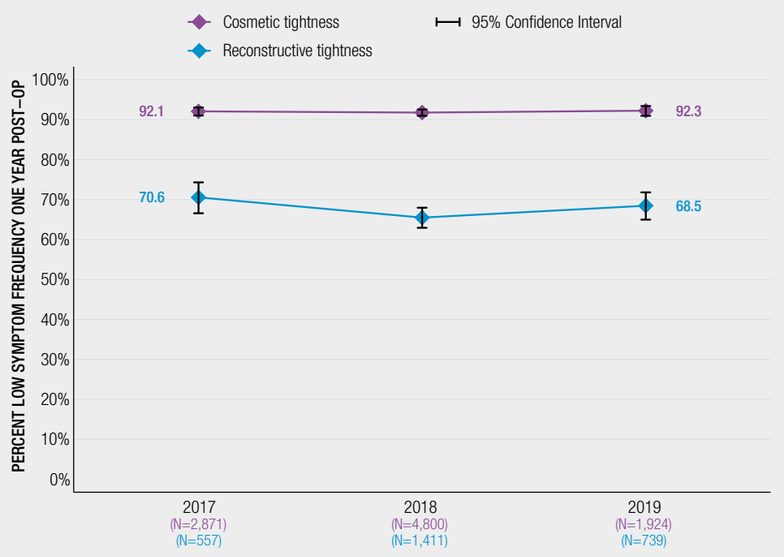



**FIGURE 48.** PROPORTION OF PATIENTS WITH LOW FREQUENCY (NONE/A LITTLE OF THE TIME) TIGHTNESS ONE-YEAR POST-OPERATION



# FUTURE INITIATIVES

The ABDR is grateful for the continued strong support and clinical leadership of the three contributing craft groups. To this end we gratefully acknowledge the commitment and contribution of A/Professors Elizabeth Elder and Colin Moore for their five years at the ABDR. We look forward to working closely with their new craft group nominees, Miss Melanie Walker and Mr. Patrick Tansley as well as A/Prof Gillian Farrell as clinical lead representing Australian Society of Plastic Surgeons whose position is unchanged. We also look forward to welcoming new consumer representation to the ABDR.

The ABDR is in a period of consolidation, and this requires it to focus on increasing population capture to as close to population levels as possible. The ABDR will continue to engage sites and surgeons from jurisdictions and sites that are currently not participating, usually for reasons related to hospital governance delays rather than lack of individual clinician support. The ABDR is also seeking to better confirm its case ascertainment, and a linkage with the Victorian Department of Health aims to pilot case ascertainment against ICD-10 hospital data in one jurisdiction, and assess its usefulness as a strategy for broader jurisdictional case ascertainment. A particular challenge with cosmetic device procedures is the lack of MBS data against which to compare ABDR registrations. We will report on progress with this strategy in the next annual report.

The ABDR is embarking on a database upgrade in 2022, which will provide contributing sites with the opportunity to enter their patient data directly into the ABDR, and to review their patient data at any time. This project will enhance clinicians and health services' ability to locally manage any future regulatory requirements relating to device warnings or recalls. It will also support increasing regulatory requirements of clinicians to monitor their clinical outcomes.

The ABDR is also participating in a Working Group established by the TGA to support the introduction of device Unique Device Identifiers (UDIs) in Australia. UDIs have the potential to provide much needed information from which to derive specific device performance, which will significantly enhance the potential of the ABDR as a quality registry into the future.

The ABDR also seeks to improve its feedback to sites and surgeons through continuous refinement of its site and surgeon reporting, and through engagement activities including conference and webinar activities. The ABDR is also currently undertaking a review of its PROMs program, to ensure that it provides value for money, and aligns with the key objectives of the ABDR in improving device and surgical safety.

# PUBLICATIONS 2020

Ng S, Parker E, Pusic A, Farrell G, Moore C, Elder E, Cooter RD, McNeil J, Hopper I. Lessons Learned in Implementing Patient Reported Outcome Measures (PROMs) in the Australian Breast Device Registry (ABDR). Aesthet Surg J. 2020 Dec 17:sjaa376. doi: 10.1093/asj/sjaa376. Epub ahead of print. PMID: 33331907.

