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AUSTRALIAN BREAST DEVICE REGISTRY

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Data period

The data contained in this document were extracted from the ABDR database 27 May 2024 and related to data that had been submitted from the initiation of the pilot ABDR on 19 January 2012 to 31 December 2023. As the Registry does not capture data in real time, there can be lag between occurrence of an event and capture in the ABDR.

Funding

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abdr.org.au

Contents

Foreword

Welcome to the 2023 Australian Breast Device Registry (ABDR) Annual Report, the Registry's eighth.

We are pleased to present the 2023 Annual Report of the Australian Breast Device Registry, highlighting another year of progress in our commitment to improving the quality of care and outcomes for patients with breast devices. Clinical quality registries, and the ABDR specifically play an essential role in monitoring healthcare by collecting, analysing, and reporting real world data that directly informs clinical practice, device performance and patient safety. This year's report reflects the continuous efforts of clinicians and researchers to enhance patient outcomes through evidence-based improvements.

During 2023, 239 health services and 443 clinicians across Australia contributed data to the ABDR, with the patient opt-out rate remaining at approximately 1%. This is a testament to the value the ABDR provides to clinicians, health services, regulators, researchers and industry in the monitoring of breast device (implant, matrices and tissue expanders) performance. As of 31st December, 2023, the ABDR had accrued nearly 100,000 patients and approximately 200,000 devices, providing a substantial resource for quality assurance monitoring, audit and research. The 2023 ABDR annual report continues to provide detailed analysis of devices used (both implanted and explanted), trends in breast reconstructive and cosmetic procedures, monitor the incidence and devices associated with Australian cases of Breast Implant Associated Anaplastic Large Cell Lymphoma, and much more.

In the 2023 report we include some new analyses. For the first time, we report the annual number of revisions undertaken on breast implant insertions performed overseas (cosmetic tourism). For reconstructive procedures we analyse the times between tissue expander insertion and implant exchange, and observe a reduction over time in second stage completion. We also report revision rates for contralateral breast implants associated with a unilateral reconstructive implant, and plot these as new graphs on the reconstructive revision curve. For the first time we have also reported use of mesh/matrix in cosmetic procedures, usually revision procedures, with the intent to observe for trends over time. Lastly, we have created a new Chapter 7, which brings together the international clinical quality indicators for breast device surgery and initial funnel plots of variation, including new plots showing variation in revision rates at 1 year for reconstructive and cosmetic surgery. In 2023, the ABDR was provided with Qualified Privilege under the *Health Services Act (Cth),* providing additional assurance to participating clinicians regarding the privacy and confidentiality of their data.

We extend our sincere gratitude to the participating clinicians/surgeons, patients, and other stakeholders whose contributions make this Registry a vital tool for improving healthcare quality. As we look to the future, we remain dedicated to strengthening our efforts in delivering meaningful data analysis, with continued focus on patient safety and clinical excellence.

Professor Susannah Ahern, Chair of the ABDR, Monash University

Dr Yvonne Chow, Australian Society of Plastic Surgery

Dr Patrick Tansley, Australasian College of Cosmetic Surgery and Medicine

Dr Melanie Walker, Breast Surgeons of Australia and New Zealand

Acknowledgements

The ABDR acknowledges the Australian Government, Department of Health and Aged Care for providing funding to the ABDR under the National Clinical Quality Registry Program, in conjunction with some in-kind support from Monash University. The ABDR are also appreciative for the unwavering commitment of our respected craft groups for ensuring the continued success of the Registry.

The work of the ABDR is shaped by its Steering Committee, Clinical Advisory Committee and Research and Data Sharing Subcommittee. We acknowledge the strong leadership provided by all craft group representatives on these committees, without which this ABDR would not be possible. The ABDR also thanks the Monash University ABDR team for their commitment to continuous improvement and further development of the ABDR (full list on page 126).

In 2023, Associate Professor Gillian Farrell stepped aside as Clinical Lead representing the Australian Society of Plastic Surgery (ASPS), and Dr Yvonne Chow has moved into this role. We thank Associate Professor Farrell for her enthusiastic support and significant commitment to the ABDR over many years of association.

We greatly appreciate the dedication of the other ABDR Clinical Leads Dr Patrick Tansley representing the Australasian College of Cosmetic Surgery and Medicine (ACCSM); and, Dr Melanie Walker representing Breast Surgeons of Australia and New Zealand. The Clinical Leads provide critically important knowledge and insight to direct and inform the activities and progress of the ABDR. We are also grateful for the time commitment that members of the ABDR Steering committee make to guide the work of the Registry, including: Dr Amanda Craig (Therapeutics Goods Administration), Dr Bernadette Aliprandi-Costa (Australian Commission on Safety and Quality in Healthcare), Ms Sally Rayner (Australian Department of Health and Aged Care), Ms Jane Synnot (Consumer representative) and Dr Jasjit Baveja (Medical Technology Association of Australia).

This Annual Report would not be possible without the Australian clinicians, nurses, theatre staff, hospital and clinic administrators who submit their Data Collection Forms to the ABDR. A sincere thanks to you all for your ongoing commitment and timely efforts to ensure that your patient data is sent to the ABDR. A special thank you to the patients who see the importance of the Registry. Your data is contributing to identifying emerging trends in implantable breast devices specifically, and patient safety more broadly into the future.

Steering Committee Representative Organisations

Monash University

Australian Government Department of Health and Aged Care (the Department)

Australian Society of Plastic Surgeons (ASPS)

Australasian College of Cosmetic Surgery and Medicine (ACCSM)

Breast Surgeons of Australia and New Zealand (BreastSurgANZ)

Therapeutic Goods Administration (TGA)

Australian Commission on Safety and Quality in Health Care (ACSQHC)

Medical Technology Association of Australia (MTAA)

Executive summary

The Australian Breast Device Registry continues to monitor breast device procedure related data from patients across Australia using an opt-out model under the direction of a Steering Committee with representation from key stakeholders including clinical craft groups, government and government agencies, consumers and industry. The registry is currently funded under the Commonwealth Department of Health and Aged Care (DoHAC)'s National Clinical Quality Registry Program, and is managed at the School of Public Health and Preventive Medicine, Monash University.

Registry participation

In 2023, **239 hospitals and health services** (referred to in this report as 'sites') participated in the ABDR. Of these, 73.6% were private hospitals, clinics and day surgeries, and 26.4% were public hospitals. Participation across Australia was widespread, with the highest proportion (34%) of participating sites from New South Wales, followed by Victoria (25%), and Queensland (19%). The 2023 calendar year also saw **281 plastic surgeons, 136 general/breast surgeons and 26 cosmetic clinicians (443 surgeons in total)** contributing data. **The majority (56%) of clinicians who contributed to the ABDR in 2023 performed both cosmetic and reconstructive procedures,** whilst the remaining cohort was split equally between cosmetic-only (22%) and reconstructive-only (22%). Most (54%) clinicians who performed both types of procedures undertook 11-50 procedures in 2023, whilst a much smaller number (2%) performed more than 200 procedures. Most clinicians who performed only one type of procedure (cosmetic or reconstructive), contributed fewer than 6 cases (46% of cosmetic-only and 60% of reconstructive-only).

Patients, procedures and devices

Since 2012, the ABDR has registered **98,460 patients,** with **10,566 (10.7%) of those recruited to the registry in 2023.** The opt-out rate for the registry remains low, **around 1% in 2023,** and <1% overall (2012-2023). Out of all the patients registered in the ABDR (2012-2023), **69,973 (71.1%) had a cosmetic indication and 20,169 (20.5%) had a reconstructive indication** for surgery, with the latter reflecting post-cancer reconstruction, risk-reducing reconstruction and development deformity correction. The registry has data on **113,439 procedures (at operation-level), reflecting 211,493 procedures at breast-level and 192,706 devices.** These numbers differ as not all procedures involve both breasts, nor do they all involve the insertion of a new device. Furthermore, the ratio of patients to procedures is not 1:1. In 2023, the registry captured data on **12,645 procedures** at operation-level (11.1% of total), reflecting **23,573 procedures** at breast-level (11.1%) and **20,380** (10.6%) new devices. Of the total number of procedures reported at breast-level to the ABDR (211,493), **85.6% involved the insertion of a new breast implant.**

Breast devices manufacturer information is also collected by the registry, with **Mentor Medical Systems** accounting for the greatest proportion of implants inserted **(48.8%)** between 2012 and 2023. **Mentor Medical Systems** and **Motiva** accounted for almost all devices inserted in 2023. The most common shell type for implants inserted in 2023 continues to be smooth for both reconstructive procedures whilst the most common shape continues to be round. The most frequently explanted or replaced devices with manufacturer details available between 2012 and 2023 were from Allergan/Inamed/McGhan/CUI and Mentor Medical Systems.

Registry case ascertainment is undertaken annually, comparing ABDR data against sales data provided by the Therapeutic Goods Administration, and procedure data publicly available from the Australian Institute of Health and Welfare (AIHW). In 2023, the registry captured a reported **86.4% of sold devices,** and approximately **72% of procedures** (2022-2023 financial year data).

For the first time, the ABDR reports data relating to revisions of procedures originally performed overseas **(cosmetic tourism).** During 2012-2023, there were 5,492 procedures involving removal of devices that were inserted overseas.

Reconstructive procedure trends

Of the **29,268 procedures involving breast devices for reconstructive purposes** in the ABDR, 3,386 (11.6%) were performed in 2023, reflecting a **minor increase in reconstruction procedures** following a 3-year downward trend suspected to relate to Covid-19. In 2023, **74.9% of initial reconstructive breast procedures were insertion procedures, whilst 19.6% were revisions and 5.5% were explant only.** The most significant change has been in explant-only procedures, up from 0.8% in 2016. **Most reconstructive procedures performed in 2023 (76.4%) occurred following mastectomy undertaken to manage breast cancer,** with a median age of 50.2 years for patients with this indication. Of these, a greater proportion were bilateral cases (42% of total reconstructive procedures), whilst bilateral risk-reducing procedures accounted for 11.6% of cases, and bilateral procedures for developmental deformity accounted for 6.1%.

The proportion of **direct-to-implant (i.e., one-stage) procedures has steadily increased from 47.5% in 2016 to 66.9% in 2023,** reflecting a change in clinical practice around the use of tissue expanders (i.e., a two-stage procedure). For two-stage procedures, approximately **75% of exchanges occur within 9 months,** with **86.1% completed within 12 months** (2012-2023). The registry has uncovered an increasing trend where tissue expanders are not subsequently revised nor exchanged, may reflect an increase in autologous flap usage (not collected by the ABDR) during this period.

In 2023, **intra-operative antibiotic use during all reconstructive procedures remained steady at 85.3%,** with **78.4%** using **post-operative antibiotics and 74.8% using an antiseptic rinse.** Intraoperative techniques of changing gloves for insertion (82.6%) and sleeve/funnel usage (43.5%) increased slightly, whilst use of an antibiotic dipping solution (55%) decreased.

The two most common **incision sites** for reconstructive procedures continues to be **inframammary (39.3%) and previous mastectomy scar (28.8%),** and the most common **surgical plane** is a sub-pectoral/dual plane (47.8%). Concurrent mastectomy, nipple sparing surgery and flap cover rates have increased over several years, whilst axillary surgery rates dropped slightly between 2022 and 2023. The most common implants used in 2023 were smooth (65.9%) and round (69.5%). **Fifty-eight percent of post-cancer direct-to implant** procedures included **matrix/mesh,** as did **28.6% of post-cancer tissue expander insertions.** The most common complication identified at revision was **capsular contracture (35.1% of complications).**

The 8-year **all-cause revision rate** following primary implant insertion for reconstructive procedures was found to be highest for cases with a **risk-reducing indication (20.4%)** followed by post-cancer **reconstruction (19.4%), developmental deformity (13.5%)** and **contralateral augmentation (15.3%)**. Revisions 8-years post primary implant insertion due to **complications** was **highest in the post-cancer cohort (13.9%)** and risk reducing cohort (13.6%), followed by contralateral augmentation (9.6%) and developmental deformity (7.9%). Complications with the **highest incidence rates at this time point were capsular contracture (5.7%) and device malposition (5.4%).**

Revisions due to complications were higher for polyurethane implants (17.1%) and textured implants (14.0%), compared to smooth implants (10.0%). At 8-years follow up, **revisions due to complications** for **direct-to-implant procedures** were similar (12.8% with matrix/mesh vs 10.9% without matrix/mesh). For **two stage procedures,** complication rates were also similar (14.0% with matrix/mesh vs 13.7% without matrix/mesh). Revisions due to complications associated with **tissue expanders** at 24 months was **5.8% for post-cancer procedures.**

Cosmetic procedure trends

During 2023, the Registry recorded **7,835 new cosmetic procedures,** reflecting almost 1,500 fewer than the previous year and **the lowest number recorded in the registry since 2016.** This decline is suspected to reflect changes in patient preferences regarding cosmetic procedures (i.e., exploration of alternatives to devices). Of all initial cosmetic procedures recorded in 2023, 71.0% were insertions, 20.9% were revisions and 8.1% were explant only, reflecting **a 12.7% decrease of insertion-only procedures, 5.0% increase in revisions** and **7.7% increase in explant-only procedures during this period.** While the median age for breast insertions was 31.4 years, the most common age group was 20-29 years, comprising 41.4% of cosmetic insertion procedures.

Intra-operative aseptic technique usage has increased over the past several years, with a 9.3% increase of antiseptic rinse usage in cosmetic procedures performed in 2023 compared with those in 2016, and a notable increase of 47.2% in the use of sleeve/funnel over the same time period for cosmetic insertion and revision procedures. The most common surgical incisions site used for cosmetic procedures was **infra-mammary, and the most common surgical plane was the sub-pectoral/dual plane** (79.1%). Fat grafting has increased 10.4%, and concurrent mastopexy has increased by 9% during this period. During 2023, 66.2% of devices were smooth, and 81% were round. The ABDR reported matrix/mesh use for the first time, with 0.1% of implant insertions and 1.3% of implant revisions being accompanied with mesh/matrix.

The 8-year **all cause revision** incidence for cosmetic procedures was **6.7%** for initial implant insertions, whilst revision incidence attributable to complications was **3.5%.** Cosmetic revision incidence 8-years post-primary implant insertion was most commonly due to capsular contracture (1.6%) or device malposition (1.4%). **Revision due to complications** at 8 years was 3.7% for polyurethane, 3.4% for textured and 3.2% for smooth implants.

BIA-ALCL

In 2023, there were three new cases of BIA-ALCL reported to, and confirmed by, the ABDR. One of the cases was initially diagnosed in 2022 while the remaining two were diagnosed in 2023. This takes the total recorded BIA-ALCL cases in the registry to 67, with 2023 having the lowest incidence of BIA-ALCL recorded since 2015. The most common duration between implant insertion and date of revision is **between 7-10 years.** The most common clinical issues associated with BIA-ALCL was seroma/haematoma and capsular contracture.

Clinical quality indicators and funnel plots

In this report, the Registry has reported variation in intra-operative techniques via a series of funnel plots for the second year in a row. For the first time the ABDR is also reporting funnel plots to show variation in revision rates due to complications at 1 year, by hospital. The **average rate of revision** for hospitals that have undertaken reconstructive breast implants is 3.4%, cosmetic implants is 0.7% (for insertions between 2020-2022). **Cumulative revision rates due to complications at 60 days has** varied between 0.6 – 1.3% from 2016 to 2023 for reconstructive procedures, and has been consistently around 0.1% for cosmetic procedures. While revision rates at 12 months have remained less than 1% for cosmetic procedures, for reconstructive procedures, rates have reduced from 3.8% in 2016 to 3.2% in 2023.

Overview of the Australian Breast Device Registry

The Australian Breast Device Registry (ABDR) is a Clinical Quality Registry that employs an opt-out consent model. It was established in 2014 with Commonwealth Government funding following the Pilot Breast Device Registry, an initiative of the Australasian Foundation of Plastic Surgery in 2011. The first patient of the ABDR was entered in June 2015.

The aims of the ABDR are three-fold: (1) to track the long-term safety and performance of breast devices including breast implants, tissue expanders and matrix/mesh, (2) to identify and report on possible trends and complications associated with breast device surgery; and (3) to identify surgical factors that may improve patient health outcomes.

Registry governance and reporting

The ABDR operates in accordance with the Australian Commission on Safety and Quality in Health Care's Framework for Australian clinical quality registries[1] and the National Clinical Quality Registry and Virtual Registry Strategy 2020-2030 (the Strategy)[2]. Aligning with the Commission gives all key stakeholders assurance that Registry data and its supporting systems satisfy security, technical and operating standards.

Steering Committee

The ABDR Steering Committee is responsible for providing the strategic oversight of the Registry's activities. The committee meets three times a year, and is comprised of the data custodian and Chair Professor Susannah Ahern (School of Public Health and Preventive Medicine) and one representative from each of the stakeholder groups (please refer to page 3).

Clinical Advisory Committee and Research and Data Sharing Subcommittee

The ABDR Clinical Advisory Committee is responsible for overseeing the Registry's daily operations. It meets six times a year, and is comprised of the data custodian and Chair Professor Susannah Ahern, the three clinical leads, with senior members of the ABDR operations team in attendance.

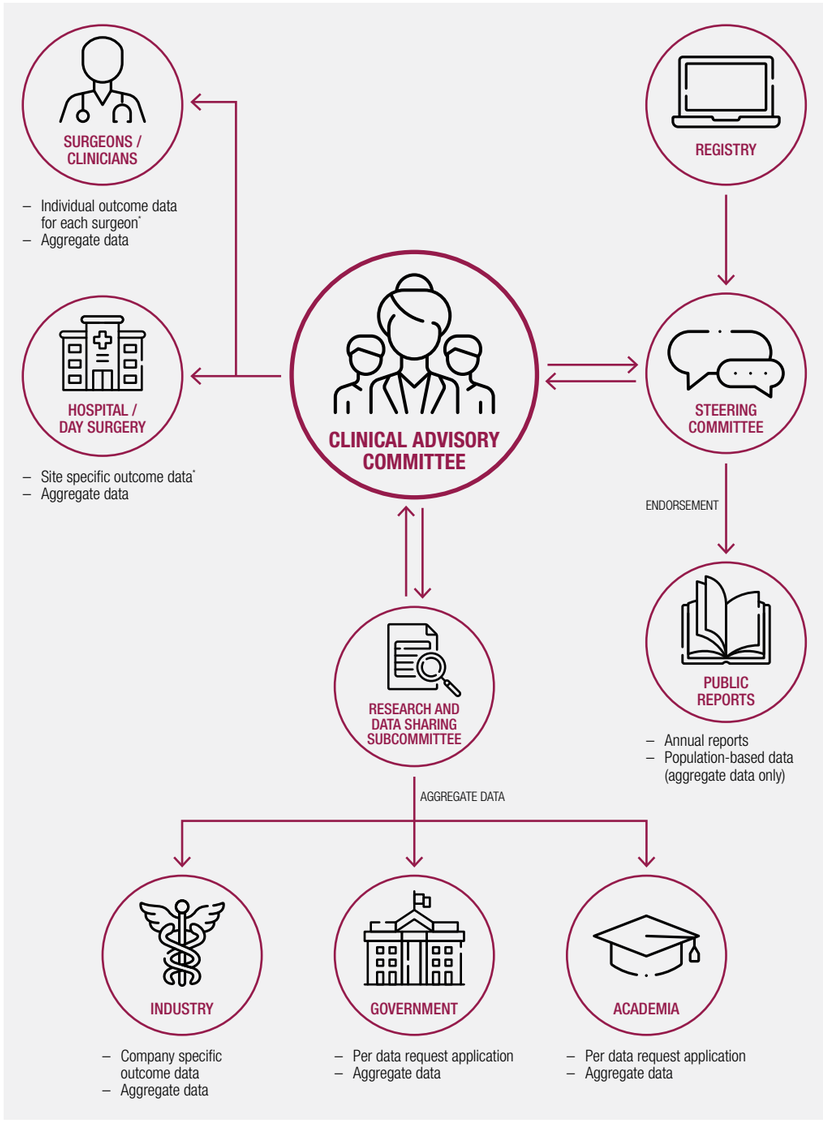
The ABDR Research and Data Sharing Subcommittee also meets six times a year. The subcommittee is comprised of the data custodian and Chair Professor Susannah Ahern, the clinical leads and additional academic-clinicians representing each of the craft groups, ABDR senior management, biostatistical and operations team members. The responsibilities of the subcommittee are to review and approve requests for ABDR data from external parties, as well as to provide clinical review of analyses, reports, and academic publications developed by the ABDR.

1 Australian Commission on Safety and Quality in Health Care, Framework for Australian clinical quality registries. Sydney. ACSQHC, March 2014.

2 Department of Health, National Clinical Quality Registry and Virtual Registry Strategy. Canberra. 2020. Retrieved from https://www.health.gov.au/sites/default/files/2023-04/a-national-strategy-for-clinical-quality-registries-and-virtual-registries-2020-2030_0.pdf

Reporting/registry output

The ABDR produce various reports that are endorsed and approved for circulation according to its respective committee/subcommittee (please refer to the infographic below).



*The Clinical Advisory Committee approve report structure and do not view individual clinician or hospital reports.

International Collaboration of Breast Registry Activities (ICOBRA)

Australia was a prominent stakeholder in establishing the International Collaboration of Breast Registry Activities (ICOBRA). The countries that have committed to ICOBRA continue to work towards a minimal data set that is standardised, incorporates epidemiologically sound data fields and demonstrates global best practice in breast device surgery. ICOBRA also has regular meetings, and annual face to face workshop and conference presentation, and produces collaborative publications of significance for international breast implant surgery.

Methods

Outcome assessment

The main outcome used to assess device performance in this report is time-to-revision. Survival analysis methods are used to investigate revision incidence rates for primary insertions of: reconstructive breast implants, cosmetic breast implants, and reconstructive tissue expanders, as well as separate analysis of matrix/mesh devices inserted with primary reconstructive breast implants/tissue expanders.

Definitions:

- **Revision surgery** includes the replacement, repositioning or explant of an in-situ breast device. Time-to-revision is defined as the time from the insertion of the device of interest to the first subsequent revision procedure of the breast.
- **All-cause revision** incidence considers revisions captured by the Registry due to any reason, whether due to complication, patient preference or other unknown reasons.
- **A revision** is considered as being due to **complication** if the reported reason for revision is complication and/or at least one issue was identified at revision (issues include any of device rupture, device deflation, capsular contracture, device malposition, skin scarring problems, deep wound infection, seroma/haematoma and BIA-ALCL).
- **Primary breast implants** are defined as those which are inserted into breasts which have no in-situ breast implant (i.e.: procedure is not a replacement of an implant) and also have no recorded history of prior procedures involving implants recorded in the Registry.
- **Primary tissue expanders** are defined as those which are inserted into breasts which have no in-situ device (i.e.: procedure is not replacement) and also have no recorded history of prior procedures involving tissue expanders or implants recorded in the Registry.

Time-to-revision outcomes are assessed with primary devices only. For each primary device, a time interval is calculated. Each interval is either a time to failure event or a time to censoring. The start of each interval is the time of primary device insertion. The end time of each interval depends whether or not there are follow up procedures captured by the Registry:

- If a revision follow-up procedure is captured, the end time of the interval is the time of the first revision. If this revision procedure involves the endpoint of interest (all-cause revision/ revision due to any complication/revision involving a specific complication), the interval is a time to event. Otherwise, the interval is a time to censoring.
- For tissue expander insertions, if a tissue expander removal and implant insertion procedure is the first follow-up procedure captured, this procedure is used as the end time for a censoring interval.
- If there are no follow up procedures, the date of the last procedure in the extract, 15 May 2024, is used as the end time for a censoring interval.

Cumulative revision incidence rates and hazard functions have been calculated based on the time intervals corresponding to primary devices inserted between 2012-2023 (inclusive).

Crude cumulative revision incidence rates have been generated using Kaplan-Meier event estimates. Larger values correspond with higher frequencies of the outcome of interest.

Hazard function estimates against time elapsed (since primary breast implant insertion) have been generated using Epanechnikov kernel smoothing. For implants which have remained unrevised up to a certain timepoint, large hazard values correspond to higher chances of the failure event (revision due to certain complication) occurring soon after. Plots of hazard against time elapsed can show typical times of failure events. They can demonstrate possible relationships between time elapsed and failure rates. Hazard functions start high then decrease for events which typically occur shortly after device insertion. Hazard functions increase over time for events which typically occur after long periods of time have elapsed. Events with failure rates that are independent of time elapsed would have flat hazard curves.

A limitation with time-to-revision analysis data is the potential under-reporting of follow-up procedures, especially for explant only procedures which do not involve new devices. It should also be noted that long periods of time can elapse between when issues are first experienced and when the revision procedures occur. Furthermore, patients with complications may not necessarily undergo revision surgeries.

Assessment of clinical variation

Funnel plots are data visualisations which are used to investigate variation in clinical practice and benchmark performance based on certain indicators. They aid in assessing performance of individual units relative to peers and the overall average.

Key features of funnel plots include:

- Dot points representing the individual units being compared (eg. clinicians/hospitals)
- Horizontal axis showing the number of procedures per unit
- Vertical axis showing the percentage of procedures with the indicator of interest per unit
- A horizontal line showing the pooled average frequency of the indicator across all units
- Contour lines are used to show 99.8% control limits. Units with points lying between both contours may be considered as having close to average performance. In contrast, units outside of these contours may be considered as outliers. The vertical range between contour lines is wider for units with smaller procedure volumes to allow for more variation from the pooled average due to random factors. The contour boundaries are calculated on the assumption that all procedures have the same probability of having the indicator, regardless of which unit they are from.

In this report funnel plots are used to compare the reported use of intra-operative techniques across clinicians and to compare the frequency of complications occurring within one year of insertion across hospitals.

CHAPTER 1

Registry Participation (2012-2023)

Site participation

The ABDR continues to work with our three clinical craft groups to identify and invite new clinicians and their respective hospitals/sites to participate in the Registry. Registry staff are involved with onboarding the site including progressing ethics and governance approvals on the site's behalf (referred to as site implementation). Public hospitals in Western Australia remain unable to participate in the Registry as they are prevented by state legislation.

Since the inception of the Registry there is no single record of all the hospital and healthcare facilities in Australia that provide breast device surgery. Additionally, sites and clinicians that perform breast device surgery change every year. Consequently, determining the precise denominator to calculate site participation is difficult. The ABDR actively monitors sites and site websites to stay informed about any changes in practices. We also document site closures, as well as site name changes that occur as a consequence of new management.

In 2023, the ABDR added an additional 3 sites, comprising 1 private site and 2 public hospitals. The ABDR employ specific terminology to demonstrate site participation in the Registry. 'Contributing' site refers to a hospital that has submitted data to the Registry in previous years but may not have submitted data in the current reporting period. 'Participating' site refers to a hospital that has maintained continuous reporting to the Registry including in the current reporting period. Differentiating 'contributing' and 'participating' sites has meant fewer participating sites, however, this provides a more accurate measure of which sites are regularly performing breast device surgery and submitting data collection forms.

In 2023 a total of **239 sites** were participating in the ABDR, specifically 176 (74%) private hospitals, clinics and day surgeries; and 63 (26%) public hospitals (Table 1.1).

TABLE 1.1 SITE PARTICIPATION BY STATE AND SITE TYPE (2023)

State	Total	Private	Public
NSW	81 (34%)	57 (32%)	24 (38%)
VIC	60 (25%)	40 (23%)	20 (32%)
QLD	46 (19%)	37 (21%)	9 (14%)
SA	20 (8%)	14 (8%)	6 (10%)
WA	16 (7%)	16 (9%)	0 (0%)
ACT	7 (3%)	6 (3%)	1 (2%)
TAS	6 (3%)	4 (2%)	2 (3%)
NT	3 (1%)	2 (1%)	1 (2%)
Total	**239 (100%)**	**176 (100%)**	**63 (100%)**

Note: the ABDR is committed to ensuring that all patients and clinicians in Australia are able to be part of the Registry. In this effort the ABDR are working closely with clinicians in Western Australian public hospitals to implement Registry operations at these sites.

TABLE 1.2 PROCEDURE BY STATE/TERRITORY SURGERY INDICATION AND SITE TYPE (PUBLIC AND PRIVATE) 2012-2023

Site State	Cosmetic		Reconstructive		Indication Not stated/Not known		Total	
	Private	Public	Private	Public	Private	Public	Private	Public
NSW	22,199 (30.1%)	83 (23.2%)	5,796 (25.7%)	1,834 (27.1%)	2,417 (26.0%)	235 (29.2%)	30,412 (28.8%)	2,152 (27.2%)
QLD	22,221 (30.1%)	111 (31.1%)	4,025 (17.9%)	1,525 (22.6%)	3,127 (33.7%)	191 (23.7%)	29,373 (27.8%)	1,827 (23.1%)
VIC	15,625 (21.2%)	73 (20.4%)	4,790 (21.3%)	1,959 (29.0%)	1,658 (17.9%)	207 (25.7%)	22,073 (20.9%)	2,239 (28.3%)
WA	8,759 (11.9%)	0 (0.0%)	3,755 (16.7%)	0 (0.0%)	1,433 (15.4%)	0 (0.0%)	13,947 (13.2%)	0 (0.0%)
SA	3,797 (5.1%)	60 (16.8%)	2,971 (13.2%)	1,024 (15.2%)	445 (4.8%)	110 (13.6%)	7,213 (6.8%)	1,194 (15.1%)
TAS	669 (0.9%)	27 (7.6%)	542 (2.4%)	197 (2.9%)	137 (1.5%)	34 (4.2%)	1,348 (1.3%)	258 (3.3%)
ACT	326 (0.4%)	3 (0.8%)	476 (2.1%)	181 (2.7%)	30 (0.3%)	23 (2.9%)	832 (0.8%)	207 (2.6%)
NT	133 (0.2%)	0 (0.0%)	155 (0.7%)	38 (0.6%)	32 (0.3%)	6 (0.7%)	320 (0.3%)	44 (0.6%)
Total, (Site type)	**73,729 (99.5%)***	**357 (0.5%)***	**22,510 (76.9%)***	**6,758 (23.1%)***	**9,279 (92.0%)***	**806 (8.0%)***	**105,518 (93.0%)***	**7,921 (7.0%)***
Total	**74,086**		**29,268**		**10,085**		**113,439**	

Note: Public hospitals in Western Australia are unable to contribute to the Registry due to state legislation.

*Percentage of procedures that are private / public out of those with the indication of interest.

Overall, 113,439 procedures were performed from 2012-2023. Approximately 8.9% of these (N=10,085) did not state the indication for surgery in the data collection form (cosmetic augmentation, reconstruction post-cancer, reconstruction benign/prophylactic or congenital deformity). Of the remainder, almost 100% of cosmetic procedures were performed in private hospitals, and 76.9% of reconstructive procedures were also performed in private hospitals (Table 1.2).

Clinician participation

All clinicians affiliated with the three craft groups represented in the ABDR are encouraged to contribute data to the Registry. In 2023, 19 new clinicians joined the Registry. Table 1.3 represents the total number of clinicians (N=443) participating (defined as those who have submitted at least one data collection form) in the ABDR during 2023, based on craft group and state/territory. Plastic surgeons are the highest contributing craft group (N=281; 63% of total). The greatest number of clinicians contributing data to the ABDR are located in New South Wales (N=153) and Victoria (N=98).

TABLE 1.3 CLINICIAN/SURGEON PARTICIPATION BY STATE AND CRAFT GROUPS (2023)

State	Plastic Surgeons	General/Breast Surgeons	Cosmetic Clinicians (associated with ACCSM)	Total
VIC	85	54	14	153
NSW	79	16	3	98
QLD	55	34	4	93
WA	27	11	3	41
SA	22	11	1	34
TAS	8	3	0	11
ACT	3	5	1	9
NT	2	2	0	4
Total	**281**	**136**	**26**	**443**

Accumulation of clinician participation

The pilot Breast Device Registry was in operation from 2012 to 2015 and preceded the establishment of the ABDR. The pilot program included accredited sites with plastics and general/breast surgeons only. In 2015 when the ABDR became an initiative of the Department, the scope was broadened to include all clinicians performing breast device surgery.

FIGURE 1.1 CUMULATIVE PARTICIPATING ABDR CLINICIANS BY CRAFT GROUP

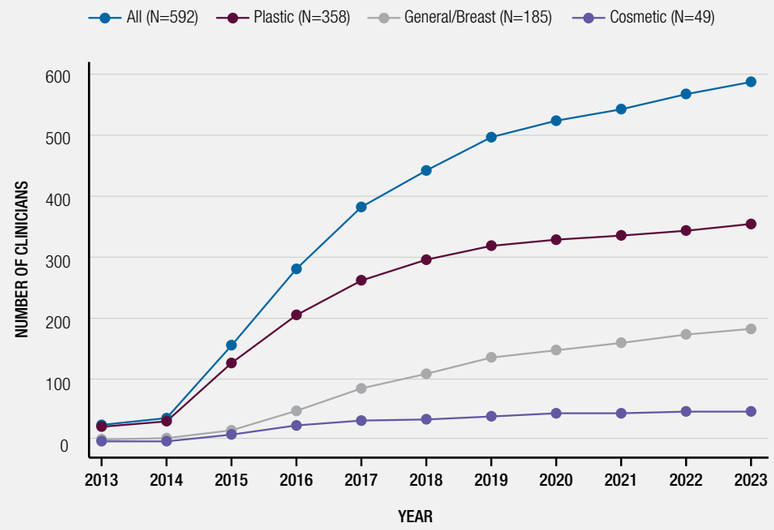


Figure 1.1 shows in the eleven years including the time of the pilot program, there has been steady growth in the number of clinicians participating in the ABDR. The highest contributors in the last decade are plastic surgeons.

In order to gain insight into the numbers of reconstructive and cosmetic procedures undertaken by individual clinicians, Table 1.4 was developed. Of the total of 443 clinicians, 5 clinicians did not have any procedure in 2023 with indication reported, thus 438 clinicians are captured in this data.

A majority of participating clinicians in 2023 (56%) performed both cosmetic and reconstructive procedures, with 22% performing only cosmetic procedures and 22% performing only reconstructive procedures. Of clinicians that perform both cosmetic and reconstructive procedures, they most commonly (54%) performed 11-50 procedures per year with 2% performing greater than 200 procedures, and 13% performing no more than 5 procedures. Of those clinicians that only perform cosmetic or reconstructive procedures, they most commonly performed no more than 5 procedures per year.

This data highlights that the vast majority of participating ABDR clinicians (nearly 86%) undertake no more than one breast device procedure per week, and as such, are not high-volume clinicians. This has implications for engagement of clinicians in the ABDR, and indicates that the data reported back to individual hospitals and clinicians has the statistical limitations associated with being low volume.

TABLE 1.4 RECONSTRUCTIVE AND COSMETIC PROCEDURES PER CLINICIAN (2023) (N=438)

Procedures per clinician/surgeon	Clinician/surgeon performed only cosmetic procedures	Clinician/surgeon performed only reconstructive procedures	Clinician/surgeons who performed both cosmetic and reconstructive procedures
	N (%)	N (%)	N (%)
>200	0 (0%)	0 (0%)	5 (2%)
101-200	5 (5%)	0 (0%)	14 (6%)
51-100	6 (6%)	0 (0%)	30 (12%)
11-50	26 (27%)	18 (19%)	134 (54%)
6-10	15 (15%)	20 (21%)	30 (12%)
≤5	45 (46%)	57 (60%)	33 (13%)
Total	**97 (22%)***	**95 (22%)***	**246 (56%)***

*Percentage of all clinicians who have submitted at least one DCF with indication stated.

Clinician and site reporting

The ABDR disseminated its fifth annual set of clinician reports in 2023 to 311 clinicians. All clinicians with a minimum case load (5 or more data collection forms) who submitted data in the reporting year received an individualised clinician report regarding their ABDR outputs. The ABDR also provided 94 sites an annual site report, having done so since 2020. These sites met the minimum requirements of three participating clinicians and the submission of twenty data collection forms within the reporting period. If a site does not meet these criteria then they are able to request a report by contacting the ABDR.

Presentation of this report

Due to the different clinical profiles between patients presenting for breast reconstructive surgery and cosmetic procedures, the Registry outputs have been presented separately for the two groups. This Annual Report, therefore, presents data analysed and recorded separately in two main sections.

