MONASH University

AUSTRALIAN BREAST DEVICE REGISTRY

2022 ANNUAL REPORT

AUSTRALIAN Breast Device REGISTRY

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

Suggested citation:

Ahern S, Herbert D, Garduce P, Kalbasi S, Earnest A, Hankin J, McInnes S, Tansley P, Walker M, Farrell G on behalf of the ABDR. The Australian Breast Device Registry 2022 Annual Report. Monash University, Department of Epidemiology and Preventive Medicine, November 2023 Report No 7. 124 pages.

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Data Period:

The data contained in this document were extracted from the ABDR database 29th May 2023 and related to data that had been submitted from the initiation of the pilot ABDR on 19 January 2012 to 31 December 2022. 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:

The Australian Breast Device Registry is supported by funding from the Australian Government, Department of Health and Aged Care, under the National Clinical Quality Registry Program.

Website: abdr.org.au

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FOREWORD

Welcome to the 2022 Australian Breast Device Registry (ABDR) Annual Report, the Registry's seventh.

This report is a true reflection of the value of the ABDR in striving to deliver excellence in reporting emerging trends in breast device surgery and practices. The Registry marked a significant milestone in this reporting period capturing more than 100,000 procedures. With more procedural data the ABDR is able to demonstrate the varying use of particular breast devices including implants, tissue expanders and matrix/mesh. The ABDR is able to report on outcomes up to 7 years post primary implant. This data is an increasingly important resource that can support patient care and informed decision making, as well as secondary use for research. Academic researchers and device manufacturers are reaching out to the ABDR to request data to better understand device and surgical performance. The ABDR is also an important resource for women with breast implants, as a source of reassurance and information regarding their implanted devices.

The ABDR is the repository for all reported cases of Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) in Australia. We are grateful for all the clinicians that notify the ABDR of their patients with this rare type of lymphoma. Data generated from these reported cases allows us to better understand associated device and procedural characteristics and contribute to international knowledge in this important clinical area.

In 2023 we welcomed additional clinicians to the ABDR who joined a newly established ABDR Research and Data Sharing Subcommittee. This important committee reviews requests for ABDR data and reports produced by the ABDR, and was developed in recognition of the increasing interest in the ABDR's data and the importance of clinician input into these activities.

The success of the ABDR would not be possible without the generous support of the Commonwealth Department of Health and Aged Care. The Registry's Steering Committee continues to provide valuable strategic direction and guidance and its Clinical Advisory Committee provides critical regular clinical oversight and review of the ABDR's activities. The ABDR continues to work closely with the Therapeutic Goods Administration (TGA) to ensure alignment with national regulatory requirements. Similarly, the ABDR is engaged in various TGA activities such as the development of unique device identifiers (UDIs) for breast devices.

We hope that you find the ABDR 7th Edition of its Annual Report a useful and informative resource and engaging reading.

Professor Susannah Ahern, Chair of the ABDR, Monash University

Associate Professor Gillian Farrell, 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, under the National Clinical Quality Registry Program, for its continued funding and support of the ABDR, with in-kind support from Monash University. The ABDR are grateful for the support of the three major craft groups in Australia for their valuable contribution to the Registry.

We greatly appreciate the dedication of the ABDR Clinical Leads: Associate Professor Gillian Farrell representing the Australian Society of Plastic Surgeons (ASPS); 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 their knowledge and expertise to the operational management and reporting outputs of the Registry. We are 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 and Ms Gwili Holme (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 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 on behalf of all people that undergo breast device surgery. 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)
Consumers Health Forum of Australia (CHF)

EXECUTIVE SUMMARY

The ABDR is a Clinical Quality Registry (CQR) that aims to: identify and report on possible trends and complications associated with implantable breast devices (implants, tissue expanders and matrix/mesh); to track the long-term safety and performance of breast devices; and to identify best surgical practice associated with optimal patient outcomes. Registry activities are governed by a national Steering Committee comprising of stakeholders from government, academia, industry, clinicians and consumers.

Registry participation

In 2022, **247 sites** participated in the ABDR, of which 74% were private and 26% were public health services. Between 2012-2022, the majority of cosmetic (99.5%) and reconstructive (77.1%) procedures recorded in the Registry were conducted in private facilities. In 2022, **445 clinicians** have contributed data to the ABDR (submitting at least one Data Collection Form in the last twelve months), including **29 new clinicians.** In 2022, plastic surgeons comprised 63% of total participating clinicians, breast/general surgeons comprised 30%, and cosmetic clinicians comprised 6.5%. An analysis of 2022 data shows that clinicians most commonly performed both cosmetic and reconstructive procedures (55%). However, nearly 85% of participating clinicians performed up to one breast device procedure per week, thus these are not high-volume procedures for most clinicians. The consumer opt-out rate for the ABDR remains very low at less than 1%.

Data overview

Since commencement, a total of **87,339 patients** undergoing a total of **100,114 procedures** involving **171,092 devices** have been recorded in the Registry. **20.5%** of participants entered the Registry with a **reconstructive** procedure, **71.4%** with a **cosmetic** procedure and 8.1% did not have indication stated. A total of **11,347 patients, 13,287 procedures and 22,022 devices** were captured in **2022.** Case ascertainment as measured via sales data from the Therapeutic Goods Administration and via Australian Institute of Health and Welfare (AIHW) data estimates that the ABDR captured between 71-76% of devices/surgeries during 2022. Importantly, AIHW data identified that primary implant insertion procedures have the highest capture rates, with tissue expander procedures and explanted devices having lower capture rates.

Devices and procedures

For the first time in 2021, the ABDR published device manufacturer data for breast implants. In the current reporting period we have extended on that to include tissue expanders and matrix/mesh. A total of 160,481 breast implants were inserted between 2012-2022, of which 99.9% have associated manufacturer details recorded. Almost 90% of inserted implants over this period were Mentor Medical Systems, Motiva or Allergan/Inamed/McGhan/CUI devices, although there was substantial variation in use of device by manufacturer over time.

For both reconstructive and cosmetic procedures, the proportion of procedures that are explants only has increased over time. For reconstructive procedures, the proportion of insertions has remained relatively stable and the proportion of revisions has decreased over time. This is also reflected in **a reduction in revision rates for reconstructive procedures within the first 6-12 months** of surgery over the last 7 years. Conversely, cosmetic surgery has seen a reduction in insertions and an increase in revisions over the same period.

Reconstructive procedures

The ABDR has recorded a total of **25,764 reconstructive procedures,** including **3,103 reconstructive procedures in 2022**, continuing the downward trend observed in the Registry since 2019. Reconstructive procedures include post-cancer reconstruction, risk-reducing reconstruction and procedures relating to developmental deformity. Post-cancer reconstruction remains as the most common indication for surgery. In 2022 the most commonly inserted devices were those from **Mentor Medical Systems and Motiva,** the most commonly inserted tissue expander was from **Mentor Medical Systems,** and the most commonly used matrix/mesh was from **Tiloop.**

The most common reconstructive procedures are **bilateral post-cancer reconstruction (40.6%)** and **unilateral post-cancer reconstruction (38.0%).** The median age for post-cancer reconstructions is 50.2 years for insertion surgery and 55 years for revision/explantation. **Risk-reducing procedures** have declined as a proportion of total procedures over time. **Direct-to-implant procedures** continue to be preferred in 2022 (61.5% vs 38.5% for two-stage procedures). **Smooth device (67.7%) shell** and **round (71.8%) shape** continue to be favoured for the purpose of insertion procedures or replacement revision procedures.

For the first time we show variation in use of specific **intra-operative techniques via a series of funnel plots.** The majority of clinicians are using intra-operative antibiotics, post-operative antibiotics, antiseptic rinse and changing their gloves. However, there is greater variation in the use of antibiotic dipping solution and sleeve/funnel. The ABDR for the first time has reported trend graphs in reconstructive surgical techniques. The most common incision site has changed from mastectomy scar incisions to infra-mammary incisions. A number of surgical techniques have increased over time, such as concurrent mastopexy, nipple sparing, axillary surgery, use of a nipple guard and fat grafting.

Matrix/mesh is commonly used in cancer reconstruction (57.9%) and risk-reducing (56.2%) direct-to-implant insertion procedures. Additionally, 28.8% of post-cancer reconstruction and 28.9% of risk-reducing tissue expander insertions involved use of matrix/mesh. The most common complications/issues identified at the time of revision in 2022 was capsular contracture (34.2%), followed by device malposition (24.8%) and rupture/deflation (19.1%).

For patients who entered the Registry with device insertion procedures, 82.2% had no revision surgery, 15.3% had one revision and the remainder (2.6%) had more than one revision.

Revision rates

Only primary implants (implants inserted in breasts with no recorded history of previous implant procedures) are included in revision rate analyses. This comprises approximately 69% of reconstructive implant insertions.

All-cause cumulative revision rate 7 years after primary implant insertion is **21.9% for risk-reducing reconstruction, 20.0% for post-cancer reconstruction** and 14.9% for developmental deformity. The **revision rate due to complication at 7 years** was **15.1% for risk-reducing reconstruction, 13.8% for post-cancer reconstruction** and **8.5% for developmental deformity. Device malposition and capsular contracture** were the most common complications with revision incidence rates of 5.7% and 5.9% respectively at 7 years. New hazard curve analyses show that the risk of device malposition and capsular contracture appeared to be highest shortly after insertion then progressively declined over time. However, the risk of device rupture/deflation increased over time.

The **all-cause cumulative revision incidence rates at 7 years by shell type** were: 27.5% for polyurethane, 21.3% for textured and 14.9% for smooth implants. **The complication cumulative revision incidence rates at 7 years were:** 19.3%, 4.0% and 11.2% respectively.

Matrix/mesh

Procedures that involve matrix/mesh have higher proportions of revisions associated with seroma/haematoma and deep wound infection. Proportions of device malposition and capsular contracture are similar for procedures with and without matrix/mesh. **Direct-to-implant** procedures involving matrix/mesh had an **all-cause cumulative revision incidence at 7 years of 22.5%** (vs 20.1% without) and **complication cumulative revision incidence at 7 years** of 13.1% (vs 9.4% without). **Two-stage procedures** involving matrix/mesh (during the tissue expander insertion procedure) had an **all-cause cumulative revision incidence** of 16.7% (vs 21.0% without) and **complication cumulative revision incidence of 9.0%** (vs 10.9% without) 7 years after insertion. The **all-cause revision incidence rate of tissue expanders 36 months** after insertion was 10.7% for post-cancer and 8.3% for risk-reducing. The cumulative revision incidence rates due to complication for post-cancer reconstruction and risk-reducing procedures were both 5.6%.

Cosmetic procedures

In 2022 the ABDR recorded a further **8,831 cosmetic procedures,** slightly fewer than the previous year. The most commonly inserted breast implants by manufacturer in 2022 were **Motiva and Mentor Medical Systems** which account for almost 90% of insertions. The most common age for women undergoing cosmetic implants was the 20–24 year age group. Cosmetic surgery showed variation in practise relating to glove change for insertion, antibiotic dipping solution, and sleeve funnel use. Surgical techniques showed an increasing use of concurrent mastopexy and fat grafting over time. **Smooth devices (66.6%)** were inserted twice as frequently as textured devices (33.4%) in 2022. **Round devices (60.9%)** were inserted more frequently than shaped/anatomical devices (19.1%) in 2022. The most common complications/issues reported to the Registry relating to cosmetic procedures in 2022 were **capsular contracture (32.3%), device rupture/deflation (23.4%) and device malposition (17.8%).**

Revision rates

77.5% of cosmetic insertions are primary breast implants and are included in revision rate analyses. The **all-cause cumulative revision incidence rate for cosmetic implants at 7 years is 6.3%** and revision rates due to **complication is 3.4% at 7 years.** Capsular contracture and malposition were the most common complications with cumulative revision incidence rates of 1.6% and 1.4% respectively.

Polyurethane devices have had the highest (8.5%) cumulative all-cause revision rate after 7 years, as well as revision due to complication (3.8%). Of women who entered the Registry with cosmetic breast implant insertion, 95.5% had no revision surgery, 4.1% had one revision, 0.3% had more than one revision.

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

In **2022, five new cases of BIA-ALCL** were confirmed by the ABDR, taking the total of reported cases to the ABDR to 64. Cases were most commonly reported from 7-10 years post insertion. The explanted device shell type was known for 52 devices, of which 37 had a textured shell and 15 had a polyurethane shell. Seroma/haematoma was the most common clinical issue associated with BIA-ALCL.

CQI

The ABDR reports three Clinical Quality Indicators (CQIs) over time in relation to (1) intra-operative antibiotic use; (2) revision due to early complication and (3) patient reported data. While the majority of measures have remained stable, it is notable that the **revision rate of reconstructive procedures at 12 months has reduced over time from 3.8% in 2016 to 2.2% in 2021.** Given that there has also been changes in surgical and antibiotic techniques over this time, it is possible that this may have played a role in this reduction.

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 formulated by the Australasian Foundation of Plastic Surgery in 2011. The first patient of the ABDR was entered in June 2015.

Aims

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

The ABDR is governed in accordance with The Australian Commission on Safety and Quality in Health Care's (ACSQHC) Operating Principles and Technical Standards for Australian Clinical Quality Registries (2008) and Framework for Australian Clinical Quality Registries (2014). Aligning with the Commission gives all key stakeholders assurance that Registry data and its supporting systems satisfy security, technical and operating standards.

The ABDR Steering Committee is responsible for strategic oversight of the Registry's activities and meets three times a year. The ABDR's daily operational aspects and emerging clinical issues are overseen by its Clinical Advisory Committee (formerly the ABDR Management Committee), which comprises the three clinical leads appointed by their respective craft groups and which meets monthly.

The Steering Committee includes the data custodian and Chair (Professor Susannah Ahern, School of Public Health and Preventive Medicine, Monash University) and one representative from each of the following organisations:

- Australian Government Department of Health and Aged Care
- Australian Commission on Safety and Quality in Healthcare (ACSQHC)
- Therapeutic Goods Administration (TGA)
- Australian Society of Plastic Surgeons (ASPS)
- Australasian College of Cosmetic Surgery and Medicine (ACCSM)
- Breast Surgeons of Australia and New Zealand (BreastSurgANZ)
- Consumers Health Forum of Australia (CHF)
- Medical Technology Association of Australia (MTAA).

Requests for ABDR data have been reviewed by the Clinical Advisory Committee. In 2023 this group expanded via nominees from the three craft groups, with three additional clinicians to form the ABDR's Research and Data Sharing (RaDS) Subcommittee. Requests for data are reviewed by this Subcommittee in line with the ABDR's Data Access policy and procedure.

Registry collaborators

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 collaborative activities were limited during the COVID pandemic, but have been re-established in early 2023.

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 reconstructive breast implants, cosmetic breast implants, (reconstructive) tissue expanders and matrix/mesh devices (inserted with primary reconstructive breast implants/tissue expanders) separately.

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 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 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, 16 May 2023, 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 2012-2022 (inclusive).

Crude cumulative revision incidence rates have been generated using Nelson-Aalen 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 failure event times. 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 explant only procedures which do not involve new devices. It should also be noted that long periods of time can elapse between the times that issues are experienced and the times that 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. In this report, the frequency of reported intra-operative aseptic technique use is compared across clinicians. The horizontal axis of each funnel plot shows the number of operations conducted by each clinician between 2020-2022 while the vertical axis shows the frequency that each clinician reported the use of a specific intra-operative technique. The pooled average frequency of reported intra-operative use across clinicians is represented by a horizontal line. Contour lines are used to show 99.8% control limits. Clinicians with points between both contours may be considered as having close to average frequency of intra-operative technique use. In contrast, clinicians with points below the lower contour line may be considered as outliers having well-below expected use. The range between contour lines is wider for clinicians who performed fewer operations to allow for more variation from the pooled average due to random factors. The contour boundaries are calculated based on the assumption that all clinicians share the same probability of using an intra-operative technique in each operation. Funnel plots have not been risk-adjusted.

CHAPTER 1: REGISTRY PARTICIPATION (2012-2022)

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 from participating by state legislation.

Since the inception of the Registry, there has been no independent record of all the hospitals and healthcare facilities in Australia that provide breast device surgery. Consequently, determining the precise denominator to calculate site participation becomes elusive. The ABDR actively monitors hospitals and site websites to stay informed about any changes in their practice. We also document site closures and site name changes that occur due to new management.

In 2022, the ABDR added an additional nine sites, comprising six private sites and three public hospitals. Another group of sites, referred to as 'contributing sites', may not have submitted data in the last twelve months but have done so in the past. These definitions differ from those previously used, particularly the definition of 'participating' as being a site that actively contributed data in 2022. This change has resulted in the number of 'participating sites' in this report being fewer than in previous years. However, we believe it provides a more accurate measure of current site participation than the previous definition.

In 2022, a total of **247 sites** were participating in the ABDR, specifically 182 (74%) private hospitals, clinics, and day surgeries, and 65 (26%) public hospitals (Figure 1.1).

FIGURE 1.1: SITE PARTICIPATION BY STATE AND SITE TYPE (2022)

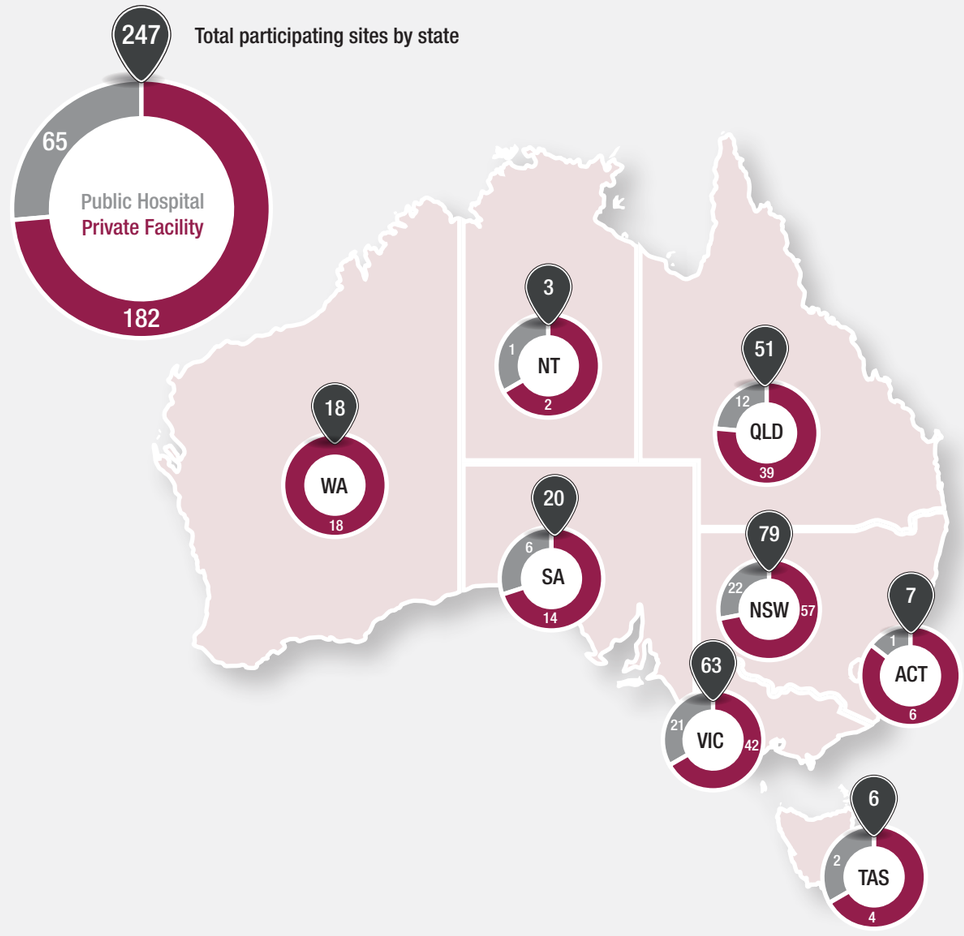


TABLE 1.1: PROCEDURE BY STATE/TERRITORY SURGERY INDICATION AND SITE TYPE (PUBLIC AND PRIVATE) (2012-2022)

Site State	Cosmetic		Reconstructive		Indication Not stated/Not known		Total	
	Private	Public	Private	Public	Private	Public	Private	Public
NSW	19,848 (30.3%)	74 (24.3%)	5,046 (25.5%)	1,610 (27.3%)	2,038 (25.8%)	191 (27.4%)	26,932 (28.9%)	1,875 (27.2%)
QLD	19,770 (30.2%)	97 (31.8%)	3,459 (17.5%)	1,350 (22.9%)	2,638 (33.5%)	176 (25.2%)	25,867 (27.8%)	1,623 (23.5%)
VIC	13,661 (20.9%)	58 (19.0%)	4,266 (21.5%)	1,683 (28.6%)	1,434 (18.2%)	176 (25.2%)	19,361 (20.8%)	1,917 (27.8%)
WA	7,824 (12.0%)	0 (0.0%)	3,398 (17.2%)	0 (0.0%)	1,215 (15.4%)	0 (0.0%)	12,437 (13.4%)	0 (0.0%)
SA	3,378 (5.2%)	50 (16.4%)	2,635 (13.3%)	890 (15.1%)	385 (4.9%)	99 (14.2%)	6,398 (6.9%)	1,039 (15.1%)
TAS	604 (0.9%)	23 (7.5%)	475 (2.4%)	171 (2.9%)	123 (1.6%)	30 (4.3%)	1,202 (1.3%)	224 (3.2%)
ACT	253 (0.4%)	3 (1.0%)	387 (2.0%)	165 (2.8%)	26 (0.3%)	23 (3.3%)	666 (0.7%)	191 (2.8%)
NT	119 (0.2%)	0 (0.0%)	131 (0.7%)	21 (0.4%)	27 (0.3%)	3 (0.4%)	277 (0.3%)	24 (0.3%)
Total, (Site type)	**65,457 (100%)**	**305 (100%)**	**19,797 (100%)**	**5,890 (100%)**	**7,886 (100%)**	**698 (100%)**	**93,140 (100%)**	**6,893 (100%)**
Total	**65,762**		**25,687**		**8,584**		**100,033**	

Note: Public hospitals in Western Australia are unable to contribute to the Registry due to state legislation. Data collection forms which have been submitted from these sites are not included in this table. Data collection forms received from these sites are no longer entered into the database.