Bargon CA, Becherer BE, Young-Afat DA, van Bommel ACM, Hommes J, Hoornweg MJ, Keuter XHA, de Fazio S, Melnikov D, Monton Echeverria J, Perks GAB, Lumenta DB, Couturaud B, von Fritschen U, Stark B, Hölmich LR, Crosbie A, Lispi L, Campanale A, Cooter RD, Pusic AL, Hopper I, Mureau MAM, Rakhorst HA. Moving breast implant registries forward: Are they FAIR and Functional? Journal of Plastic, Reconstructive & Aesthetic Surgery. 2020 Journal pre-proof published online October 17. doi.org/10.1016/j.bjps.2020.10.001

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

# PRESENTATIONS 2020

As part of our continued efforts to remain engaged with our contributors and patients, previously ADBR have conducted presentations at a variety of research, health education and advocate forums. However, due to the COVID-19 pandemic and subsequent restrictions all of our public presentations were cancelled in 2020.

# REFERENCES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2. Australian Commission on Safety and Quality in Health Care, Framework for Australian Clinical Quality Registries. Sydney. ACSQHC, March 2014
3. Australian Commission on Safety and Quality in Health Care. Operating Principles and Technical Standards for Australian Clinical Quality Registries 2008
4. The Australian Senate CARC. The role of the Therapeutic Goods Administration regarding medical devices, particularly Poly Implant Prosthese (PIP) breast implants., 2012.
5. Ng S, Pusic A, Parker E, et al. Patient-Reported Outcome Measures for Breast Implant Surgery: A Pilot Study. Aesthetic Surgery Journal 2019;39(8):314-21. doi: 10.1093/asj/sjz023
6. Ng S, Kirkman M, Fisher J, et al. Establishing the acceptability of a brief patient reported outcome measure and feasibility of implementing it in a breast device registry - a qualitative study. Journal of patient-reported outcomes 2019;3(1):63. doi: 10.1186/s41687-019-0152-z
7. Ng S, Parker E, Pusic A, et al. Lessons Learned in Implementing Patient Reported Outcome Measures (PROMs) in the Australian Breast Device Registry (ABDR). Aesthet Surg J 2020 doi: 10.1093/asj/sjaa376
8. Pocock SJ, Clayton TC, DG. A. Survival plots of time-to-event outcomes in clinical trials: good practice and pitfalls. Lancet 2002;359:1686-89.
9. Begum H, Vishwanath S, Merenda M, et al. Defining Quality Indicators for Breast Device Surgery: Using Registries for Global Benchmarking. Plastic and reconstructive surgery Global open 2019;7(8):e2348. doi: 10.1097/gox.0000000000002348 [published Online First: 2019/10/09]


# GLOSSARY

| | |
|---|---|
| ABDR | Australian Breast Device Registry |
| ACCSM | Australasian College of Cosmetic Surgery and Medicine |
| 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 |
| 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 |
| 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 or reposition procedures. The initial device insertion may or may not have also been captured by the registry. Also included procedures involving the removal of an implant and insertion of a tissue expander |
| 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 |

# LIST OF FIGURES

# LIST OF TABLES



# APPENDIX 1– DATA COMPLETENESS

The ABDR is designed to collect information about surgical procedures involving breast implants, tissue expanders and matrix if used. Appendix 1 shows a summary of the completeness of data elements captured within the ABDR database for procedures in 2018, 2019 and 2020. Noticeable improvements in data completeness for procedures in 2019 were seen and this high level of data completeness was maintained for procedures in 2020. 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. 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. The patient opt-out rate is less than one percent.