- Reconstructive indications will include procedures for post-cancer reconstruction, risk-reducing reconstruction and developmental deformity
- Cosmetic indications will include cosmetic procedures only

Patients whose records omitted the indication for surgery (not stated) were excluded from further analysis in this report (refer to Table 2.1 and Table 2.2). Within the two Registry output sections, reconstructive and cosmetic results have been analysed and presented across three types of procedural interventions where possible.

- **Insertion surgery,** which captures surgery involving insertion of a new device, either a breast implant or tissue expander. Patients from the reconstructive cohort are also assigned to this group when the procedure involves inserting a first breast implant following removal of a tissue expander.
- **Revision surgery,** which includes unplanned replacement or reposition procedures. The initial device insertion may or may not have been captured by the Registry. Also included are reconstructive procedures involving the removal of an implant and insertion of a tissue expander or new implant.
- **Explant only surgery,** which includes the removal (explant) of an in-situ device without replacement, including both tissue expanders and breast implants.

CHAPTER 2

ABDR Data Overview

ABDR patient, procedure and device numbers (2012-2023)

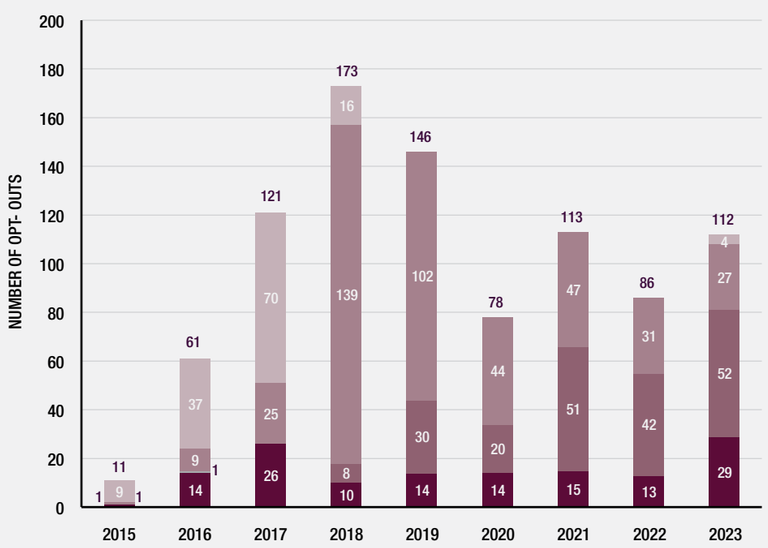
Patients

From 2012 to 2023, the ABDR had **98,460 patients** registered, **reflecting an addition of 10,566 patients** since the previous year. 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 site to the ABDR, additional patients may have had surgery in this timeframe but are yet to be included in the database.

Opt-Outs

The ABDR was established as an opt-out Registry with the first patients recruited in 2015. Patients have the opportunity to opt out of the ABDR at any time. Data from patients who chose to opt out (N=925 for 2012-2023) are not included in the analysis for the reported figures and tables. Figure 2.1 shows the number of opt-outs per year by reason for opting out during 2015-2023 (inclusive). In order of frequency, the reasons for opting out during this reporting period were: patients not being interested (N=425; 47%), having devices explanted (N=203; 23%), other (N=136; 15%), being concerned about data privacy (N=136; 15%) and loss of contact (N=1; 0.1%).

FIGURE 2.1 NUMBER OF OPTED-OUT PATIENTS BY REASON FOR OPT-OUT (2015-2023) (N=901)



Tables 2.1-2.3 present the number of registered patients, procedures and breast level procedures by indication of surgery and jurisdiction for the period between 2012-2023. Patients are assigned to the indication for their first operation as recorded in the Data Collection Forms submitted by their clinicians and subsequently recorded in the ABDR database. For bilateral operations with different indications in each breast, a four-tier hierarchy was applied for assigning the indication. Post-cancer reconstruction has the highest priority, followed by risk-reducing reconstruction, developmental deformity, and finally cosmetic augmentation.

Table 2.1 shows the residency by state/territory of patients by surgical indication. New South Wales and Queensland have the highest proportion of patients having cosmetic procedures, whereas New South Wales and Victoria have the highest proportion of patients having reconstructive procedures.

TABLE 2.1 PATIENT RESIDENCY BY INDICATION (2012-2023)

	Reconstructive		Cosmetic		Indication not stated		Total	
	N	(%)	N	(%)	N	(%)	N	(%)
NSW	5,681	28.2%	18,680	26.7%	2,173	26.1%	26,534	26.9%
VIC	4,580	22.7%	14,853	21.2%	1,539	18.5%	20,972	21.3%
QLD	3,598	17.8%	19,432	27.8%	2,637	31.7%	25,667	26.1%
SA	2,258	11.2%	3,924	5.6%	410	4.9%	6,592	6.7%
WA	2,464	12.2%	8,163	11.7%	1,122	13.5%	11,749	11.9%
TAS	567	2.8%	887	1.3%	120	1.4%	1,574	1.6%
NT	154	0.8%	413	0.6%	54	0.6%	621	0.6%
ACT	412	2.0%	439	0.6%	55	0.7%	906	0.9%
Unknown	450	2.2%	2,901	4.1%	201	2.4%	3,552	3.6%
Overseas Resident	5	0.0%	281	0.4%	7	0.1%	293	0.3%
Total	**20,169**	**100.0%**	**69,973**	**100.0%**	**8,318**	**100.0%**	**98,460**	**100.0%**

Note: N=98,460 patients. This includes 293 overseas residents and 3,552 with unknown residency. Patients with unknown residency are those who have elected email as the form of correspondence. The ABDR does not collect data on country of residency.

Patients, procedures and devices

Of the **98,460 patients** in the ABDR, 71.1% had a cosmetic indication for surgery and 20.5% had a reconstructive indication (15.2% post-cancer reconstruction, 3.2% risk-reducing reconstruction, and 2.2% for correction of developmental deformity) (Table 2.2). Approximately 8.4% of patients did not have an indication for surgery noted on their form.

The total number of **procedures** captured at operation level by the Registry is **113,439** indicating that some patients have more than one procedure captured by the Registry, particularly reconstructive patients who comprise **20.5%** of total **patients** but **25.8%** of total **procedures.** The ABDR has recorded **211,493 procedures** at breast level, and **192,706 devices.** The number of devices is fewer than the number of procedures (at breast level) because some procedures may not result in a new device insertion i.e.: explantation and reposition procedures. Furthermore, the number of procedures (at breast level) accounts for all procedures recorded by the ABDR and thus a specific breast may be included in this total more than once.

TABLE 2.2 THE TOTAL NUMBER AND PERCENTAGE OF REGISTERED PATIENTS, PROCEDURES PER PATIENT, PROCEDURES PER BREAST, AND TOTAL DEVICES CAPTURED BY CLINICAL INDICATION FOR SURGERY (2012-2023)

	Patients*		Procedures (operation level) **		Procedures (breast level) ***		Devices captured by Registry #	
	N	(%)	N	(%)	N	(%)	N	(%)
Reconstructive								
Post-cancer reconstruction	14,939	15.2%	22,229	19.6%	28,180	13.3%	26,869	13.9%
Risk-reducing reconstruction	3,110	3.2%	4,583	4.0%	13,089	6.2%	12,446	6.5%
Developmental deformity	2,120	2.2%	2,456	2.2%	4,133	2.0%	3,949	2.0%
Total reconstructive	**20,169**	**20.5%**	**29,268**	**25.8%**	**45,402**	**21.5%**	**43,264**	**22.5%**
Total cosmetic	**69,973**	**71.1%**	**74,086**	**65.3%**	**147,140**	**69.6%**	**139,066**	**72.2%**
Not stated	8,318	8.4%	10,085	8.9%	18,951	9.0%	10,376	5.4%
Total	**98,460**	**100.0%**	**113,439**	**100.0%**	**211,493**	**100.0%**	**192,706**	**100.0%**

Note: The indication of each operation was assigned based on the four-tier hierarchy beginning with post-cancer reconstruction, followed by risk-reducing reconstruction, developmental deformity and then cosmetic augmentation.
* Patients were assigned to the indication for their first procedure recorded in the ABDR.
** The number of procedures at the operation level have been reported, where the primary reason for the procedure determines the classification by indication.
*** The number of procedures at breast level have been reported.
# Breast level procedures involving device insertions (breast implants/tissue expanders). Included device operation types: first implant insertion; tissue expander insertion; tissue expander removal and implant insertion; implant revision - with revision type: replacement; tissue expander revision - with revision type: replacement; implant removal and tissue expander insertion.
Procedures marked as cosmetic augmentation but with clashes against this indication i.e.: concurrent mastectomy/previous radiotherapy/procedures involving tissue expander have been moved to the "Not stated" group.
Cosmetic device count includes: 735 device insertion procedures reported as cosmetic but with the opposite breast reported as reconstructive.

A total of **10,566 patients, 12,645 procedures** and **20,380 devices** were captured in 2023 (Table 2.3). The Registry recognises that the "not stated" category has increased in the current reporting period. It is exploring the reasons for this discrepancy and ways that the Registry can encourage sites and clinicians to identify the indication for surgery for all procedures.

TABLE 2.3 THE TOTAL NUMBER AND PERCENTAGE OF REGISTERED PATIENTS, PROCEDURES PER PATIENT, PROCEDURES PER BREAST, AND TOTAL DEVICE CAPTURED BY CLINICAL INDICATION FOR SURGERY (2023)

	Patients*		Procedures (operation level) **		Procedures (breast level) ***		Devices captured by Registry #	
	N	(%)	N	(%)	N	(%)	N	(%)
Reconstructive								
Post-cancer reconstruction	1,696	16.1%	2,589	20.5%	3,282	13.9%	3,032	14.9%
Risk-reducing reconstruction	343	3.2%	523	4.1%	1,571	6.7%	1,461	7.2%
Developmental deformity	236	2.2%	274	2.2%	475	2.0%	431	2.1%
Total reconstructive	**2,275**	**21.5%**	**3,386**	**26.8%**	**5,328**	**22.6%**	**4,924**	**24.2%**
Total cosmetic	**7,136**	**67.5%**	**7,835**	**62.0%**	**15,559**	**66.0%**	**14,145**	**69.4%**
Not stated	1,155	10.9%	1,424	11.3%	2,686	11.4%	1,311	6.4%
Total	**10,566**	**100.0%**	**12,645**	**100.0%**	**23,573**	**100.0%**	**20,380**	**100.0%**

Note: The indication of each operation was assigned based on the four-tier hierarchy beginning with post-cancer reconstruction, followed by risk-reducing reconstruction, developmental deformity and then cosmetic augmentation.
* Patients were assigned to the indication for their first procedure recorded in the ABDR.
** The number of procedures at the operation level have been reported, where the primary reason for the procedure determines the classification by indication.
*** The number of procedures at breast level have been reported.
# Breast level procedures involving device insertions (breast implants/tissue expanders). Included device operation types: first implant insertion; tissue expander insertion; tissue expander removal and implant insertion; implant revision - with revision type: replacement; tissue expander revision - with revision type: replacement; implant removal and tissue expander insertion.
Procedures with marked as cosmetic augmentation but with clashes against this indication: concurrent mastectomy/previous radiotherapy/procedures involving tissue expander have been moved to the "Not stated" group.
Cosmetic device count includes: 54 device insertion procedures reported as cosmetic but with the opposite breast reported as reconstructive.

ABDR case ascertainment (2023)

The ABDR annually undertakes a number of activities to attempt to determine its capture rate (case-ascertainment) of all breast implant procedures in the ABDR.

1. The ABDR compares **device insertions** reported to the Registry by participating clinicians against device sales data for that year provided by the **Therapeutic Goods Administration (TGA).** For 2023, the TGA reported sales of 23,601 devices of which 20,380 were captured by the ABDR, resulting in an **86.4% device insertion capture rate.** Previous reported device insertion capture rates using this method have been 76.3% (2022), 94% (2021), and 73% in 2019 and 2020. These capture rates have limited accuracy however as devices may be sold to hospitals and clinicians but not yet implanted during the same calendar year.
2. **Linkage of ABDR with Victorian Centre for Data Linkage (CVDL):** Site specific reports on capture rate have been distributed to eligible sites in Victoria. The overall capture rate at breast level across participating Victorian sites is **79%** (2017-2022).
3. The ABDR compares national **breast implant operation numbers** against publicly available **Australian Institute of Health and Welfare (AIHW) data** to verify procedure data capture. The ACHI (Australian Classification of Health Interventions) procedure codes used for this analysis mapped against ABDR operation types are shown in Figure 2.2.

FIGURE 2.2 MAPPING OF ABDR OPERATION TYPES TO ACHI PROCEDURE CODES

ABDR-OPERATION TYPE: First implant insertion

ACHI CODE

Block No.	Block Description
1753	Augmentation mammoplasty Includes: insertion of a prosthesis Excludes: that by injection

ACHI Code	ACHI Code Description
45524-00	Augmentation mammoplasty, unilateral
45528-00	Augmentation mammoplasty, bilateral
45527-00	Augmentation mammoplasty, following mastectomy, unilateral
45527-01	Augmentation mammoplasty, following mastectomy, bilateral

ABDR-OPERATION TYPE: Tissue expander insertion

Block No.	Block Description
1756	Reconstruction procedures on breast

ACHI Code	ACHI Code Description
45539-00	Reconstruction of breast with insertion of tissue expander

ABDR-OPERATION TYPE: Tissue expander revision, removal, or replacement

Block No.	Block Description
1758	Procedures involving removal or adjustment of breast prosthesis or tissue expander (note: performmed following breast reconstruction after mastectomy or previous augmentation mammoplasty)

ACHI Code	ACHI Code Description
45548-02	Adjustment of breast tissue expander Relocation of breast tissue expander
45548-01	Removal of breast tissue expander

ABDR-OPERATION TYPE: Tissue expander removal and implant insertion

Block No.	Block Description
1758	Procedures involving removal or adjustment of breast prosthesis or tissue expander (note: performmed following breast reconstruction after mastectomy or previous augmentation mammoplasty)

ACHI Code	ACHI Code Description
45542-00	Removal of breast tissue expander and insertion of permanent prosthesis

ABDR-OPERATION TYPE: Implant revision, removal, or replacement

Block No.	Block Description
1758	Procedures involving removal or adjustment of breast prosthesis or tissue expander (note: performmed following breast reconstruction after mastectomy or previous augmentation mammoplasty)

ACHI Code	ACHI Code Description
45548-00	Removal of breast prosthesis Includes: capsulectomy Excision of fibrous capsule (capsulectomy) Excludes: that with replacement
45552-00	Replacement of breast prosthesis removal and reinsertion of breast prosthesis Includes: capsulectomy Excision of fibrous capsule Formation of new pocket

ABDR-OPERATION TYPE: Implant removal and tissue expander insertion*

Note: there is no single ACHI code available for 'implant removal and tissue expander insertion (*)' procedure. The 'implant removal' and 'tissue expander' ACHI codes are used together for coding this procedure so the number of this procedure is included in the mentioned numbers about 'implant revision, removal, or replacement' and 'tissue expander insertion' procedures.

AIHW data is captured in financial years, rather than calendar years, and is approximately 12 months delayed. However, it provides an approximation of ABDR case ascertainment by procedure type.

Table 2.4 and Figure 2.3 show data the **ABDR operation capture rate overall** and **by procedure type** for the financial years 2017-2018 to 2022-2023. Overall data capture rates have increased from **65.9%** in **2018-2019** to **72%** in 2022-2023.

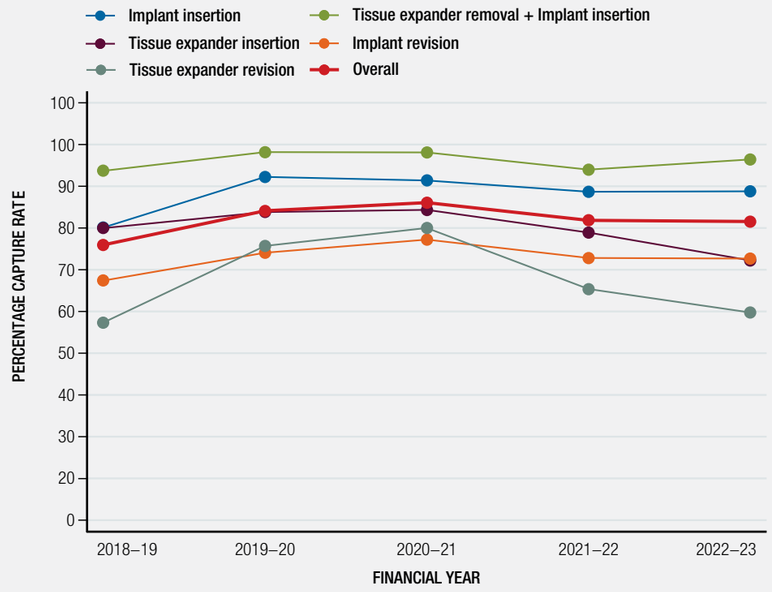
Tissue expander removal and implant insertion have the highest rates of capture. During 2022-2023, the capture rate was: 79% for first implant insertion; 86% for tissue expander removal and implant insertion; 62% for tissue expander insertion; 63% for implant revision removal or replacement; and 50% for tissue expander revision, removal or replacement. This provides very useful information to the ABDR in providing training and feedback to clinicians regarding data completeness, especially for revision procedures.

TABLE 2.4 CAPTURE RATE BY FINANCIAL YEAR BASED ON NUMBERS OF PROCEDURES CAPTURED BY ABDR AND AIHW (2018-2019 TO 2021-2023)

Operation Type	FY 2018-2019			FY 2019-2020			FY 2020-2021			FY 2021-2022			FY 2022-2023		
	ABDR	AIHW	ABDR DATA CAPTURE RATE	ABDR	AIHW	ABDR DATA CAPTURE RATE	ABDR	AIHW	ABDR DATA CAPTURE RATE	ABDR	AIHW	ABDR DATA CAPTURE RATE	ABDR	AIHW	ABDR DATA CAPTURE RATE
First implant insertion	13,848	19,751	70%	12,247	14,891	82%	19,246	23,646	81%	14,522	18,455	79%	14,934	18,954	79%
Tissue expander insertion	1,729	2,471	70%	1,452	1,967	74%	1,484	1,996	74%	1,341	1,946	69%	1,061	1,705	62%
Tissue expander removal and implant insertion	1,781	2,128	84%	1,486	1,685	88%	1,423	1,615	88%	1,185	1,411	84%	1,108	1,282	86%
Implant revision, removal, or replacement	8,201	14,288	57%	8,984	14,022	64%	10,567	15,720	67%	9,179	14,611	63%	9,269	14,788	63%
Tissue expander revision, removal, or replacement	196	414	47%	228	347	66%	280	400	70%	211	381	55%	203	408	50%
Total	**25,755**	**39,052**	**66%**	**24,397**	**32,912**	**74%**	**33,000**	**43,377**	**76%**	**26,438**	**36,804**	**72%**	**26,575**	**37,137**	**72%**

Note: ABDR procedure counts are based on data available on 18 August 2024.

FIGURE 2.3 CAPTURE RATE BY FINANCIAL YEAR BASED ON NUMBERS OF PROCEDURES CAPTURED BY ABDR AND AIHW (2018-2019 TO 2022-2023)



Note: Some of the decrease in capture rate in the most recent financial year may be explained by the delay between procedures and data collection forms being entered into the Registry.

ABDR breast devices captured (2012-2023)

The ABDR records and reports data on breast devices including implants and tissue expanders, by procedure (at breast level). Of the 211,493 procedures reported at breast level, 85.6% of procedures involved insertion of a new breast implant, 5.6% involved insertion of a new tissue expander and the remaining procedures involved only explants or repositions (Table 2.5). Information regarding matrix/mesh use is reported later in Chapter 3.

TABLE 2.5 PROCEDURE TYPES CAPTURED BY THE ABDR (2012-2023)

Procedure Type	N	%
Implant inserted: (incl. replacement)	180,965	85.6%
Implant reposition only	928	0.4%
Implant explant only	16,968	8.0%
TE inserted: (incl. replacement)	11,741	5.6%
TE reposition only	17	<0.1%
TE explant only	874	0.4%
Total	**211,493**	**100.0%**

Note: Procedures involving implant insertions include those with device operation types: first implant insertion; tissue expander removal and implant insertion; implant revision - with revision type: replacement. Procedures involving tissue expander insertions include those with device operation types: Tissue expander insertion; tissue expander revision - with revision type: replacement; implant removal and tissue expander insertion.

ABDR breast device procedure information by manufacturer (2012-2023)

Devices – breast implant insertions by manufacturer

The following tables identify the manufacturers of inserted breast implants. Data is reported at breast level and shows data completeness. Table 2.6 and Figure 2.4 relate to **aggregate device data on breast implants.** Similar tables based on reconstruction and cosmetic indication for surgery can be found in their respective chapters.

TABLE 2.6 BREAST IMPLANTS INSERTED BY MANUFACTURER, PER BREAST (2012-2023)

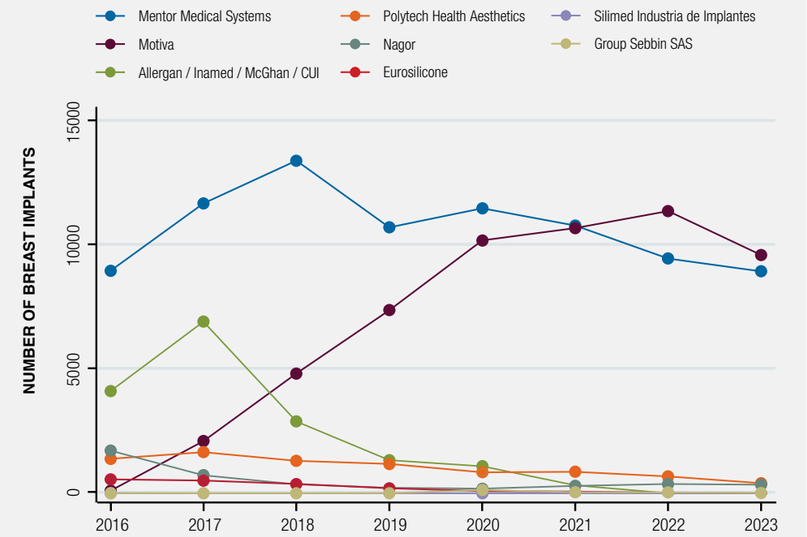
Manufacturer	N	%
Mentor Medical Systems	88,299	48.8%
Motiva	56,161	31.0%
Allergan/Inamed/McGhan/CUI	19,890	11.0%
Polytech Health & Aesthetics	8,513	4.7%
Nagor	5,072	2.8%
Eurosilicone	1,976	1.1%
Silimed Industria de Implantes	602	0.3%
Group Sebbin SAS	223	0.1%
Cereplas	44	0.0%
Not stated	**185**	**0.1%**
Total	**180,965**	**100.0%**

Note: Includes (breast level) procedures with device operation types: first implant insertion; tissue expander removal and implant insertion; implant revision - with revision type: replacement.

Table 2.6 provides the breakdown of **breast implants inserted** by manufacturer from any surgical indication as reported to the Registry. From 2012-2023, a total of 180,965 implant devices were inserted of which **99.9% had manufacturer details provided.** The most frequently inserted devices by manufacturer were Mentor Medical Systems, Motiva and Allergan/Inamed/McGhan/CUI which together contribute to 90.8% of the implants inserted.

Figure 2.4 shows the change in the number of breast implants inserted by manufacturer 2016-2023 (data collected during the pilot program 2012-2015 is omitted from this figure due to the low capture rate reported during this time). Motiva implants were the most commonly used devices in 2023, followed by Allergan/Inamed/McGhan/CUI over this time period. Of note, all Allergan macro-textured implants were withdrawn from use in Australia in 2019.

FIGURE 2.4 BREAST IMPLANTS INSERTED BY MANUFACTURER, PER BREAST (2016-2023)



Note: Includes (breast level) procedures with device operation types: first implant insertion; tissue expander removal and implant insertion; implant revision - with revision type: replacement.

Devices – breast device explants from replacement procedures

The most frequently **explanted devices** from implant replacement procedures between 2012-2023 by manufacturer were: Allergan/Inamed/McGhan/CUI and Mentor Medical Systems devices which together comprised 44.2% of devices (Table 2.7). This information does not necessarily reflect device performance as there are a number of reasons why a device may be revised including patient, procedure and device factors. Of a total of 47,436 implant replacement procedures recorded in the ABDR, **63.2% had explant manufacturer information** reported to the Registry.

TABLE 2.7 EXPLANTED DEVICES FROM IMPLANT REPLACEMENT PROCEDURES BY MANUFACTURER (NOT INCLUDING TISSUE EXPANDERS) (2012-2023)

Manufacturer	N	%
Allergan/Inamed/McGhan/CUI	12,396	26.1%
Mentor Medical Systems	8,575	18.1%
Silimed Industria de Implantes	2,193	4.6%
Nagor	2,044	4.3%
Motiva	1,742	3.7%
Eurosilicone	968	2.0%
PIP	870	1.8%
Polytech Health & Aesthetics	808	1.7%
Dow Corning	193	0.4%
Cereplas	130	0.3%
Group Sebbin SAS	62	0.1%
LifeSil	4	0.0%
Not Stated	**17,451**	**36.8%**
Total	**47,436**	**100.0%**

Note: Includes implant revision procedures with revision type recorded as: replacement; as well as implant removal and tissue expander insertion procedures. Proportions are not reflective of device performance (typical times of insertion and volumes of devices inserted vary across manufacturers). The LifeSil implants were all inserted overseas.

Devices – breast devices explanted only

The most frequently **explanted devices from explant only procedures (of breast implants)** between 2012-2023 by manufacturer were: Allergan/Inamed/McGhan/CUI and Mentor Medical Systems devices which together comprised 51.0% of the explanted devices (Table 2.8). Of the total 16,968 explants only, procedures reported to the Registry **74.4%** had manufacturer information provided.

TABLE 2.8 EXPLANTED DEVICES FROM EXPLANT ONLY PROCEDURES BY MANUFACTURER (NOT INCLUDING TISSUE EXPANDERS) (2012-2023)

Manufacturer	N	%
Allergan/Inamed/McGhan/CUI	4,950	29.2%
Mentor Medical Systems	3,702	21.8%
Silimed Industria de Implantes	1,261	7.4%
Nagor	929	5.5%
Eurosilicone	430	2.5%
Polytech Health & Aesthetics	391	2.3%
Motiva	354	2.1%
PIP	329	1.9%
Dow Corning	152	0.9%
Cereplas	86	0.5%
Group Sebbin SAS	32	0.2%
LifeSil	4	0.0%
Not stated	**4,348**	**25.6%**
Total	**16,968**	**100.0%**

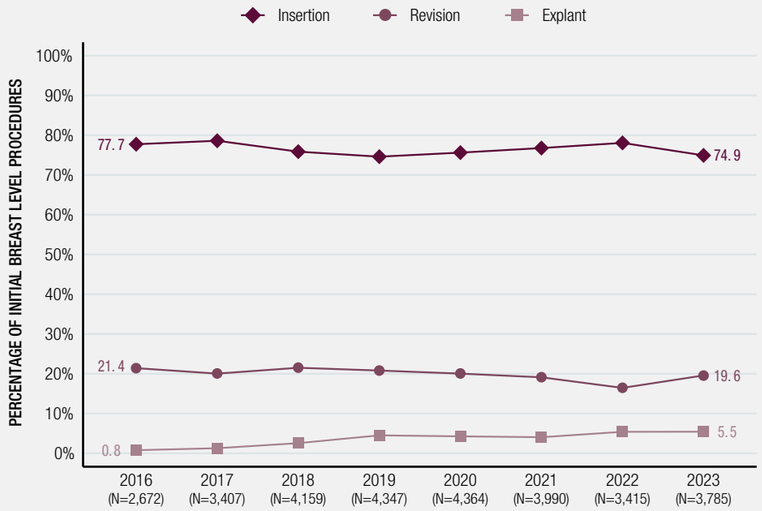
Note: Includes implant revision procedures with revision type: explant. Proportions are not reflective of device performance (typical times of insertion and volumes of devices inserted vary across manufacturers). The LifeSil implants were all inserted overseas.

ABDR procedures – insertion, revision and explantation

The first procedure of a breast captured by the Registry is referred to as an initial procedure in this report. The number of initial procedures classified as insertion, revision and explant per breast are presented in Figure 2.5 and Figure 2.6. They provide 8 years of data for both reconstructive and cosmetic initial procedures at breast level.

During 2023 a total of 2,836 (74.9%) breasts entered the Registry with a **reconstructive insertion procedure;** 742 (19.6%) with a reconstructive **revision** procedure; and 207 (5.5%) with a reconstructive **explant** procedure (total of 3,785 reconstructive procedures). Patients were assigned according to their first procedure as recorded by the ABDR.

FIGURE 2.5 INSERTION, REVISION AND EXPLANT PROCEDURES OVER TIME – RECONSTRUCTIVE INITIAL BREAST LEVEL PROCEDURES (2016-2023)



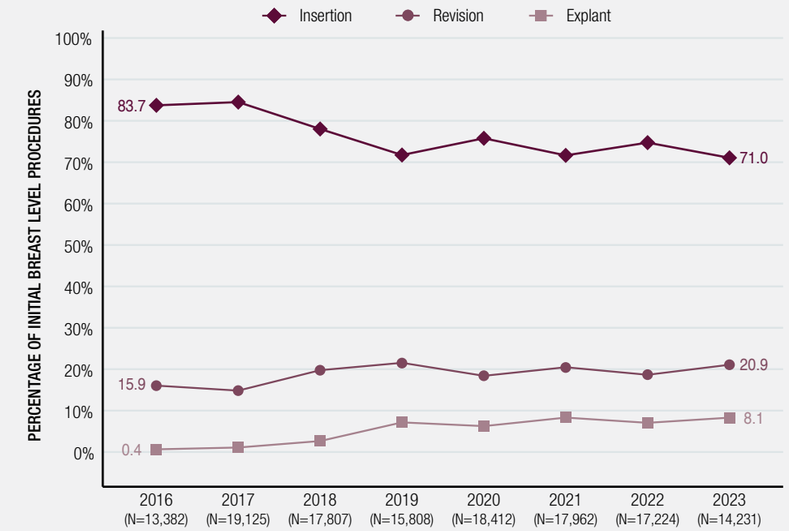
Note: The first procedure of each breast captured by the Registry is considered as an 'initial' procedure. First implant insertion; tissue expander removal and implant insertion; tissue expander insertion procedures are classified as insertions. The revision category includes breast implant/tissue expander revisions with device replacement/reposition (not explant only procedures).

Figure 2.5 shows the percentage of **reconstructive breast procedures** classified as device insertion, revision and explant of the procedures entering the Registry in the reporting period (2016-2023). During the last eight years, the proportion of device insertion procedures at breast level have decreased by 2.8%, and revision procedures have decreased by 1.8%. Device explant only procedures continue to increase, from 0.8% in 2016 to 5.5% in 2023.

During 2023 a total of 10,104 (71.0%) breasts entered the Registry with a **cosmetic insertion** procedure; with 2,975 (20.9%) having a cosmetic **revision** procedure and 1,152 (8.1%) having a cosmetic **explant** procedure (total of 14,231 cosmetic procedures). Patients were assigned according to their first procedure as recorded in the ABDR.

Figure 2.6 shows the percentage of **cosmetic breast procedures** classified as insertion, revision and explant during the reporting period. The percentage of devices insertion procedures at breast level decreased by 12.7% during this eight-year period. In contrast, revision procedures increased by 5.0% and device explant only procedures increased from 0.4% in 2016 to 8.1% of procedures in 2023.

FIGURE 2.6 INSERTION, REVISION AND EXPLANT PROCEDURES OVER TIME – COSMETIC INITIAL BREAST LEVEL PROCEDURES (2016-2023)

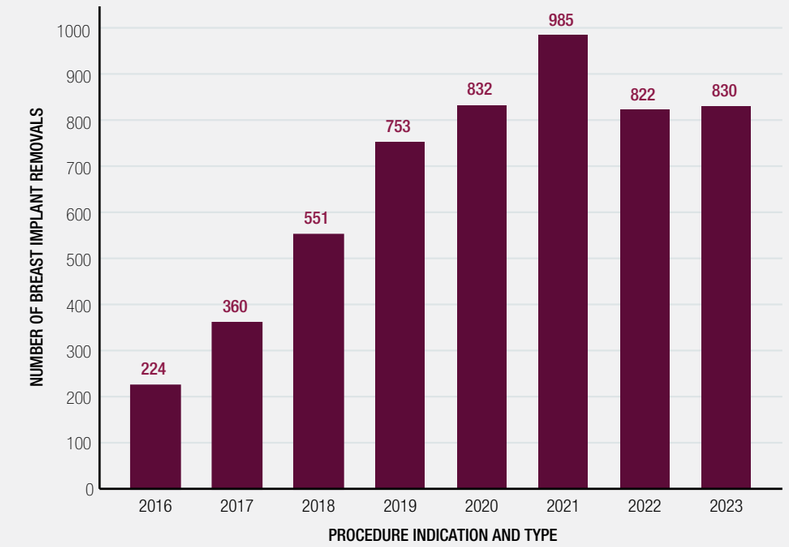


Note: The first procedure of each breast captured by the Registry is considered as an 'initial' procedure. First implant insertion procedures are classified as insertions. The revision category includes breast implant revisions with device replacement/reposition (not explant only procedures).

Removal of implants from overseas

The ABDR collects information regarding when an implant is **removed** that the outgoing device was **originally inserted overseas (cosmetic tourism).** A total of **5,492 procedures** were captured from 2012-2023 which involved removal of devices originally inserted overseas. The annual numbers of such procedures have increased since 2016, with over 800 removal of overseas-inserted implants being undertaken each year since 2020 (Figure 2.7).

FIGURE 2.7 REMOVALS OF IMPLANTS INSERTED OVERSEAS (2016-2023) (N=5,357)

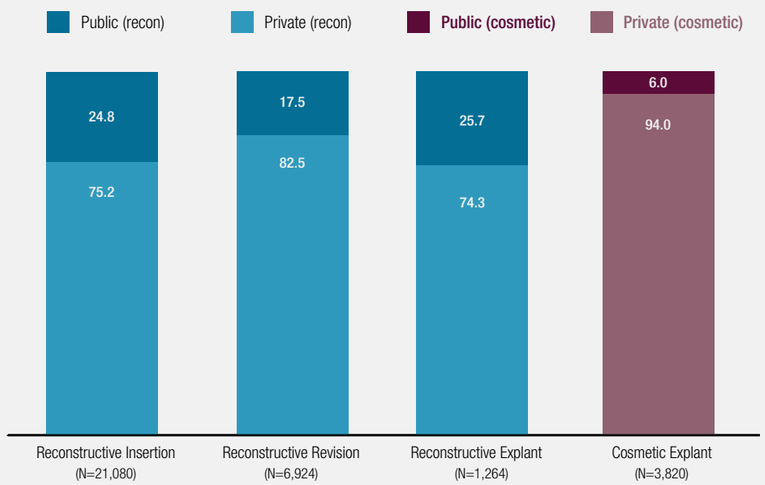


Note: Includes breast level procedures where it is reported that removal of an implant inserted overseas is involved and device operation type is one of: implant revision - with revision type: (replacement/explant); implant removal and tissue expander insertion.

Procedures by site type

The majority of both cosmetic and reconstructive breast device procedures (operation level) recorded in the ABDR are performed in private facilities (Figure 2.8; the site type distributions for cosmetic insertion and revision procedures are not shown because the vast majority of these occur in private hospitals). Reconstructive procedures are predominantly undertaken in private sites, particularly revisions (82.5%), but also insertions (75.2%) and explants (74.3%). Cosmetic explants are the only cosmetic procedure that may be reimbursed to be undertaken in a public hospital. Approximately 6% of cosmetic implants are explanted in public hospitals.

FIGURE 2.8 PROCEDURE BY SITE TYPE FOR RECONSTRUCTION (BY INDICATION) AND COSMETIC (EXPLANT ONLY) PROCEDURES DURING (2012-2023)



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 per breast.