Overall, just above 100,000 procedures were performed in 2012-2022. Approximately 8.6% of these (N=8,584) did not state the procedure indication (reconstructive or cosmetic). Of the remainder, almost 100% of cosmetic procedures were performed in private hospitals, and 77% of reconstructive procedures were also performed in private hospitals (Table 1.1).

Clinician participation

All clinicians affiliated with the three craft groups represented in the ABDR are encouraged to contribute data to the Registry. In 2022, 29 new clinicians joined the Registry. Table 1.2 represents the total number of clinicians (N=445) participating (those who have submitted at least one data collection form) with the ABDR in the year 2022, based on craft group and state/territory. Plastic surgeons are the highest contributing craft group (N=282; 63% of total). The greatest number of clinicians contributing data to the ABDR are located in New South Wales (N=150) and Victoria (N=106).

TABLE 1.2: CLINICIAN/SURGEON PARTICIPATION BY STATE AND CRAFT GROUPS (2022)

State	Plastic Surgeons	General/Breast Surgeons	Cosmetic Clinicians (associated with ACCSM)	Total
VIC	84	18	4	106
NSW	82	52	16	150
QLD	55	31	4	90
WA	27	14	4	45
SA	20	9	0	29
TAS	9	4	0	13
ACT	3	5	1	9
NT	2	1	0	3
Total	**282**	**134**	**29**	**445**

Accumulation of clinician participation

The Breast Device Registry (BDR) 2012-2015, was the pilot program that preceded the establishment of the ABDR. The pilot program included accredited sites with plastic and general/breast surgeons only. In 2015, when the ABDR became an initiative of the Department, the scope was broadened to include all medical practitioners performing breast device surgery.

FIGURE 1.2: CUMULATIVE PARTICIPATING ABDR CLINICIANS BY CRAFT GROUP

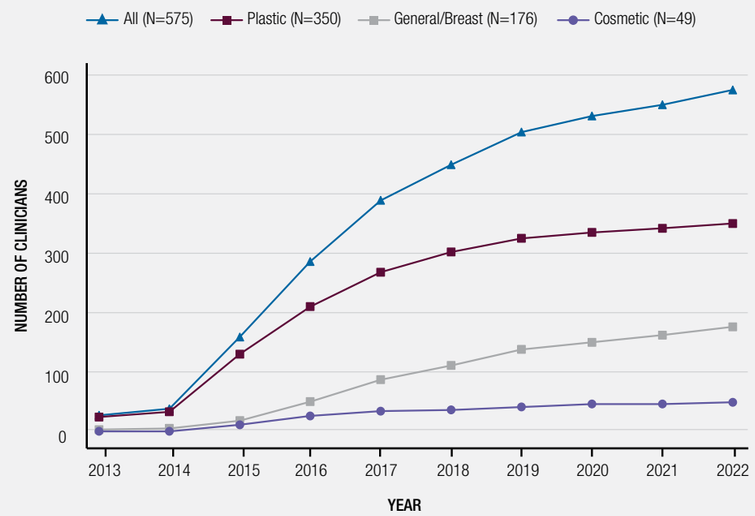


Figure 1.2 shows that in the ten years, including the time of the pilot program, there has been steady growth in the number of clinicians participating in the ABDR. The highest contributors in the last decade are plastic surgeons.

In order to gain insight into the numbers of reconstructive and cosmetic procedures undertaken by individual clinicians, Table 1.3 was developed. Of the total of 445 clinicians, 9 clinicians did not state their craft group or indication for surgery, thus 436 clinicians are captured in this data.

A majority of participating clinicians in 2022 (55%) performed both cosmetic and reconstructive procedures, with 24% performing only cosmetic procedures and 21% performing only reconstructive procedures.

Of clinicians that perform both cosmetic and reconstructive, they most commonly (52%) performed 11-50 procedures per year with 2% performing greater than 200 procedures, and 9% performing only up to 5 procedures. Of clinicians that only perform cosmetic procedures, they were more likely (43%) to perform up to 5 procedures, and only 4% undertaking more than 200 procedures per year. Of clinicians who performed reconstructive surgery, the highest proportion (62%) undertook up to five procedures per year, followed by 6-10 procedures per year.

This data highlights that the vast majority of participating ABDR clinicians (nearly 85%) undertake up to one breast device procedure per week, and as such, these are not high-volume procedures. This has implications for engagement of clinicians in the ABDR.

TABLE 1.3: RECONSTRUCTIVE AND COSMETIC PROCEDURES PER CLINICIAN (2022) (N=436)

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	4 (4%)	0 (0%)	4 (2%)
101-200	6 (6%)	0 (0%)	15 (6%)
51-100	5 (5%)	1 (1%)	33 (14%)
11-50	34 (32%)	12 (13%)	124 (52%)
6-10	11 (10%)	22 (24%)	41 (17%)
≤5	45 (43%)	57 (62%)	22 (9%)
Total	**105 (24%)**	**92 (21%)**	**239 (55%)**

Clinician and site reporting

The ABDR disseminated its fourth round of clinician reports in 2022 to 410 clinicians. All clinicians with a minimum case load who contributed data in the reporting year received an individualised clinician report regarding their ABDR outputs. Site reports were also generated for the fourth time and provided to the top 50 of sites contributing data in 2022, thus 104 site reports.

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 analyzed 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 1.2 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 or explant of an in-situ device without replacement, including both tissue expanders and breast implants.

CHAPTER 2: ABDR DATA OVERVIEW

Patient, procedures and device numbers (2012-2022)

Patients

From 2012 to 2022, the ABDR had **87,339 patients** registered, reflecting **an addition of 11,347 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 clinician 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=813 for 2015-2022) are not included in the reported figures and tables. Figure 2.1 shows the number of opt-outs per year by reason for opt-out for years 2015–2022. In order of frequency, the reasons for opting out during this period were: patients not being interested (N=398; 50.4%), having devices explanted (N=151; 19.1%), other (N=132; 16.7%), being concerned about data privacy (N=107; 13.6%) and loss of contact (N=1; 0.1%).

FIGURE 2.1: NUMBER OF OPTED-OUT PATIENTS BY REASON FOR OPT-OUT (2015-2022) (N=789)

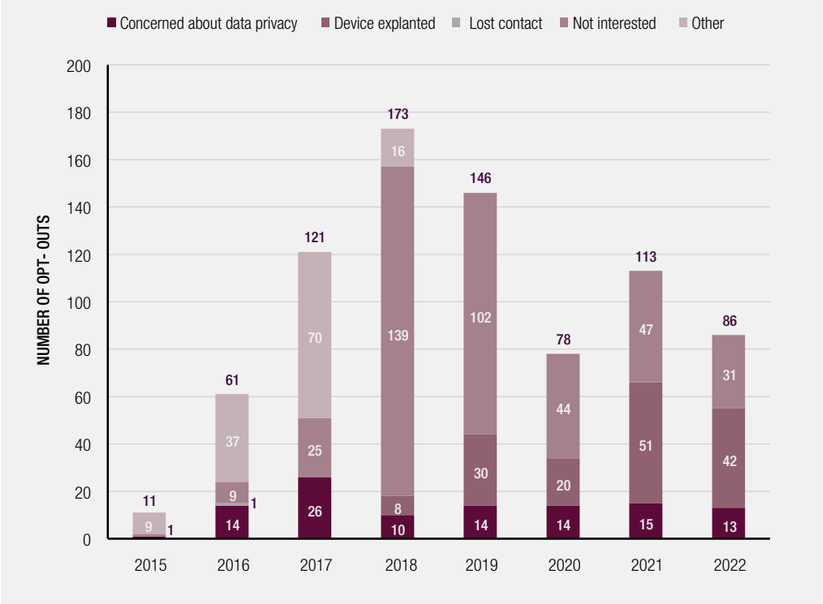
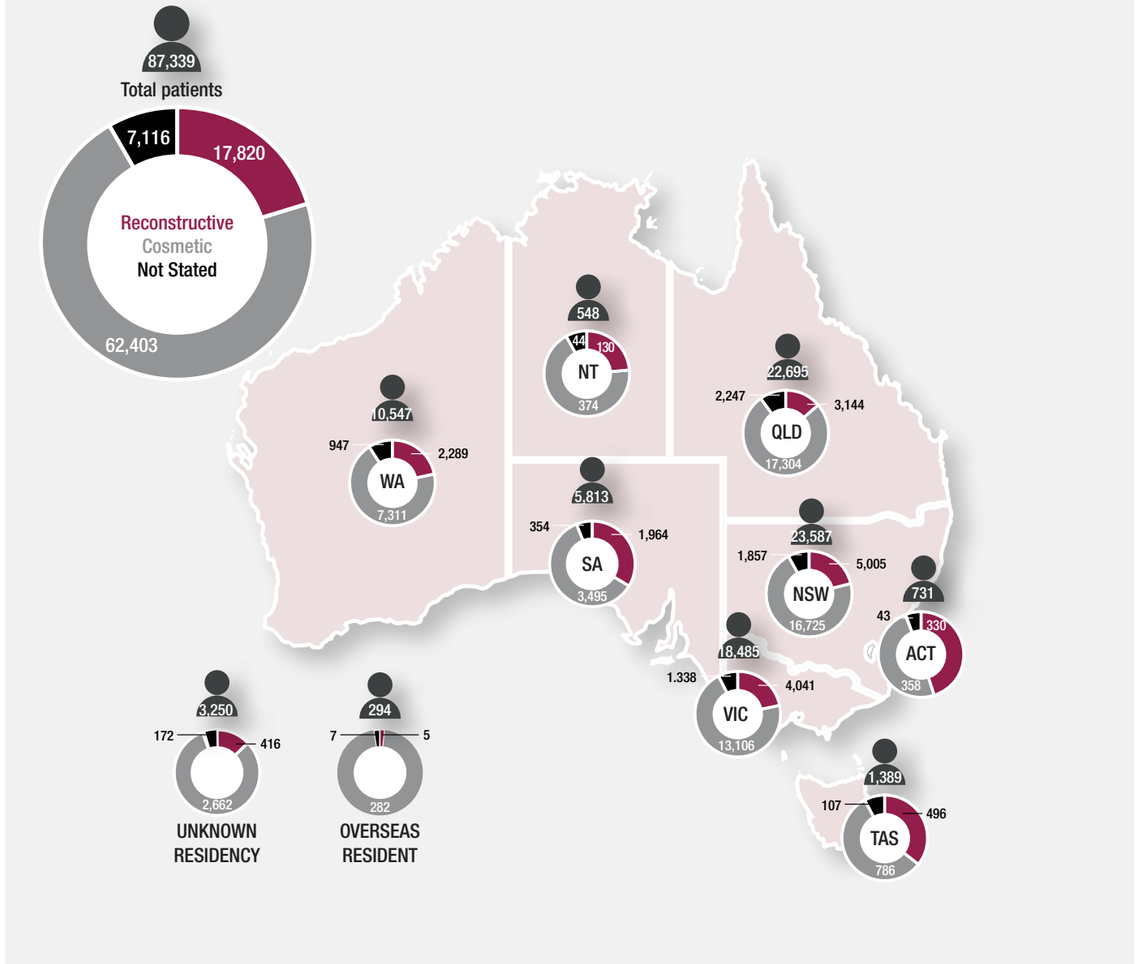


Figure 2.2 and Tables 2.1 and 2.2 present the numbers of registered patients, procedures and breast level procedures by indication of surgery for the period between 2012-2022. Patients were assigned to the indication for their first operation as recorded in the Data Collection Form submitted by their clinicians and subsequently recorded in the ABDR database. For bilateral operations with different indications in each breast, the 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.

Figure 2.2 shows the residency by state/territory of patients by surgical indication. Queensland and New South Wales have the highest proportion of patients having cosmetic procedures (27.7% and 26.8% respectively), whereas New South Wales and Victoria have the highest proportion of patients having reconstructive procedures (28.1% and 22.7% respectively).

FIGURE 2.2: PATIENT RESIDENCY BY SURGICAL INDICATION (2012-2022)



Note: N=87,339 patients. This includes 249 overseas residents and 3,250 with unknown residency. Patients with unknown residency are those who have elected email as the form of correspondence. The ABDR did not collect data on country of residency for this report.

Patients, Procedures and Devices

Of the **87,339 patients** in the ABDR, 71.4% had a cosmetic indication for surgery and 20.5% had a reconstructive indication (15.1% for post-cancer reconstruction, 3.2% for risk-reducing reconstruction, and 2.2% for correction of developmental deformity) (Table 2.1). Approximately 8% of patients did not have an indication for surgery noted on their form.

TABLE 2.1: THE TOTAL NUMBER AND PERCENTAGE OF REGISTERED PATIENTS, OPERATIONS, BREAST LEVEL PROCEDURES, AND TOTAL DEVICES CAPTURED BY CLINICAL INDICATION FOR SURGERY (2012-2022)

	Patients*		Procedures (operation level) **		Procedures (breast level) ***		Devices captured by Registry #	
	N	(%)	N	(%)	N	(%)	N	(%)
Reconstructive								
Post-cancer reconstruction	13,174	15.1%	19,533	19.5%	24,757	13.3%	23,721	13.9%
Risk-reducing reconstruction	2,768	3.2%	4,056	4.1%	11,489	6.2%	10,958	6.4%
Developmental deformity	1,878	2.2%	2,175	2.2%	3,650	2.0%	3,511	2.1%
Total reconstructive	**17,820**	**20.5%**	**25,764**	**25.8%**	**39,896**	**21.5%**	**38,190**	**22.4%**
Total cosmetic	**62,403**	**71.4%**	**65,764**	**65.7%**	**130,620**	**70.0%**	**123,977**	**72.5%**
Not stated	7,116	8.1%	8,586	8.6%	16,126	8.6%	8,925	5.2%
TOTAL	**87,339**	**100.0%**	**100,114**	**100.0%**	**186,642**	**100.0%**	**171,092**	**100.0%**

Notes: 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. For example, a unilateral procedure will increase the count by one whereas a bilateral procedure will increase the count by two.
# 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 676 device insertions from procedures reported as cosmetic but with the opposite breast reported as reconstructive.

The total number of **procedures** captured at operation level by the Registry is **100,114** indicating that some patients have more than one procedure captured by the Registry, particularly reconstructive patients who comprise of 20.5% of total patients but 25.8% of total procedures. The ABDR has recorded **186,642 procedures** at breast level, and **171,092 devices** have been captured in the Registry. 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.

A total of **11,347 patients, 13,287 procedures** and **22,022 devices** were captured in 2022 (Table 2.2).

TABLE 2.2: THE TOTAL NUMBER AND PERCENTAGE OF REGISTERED PATIENTS, OPERATIONS, BREAST LEVEL PROCEDURES, AND TOTAL DEVICES CAPTURED BY CLINICAL INDICATION FOR SURGERY (2022)

	Patients*		Procedures (operation level) **		Procedures (breast level) ***		Devices captured by Registry #	
	N	(%)	N	(%)	N	(%)	N	(%)
Reconstructive								
Post-cancer reconstruction	1,533	13.5%	2,438	18.3%	3,080	12.4%	2,864	13.0%
Risk-reducing reconstruction	279	2.5%	430	3.2%	1,307	5.2%	1,213	5.5%
Developmental deformity	204	1.8%	235	1.8%	401	1.6%	375	1.7%
Total reconstructive	**2,016**	**17.8%**	**3,103**	**23.3%**	**4,788**	**19.2%**	**4,452**	**20.2%**
Total cosmetic	**8,221**	**72.5%**	**8,831**	**66.5%**	**17,554**	**70.5%**	**16,212**	**73.6%**
Not stated	1,110	9.8%	1,353	10.2%	2,559	10.3%	1,358	6.2%
TOTAL	**11,347**	**100.0%**	**13,287**	**100.0%**	**24,901**	**100.0%**	**22,022**	**100.0%**

Notes: 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. For example, a unilateral procedure will increase the count by one whereas a bilateral procedure will increase the count by two.
# 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: concurrent mastectomy/previous radiotherapy/ procedures involving tissue expander have been moved to the "Not stated" group.
Cosmetic device count includes 61 device insertions from procedures reported as cosmetic but with the opposite breast reported as reconstructive.

Devices captured

The ABDR undertakes an annual case ascertainment of devices reported to the Registry by participating clinicians against sales data for that year provided by the Therapeutic Goods Administration (TGA). For 2022, the TGA reported sales of 28,875 devices of which 22,022 were captured by the ABDR, resulting in a **76.3% capture rate.** This is a slight increase from the reported capture rate of 73% in 2019 and 2020, and a decrease from the 2021 sales capture rate of 94% of sales, which appears to be an outlier. 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.

For the first time, the ABDR has also reviewed publicly available **Australian Institute of Health and Welfare (AIHW)** data to verify data capture. The ACHI (Australian Classification of Health Interventions) procedure codes used for this analysis mapped against ABDR operation types are shown in Figure 2.3.

FIGURE 2.3: 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

ACHI CODE

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

ACHI CODE

Block No.	Block Description
1758	Procedures involving removal or adjustment of breast prosthesis or tissue expander (note: perforrmed 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

ACHI CODE

Block No.	Block Description
1758	Procedures involving removal or adjustment of breast prosthesis or tissue expander (note: perforrmed 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

ACHI CODE

Block No.	Block Description
1758	Procedures involving removal or adjustment of breast prosthesis or tissue expander (note: perforrmed 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 a similar approximation of ABDR case ascertainment, including by procedure type.