| | 2018 | 2019 | 2020 |
|---|---|---|---|
| **PATIENT CHARACTERISTICS (Patient Level)** | **13,454** | **13,148** | **14,072** |
| Name | 100% | 100% | 100% |
| Surname | 100% | 100% | 100% |
| Medicare number | 87.9% | 88.7% | 90.2% |
| Date of birth | 100% | 100% | 100% |
| Address | 96.2% | 97.8% | 97.9% |
| Telephone | 86.1% | 87.7% | 85.3% |
| **SURGERY CHARACTERISTICS (Procedure Level)** | **14,174** | **13,870** | **14,708** |
| Operation date | 100% | 100% | 100% |
| Patient UR | 100% | 100% | 100% |
| Hospital | 100% | 100% | 100% |
| Surgeon | 100% | 100% | 100% |
| Intraoperative Techniques | 89.4% | 88.1% | 88.3% |
| **SURGERY CHARACTERISTICS (Breast Level)** | **26,277** | **25,658** | **27,539** |
| Side of breast | 100% | 100% | 100% |
| Indication for surgery | 94.0% | 90.7% | 90.5% |
| Surgery type (device insertion or revision) | 99.9% | 100% | 100% |
| Previous radiotherapy (if indication = reconstruction) | 90.4% | 90.7% | 90.2% |
| Incision site | 89.6% | 88.6% | 88.2% |
| Plane | 85.3% | 84.7% | 84.9% |
| Concurrent mastectomy | 92.3% | 92.7% | 91.6% |
| Axillary surgery | 92.2% | 92.7% | 91.6% |
| Concurrent mastopexy / reduction | 92.4% | 92.7% | 91.6% |
| Concurrent flap cover | 92.1% | 92.6% | 91.5% |
| Previous mastopexy / reduction | 92.1% | 92.6% | 91.5% |
| Fat grafting | 90.3% | 92.4% | 91.5% |
| Fat grafting volume (if fat grafting = yes) | 89.1% | 92.0% | 91.9% |
| Intraoperative fill volume (if tissue expander) | 67.6% | 67.8% | 64.7% |

| | 2018 | 2019 | 2020 |
|---|---|---|---|
| **REVISION SURGERY CHARACTERISTICS (Breast Level)** | **7,743** | **9,220** | **9,185** |
| Revision surgery type | 100% | 99.9% | 99.9% |
| Indication for revision surgery | 94.5% | 95.6% | 94.3% |
| Capsulectomy | 86.1% | 88.3% | 87.7% |
| Neo pocket formation | 74.8% | 74.3% | 73.3% |
| Neo pocket formation details (if neo pocket formation = yes) | 81.3% | 85.1% | 84.0% |
| Revision of an implant inserted overseas | 84.3% | 84.6% | 82.5% |
| Device rupture | 93.1% | 94.9% | 94.3% |
| Device deflation | 94.0% | 95.6% | 94.4% |
| Capsular contracture | 94.0% | 95.5% | 94.3% |
| Device malposition | 93.9% | 95.6% | 94.4% |
| Skin scarring problems | 94.1% | 95.7% | 94.4% |
| Deep wound infection | 94.1% | 95.7% | 94.4% |
| Seroma / Haematoma | 94.1% | 95.7% | 94.4% |
| Anaplastic Large Cell Lymphoma | 93.9% | 95.6% | 94.4% |
| **DEVICE CHARATERISTICS (Breast Level, inserted)** | **24,742** | **22,635** | **24,484** |
| Breast implant/tissue expander Device ID | 99.9% | 99.7% | 99.9% |
| Matrix used | 99.0% | 99.4% | 97.0% |
| Matrix Device ID (if Matrix = yes) | 99.7% | 99.4% | 99.4% |
| **DEVICE CHARACTERISTICS (Breast Level, explanted)** | **7,569** | **9,088** | **9,082** |
| Explanted device details provided | 76.8% | 84.2% | 84.5% |
| **ABDR DEVICE CAPTURE RATE BASED ON TGA SUPPLY DATA** | **71%** | **73%** | **73%** |
| **PATIENT OPT OUT RATE** | **1.4%** | **1.3%** | **0.9%** |

# APPENDIX 2– DATA COLLECTION FORM

## AUSTRALIAN BREAST DEVICE REGISTRY FORM

AUSTRALIAN Breast Device REGISTRY

MONASH University Medicine, Nursing and Health Sciences

Australian Society of Plastic Surgeons

Breast Surgeons of Australia & New Zealand

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 — BREAST **LEFT**

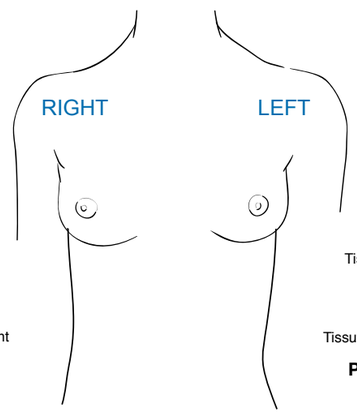
**Category of operation**
- Cosmetic augmentation
- Reconstruction - post cancer
- Reconstruction - benign / prophylactic
- Congenital deformity