CHAPTER 3

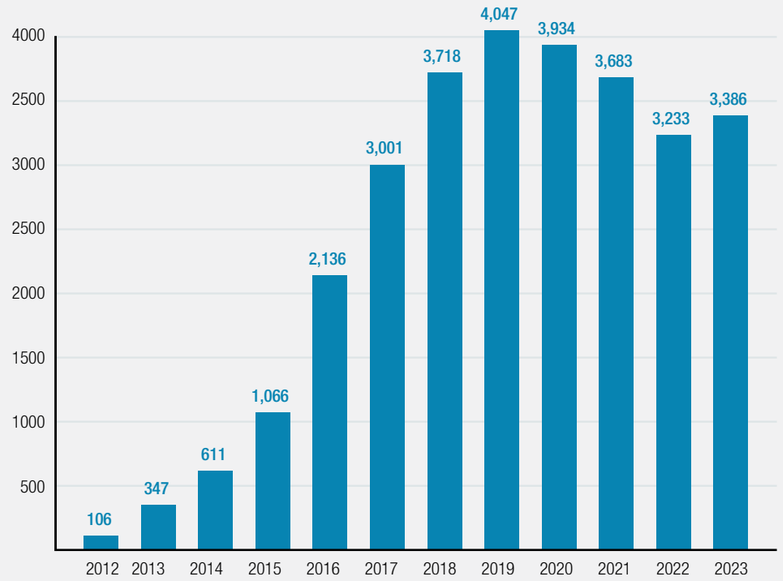
Registry Outputs – Reconstructive Indications

Reconstructive procedure numbers and manufacturer details

The ABDR has captured a **total of 29,268 procedures** involving breast devices for reconstructive surgery, where the reasons for reconstructive surgery included post-cancer reconstruction, risk-reducing reconstruction and developmental deformity.

Figure 3.1 shows the annual number of reconstructive procedures captured from 2012 to 2023. In 2023 there were **3,386 reconstructive procedures** captured by the ABDR, a slight increase on 2022 procedures, although lower than the peak of over 4,000 procedures captured in 2019.

FIGURE 3.1 REGISTERED PROCEDURES – RECONSTRUCTIVE PROCEDURES (2012-2023)



Implants used in reconstructive procedures

The Registry records implant manufacturer based on the device sticker affixed to the data collection form.

TABLE 3.1 BREAST IMPLANTS INSERTED BY MANUFACTURER, PER BREAST – RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2012-2023)

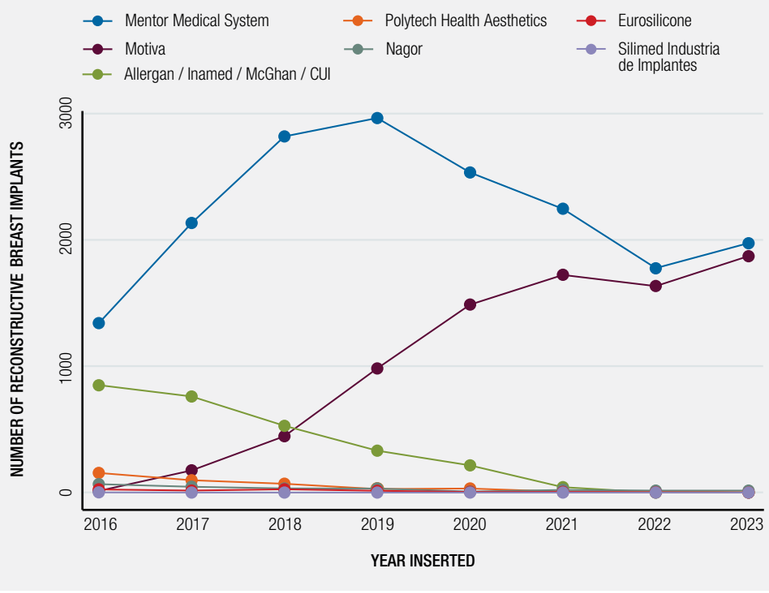
Manufacturer	N	%
Mentor Medical Systems	18,642	58.2%
Motiva	8,369	26.1%
Allergan/Inamed/McGhan/CUI	4,055	12.7%
Polytech Health & Aesthetics	420	1.3%
Nagor	294	0.9%
Eurosilicone	98	0.3%
Silimed Industria de Implantes	95	0.3%
Cereplas	11	0.0%
Not stated	**43**	**0.1%**
Total	**32,027**	**100.0%**

Note: Includes (breast level) procedures with device operation types: first implant insertion; tissue expander removal and implant insertion; implant revision - with revision type: replacement.

Table 3.1 shows the breakdown of breast implants inserted by manufacturer for **reconstructive procedures** as reported to the Registry. From 2012-2023 a total of **32,027 reconstructive breast implants were inserted** of which 99.9% had manufacturer details provided. The most frequently inserted breast implants by manufacturer were: Mentor Medical Systems and Motiva, which combined comprised 84.3% of reconstructive breast implants inserted.

Figure 3.2 shows the annual **number of implant devices inserted by manufacturer 2016-2023** (data collected during the pilot program 2012-2015 are omitted from this figure due to the low capture rate of procedures reported during this time). Mentor Medical Systems has manufactured the majority of implants used for reconstruction procedures in the Registry, but the proportion of devices from Motiva has been steadily increasing. Allergan/Inamed/McGhan/CUI device use continued to decrease over this time period. Of note, all Allergan macro-textured implants were withdrawn from use in Australia in 2019.

FIGURE 3.2 BREAST IMPLANTS INSERTED BY MANUFACTURER, PER BREAST – RECONSTRUCTIVE PROCEDURES (2016-2023)



Note: Includes (breast level) procedures with device operation types: first implant insertion; tissue expander removal and implant insertion; implant revision - with revision type: replacement.

Tissue expanders used in reconstructive procedures

TABLE 3.2 TISSUE EXPANDERS INSERTED BY MANUFACTURER, PER BREAST – RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2012-2023)

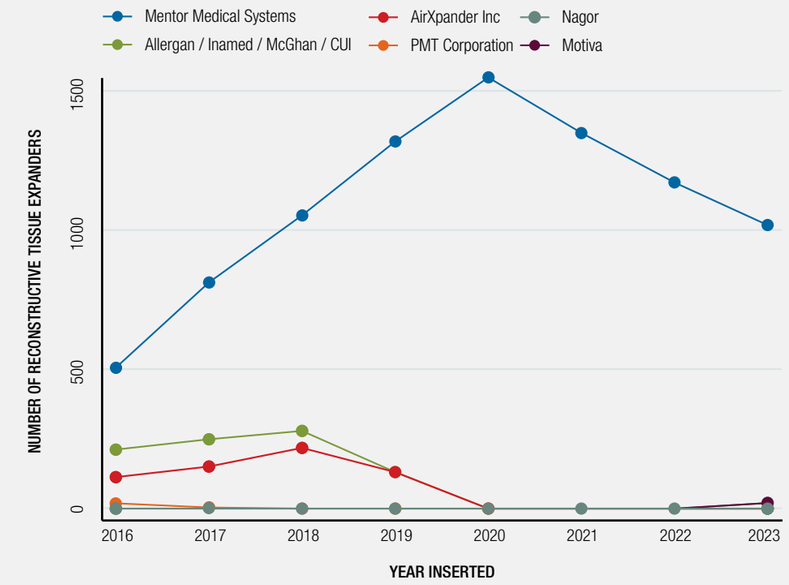
Manufacturer	N	%
Mentor Medical Systems	9,059	80.6%
Allergan/Inamed/McGhan/CUI	1,454	12.9%
AirXpander Inc	632	5.6%
PMT Corporation	35	0.3%
Motiva	20	0.2%
Silimed Industria de Implantes	10	0.1%
Nagor	2	<0.1%
Not Stated	**25**	**0.2%**
Total	**11,237**	**100.0%**

Note: Includes (breast level) procedures with device operation types: tissue expander insertion; tissue expander revision - with revision type: replacement; implant removal and tissue expander insertion. Only breast procedures recorded as having reconstructive indication are included (N=11,741 tissue expanders have been inserted overall between 2012-2023)

Table 3.2 shows the breakdown of **tissue expanders** inserted by manufacturer for reconstructive procedures as reported to the Registry. From 2012-2023 a total of 11,237 tissue expanders were inserted, of which 99.8% had manufacturer details provided. The most frequently inserted tissue expanders by manufacturer were: Mentor Medical Systems and Allergan/Inamed/McGhan/CUI which combined comprised 93.5% of tissue expanders inserted.

Figure 3.3 shows the annual number of tissue expanders inserted by manufacturer 2016-2023 (data collected during the pilot program 2012-2015 are omitted from this figure due to the low case ascertainment rates reported during this time). Mentor Medical Systems tissue expanders has been the primary tissue expander used since 2020. Of note, Allergan tissue expanders were withdrawn in 2019.

FIGURE 3.3 TISSUE EXPANDERS INSERTED BY MANUFACTURER, PER BREAST – RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2016-2023)



Note: Includes (breast level) procedures with device operation types: tissue expander insertion; tissue expander revision - with revision type: replacement; implant removal and tissue expander insertion. Only breast procedures recorded as having reconstructive indication are included.

Matrix/mesh use in reconstructive procedures

TABLE 3.3 MATRIX/MESH DEVICES INSERTED BY PRODUCT, PER BREAST – RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2012-2023)

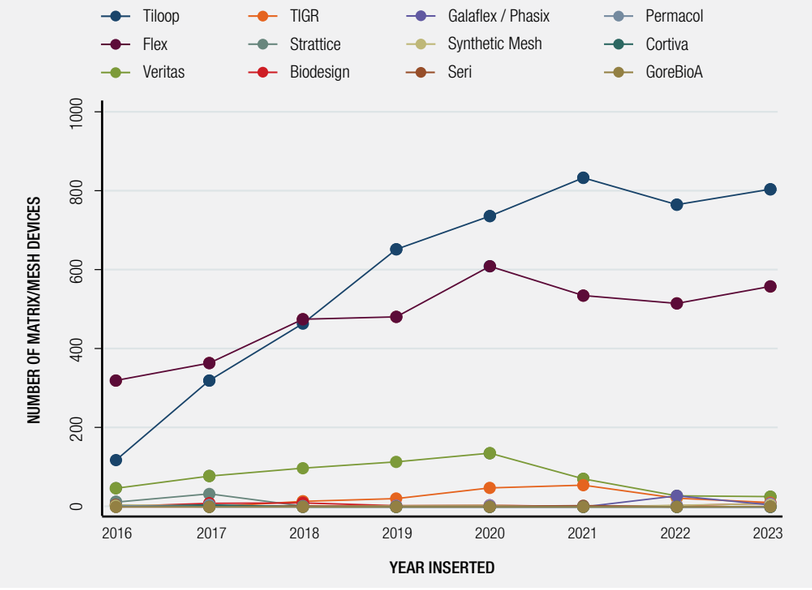
Product name	N	%
Tiloop	4,715	47.8%
Flex	3,989	40.5%
Veritas	609	6.2%
TIGR	171	1.7%
Strattice	47	0.5%
Biodesign	46	0.5%
Galaflex/Phasix	33	0.3%
Synthetic Mesh	33	0.3%
Permacol	15	0.2%
Cortiva	5	0.1%
Seri	4	<0.1%
Gore Bio-A	1	<0.1%
Not Stated	**190**	**1.9%**
Total	**9,858**	**100.0%**

Note: Includes (breast level) procedures with reported use of matrix/mesh devices. Only breast procedures recorded as having reconstructive indications are included (N=10,755 matrix/mesh have been inserted overall between 2012-2023).

Table 3.3 shows the breakdown of matrix/mesh devices inserted by manufacturer for reconstructive procedures as reported to the Registry. From 2012-2023 a total of **9,858 matrix/mesh** were inserted, of which **98.1% had manufacturer details provided.** The most common matrix/mesh devices by product group were: Tiloop, Flex and Veritas which combined comprised 94.5% of matrix/mesh inserted for reconstructive procedures.

Figure 3.4 shows the annual number of matrix/mesh devices inserted by manufacturer 2016-2023 (data collected during the pilot program 2012-2015 are omitted from this figure due to low case ascertainment of procedures reported during this time). Since 2018 Tiloop has been the most frequently used matrix/mesh in reconstructive breast procedures.

FIGURE 3.4 MATRIX/MESH DEVICES INSERTED BY PRODUCT, PER BREAST – RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2016-2023)



Note: Includes (breast level) procedures with reported use of matrix/mesh devices. Only breast procedures recorded as having reconstructive indication are included.

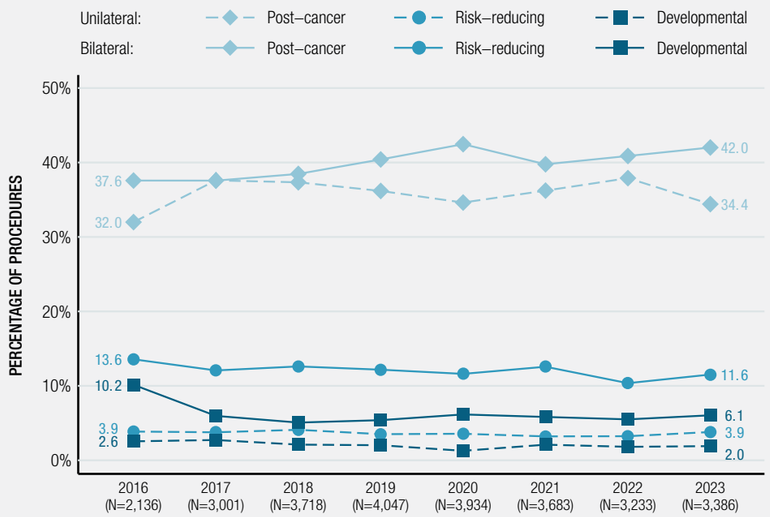
Reconstructive procedural types

The reconstructive procedure captured in the Registry include: post-cancer, risk-reducing and developmental deformity.

Bilateral and unilateral procedures

Reconstructive procedures are most commonly undertaken following mastectomy for breast cancer. Procedures may be **unilateral or bilateral.** In 2023, of a total of 3,386 procedures were undertaken. Of these, 1,423 (42%) were bilateral and 1,166 (34.4%) were unilateral **post-cancer procedures.** A further 11.6% of reconstructive procedures were **bilateral risk-reducing procedures.** Less common reconstructive procedures were bilateral procedures for developmental deformity (6.1% of procedures in 2023); unilateral risk reducing procedures (3.9%), and unilateral developmental deformity procedures (2.0%). Overall the proportion of reconstructive surgery for post-cancer indications has slightly increased whereas reconstructive surgery for other indications has slightly decreased over time (Figure 3.5).

FIGURE 3.5 PROCEDURE INDICATION AND LATERALITY – RECONSTRUCTIVE PROCEDURES (2016-2023)

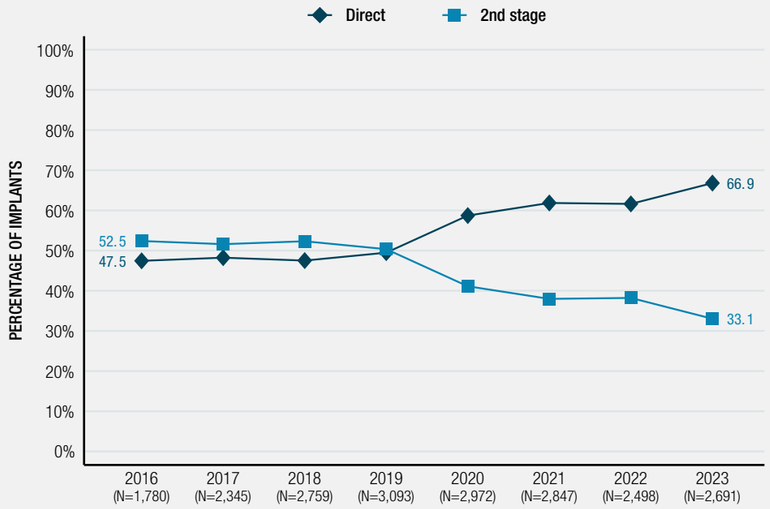


Note: A procedure indication hierarchy has been applied to bilateral procedures with different indication and procedure type details per breast. Primary reason for procedure has been applied for all patients.

One-stage (direct-to-implant) and two-stage (tissue expander and implant) procedures

Since 2016, the proportion of one-stage (direct-to-implant) procedures has increased, overtaking 2-stage procedures (tissue expander followed by an implant) from 2019 (Figure 3.6).

FIGURE 3.6 PROPORTION OF DIRECT-TO-IMPLANT VS TWO-STAGE INSERTION PROCEDURES PERFORMED DURING (2016-2023)



Note: Data was collected at the breast level for (direct) implant insertion or TE removal and subsequent implant insertion. Revisions and explants are not considered here.

Capture of procedures after tissue expander insertion

The ABDR was interested in understanding typical durations between tissue expander insertion and subsequent exchange procedures to second stage implant, with the aim of establishing follow-up procedures to maximise capture of second stage procedures in the Registry.

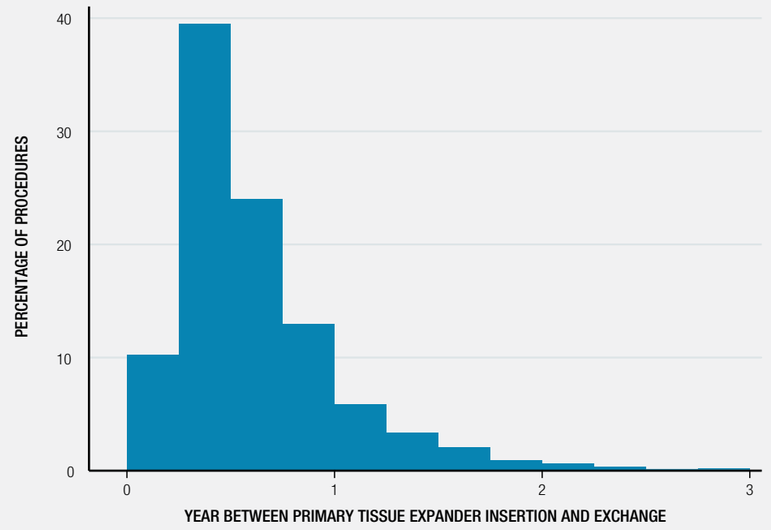
Table 3.4 and Figure 3.7 show the distribution in times to exchange of 6,993 primary tissue expander insertions. They include breasts which entered the Registry with a primary tissue expander insertion procedure and also have exchange to second stage implant as the next procedure captured in the Registry. The majority (86.3%) of exchanges occurred within 12 months, with very few (1.7%) occurring after 24 months. The ABDR will use this information to implement a follow-up (reminder) process for collection of second-stage procedures, to maximise their data capture.

TABLE 3.4 TIME BETWEEN PRIMARY TISSUE EXPANDER INSERTION AND EXCHANGE TO IMPLANT PROCEDURE (2012-2023)

Time between TE insertion and exchange to implant procedure	N	%
0 to <3 months	712	10.2%
3 to <6 months	2,745	39.3%
6 to <9 months	1,668	23.9%
9 to <12 months	901	12.9%
12 to <15 months	408	5.8%
15 to <18 months	234	3.3%
18 to <21 months	144	2.1%
21 to <24 months	64	0.9%
≥ 24 months	117	1.7%
Total	**6,993**	**100.0%**

Note: Includes breasts which entered Registry with a reconstructive primary tissue expander procedure then had a tissue expander removal and implant insertion as the next procedure.

FIGURE 3.7 TIME BETWEEN PRIMARY TISSUE EXPANDER INSERTION AND EXCHANGE TO IMPLANT PROCEDURE (2012-2023)



Note: Includes breasts which entered Registry with a reconstructive primary tissue expander procedure then had a tissue expander removal and implant insertion as the next procedure.

Table 3.5 includes breasts which entered the Registry with primary reconstructive tissue expander insertion procedures from 2016-2022. It shows what type of procedure was next captured by the ABDR (if any) for each breast. The number of tissue expander insertions has been relatively stable at over 1,000 from 2017 to 2022. In 2016, 81% of tissue expander insertion procedures are followed by exchange to implant procedures. However, this proportion declines annually to 2022, where the proportion of TEs with an exchange is 60.2% (the 2023 year is not included due to many exchanges not occurring within the same calendar year). At the same time, the proportion of TEs having no reported subsequent procedure has increased from 14.2% in 2016 to 29.1% in 2022. This may be due to delay in second stage procedures (e.g. during COVID) or data entry into the ABDR, or it may reflect changes in practice, such as first stages of TE not progressing to second stage and being replace with an autologous flap. By implementing a follow-up process for tissue expander insertions, the ABDR hopes to better understand if this is an actual change in practice.

TABLE 3.5 PROCEDURE CAPTURED AFTER PRIMARY TISSUE EXPANDER INSERTION (2016-2022)

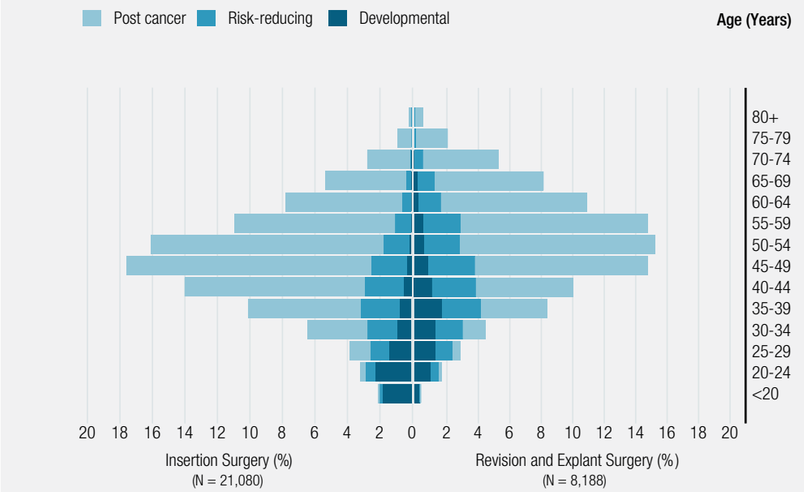
	Year of Primary TE insertion							
	2016	2017	2018	2019	2020	2021	2022	Total (2016-2022)
Next captured procedure following primary TE	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
None	113 (14.2%)	167 (15.3%)	201 (14.5%)	238 (16.4%)	285 (20.7%)	336 (28.0%)	300 (29.1%)	1,640 (19.7%)
TE revision	26 (3.3%)	57 (5.2%)	69 (5.0%)	75 (5.2%)	87 (6.3%)	91 (7.6%)	83 (8.0%)	488 (5.9%)
Exchange to implant	643 (81.0%)	846 (77.3%)	1,071 (77.1%)	1,108 (76.5%)	956 (69.5%)	745 (62.0%)	621 (60.2%)	5,990 (71.8%)
Other	12 (1.5%)	25 (2.3%)	48 (3.5%)	28 (1.9%)	48 (3.5%)	30 (2.5%)	28 (2.7%)	219 (2.6%)
Total	**794 (100.0%)**	**1,095 (100.0%)**	**1,389 (100.0%)**	**1,449 (100.0%)**	**1,376 (100.0%)**	**1,202 (100.0%)**	**1,032 (100.0%)**	**8,337 (100.0%)**

Patient age at reconstructive procedure

The age distribution at the time of reconstructive procedure is shown in Figure 3.8 and Table 3.6. Age differences can be seen by procedure indication and type: insertion, revision or explant.

In 2012-2023, the median patient age for post-cancer reconstruction insertion, revision and explant procedures were approximately 50, 55 and 55 years respectively. Risk-reducing procedure patients had a median age of 42, 47 and 46 years respectively. For patients undergoing reconstruction surgery for developmental deformity the median age was 25 years for insertions, 37 for revisions and 38 years for explants.

FIGURE 3.8 AGE DISTRIBUTION AT TIME OF PROCEDURE – RECONSTRUCTIVE PROCEDURES (2012-2023)



Notes: Insertion, revision and explant only procedures have been analysed independently.
Both unilateral and bilateral procedures have been included. Counts are on the operation level.
A four-tier hierarchy has been applied for bilateral procedures with different indication and procedure type details per breast.
Counts are on the operation level.

TABLE 3.6 SUMMARY STATISTICS FOR AGE AT TIME OF PROCEDURE – RECONSTRUCTIVE PROCEDURES (2012-2023)

	Insertion Surgery		Revision Surgery		Explant Only	
	N	Median Age (IQR)	N	Median Age (IQR)	N	Median Age (IQR)
Post-cancer	16,426	50.2 (43.4, 57.9)	4,898	54.8 (47.6, 62.9)	905	55.0 (47.9, 63.3)
Risk-reducing	2,997	41.9 (34.7, 49.9)	1,327	47.2 (38.8, 57.0)	259	45.6 (36.2, 55.8)
Developmental	1,657	24.9 (20.4, 33.3)	699	36.6 (28.8, 46.7)	100	37.8 (29.6, 46.2)
Total	**21,080**		**6,924**		**1,264**	

Notes: Insertion, revision and explant only procedures have been analysed independently.
Both unilateral and bilateral procedures have been included. Counts are on the operation level.
A procedure indication hierarchy has been applied for bilateral procedures with different indication and procedure type details per breast. Counts are on the operation level.
The interquartile range reports observed patient age at the 25th and 75th percentiles.

Reconstructive procedure intra-operative aseptic techniques

The ABDR collects data on intra-operative aseptic techniques used in breast device surgery. Clinicians may record one or more intra-operative aseptic technique for each procedure recorded in the Registry.

Table 3.7, Figures 3.9 and Figure 3.10 show the intra-operative aseptic techniques used during breast reconstruction surgery. Overall, the use of intra-operative aseptic techniques has increased during this period.

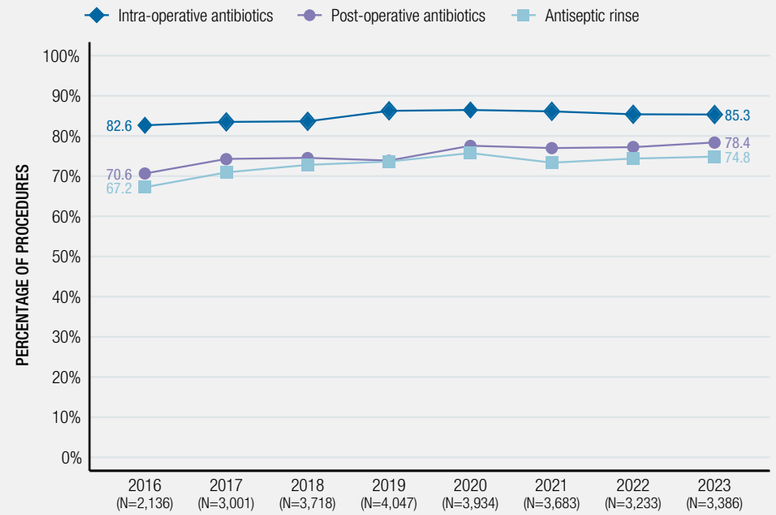
TABLE 3.7 INTRA-OPERATIVE ASEPTIC TECHNIQUES – RECONSTRUCTIVE PROCEDURES (2012-2023)

	2012-2023		
	N	(%)	Total eligible
Intra-op/post-op antibiotics[1]	25,308	(86.5%)	29,268
Antiseptic rinse[1]	21,337	(72.9%)	29,268
Not stated[1]	3,492	(11.9%)	29,268
Glove change for insertion[2]	21,562	(77.0%)	28,004
Antibiotic dipping solution[2]	14,046	(50.2%)	28,004
Sleeve/funnel[3]	6,678	(32.7%)	20,396

Note: More than one intra-operative technique can be used and recorded per procedure. Counts are at the operation level. The use of intra-operative and post-operative antibiotics is reported together for 2012-2022 because the data fields were not collected separately until 2015. Denominator for percentage calculation: [1]all procedures; [2]excludes explant only procedures; [3]only includes device operation types: first implant insertion; tissue expander removal and implant insertion; implant revision – with revision types: replacement/reposition.

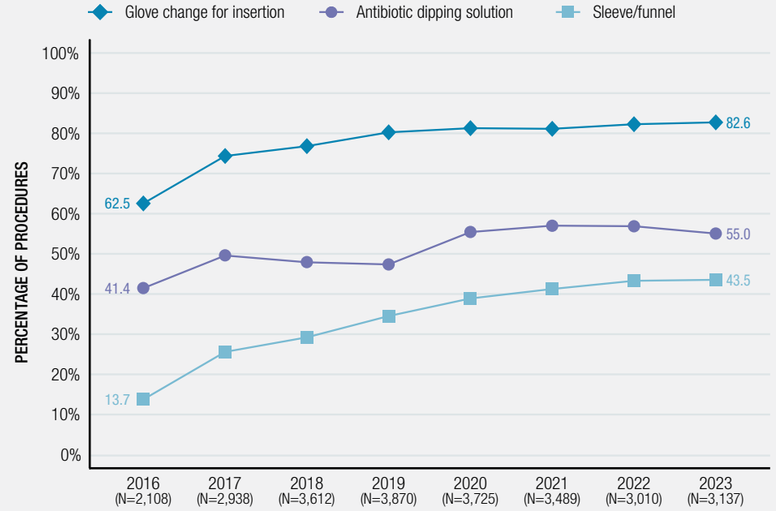
Out of the 3,386 reconstructive operations in 2023, 2,889 used intra-operative antibiotics, 2,653 used post-operative antibiotics and 2,533 involved antiseptic rinse. (Figure 3.9). Out of the 3,137 reconstructive insertion and revision operations (not explant only) in 2023; 2,592 involved changing gloves for insertion and 1,725 used antibiotic dipping solution. 1,380 used a sleeve/funnel out of 2,442 procedures involving insertion of new implant or replacement/ reposition of an implant (Figure 3.10).

FIGURE 3.9 INTRA-OPERATIVE ASEPTIC TECHNIQUES RELEVANT FOR ALL RECONSTRUCTIVE PROCEDURES (2016-2023)



Note: Information regarding intra-operative and post-operative antibiotics have been collected separately since 2015.
A procedure indication hierarchy has been applied for bilateral procedures with different indication and procedure type details per breast.

FIGURE 3.10 INTRA-OPERATIVE ASEPTIC TECHNIQUES RELEVANT FOR RECONSTRUCTIVE INSERTION AND REVISION (NOT EXPLANT ONLY) PROCEDURES (2016-2023)



Note: A procedure indication hierarchy has been applied for bilateral procedures with different indication and procedure type details per breast. Sleeve/funnel denominator only includes device operation types: first implant insertion; tissue expander removal and implant insertion; implant revision – with revision types: replacement / reposition.

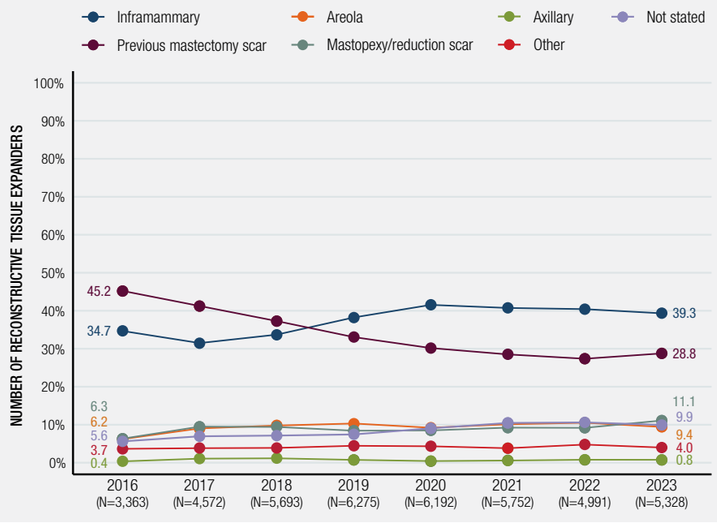
Reconstructive surgical techniques

Trends in surgical elements over time are shown in Figures 3.11-3.14 and further details can be found in Appendix 2.

Surgical incision site

Over the last five years, the most common incision site used has changed from previous mastectomy scar incisions in favour of infra-mammary incisions (Figure 3.11).

FIGURE 3.11 SURGICAL ELEMENTS – INCISION SITE – RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2016-2023)

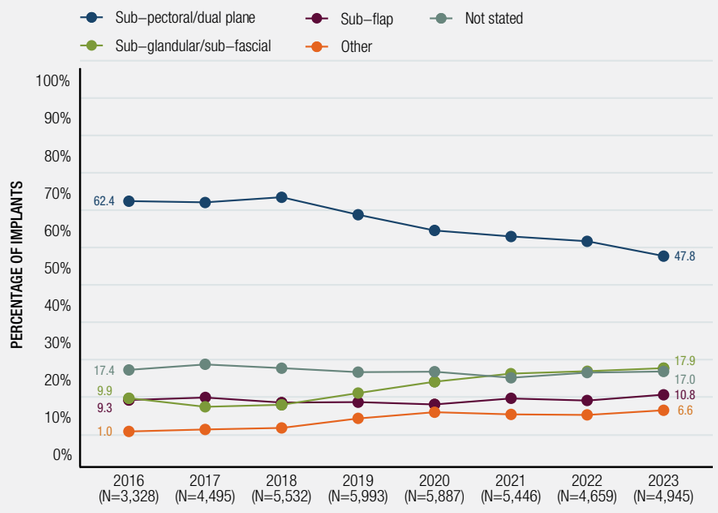


Note: Details are at the breast procedure level. More than one incision site can be recorded.

Surgical plane

The most commonly used surgical plane remains sub-pectoral, however this has reduced over the last 6 years. During this time, the use of the sub-glandular/sub-fascial plane has increased (Figure 3.12).

FIGURE 3.12 SURGICAL ELEMENTS – SURGICAL PLANE – RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2016-2023)

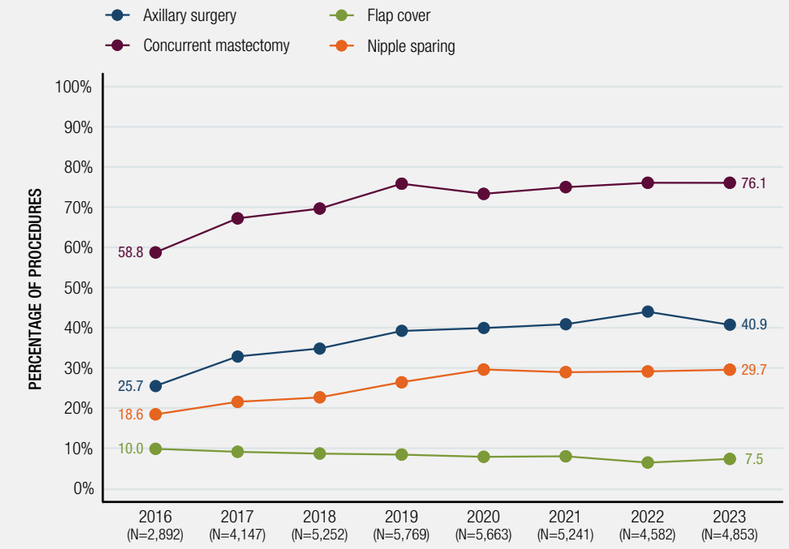


Note: Details are at the breast procedure level. Sub-glandular/sub-facial plane: includes sub-cutaneous placement after mastectomy per data reported to the Registry. Only insertion and revision procedures (which are not explant only) are included.

Other surgical elements

Over the last 8 years the ABDR notes increased frequency of concurrent mastectomy, nipple sparing surgery, and axillary surgery (Figure 3.13).