Table 2.3 and Figure 2.4 show data capture rate by procedure type and overall for the financial years 2017-2018 to 2021-2022. Overall data capture rates have increased from 62% in 2017-2018 to a maximum of 76% in 2020-2021 and reducing slightly to 71% in 2021-2022.

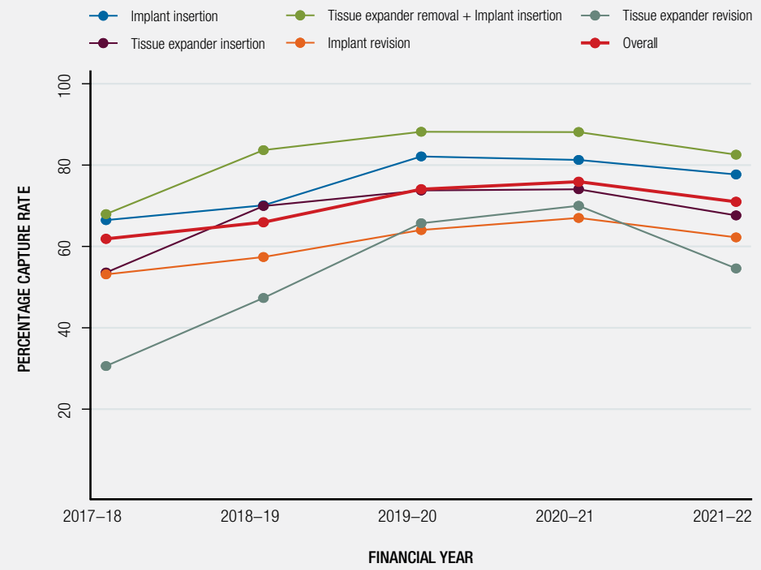
Primary implant insertion procedures have the highest rates of capture, at approximately **80%.** During 2021-2022, 83% of tissue expander removal and associated implant insertions were captured, and 83% of first implant insertions (78%) were captured. However, **tissue expander insertion** was only captured by the ABDR in 68% of cases; and implant revision, removal or replacement was only captured in 62% of cases. Further, tissue expander, revision, removal or replacement was captured by the ABDR in 55% of cases. This provides very useful information to the ABDR in providing training and feedback to clinicians in data completeness.

TABLE 2.3: CAPTURE RATE BY FINANCIAL YEAR BASED ON NUMBERS OF PROCEDURES CAPTURED BY ABDR AND AIHW (2017-2018 TO 2021-2022)

Operation Type	FY 2017-2018			FY 2018-2019			FY 2019-2020			FY 2020-2021			FY 2021-2022		
	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	17,409	26,192	66.5%	13,848	19,751	70.1%	12,229	14,891	82.1%	19,216	23,646	81.3%	14,338	18,455	77.7%
Tissue expander insertion	1,317	2,458	53.6%	1,728	2,471	69.9%	1,451	1,967	73.8%	1,478	1,996	74.0%	1,316	1,946	67.6%
Tissue expander removal and implant insertion	1,459	2,147	68.0%	1,781	2,128	83.7%	1,486	1,685	88.2%	1,423	1,615	88.1%	1,165	1,411	82.6%
Implant revision, removal, or replacement	6,181	11,633	53.1%	8,201	14,288	57.4%	8,980	14,022	64.0%	10,536	15,720	67.0%	9,093	14,611	62.2%
Tissue expander revision, removal, or replacement	112	366	30.6%	196	414	47.3%	228	347	65.7%	280	400	70.0%	208	381	54.6%
Total	**26,478**	**42,796**	**61.9%**	**25,754**	**39,052**	**65.9%**	**24,374**	**32,912**	**74.1%**	**32,933**	**43,377**	**75.9%**	**26,120**	**36,804**	**71.0%**

Note: ABDR does not capture procedures from public hospitals in WA. ABDR procedure counts are based on data available on 19 October 2023.

FIGURE 2.4: CAPTURE RATE BY FINANCIAL YEAR BASED ON NUMBERS OF PROCEDURES CAPTURED BY ABDR AND AIHW (2017-2018 TO 2021-2022)



Note: 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.

The ABDR currently records and reports data on **breast devices** including **implants** and **tissue expanders,** by procedure (at breast level) Table 2.4. Of the 186,642 procedures reported at breast level, **93.9%** relate to **breast implants** (includes initial insertions as well as device replacement procedures), and 6.1% relate to tissue expanders. While the ABDR records information regarding the use of matrix/mesh it has not previously separately analysed these devices. However as this is an area of increasing interest by clinicians and regulators, initial information regarding matrix/mesh has been included in the following section of this report.

TABLE 2.4: BREAKDOWN OF DEVICE BY PROCEDURE TYPE

Procedure Type	N	%
Implant insertion (incl. replacement)	160,481	86.0%
Implant reposition only	830	0.4%
Implant explant only	13,857	7.4%
TE inserted: (incl. replacement)	10,611	5.7%
TE reposition only	16	<0.1%
TE explant only	732	0.4%
Not known	115	0.1%
Total	**186,642**	**100.0%**

Note: Procedures involving implant insertions include those with device operation types: first implant insertion; tissue expander (TE) 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.

Devices

The following tables identify the devices captured as well as the completeness of reporting of information regarding the devices collected in the Registry from 2012-2022. Data is reported at breast level. Table 2.5 and Figure 2.5 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.

Breast implant insertions

TABLE 2.5: BREAST IMPLANTS INSERTED BY MANUFACTURER, PER BREAST (2012-2022)

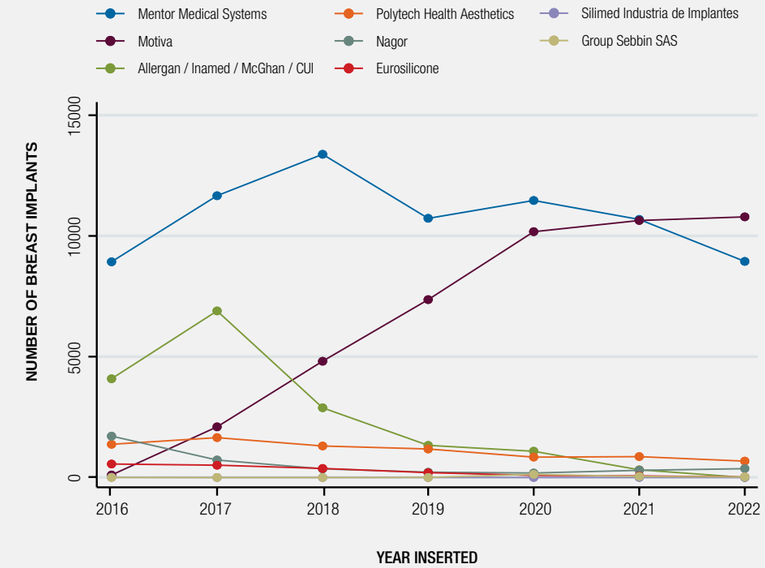
Manufacturer	N	%
Mentor Medical Systems	78,823	49.1%
Motiva	45,993	28.7%
Allergan/Inamed/McGhan/CUI	19,850	12.4%
Polytech Health & Aesthetics	8,092	5.0%
Nagor	4,719	2.9%
Eurosilicone	1,968	1.2%
Silimed Industria de Implantes	604	0.4%
Group Sebbin SAS	199	0.1%
Cereplas	44	<0.1%
Not stated	**189**	**0.1%**
Total	**160,481**	**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 2.5 provides the breakdown of **breast implants inserted** by manufacturer from any surgical indication as reported to the Registry. From 2012-2022, a total of 160,481 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% of the implants inserted.

Figure 2.5 shows the change in the number of implant devices inserted by manufacturer 2016-2022 (data collected during the pilot program 2012-2015 are omitted from this figure due to the small number of procedures reported during this time). Motiva implants were the most commonly used devices in 2022, whilst Allergan/Inamed/McGhan/CUI had fewer of its devices implanted over this time period. Of note, all Allergan macro-textured implants were withdrawn from use in Australia in 2019.

FIGURE 2.5: BREAST IMPLANTS INSERTED BY MANUFACTURER, PER BREAST (2016-2022)



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

Breast device explants from replacement procedures

The most frequently **explanted devices** from implant replacement procedures between 2012-2022 by manufacturer were: Allergan/Inamed/McGhan/CUI and Mentor Medical Systems devices which together comprised 44.3% of these devices (Table 2.6). 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 41,165 implant replacement procedures recorded in the ABDR, **63% had explant manufacturer information** reported to the Registry.

TABLE 2.6: EXPLANTED DEVICES FROM IMPLANT REPLACEMENT PROCEDURES BY MANUFACTURER (NOT INCLUDING TISSUE EXPANDERS) (2012-2022)

Manufacturer	N	%
Allergan/Inamed/McGhan/CUI	10,947	26.6%
Mentor Medical Systems	7,292	17.7%
Silimed Industria de Implantes	1,893	4.6%
Nagor	1,788	4.3%
Motiva	1,309	3.2%
Eurosilicone	869	2.1%
PIP	780	1.9%
Polytech Health & Aesthetics	717	1.7%
Dow Corning	180	0.4%
Cereplas	113	0.3%
Group Sebbin SAS	54	0.1%
LifeSil	4	0.0%
Not stated	**15,219**	**37.0%**
Total	**41,165**	**100.0%**

Note: Includes: implant revision procedures with revision type recorded as: replacement; as well as implant removal and tissue expander insertion procedures. The LifeSil implants were all inserted overseas.

Breast devices explanted

The most frequently **explanted devices from explant only procedures (of breast implants)** between 2012-2022 by manufacturer were: Allergan/Inamed/McGhan/CUI and Mentor Medical Systems devices which together comprised 51.5% of the explanted devices (Table 2.7). Of the total 13,857 explant only procedures reported to the Registry **74.8%** had manufacturer information provided.

TABLE 2.7: EXPLANTED DEVICES FROM EXPLANT ONLY PROCEDURES (NOT INCLUDING TISSUE EXPANDERS) (2012-2022)

Manufacturer	N	%
Allergan/Inamed/McGhan/CUI	4,133	29.8%
Mentor Medical Systems	3,006	21.7%
Silimed Industria de Implantes	1,064	7.7%
Nagor	748	5.4%
Eurosilicone	356	2.6%
Polytech Health & Aesthetics	282	2.0%
Motiva	280	2.0%
PIP	272	2.0%
Dow Corning	128	0.9%
Cereplas	68	0.5%
Group Sebbin SAS	25	0.2%
LifeSil	4	0.0%
Not stated	**3,491**	**25.2%**
Total	**13,857**	**100.0%**

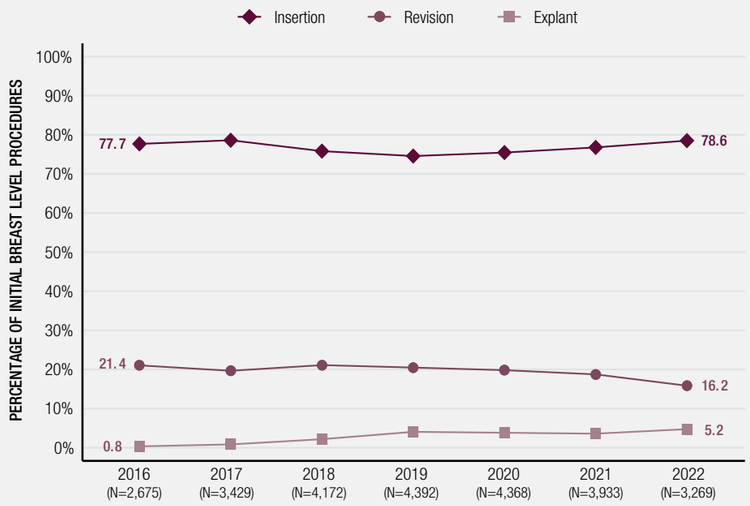
Note: Includes implant revision procedures with revision type: explant. The LifeSil implants were all inserted overseas.

Insertion, revision and explant procedures

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 2.6 and Figure 2.7. They provide 7 years of data for both reconstructive and cosmetic initial procedures at breast level. The insertion procedures in Figure 2.3 include tissue expander insertion, direct-to-implant insertion and tissue expander removal and implant insertion. The revisions include breast implant/tissue expander revisions with device replacement and reposition (not explant only procedures).

During 2022, 2,568 breasts entered the Registry with a **reconstructive insertion procedure,** 531 with a revision surgery and 170 with an explant procedure (total of 3,269 reconstructive procedures). Patients were assigned according to their first procedure as recorded by the ABDR.

FIGURE 2.6: INSERTION, REVISION AND EXPLANT PROCEDURES OVER TIME – RECONSTRUCTIVE INITIAL BREAST LEVEL PROCEDURES (2016-2022)



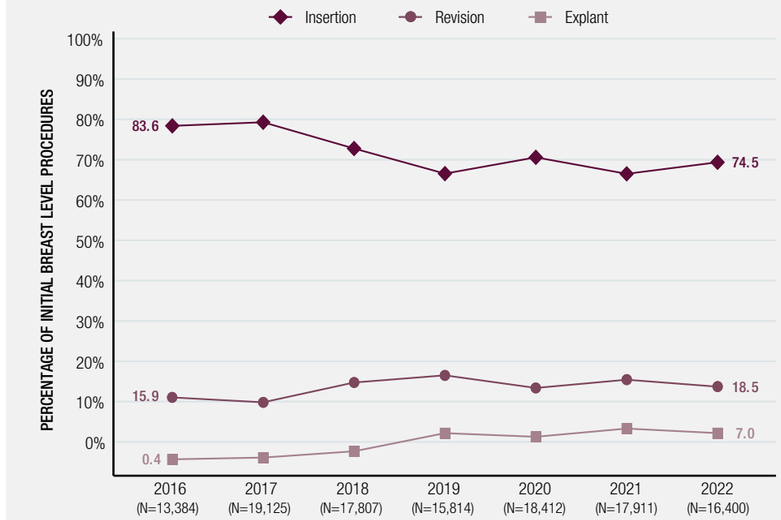
Notes: The first procedure of each breast captured by the Registry is considered as an 'initial' procedure.
Procedures with unknown procedure type (insertion, revision or explant) have been excluded.

Figure 2.6 shows the percentage of **reconstructive breast procedures** classified as device insertion, revision and explant of the procedures entering the Registry in the reporting period (2016-2022). During this time, the percentage of device insertion procedures at breast level have remained relatively stable, increasing by 0.9%, while revision procedures have decreased by 5.2%. Device explant only procedures continue to increase, from 0.8% in 2016 to 5.2% in 2022.

During 2022, 12,217 procedures at breast level entered the Registry with a **cosmetic indication procedure,** with 3,041 having a revision procedure and 1,142 having an explant procedure (total of 16,400 cosmetic procedures). Patients were assigned according to their first procedure as recorded in the ABDR.

Figure 2.7 shows the percentage of **cosmetic breast procedures** classified as insertion, revision and explant during the reporting period (2016-2022). The percentage of device insertion procedures at breast level decreased by 9.1% during this period, while revision procedures increased by 2.6%. Device explant only procedures increased from 0.4% in 2016 to 7.0% of procedures in 2022.

FIGURE 2.7 INSERTION, REVISION AND EXPLANT SURGERY OVER TIME – COSMETIC INITIAL BREAST LEVEL PROCEDURES (2016-2022)

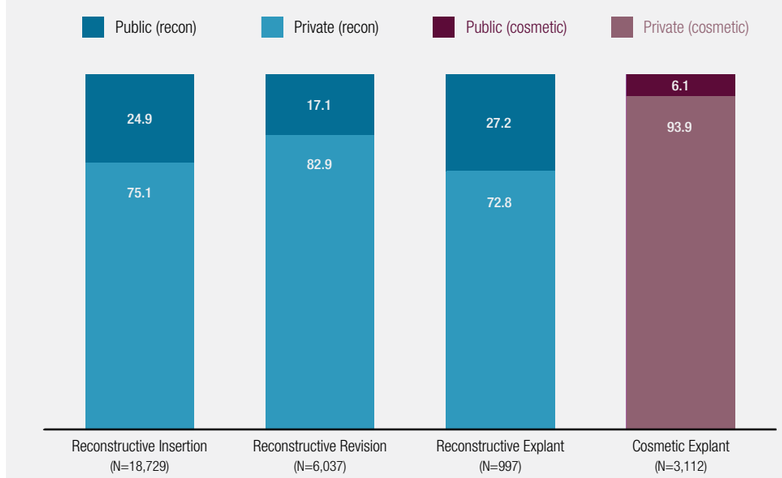


Notes: The first procedure of each breast captured by the Registry is considered as an 'initial' procedure.
Procedures with unknown procedure type (insertion, revision or explant) have not been included.

Procedures by site type

The majority of breast device procedures (operation level) recorded in the ABDR are performed in private facilities for both cosmetic or reconstructive indications for surgery (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 (82.9%), but also insertions (75.1%) and explants (72.8%). Cosmetic explants are the only cosmetic procedure that may be reimbursed and 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 (2012-2022)



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

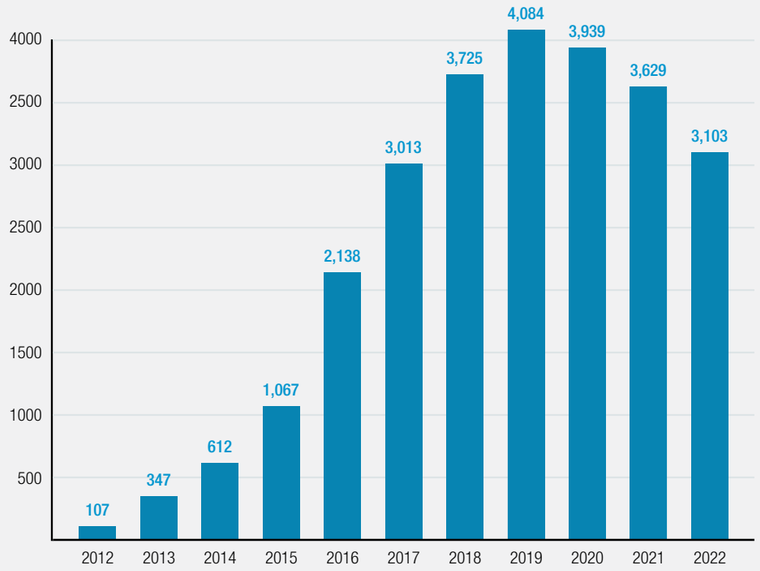
CHAPTER 3: REGISTRY OUTPUTS – RECONSTRUCTIVE INDICATIONS

Reconstructive procedure numbers and manufacturer details

The ABDR has captured a **total of 25,764 procedures** involving breast devices for reconstructive surgery, where reason for reconstruction surgery included post-cancer reconstruction, risk-reducing reconstruction and developmental deformity.

Figure 3.1 shows a rise in the annual number of reconstructive procedures captured until 2019, and then a reduction for each of 2020, 2021 and 2022. In 2022 there were **3,103 reconstructive procedures** captured by the ABDR. This decline may be due to ongoing impact from COVID-19 restrictions or may reflect a shift away from the use of breast devices in favour of other options such as fat grafting and use of autologous flaps in reconstructive procedures, or a preference to not have reconstructive surgery.