**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

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## ELEMENTS OF OPERATION

**RIGHT** BREAST — Tick if Same Bilateral — BREAST **LEFT**

**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

**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 — BREAST **LEFT**

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

## FOR REVISION SURGERY ONLY

**RIGHT** BREAST — Tick if Same Bilateral — 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 | ☐ | ☐ | ☐ |

# APPENDIX 3 – ABDR STAFF

Professor Susannah Ahern, ABDR Steering Committee Chair/ABDR Academic Lead

Dr. Pragya Gartoulla, ABDR Research Manager

Mr. Saeid Kalbasi, Database and Data Linkage Projects Manager

Ms. Trisha Nichols, Communications Officer

Ms. Ying Khu, PROMs Research Officer

Ms. Judith Hankin, Relationship Manager

Ms. Sally McInnes, Registry Operations Manager

Mr. Sean Smith, Research Officer

Ms. Uma Symons, Research Officer

Mr. Leonardo Morandini, Data Entry

Ms. Chethana Mundanna, Data Entry

Ms. Randi Jayasinghe, Data Entry

Ms Hazel Loo, PROMs Telephone follow-up

Ms Renee Conroy, PROMs Telephone Follow-up

Ms. Jessy Hansen, Data Analyst, DEPM, Monash University

A/Prof Arul Earnest, Senior Biostatistician, DEPM, Monash University



# APPENDIX 4 – LIST OF PARTICIPATING SITES AS AT DECEMBER 2020

| State | Site Name |
|---|---|
| ACT | Barton Private Hospital |
| ACT | Calvary Bruce Private Hospital |
| ACT | Calvary John James Hospital |
| ACT | Calvary Public Hospital ACT |
| ACT | Canberra Private Hospital |
| ACT | National Capital Private Hospital |
| NSW | Aesthetic Day Surgery |
| NSW | Albury Wodonga Private Hospital |
| NSW | Alexandria Specialist Day Hospital |
| NSW | Auburn Hospital & Community Health Services |
| NSW | Bankstown-Lidcombe Hospital |
| NSW | Baringa Private Hospital |
| NSW | Bathurst Base Hospital |
| NSW | Bathurst Private Hospital |
| NSW | Belmont Hospital |
| NSW | Bondi Junction Private Hospital |
| NSW | Brisbane Waters Private Hospital |
| NSW | Calvary Mater Newcastle |
| NSW | Calvary Riverina Hospital |
| NSW | Campbelltown Private Hospital |
| NSW | Castlecrag Private Hospital |
| NSW | Charlestown Private Hospital |
| NSW | Chris O'Brien Lifehouse |
| NSW | Coffs Day Hospital |
| NSW | Coffs Harbour Base Hospital |
| NSW | Concord Repatriation Hospital |
| NSW | Crows Nest Day Hospital |
| NSW | Double Bay Day Hospital |
| NSW | East Sydney Private Hospital |
| NSW | Gosford Hospital |
| NSW | Gosford Private Hospital |
| NSW | Holroyd Private Hospital |
| NSW | Honeysuckle Day Hospital |
| NSW | Hornsby Ku-Ring-Gai 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 |
| NSW | Lingard Private Hospital |
| NSW | Liverpool Hospital |
| NSW | Macquarie St Day Surgery |
| NSW | Macquarie University Hospital |
| NSW | Maitland Private Hospital |
| NSW | Mater Hospital Sydney |
| NSW | Mount Druitt Hospital |
| NSW | Nepean Hospital |
| NSW | Nepean Private Hospital |
| NSW | North Shore Private Hospital |
| NSW | North Shore Specialist Day Hospital |
| NSW | Northern Beaches Hospital |
| NSW | Norwest Day Hospital |
| NSW | Norwest 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 |
| NSW | Royal North Shore Hospital |
| NSW | Shellharbour Private Hospital |
| NSW | Southern Highlands Private Hospital |
| NSW | St George Hospital |
| NSW | St George Private Hospital |
| NSW | St Luke's Hospital |
| NSW | St Vincent's Private Community Hospital Griffith |
| NSW | St Vincent's Hospital (Darlinghurst) |
| NSW | St Vincent's Private Hospital (Darlinghurst) |
| NSW | Strathfield Private Hospital |
| NSW | Surry Hills Day Hospital |
| NSW | Sydney Adventist Hospital |
| NSW | Sydney Children's Hospital |
| NSW | Sydney Day Hospital |
| NSW | Sydney Southwest Private Hospital |
| NSW | Sydney Surgical Centre |
| NSW | Tamara Private Hospital |
| NSW | The Double Bay Day Surgery |
| NSW | The San Day Surgery |
| NSW | The Sydney Private Hospital |
| NSW | The Tweed Hospital |
| NSW | Tweed Day Surgery |
| 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 Hospital |
| NSW | Wollongong Private Hospital |
| NT | Darwin Day Surgery |