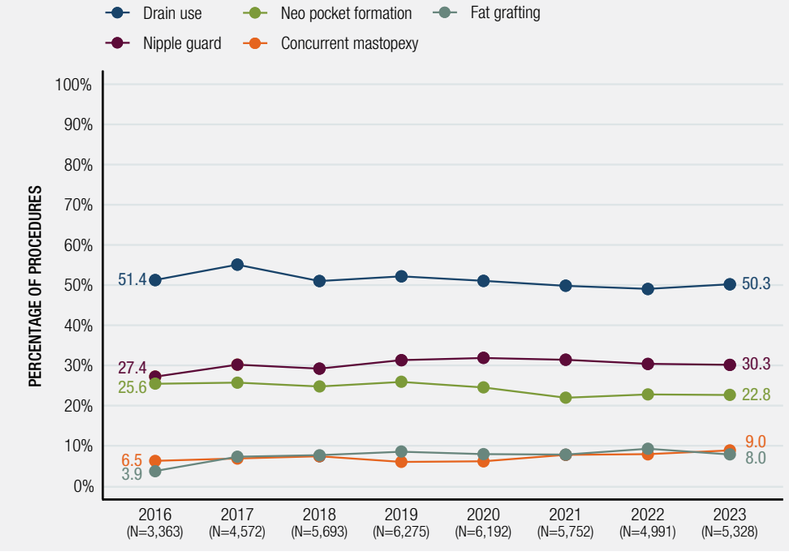
FIGURE 3.13 SURGICAL ELEMENTS RELEVANT FOR CANCER RELATED PROCEDURES – RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2016-2023)



Note: Details are at the breast procedure level. Only procedures with post-cancer or risk-reducing indication are included. The denominator for concurrent mastectomy and axillary surgery figure is number of procedures with device operation type recorded as first implant insertion or tissue expander insertion.
The denominator for flap cover excludes explant only procedures

Other surgical techniques have remained relatively stable including drain use and concurrent mastopexy. The use of nipple guards and fat grafting has increased over the last three years (Figure 3.14).

FIGURE 3.14 OTHER SURGICAL ELEMENTS – RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2016-2023)



Note: Details are at the breast procedure level. The denominator for Nipple guard excludes procedures with nipple absent selected. The denominator for Neo pocket formation includes only revision (not explant only) procedures.

Device characteristics for breast reconstruction procedures

The ABDR collects data on breast devices including breast implants, tissue expanders and matrix/mesh. Table 3.8 reports characteristics of **implants and tissue expanders** (shell/texture, shape and fill) used for breast reconstruction procedures.

The most common device characteristics for breast implants from 2012-2023 are textured shell type (51.8%), round shape (55.9%), and silicone filled (97.8%). The most common device characteristics for tissue expanders over the same period are textured shell type (99.5%), anatomical shape (99.6%) and saline fill (94.2%). Of note, carbon dioxide is no longer used in tissue expanders although during this reporting period 5.6% were recorded with this type of fill.

TABLE 3.8 DEVICE CHARACTERISTICS – RECONSTRUCTIVE BREAST DEVICES (2012-2023)

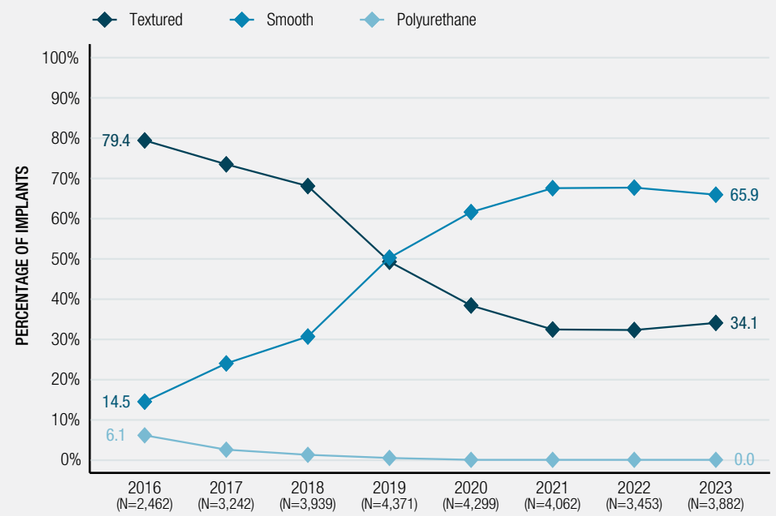
	Implant		Tissue Expander	
	N	(%)	N	(%)
Shell/Texture				
Textured	16,585	(51.8%)	11,179	(99.5%)
Smooth	15,016	(46.9%)	33	(0.3%)
Polyurethane	383	(1.2%)	-	-
Not stated	43	(0.1%)	25	(0.2%)
Shape				
Round	17,902	(55.9%)	18	(0.2%)
Shaped/anatomical	14,082	(44.0%)	11,194	(99.6%)
Not stated	43	(0.1%)	25	(0.2%)
Fill				
Silicone	31,322	(97.8%)	0	(0.0%)
Saline	238	(0.7%)	10,580	(94.2%)
Silicone/Saline	424	(1.3%)		
Carbon dioxide	-	-	632	(5.6%)
Not stated	43	(0.1%)	25	(0.2%)
Total	32,027		11,237	

Note: Implant counts include (breast level) procedures with device operation types: first implant insertion; tissue expander removal and implant insertion; implant revision – with revision type: replacement. Tissue expander counts include (breast level) procedures with device operation types: tissue expander insertion; tissue expander revision – with revision type: replacement; implant removal and tissue expander insertion.

Implant shell

Figure 3.15 shows the pattern of **device shell** used in reconstructive procedures (2016-2023). The most commonly used breast implant shell type has changed from textured breast implants (79.4% in 2016 to 34.0% in 2023) to smooth breast implants (14.5% in 2016 to 65.9% in 2023). From 2019 onwards, smooth implants were inserted more frequently than textured implants. Of note, 2019 marks the point in time that the TGA suspended some textured and polyurethane implants.

FIGURE 3.15 DEVICE SHELL – RECONSTRUCTIVE IMPLANTS (2016-2023)

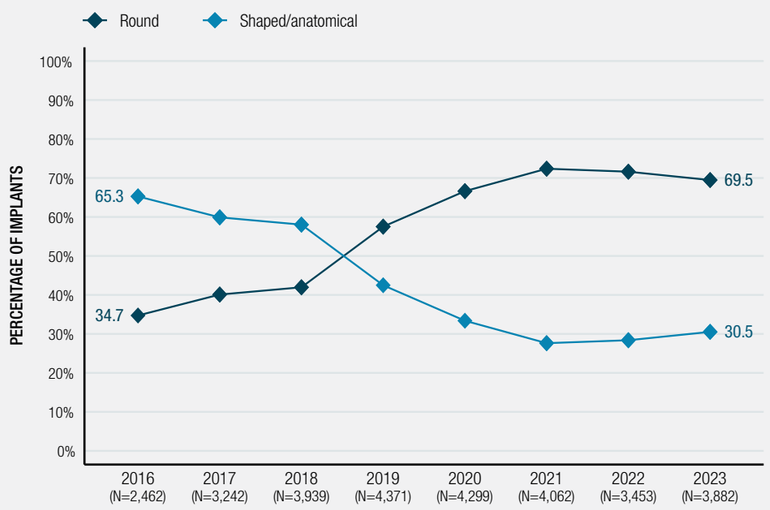


Notes: Device texture is reported for new implants during an insertion procedure or a replacement revision procedure. Implants with an unknown shell type have not been included.

Implant shape

Figure 3.16 demonstrates the **device shape** used in reconstructive surgery (2016-2023). The most commonly used breast implant shape has changed from anatomical (65.3% in 2016 to 30.5% in 2023) to round (34.7% in 2016 to 69.5% in 2023). This change occurred from 2018-19. This aligns with most smooth implants also being of round shape.

FIGURE 3.16 DEVICE SHAPE – RECONSTRUCTIVE IMPLANTS (2016-2023)



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.

Matrix/mesh use in reconstructive procedures

The use of **matrix/mesh** is reported most often in **reconstructive breast surgery.** The ABDR captures the use of matrix/mesh when used concurrently with a breast implant or tissue expander. The ABDR has adopted the terminology matrix/mesh in this report to be inclusive of both synthetic and non-synthetic devices.

TABLE 3.9 MATRIX/MESH USE – RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2012-2023)

	Number of procedures with matrix/mesh use (N)	Proportion of procedures with matrix/mesh use (%)	Total number of procedures (N)
Breast Implants			
Direct-to-implant insertion			
Post-cancer	3,463	58.8%	5,894
Risk-reducing	2,225	57.2%	3,891
Developmental	3	0.1%	2,527
Total	5,691	46.2%	12,312
Tissue expander removal and implant insertion			
Post-cancer	209	2.8%	7,572
Risk-reducing	61	2.3%	2,605
Developmental	0	0.0%	184
Total	270	2.6%	10,361
Revision (replacement/reposition, not explant only)			
Post-cancer	574	9.6%	6,003
Risk-reducing	298	10.7%	2,796
Developmental	32	2.9%	1,117
Total	904	9.1%	9,916
Tissue Expander			
Insertion			
Post-cancer	2,039	28.6%	7,137
Risk-reducing	899	28.7%	3,135
Developmental	1	0.7%	138
Total	2,939	28.2%	10,410
Revision (replacement/reposition, not explant only)			
Post-cancer	42	10.4%	405
Risk-reducing	12	12.4%	97
Developmental	0	0.0%	1
Total	54	10.7%	503
Total procedures	9,858	22.7%	43,502

Notes: Details are at the breast procedure level.

Table 3.9 reports matrix/mesh use in reconstructive procedures with a breast implant or tissue expander. The procedures most often using matrix/mesh are reconstructive post-cancer direct-to-implant procedures (58.8%) followed by reconstructive risk-reducing procedures (57.2%). The next most common use of matrix/mesh was minimal was with insertion of a tissue expander associated with reconstructive cancer procedures (28.6%) and for risk reducing reasons (28.7%). Matrix/mesh was less commonly used for other procedure types/indications.

Primary and legacy breast devices

The Registry collects details of issues and complications arising at the time of revision procedures involving breast implants, tissue expanders and matrix/mesh. **Revision surgery for the purpose of this analysis is defined as unplanned replacement, reposition or explant of an in-situ breast device.**

Table 3.10 shows the number of inserted implants classified as **primary** or **legacy.** An implant is classified based on the available history of the breast it is inserted in. Primary implants are defined as those which are inserted into breasts which have no in-situ breast implant (i.e.: procedure is not a replacement of an implant) and also have no recorded history of prior procedures involving implants recorded in the Registry. Legacy implants are defined as those that are inserted into breasts which have an in-situ implant or a prior history of one.

Of the 32,027 reconstructive breast implant insertions recorded in the ABDR between 2012-2023, (69.0%) were primary breast implants and 9,920 (31.0%) were legacy breast implant insertions. **Only the primary breast implants are included in the following revision rate analyses.**

TABLE 3.10 BREAST IMPLANT INSERTIONS BY PRIMARY/LEGACY STATUS (2012-2023)

Breast implant insertion type	N	%
Primary	22,107	69.0%
Legacy	9,920	31.0%
Total	**32,027**	**100.0%**

Primary tissue expanders are defined as those which are inserted into breasts which have no in-situ device (i.e.: procedure is not a replacement) and also have no recorded history of prior procedures involving tissue expanders or implants recorded in the Registry. Legacy tissue expanders are defined as those that are inserted into breasts which have an in-situ breast device or a prior history of one.

The ABDR has recorded 10,082 (89.7%) primary tissue expanders and 1,155 (10.3%) legacy tissue expanders (Table 3.11). In total 11,237 tissue expanders were inserted for reconstructive reasons. **Analysis to assess device performance-based time to event analysis uses primary devices only.**

TABLE 3.11 TISSUE EXPANDER INSERTIONS BY PRIMARY/LEGACY STATUS (2012-2023)

Tissue expander insertion type	N	%
Primary	10,082	89.7%
Legacy	1,155	10.3%
Total	**11,237**	**100.0%**

Complications and revision incidence – breast implants for reconstructive procedures

The Registry captures data relating to complications found at revision surgery. Revision surgery is described as a procedure for the unplanned replacement, reposition or explant of an in-situ breast device. These complications include capsular contracture, device malposition, device rupture/deflation, skin scarring problems, seroma/haematoma and deep wound infection.

TABLE 3.12 ISSUES IDENTIFIED AT REVISION PROCEDURE – RECONSTRUCTIVE BREAST IMPLANTS

Complications and issues identified at revision (N.B. Not complication rates)	2012-2023		2023	
	N	(%)	N	(%)
Capsular contracture	4,180	(36.7%)	555	(35.1%)
Device malposition	3,141	(27.6%)	358	(22.6%)
Rupture/deflation	2,026	(17.7%)	300	(18.8%)
Skin scarring problems	810	(7.1%)	115	(7.3%)
Seroma/haematoma	481	(4.2%)	70	(4.4%)
Deep wound infection	349	(3.1%)	50	(3.2%)
Total revision procedures	**11,466**		**1,598**	

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

Table 3.12 reports **the frequency of issues out of all reconstructive breast implant revision procedures,** regardless of whether or not the insertion of the initial implant was captured by the Registry. Please note, **this table does not represent complication rates.** Complication rates are described in the following section using Kaplan-Meier (event) curves. This table indicates only the most common complications that are reported to the Registry.

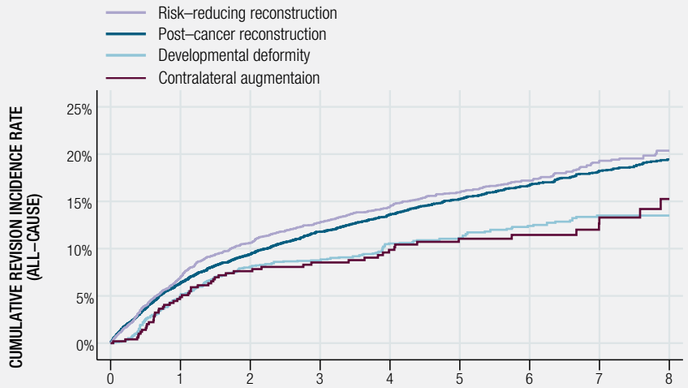
Multiple issues and complications can be reported at the time of revision surgery. They can be identified as the **reason for the revision** procedure or **found incidentally** during the revision procedure. In 2023 capsular contracture was the most common issue reported to the Registry at 35.1% of reconstructive breast implant revisions, followed by device malposition at 22.6% and device rupture/deflation at 18.8%.

Revision incidence by reconstructive indication

For the first-time contralateral augmentation (augmentation procedure on breast opposite to the one being reconstructed) has been included as a cohort in revision incidence curves, for comparison with other indications. Please note that contralateral procedures are not included in other breast level tables/figures of this report which are split by reconstructive/ cosmetic indication.

Figure 3.17 demonstrates the **all-cause revision incidence curve** based on the three reconstructive indications for surgery. The all-cause cumulative revision incidence 8 years after primary implant insertion is **20.4% for risk-reducing reconstruction, 19.4% for post-cancer reconstruction, 13.5% for developmental deformity and 15.3% for contralateral augmentation,** which is higher than the cosmetic revision rate of 6.7% seen in Figure 4.11 (refer to Appendix 3 relating to Figure 3.17-3.19). The revision profile of contralateral augmentation procedures aligns closely with that of the developmental deformity cohort.

FIGURE 3.17 ALL-CAUSE REVISION INCIDENCE – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS



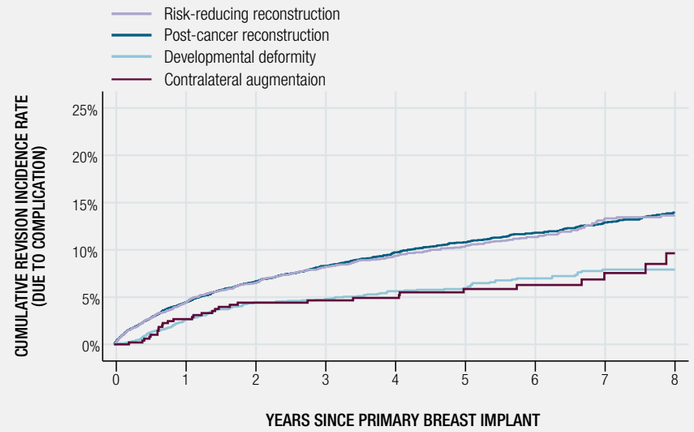
Number at risk

6,347	5,368	4,495	3,686	2,854	2,100	1,387	809	392	Risk–reducing
13,066	11,277	9,504	7,874	6,224	4,655	3,175	1,902	1,023	Post–cancer
2,694	2,356	2,033	1,718	1,319	1,067	820	591	338	Developmental
498	460	412	384	323	270	204	134	76	Contralat. aug.

Notes: Revision incidence (all–cause) is based on reconstructive primary breast implants inserted from 2012 to 2023.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the first revision procedure.
The accompanying table provides the number of breasts at risk of revision, following from the initial implant procedure at Year=0.

Figure 3.18 provides **revision incidence due to complication** by indication. At 8 years after primary implant insertion, revision incidence due to complication was **13.9% for post-cancer, 13.6% for risk reducing reconstruction, 7.9% for developmental deformity and 9.6% contralateral augmentation,** which is higher than the cosmetic revision rate of 3.5% seen in Figure 4.12.

FIGURE 3.18 REVISION INCIDENCE DUE TO COMPLICATION BY INDICATION – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS



Number at risk

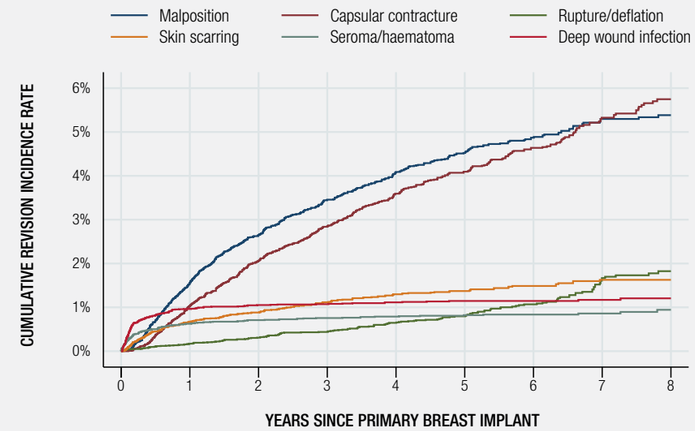
6,347	5,368	4,495	3,686	2,854	2,100	1,387	809	392	Risk–reducing
13,066	11,277	9,504	7,874	6,224	4,655	3,175	1,902	1,023	Post–cancer
2,694	2,356	2,033	1,718	1,319	1,067	820	591	338	Developmental
498	460	412	384	323	270	204	134	76	Contralat. aug.

Notes: Revision incidence (due to complication) is based on reconstructive primary breast implants inserted from 2012 to 2023.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the first revision procedure.
The accompanying table provides the number of breasts at risk of revision, following from the initial implant procedure at Year=0.

Revision incidence of specific complications

Figure 3.19 shows the **cumulative revision incidence rates by complication type up to 8 years** after the date of primary implant insertion. It shows that over time capsular contracture and malposition have higher incidence compared to other outcomes. At 8 years post implant insertion, the revision incidence was 5.7% for capsular contracture, 5.4% for device malposition, 1.8% for device rupture/deflation, 1.6% for skin scarring, 1.2% for deep wound infection, and 0.9% for seroma/haematoma.

FIGURE 3.19 CUMULATIVE REVISION INCIDENCE RATE BY COMPLICATION TYPE – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS



Number at risk

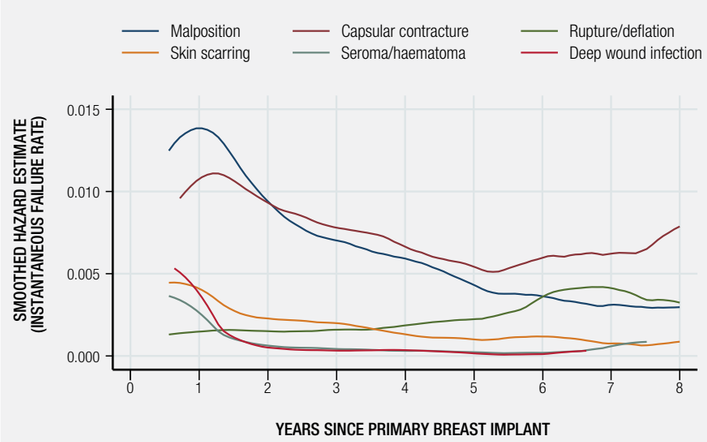
22,107	19,001	16,032	13,278	10,397	7,822	5,382	3,302	1,753

The risk of particular issues occurring may vary over time. Hazard curves can aid with understanding when certain issues typically occur. They can demonstrate potential relationships between time elapsed and rates of complications. (Here, times to revisions are used as proxies for times of when complications are first experienced since it is not possible to capture this. It should be noted that experience of complications may not lead to revisions. Furthermore, there may be long periods of time between when complications are first experienced and when revision procedures can occur.)

The risk of certain complications may be highest shortly after implant insertion. These complications would have hazards which are highest early on (i.e.: malposition, capsular contracture, skin scarring, deep wound infection, haematoma/seroma). Other complications may be wear-out failures that only become relevant after long periods of time have passed. These complications would have hazards which are highest later on (e.g. rupture/deflation).

Hazard estimates over time elapsed are shown for each type of complication in Figure 3.20 to demonstrate when revisions involving specific complications typically occur. Rates are generally highest in the first year following implant insertion. Rates of revisions due to malposition and deep wound infection, in particular have distinct peaks early on followed by steep decreases over the years. Unlike other complications, rupture/deflation appears to be an outcome corresponding to wear out with its rate increasing as more time elapses. Malposition, capsular contracture, deep wound infection, skin scarring and seroma/haematoma are associated with revisions most commonly in the first 2 years. Rates of capsular contracture increase slightly again from about year 5, and rates of rupture/deflation increase slightly from year 3-4 post implant insertion.

FIGURE 3.20 HAZARD BY COMPLICATION TYPE – REVISIONS OF RECONSTRUCTIVE PRIMARY BREAST IMPLANTS

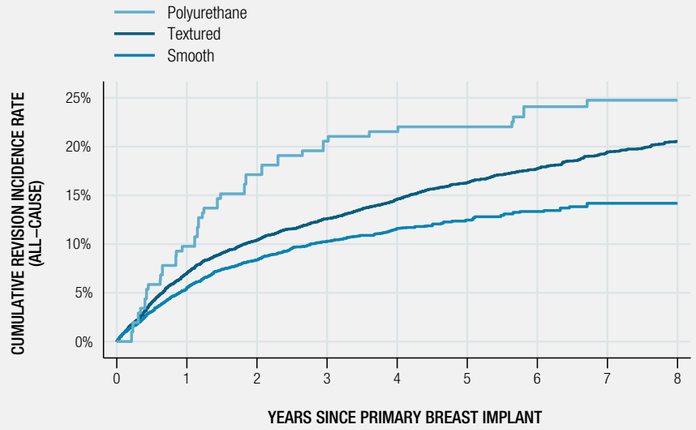


Note: Curves are truncated when smoothed estimates of hazard cannot be calculated (shortly after the start and when case numbers for the complication of interest are low). Experience of complications may not necessarily lead to a revision procedure. There may be long periods of time between when complications are first experienced and when revision procedures occur.

Revision incidence by device characteristics

Figure 3.21 provides the **all-cause revision incidence** for reconstructive implants based on device shell characteristics. The all-cause revision incidence rate at 8 years since primary implant insertion was 24.8% for polyurethane implants, 20.5% for textured implants and 14.2% for smooth implants. The higher incidence of all-cause revisions for polyurethane implants at 8 years may be due in part to patients having these types of devices removed following the TGA device recall in 2019.

FIGURE 3.21 ALL-CAUSE REVISION INCIDENCE BY SHELL – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS



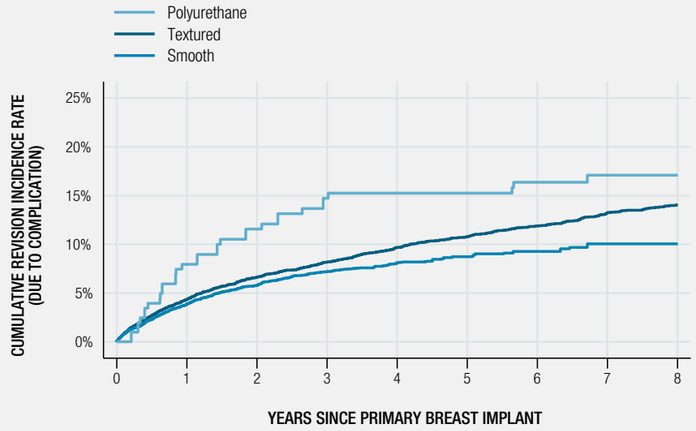
Number at risk

12,141	10,699	9,543	8,526	7,257	6,034	4,366	2,822	1,526	Textured
9,739	8,098	6,301	4,574	2,968	1,623	871	373	163	Smooth
205	184	169	162	160	159	140	104	61	Polyurethane

Notes: Revision incidence (all-cause) is based on reconstructive primary breast implants inserted from 2012 to 2023.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the first revision procedure.
The accompanying table provides the number of breasts at risk of revision, following from the initial implant procedure at Year=0.
Implants with unknown shell have not been included.

Figure 3.22 provides the **revision incidence due to complication** for reconstructive primary implants by device shell characteristics. The revision due to complication incidence rate at 8 years since primary implant insertion was 17.1% for polyurethane implants, 14.0% for textured implants and 10.0% for smooth implants. The revision incidence rates for specific complications can be found in Appendix 4.

FIGURE 3.22 REVISION INCIDENCE DUE TO COMPLICATION BY SHELL – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS



Number at risk

12,141	10,699	9,543	8,526	7,257	6,034	4,366	2,822	1,526	Textured
9,739	8,098	6,301	4,574	2,968	1,623	871	373	163	Smooth
205	184	169	162	160	159	140	104	61	Polyurethane

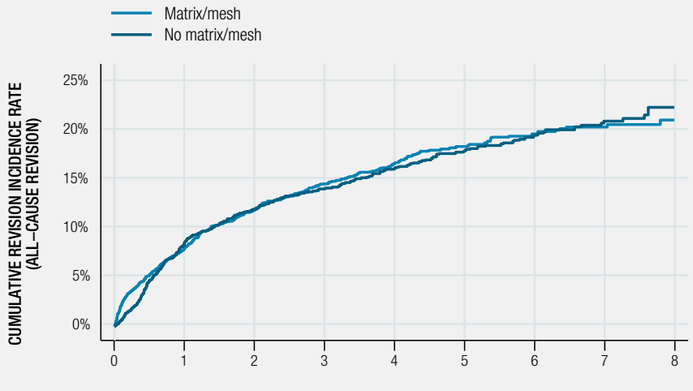
Notes: Revision incidence (due to complication) is based on reconstructive primary breast implants inserted from 2012 to 2023.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the first revision procedure.
The accompanying table provides the number of breasts at risk of revision, following from the initial implant procedure at Year=0
Implants with unknown shell have not been included.

Revision incidence by use of matrix/mesh (direct-to-implant procedures)

The ABDR collects details of issues and complication that are found at the time of revision procedures for primary implants inserted with matrix/mesh. Only breasts which enter the Registry with a direct-to-implant insertion procedure are included in the following figures. Very few developmental deformity procedures involved matrix/mesh. In order to keep matrix/mesh use groups comparable, only post-cancer and risk-reducing procedures have been included here (Figures 3.23-3.24).

Figure 3.23 provides the **all-cause revision incidence curve** for reconstructive **direct-to-implant** primary breast implants **by matrix/mesh use.** The all-cause revision incidence 8 years after insertion was 20.8% for the implants with matrix/mesh and 22.0% without matrix/mesh.

FIGURE 3.23 ALL-CAUSE REVISION INCIDENCE BY MATRIX/MESH USE – RECONSTRUCTIVE PRIMARY DIRECT-TO-IMPLANT PROCEDURES



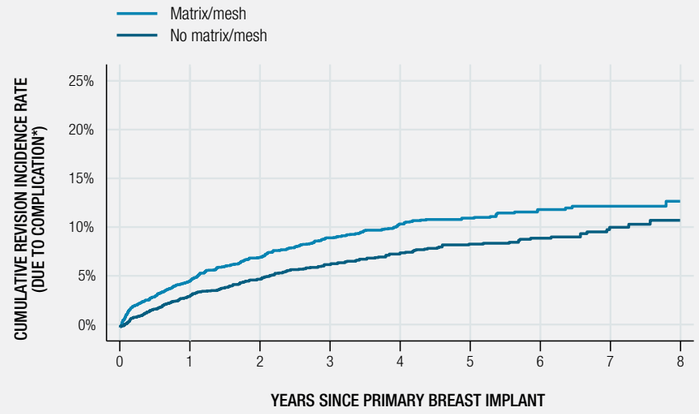
Number at risk

5,648	4,598	3,604	2,712	1,898	1,188	682	331	135	Matrix/mesh
3,571	2,909	2,412	1,948	1,491	1,130	770	375	148	No matrix/mesh

Note: Revision incidence (all-cause revision) is based on reconstructive primary direct-to-implant procedures beginning from 2012 to 2023.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the first revision procedure.
The accompanying table provides the number of breasts at risk of revision, following from the initial implant procedure at Year=0.

Figure 3.24 provides the **revision due to complication incidence** curve for direct-to-implant reconstructive primary breast implants by matrix/mesh use. The outcome of interest here is any one of: malposition, capsular contracture, seroma/haematoma, or deep wound infection. The revision incidence due to complication 8 years after insertion was 12.8% for the implants with matrix/mesh and 10.9% without matrix/mesh. The revision incidence rates for specific issues are found in the Appendix 5.

FIGURE 3.24 REVISION DUE TO COMPLICATION INCIDENCE BY MATRIX/MESH USE – RECONSTRUCTIVE PRIMARY DIRECT-TO-IMPLANT PROCEDURES



Number at risk

5,648	4,598	3,604	2,712	1,898	1,188	682	331	135	Matrix/mesh
3,571	2,909	2,412	1,948	1,491	1,130	770	375	148	No matrix/mesh

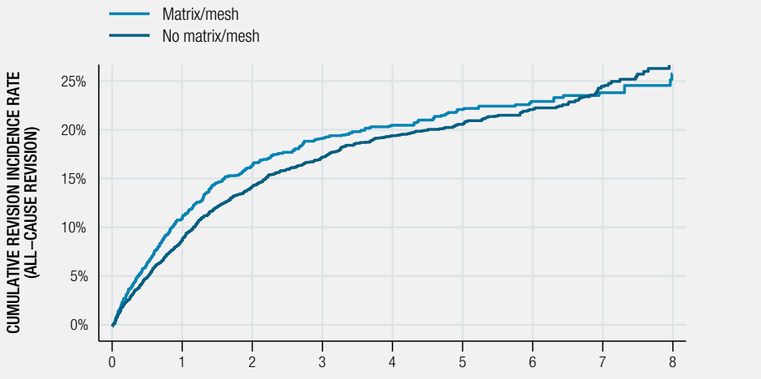
Note: Revision incidence (due to complication*) is based on reconstructive primary breast implants inserted from 2012 to 2023.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the first revision procedure.
The accompanying table provides the number of breasts at risk of revision, following from the initial implant procedure at Year=0
*Involves at least one of: malposition, capsular contracture, seroma/haematoma, or deep wound infection

Revision incidence by use of matrix/mesh (two-stage procedures)

The following analysis is based on **two-stage** reconstructive procedures. Subsequent procedures after tissue expander insertion have often not been captured in the Registry (Table 3.5). Therefore, only breasts which entered the Registry with a tissue expander insertion procedure and also have a subsequent procedure captured in the Registry are included in Figures 3.25-3.26. Very few developmental deformity procedures involved matrix/mesh. In order to keep matrix/mesh use groups comparable, only post-cancer and risk-reducing procedures have been included here (Figures 3.25-3.26). Breasts with matrix/mesh inserted with the second stage breast implant are excluded from the following analysis due to small volume. The first revision is used as the endpoint (whether this is a revision of the tissue expander or the following implant).

The all-cause revision incidence 8 years after tissue expander insertion was 25.8% for two-stage procedures with matrix/mesh and 26.7% for those without matrix/mesh. (Figure 3.25)

FIGURE 3.25 ALL-CAUSE REVISION INCIDENCE BY MATRIX/MESH USE – RECONSTRUCTIVE PRIMARY TWO-STAGE PROCEDURES



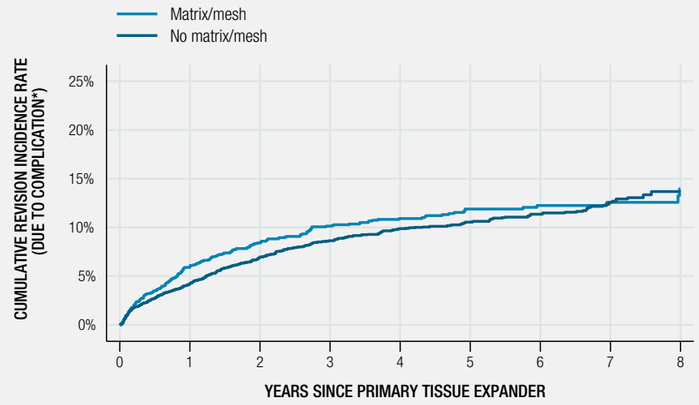
Number at risk

2,128	1,826	1,555	1,282	1,001	732	453	261	116	Matrix/mesh
5,115	4,542	3,942	3,381	2,774	2,162	1,385	808	405	No matrix/mesh

Note: Revision incidence (all-cause revision) is based on reconstructive primary two-stage procedures beginning from 2012 to 2023.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary tissue expander insertion date to the first revision procedure.
The accompanying table provides the number of breasts at risk of revision, following from the initial implant procedure at Year=0.

The revision due to **complication incidence for two-stage procedures by matrix/mesh** use and non-use is shown in Figure 3.26. The outcome of interest here is any one of: malposition, capsular contracture, seroma/haematoma, or deep wound infection. The cumulative revision incidence at 8 years for two-stage procedures with matrix/mesh is 14.0% while it is 13.7% for procedures without matrix/mesh. The revision incidence rates for specific issues are found in Appendix 6.

FIGURE 3.26 REVISION DUE TO COMPLICATION INCIDENCE BY MATRIX/MESH USE – RECONSTRUCTIVE PRIMARY TWO-STAGE PROCEDURES



Number at risk

2,128	1,826	1,555	1,282	1,001	732	453	261	116	Matrix/mesh
5,115	4,542	3,942	3,381	2,774	2,162	1,385	808	405	No matrix/mesh

Note: Revision incidence (due to complication*) is based on reconstructive primary two-stage procedures beginning from 2012 to 2023.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary tissue expander insertion date to the first revision procedure.
The accompanying table provides the number of breasts at risk of revision, following from the initial implant procedure at Year=0.
*Involves at least one of: malposition, capsular contracture, seroma/haematoma, or deep wound infection.

Issues identified with tissue expander revision procedures

Table 3.13 the frequency of issues of reconstructive tissue expander revision procedures, regardless of whether or not the insertion of the initial implant was captured by the Registry. Please note, this table does not represent complication rates.

TABLE 3.13 ISSUES IDENTIFIED AT REVISION PROCEDURE – RECONSTRUCTIVE PRIMARY TISSUE EXPANDERS

Complications and issues identified at revision (N.B. Not complication rates)	2012-2023		2023	
	N	(%)	N	(%)
Deep wound infection	186	(21.8%)	25	(22.9%)
Device rupture/deflation	169	(19.8%)	24	(22.0%)
Seroma/haematoma	123	(14.4%)	19	(17.4%)
Capsular contracture	108	(12.7%)	14	(12.8%)
Device malposition	82	(9.6%)	14	(12.8%)
Skin scarring problems	73	(8.6%)	10	(9.2%)
Total number of procedures	**853**		**109**	

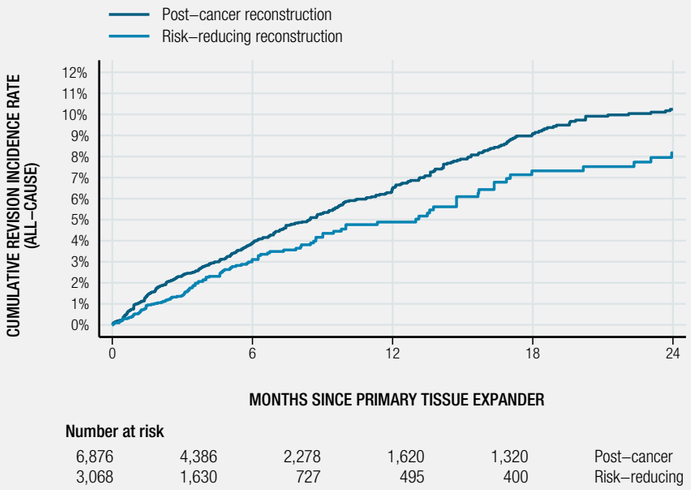
Notes: Listed in order of frequency are issues identified during unplanned reconstructive tissue expander revision procedures.
Multiple issues can be recorded at the time of revision surgery and issues were either identified as a reason for revision or found incidentally during the revision procedure.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

Issues identified at revision for tissue expanders in 2023 include most commonly deep wound infection (22.9% of issues identified) and device rupture/deflation (22.0% of issues identified), followed by seroma/haematoma and capsular contracture (17.4% and 12.8% % of issues identified respectively). The proportion of device rupture/deflations of total issues identified has increased in 2023.