FIGURE 3.1: REGISTERED PROCEDURES – RECONSTRUCTIVE (2012-2022)



Implants used in Reconstructive Procedures

TABLE 3.1: BREAST IMPLANTS INSERTED BY MANUFACTURER – RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2012-2022)

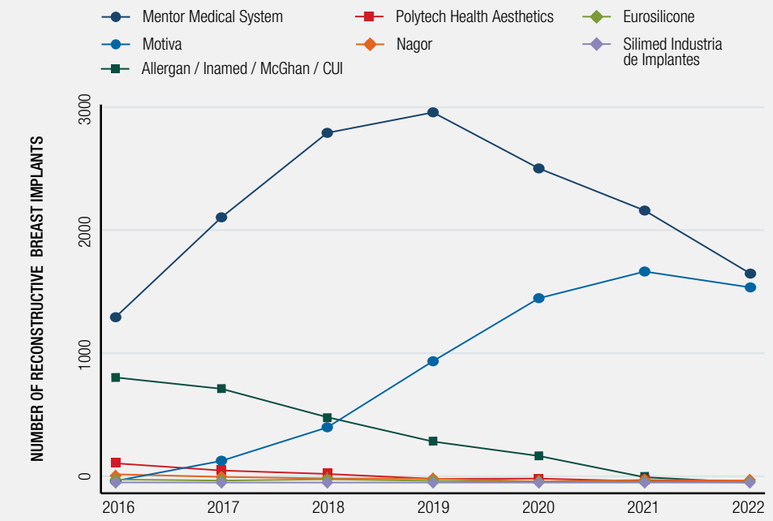
Manufacturer	N	%
Mentor Medical Systems	16,594	59.2%
Motiva	6,423	22.9%
Allergan/Inamed/McGhan/CUI	4,053	14.5%
Polytech Health & Aesthetics	423	1.5%
Nagor	278	1.0%
Eurosilicone	98	0.3%
Silimed Industria de Implantes	97	0.3%
Cereplas	11	<0.1%
Not stated	**45**	**0.2%**
Total	**28,022**	**100.0%**

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 2012-2022 a total of **28,022 breast implants were inserted** of which 99.8% had manufacturer details provided. The most frequently inserted breast implants by manufacturer were Mentor Medical Systems or Motiva, which combined comprised 82.1% of breast implants inserted.

Figure 3.2 shows the change in the **number of implant devices inserted by manufacturer 2016-2022** (data collected during the pilot program 2012-2015 are omitted from this figure due to the small number of procedures reported during this time). Mentor Medical Systems has manufactured the majority of implants used for reconstruction in the Registry, but the proportion of devices from Motiva has been 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 – RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2016-2022)



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 – RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2012-2022)

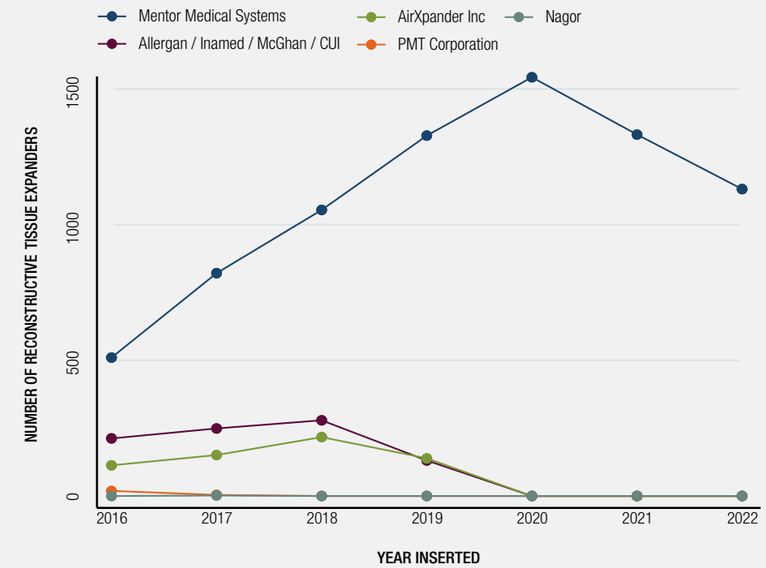
Manufacturer	N	%
Mentor Medical Systems	8,003	78.70%
Allergan/Inamed/McGhan/CUI	1,454	14.30%
AirXpander Inc	639	6.30%
PMT Corporation	35	0.30%
Silimed Industria de Implantes	10	0.10%
Nagor	2	0.00%
Not stated	**25**	**0.20%**
Total	**10,168**	**100.00%**

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=10,611 tissue expanders have been inserted overall between 2012-2022).

Table 3.2 shows the breakdown of **tissue expanders** inserted by manufacturer for reconstructive procedures as reported to the Registry. From 2012-2022 a total of 10,168 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% of tissue expanders inserted.

Figure 3.3 shows the change in the number of tissue expanders inserted by manufacturer 2016-2022 (data collected during the pilot program 2012-2015 are omitted from this figure due to the small number of procedures reported during this time). The use of Mentor Medical Systems tissue expanders is much higher than that of other manufacturers. However, there has been a decline in tissue expander use over the previous two years due to a decrease in two-stage procedures in favour of direct-to-implant procedures. Of note, Allergan tissue expanders were withdrawn in 2019.

FIGURE 3.3: TISSUE EXPANDERS INSERTED BY MANUFACTURER – RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2016-2022)



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 – RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2012-2022)

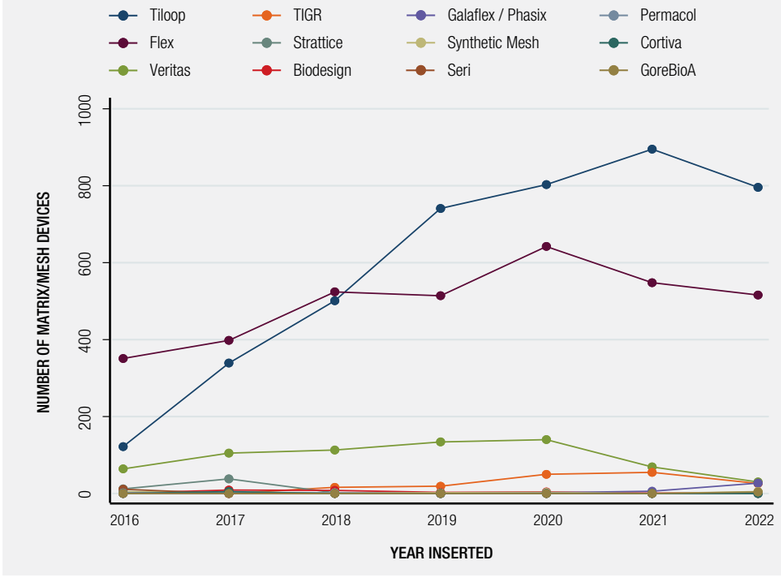
Product name	N	%
Tiloop	3,887	46.4%
Flex	3,409	40.7%
Veritas	577	6.9%
TIGR	155	1.9%
Strattice	47	0.6%
Biodesign	34	0.4%
Synthetic Mesh	23	0.3%
Galaflex/Phasix	14	0.2%
Permacol	11	0.1%
Cortiva	5	0.1%
Seri	4	0.0%
Not stated	**209**	**2.5%**
Total	**8,375**	**100.0%**

Note: Includes (breast level) procedures with reported use of matrix/mesh devices. Only breast procedures recorded as having reconstructive indication are included (N=9,131 matrix/mesh have been inserted overall between 2012-2022).

Table 3.3 shows the breakdown of matrix/mesh devices inserted by manufacturer for reconstructive procedures as reported to the Registry. From 2012-2022 a total of **8,375 matrix/mesh** were inserted of which **97.5% had manufacturer details provided.** The most common matrix/mesh devices by product group were: Tiloop, Flex and Veritas which combined comprised 94% of matrix/mesh inserted.

Figure 3.4 shows the change in number of matrix/mesh devices inserted by manufacturer 2016-2022 (data collected during the pilot program 2012-2015 are omitted from this figure due to the small number of procedures reported during this time). Since 2019 Tiloop has been the most frequently used matrix/mesh in reconstructive breast procedures.

FIGURE 3.4: MATRIX/MESH DEVICES INSERTED BY PRODUCT – RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2016-2022)



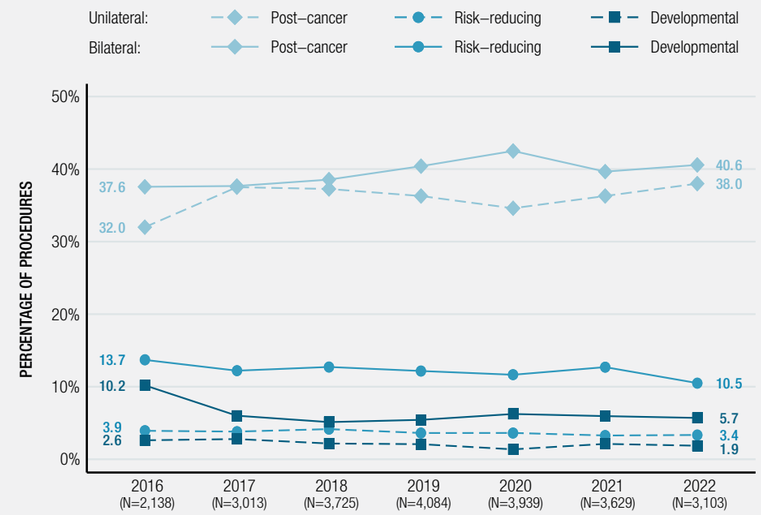
Note: Includes (breast level) procedures with reported use of matrix/mesh devices. Only breast procedures recorded as having reconstructive indication are included.

Reconstructive procedural characteristics

Bilateral and unilateral procedures

Reconstructive procedures are most commonly undertaken following mastectomy for breast cancer. Procedures may be unilateral or bilateral. In 2022, of a total of 3,103 procedures, 1,259 (40.6%) were bilateral post-cancer and 1,179 (38.0%) were unilateral post-cancer. The next most common indication is risk-reducing mastectomy, of which bilateral procedures in 2022 comprised 10.5% of total procedures. Bilateral procedures for developmental deformity comprised 5.7% of procedures in 2022. Less commonly, risk-reducing or developmental deformity reconstructive procedures are unilateral (3.4% for risk-reducing surgery and 1.9% for developmental deformity). 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 (2016-2022)

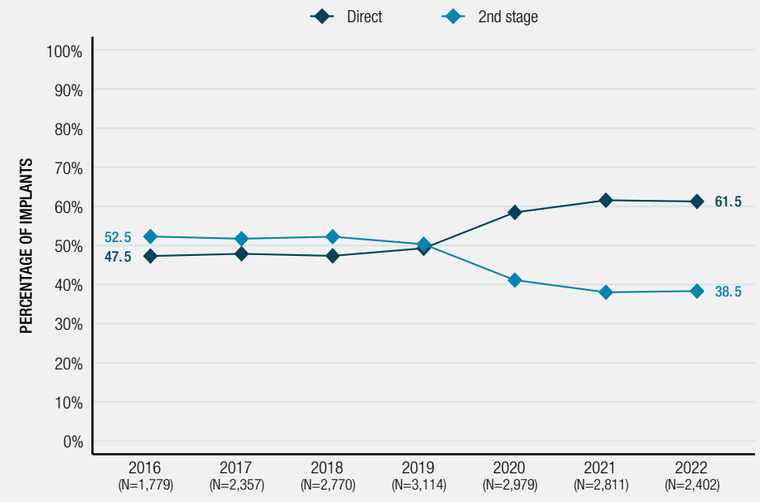


Note: A procedure indication hierarchy has been applied to bilateral procedures with different indication and procedure type details per breast. Primary reason for procedure has been applied for all patients.

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

Figure 3.6 demonstrates that the proportion of one-stage (direct-to-implant) procedures conducted has increased in use since 2019 while two-stage insertion procedures (tissue expander followed by an implant) have decreased over the same period.

FIGURE 3.6: PROPORTION OF DIRECT-TO-IMPLANT VS TWO-STAGE INSERTION PROCEDURES PERFORMED DURING (2016-2022)



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.

Patient age at reconstructive procedure

The age distribution at the time of reconstructive procedure is shown in Figure 3.7 and Table 3.4. Age differences can be seen by procedure indication and type: insertion, revision or explant.

In 2012-2022, the median patient ages for post-cancer reconstruction insertion, revision and explant procedures were approximately 50, 55 and 55 years respectively. Risk-reducing procedure patients had median ages of 42, 47 and 45 years respectively. For patients undergoing reconstruction surgery for developmental deformity the median age was 25 years for insertions, 37 for revisions and 39 years for explants.

FIGURE 3.7: AGE DISTRIBUTION AT TIME OF PROCEDURE – RECONSTRUCTIVE PROCEDURES (2012-2022)

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

TABLE 3.4: SUMMARY STATISTICS FOR AGE AT TIME OF PROCEDURE – RECONSTRUCTIVE PROCEDURES (2012-2022)

	Insertion Surgery		Revision Surgery		Explant Only	
	N	Median Age (IQR)	N	Median Age (IQR)	N	Median Age (IQR)
Post-cancer	14,578	50.2 (43.4, 57.9)	4,251	54.7 (47.5, 62.8)	703	55.3 (47.9, 63.5)
Risk-reducing	2,671	41.8 (34.7, 49.8)	1,168	47.2 (38.8, 57.1)	217	44.5 (35.9, 55.3)
Developmental	1,480	24.8 (20.4, 32.8)	618	36.5 (27.9, 46.1)	77	38.9 (30.1, 48.0)
Total	**18,729**		**6,037**		**997**	

Note: 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.
Procedures with unknown procedure type (insertion, revision or explant) have not been included.
The interquartile range reports observed patient age at the 25th and 75th percentiles.

Reconstructive procedures 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 3.5, Figures 3.8 and Figure 3.9 show the intra-operative aseptic techniques used during breast reconstruction surgery. Overall, the use of intra-operative aseptic techniques has increased during this period.

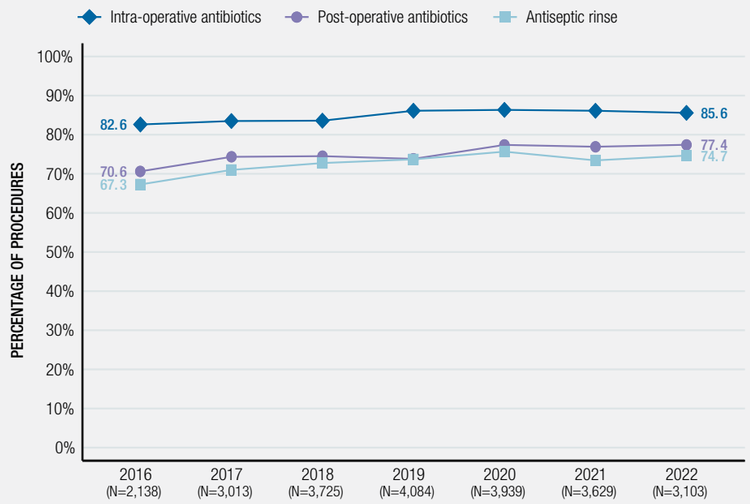
TABLE 3.5: INTRA-OPERATIVE ASEPTIC TECHNIQUES – RECONSTRUCTIVE PROCEDURES (2012-2022)

	2012-2022	
	N	(%)
Intra-op/post-op antibiotics	22,302	(86.6%)
Antiseptic rinse	18,738	(72.7%)
Not stated	3,024	(11.7%)
Total number of procedures	**25,764**	
Glove change for insertion	18,881	(76.2%)
Antibiotic dipping solution	12,267	(49.5%)
Sleeve/funnel	6,378	(25.8%)
Total number insertion/revision of procedures (not explant only)	**24,766**	

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.

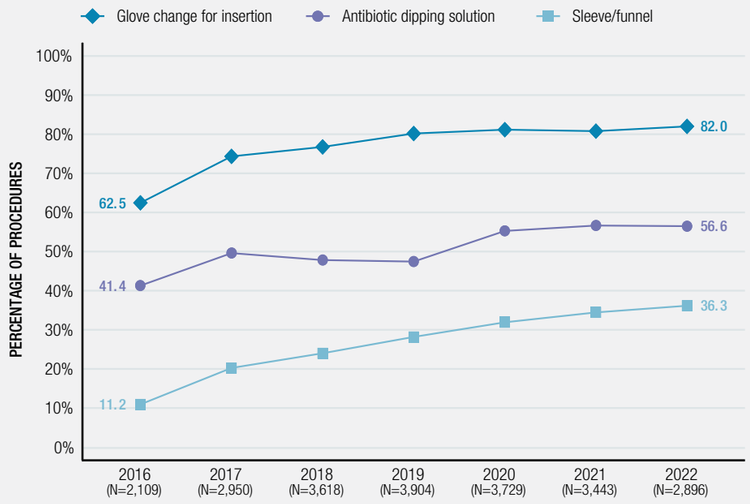
Out of the 3,103 reconstructive operations in 2022, 2,657 used intra-operative antibiotics, 2,403 used post-operative antibiotics and 2,317 involved antiseptic rinse (Figure 3.8). Out of the 2,896 reconstructive insertion and revision operations (not explant only) in 2022; 2,375 involved changing gloves for insertion, 1,369 used antibiotic dipping solution and 1,052 used a sleeve/funnel (Figure 3.9; this figure only considers insertion and revision procedures since the intra-operative techniques included here are not relevant for explant only procedures).

FIGURE 3.8: INTRA-OPERATIVE ASEPTIC TECHNIQUES RELEVANT FOR ALL RECONSTRUCTIVE PROCEDURES (2016-2022)



Notes: 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 3.9: INTRA-OPERATIVE ASEPTIC TECHNIQUES RELEVANT FOR RECONSTRUCTIVE INSERTION AND REVISION (NOT EXPLANT ONLY) PROCEDURES (2016-2022)



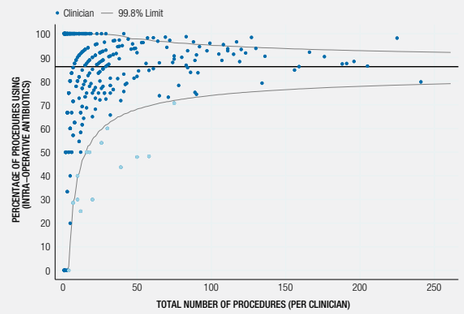
Note: A procedure indication hierarchy has been applied for bilateral procedures with different indication and procedure type details per breast.

Intra-operative aseptic techniques variation

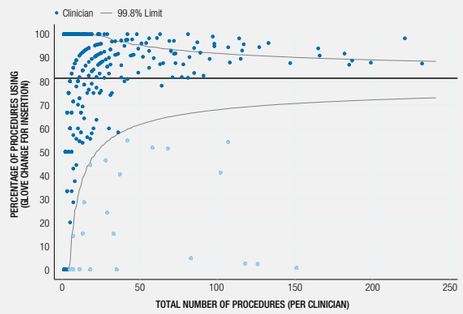
Funnel plots are used to investigate variation in clinical practice and benchmark performance. Figures 3.10 (A-F) are funnel plots for the frequency of reported use of the various intra-operative techniques by individual clinicians. In these plots, each point represents a clinician. The horizontal axis shows the number of operations conducted by each clinician between 2020-2022 while the vertical axis shows the frequency that each clinician reported the use of a specific intra-operative technique in this time period. The pooled average frequency of reported intra-operative use across clinicians is represented by the horizontal line. Contour lines are used to show 99.8% control limits. Clinicians below the lower contour line may be considered as outliers having statistically below average 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 use of antibiotic dipping solution and a sleeve/funnel.