| State | Site Name |
|---|---|
| NT | Darwin Private Hospital |
| NT | Royal Darwin Hospital |
| QLD | Brisbane Day Hospital |
| QLD | Brisbane Private Hospital |
| QLD | Buderim Private Hospital |
| QLD | Caboolture Private Hospital |
| QLD | Cairns Base Hospital |
| QLD | Cairns Day Surgery |
| QLD | Cairns Private Hospital |
| QLD | Canossa Private Hospital |
| QLD | Chermside Day Hospital |
| QLD | Far North Day Hospital |
| QLD | Friendly Society Private 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 | Ipswich Hospital |
| QLD | John Flynn Private Hospital |
| QLD | Kawana Private Hospital |
| QLD | Mater Adult's Hospital |
| QLD | Mater Private Hospital (South Brisbane) |
| QLD | Mater Private Hospital Mackay |
| QLD | Mater Private Hospital Springfield |
| QLD | Mater Private Hospital Townsville |
| QLD | Mater Private Hospital Townsville (Hyde Park Campus) |
| QLD | Mater Private Rockhampton |
| QLD | Miami Private Hospital |
| QLD | Noosa Hospital |
| QLD | North Lakes Day Hospital |
| QLD | North West Private Hospital |
| QLD | Pacific Day Surgery Centre |
| QLD | Pacific Private Day Hospital |
| QLD | Pindara Day Procedure Centre |
| QLD | Pindara Private Hospital |
| QLD | Princess Alexandra Hospital |
| QLD | Queen Elizabeth II Jubilee Hospital |
| QLD | Queensland Children's Hospital |
| QLD | Redland Hospital |
| QLD | Renaissant Aesthetic Health |
| QLD | Robina Hospital |
| QLD | Rockhampton Base Hospital |
| QLD | Royal Brisbane & Women's Hospital |
| QLD | Samford Road Day Hospital |
| QLD | South Bank Day Hospital |

| State | Site Name |
|---|---|
| QLD | Southport Day Hospital |
| QLD | Spring Hill Specialist Day Hospital |
| QLD | St Andrew's Ipswich Private Hospital |
| QLD | St Andrew's Toowoomba Hospital |
| QLD | St Andrew's War Memorial Hospital |
| QLD | St Stephen's Hospital Hervey Bay |
| QLD | St Vincent's Private Hospital Brisbane |
| QLD | St Vincent's Private Hospital Northside |
| QLD | St Vincent's Private Hospital Toowoomba |
| QLD | Sunnybank Private Hospital |
| QLD | Sunshine Coast Day Surgery |
| QLD | Sunshine Coast University Private Hospital |
| QLD | The Wesley Hospital |
| QLD | Toowoomba Surgicentre |
| QLD | Townsville University Hospital |
| QLD | Varsity Lakes Day Hospital |
| QLD | Westside Private Hospital |
| SA | Adelaide Day Surgery |
| SA | Ashford Community Hospital |
| SA | Brighton Day Surgery |
| SA | Calvary Adelaide Hospital |
| SA | Calvary North Adelaide Hospital |
| SA | Calvary Wakefield Surgicentre |
| SA | Flinders Medical Centre |
| SA | Flinders Private Hospital |
| SA | Glenelg Community Hospital |
| SA | Hamilton House Day Surgery |
| SA | Lyell McEwin Hospital |
| SA | Memorial Hospital |
| SA | Noarlunga Health Service |
| SA | North Adelaide Day Surgery Centre |
| SA | North Eastern Community Hospital |
| SA | Norwood Day Surgery |
| SA | St Andrew's Hospital INC |
| SA | Stirling Hospital INC |
| SA | The Burnside War Memorial Hospital |
| SA | The Queen Elizabeth Hospital |
| SA | The Royal Adelaide Hospital |
| SA | Waverley House Plastic Surgery Centre |
| SA | Western Hospital (SA) |
| SA | Womens and Childrens Hospital |
| TAS | Calvary - St John's Hospital |
| TAS | Calvary - St Vincent's Hospital |
| TAS | Hobart Private Hospital |
| TAS | Launceston General Hospital |
| TAS | North Tas Day Hospital |