Revision Incidence for Tissue Expanders

The **all-cause revision incidence for primary reconstructive tissue expanders** is presented in Figure 3.27. Revision incidence is only shown up to 24 months because tissue expanders are only used temporarily before being replaced, and ABDR data shows only 1.7% of tissue expanders are replaced after two years. In post-cancer reconstruction the cumulative revision incidence rate 24 months after insertion is 10.2%, with revision incidence for risk reducing procedures at 8.2%. Reconstruction for developmental deformity are not presented in this figure because there are only a small number of reported cases in this cohort (there were 138 primary tissue expanders inserted for developmental deformity). Please refer to Appendix 7.

FIGURE 3.27 ALL-CAUSE REVISION INCIDENCE – PRIMARY RECONSTRUCTIVE TISSUE EXPANDERS



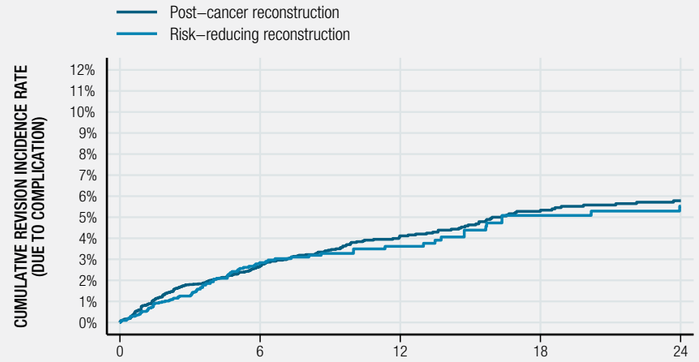
Number at risk

6,876	4,386	2,278	1,620	1,320	Post–cancer
3,068	1,630	727	495	400	Risk–reducing

Note: Revision incidence (all-cause) is based on reconstructive primary tissue expanders inserted from 2012 to 2023.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary tissue expander insertion date to the first revision procedure.
The accompanying table provides the number of breasts at risk of revision, following from the initial implant procedure at Year=0.

The **revision incidence due to complication** for primary reconstructive procedures with a **tissue expander** are presented in Figure 3.28. The revision incidence at 24 months is 5.8% for post-cancer and 5.5% for risk-reducing procedures. Again, developmental deformity is not presented in this figure due to the small number of reported cases in this cohort.

FIGURE 3.28 REVISION INCIDENCE DUE TO COMPLICATION – PRIMARY RECONSTRUCTIVE TISSUE EXPANDERS



Number at risk

6,876	4,386	2,278	1,620	1,320	Post–cancer
3,068	1,630	727	495	400	Risk–reducing

Note: Revision incidence (due to complication) is based on reconstructive primary tissue expanders inserted from 2012 to 2023.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary tissue expander insertion date to the first revision procedure.
The accompanying table provides the number of breasts at risk of revision, following from the initial implant procedure at Year=0.

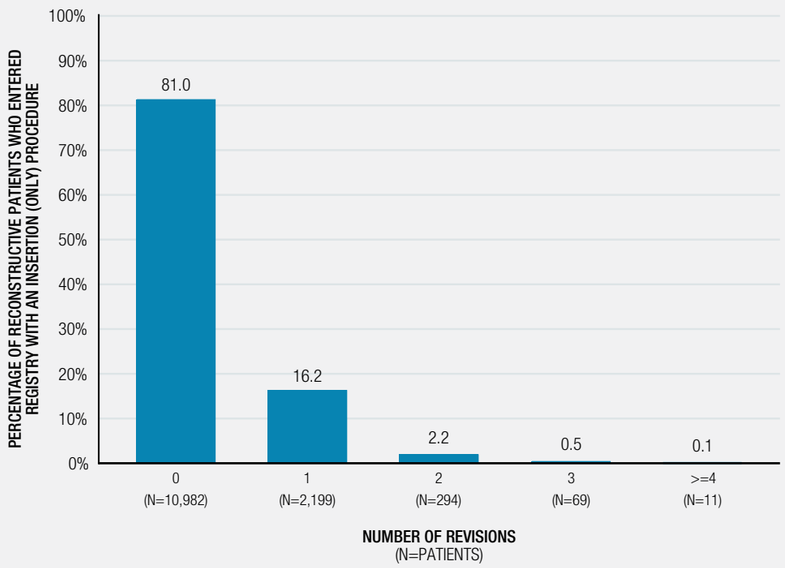
Multiple revision procedures

As the Registry matures there is growing interest to provide a comprehensive report on revision procedures. It is also an opportunity to explore the patient journey to show emerging trends in device performance and patient safety.

Patients may have multiple revision procedures. Figure 3.29 shows the percentages and counts of patients by the number of revisions they had (the breast with the most revisions is used for the count). Patients whose first operation involved only tissue expander insertions or direct-to-implant insertions are included (since those who enter the Registry with other operation types could potentially have had prior revisions that cannot not be counted). Of the 13,555 patients included, 81.0% had no revisions (10,982), 16.2% had one revision (2,199), 2.2% (294) had two revisions, 0.5% had 3 revisions and 0.1% had 4 or more revisions.

Issues identified at revision for tissue expanders in 2022 include most commonly device rupture/deflation (23.0% of issues identified) and deep wound infection (19.0% of issues identified), followed by seroma/haematoma and capsular contracture (each at 12.7% of issues identified). The proportion of device rupture/deflations has increased in 2022.

FIGURE 3.29 NUMBER OF REVISIONS PER RECONSTRUCTIVE PATIENT.
PATIENTS WHOSE FIRST PROCEDURE IN THE REGISTRY ONLY INVOLVED DEVICE INSERTIONS.



Notes: For each patient, the breast with the most revisions is used for the count. Only includes patients who enter the Registry with tissue expander insertions or direct-to-implant insertions.

Clinician conducting revision procedure

Revision procedures are not necessarily conducted by the same clinician who performed prior insertions. The frequency of revisions being conducted by a different clinician has been investigated using breasts with both a primary implant insertion procedure and implant revision procedure captured. Of the 3,012 breasts included, 2,468 (81.9%) had both procedures conducted by the same clinician while 544 (18.1%) had insertion and revision procedures conducted by different clinicians.

CHAPTER 4

Registry Outputs – Cosmetic Indications

Cosmetic procedure numbers and manufacturer details

At the end of the 2023 calendar year, the ABDR had recorded a total of **74,086** surgical procedures involving breast devices for **cosmetic indications.** The types of procedures captured in this analysis includes bilateral and unilateral cosmetic surgery. Procedures where one breast has a reconstructive indication and the other breast has a cosmetic indication are not included here.

Figure 4.1 shows that in 2023 the total number of cosmetic procedures was **7,835,** the lowest number since 2016. Given that case ascertainment of ABDR procedures has been fairly steady over this period, it is likely that this reflects a true reduction in the number of cosmetic procedures undertaken. This may be due to a reduction in cosmetic breast procedures and/or a reduction in implant-based cosmetic breast procedures being performed in Australia. Note that a hundred or so 2023 procedures are likely to have delayed entry into the Registry, and these procedures will be captured and reported in the 2024 year.

FIGURE 4.1 REGISTERED PROCEDURES – COSMETIC PROCEDURES (2012-2023)

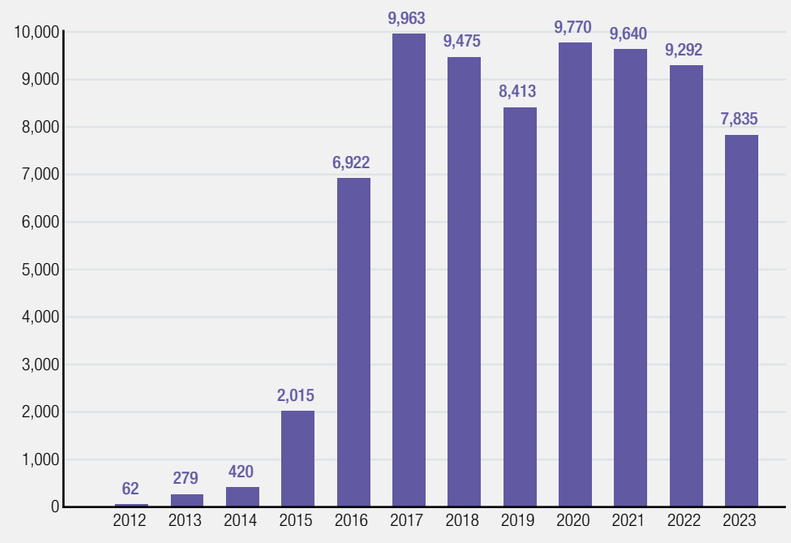


TABLE 4.1 BREAST IMPLANTS INSERTED BY MANUFACTURER, PER BREAST – COSMETIC BREAST LEVEL PROCEDURES (2012-2023)

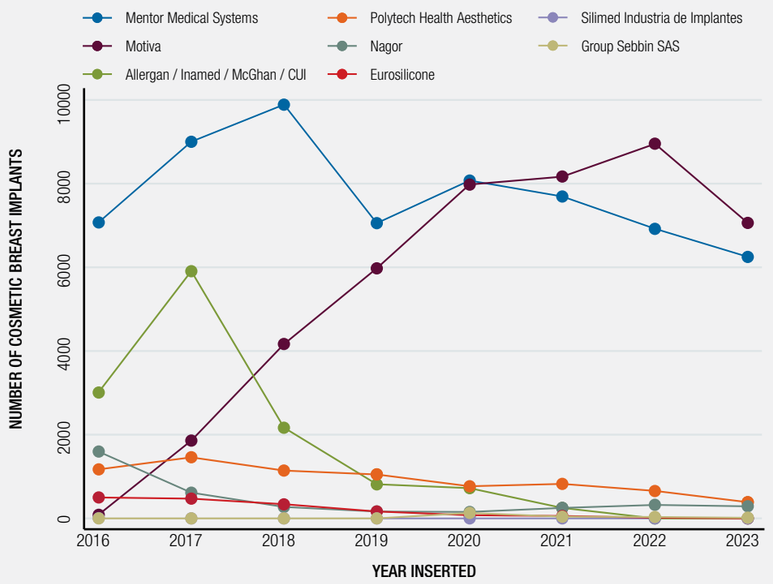
Manufacturer	N	%
Mentor Medical Systems	64,401	46.6%
Motiva	44,514	32.2%
Allergan/Inamed/McGhan/CUI	14,686	10.6%
Polytech Health & Aesthetics	7,683	5.6%
Nagor	4,440	3.2%
Eurosilicone	1,781	1.3%
Silimed Industria de Implantes	472	0.3%
Group Sebbin SAS	221	0.2%
Cereplas	26	0.0%
Not Stated	**107**	**0.1%**
Total	**138,331**	**100.0%**

Note: Includes (breast level) procedures with device operation types: first implant insertion; implant revision - with revision type: replacement.

Table 4.1 shows the frequency of inserted cosmetic breast implants in the Registry by manufacturer. Since 2012-2023 a total of **138,331 breast implants for cosmetic indications** were inserted, of which 99.9% had manufacturer details provided. Implants in this reporting period were mostly manufactured by Mentor Medical Systems, Motiva and Allergan/ Inamed/McGhan/CUI which together account for 89.4% of the implants inserted.

In Figure 4.2, the number of cosmetic breast implants inserted annually between 2016-2023 are presented. Data collected during the pilot program 2012-2015 has not been included due to the small number of procedures reported during this time. Since 2019 the most common devices used by manufacturer for cosmetic procedures were Mentor Medical Systems and Motiva.

FIGURE 4.2 BREAST IMPLANTS INSERTED BY MANUFACTURER PER BREAST – COSMETIC PROCEDURES (2016-2023)

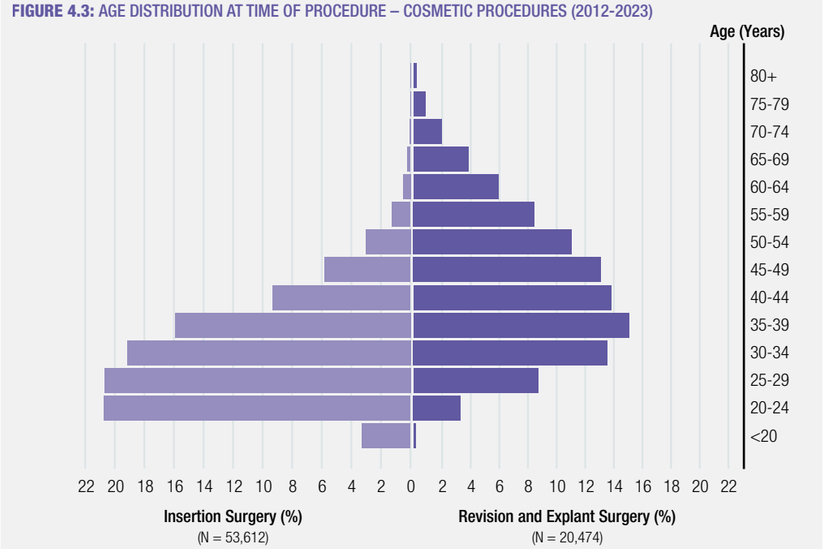


Note: Includes (breast level) procedures with device operation types: first implant insertion; implant revision - with revision type: replacement.

Patient age at cosmetic procedure

The distribution of age at the time of cosmetic procedure is depicted in Figure 4.3 and Table 4.2. Overall, the median age at the time of insertion surgery was 31 years, 43 years for revision procedures, and 45 years for explant procedures. The most common age groups for insertion procedures overall were the 20-24-year and 25-29-year age groups (20.7% of procedures each). 3.3% of the cosmetic insertion procedures captured by the Registry were performed on patients under 20 years old.

FIGURE 4.3: AGE DISTRIBUTION AT TIME OF PROCEDURE – COSMETIC PROCEDURES (2012-2023)



Notes: Insertion, revision and explant only procedures have been analysed independently.
Both unilateral and bilateral procedures have been included. Counts are on the operation level.
A four-tier hierarchy has been applied for bilateral procedures with different indication and procedure type details per breast.
Counts are on the operation level.

TABLE 4.2 SUMMARY STATISTICS FOR AGE AT TIME OF PROCEDURE – COSMETIC PROCEDURES (2012-2023)

Cosmetic	Insertion surgery	Revision surgery	Explant only
N	53,612	16,654	3,820
Median Age (Interquartile range)	31.4 (25.2, 38.4)	43.0 (34.8, 52.3)	44.6 (34.5, 56.6)

Notes: Insertion, revision and explant only procedures have been analysed independently.
Both unilateral and bilateral procedures have been included. Counts are on the operation level.
A four-tier hierarchy has been applied for bilateral procedures with different indication and procedure type details per breast. Counts are on the operation level.
The interquartile range reports observed patient age at the 25th and 75th percentiles.

Cosmetic procedure intra-operative aseptic techniques

The ABDR reports on the following intra-operative aseptic techniques: intra-operative/post-operative antibiotics, antiseptic rinse, glove change for insertion, antibiotic dipping solution and sleeve/funnel use. Clinicians have the option to select one or more of these intra-operative aseptic techniques when completing the data collection form. Overall, intra-operative aseptic techniques are increasingly used in cosmetic procedures.

TABLE 4.3 INTRA-OPERATIVE ASEPTIC TECHNIQUES – COSMETIC PROCEDURES (2012-2023)

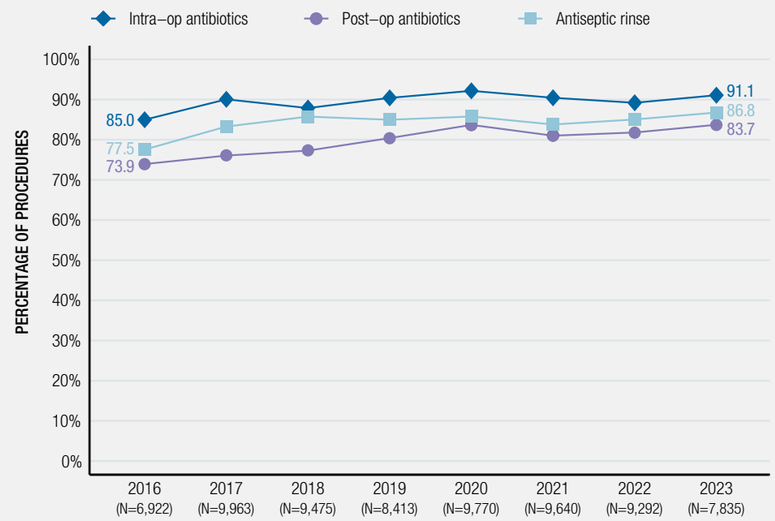
	2012-2023		
	N	(%)	Total eligible
Intra-op/post-op antibiotics[1]	67,225	(90.7%)	74,086
Antiseptic rinse[1]	62,218	(84.0%)	74,086
Not stated[1]	4,891	(6.6%)	74,086
Glove change for insertion[2]	52,157	(74.2%)	70,266
Antibiotic dipping solution[2]	42,716	(60.8%)	70,266
Sleeve/funnel[2]	35,649	(50.7%)	70,266

Note: More than one intra-operative technique can be used and recorded per procedure. Counts are at the operation level. The use of intra-operative and post-operative antibiotics is reported together for 2012-2022 because the data fields were not collected separately until 2015. Denominator for percentage calculation: [1] all procedures; [2] excludes explant only procedures.

Table 4.3 shows that intra-operative/post-operative antibiotics are used in 90.7% of cosmetic procedures while antiseptic rinse is used in 84.0% of these. Glove change was reported in 74.2% of cosmetic insertion/revision procedures (not explant only).

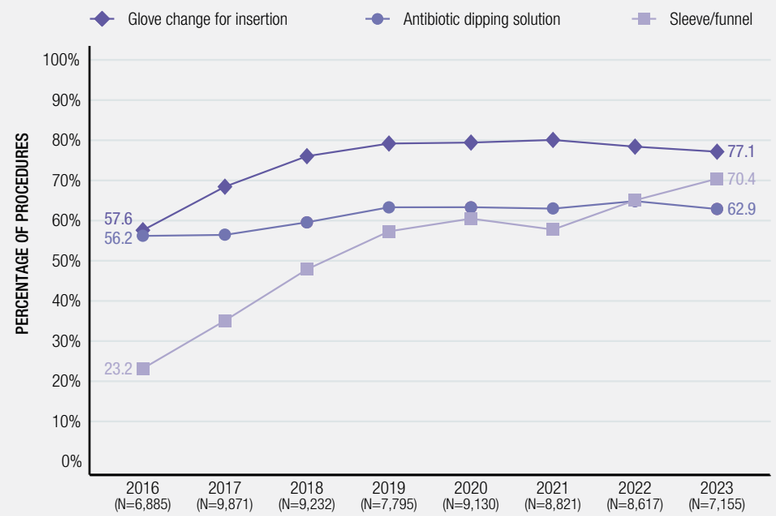
Figures 4.4 and 4.5 demonstrate that intra-operative aseptic technique use has increased for cosmetic procedures. Intra-operative antibiotics, post-operative antibiotics and antiseptic rinse is applicable for all device operation types. Since 2016, antiseptic rinse has increased by 9.3% (Figure 4.4). The greatest increase has been in the utilisation of sleeve/funnel, increasing by 47.2% since 2016 (Figure 4.5) in cosmetic insertion and revision procedures (excludes explant only procedures).

FIGURE 4.4 INTRA-OPERATIVE ASEPTIC TECHNIQUES RELEVANT FOR ALL COSMETIC PROCEDURES (2016-2023)



Note: Information regarding intra-operative and post-operative antibiotics have been collected separately since 2015.
A procedure indication hierarchy has been applied for bilateral procedures with different indication and procedure type details per breast.

FIGURE 4.5: INTRA-OPERATIVE ASEPTIC TECHNIQUES RELEVANT FOR COSMETIC INSERTION AND REVISION (NOT EXPLANT ONLY) PROCEDURES (2016-2023)



Note: Information regarding intra-operative and post-operative antibiotics have been collected separately since 2015.
A procedure indication hierarchy has been applied for bilateral procedures with different indication and procedure type details per breast.

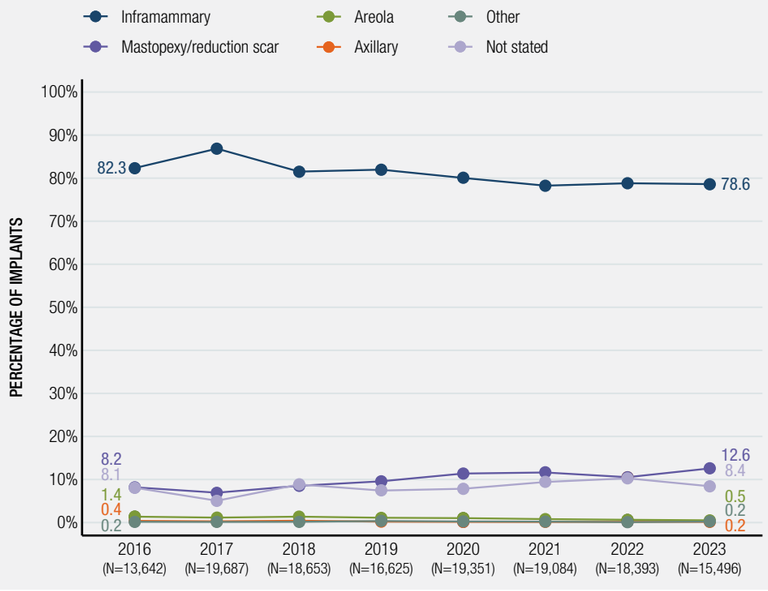
Cosmetic surgical techniques

Trends in surgical techniques over time are shown in Figure 4.6-4.8 and further details can be found in Appendix 8.

Surgical incision sites

Around 80% of surgical incisions for cosmetic procedures are infra-mammary. The next most common is incision site is mastopexy/reduction scar (Figure 4.6). Please refer to Appendix 8 for more detail.

FIGURE 4.6 SURGICAL ELEMENTS – INCISION SITE – COSMETIC BREAST LEVEL PROCEDURES

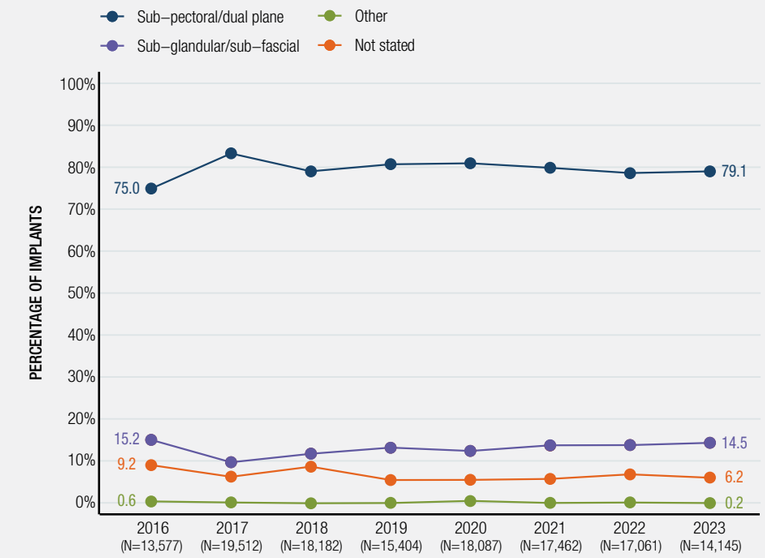


Note: Details are at the breast procedure level. More than one incision site can be recorded

Surgical plane

Figure 4.7 demonstrates that the most common surgical plane for cosmetic procedures is the sub-pectoral/dual plane 79.1%, followed by the sub-glandular/sub-fascial plane 14.5% (in 2023).

FIGURE 4.7 SURGICAL ELEMENTS – SURGICAL PLANE – COSMETIC BREAST LEVEL PROCEDURES (2016-2023)

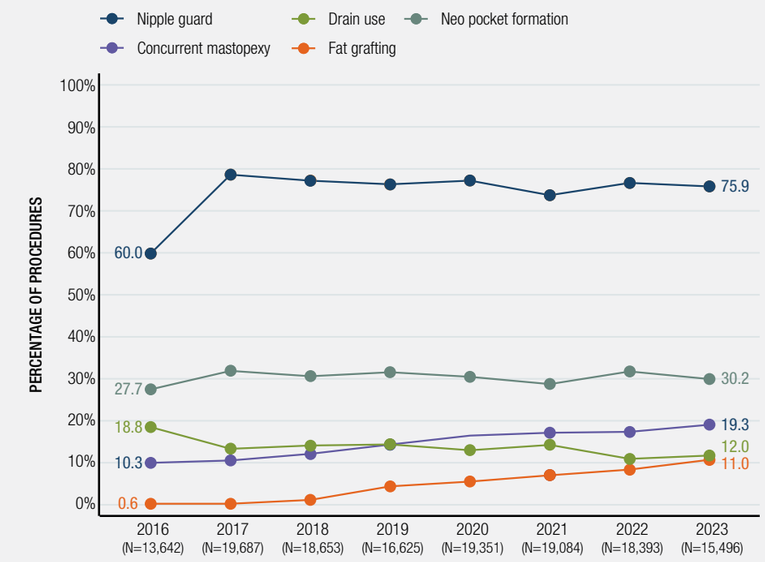


Note: Details are at the breast procedure level. Only insertion and revision procedures (which are not explant only) are included.

Other surgical elements

In other surgical techniques, increases over time (2016-2023) are observed in the use of fat grafting (0.6 to 11%) and concurrent mastopexy (10.3-19.3%), with most other surgical techniques remaining stable, with a slight decline in drain use (18.8-12.0%) (Figure 4.8).

FIGURE 4.8 SURGICAL ELEMENTS – COSMETIC BREAST LEVEL PROCEDURES (2016-2023)



Note: Details are at the breast procedure level. The denominator for Neo pocket formation includes only revision (not explant only) procedures.

Device characteristics for breast cosmetic procedures

Device characteristics are ascertained by the Registry from manufacturer catalogues. The ABDR characterises these according to implant shell/texture, shape and fill. A total of 138,331 devices used in cosmetic procedures have been recorded by the ABDR since 2012.

TABLE 4.4 DEVICE CHARACTERISTICS – COSMETIC BREAST IMPLANTS (2012-2023)

	Implant	
	N	(%)
Shell/Texture		
Smooth	69,911	(50.5%)
Textured	64,738	(46.8%)
Polyurethane	3,575	(2.6%)
Not stated	107	(0.1%)
Shape		
Round	103,046	(74.5%)
Shaped/anatomical	35,178	(25.4%)
Not stated	107	(0.1%)
Fill		
Silicone	137,225	(99.2%)
Saline	978	(0.7%)
Silicone/Saline	21	(<0.1%)
Not stated	107	(0.1%)
Total	**138,331**	

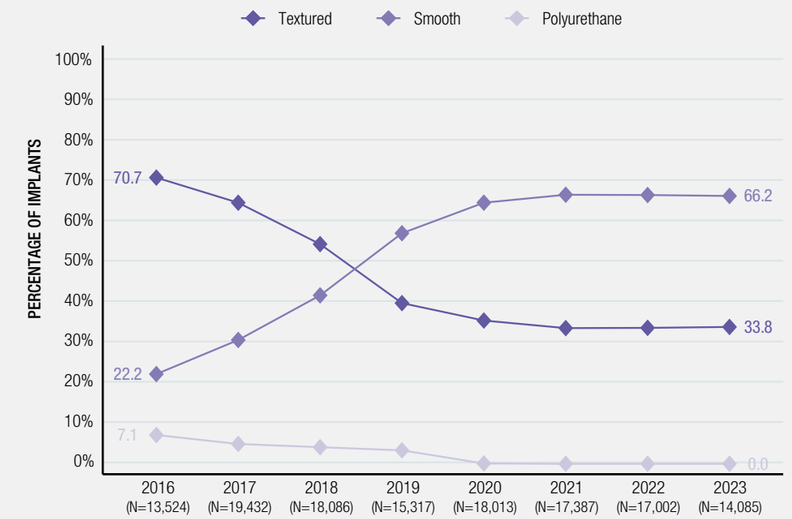
Note: Includes (breast level) procedures with device operation types: first implant insertion; implant revision – with revision type: replacement.

Table 4.4 demonstrates that there are more smooth devices (50.5%) in the Registry for cosmetic procedures, compared to textured devices (46.8%). Round devices (74.5%) continue to be used often compared to shaped/anatomical devices. Of note, smooth devices tend to also be round shaped. The majority of implants have silicone fill (99.2%).

Implant shell

The Registry is able to show the trends in use of breast implants by shell and shape respectively over time. Figure 4.9 demonstrates that the proportion of smooth and textured devices has plateaued during 2021-2023, with smooth devices comprising 66.2% and textured devices comprising 33.8% of total devices. Of the 14,085 cosmetic breast implants inserted in 2023, 9,322 were smooth while 4,763 were textured.

FIGURE 4.9 DEVICE SHELL – COSMETIC IMPLANTS (2016-2023)

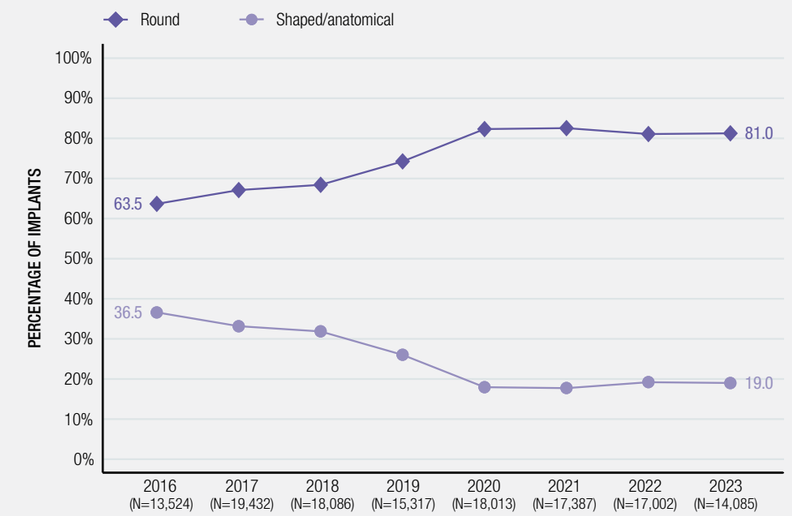


Notes: Device texture is reported for new implants during an insertion procedure or a replacement revision procedure. Implants with an unknown shell type have not been included.

Implant shape

Figure 4.10 highlights the continued trends in the use of round breast implants in cosmetic surgery. Round implants have increased from 63.5% to 81.0% in 2023 while shaped/anatomical implants decreased from 36.5% to 19.0% in 2023. Out of the 14,085 cosmetic breast implants inserted in 2023, 11,414 were round while 2,671 were shaped/anatomical.

FIGURE 4.10 DEVICE SHAPE – COSMETIC IMPLANTS (2016-2023)



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.

Matrix/mesh use in cosmetic procedures

For the first time, the ABDR is reporting on the use of matrix/mesh in cosmetic procedures.

TABLE 4.5 MATRIX/MESH USE – COSMETIC BREAST LEVEL PROCEDURES (2012-2023)

	Number of procedures with matrix/mesh use (N)	Proportion of procedures with matrix/mesh use (%)	Total number of procedures (N)
Breast Implants			
Implant insertion (direct)	86	0.1%	107,001
Revision (replacement/reposition, not explant only)	420	1.3%	31,832
Total procedures	**506**	**0.4%**	**138,833**

Notes: Details are at the breast procedure level.

Table 4.5 shows in total of 138,833 cosmetic procedures, a small proportion have used matrix/mesh (0.4%). Matrix/mesh was used more frequently in revision procedures than in insertion (only) procedures.

Primary and legacy breast devices

The Registry collects details of issues and complications arising at the time of revision procedures. Revision surgery for the purpose of this analysis is defined as unplanned replacement, reposition or explant of an in-situ breast device

TABLE 4.6 BREAST IMPLANT INSERTIONS BY PRIMARY/LEGACY STATUS (2012-2023)

Breast implant insertion type	N	%
Primary	106,413	76.9%
Legacy	31,918	23.1%
Total	**138,331**	**100%**

Table 4.6 shows the number of implants classified as primary or legacy. An implant is classified based on the available history of the breast it is inserted in. Primary implants are defined as those which are inserted into the breast area with no in-situ breast implant (i.e.: procedure is not a replacement of an implant) and also no recorded history of prior procedures involving implants in the Registry. The ABDR has recorded 138,331 breast implant insertion procedures, where 106,413 (76.9%) are **cosmetic primary breast implants** and 31,981 (23.1%) **legacy implants.** Analysis to assess device performance based on time to event analysis i.e.: revision incidence, uses **primary devices only.**

Complications and revision incidence – breast implants for cosmetic procedures

The ABDR 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. Clinicians have the option to select one or more complications/issues during a revision procedure.

TABLE 4.7 ISSUES IDENTIFIED AT REVISION PROCEDURES – COSMETIC BREAST IMPLANTS

Complications and issues identified at revision (N.B. Not complication rates)	2012-2023		2023	
	N	(%)	N	(%)
Capsular contracture	14,415	(36.6%)	1,802	(34.3%)
Device rupture/deflation	9,213	(23.4%)	1,299	(24.7%)
Device malposition	7,994	(20.3%)	914	(17.4%)
Seroma/haematoma	983	(2.5%)	104	(2.0%)
Skin scarring problems	908	(2.3%)	76	(1.4%)
Deep wound infection	240	(0.6%)	24	(0.5%)
Total number of procedures	**39,364**		**5,249**	

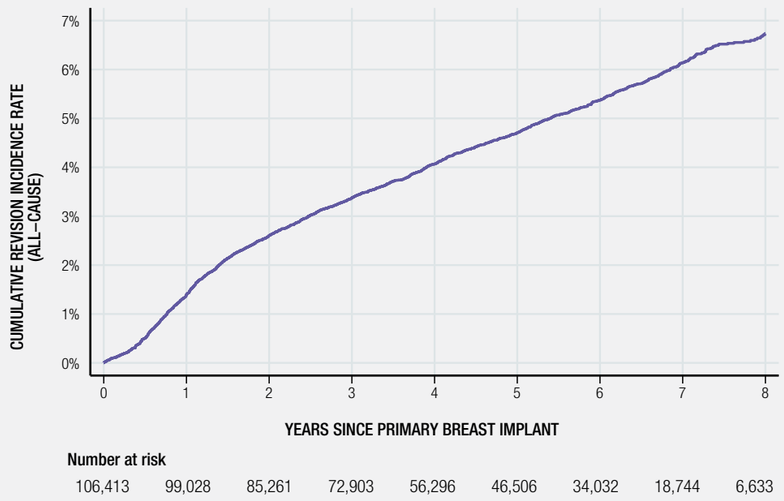
Notes: Listed in order of frequency are issues identified during cosmetic breast implant revision procedures. Multiple issues can be recorded at the time of revision surgery and issues were either identified as a reason for revision or found incidentally during the revision procedure. The crude percentage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

Table 4.7 reports the frequency of issues identified in cosmetic breast implant revision procedures, regardless of whether or not the insertion of the initial implant was captured by the ABDR. In 2023, capsular contracture (34.3%) was reported most often as a complication or issue identified at the time of revision surgery, followed by device rupture/deflation (24.7%) and device malposition (17.4%).

Overall revision incidence for cosmetic procedures

Figure 4.11 and Figure 4.12 provides the **revision incidence** curve for cosmetic procedures. At 8 years after initial implant insertion, the all-cause cumulative revision incidence was 6.7% (Appendix 9).