FIGURE 3.10 (A-F): INTRA-OPERATIVE ASEPTIC TECHNIQUES VARIATION FOR RECONSTRUCTIVE PROCEDURES (OPERATION LEVEL) – FUNNEL PLOTS, COMPARING CLINICIANS (2020-2022)

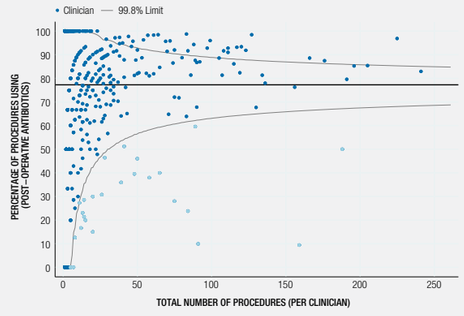
A: INTRA-OPERATIVE ANTIBIOTICS



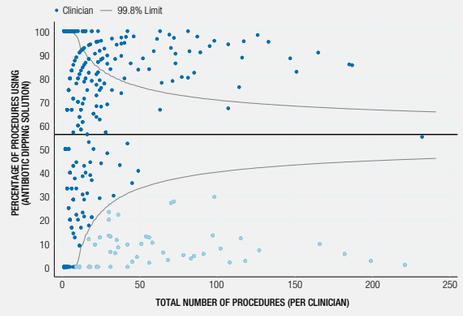
D: GLOVE CHANGE



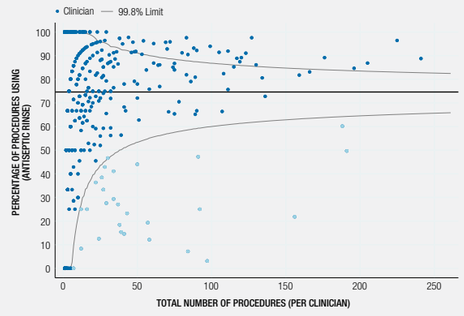
B: POST-OPERATIVE ANTIBIOTICS



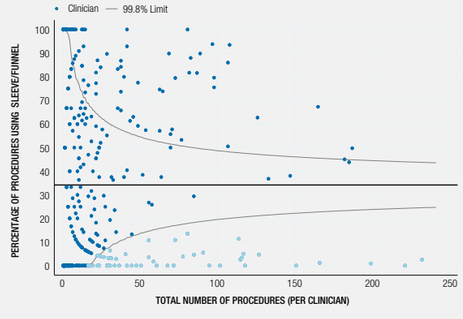
E: ANTIBIOTIC DIPPING SOLUTION



C: ANTISEPTIC RINSE



F: SLEEVE/FUNNEL



Notes A, B & C: 438 Clinicians included for reconstructive procedures.
Based on 10,671 reconstructive procedures during 2020 to 2022.

Notes D, E & F: 423 Clinicians included for reconstructive procedures.
Based on 10,068 reconstructive procedures during 2020 to 2022.
Includes insertion and revision (replacement/reposition) procedures only.

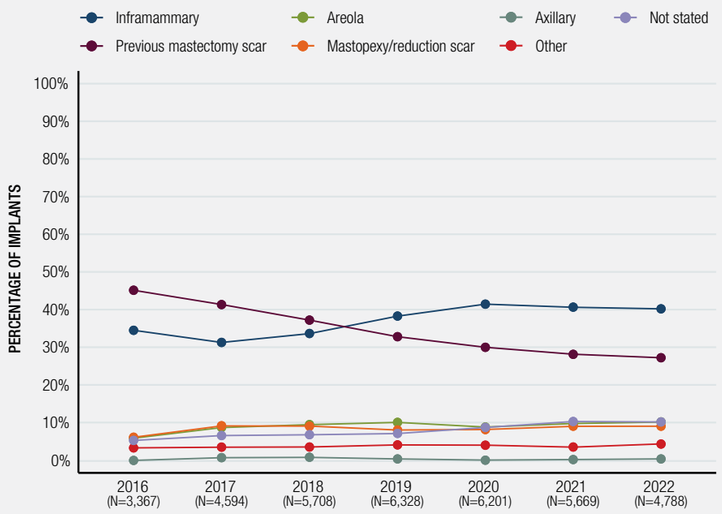
Reconstructive surgical elements

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 (2016-2022)

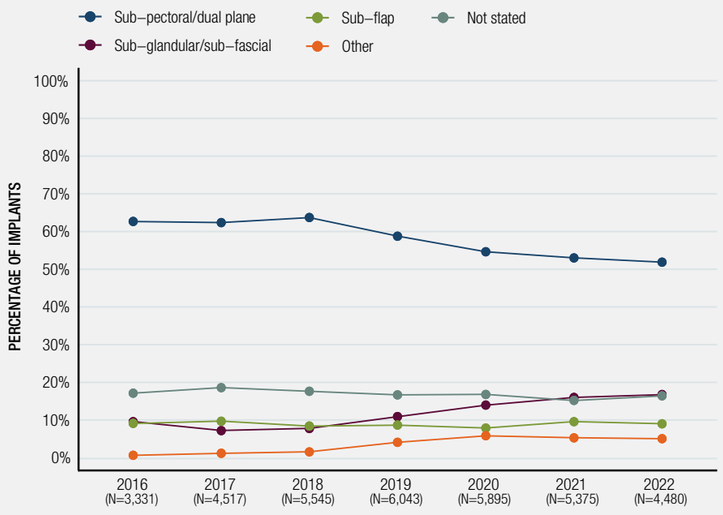


Note: Details are at the breast procedure level. More than one incision site can be recorded.

Surgical plane

The most commonly used surgical plane remains sub-pectoral, however this has reduced over the last 5 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 (2016-2022)

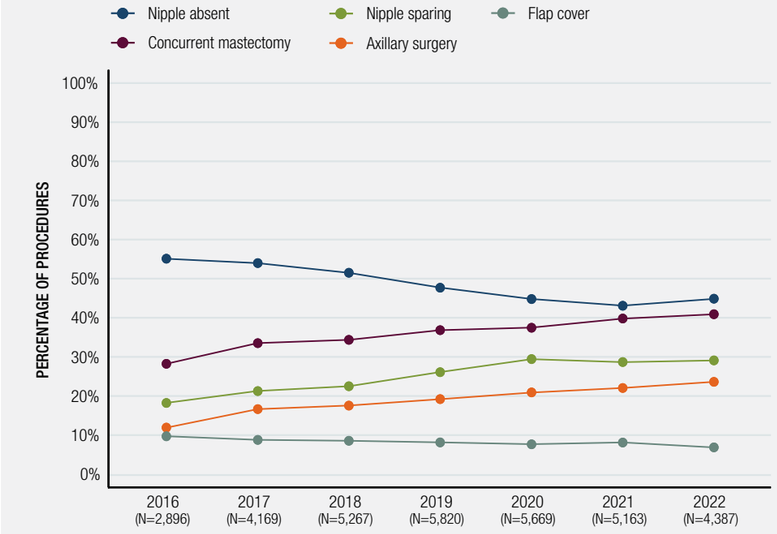


Note: Details are at the breast procedure level. Sub-glandular/sub-facial plane: includes sub-cutaneous placement after mastectomy per data reported to the Registry. Only insertion and revision procedures (which are not explant only) are included.

Other surgical elements

Over the last 7 years the ABDR notes increased frequency of concurrent mastectomy, nipple sparing surgery, and axillary surgery (Figure 3.13) for cancer related procedures.

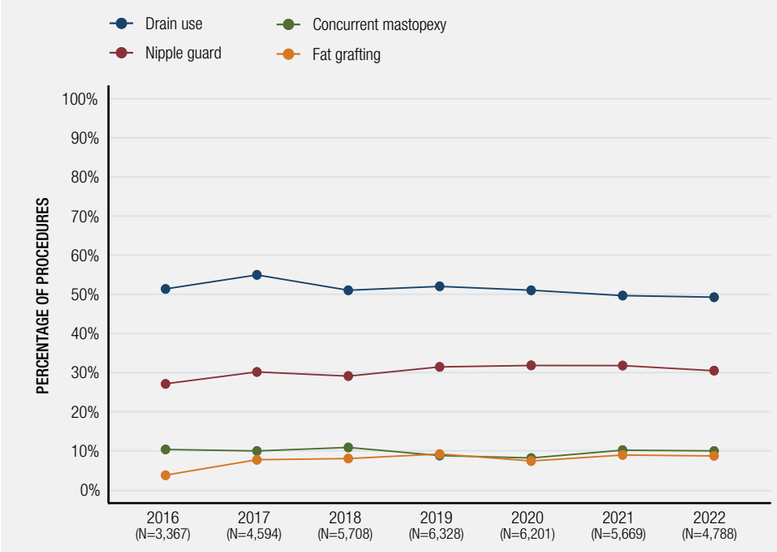
FIGURE 3.13: SURGICAL ELEMENTS RELEVANT FOR CANCER RELATED PROCEDURES – RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2016-2022)



Note: Details are at the breast procedure level. Only procedures with post-cancer or risk-reducing indication are included.

Other surgical techniques have remained relatively stable including drain use and concurrent mastopexy. The use of nipple guards and fat grafting has increased during this time (Figure 3.14).

FIGURE 3.14: OTHER SURGICAL ELEMENTS – RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2016-2022)



Note: Details are at the breast procedure level. The totals used for calculating the percentages of procedures with nipple guard exclude those where nipple absent is selected.

Device characteristics for breast reconstruction

The ABDR collects data on breast devices including breast implants, tissue expanders and matrix/mesh. Table 3.6 reports on characteristics **of implant and tissue expanders** (shell/texture, shape and fill) used for breast reconstruction during insertion, tissue expander removal and implant insertion, or implant revision including device replacement procedures.

The most common shell type is textured for both breast implants (54.4%) and tissue expanders (99.6%). Breast implants were mostly round (53.8%), whereas the vast majority of tissue expanders were shaped/anatomical (99.6%). Breast implants were mostly silicone filled (97.8%) while most tissue expanders were saline filled (93.5%). Of note, carbon dioxide is no longer used in tissue expanders although during this reporting period 6.3% were listed with this type of fill.

TABLE 3.6: DEVICE CHARACTERISTICS – RECONSTRUCTIVE BREAST DEVICES (2012-2022)

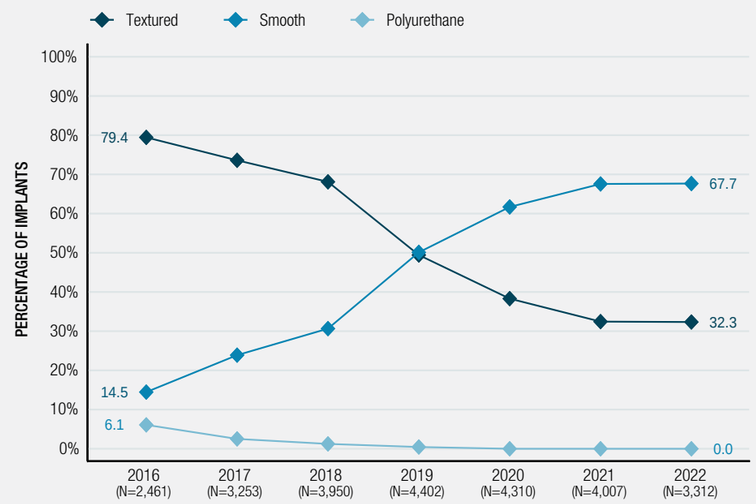
	Implant		Tissue Expander	
	N	(%)	N	(%)
Shell/Texture				
Textured	15,245	(54.4%)	10,128	(99.6%)
Smooth	12,343	(44.0%)	13	(0.1%)
Polyurethane	385	(1.4%)	0	(0.0%)
Not stated	49	(0.2%)	27	(0.3%)
Shape				
Round	15,088	(53.8%)	18	(0.2%)
Shaped/anatomical	12,885	(46.0%)	10,123	(99.6%)
Not stated	49	(0.2%)	27	(0.3%)
Fill				
Silicone	27,410	(97.8%)	0	(0.0%)
Saline	216	(0.8%)	9,502	(93.5%)
Silicone/Saline	347	(1.2%)	0	(0.0%)
Carbon dioxide	0	(0.0%)	639	(6.3%)
Not stated	49	(0.2%)	27	(0.3%)
Total	28,022		10,168	

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

Device shell

Figure 3.15 shows the **pattern of device shell used in reconstructive procedures.** Textured breast implants declined over the reporting period from 79.4% in 2016 to 32.3% in 2022. In contrast, smooth breast implants increased from 14.5% in 2016 to 67.7% in 2022. 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 implants. It was also around this time that the Registry reported fewer polyurethane breast implants and in 2022 none of these devices were reported.

FIGURE 3.15: DEVICE SHELL – RECONSTRUCTIVE IMPLANTS (2016-2022)

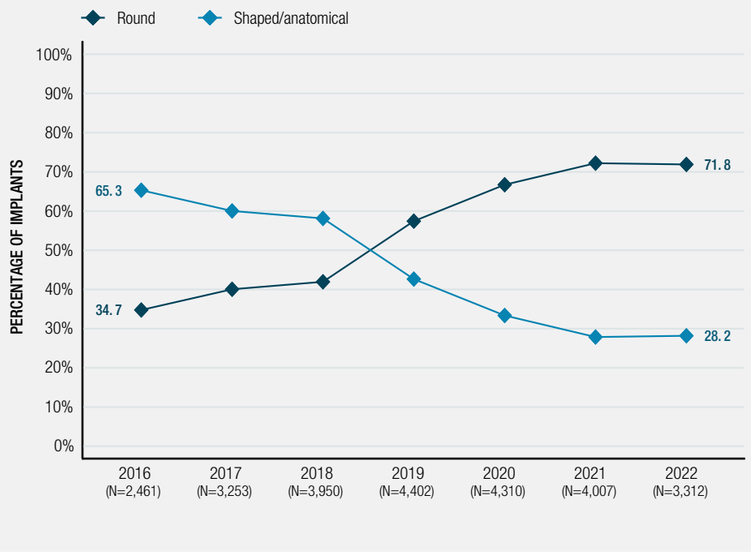


Notes: Device texture is reported for new implants during an insertion procedure or a replacement revision procedure. Implants with an unknown shell type have not been included.

Device shape

Figure 3.16 demonstrates the device shape reported to the Registry. Round breast implants increased over the reporting period 34.7% in 2016 to 71.8% in 2022. Shaped/anatomical breast implants decreased over the reporting period from 65.3% in 2016 to 28.2% in 2022. From 2019 onwards, round devices were inserted more frequently than shaped/anatomical devices. Of note, per findings reported in Figure 3.16 most smooth breast implants are round.

FIGURE 3.16: DEVICE SHAPE – RECONSTRUCTIVE IMPLANTS (2016-2022)



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 Registry 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 3.7: MATRIX/MESH USE – RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2012-2022)

	Total number of procedures (N)	Number of procedures with matrix/mesh use (N)	Proportion of procedures with matrix/mesh use (%)
Breast Implants			
Direct-to-implant insertion			
Post-cancer	4,920	2,848	57.9%
Risk-reducing	3,272	1,839	56.2%
Developmental	2,242	1	0.0%
Total	10,434	4,688	44.9%
Two-stage insertion* (2nd stage)			
Post-cancer	6,914	174	2.5%
Risk-reducing	2,390	55	2.3%
Developmental	166	0	0.0%
Total	9,470	229	2.4%
Revision (not explant)			
Post-cancer	5,179	461	8.9%
Risk-reducing	2,422	230	9.5%
Developmental	984	30	3.0%
Total	8,585	721	8.4%
Tissue Expander			
Insertion			
Post-cancer	6,463	1,861	28.8%
Risk-reducing	2,855	824	28.9%
Developmental	133	1	0.8%
Total	9,451	2,686	28.4%
Revision (not explant)			
Post-cancer	375	39	10.4%
Risk-reducing	91	12	13.2%
Developmental	1	0	0.0%
Total	467	51	10.9%
Total procedures	38,407	8,375	21.8%

Notes: Details are at the breast procedure level.
Insertion and revision procedures have been analysed independently.
Explant only and procedures with unknown procedure type (insertion, revision or explant) have not been included.
*"Two-stage" refers to use of matrix/mesh when the tissue expander is removed and implant is inserted.

Table 3.7 reports matrix/mesh use in reconstructive procedures with a breast implant or tissue expanders. It shows the proportion of breast level procedures reconstruction post-cancer that have a direct-to-implant procedure use matrix/mesh at 57.9%, with slightly fewer patients having reconstruction for risk-reducing reasons use matrix/mesh at 56.2%. The use of matrix/mesh was minimal for the second stage of a two-stage insertion procedure. In regards to tissue expanders, nearly the same number of patients have matrix/mesh for post-cancer (28.8%) as for risk reducing reasons (28.9%). In contrast matrix/mesh use was between 8.9% and 13.2% of implant and tissue expander revisions for cancer related procedures.

Primary and legacy breast devices

The Registry collects details of issues and complications arising at the time of review 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 3.8 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. The remaining implants inserted are classified as legacy. The ABDR has recorded 19,424 (69.3%) reconstructive primary breast implants and 8,598 (30.7%) legacy breast implant insertions. In total 28,022 breast implants inserted have been captured by the ABDR for reconstructive reasons.

TABLE 3.8: BREAST IMPLANT INSERTIONS BY PRIMARY/LEGACY STATUS

Breast implant insertion type	N	%
Primary	19,424	69.3%
Legacy	8,598	30.7%
Total	**28,022**	**100%**

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. The ABDR has recorded 9,166 (90.1%) primary tissue expanders and 1,002 (9.9%) legacy tissue expanders. In total 10,168 tissue expanders were inserted for reconstructive reasons. **Analysis to assess device performance-based time to event analysis uses primary devices only.**

TABLE 3.9: TISSUE EXPANDER INSERTIONS BY PRIMARY/LEGACY STATUS

Tissue expander insertion type	N	%
Primary	9,166	90.1%
Legacy	1,002	9.9%
Total	**10,168**	**100%**

Complications and revision incidence – breast implants for reconstructive procedures

TABLE 3.10: ISSUES IDENTIFIED AT REVISION PROCEDURE – RECONSTRUCTION BREAST IMPLANTS

Complications and Issues Identified at Revision (N.B. Not complication rates)	2012-2022		2022	
	N	(%)	N	(%)
Capsular contracture	3,581	(36.8%)	413	(34.2%)
Device malposition	2,765	(28.4%)	299	(24.8%)
Rupture/deflation	1,722	(17.6%)	233	(19.1%)
Skin scarring problems	684	(7.0%)	71	(5.9%)
Seroma/haematoma	409	(4.2%)	50	(4.1%)
Deep wound infection	294	(3.0%)	41	(3.4%)
Total revision procedures	**9,792**		**1,220**	

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 3.10 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 (survival) curves. The table indicates only the most common complications that are reported to the Registry.

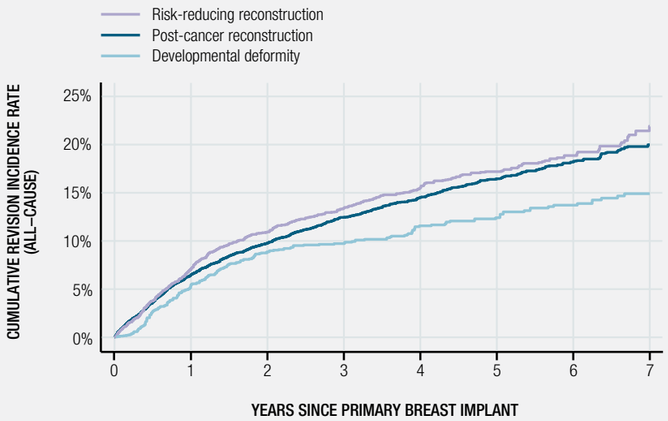
Multiple issues and complications can be reported at the time of revision surgery. They can be identified as the **reason for the revision** procedure or **found incidentally** during the revision procedure. In 2022, capsular contracture was the most common issue reported to the Registry at 34.2% of reconstructive breast implant revisions, followed by device malposition at 24.8% and device rupture/deflation at 19.1%.

Revision rates

Revision incidence by reconstructive 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 7 years after primary implant insertion is 21.9% for risk-reducing reconstruction, 20.0% for post-cancer reconstruction and 14.9% for developmental deformity (refer to Appendix 3 relating to Figures 3.17, 3.18 and 3.19).