| State | Site Name |
|---|---|
| TAS | Royal Hobart Hospital |
| VIC | Austin Health - Austin Hospital |
| VIC | Austin Health - Heidelberg Repatriation Hospital |
| VIC | Ballarat Health Services (Base Hospital) |
| VIC | Barwon Health - Geelong Hospital Campus |
| VIC | Beleura Private Hospital |
| VIC | Bellbird Private Hospital |
| VIC | Bendigo Day Surgery |
| VIC | Bendigo Health - The Bendigo Hospital |
| VIC | Box Hill Hospital |
| VIC | Cabrini Brighton |
| VIC | Cabrini Malvern |
| VIC | Casey Hospital |
| VIC | Corymbia Day Hospital |
| VIC | Dandenong Hospital |
| VIC | Dr Lanzer & Associates Cosmetic Day Hospital |
| VIC | Epworth Cliveden |
| VIC | Epworth Eastern |
| VIC | Epworth Freemasons |
| VIC | Epworth Geelong |
| VIC | Epworth Hawthorn |
| VIC | Epworth Richmond |
| 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 | Mitcham Private Hospital |
| VIC | Monash House Private Hospital |
| VIC | Monash Medical Centre - Moorabbin Campus |
| VIC | Mulgrave Private Hospital |
| VIC | Northpark Private Hospital |
| VIC | Peninsula Private Hospital (VIC) |
| VIC | Peter MacCallum Cancer Centre |
| VIC | Ringwood Private Hospital |
| VIC | Royal Melbourne Hospital - City Campus |
| VIC | Sir John Monash Private Hospital |
| VIC | South West Healthcare-Warrnambool Campus |
| VIC | St John of God Ballarat Hospital |
| VIC | St John of God Bendigo Hospital |
| VIC | St John of God Berwick Hospital |

| State | Site Name |
|---|---|
| VIC | St John of God Geelong Hospital |
| VIC | St John Of God Warrnambool 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 |
| VIC | Sunshine Hospital |
| VIC | The Alfred |
| VIC | The Avenue Private Hospital |
| VIC | The Bays Hospital |
| VIC | The Melbourne Eastern Private Hospital |
| VIC | The Northern Hospital |
| VIC | The Royal Childrens Hospital |
| VIC | The Royal Women's Hospital |
| VIC | VCI Day Surgery |
| VIC | Vermont Private Hospital |
| VIC | Warringal Private Hospital |
| VIC | Waverley Private Hospital |
| VIC | Western Hospital |
| VIC | Western Private Hospital |
| VIC | Williamstown Hospital |
| VIC | Windsor Private Hospital |
| WA | Bethesda Hospital |
| WA | Bunbury Day Hospital |
| WA | Cambridge Day Surgery |
| WA | Concept Day Hospital |
| WA | Hollywood Private Hospital |
| WA | Joondalup Health Campus |
| WA | McCourt Street Day Surgery |
| WA | Mount Hospital |
| WA | Peel Health Campus - Private |
| WA | Southbank Day Surgery |
| WA | St John of God Bunbury Hospital |
| WA | St John of God Geraldton Hospital |
| WA | St John of God Hospital, Subiaco |
| WA | St John of God Midland Public & Private Hospital |
| WA | St John of God Mt Lawley Hospital |
| WA | St John of God Murdoch Hospital |
| WA | St John of God Wembley Day Surgery |
| WA | Subiaco Private Hospital |
| WA | Sundew Day Surgery |
| WA | Waikiki Private Hospital |
| WA | West Leederville Private Hospital |

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