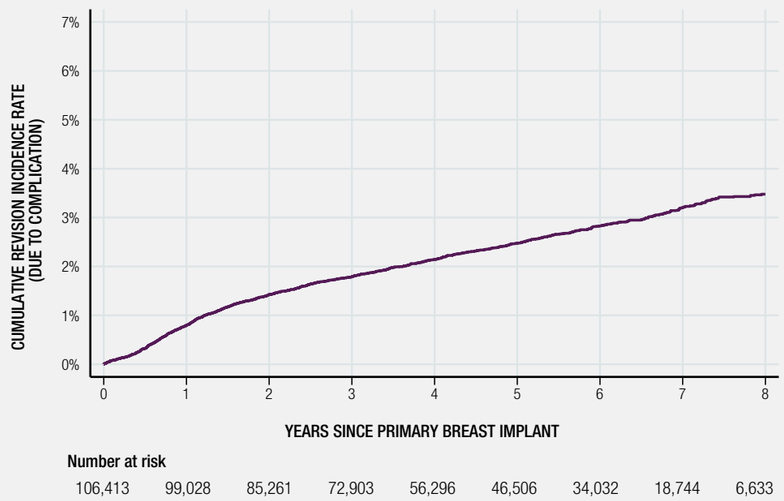
FIGURE 4.11 ALL-CAUSE REVISION INCIDENCE – COSMETIC PRIMARY BREAST IMPLANTS



Notes: Revision incidence (all-cause) is based on reconstructive primary breast implants inserted from 2012 to 2023.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the first revision procedure.
The accompanying table provides the number of breasts at risk of revision following from the initial implant procedure at Year=0.

At 8 years after insertion the **revision** incidence due to **complication** was 3.5 % (Figure 4.12).

FIGURE 4.12 REVISION INCIDENCE DUE TO COMPLICATION – COSMETIC PRIMARY BREAST IMPLANTS

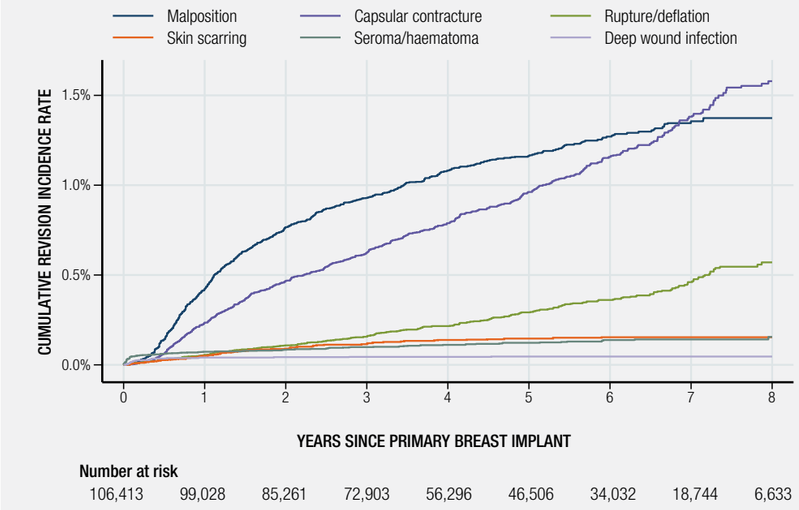


Notes: Revision incidence (due to complication) is based on reconstructive primary breast implants inserted from 2012 to 2023.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the first revision procedure.
The accompanying table provides the number of breasts at risk of revision following from the initial implant procedure at Year=0.

Revision incidence of specific complications

Figure 4.13 shows the cumulative revision incidence rates by type of complication up to 8 years after the date of primary implant insertion. At 8 years post implant insertion, the revision incidence was 1.6% for capsular contracture, 1.4% for device malposition, 0.6% for rupture/deflation, 0.2% for seroma/haematoma, 0.2% for skin scarring and <0.1% for deep wound infection.

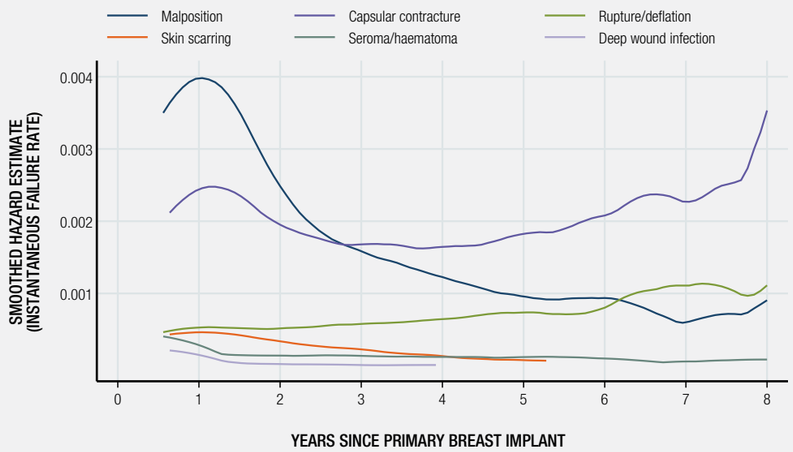
FIGURE 4.13 CUMULATIVE REVISION INCIDENCE RATE BY COMPLICATION TYPE – COSMETIC PRIMARY BREAST IMPLANTS



Concepts of hazard curves were introduced in the Methods section of Overview of the Australian Breast Device Registry and in the explanation for Figure 3.20 (page 54).

Hazard estimates over time for each type of complication are shown in Figure 4.14 and show the time points when revisions involving specific complications typically occur. Malposition appears to be an early failure outcome, having a distinct peak at around one year post insertion before rapidly decreasing. Rupture/deflation appears to be an outcome corresponding to wear out with its rate generally increasing as time elapses. Capsular contracture appears to have a peak at one year before decreasing then increasing again in later years. Risk of revision due to malposition and capsular contracture appears to be higher than that of other outcomes within 8 years post insertion in general.

FIGURE 4.14 HAZARD BY COMPLICATION TYPE – REVISIONS OF COSMETIC PRIMARY BREAST IMPLANTS

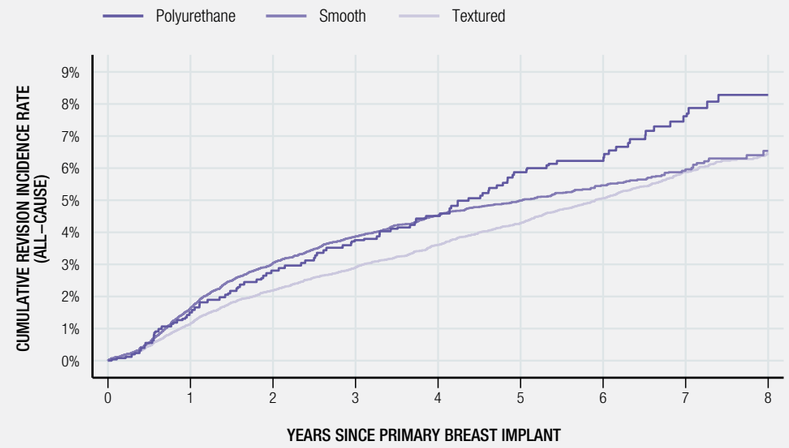


Note: Curves are truncated when smoothed estimates of hazard cannot be calculated (shortly after the start and when case numbers for the complication of interest are low). Experience of complications may not necessarily lead to a revision procedure. There may be long periods of time between when complications are first experienced and when revision procedures occur.

Revision incidence by implant characteristics

Figure 4.15 provides the **all-cause revision incidence by device shell** type for primary cosmetic breast implants. The all-cause cumulative revision incidence at 8 years post insertion was 8.3% for polyurethane, and 6.5% for textured and smooth implants.

FIGURE 4.15 ALL-CAUSE REVISION INCIDENCE BY SHELL – COSMETIC PRIMARY BREAST IMPLANT



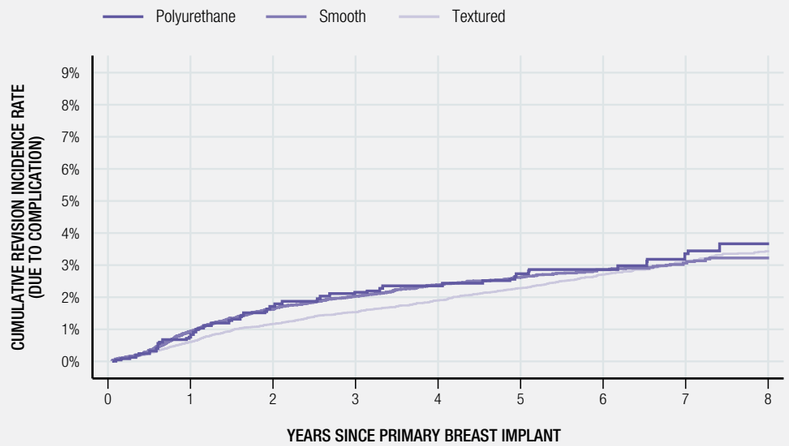
Number at risk

53,307	50,526	45,367	40,621	34,464	30,197	23,561	13,500	4,926	Textured
50,520	45,958	37,388	29,806	19,391	14,057	8,707	4,138	1,283	Smooth
2,530	2,492	2,457	2,433	2,410	2,233	1,752	1,094	417	Polyurethane

Notes: Revision incidence (all-cause) is based on reconstructive primary breast implants inserted from 2012 to 2023.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the first revision procedure.
The accompanying table provides the number of breasts at risk of revision, following from the initial implant procedure at Year=0.

Figure 4.16 provides revision incidence **due to complication by device shell** type for primary breast implants. The revision incidence is closely aligned between the three shell types. The revision incidence due to complication at 8 years post insertion was 3.7% for polyurethane, 3.4% for textured and 3.2% for smooth implants (Appendix 10).

FIGURE 4.16 REVISION INCIDENCE DUE TO COMPLICATION BY SHELL – COSMETIC PRIMARY BREAST IMPLANTS



Number at risk

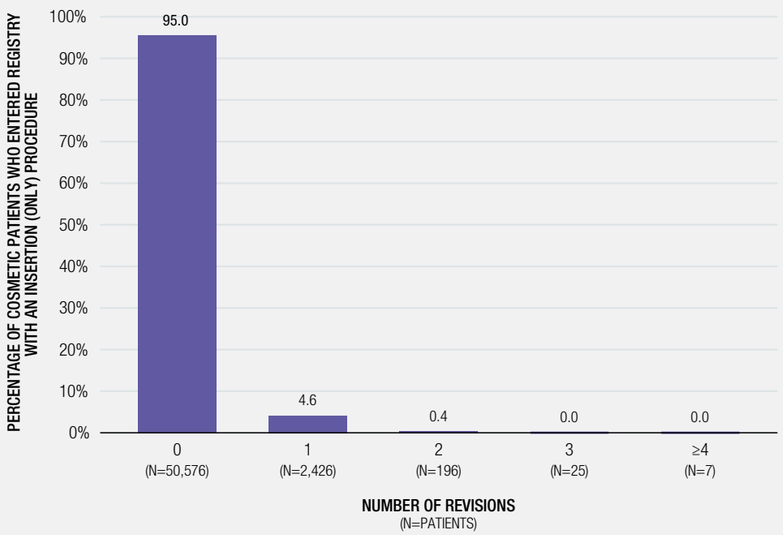
53,307	50,526	45,367	40,621	34,464	30,197	23,561	13,500	4,926	Textured
50,520	45,958	37,388	29,806	19,391	14,057	8,707	4,138	1,283	Smooth
2,530	2,492	2,457	2,433	2,410	2,233	1,752	1,094	417	Polyurethane

Notes: Revision incidence (due to complication) is based on reconstructive primary breast implants inserted from 2012 to 2023.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the first revision procedure.
The accompanying table provides the number of breasts at risk of revision, following from the initial implant procedure at Year=0.

Multiple revision procedures

Figure 4.17 shows the percentages and counts of patients by the number of revisions they had (the breast with the most revisions is used for the count). Patients whose first operation involved only insertions are included (since those who enter the Registry with other operation types could potentially have had prior revisions that cannot not be counted). Of the 53,230 patients included, 95.0% had no revisions (50,574), 4.6% had one revision (2,426) and 0.4% had two or more revisions.

FIGURE 4.17 NUMBER OF REVISIONS PER COSMETIC PATIENT.
PATIENTS WHOSE FIRST PROCEDURE IN THE REGISTRY ONLY INVOLVED BREAST IMPLANT INSERTIONS.



Note: For each patient, the breast with the most revisions is used for the count. Only includes patients who enter the Registry with (direct) implant insertions.

Clinician conducting revision procedure

The frequency of revisions being conducted by a different clinician has been investigated using breasts with both a primary implant insertion procedure and implant revision procedure captured. Of the 4,686 breasts included, **3,247 (69.3%) had both procedures conducted by the same clinician** and 1,439 (30.7%) had insertion and revision procedures conducted by different clinicians. The frequency of revisions being conducted by a different clinician is higher for the cosmetic cohort than for reconstructive (18.1%).

CHAPTER 5

Registry Outcomes

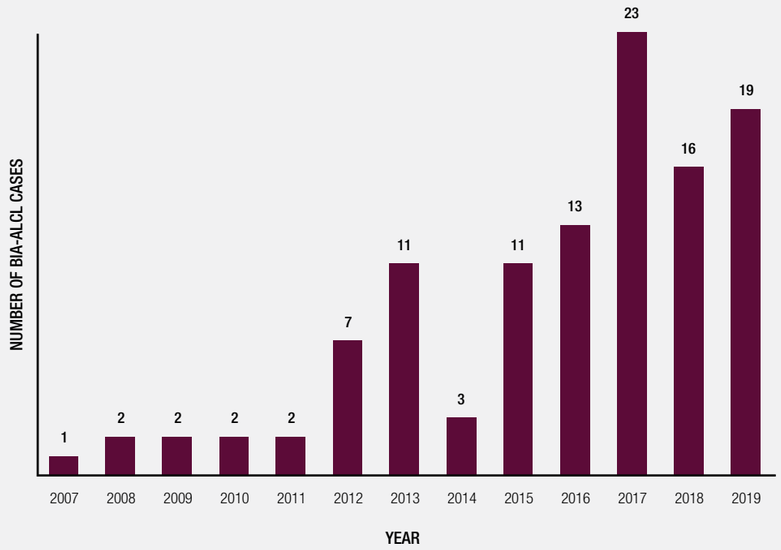
Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

Clinicians are encouraged to report all new cases of BIA-ALCL to the Registry. The ABDR working in partnership with the TGA are the main reporting channels in Australia for this rare cancer. Prior to 2019, BIA-ALCL cases were reported to the Macquarie University (MQU) Research Group.

The data presented in this report is in two parts: (1) Data provided by MQU and (2) Data reported directly to the ABDR. Of note, some cases reported during the transition period may overlap between the two groups. The ABDR are able to provide additional data relating to operation category, associated complications and explant device details.

MQU data comprised of 112 confirmed BIA-ALCL cases reported between 2007-2019 (Figure 5.1).

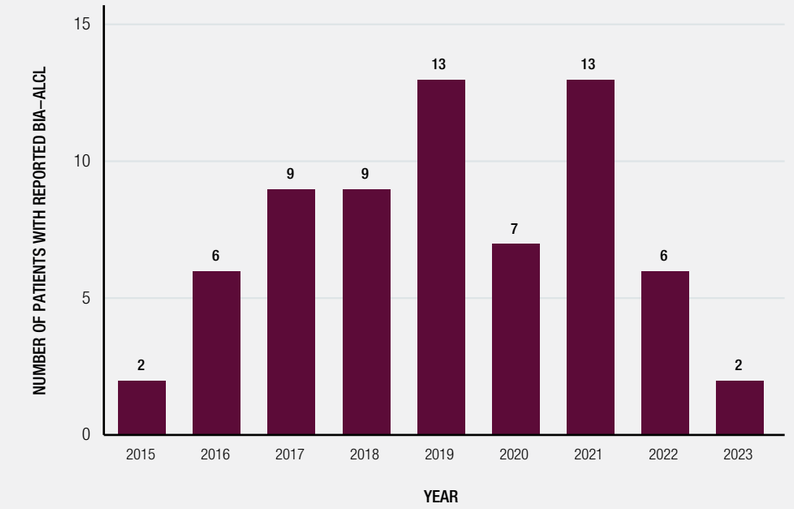
FIGURE 5.1 NUMBER OF BIA-ALCL CASES 2007-2019 MACQUARIE UNIVERSITY (N=112)



ABDR data

The ABDR are notified by clinicians when their patient is suspected or confirmed to have BIA-ALCL. All cases of BIA-ALCL are followed-up by Registry. Clinicians are required to confirm via email if their records indicate that their patient is confirmed to have BIA-ALCL. The lymphoma could either be the reason that the patient has returned to surgery for a revision procedure or may be discovered incidentally. In 2023 there have been 3 new cases of BIA-ALCL reported (one case was added to 2022 and 2 cases in 2023) to and confirmed by the Registry. There are a total of 67 patients reported with BIA-ALCL recorded in the ABDR (Figure 5.2). Of the 67 cases, two patients were diagnosed with bilateral BIA-ALCL. One confirmed case reported in 2020 has since opted-out of the Registry.

FIGURE 5.2 PATIENTS REPORTED WITH BIA-ALCL BY YEAR (2015-2023)



The **jurisdiction** with the highest reported number of BIA-ALCL cases is Queensland followed by New South Wales and Victoria (Table 5.1).

TABLE 5.1 NUMBER OF BIA-ALCL PATIENTS BY STATE/TERRITORY ABDR (2015-2023)

State	Total
QLD	23
NSW	14
VIC	14
WA	8
Other/Unknown	8
Total	**67**

Analysis of device and clinical characteristics have been performed for patients where this information has been captured in the data collection form. Table 5.2 shows the number of BIA-ALCL cases by **indication for surgery.** At breast level, the majority of BIA-ALCL cases were related to cosmetic procedures (N=37), followed by reconstruction following breast cancer (N=16) and benign/prophylactic reconstruction(N=6). There was one reported reconstructive procedure where the specific surgery indication was unknown. Furthermore, for 10 cases the indication for surgery was not stated.

TABLE 5.2 NUMBER OF BIA-ALCL CASES (AT BREAST LEVEL) BY INDICATION FOR SURGERY ABDR (2015-2023)

Indication for Surgery	N	%
Cosmetic augmentation	37	53.6%
Reconstruction post cancer	16	23.2%
Reconstruction benign/prophylactic	6	8.7%
Not stated	10	14.5%
Total	**69**	**100.0%**

Notes: Includes 67 patients. 2 of these patients have bilateral BIA-ALCL.

Figure 5.3 shows the duration between insertion of the breast implant and date of revision/explantation of that same implant (where this data is reported to the ABDR). The date of implant insertion is recorded in 52 of the 69 (breast level) cases of BIA-ALCL reported to the Registry. The most common number of years that an associated device remained in-situ was for 7-10 years before being explanted, with a range of 3-18 years.

FIGURE 5.3 NUMBER OF EXPLANTED DEVICES BY EXPOSURE TIME (YEARS) IN BIA-ALCL PATIENTS ABDR (2015-2023)

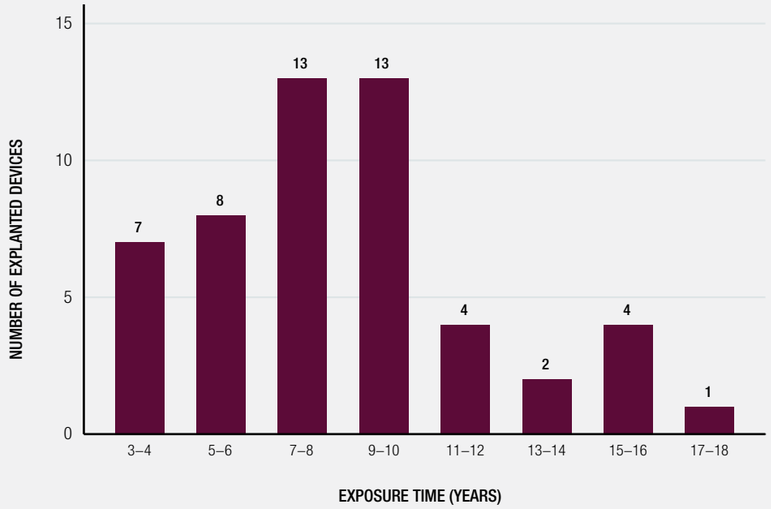


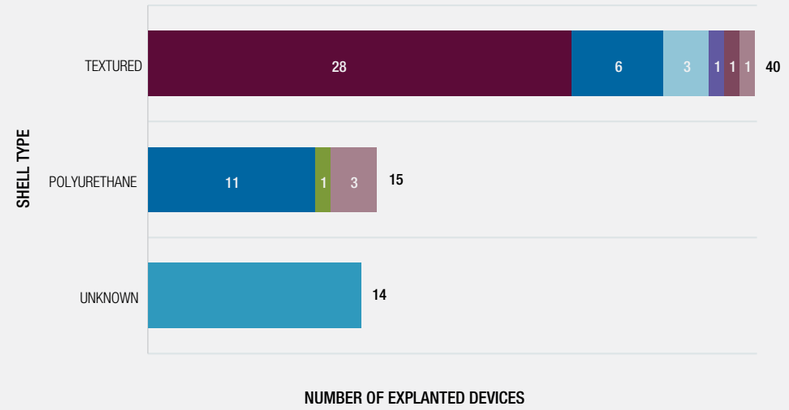
Table 5.3 demonstrates the number of BIA-ALCL cases at breast level by revision type; of the 69 procedures at breast level, 48 were recorded as device explant only procedures, and 21 as device replacement procedures. A full capsulectomy was performed in 45 of the explant only procedures, and 10 of the replacement procedures. Partial capsulectomy was performed in 4 cases (breast level). In 4 cases (breast level) there was no capsulectomy performed. There were 6 instances where capsulectomy type information was not stated.

TABLE 5.3 NUMBER OF BIA-ALCL CASES (BREAST LEVEL) BY REVISION TYPE AND CAPSULECTOMY TYPE ABDR (2015-2023)

Revision Type	Capsulectomy Type				Total
	Full	Partial	None	Not stated/Null	
Explant only	45	0	0	3	**48**
Replacement	10	4	4	3	**21**
Total	**55**	**4**	**4**	**6**	**69**

Figure 5.4 shows the explanted devices by shell type. Of the 69 breast implants in the Registry, 40 had a textured shell while 15 had polyurethane shell. There remain 14 devices that are of unknown shell type recorded in the Registry. Where device manufacturer information is available, 28 were identified as Allergan/Inamed/McGhan/CUI. Of note, the Silimed Industria de Implantes foam covered implants had a manufacturing defect identified that caused surface delamination[3].

FIGURE 5.4 EXPLANTED DEVICES BY SHELL TYPE ABDR (2015-2023)



3 Hamdi, Moustapha. (2019). Association Between Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) Risk and Polyurethane Breast Implants: Clinical Evidence and European Perspective. Aesthetic Surgery Journal, 39(Supplement_1), S49–S54. https://doi.org/10.1093/asj/sjy328

Clinical presentations associated with BIA-ALCL identified at revision are noted in Table 5.4 and Table 5.5. In 35 cases (breast level) BIA-ALCL was reported with no associated clinical issues; in 19 cases one other clinical issue was reported; and in 11 patients there were at least two clinical issues reported. The common adjunct clinical issues reported in BIA-ALCL cases was seroma/haematoma (N=21) and capsular contracture (N=11).

TABLE 5.4 NUMBER OF CLINICAL ISSUES ASSOCIATED WITH BIA-ALCL CASES IDENTIFIED AT REVISION ABDR (2015-2023)

Clinical issues reported	N
Only BIA-ALCL reported	35
One clinical issue reported	19
Two or more clinical issues reported	11
Asymptomatic	4
Total	**69**

Of these clinical issues reported, seroma/haematoma was the most common issue identified at revision (reason for revision or found incidentally) (Table 5.5).

TABLE 5.5 ADJUNCT CLINICAL ISSUES REPORTED IN BIA-ALCL CASES ABDR (2015-2023)

Issue identified at revision	Reason for revision	Found incidentally
Seroma/Haematoma	16	5
Capsular contracture	5	6
Device rupture/deflation	5	0
Other issues	4	2

Data requests

The ABDR continued to experience an increase in enquiries from patients during this reporting period. Patients contacting the ABDR are interested to learn their device details, to change their postal address, to opt-out of the Registry and various other reasons. In 2023, the ABDR was contacted via email and phone by patients (N=127) and clinicians (N=11) specifically related to device inquiries, with 275 calls overall being received in 2023.

Data requests were received by industry, government and academic researchers (Table 5.6). The growing number of requests demonstrates the maturity of the Registry and its relevance to a broad range of stakeholders. All ABDR data reported to industry or government is via reports that are produced by the ABDR and reviewed by the ABDR's Research and Data Sharing Subcommittee (for further information please refer to 'Overview of the Australian Breast Device Registry'. No patient level or identifiable information is shared in these reports.

The ABDR also encourages the secondary uses of its data for research purposes. Two formal research data access requests were approved by the ABDR in 2023 from PhD and surgeon researchers.

TABLE 5.6 DATA REQUESTS APPROVED IN 2023

Date of approval	Name	Organisation	Request type	Title of project
06/03/2023	Dr Gillian Farrell	ASPS Clinical Lead	Research	A comparison of revision rates based on ADM/Mesh in breast reconstruction surgery, a prospective study
15/03/2023	-	Mentor part of Johnson and Johnson	Report	Post-market clinical follow-up requirements for regulatory bodies
23/06/2023	-	Establishment labs	Report	Motiva® Implants Industry Report
26/06/2023	Ms Michelle Merenda	Monash University	Research (PhD student)	The BREAST-Q IS as a Predictor of Breast Implant Revision Surgery
24/07/2023	-	Medical Specialties Australasia Pty, Ltd (MSA)	Report	TiLOOP® Device Industry Report 2023
22/11/2023	-	Office of the Chief Health Officer, New South Wales Ministry of Health	Report	Update to the NSW Health clinical guidance (BIA-ALCL)
12/12/2023	Dr Oliver Chow	Macquarie University New South Wales	Research	Contamination minimisation strategies and capsular contracture

CHAPTER 6

Patient Reported Outcome Measures (PROMs)

In 2023, the ABDR team continued to develop the new PROMs program, which will commence once the new ABDR database goes live.

The reconceptualised ABDR PROMs program is seeking to explore patient lived experiences and satisfaction of implant-based breast reconstruction. An acceptability study employing qualitative research methods was used to determine which scales of the Breast-Q PROMs tool to implement into the ABDR. This study revealed that ‘satisfaction of breasts’ and ‘psychosocial wellbeing’ were considered the most relevant scales among reconstructive surgeons and women who have had device-based breast reconstruction surgery.

The new PROMs tool comprises twenty-five questions, and registrants may respond using a likert scale. In the new database registrants will receive a unique link to the PROMs tool and use a series of radio-buttons to enter their answer to each question.

The new custom-built database will identify all ABDR registrants that have undergone reconstruction surgery, for primary breast implant procedures. The registrant will receive their PROMs initially at three timepoints 6-, 12- and 24-months post-surgery. The database will endeavour to contact each registrant according to their preferred contact method noted on their data collection form. The ABDR team will attempt to contact registrants up to three times. The database is capable of tracking registrant follow up.

CHAPTER 7

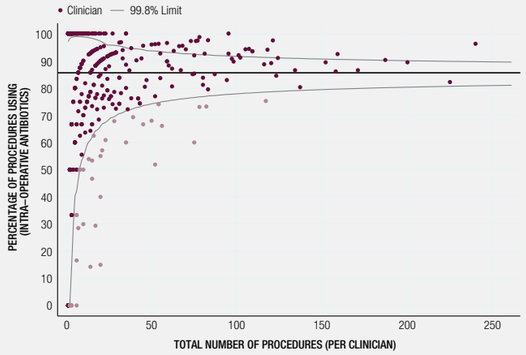
Clinical Variation and Clinical Quality Indicators

Variation in intra-operative aseptic techniques

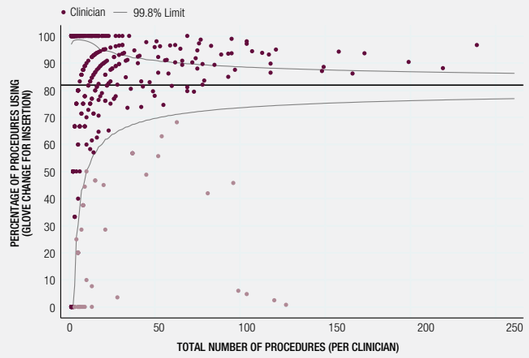
Funnel plots can be used to investigate variation in clinical practice. Figures 7.1 (A-F) and 7.2 (A-F) are funnel plots that show the number of clinicians using various intra-operative techniques (for reconstructive and cosmetic cohorts respectively). Funnel plots are described in more detail in the methods section. In these plots, each point represents a clinician. The horizontal axes show the number of operations conducted by each clinician between 2021-2023 while the vertical axes show the frequency that each clinician reported the use of a specific intra-operative technique in this time period. Clinicians below the lower contour line may be considered as outliers having statistically below average use of an intra-operative technique. These funnel plots show high levels of consistency in the use of intra-operative antibiotics, post-operative antibiotics, antiseptic rinse and glove change; and greater variation in the use of antibiotic dipping solution and a sleeve/funnel in both the reconstructive and cosmetic cohorts.

FIGURE 7.1 (A-F) INTRA-OPERATIVE TECHNIQUES FOR RECONSTRUCTIVE PROCEDURES (OPERATION LEVEL) – FUNNEL PLOTS, COMPARING CLINICIANS (2021-2023)

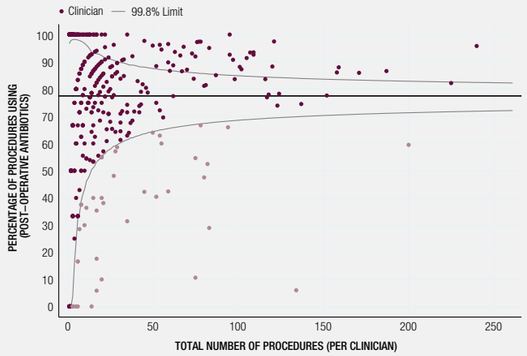
A: INTRA-OPERATIVE ANTIBIOTICS



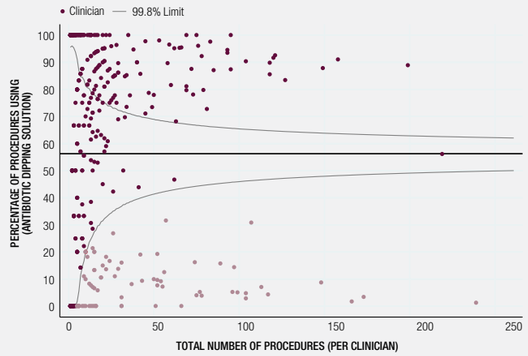
D: GLOVE CHANGE



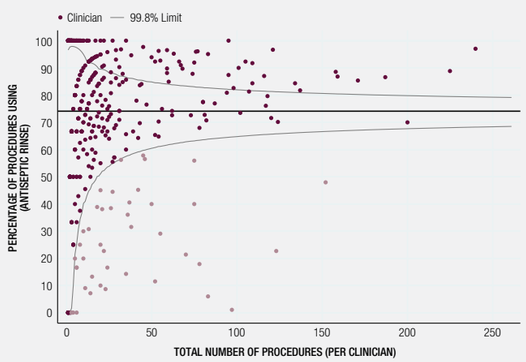
B: POST-OPERATIVE ANTIBIOTICS



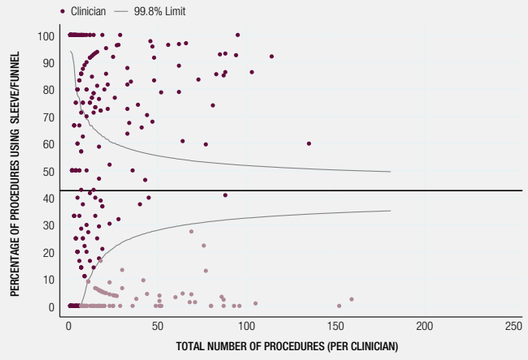
E: ANTIBIOTIC DIPPING SOLUTION



C: ANTISEPTIC RINSE



F: SLEEVE/FUNNEL



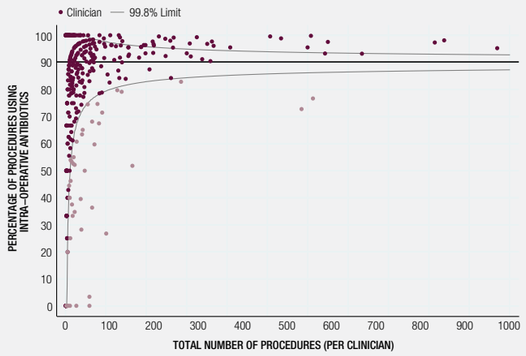
Notes A, B & C: 425 Clinicians included for reconstructive procedures. Based on 10,302 reconstructive procedures during 2021 to 2023.

Notes D & E: 415 Clinicians included for reconstructive procedures. Based on 9,636 reconstructive procedures during 2021 to 2023. Excludes explant only procedures.

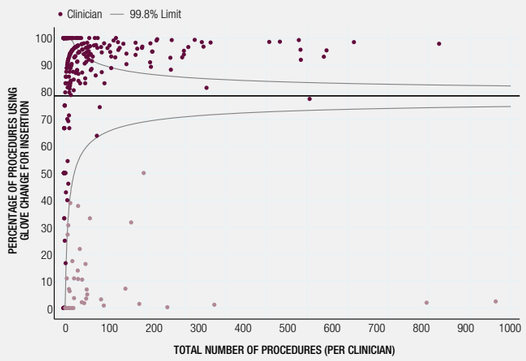
Notes F: 404 Clinicians included for reconstructive procedures. Based on 7,201 reconstructive procedures during 2021 to 2023. Excludes explant only procedures.

FIGURE 7.2 (A-F) INTRA-OPERATIVE TECHNIQUES FOR COSMETIC PROCEDURES (OPERATION LEVEL) 2021-2023 – FUNNEL PLOTS, COMPARING CLINICIANS

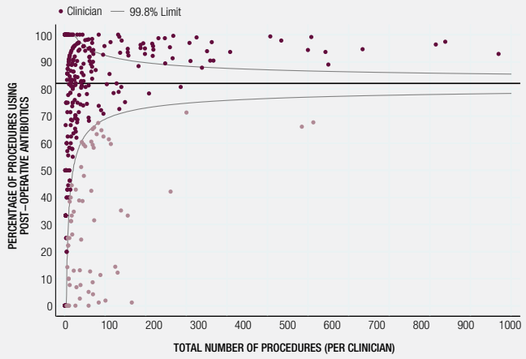
A: INTRA-OPERATIVE ANTIBIOTICS



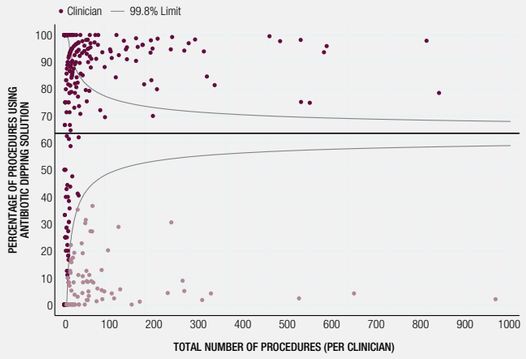
D: GLOVE CHANGE FOR INSERTION



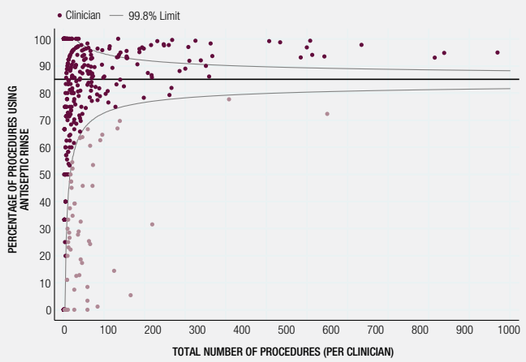
B: POST-OPERATIVE ANTIBIOTICS



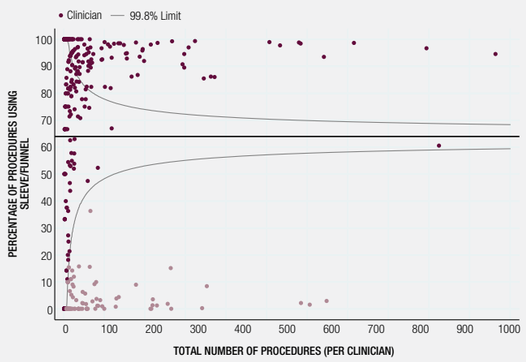
E: ANTIBIOTIC DIPPING SOLUTION



C: ANTISEPTIC RINSE



F: SLEEVE/FUNNEL



Notes A, B & C: 412 Clinicians included for reconstructive procedures.
Based on 26,767 reconstructive procedures during 2021 to 2023.