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



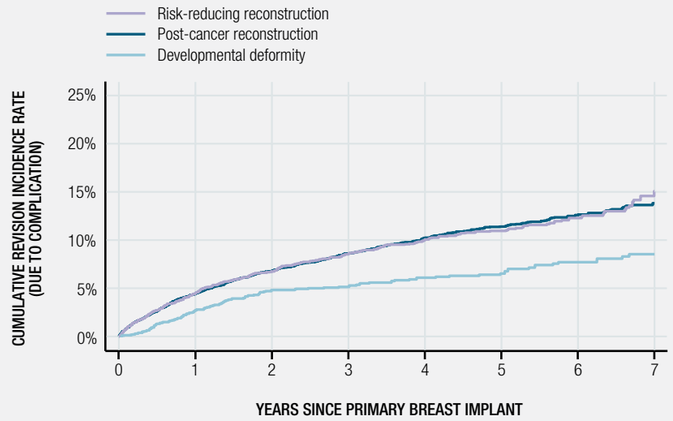
Number at risk

5,536	4,698	3,816	2,943	2,166	1,422	835	401	Risk–reducing
11,495	9,846	8,126	6,399	4,782	3,244	1,950	1,043	Post–cancer
2,393	2,104	1,735	1,349	1,078	834	600	338	Developmental

Notes: Revision incidence (all–cause) is based on reconstructive primary breast implants inserted from 2012 to 2022.
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** for the three reconstructive indications. At 7 years after the date of primary implants insertion, revision incidence due to complication was 15.1% for risk-reducing reconstruction, 13.8% for post-cancer reconstruction and 8.5% for developmental deformity.

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



Number at risk

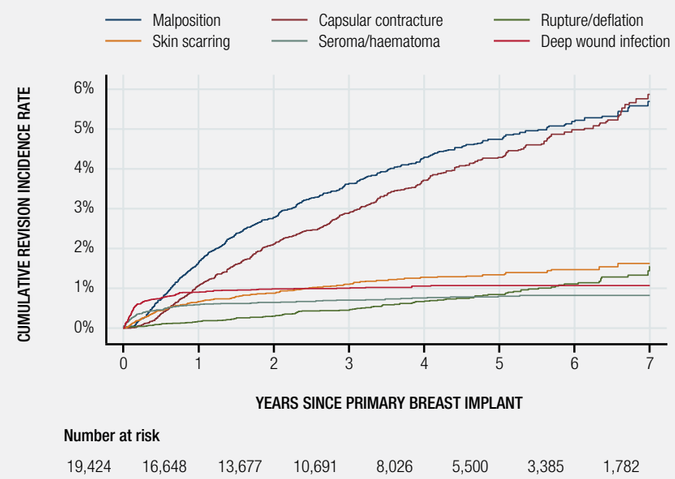
5,536	4,698	3,816	2,943	2,166	1,422	835	401	Risk–reducing
11,495	9,846	8,126	6,399	4,782	3,244	1,950	1,043	Post–cancer
2,393	2,104	1,735	1,349	1,078	834	600	338	Developmental

Notes: Revision incidence (due to complication) is based on reconstructive primary breast implants inserted from 2012 to 2022.
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 by complication type

Figure 3.19 shows the **cumulative revision incidence rates by complication type up to 7 years** after the date of primary implant insertion where ABDR data is available. It shows that over time capsular contracture and malposition have higher incidence compared to other outcomes. At 7 years post implant insertion, the revision incidence was 5.9% for capsular contracture, 5.7% for device malposition, 1.6% for skin scarring, 1.6% for device rupture/deflation, 1.1% for deep wound infection and 0.8% for seroma/haematoma.

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



Number at risk

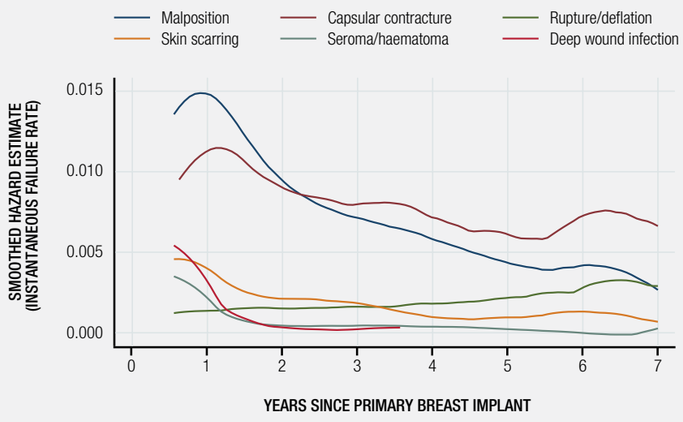
19,424	16,648	13,677	10,691	8,026	5,500	3,385	1,782

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 since the implant is inserted. Rates of revisions due to malposition and deep wound infection, in particular, appear to have distinct peak early 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. Rates of capsular contracture appear to peak early on before decreasing then increasing again in later years. Within the first 7 years post-insertion, the rates of revision due to malposition and capsular contracture appear to generally be higher than the other outcomes.

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

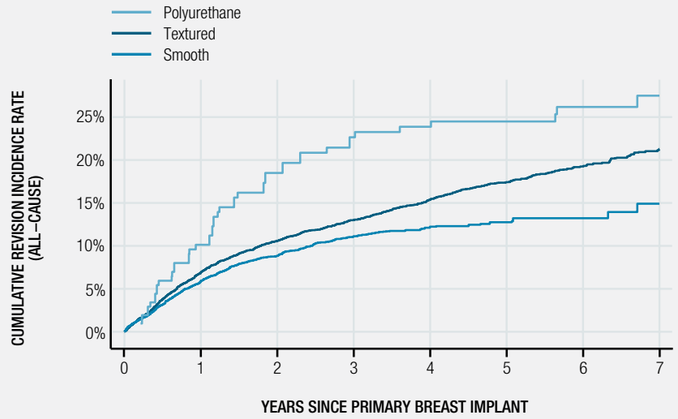


Note: Curves are truncated when smoothed estimates of hazard cannot be calculated (shortly after the start and when case numbers for the complication of interest are low). Experience of complications may not necessarily lead to a revision procedure. There may be long periods of time between when complications 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 shell characteristics. The all-cause revision incidence rate at 7 years since primary implant insertion was 27.5% for polyurethane implants, 21.3% for textured implants and 14.9% for smooth implants. The higher incidence of all-cause revisions for polyurethane implants at 7 years may be due 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



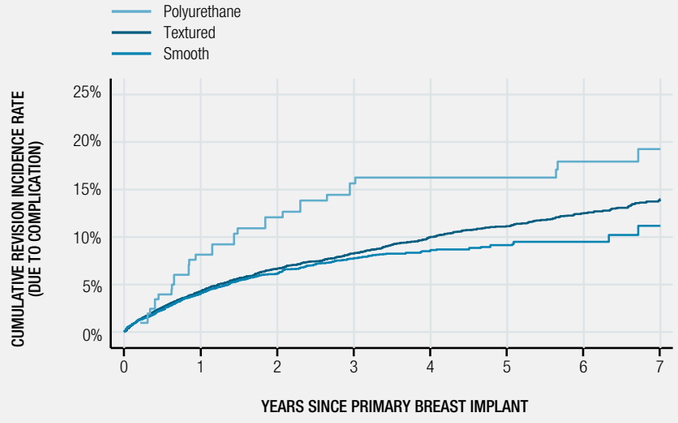
Number at risk

11,229	9,942	8,778	7,476	6,206	4,461	2,896	1,553	Textured
7,965	6,498	4,708	3,036	1,649	886	379	163	Smooth
207	186	171	164	162	146	107	63	Polyurethane

Notes: Revision incidence (all-cause) is based on reconstructive primary breast implants inserted from 2012 to 2022.
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 shell characteristics. The revision due to complication incidence rate at 7 years since primary implant insertion was 19.3% for polyurethane implants, 14.0% for textured implants and 11.2% for smooth implants. The revision incidence rates for specific complications can be found in the appendix (Appendix 4).

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



Number at risk

11,229	9,942	8,778	7,476	6,206	4,461	2,896	1,553	Textured
7,965	6,498	4,708	3,036	1,649	886	379	163	Smooth
207	186	171	164	162	146	107	63	Polyurethane

Notes: Revision incidence (due to complication) is based on reconstructive primary breast implants inserted from 2012 to 2022.
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.

Issues identified with matrix/mesh use (direct-to-implant)

The ABDR collects details of issues and complications that are found at the time of revision procedures for primary implants inserted with matrix/mesh. Revision surgery includes the unplanned replacement, reposition or explant of an in-situ breast device. The following analysis is based on **direct-to-implant** reconstructive procedures. Only breasts which enter the Registry with a direct-to-implant insertion procedure are included.

TABLE 3.11: FREQUENCY OF ISSUES IDENTIFIED AT REVISION PROCEDURE BY MATRIX/MESH USE – REVISIONS OF RECONSTRUCTIVE PRIMARY DIRECT-TO-IMPLANT PROCEDURES

Complications and issues identified at revision (N.B. Not complication rates)	Matrix/mesh use at primary implant insertion (direct-to-implant)					
	Yes		No		Not stated	
	N	(%)	N	(%)	N	(%)
Device malposition	161	(25.0%)	146	(25.3%)	14	(20.0%)
Capsular contracture	152	(23.6%)	132	(22.9%)	24	(34.3%)
Seroma/haematoma	67	(10.4%)	25	(4.3%)	10	(14.3%)
Deep wound infection	106	(16.4%)	32	(5.5%)	3	(4.3%)
Revision due to at least one of the above four complications	386	(59.5%)	275	(43.6%)	41	(58.6%)
Total revision procedures	**649**		**631**		**70**	

Note: 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. Each reported percentage applies to the proportion of total revisions with the complication of interest.

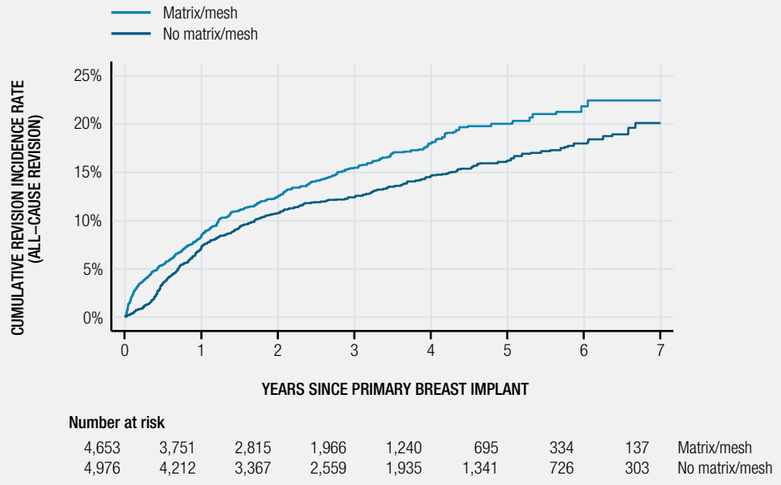
Table 3.11 reports the frequency of issues identified at revision procedures by matrix/mesh use in direct-to-implant procedures. Multiple issues can be recorded at the time of revision surgery, and issues are either identified as a reason for the revision or found incidentally during the revision procedure. 649 revisions occurred out of 4,653 primary direct-to-implant procedures with matrix/mesh used (13.9%), while 631 revisions occurred out of 4,976 procedures with no matrix/mesh used (12.7%). These proportions are similar but it should be noted that these do not account for differences in times that breasts enter the Registry. Furthermore, experience of complications may not necessarily lead to revision procedures.

Procedures that involve matrix/mesh have higher proportions of revisions associated with seroma/haematoma and deep wound infection. Proportions of device malposition and capsular contracture are similar for procedures with and without matrix/mesh.

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

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 7 years after insertion was 22.5% for the implants with matrix/mesh and 20.1% without matrix/mesh.

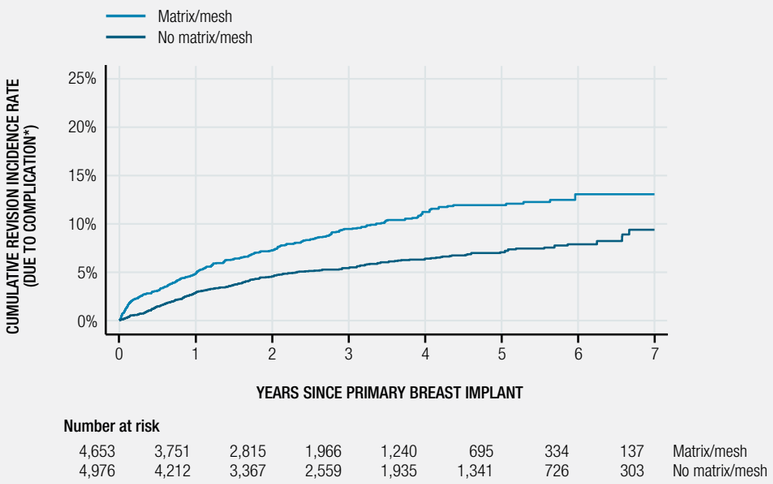
FIGURE 3.23: ALL-CAUSE REVISION INCIDENCE BY MATRIX/MESH USE – RECONSTRUCTIVE PRIMARY DIRECT-TO-IMPLANT PROCEDURES



Notes: Revision incidence (all–cause revision) is based on reconstructive primary direct-to-implant procedures beginning from 2012 to 2022.
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 7 years after insertion was 13.1% for the implants with matrix/mesh and 9.4% without matrix/mesh. The revision incidence rates for specific issues are found in the appendix (Appendix 5).

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



Notes: Revision incidence (due to complication*) is based on reconstructive primary direct-to-implant procedures beginning from 2012 to 2022.
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.

Issues identified with matrix/mesh use (two-stage procedures)

The following analysis is based on **two-stage** reconstructive procedures. Only breasts which entered the Registry with a tissue expander insertion procedure, and also have the following second stage implant insertion procedure recorded in the Registry, are included. 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).

TABLE 3.12: ISSUES IDENTIFIED AT REVISION PROCEDURE OF IMPLANTS INSERTED WITH AND WITHOUT MATRIX/MESH – RECONSTRUCTIVE TWO-STAGE PROCEDURES

Complications and issues identified at revision (N.B. Not complication rates)	Matrix/mesh use at primary tissue expander insertion					
	Yes		No		Not stated	
	N	(%)	N	(%)	N	(%)
Device malposition	67	(31.0%)	159	(26.7%)	15	(33.3%)
Capsular contracture	34	(15.7%)	133	(22.4%)	17	(37.8%)
Seroma/haematoma	16	(7.4%)	36	(6.1%)	3	(6.7%)
Deep wound infection	22	(10.2%)	48	(8.1%)	3	(6.7%)
Revision due to at least one of the above four complications	114	(52.8%)	306	(51.4%)	32	(71.1%)
Total revision procedures	**216**		**595**		**45**	

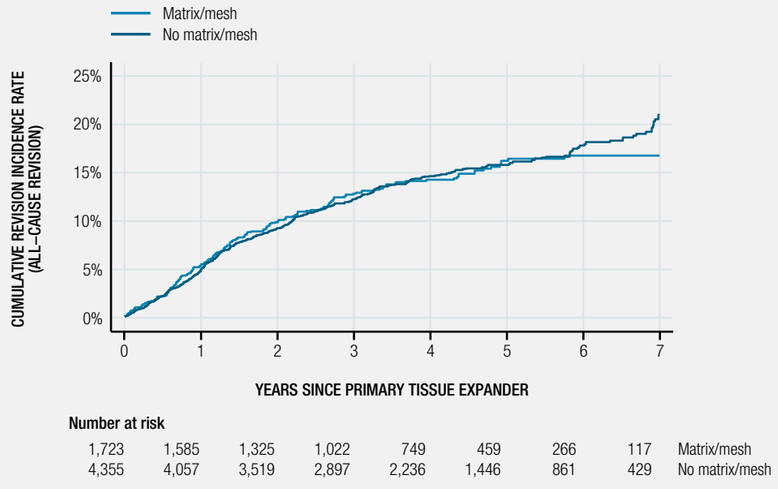
Note: Multiple issues can be recorded at the time of revision surgery and issues were either identified as a reason for revision or found incidentally during the revision procedure. The crude percentage attached to each issue identified at revision is an observational proportion that has not accounted for censoring and patient follow-up time so cannot be interpreted as a complication rate. Each reported percentage applies to the proportion of total revisions with the complication of interest.

Table 3.12 reports the frequency of **issues identified at revision** procedures by matrix/mesh use in the **first stage of primary two-stage procedures.** Multiple issues can be recorded at the time of revision surgery, and issues are either identified as a reason for the revision or found incidentally during the revision procedure. Out of 1,723 primary two-stage procedures with matrix/mesh used (in the first stage), 216 (12.5%) had a revision. Of the 4,355 primary two-stage procedures with matrix/mesh not used (in the first stage), 595 (13.7%) had a revision. Higher proportions of all complications except capsular contractures were identified in procedures that included matrix/mesh. It should be noted that these proportions do not account for differences in times that breasts enter the Registry. Furthermore, experience of complications may not necessarily lead to revision procedures.

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

The **all-cause revision incidence** 7 years after insertion was 16.7% for two-stage procedures with matrix/mesh and 21.0% without matrix/mesh. (Figure 3.25)

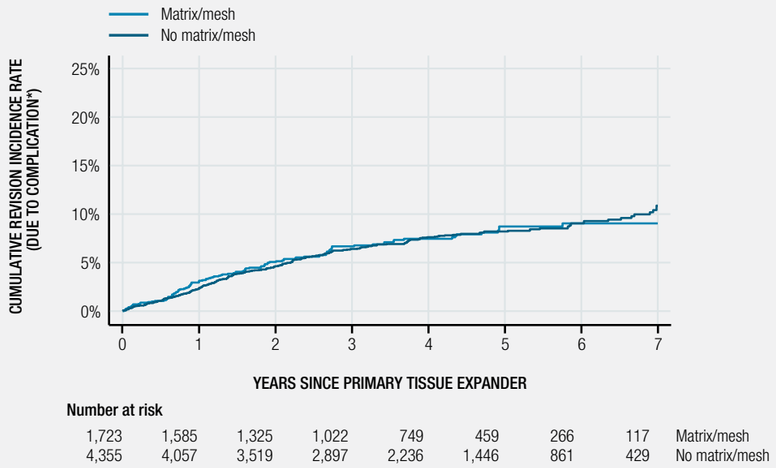
FIGURE 3.25: ALL-CAUSE REVISION INCIDENCE BY MATRIX/MESH USE – RECONSTRUCTIVE PRIMARY TWO-STAGE PROCEDURES



Notes: Revision incidence (all–cause revision) is based on reconstructive primary two-stage procedures beginning from 2012 to 2022.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from 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 7 years for two-stage procedures with matrix/mesh is 9.0% while it is 10.9% for procedures without matrix/mesh. The revision incidence rates for specific issues are found in the appendix (Appendix 6).