Notes D, E & F: 376 Clinicians included for reconstructive procedures.
Based on 24,593 reconstructive procedures during 2021 to 2023.
Excludes explant only procedures.

Variation in revision rates

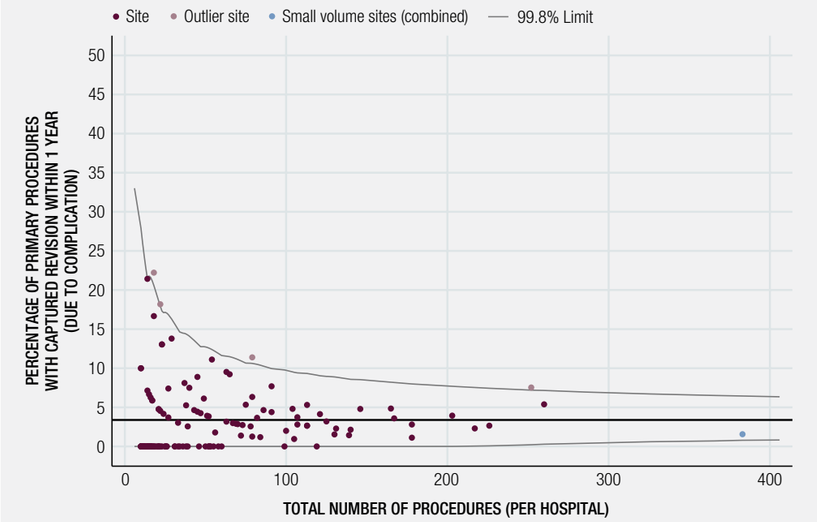
For the first time the Registry is reporting variation in **revision rates by hospital,** specifically **revision due to complication.**

Figure 7.3 and 7.4 show the variation in **rates of revision due to complication within 1 year** across hospitals, separately for reconstructive and cosmetic procedures. In these plots, each point represents a hospital. The horizontal axes show the number (breast level) of primary implant insertion procedures conducted by a hospital over a 3-year period between 2020-2022. The inclusion of multiple years improves the accuracy of the analysis where hospital procedures are often low volume per site.

The vertical axes show the percentage of breasts with a subsequent revision due to complication procedure captured within 1 year of insertion. Hospitals above the contour line may be considered as outliers, having statistically above average revision rates. Three points corresponding to outlier sites have been removed from Figures 7.3-7.4 as their data could not be verified in time for the report publication. For the individual hospital reports associated with these funnel plots, each hospital will be identified within its own report, to allow it to compare itself with other hospitals undertaking reconstructive or cosmetic procedures.
In 2025, the ABDR will develop a risk adjustment model for this analysis to allow for variation in case-mix between hospitals, and develop a process of confidential communication of outlier status to sites, in accordance with the requirements of Qualified Privilege.

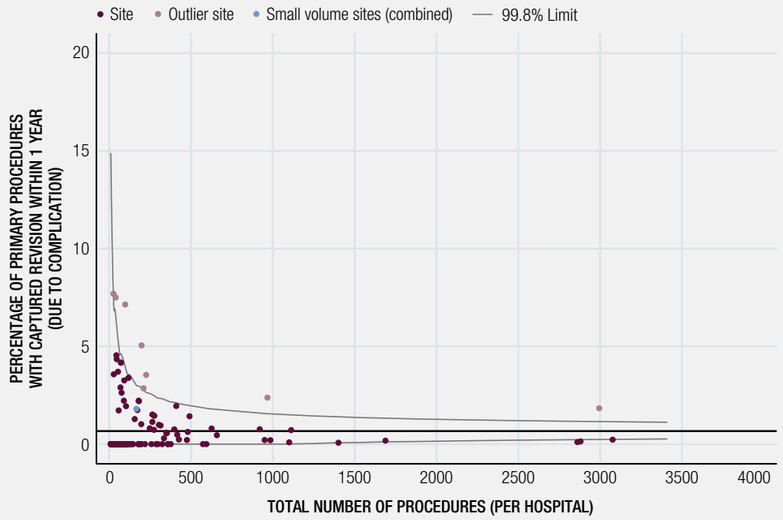
The **average rate of revision within one year** (of insertion) for hospitals that have undertaken reconstructive breast implants is **3.4%** and for cosmetic implants is **0.7%** (for insertions between 2020-2022).

FIGURE 7.3 VARIATION IN PERCENTAGE REVISED DUE TO COMPLICATION WITHIN 1 YEAR BY HOSPITAL – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS.



Notes: 225 Sites included.
Based on 8,060 reconstructive primary breast implant procedures.
86 sites with <10 primary insertions between 2020–2022 have been grouped together as one unit (383 breast level procedures).

FIGURE 7.4 VARIATION IN PERCENTAGE REVISED DUE TO COMPLICATION WITHIN 1 YEAR BY HOSPITAL – COSMETIC PRIMARY BREAST IMPLANTS



Notes: 197 Sites included.
Based on 39,663 cosmetic primary breast implant procedures.
42 sites with <10 primary insertions between 2020–2022 have been grouped together as one unit (166 breast level procedures).

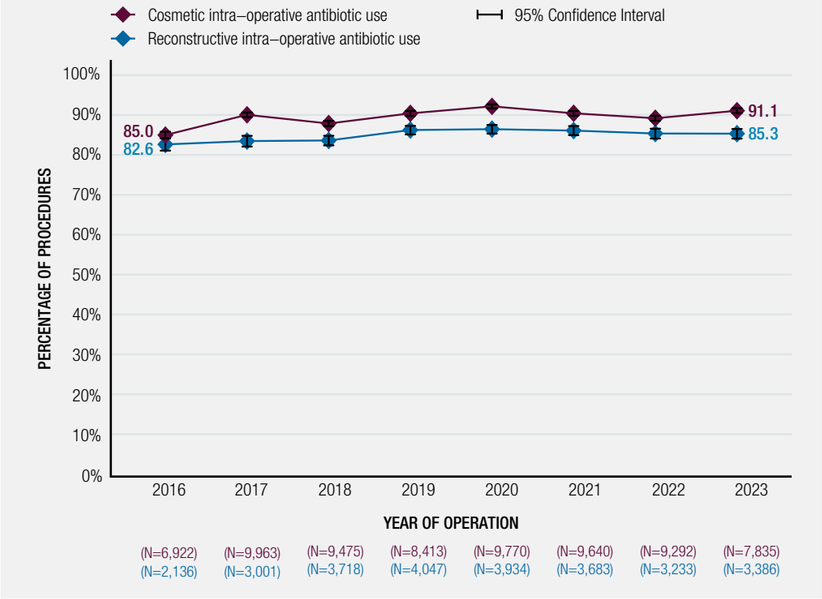
Clinical Quality Indicators (CQIs)

The ABDR reports on three clinical quality indicators (CQIs) developed by the International Consortium of Breast Registry Activities (ICOBRA) in 2016.

CQI 1 Intra-operative antibiotics use

The proportion of procedures that had intra-operative antibiotics provided before skin incision is presented in Figure 7.5. There has been an increasing use of reported intra-operative antibiotic use for both reconstructive and cosmetic groups from 2016-2023 (all procedures).

FIGURE 7.5 PROPORTION OF PROCEDURES WITH REPORTED INTRA-OPERATIVE ANTIBIOTICS USE

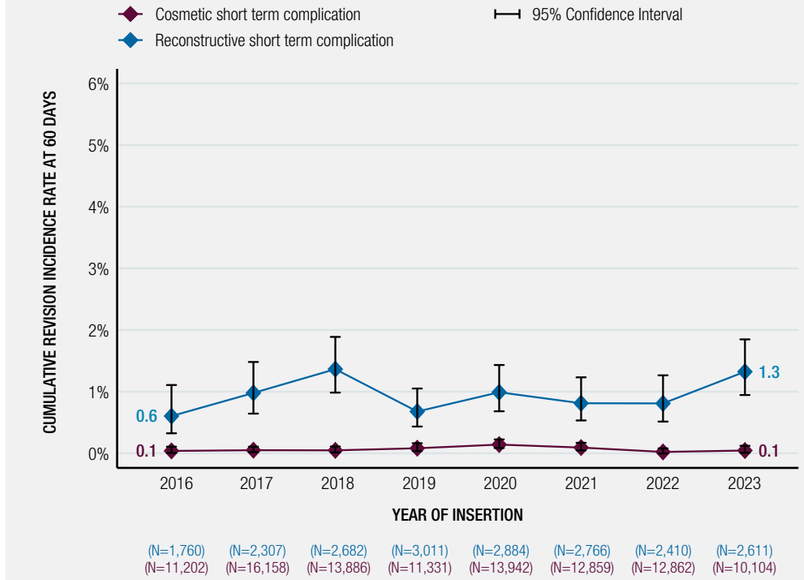


Note: Data was recorded at the operation level, and procedure hierarchy was applied to determine indication.

CQI 2 Revision due to short-term complications

Reoperation rates due to short term (within 60 days) complications for the reconstructive and cosmetic cohorts are provided in Figure 7.6, where the complication involves at least one of the following: deep wound infection, capsular contracture, device malposition, device rupture/deflation, seroma/haematoma, or 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 preferences. The revision incidence rate at 60 days post operation due to short term complications has varied between 0.6-1.3% from 2016 to 2023 for reconstructive procedures, and has been consistently around 0.1% for cosmetic procedures.

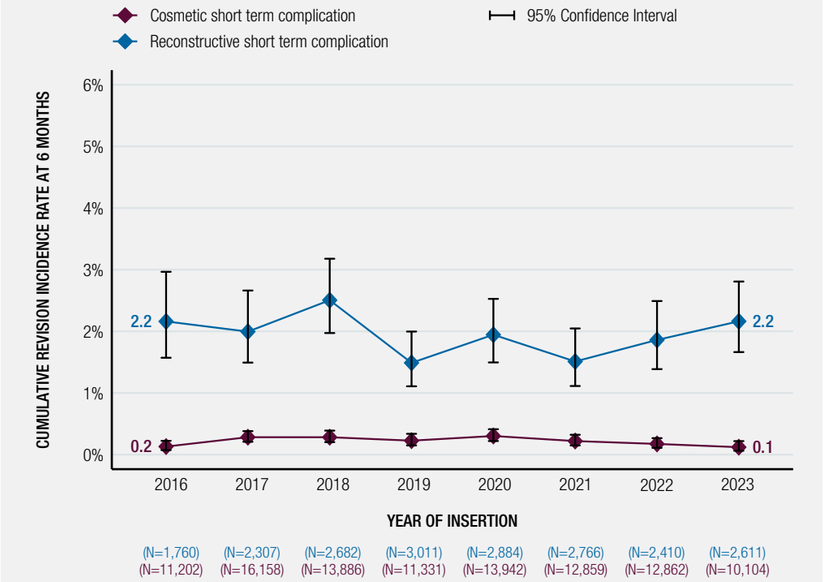
FIGURE 7.6 CUMULATIVE REVISION INCIDENCE RATE AT 60 DAYS POST PRIMARY BREAST IMPLANT INSERTION DUE TO SHORT TERM COMPLICATIONS BY INSERTION YEAR



Note: Data was collected at the breast level for primary breast implants.

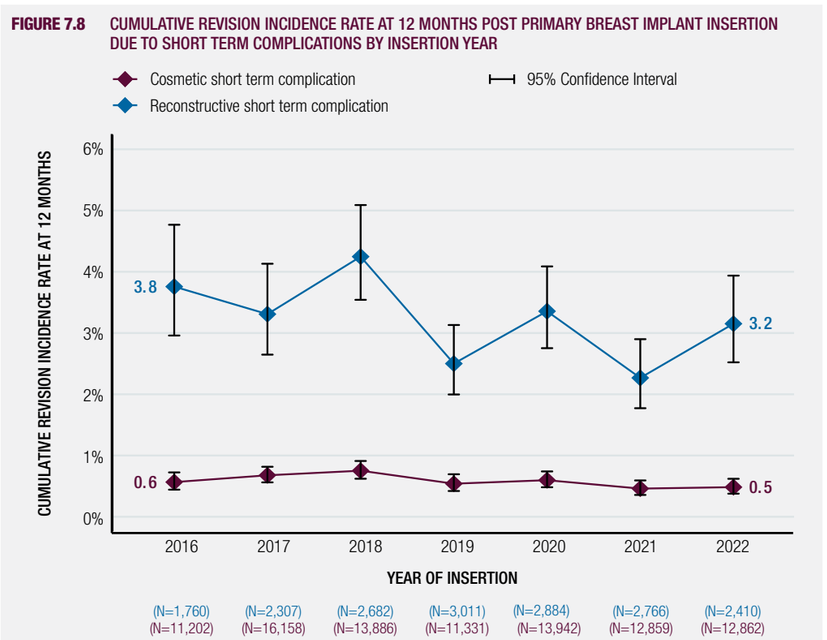
Figure 7.7 and Figure 7.8 considers the cumulative revision incidence at 6- and 12- months, respectively. Reconstructive revision rates have fluctuated between approximately 1.5-2.5% over the period from 2016-2023 for revision at 6 months, and fluctuated between 2.5-4.2% for revisions at 12 months. Cosmetic reconstructive procedures have varied little during this time, having revision rates of 0.1-0.3% at 6 months, and 0.5-0.8% at 12 months.

FIGURE 7.7 CUMULATIVE REVISION INCIDENCE RATE AT 6 MONTHS POST PRIMARY BREAST IMPLANT INSERTION DUE TO SHORT TERM COMPLICATIONS BY INSERTION YEAR



Note: Data was collected at the breast level for primary breast implants

FIGURE 7.8 CUMULATIVE REVISION INCIDENCE RATE AT 12 MONTHS POST PRIMARY BREAST IMPLANT INSERTION DUE TO SHORT TERM COMPLICATIONS BY INSERTION YEAR



Note: Data was collected at the breast level for primary breast implants.

CHAPTER 8

Future Initiatives

At the time of this report's publication, the ABDR is undergoing considerable changes with the imminent launch of a new custom-built platform which will allow participating sites and clinicians/surgeons to enter data directly into the Registry. Overtime this will replace the current model of data collection via the paper-based form, which is then transcribed by Registry staff into the ABDR database. This new platform and method of data collection will streamline Registry operations, increasing efficiencies whilst providing contributing sites and clinicians/surgeons with direct access to their own data. Real-time reporting will be developed in due course, ensuring that the feedback loop is shortened and the ABDR's potential impact on real-world care is more timely and more effective. The launch of this new platform will also coincide with the re-launch of the Registry's Patient Reported Outcome Measures (PROMs) program. This will see the ABDR able to monitor and report on patient-reported outcomes in conjunction with clinical outcomes, and will allow for easier collection and ultimately, greater quality and breadth of the data collected.

Furthermore, the ABDR is undergoing other operational efficiencies including the transfer of ethical oversight from multiple (15) Human Research Ethics Committees, to one overarching Committee. This will see the ethics and site governance management of the Registry be far easier to manage, and will facilitate the more seamless engagement and onboarding of new hospitals and health services. Excitingly, the Registry is embarking on a pilot program which will see the recruitment of patients from Western Australia's public health system for the first time. Patient recruitment and the transfer of data from WA-based hospitals has until this point been unattainable due to legislative requirements around the opt-out model. This has led to WA public patients being the only cohort in Australia unable to access the Registry and/or benefit from Registry reporting. Working closely with WA Health, the ABDR hopes to roll out this pilot program which will involve obtaining explicit consent at the time of consenting to surgery, to engage this new cohort of patients.

In 2025, the ABDR will continue to focus its efforts on increasing case ascertainment through expanding its data linkage activities with jurisdictional administrative datasets, and reporting these results to individual sites for their reflection. In particular, we aim to increase the proportion of revisions and explants captured, which are critical outcomes required to inform accurate complication and revision rates. The ABDR is growing its research activities and academic presentations via collaboration with participating clinicians. The Registry also looks forward to providing more meaningful site reports with more comparative, trend and outcome data for clinicians and hospitals, supported by the additional protection of identified data provided by Qualified Privilege.

CHAPTER 9

Academic Outputs 2023

The ABDR produced 3 academic publications in 2022-2023:

Ahern, Susannah. “Clinical Registries: Not yet Perfect, but Essential for a High-Functioning Health System.” Respirology (Carlton, Vic.) 28, no. 11 (2023): 983–85. https://doi.org/10.1111/resp.14562.

Becherer BE, Hopper I, Cooter RD, Couturaud B, von Fritschen U, Mullen E, Perks AGB, Pusic AL, Stark B, Mureau MAM, Rakhorst HA. Improving Breast Implant Safety through International Collaboration of National Registries – A Review of over 85,000 Patients and 200,000 Implants from Four Countries. Plast Reconstr Surg. 2023 Jan 13. doi: 10.1097/PRS.0000000000010208. Epub ahead of print. PMID: 36728275.

Hoque SS, Zhou J, Gartoulla, P, Hansen J, Farrell G, Hopper I. Comparing direct-to-implant and two-stage breast reconstruction in the Australian Breast Device Registry. Plastic and Reconstructive Surgery, online December 19, 2022. doi: 10.1097/PRS.0000000000010066

As part of our continued efforts to remain engaged with our contributors, participating site staff and patients, the ADBR presented at various research, and health education forums. In 2023, abstracts were accepted: for an oral and poster presentations. The ABDR were also invited to speak at various meetings.

International meetings:

- International Confederation of Plastic Surgery Societies World Congress 2023, International Collaboration of Breast Registry Activities (ICOBRA) meeting. Dubai, United Arab Emirates
- Breast Oncoplastic Surgery around 24 hours (Breastics24h). Online

National meetings:

- Australasian College of Cosmetic Surgery and Medicine hosted Cosmetex23. Sydney, New South Wales
- Royal Australasian College of Surgeons 91st Annual Scientific Congress. Adelaide, South Australia
- Australasian Society of Aesthetic Plastic Surgeons 45th Annual Conference. Gold Coast, Queensland
- Australian Clinical Trials Alliance, Australian Clinical Registry Annual Scientific Meeting 2023, Melbourne, Victoria

Glossary

Capsular contacture	The scar tissue that forms around implant causes the implant to feel firm.
Contributing site	Any site that has contributed data to the ABDR at any point in time.
Deep wound infection	Infection leading to explantation: An infection associated with a breast implant in place, which leads to its explantation. Usually involves redness, localised pain or tenderness, abscess or persistent serous liquid formation around the implant even with distinct clinical signs it might be culture-negative.
Device deflation	The occurrence of saline implant deflation.
Device malposition	Any instance in which the implant is outside its intended position.
Device rupture	Silicone implant that has ruptured.
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.
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
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.
Participating site	A site that has contributed data in the current reporting period (2023).
Primary breast implant	A breast implant which is inserted into a breast which has no in-situ breast implant (i.e.: procedure is not a replacement of an implant) and also has no recorded history of prior procedures involving implants recorded in Registry.
Primary tissue expander	A tissue expander which is inserted into a breast which has no in-situ device (i.e.: procedure is not replacement) and also has no recorded history of prior procedures involving tissue expanders or implants recorded in Registry.
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 includes procedures involving the removal of an implant and insertion of a tissue expander.
Seroma/haematoma	An abnormal accumulation of serum around the device/a collection of blood adjacent to breast device.
Skin scarring	Unsightly scarring following reconstructive breast surgery.
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.

Abbreviations

ABDR	Australian Breast Device Registry
ACCSM	Australasian College of Cosmetic Surgery and Medicine
ACHI	Australian Classification of Health Interventions
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
CQI	Clinical Quality Indicators
CQR	Clinical Quality Registry
The Department	Department of Health and Aged Care
HREC	Human Research Ethics Committee
MTAA	Medical Technology Association of Australia
TE	Tissue Expander
TGA	Therapeutics Goods Administration
UDI	Unique Device Identifiers

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APPENDIX 1

Data completeness

Patient characteristics (patient level)	2019	2020	2021	2022	2023
	13,181	14,707	14,511	13,426	12,181
Name	100.0%	100.0%	100.0%	100.0%	100.0%
Surname	100.0%	100.0%	100.0%	100.0%	100.0%
Medicare number	89.0%	89.9%	91.9%	91.7%	92.9%
Date of birth	100.0%	100.0%	100.0%	100.0%	100.0%
Address	97.5%	97.7%	97.7%	97.6%	97.9%
Telephone	88.3%	86.6%	87.3%	89.5%	90.1%
Surgery characteristics (procedure level)	**13,907**	**15,386**	**15,089**	**13,946**	**12,645**
Operation date	100.0%	100.0%	100.0%	100.0%	100.0%
Hospital	100.0%	100.0%	100.0%	100.0%	100.0%
Surgeon	100.0%	100.0%	100.0%	100.0%	100.0%
Intra-operative techniques	88.1%	88.2%	86.4%	86.7%	86.7%
Surgery characteristics (breast level)	**25,736**	**28,827**	**28,232**	**26,141**	**23,573**
Side of breast	100.0%	100.0%	100.0%	100.0%	100.0%
Indication for surgery	89.4%	89.0%	88.2%	89.7%	88.6%
Surgery type	100.0%	100.0%	100.0%	100.0%	100.0%
Previous radiotherapy if reconstruction	90.0%	89.2%	87.8%	89.0%	90.4%
Incision site	88.6%	87.9%	85.7%	85.9%	86.5%
Plane	84.8%	85.1%	84.4%	84.5%	83.1%
Concurrent mastectomy	92.7%	91.6%	90.6%	90.3%	90.6%
Axillary surgery	92.7%	91.6%	90.6%	90.3%	90.6%
Concurrent mastopexy/reduction	92.7%	91.7%	90.6%	90.3%	90.7%
Concurrent flap cover	92.7%	91.6%	90.6%	90.2%	90.6%
Previous mastopexy/reduction	92.7%	91.5%	90.6%	90.2%	90.6%
Fat grafting	92.4%	91.6%	90.1%	89.7%	90.4%
Fat graft vol if fat grafting is selected	94.2%	92.8%	94.7%	92.3%	97.4%
Intra-op fill volume if tissue expander	68.1%	64.7%	64.8%	66.3%	67.3%
Revision characteristics (breast level)	**9,204**	**9,609**	**10,515**	**8,906**	**9,223**
Revision surgery type	100.0%	100.0%	100.0%	100.0%	100.0%
Indication for revision surgery	95.8%	94.3%	95.4%	94.4%	95.4%
Capsulectomy	88.3%	87.5%	88.1%	87.2%	88.7%
Neo pocket formation	74.3%	73.0%	73.4%	72.7%	74.4%
Neo pocket formation details	85.3%	83.8%	85.6%	86.9%	87.1%
Revision overseas implant	84.5%	82.3%	82.7%	81.3%	83.8%
Breast cancer	95.7%	94.1%	95.5%	94.4%	96.1%
Device rupture	95.0%	94.0%	95.3%	94.1%	95.8%
Device deflation	95.6%	94.1%	95.4%	94.1%	96.0%

Patient characteristics (patient level)	2019	2020	2021	2022	2023
	13,181	14,707	14,511	13,426	12,181
Capsular contracture	95.6%	94.1%	95.4%	94.3%	96.1%
Device malposition	95.7%	94.1%	95.5%	94.4%	96.1%
Skin scarring problems	95.7%	94.1%	95.5%	94.3%	96.1%
Deep wound infection	95.7%	94.2%	95.5%	94.3%	96.1%
Seroma/haematoma	95.8%	94.1%	95.5%	94.4%	96.1%
BIA-ALCL	95.8%	94.1%	95.5%	94.3%	96.0%
Device characteristics (breast level, inserted)	**22,703**	**25,638**	**24,498**	**23,124**	**20,380**
Implant/tissue expander device ID	99.8%	99.8%	99.8%	100.0%	99.9%
Matrix/mesh used	99.4%	97.1%	99.6%	99.9%	99.9%
Matrix/mesh device ID if matrix/mesh used	99.4%	99.0%	98.3%	95.7%	96.3%
Device characteristics (breast level, explanted)	**9,088**	**9,500**	**10,411**	**8,805**	**9,129**
Explanted device details	84.6%	84.4%	86.6%	84.4%	76.0%
Explanted device ID	9.5%	10.2%	10.3%	11.5%	10.8%
Patient opt-out rate	**1.3%**	**0.9%**	**0.7%**	**0.8%**	**0.9%**

APPENDIX 2

Tables supporting in text figures

Surgical elements (2016-2023) – reconstructive breast level procedures

	2016	2017	2018	2019	2020	2021	2022	2023
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Incision site*[1]								
Previous mastectomy scar	1,521 (45.2%)	1,886 (41.3%)	2,123 (37.3%)	2,075 (33.1%)	1,869 (30.2%)	1,640 (28.5%)	1,366 (27.4%)	1,533 (28.8%)
Inframammary	1,166 (34.7%)	1,440 (31.5%)	1,919 (33.7%)	2,399 (38.2%)	2,573 (41.6%)	2,343 (40.7%)	2,018 (40.4%)	2,095 (39.3%)
Areola	209 (6.2%)	413 (9.0%)	557 (9.8%)	648 (10.3%)	570 (9.2%)	582 (10.1%)	525 (10.5%)	502 (9.4%)
Mastopexy/reduction scar	213 (6.3%)	434 (9.5%)	536 (9.4%)	529 (8.4%)	526 (8.5%)	531 (9.2%)	458 (9.2%)	592 (11.1%)
Axillary	12 (0.4%)	49 (1.1%)	66 (1.2%)	47 (0.7%)	27 (0.4%)	33 (0.6%)	39 (0.8%)	41 (0.8%)
Other	123 (3.7%)	175 (3.8%)	222 (3.9%)	280 (4.5%)	268 (4.3%)	220 (3.8%)	238 (4.8%)	213 (4.0%)
Not stated	189 (5.6%)	318 (7.0%)	407 (7.1%)	467 (7.4%)	561 (9.1%)	602 (10.5%)	529 (10.6%)	530 (9.9%)
Surgical plane[2]								
Sub-pectoral/Dual plane	2,078 (62.4%)	2,792 (62.1%)	3,512 (63.5%)	3,524 (58.8%)	3,214 (54.6%)	2,887 (53.0%)	2,410 (51.7%)	2,363 (47.8%)
Sub-flap	311 (9.3%)	450 (10.0%)	480 (8.7%)	527 (8.8%)	481 (8.2%)	532 (9.8%)	429 (9.2%)	533 (10.8%)
Sub-glandular/ sub-fascial**	328 (9.9%)	339 (7.5%)	447 (8.1%)	671 (11.2%)	838 (14.2%)	893 (16.4%)	794 (17.0%)	883 (17.9%)
Other	32 (1.0%)	67 (1.5%)	105 (1.9%)	265 (4.4%)	359 (6.1%)	301 (5.5%)	250 (5.4%)	327 (6.6%)
Not stated	579 (17.4%)	847 (18.8%)	988 (17.9%)	1006 (16.8%)	995 (16.9%)	833 (15.3%)	776 (16.7%)	839 (17.0%)
Axillary surgery[5]								
Yes	338 (25.7%)	658 (33.0%)	875 (35.0%)	1,059 (39.3%)	1,129 (40.0%)	1,104 (41.0%)	1,042 (44.1%)	999 (40.9%)
Concurrent mastectomy[5]								
Yes	775 (58.8%)	1,342 (67.3%)	1,744 (69.7%)	2,044 (75.9%)	2,069 (73.4%)	2,021 (75.0%)	1,799 (76.1%)	1,861 (76.1%)
Concurrent mastopexy[1]								
Yes	217 (6.5%)	322 (7.0%)	432 (7.6%)	388 (6.2%)	393 (6.3%)	457 (7.9%)	405 (8.1%)	482 (9.0%)
Flap cover[4]								
Yes	287 (10.0%)	379 (9.3%)	452 (8.9%)	474 (8.6%)	434 (8.1%)	407 (8.2%)	283 (6.6%)	340 (7.5%)
Previous mastopexy[1]								
Yes	119 (3.5%)	217 (4.7%)	225 (4.0%)	227 (3.6%)	250 (4.0%)	261 (4.5%)	225 (4.5%)	257 (4.8%)

	2016	2017	2018	2019	2020	2021	2022	2023
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Fat grafting[1]								
Yes	132 (3.9%)	342 (7.5%)	448 (7.9%)	547 (8.7%)	503 (8.1%)	461 (8.0%)	472 (9.5%)	428 (8.0%)
Drain use[1]								
Yes	1,728 (51.4%)	2,523 (55.2%)	2,910 (51.1%)	3,281 (52.3%)	3,168 (51.2%)	2,872 (49.9%)	2,454 (49.2%)	2,681 (50.3%)
Nipple guard[6]								
Yes	482 (27.4%)	708 (30.3%)	873 (29.4%)	1,105 (31.5%)	1,165 (32.0%)	1,097 (31.6%)	897 (30.6%)	968 (30.3%)
Nipple absent[3]								
Yes	1,599 (55.3%)	2,238 (54.0%)	2,717 (51.7%)	2,764 (47.9%)	2,552 (45.1%)	2,274 (43.4%)	2,052 (44.8%)	2,132 (43.9%)
Nipple sparing[3]								
Yes	538 (18.6%)	901 (21.7%)	1,198 (22.8%)	1,535 (26.6%)	1,685 (29.8%)	1,524 (29.1%)	1,342 (29.3%)	1,441 (29.7%)
Neo pocket formation[7]								
Yes	192 (25.6%)	264 (25.9%)	334 (24.9%)	369 (26.1%)	364 (24.7%)	299 (22.1%)	249 (22.9%)	302 (22.8%)
Denominators								
All procedures[1]	3,363	4,572	5,693	6,275	6,192	5,752	4,991	5,328
Not explant only[2]	3,328	4,495	5,532	5,993	5,887	5,446	4,659	4,945
Post-cancer and risk-reducing[3]	2,892	4,147	5,252	5,769	5,663	5,241	4,582	4,853
Post-cancer and risk-reducing; not explant only[4]	2,858	4,076	5,102	5,511	5,383	4,968	4,275	4,511
Post-cancer and risk-reducing; first implant insertion or tissue expander insertion only[5]	1,317	1,994	2,502	2,693	2,819	2,693	2,363	2,445
Nipple absent not selected[6]	1,762	2,333	2,974	3,510	3,640	3,476	2,936	3,194
Replacement/reposition revisions[7]	750	1,020	1,340	1,416	1,475	1,351	1,085	1,324

Notes: Details are at the breast procedure level.
*More than one incision site can be recorded.
**This includes sub-cutaneous placement after mastectomy per data reported to the Registry.
1,2,3,4,5,6,7 Denominators used for each surgical element are shown at the bottom of the table.

APPENDIX 3

Tables supporting in text figures

Cumulative revision incidence rate by indication – reconstructive primary breast implants.

	N Primary Breast Implants	Number at risk							
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8
Post-cancer	13,066	11,277	9,504	7,874	6,224	4,655	3,175	1,902	1,023
Risk-reducing	6,347	5,368	4,495	3,686	2,854	2,100	1,387	809	392
Developmental	2,694	2,356	2,033	1,718	1,319	1,067	820	591	338
Above 3 combined	22,107	19,001	16,032	13,278	10,397	7,822	5,382	3,302	1,753
Contralateral augmentation	498	460	412	384	323	270	204	134	76

	N Revised	Cumulative revision incidence							
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8
All-cause revision									
Post-cancer	1,781	6.4%	9.4%	11.8%	13.6%	15.3%	16.7%	18.2%	19.4%
Risk-reducing	905	7.0%	10.6%	12.8%	14.4%	15.9%	17.2%	19.3%	20.4%
Developmental	278	5.0%	8.1%	8.8%	10.5%	11.1%	12.4%	13.5%	13.5%
Above 3 combined	2,964	6.4%	9.6%	11.7%	13.5%	14.9%	16.3%	17.9%	18.9%
Contralateral augmentation	56	4.9%	7.6%	8.5%	9.9%	11.1%	11.5%	13.3%	15.3%
Revision due to complication									
Post-cancer	1,231	4.4%	6.6%	8.3%	9.7%	10.8%	11.8%	12.9%	13.9%
Risk-reducing	572	4.3%	6.5%	8.2%	9.4%	10.3%	11.4%	13.3%	13.6%
Developmental	151	2.5%	4.5%	4.7%	5.6%	5.9%	7.0%	7.9%	7.9%
Above 3 combined	1,954	4.1%	6.3%	7.8%	9.1%	10.1%	11.1%	12.4%	13.1%
Contralateral augmentation	31	2.7%	4.4%	4.7%	4.9%	5.9%	6.3%	7.5%	9.6%
Revision due to device malposition									
Post-cancer	483	1.5%	2.5%	3.4%	4.1%	4.7%	5.0%	5.4%	5.5%
Risk-reducing	253	1.8%	3.1%	4.1%	4.5%	4.9%	5.2%	5.7%	5.7%
Developmental	74	1.1%	2.3%	2.4%	2.8%	3.0%	3.6%	3.9%	3.9%
Above 3 combined	810	1.6%	2.6%	3.5%	4.1%	4.5%	4.9%	5.3%	5.4%
Contralateral augmentation	15	1.7%	2.3%	2.6%	2.8%	2.8%	3.3%	3.3%	4.3%
Revision due to capsular contracture									
Post-cancer	492	1.1%	2.2%	3.3%	4.1%	4.7%	5.3%	6.0%	6.6%
Risk-reducing	179	0.9%	1.8%	2.4%	3.1%	3.6%	4.0%	4.9%	5.2%
Developmental	62	1.0%	1.9%	1.9%	2.6%	2.6%	2.9%	3.3%	3.3%
Above 3 combined	733	1.0%	2.1%	2.8%	3.6%	4.1%	4.6%	5.3%	5.7%
Contralateral augmentation	9	0.4%	1.1%	1.1%	1.4%	1.7%	1.7%	2.3%	3.5%

	N Revised	Cumulative revision incidence							
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8
Revision due to rupture/deflation									
Post-cancer	100	0.2%	0.3%	0.5%	0.7%	0.9%	1.1%	1.5%	1.8%
Risk-reducing	49	0.2%	0.3%	0.4%	0.5%	0.7%	1.1%	2.3%	2.3%
Developmental	17	0.1%	0.3%	0.4%	0.7%	0.7%	0.8%	1.2%	1.2%
Above 3 combined	166	0.2%	0.3%	0.4%	0.6%	0.8%	1.1%	1.7%	1.8%
Contralateral augmentation	4	0.0%	0.0%	0.0%	0.3%	0.6%	0.6%	1.3%	2.5%
Revision due to skin scarring									
Post-cancer	159	0.7%	0.9%	1.2%	1.4%	1.5%	1.6%	1.7%	1.7%
Risk-reducing	87	0.9%	1.2%	1.4%	1.5%	1.5%	1.6%	1.8%	1.8%
Developmental	12	0.0%	0.3%	0.3%	0.4%	0.4%	0.6%	0.8%	0.8%
Above 3 combined	258	0.7%	0.9%	1.1%	1.3%	1.4%	1.5%	1.6%	1.6%
Contralateral augmentation	2	0.0%	0.2%	0.2%	0.2%	0.2%	0.7%	0.7%	0.7%
Revision due to seroma/haematoma									
Post-cancer	106	0.7%	0.8%	0.8%	0.8%	0.9%	0.9%	0.9%	1.0%
Risk-reducing	54	0.6%	0.8%	0.9%	0.9%	0.9%	0.9%	0.9%	1.2%
Developmental	8	0.3%	0.3%	0.3%	0.3%	0.4%	0.4%	0.4%	0.4%
Above 3 combined	168	0.6%	0.7%	0.8%	0.8%	0.8%	0.8%	0.9%	0.9%
Contralateral augmentation	2	0.2%	0.2%	0.2%	0.2%	0.6%	0.6%	0.6%	0.6%
Revision due to deep wound infection									
Post-cancer	164	1.1%	1.2%	1.2%	1.3%	1.3%	1.3%	1.4%	1.4%
Risk-reducing	67	0.9%	1.1%	1.1%	1.1%	1.1%	1.1%	1.1%	1.1%
Developmental	7	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%
Above 3 combined	238	1.0%	1.1%	1.1%	1.1%	1.1%	1.1%	1.2%	1.2%
Contralateral augmentation	1	0.0%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%

Notes: Cumulative revision incidence is based on reconstructive primary breast implants inserted from 2012-2023.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the date of the first recorded revision procedure (censored if there are no recorded revision procedures before the date of the last procedure in the extract).

APPENDIX 4

Tables supporting in text figures

Cumulative revision incidence by device shell – reconstructive primary breast implant

	N Primary Breast Implants	Number at risk							
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8
Textured	12,141	10,699	9,543	8,526	7,257	6,034	4,366	2,822	1,526
Smooth	9,739	8,098	6,301	4,574	2,968	1,623	871	373	163
Polyurethane	205	184	169	162	160	159	140	104	61
Total	22,085	18,981	16,013	13,262	10,385	7,816	5,377	3,299	1,750

	N Revised	Cumulative revision incidence							
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8
All-cause revision									
Textured	1,956	7.0%	10.4%	12.6%	14.6%	16.3%	17.7%	19.5%	20.5%
Smooth	958	5.5%	8.4%	10.3%	11.6%	12.5%	13.3%	14.2%	14.2%
Polyurethane	50	9.8%	17.1%	20.6%	21.5%	22.0%	24.1%	24.8%	24.8%
Total	2,964	6.4%	9.6%	11.7%	13.5%	15.0%	16.3%	17.9%	18.9%
Revision due to complication									
Textured	1,262	4.3%	6.6%	8.1%	9.7%	10.8%	11.8%	13.2%	14.0%
Smooth	659	3.9%	5.8%	7.2%	8.1%	8.7%	9.3%	10.0%	10.0%
Polyurethane	33	7.9%	11.5%	14.7%	15.2%	15.2%	16.3%	17.1%	17.1%
Total	1,954	4.1%	6.3%	7.8%	9.1%	10.1%	11.1%	12.4%	13.1%
Revision due to device malposition									
Textured	494	1.5%	2.5%	3.4%	4.1%	4.6%	5.0%	5.4%	5.5%
Smooth	298	1.6%	2.7%	3.4%	3.9%	4.1%	4.3%	4.5%	4.5%
Polyurethane	18	4.0%	5.1%	7.9%	7.9%	7.9%	9.1%	9.9%	9.9%
Total	810	1.6%	2.7%	3.5%	4.1%	4.5%	4.9%	5.3%	5.4%
Revision due to capsular contracture									
Textured	546	1.3%	2.5%	3.3%	4.3%	4.9%	5.5%	6.3%	6.8%
Smooth	176	0.7%	1.4%	2.1%	2.4%	2.6%	2.7%	3.0%	3.0%
Polyurethane	11	2.6%	3.2%	4.3%	4.9%	4.9%	6.2%	6.2%	6.2%
Total	733	1.0%	2.1%	2.8%	3.6%	4.1%	4.6%	5.3%	5.8%
Revision due to rupture/deflation									
Textured	115	0.2%	0.3%	0.4%	0.6%	0.8%	1.1%	1.8%	1.9%
Smooth	47	0.2%	0.3%	0.4%	0.7%	0.8%	0.9%	1.3%	1.3%
Polyurethane	4	0.5%	1.6%	2.2%	2.2%	2.2%	2.2%	2.2%	2.2%
Total	166	0.2%	0.3%	0.4%	0.6%	0.8%	1.1%	1.7%	1.8%
Revision due to skin scarring									
Textured	143	0.6%	0.8%	1.0%	1.2%	1.3%	1.4%	1.5%	1.5%
Smooth	110	0.8%	1.0%	1.2%	1.3%	1.4%	1.6%	1.8%	1.8%
Polyurethane	5	1.0%	1.6%	1.6%	2.2%	2.2%	2.9%	2.9%	2.9%
Total	258	0.7%	0.9%	1.1%	1.3%	1.4%	1.5%	1.6%	1.6%
Revision due to seroma/haematoma									
Textured	98	0.6%	0.7%	0.8%	0.8%	0.9%	0.9%	0.9%	1.0%
Smooth	62	0.6%	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%
Polyurethane	8	3.1%	3.1%	4.2%	4.2%	4.2%	4.2%	4.2%	4.2%
Total	168	0.6%	0.7%	0.8%	0.8%	0.8%	0.8%	0.9%	0.9%
Revision due to deep wound infection									
Textured	142	1.0%	1.1%	1.1%	1.2%	1.2%	1.2%	1.3%	1.3%
Smooth	94	0.9%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%
Polyurethane	2	0.5%	0.5%	0.5%	1.1%	1.1%	1.1%	1.1%	1.1%
Total	238	1.0%	1.1%	1.1%	1.1%	1.1%	1.1%	1.2%	1.2%

Notes: Cumulative revision incidence is based on reconstructive primary breast implants inserted from 2012 to 2023.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the date of the first recorded revision procedure (censored if there are no recorded revision procedures before the date of the last procedure in the extract).

APPENDIX 5

Tables supporting in text figures

Cumulative revision incidence by matrix/mesh use – reconstructive primary direct-to-implant procedures (post-cancer and risk-reducing indications only)

	N Primary Breast Implants	Number at risk							
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8
Matrix/mesh	5,648	4,598	3,604	2,712	1,898	1,188	682	331	135
No matrix/mesh	3,571	2,909	2,412	1,948	1,491	1,130	770	375	148
Not stated	202	185	180	164	152	145	143	131	97
Total	9,421	7,692	6,196	4,824	3,541	2,463	1,595	837	380

	N Revised	Cumulative revision incidence							
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8
All-cause revision									
Matrix/mesh	818	7.9%	11.7%	14.3%	16.4%	18.1%	19.4%	20.1%	20.8%
No matrix/mesh	545	8.5%	11.8%	13.8%	15.9%	17.7%	19.2%	20.6%	22.0%
Not stated	32	7.9%	9.4%	11.5%	12.6%	13.8%	14.4%	16.3%	17.0%
Total	1,395	8.1%	11.7%	14.1%	16.1%	17.8%	19.2%	20.4%	21.4%
Revision due to any of the below 4 complications									
Matrix/mesh	489	4.7%	7.1%	9.1%	10.5%	11.1%	12.0%	12.3%	12.8%
No matrix/mesh	239	3.2%	4.9%	6.4%	7.6%	8.4%	9.0%	10.2%	10.9%
Not stated	20	6.0%	7.0%	8.2%	9.3%	9.9%	9.9%	10.5%	10.5%
Total	748	4.2%	6.3%	8.0%	9.3%	10.0%	10.7%	11.5%	11.9%
Revision due to device malposition									
Matrix/mesh	199	1.5%	2.7%	4.0%	4.6%	5.1%	5.4%	5.6%	5.6%
No matrix/mesh	115	1.4%	2.1%	3.1%	4.1%	4.5%	4.6%	5.1%	5.1%
Not stated	5	1.0%	1.0%	2.2%	2.2%	2.2%	2.2%	2.9%	2.9%
Total	319	1.5%	2.4%	3.6%	4.4%	4.8%	5.0%	5.4%	5.4%
Revision due to capsular contracture									
Matrix/mesh	199	1.1%	2.5%	3.8%	4.9%	5.3%	6.2%	6.4%	6.9%
No matrix/mesh	106	0.9%	2.2%	2.8%	3.3%	3.9%	4.4%	5.4%	5.9%
Not stated	13	3.6%	4.1%	5.3%	6.4%	7.1%	7.1%	7.1%	7.1%
Total	318	1.1%	2.4%	3.5%	4.3%	4.8%	5.4%	6.0%	6.4%
Revision due to seroma/haematoma									
Matrix/mesh	85	1.3%	1.5%	1.6%	1.7%	1.7%	1.7%	1.7%	2.2%
No matrix/mesh	29	0.7%	0.7%	0.8%	0.8%	0.9%	0.9%	0.9%	1.2%
Not stated	6	2.0%	2.5%	3.1%	3.1%	3.1%	3.1%	3.1%	3.1%
Total	120	1.1%	1.2%	1.3%	1.4%	1.4%	1.4%	1.4%	1.8%
Revision due to deep wound infection									
Matrix/mesh	129	2.1%	2.4%	2.4%	2.4%	2.4%	2.4%	2.4%	2.4%
No matrix/mesh	37	1.0%	1.0%	1.0%	1.1%	1.1%	1.1%	1.1%	1.4%
Not stated	2	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%
Total	168	1.6%	1.8%	1.8%	1.9%	1.9%	1.9%	1.9%	2.0%

Notes: Revision incidence is based on reconstructive direct-to-implant procedures with primary implants inserted from 2012 to 2023. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary implant insertion date to the date of the first recorded revision procedure (censored if there are no recorded revision procedures before the date of the last procedure in the extract).

APPENDIX 6

Tables supporting in text figures

Cumulative revision incidence by matrix/mesh use (in tissue expander insertion procedure) – reconstructive primary two-stage procedures (post-cancer and risk-reducing indications only)

	N Primary Breast Procedures	Number at risk							
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8
Matrix/mesh	2,128	1,826	1,555	1,282	1,001	732	453	261	116
No matrix/mesh	5,115	4,542	3,942	3,381	2,774	2,162	1,385	808	405
Not stated	301	288	268	259	245	237	224	210	161
Total	7,544	6,656	5,765	4,922	4,020	3,131	2,062	1,279	682

	N Revised	Cumulative revision incidence							
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8
All-cause revision									
Matrix/mesh	438	11.2%	16.4%	19.2%	20.5%	22.1%	22.9%	23.8%	25.8%
No matrix/mesh	1,046	8.9%	14.3%	17.3%	19.5%	20.6%	22.1%	24.5%	26.7%
Not stated	55	4.3%	10.3%	12.0%	13.7%	15.8%	15.8%	17.4%	19.2%
Total	1,539	9.4%	14.7%	17.6%	19.5%	20.9%	22.1%	24.0%	26.0%
Revision due to any of the below 4 complications									
Matrix/mesh	219	6.1%	8.4%	10.2%	10.9%	11.9%	12.3%	12.6%	14.0%
No matrix/mesh	501	4.3%	7.0%	8.7%	9.9%	10.6%	11.4%	12.6%	13.7%
Not stated	37	2.7%	7.8%	9.5%	10.2%	11.7%	11.7%	11.7%	13.2%
Total	757	4.7%	7.4%	9.1%	10.2%	11.0%	11.6%	12.5%	13.7%
Revision due to device malposition									
Matrix/mesh	83	1.6%	3.2%	4.1%	4.5%	5.1%	5.3%	5.3%	5.3%
No matrix/mesh	222	1.2%	2.9%	3.8%	4.7%	5.1%	5.5%	6.1%	6.6%
Not stated	15	1.0%	2.8%	3.9%	4.7%	5.4%	5.4%	5.4%	5.4%
Total	320	1.3%	3.0%	3.9%	4.7%	5.1%	5.4%	5.8%	6.2%
Revision due to capsular contracture									
Matrix/mesh	65	0.6%	1.7%	2.9%	3.3%	4.2%	4.6%	4.9%	6.4%
No matrix/mesh	185	0.5%	1.7%	2.8%	3.6%	4.3%	4.8%	5.7%	6.7%
Not stated	20	0.3%	4.5%	5.2%	5.2%	6.0%	6.0%	6.0%	7.6%
Total	270	0.5%	1.8%	2.9%	3.6%	4.3%	4.8%	5.4%	6.6%
Revision due to seroma/haematoma									
Matrix/mesh	56	2.4%	2.6%	2.6%	2.8%	2.9%	2.9%	2.9%	2.9%
No matrix/mesh	87	1.5%	1.7%	1.8%	1.8%	1.8%	1.8%	1.8%	1.8%
Not stated	4	1.0%	1.4%	1.4%	1.4%	1.4%	1.4%	1.4%	1.4%
Total	147	1.8%	2.0%	2.0%	2.0%	2.1%	2.1%	2.1%	2.1%
Revision due to deep wound infection									
Matrix/mesh	74	3.4%	3.5%	3.6%	3.6%	3.7%	3.7%	3.7%	3.7%
No matrix/mesh	131	2.3%	2.6%	2.7%	2.7%	2.7%	2.7%	2.7%	2.7%
Not stated	5	1.0%	1.7%	1.7%	1.7%	1.7%	1.7%	1.7%	1.7%
Total	210	2.5%	2.8%	2.9%	2.9%	2.9%	2.9%	2.9%	2.9%

Notes: Revision incidence is based on reconstructive two-stage procedures with primary tissue expanders inserted from 2012 to 2023. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary tissue insertion date to the date of the first recorded revision procedure (censored if there are no recorded revision procedures before the date of the last procedure in the extract; the first revision procedure can either be a tissue expander revision or a breast implant revision procedure). Includes breasts which enter the Registry with a primary reconstructive tissue expander insertion procedure and also have at least one subsequent procedure captured.

APPENDIX 7

Tables supporting in text figures

Cumulative revision incidence – primary reconstructive tissue expanders

	N Tissue Expanders	Number at risk			
		6 Mo	12 Mo	18 Mo	24 Mo
Post-cancer	6,876	4,386	2,278	1,620	1,320
Risk-reducing	3,068	1,630	727	495	400
Developmental	138	86	54	33	24
Total	10,082	6,102	3,059	2,148	1,744

	N Revised	Cumulative revision incidence			
		6 Mo	12 Mo	18 Mo	24 Mo
All-cause revision					
Post-cancer	404	3.9%	6.4%	9.1%	10.2%
Risk-reducing	122	3.1%	4.9%	7.3%	8.2%
Developmental	2	0.0%	3.4%	3.4%	3.4%
Total	528	3.6%	6.0%	8.5%	9.6%
Revision due to complication					
Post-cancer	248	2.7%	4.1%	5.3%	5.8%
Risk-reducing	95	2.8%	3.6%	5.1%	5.5%
Developmental	2	0.0%	3.4%	3.4%	3.4%
Total	345	2.7%	4.0%	5.2%	5.7%

Notes: Revision incidence is based on reconstructive primary tissue expanders inserted from 2012 to 2023.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary tissue expander insertion date to the date of the first recorded revision procedure (censored if there are no recorded revision procedures before the date of the last procedure in the extract; tissue expander removal and implant insertion procedures do not count as revisions).

APPENDIX 8

Tables supporting in text figures

Surgical elements (2012-2023) – cosmetic breast level procedures

	2016	2017	2018	2019	2020	2021	2022	2023
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Incision site*[1]								
Inframammary	11,234 (82.3%)	17,099 (86.9%)	15,206 (81.5%)	13,628 (82.0%)	15,490 (80.0%)	14,934 (78.3%)	14,497 (78.8%)	12,182 (78.6%)
Mastopexy/ reduction scar	1,117 (8.2%)	1,365 (6.9%)	1,593 (8.5%)	1,593 (9.6%)	2,204 (11.4%)	2,220 (11.6%)	1,939 (10.5%)	1,948 (12.6%)
Areola	187 (1.4%)	226 (1.1%)	256 (1.4%)	185 (1.1%)	199 (1.0%)	153 (0.8%)	119 (0.6%)	81 (0.5%)
Axillary	53 (0.4%)	56 (0.3%)	80 (0.4%)	36 (0.2%)	32 (0.2%)	27 (0.1%)	33 (0.2%)	24 (0.2%)
Other	25 (0.2%)	29 (0.1%)	34 (0.2%)	59 (0.4%)	50 (0.3%)	42 (0.2%)	18 (0.1%)	35 (0.2%)
Not stated	1,102 (8.1%)	998 (5.1%)	1,650 (8.8%)	1,236 (7.4%)	1,519 (7.8%)	1,799 (9.4%)	1,891 (10.3%)	1,308 (8.4%)
Surgical plane[2]								
Sub-pectoral/ Dual plane	10,177 (75.0%)	16,257 (83.3%)	14,377 (79.1%)	12,437 (80.7%)	14,647 (81.0%)	13,953 (79.9%)	13,421 (78.7%)	11,184 (79.1%)
Sub-glandular/ sub-fascial	2,067 (15.2%)	1,931 (9.9%)	2,167 (11.9%)	2,061 (13.4%)	2,277 (12.6%)	2,433 (13.9%)	2,385 (14.0%)	2,053 (14.5%)
Other	81 (0.6%)	65 (0.3%)	28 (0.2%)	32 (0.2%)	130 (0.7%)	39 (0.2%)	56 (0.3%)	28 (0.2%)
Not stated	1,252 (9.2%)	1,259 (6.5%)	1,610 (8.9%)	874 (5.7%)	1,033 (5.7%)	1,037 (5.9%)	1,199 (7.0%)	880 (6.2%)
Concurrent mastopexy/reduction[1]								
Yes	1,404 (10.3%)	2,136 (10.8%)	2,316 (12.4%)	2,431 (14.6%)	3,240 (16.7%)	3,326 (17.4%)	3,245 (17.6%)	2,996 (19.3%)
Previous mastopexy/reduction[1]								
Yes	229 (1.7%)	396 (2.0%)	447 (2.4%)	482 (2.9%)	476 (2.5%)	568 (3.0%)	603 (3.3%)	601 (3.9%)
Fat grafting[1]								
Yes	79 (0.6%)	114 (0.6%)	276 (1.5%)	782 (4.7%)	1,129 (5.8%)	1,399 (7.3%)	1,597 (8.7%)	1,706 (11.0%)
Drain use[1]								
Yes	2,560 (18.8%)	2,680 (13.6%)	2,686 (14.4%)	2,436 (14.7%)	2,568 (13.3%)	2,775 (14.5%)	2,065 (11.2%)	1,862 (12.0%)
Nipple guard[1]								
Yes	8,184 (60.0%)	15,491 (78.7%)	14,412 (77.3%)	12,702 (76.4%)	14,954 (77.3%)	14,087 (73.8%)	14,114 (76.7%)	11,762 (75.9%)
Neo pocket formation[3]								
Yes	654 (27.7%)	1,070 (32.1%)	1,314 (30.9%)	1,283 (31.8%)	1,247 (30.7%)	1,301 (29.0%)	1,300 (32.0%)	1,176 (30.2%)
Denominators								
All procedures[1]	13,642	19,687	18,653	16,625	19,351	19,084	18,393	15,496
Not explant only[2]	13,577	19,512	18,182	15,404	18,087	17,462	17,061	14,145
Replacement/ reposition revisions[3]	2,359	3,332	4,260	4,036	4,062	4,491	4,066	3,898

Note: Details are at the breast procedure level. *More than one incision site can be recorded.
1,2,3 Denominators used for each surgical element are shown at the bottom of the table.

APPENDIX 9

Tables supporting in text figures

Cumulative revision incidence – cosmetic primary breast implants

	N Primary Breast Implants	Number at risk							
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8
	106,413	99,028	85,261	72,903	56,296	46,506	34,032	18,744	6,633

Issues at revision (/reason)	N Revised	Cumulative revision incidence							
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8
All-cause	4,637	1.4%	2.6%	3.4%	4.1%	4.7%	5.4%	6.1%	6.7%
Complication	2,417	0.8%	1.4%	1.8%	2.1%	2.5%	2.8%	3.2%	3.5%
Malposition	1,106	0.4%	0.8%	0.9%	1.1%	1.2%	1.3%	1.4%	1.4%
Capsular contracture	950	0.2%	0.5%	0.6%	0.8%	1.0%	1.2%	1.4%	1.6%
Rupture/deflation	295	0.1%	0.1%	0.2%	0.2%	0.3%	0.4%	0.5%	0.6%
Skin scarring	133	0.1%	0.1%	0.1%	0.1%	0.1%	0.2%	0.2%	0.2%
Seroma/haematoma	121	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.2%
Deep wound infection	47	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Notes: Cumulative revision incidence is based on cosmetic primary breast implants inserted from 2012 to 2023.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the date of the first recorded revision procedure (censored if there are no recorded revision procedures before the date of the last procedure in the extract).

APPENDIX 10

Tables supporting in text figures

Cumulative revision incidence by device shell – cosmetic primary breast implant

	N Primary Breast Implants	Number at risk							
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8
Textured	53,307	50,526	45,367	40,621	34,464	30,197	23,561	13,500	4,926
Smooth	50,520	45,958	37,388	29,806	19,391	14,057	8,707	4,138	1,283
Polyurethane	2,530	2,492	2,457	2,433	2,410	2,233	1,752	1,094	417
Total	106,357	98,976	85,212	72,860	56,265	46,487	34,020	18,732	6,626

	N Revised	Cumulative revision incidence							
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8
All-cause revision									
Textured	2,379	1.2%	2.2%	2.9%	3.6%	4.3%	5.1%	5.9%	6.5%
Smooth	2,064	1.7%	3.0%	3.9%	4.5%	5.0%	5.5%	6.0%	6.5%
Polyurethane	185	1.5%	2.8%	3.8%	4.5%	5.9%	6.2%	7.6%	8.3%
Total	4,628	1.4%	2.6%	3.4%	4.1%	4.7%	5.4%	6.1%	6.7%
Revision due to complication									
Textured	1,253	0.6%	1.2%	1.5%	1.9%	2.3%	2.7%	3.1%	3.4%
Smooth	1,079	1.0%	1.7%	2.0%	2.4%	2.6%	2.9%	3.1%	3.2%
Polyurethane	81	0.9%	1.8%	2.1%	2.4%	2.7%	2.9%	3.4%	3.7%
Total	2,413	0.8%	1.4%	1.8%	2.1%	2.5%	2.8%	3.2%	3.5%
Revision due to device malposition									
Textured	457	0.3%	0.5%	0.7%	0.8%	0.9%	1.0%	1.1%	1.1%
Smooth	609	0.6%	1.0%	1.2%	1.4%	1.5%	1.6%	1.6%	1.6%
Polyurethane	40	0.6%	1.2%	1.4%	1.4%	1.4%	1.5%	1.7%	1.7%
Total	1,106	0.4%	0.8%	0.9%	1.1%	1.2%	1.3%	1.4%	1.4%
Revision due to capsular contracture									
Textured	566	0.2%	0.4%	0.6%	0.8%	1.0%	1.2%	1.5%	1.7%
Smooth	342	0.3%	0.5%	0.6%	0.8%	0.9%	1.0%	1.1%	1.2%
Polyurethane	39	0.2%	0.5%	0.7%	0.8%	1.2%	1.3%	1.7%	1.9%
Total	947	0.2%	0.5%	0.6%	0.8%	1.0%	1.2%	1.4%	1.6%
Revision due to rupture/deflation									
Textured	184	0.0%	0.1%	0.1%	0.2%	0.3%	0.4%	0.5%	0.6%
Smooth	105	0.1%	0.1%	0.2%	0.2%	0.3%	0.3%	0.4%	0.4%
Polyurethane	6	0.0%	0.1%	0.1%	0.1%	0.2%	0.2%	0.2%	0.3%
Total	295	0.1%	0.1%	0.2%	0.2%	0.3%	0.4%	0.5%	0.6%

	N Revised	Cumulative revision incidence							
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8
Revision due to skin scarring									
Textured	63	0.0%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Smooth	69	0.1%	0.1%	0.1%	0.2%	0.2%	0.2%	0.2%	0.2%
Polyurethane	1	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Total	133	0.1%	0.1%	0.1%	0.1%	0.1%	0.2%	0.2%	0.2%
Revision due to seroma/haematoma									
Textured	76	0.1%	0.1%	0.1%	0.1%	0.1%	0.2%	0.2%	0.2%
Smooth	37	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Polyurethane	7	0.2%	0.2%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%
Total	120	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.2%
Revision due to deep wound infection									
Textured	29	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Smooth	18	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Polyurethane	0	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Total	47	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Notes: Cumulative revision incidence is based on cosmetic primary breast implants inserted from 2012 to 2023.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the date of the first recorded revision procedure (censored if there are no recorded revision procedures before the date of the last procedure in the extract).

APPENDIX 11

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**

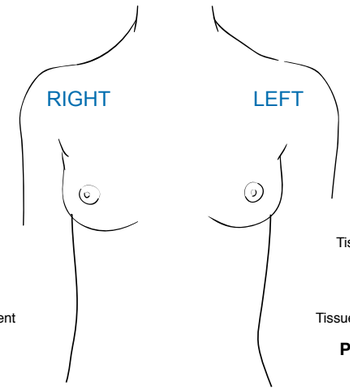
Category of operation
- Cosmetic augmentation
- Reconstruction - post cancer
- Reconstruction - benign / prophylactic
- Congenital deformity

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**

RIGHT			LEFT	
Incision site	**Plane**		**Plane**	**Incision site**
Axillary	Sub-glandular / Sub-fascial		Subglandular / Sub-fascial	Axillary
Areolar	Sub-pectoral		Sub-pectoral	Areolar
Infra-mammary	Sub-flap		Sub-flap	Infra-mammary
Previous mastectomy scar				Previous mastectomy scar
Mastopexy/reduction wound				Mastopexy/reduction wound
.....				.....
Concurrent Mastectomy.....		Yes No	Yes No	**Concurrent Mastectomy**
Axillary surgery incl. sentinel node biopsy		Yes No	Yes No	**Axillary surgery incl. sentinel node biopsy**
Concurrent Mastopexy / Reduction		Yes No	Yes No	**Concurrent Mastopexy / Reduction**
Concurrent Flap cover		Yes No	Yes No	**Concurrent Flap cover**
Previous Mastopexy/Reduction		Yes No	Yes No	**Previous Mastopexy/Reduction**
Fat grafting Yes Volume.....mLs		No	**Fat grafting** Yes Volume.....mLs	No
IF TISSUE EXPANDER, Intra Operative fill volume: .....mLs			**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**

RIGHT		LEFT	
Nipple absent	Occlusive nipple shield	Occlusive nipple shield	Nipple absent
Nipple sparing	Drain used	Drain used	Nipple sparing

FOR REVISION SURGERY ONLY

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

RIGHT	LEFT
Revision Type: Replacement; Reposition existing implant; Explant only	**Revision Type:** Replacement; Reposition existing implant; Explant only
Capsulectomy ..... Full Partial None	**Capsulectomy** ..... Full Partial None
Neo pocket formation ... Yes No Subglandular Submuscular	**Neo pocket formation** ... Yes No Subglandular Submuscular
Explanted device: Ref.No. / Manufacturer: ..... Shell: ..... Fill: ..... Vol: ..... Date of Insert: ...../...../..... Round Anatomical Indeterminate	**Explanted device:** Ref.No. / Manufacturer: ..... Shell: ..... Fill: ..... Vol: ..... Date of Insert: ...../...../..... Round Anatomical Indeterminate

Reason for Revision — Tick if Same Bilateral

RIGHT	LEFT
Complication; Asymptomatic; Patient Preference	Complication; Asymptomatic; Patient Preference
Is the operation removing an implant inserted overseas Yes No	**Is the operation removing an implant inserted overseas** Yes No
Details :	Details : .....

Device rupture? — Tick if Same Bilateral

RIGHT	LEFT
Yes, reason for revision; Yes, found incidentally; No	Yes, reason for revision; Yes, found incidentally; No
If yes, please indicate whether silicone extravasation was found: Intracapsular; Extracapsular; Distant	**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	☐	☐	☐

ABDR_Data Collection Form_v1.0_20150310

APPENDIX 12

ABDR staff

Professor Susannah Ahern, ABDR Steering Committee Chair/ABDR Academic Lead
Professor Arul Earnest, Senior Biostatistician, SPHPM Monash University
Ms. Natalie Heriot, Senior Manager Surgical Registries
Dr. Dilinie Herbert, Research Fellow
Mr. Saeid Kalbasi, Database and Data Linkage Projects Manager
Ms. Judith Hankin, Relationship Manager
Ms. Sally McInnes, Registry Operations Manager
Ms. Delphine Allan, Senior Project Officer
Mr Patrick Garduce, Data Analyst
Ms. Trisha Nichols, Communications Officer
Ms. Uma Symons, Research Officer
Ms Sharon Lee, Project Officer
Mr. Leonardo Morandini, Data Entry
Mr. Sam Ahern, Data Entry
Mr. Adriano Morandini, Data Entry
Ms Renee Conroy, Data Entry
Mr Mudit Sharma, Data Entry

APPENDIX 13

List of participating sites as at end of 2023

State	Site Name
ACT	Barton Private Hospital
ACT	Calvary Bruce Private Hospital
ACT	Calvary John James Hospital
ACT	Canberra Private Hospital
ACT	National Capital Private Hospital
ACT	North Canberra Hospital
ACT	Sole Vita Surgery
NSW	Aesthetic Day Surgery
NSW	Albury Wodonga Health – Albury Campus
NSW	Albury Wodonga Private Hospital
NSW	Auburn Hospital & Community Health Services
NSW	Bankstown-Lidcombe Hospital
NSW	Baringa Private Hospital
NSW	Bathurst Base Hospital
NSW	Bathurst Private Hospital
NSW	Bella Vista Day Hospital
NSW	Belmont Hospital
NSW	Bondi Junction Private Hospital
NSW	Brisbane Waters Private Hospital
NSW	Calvary Mater Newcastle
NSW	Calvary Riverina Hospital
NSW	Campbelltown Hospital
NSW	Campbelltown Private Hospital
NSW	Castlecrag Private Hospital
NSW	Charlestown Private Hospital
NSW	Chris O'Brien Lifehouse
NSW	City West Specialist 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	Honeysuckle Day Hospital
NSW	Hornsby Ku-Ring-Gai Hospital
NSW	Hunter Valley Private Hospital
NSW	Hunters Hill Private Hospital
NSW	Kareena Private Hospital
NSW	Kingsgrove Day Hospital
NSW	Lake Macquarie Private Hospital
NSW	Lakeview Private Hospital
NSW	Lingard Private Hospital
NSW	Lismore Base Hospital
NSW	Liverpool Hospital
NSW	Macquarie University Hospital
NSW	Maitland Private Hospital
NSW	Mater Hospital Sydney
NSW	Mount Druitt Hospital
NSW	Nepean Hospital
NSW	Nepean Private Hospital
NSW	Newcastle Private Hospital
NSW	North Shore Private Hospital
NSW	North Shore Specialist Day Hospital
NSW	Northern Beaches Hospital
NSW	Norwest Private Hospital
NSW	Port Macquarie Private Hospital
NSW	Prince of Wales Hospital
NSW	Prince of Wales Private Hospital
NSW	Ramsay Surgical Centre Miranda
NSW	Riverina Day Surgery
NSW	Royal Hospital for Women
NSW	Royal North Shore Hospital
NSW	Somerset 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 Hospital (Darlinghurst)
NSW	St Vincent's Private Hospital (Darlinghurst)
NSW	St Vincent's Private Hospital (Lismore)
NSW	Strathfield Private Hospital
NSW	Swan Clinic for Plastic Surgery
NSW	Sydney Adventist Hospital
NSW	Sydney Day Hospital
NSW	Sydney Southwest Private Hospital
NSW	The Double Bay Day Surgery
NSW	The San Day Surgery
NSW	The Sydney Private Hospital
NSW	The Tweed Hospital
NSW	Wagga Wagga Rural Referral Hospital
NSW	Waratah Private Hospital
NSW	Warners Bay Private Hospital
NSW	Westmead Hospital
NSW	Westmead Private Hospital
NSW	Wollongong Day Surgery
NSW	Wollongong Hospital
NSW	Wollongong Private Hospital
NT	Darwin Day Surgery
NT	Darwin Private Hospital
NT	Royal Darwin Hospital
QLD	Brisbane Day Hospital
QLD	Brisbane Private Hospital
QLD	Buderim Private Hospital

State	Site Name
QLD	Caboolture Private Hospital
QLD	Cairns Base Hospital
QLD	Cairns Private Hospital
QLD	Canossa Private Hospital
QLD	Chermside Day Hospital
QLD	Far North Day Hospital
QLD	Gold Coast Private Hospital
QLD	Gold Coast University Hospital
QLD	Greenslopes Private Hospital
QLD	Herston Private Hospital
QLD	Hillcrest – Rockhampton Private Hospital
QLD	John Flynn Private Hospital
QLD	Kawana Private Hospital
QLD	Mater Adult Hospital
QLD	Mater Private Hospital (South Brisbane)
QLD	Mater Private Hospital Rockhampton
QLD	Mater Private Hospital Springfield
QLD	Mater Private Hospital Townsville
QLD	Miami Private Hospital
QLD	North Lakes Day Hospital
QLD	North West Private Hospital
QLD	Pacific Day Surgery Centre
QLD	Pacific Private Day Hospital
QLD	Pindara Private Hospital
QLD	Princess Alexandra Hospital
QLD	Queen Elizabeth II Jubilee Hospital
QLD	Queensland Children's Hospital
QLD	Ramsay Surgical Centre Cairns
QLD	Redland Hospital
QLD	Robina Hospital
QLD	Royal Brisbane & Women's Hospital
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 Northside
QLD	Sunshine Coast Day Surgery
QLD	Sunshine Coast University Private Hospital
QLD	The Wesley Hospital
QLD	Westside Private Hospital
QLD	South Bank Day Hospital (closed)
SA	Adelaide Day Surgery
SA	Calvary Adelaide Hospital
SA	Calvary North Adelaide Hospital
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	Modbury Hospital

State	Site Name
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	Western Hospital (SA)
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
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	Bendigo Day Surgery
VIC	Bendigo Health – The Bendigo Hospital
VIC	Cabrini Brighton
VIC	Cabrini Malvern
VIC	Casey Hospital
VIC	Chelsea Heights Day Surgery and Endoscopy
VIC	Corymbia Day Hospital
VIC	Dandenong Hospital
VIC	Epworth Eastern
VIC	Epworth Freemasons
VIC	Epworth Geelong
VIC	Epworth Hawthorn
VIC	Epworth Richmond
VIC	Frances Perry House
VIC	Frankston Hospital
VIC	Holmesglen Private Hospital
VIC	John Fawkner Private Hospital
VIC	Knox Private Hospital
VIC	Linacre Private Hospital
VIC	Maroondah Hospital
VIC	Masada Private Hospital
VIC	Mitcham 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	Ramsay Surgical Centre Glenferrie
VIC	Ringwood Private Hospital
VIC	Royal Melbourne Hospital – City Campus
VIC	Sir John Monash Private Hospital
VIC	South West Healthcare – Warrnambool Campus

State	Site Name
VIC	Specialist Surgicentre Geelong
VIC	St John of God Bendigo Hospital
VIC	St John of God Berwick Hospital
VIC	St John Of God Warrnambool Hospital
VIC	St Kilda Day Hospital
VIC	St Vincent's Hospital (Melbourne) LTD
VIC	St Vincent's Private Hospital East Melbourne
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 Northern Hospital
VIC	The Royal Childrens Hospital
VIC	The Royal Women's Hospital
VIC	Vermont Private Hospital
VIC	Warringal Private Hospital
VIC	Waverley Private Hospital
VIC	West Gippsland Healthcare Group
VIC	Western Private Hospital
VIC	Windsor Private Hospital
WA	Bethesda Hospital
WA	Bunbury Day Hospital
WA	Cambridge Day Surgery
WA	Concept Day Hospital
WA	Glengarry Private Hospital
WA	Hollywood Private Hospital
WA	Mount Hospital
WA	Southbank Day Surgery
WA	St John of God Bunbury Hospital
WA	St John of God Hospital, Subiaco
WA	St John of God Mt Lawley Hospital
WA	St John of God Murdoch Hospital
WA	Subiaco Private Hospital
WA	The Park Private Hospital
WA	Waikiki Private Hospital
WA	West Leederville Private Hospital
WA	St John of God Mt Lawley Hospital
WA	St John of God Murdoch Hospital
WA	St John of God Subiaco Eye Hospital
WA	Subiaco Private Hospital
WA	Sundew Day Surgery
WA	The Park Private Hospital
WA	Waikiki Private Hospital
WA	West Leederville Private Hospital

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