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



Notes: Revision incidence (due to complication*) is based on reconstructive primary two-stage procedures beginning from 2012 to 2022.
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 shows 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)	2012-2022		2022	
	N	(%)	N	(%)
Deep wound infection	164	(21.9%)	24	(19.0%)
Device rupture/deflation	145	(19.4%)	29	(23.0%)
Seroma/haematoma	105	(14.0%)	16	(12.7%)
Capsular contracture	95	(12.7%)	16	(12.7%)
Skin scarring problems	64	(8.6%)	7	(5.6%)
Device malposition	68	(9.1%)	8	(6.3%)
Total number of procedures	**748**		**126**	

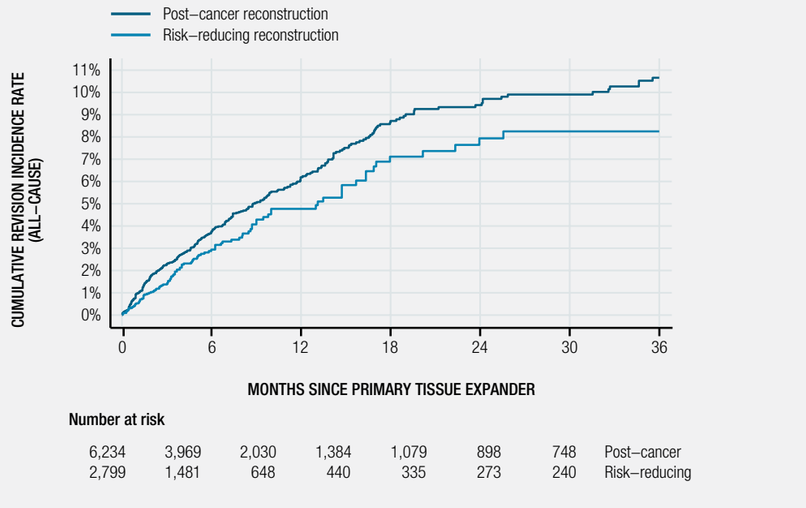
Notes: Listed in order of frequency are issues identified during unplanned reconstructive tissue expander revision procedures.
Multiple issues can be recorded at the time of revision surgery and issues were either identified as a reason for revision or found incidentally during the revision procedure.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

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 36 months because tissue expanders are only used temporarily before being replaced. In post-cancer reconstruction the cumulative revision incidence rate 36 months after insertion is 10.7%, with revision incidence for risk reducing procedures at 8.3%. 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 133 primary tissue expanders inserted for developmental deformity). Please refer to Appendix 7.

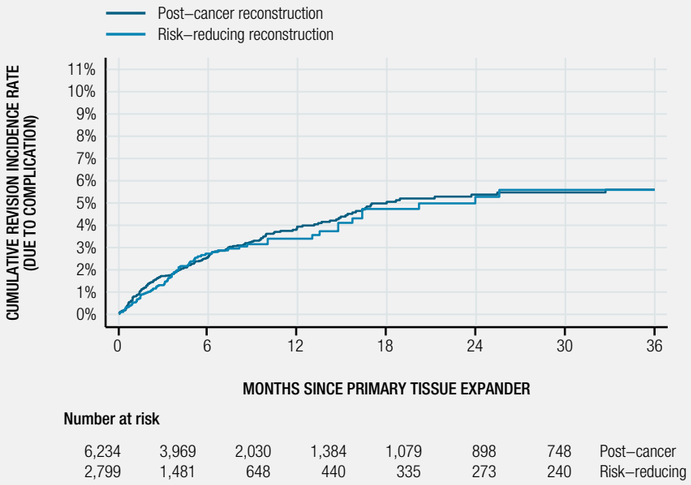
FIGURE 3.27: ALL-CAUSE REVISION INCIDENCE – PRIMARY RECONSTRUCTIVE TISSUE EXPANDERS



Notes: Revision incidence (all–cause) is based on reconstructive primary tissue expanders inserted from 2012 to 2022.
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 36 months is 5.6% for both post-cancer and 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

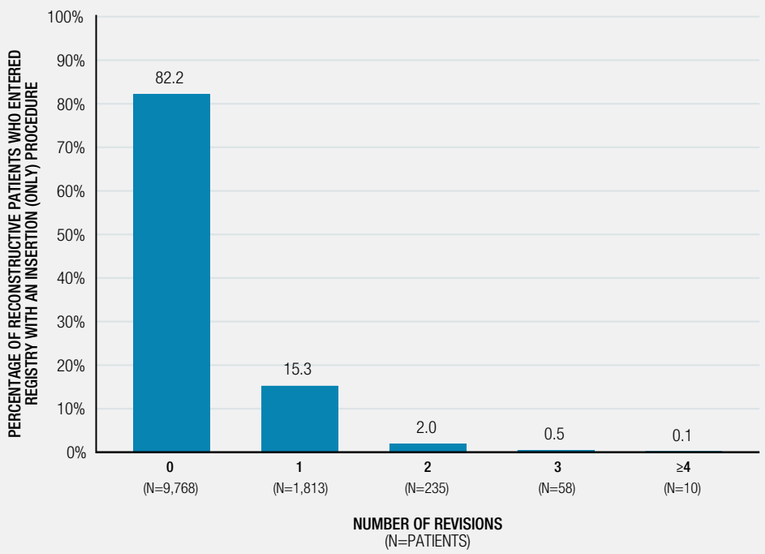
6,234	3,969	2,030	1,384	1,079	898	748	Post–cancer
2,799	1,481	648	440	335	273	240	Risk–reducing

Notes: Revision incidence (due to complication) is based on reconstructive primary tissue expanders inserted from 2012 to 2022.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary tissue expander 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

Patients may have multiple revision procedures. Figure 3.29 shows the percentages and counts of patients by the number of revisions they had. Only the 11,884 patients who entered the Registry with either tissue expander insertions or direct-to-implant insertions (at least one of which has reconstructive indication) are included. Of the 11,884 patients, 82.2% had no revisions (9,768), 15.3% had one revision (1,813), 2.0% (303) had two revisions, 0.5% had 3 revisions and 0.1% had 4 or more revisions.

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



Note: 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.

CHAPTER 4: REGISTRY OUTPUTS – COSMETIC INDICATIONS

Cosmetic procedure numbers and manufacturer details

At the end of the 2022 calendar year, the ABDR had recorded a total of **65,764** 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 2022 the total number of cosmetic procedures was **8,831.**

FIGURE 4.1: REGISTERED PROCEDURES – COSMETIC PROCEDURES (2012-2022)

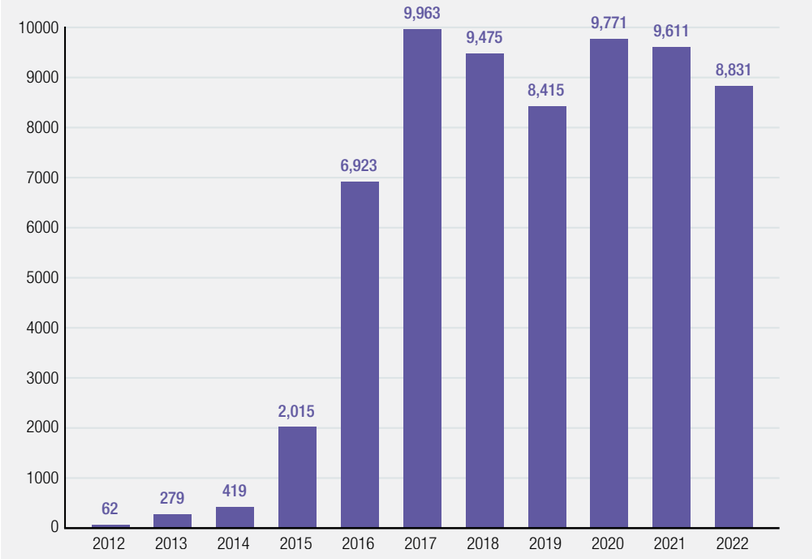


TABLE 4.1: BREAST IMPLANTS INSERTED BY MANUFACTURER – COSMETIC BREAST LEVEL PROCEDURES (2012-2022)

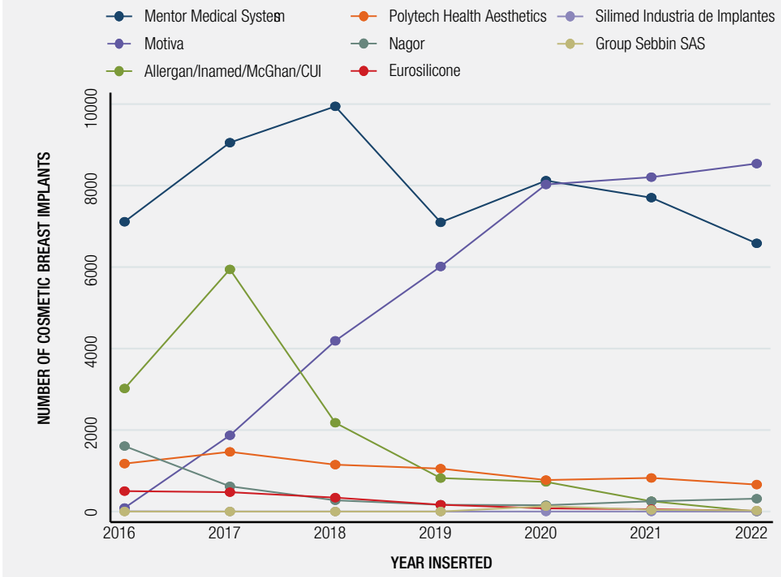
Manufacturer	N	%
Mentor Medical Systems	57,685	46.8%
Motiva	36,940	30.0%
Allergan/Inamed/McGhan/CUI	14,673	11.9%
Polytech Health & Aesthetics	7,283	5.9%
Nagor	4,143	3.4%
Eurosilicone	1,775	1.4%
Silimed Industria de Implantes	472	0.4%
Group Sebbin SAS	197	0.2%
Cereplas	26	<0.1%
Not stated	**107**	**0.1%**
Total	**123,301**	**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 2012-2022 a total of **123,301 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 almost 89% of the implants inserted.

In Figure 4.2, the number of cosmetic breast implants inserted annually between 2016-2022 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 (2016-2022)

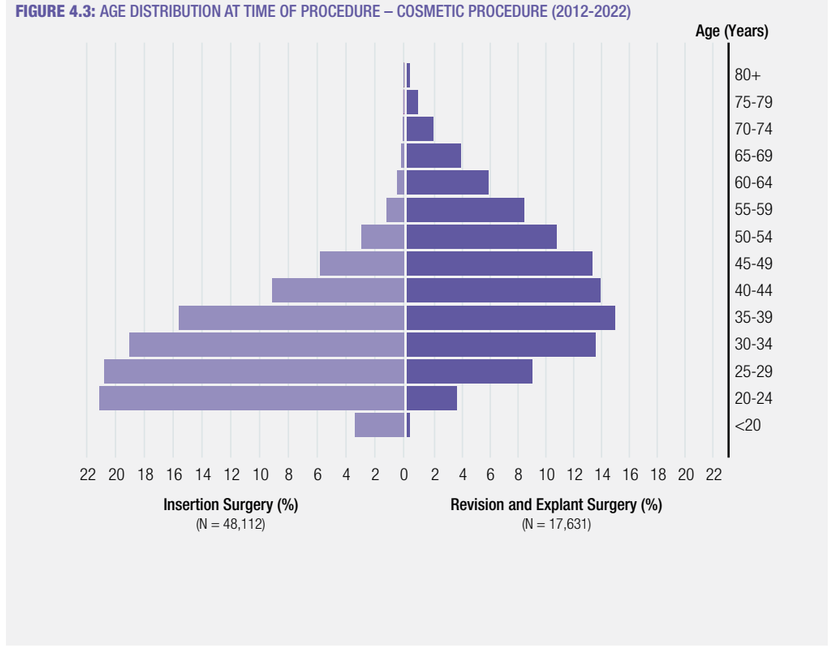


Note: Includes (breast level) procedures with device operation types: first implant insertion; implant revision –with revision type: replacement.

Patient age at cosmetic procedures

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 44 years for explant procedures. The most common age group for insertion procedures overall was the 20-24-year age group (21.2%), followed by the 25-29-year age group (20.8%). 3.4% 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 PROCEDURE (2012-2022)



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

TABLE 4.2: SUMMARY STATISTICS FOR AGE AT TIME OF COSMETIC PROCEDURES

Cosmetic	Insertion surgery	Revision surgery	Explant only
N	48,112	14,519	3,112
Median Age (Interquartile range)	31.2 (25.1, 38.2)	43.0 (34.7, 52.2)	44.0 (34.2, 56.3)

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.
Procedures with unknown procedure type (insertion, revision or explant) have not been included.
The interquartile range reports observed patient age at the 25th and 75th percentiles.

Cosmetic procedures intra-operative aseptic techniques

The ABDR reports on the following intra-operative techniques: intra-operative/post-operative antibiotics (reported together for 2012-2022 because the data fields were not collected separately until 2015), 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 during each procedure. Overall, intra-operative aseptic techniques are increasingly used in cosmetic procedures.

TABLE 4.3: INTRA-OPERATIVE ASEPTIC TECHNIQUES – COSMETIC PROCEDURES (2012-2022)

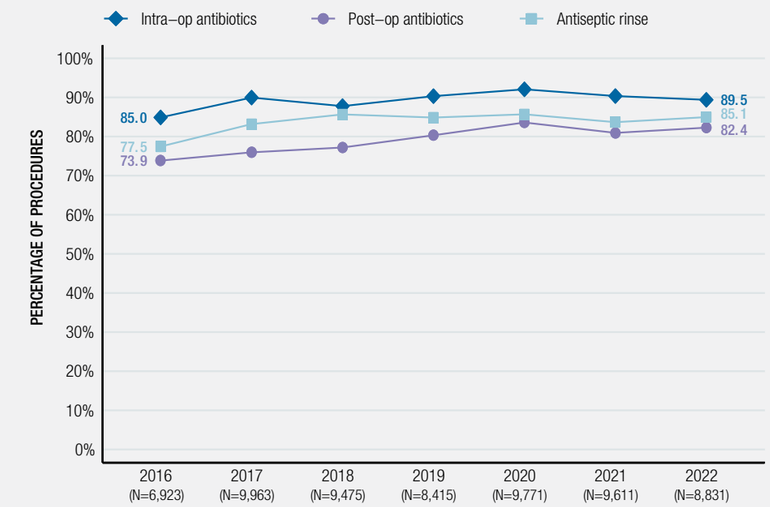
	2012-2022	
	N	(%)
Intra-op/post-op antibiotics	59,620	(90.7%)
Antiseptic rinse	55,006	(83.6%)
Not stated	4,364	(6.6%)
Total number of procedures	**65,764**	
Glove change for insertion	46,300	(73.9%)
Antibiotic dipping solution	37,937	(60.6%)
Sleeve/funnel	30,432	(48.6%)
Total number insertion/revision of procedures (not explant only)	**62,631**	

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.

Table 4.3 shows that intra-operative/post-operative antibiotics are used in 90.7% of cosmetic procedures while antiseptic rinse is used in 83.6% of these. Glove change was reported in 73.9% of cosmetic insertion/revision procedures (not explant only).

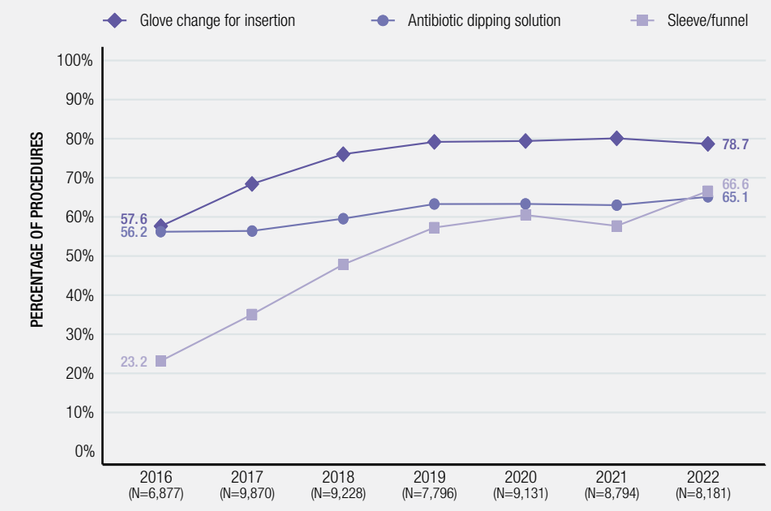
Figures 4.4 and 4.5 demonstrate that since 2016 the use of intra-operative antibiotics, antiseptic rinse, post-operative antibiotics and antibiotic dipping solution use has increased over time. Figure 4.5 only includes insertion and revision procedures since the intra-operative techniques included are not relevant for explant only procedures.

FIGURE 4.4: INTRA-OPERATIVE ASEPTIC TECHNIQUES RELEVANT FOR ALL COSMETIC PROCEDURES (2016-2022)



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 per breast.

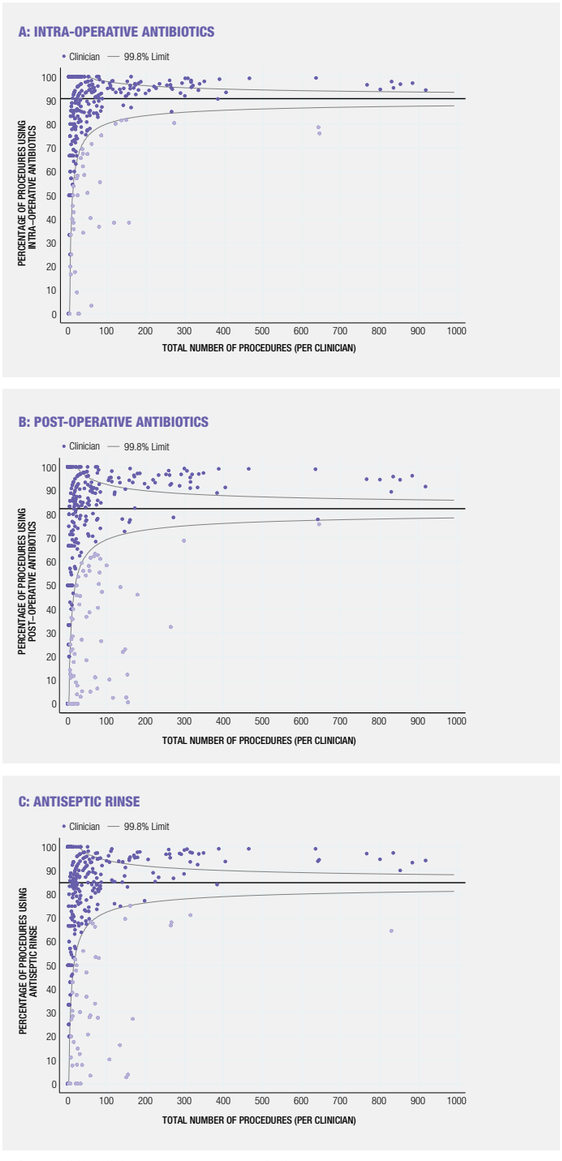
FIGURE 4.5: INTRA-OPERATIVE ASEPTIC TECHNIQUES RELEVANT FOR COSMETIC INSERTION AND REVISION (NOT EXPLANT ONLY) PROCEDURES (2016-2022)



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 per breast.

Funnel plots are used to investigate variation in clinical practice and benchmark performance. Figures 4.6 (A-F) are funnel plots for the reported use of intra-operative techniques by individual clinicians. In these plots, each point represents a clinician. The horizontal axis shows the number of procedures conducted by each clinician between 2020-2022 while the vertical axis shows the frequency that each clinician reported the use of a specific intra-operative technique in this time period. The pooled average frequency of reported intra-operative use across clinicians is represented by the horizontal line. Contour lines are used to show 99.8% control limits. Clinicians below the lower contour line may be considered as outliers having statistically below average use of an intra-operative technique. Similar to reconstructive procedures 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 use of antibiotic dipping solution and a sleeve/funnel.

FIGURE 4.6 (A-F): INTRA-OPERATIVE ASEPTIC TECHNIQUES FOR COSMETIC PROCEDURES (OPERATION LEVEL) – FUNNEL PLOTS, COMPARING CLINICIANS (2020-2022)



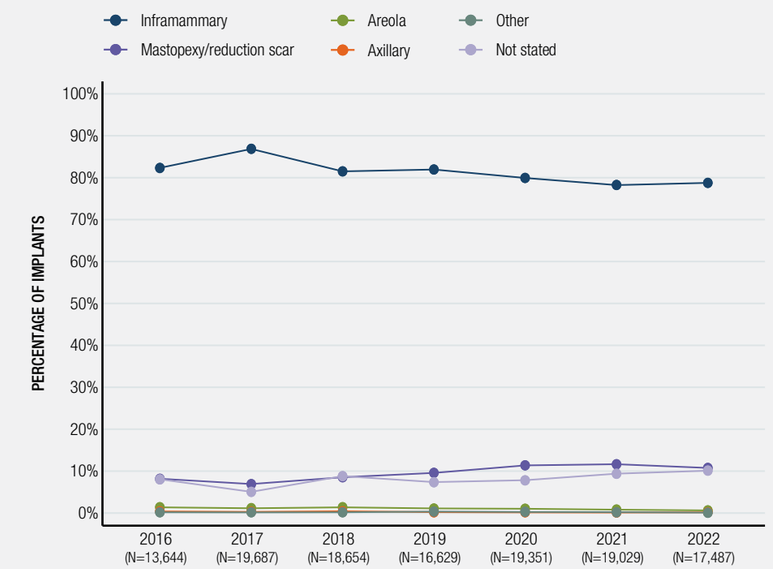
Notes A, B & C: 416 Clinicians included for reconstructive procedures.
Based on 28,213 reconstructive procedures during 2020 to 2022.

Notes D, E & F: 381 Clinicians included for reconstructive procedures.
Based on 26,106 reconstructive procedures during 2020 to 2022.
Includes insertion and revision (replacement/reposition) procedures only.

Incision sites

Approximately 80% of surgical incisions for cosmetic procedures are infra-mammary, with the most common alternative sites being mastopexy/reduction scar or not stated (Figure 4.7). Please refer to Appendix 8.

FIGURE 4.7: SURGICAL ELEMENTS – INCISION SITE – COSMETIC BREAST LEVEL PROCEDURES

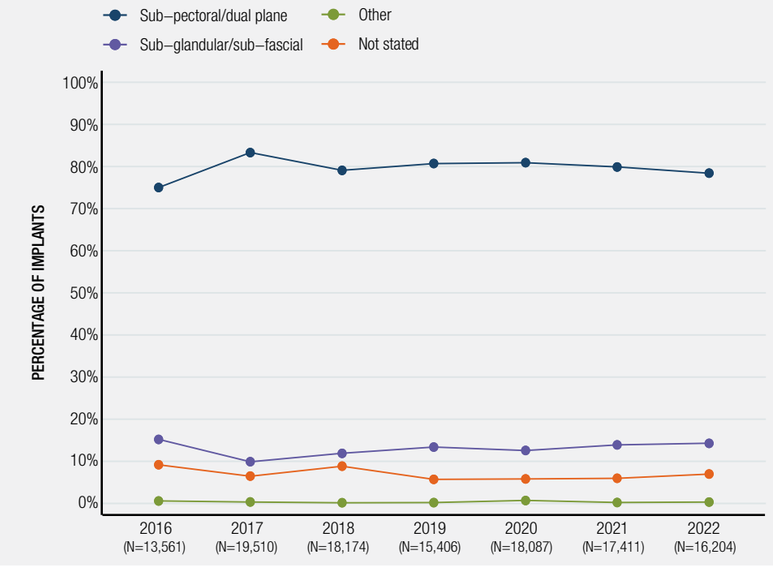


Note: Details are at the breast procedure level. More than one incision site can be recorded.

Surgical plane

Figure 4.8 demonstrates that the most common surgical plane for cosmetic procedures is the sub-pectoral/dual plane (approximately 80% in 2022), followed by the sub-glandular/sub-fascial plane (approximately 15% in 2022).

FIGURE 4.8: SURGICAL ELEMENTS – SURGICAL PLANE – COSMETIC BREAST LEVEL PROCEDURES (2016-2022)

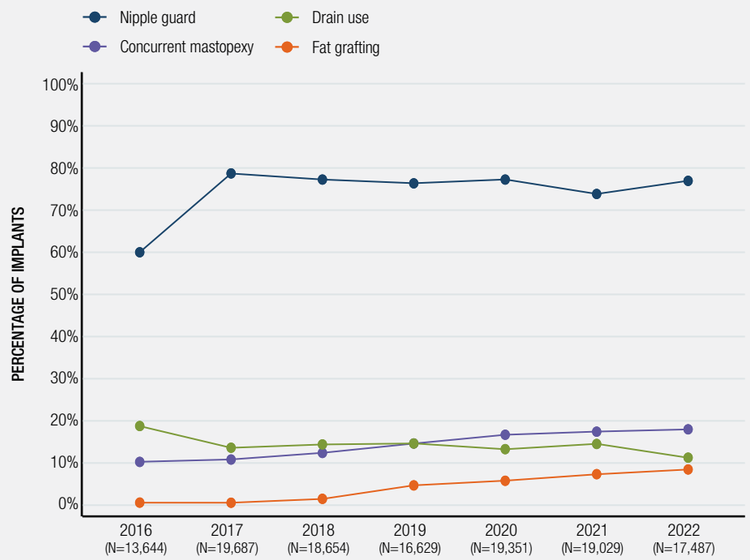


Note: Details are at the breast procedure level. Only insertion and revision procedures (which are not explant only) are included.

Other surgical elements

Figure 4.9 demonstrates that the use of a nipple guard since 2017 has been nearly 80%. Concurrent mastopexy and fat grafting have also increased during this period, however, drain use has decreased.

FIGURE 4.9: SURGICAL ELEMENTS – COSMETIC BREAST LEVEL PROCEDURES (2016-2022)



Note: Details are at the breast procedure level.

Device characteristics for cosmetic implants

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 123,301 devices used in cosmetic procedures have been recorded by the ABDR since 2012.

TABLE 4.4: DEVICE CHARACTERISTICS – COSMETIC BREAST IMPLANTS (2012-2022)

	Implant	
	N	(%)
Shell/Texture		
Smooth	60,003	(48.7%)
Textured	59,566	(48.3%)
Polyurethane	3,570	(2.9%)
Not stated	162	(0.1%)
Shape		
Round	90,826	(73.7%)
Shaped/anatomical	32,313	(26.2%)
Not stated	162	(0.1%)
Fill		
Silicone	122,189	(99.1%)
Saline	931	(0.8%)
Silicone/Saline	19	(<0.1%)
Not stated	162	(0.1%)
Total	**123,301**	

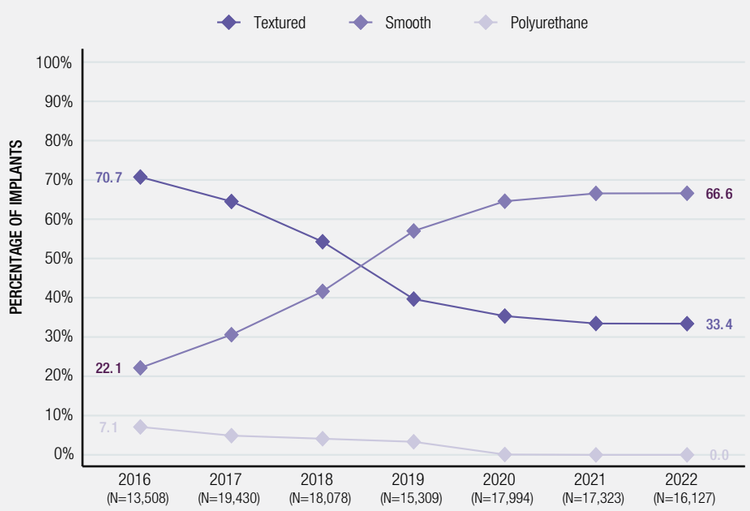
Note: Includes (breast level) procedures with device operation types: first implant insertion; implant revision – with revision type: replacement.

Table 4.4 demonstrates that for the first time since 2012, there were more smooth devices (48.7%) in the Registry compared with textured devices (43.8 in cosmetic implant insertion or replacement revision procedures). Round devices (73.7%) continue to be much more commonly used than shaped/anatomical devices. Of note, smooth devices tend to also be round shaped. The vast majority of implants have silicone fill (99.1%).

The Registry is able to show the trends in use of breast implants by shell and shape respectively over time.

Figure 4.10 demonstrates that the proportion of smooth and textured devices has plateaued over 2021-2022, with smooth devices comprising 66.6% and textured devices comprising 33.4% of total devices. Of the 16,127 cosmetic breast implants inserted in 2022, 10,741 were smooth while 5,386 were textured.

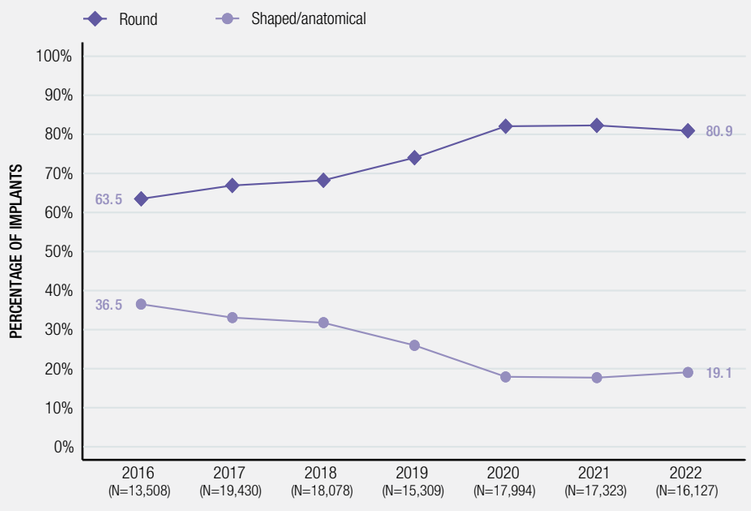
FIGURE 4.10: DEVICE SHELL – COSMETIC IMPLANTS (2016-2022)



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.

Figure 4.11 highlights the continued trends in the use of round breast implants in cosmetic surgery. Round implants have increased from approximately 64% to 80.9% in 2022 while shaped/anatomical implants decreased from approximately 36% to 19.1% in 2022. Out of the 16,127 cosmetic breast implants inserted in 2022, 13,051 were round while 3,076 were shaped/anatomical.

FIGURE 4.11: DEVICE SHAPE – COSMETIC IMPLANTS (2016-2022)



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

Complications and revision incidence – breast implants for 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 4.5: BREAST IMPLANT INSERTIONS BY PRIMARY/LEGACY STATUS

Breast implant insertion type	N	%
Primary	95,594	77.5%
Legacy	27,707	22.5%
Total	**123,301**	**100%**

Table 4.5 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 (excluding replacement of an implant) and also no recorded history of prior procedures involving implants in the Registry. The ABDR has recorded 95,594 (77.5%) **cosmetic primary breast implants** and 27,707 (22.5%) **legacy implants,** totalling 123,301 breast implants inserted for cosmetic reasons. Analysis to assess device performance based on time to event analysis i.e. revision incidence, uses **primary devices only.**

TABLE 4.6: ISSUES IDENTIFIED AT REVISION PROCEDURES – COSMETIC BREAST IMPLANTS

Complications and Issues Identified at Revision (N.B. Not complication rates)	2012-2022		2022	
	N	(%)	N	(%)
Capsular contracture	12,541	(37.1%)	1,660	(32.3%)
Device rupture/deflation	7,865	(23.2%)	1,205	(23.4%)
Device malposition	7,036	(20.8%)	916	(17.8%)
Seroma/haematoma	872	(2.6%)	67	(1.3%)
Skin scarring problems	823	(2.4%)	95	(1.8%)
Deep wound infection	214	(0.6%)	25	(0.5%)
Total number of procedures	**33,843**		**5,144**	

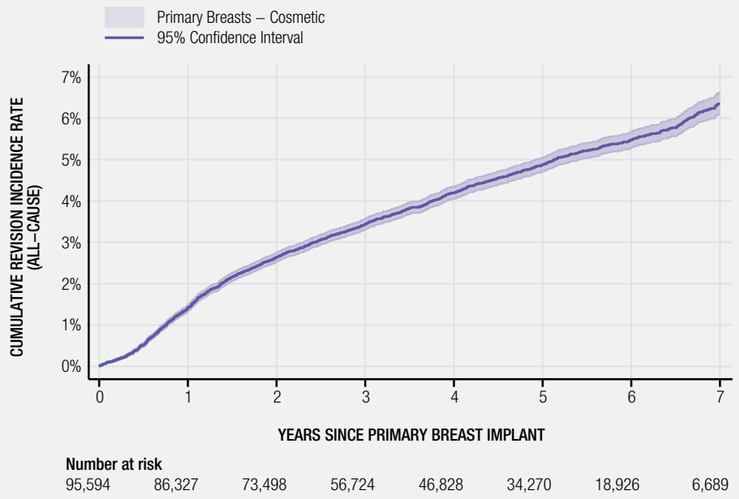
Note: Listed in order of frequency are issues identified during cosmetic breast implant revision procedures. Multiple issues can be recorded at the time of revision surgery and issues were either identified as a reason for revision or found incidentally during the revision procedure. The crude percentage 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 4.6 reports the frequency of issues identified from cosmetic breast implant revision procedures, regardless of whether or not the insertion of the initial implant was captured by the ABDR. In 2022, capsular contracture (32.3%) was reported most often as a complication or issue identified at the time of revision surgery, followed by device rupture/deflation (23.4%) and device malposition (17.8%).

Revision incidence for cosmetic procedures

Figure 4.12 and Figure 4.13 provide the **all-cause revision incidence** curve for cosmetic procedures. At 7 years after initial implant insertion, the all-cause cumulative revision incidence was 6.3% (Appendix 9).

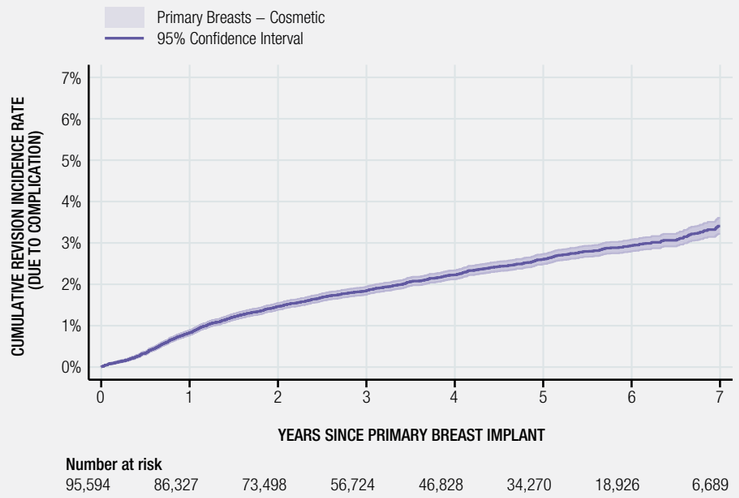
FIGURE 4.12: ALL-CAUSE REVISION INCIDENCE – COSMETIC PRIMARY BREAST IMPLANTS



Notes: Revision incidence (all-cause) is based on reconstructive primary breast implants inserted from 2012 to 2022.
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 7 years after insertion the **revision** incidence due to **complication** was 3.4% (Figure 4.13).

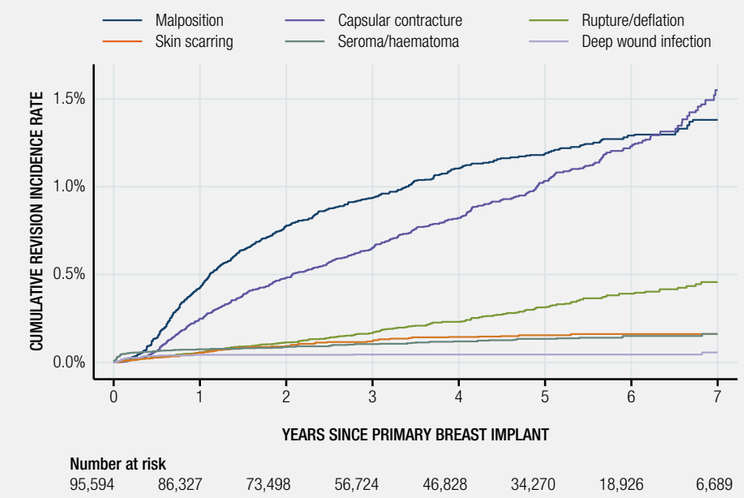
FIGURE 4.13: REVISION INCIDENCE DUE TO COMPLICATION – COSMETIC PRIMARY BREAST IMPLANTS



Notes: Revision incidence (due to complication) is based on reconstructive primary breast implants inserted from 2012 to 2022.
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 4.14 shows the cumulative revision incidence rates by type of complication up to 7 years after the date of primary implant insertion. At 7 years post implant insertion, the revision incidence was 1.6% for capsular contracture, 1.4% for device malposition, 0.5% for rupture/deflation, 0.2% for seroma/haematoma, 0.2% for skin scarring and 0.1% for deep wound infection.

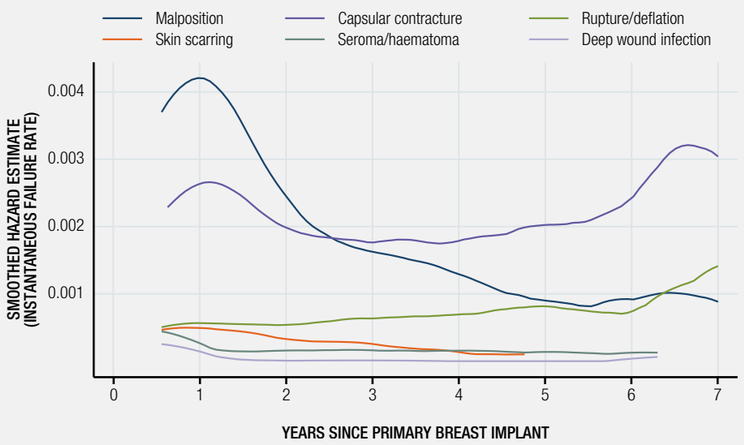
FIGURE 4.14: CUMULATIVE REVISION INCIDENCE RATE BY COMPLICATION TYPE – COSMETIC PRIMARY BREAST IMPLANTS



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.

Hazard estimates over time for each type of complication are shown in Figure 4.15 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 more 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 7 years post-insertion in general.

FIGURE 4.15: HAZARD BY COMPLICATION TYPE – REVISIONS OF COSMETIC PRIMARY BREAST IMPLANTS

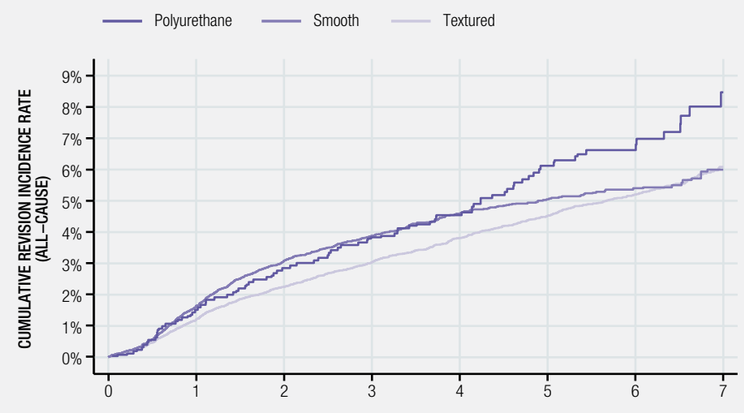


Note: Curves are truncated when smoothed estimates of hazard cannot be calculated (shortly after the start and when case numbers for the complication of interest are low). Experience of complications may not necessarily lead to a revision procedure. There may be long periods of time between when complications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

Revision incidence by device characteristics

Figure 4.16 provides the **all-cause revision incidence by device shell** type for primary cosmetic breast implants. The device revision incidence is on a common trajectory up to the first four years but after this the revision incidence for polyurethane devices increases significantly. The all-cause cumulative revision incidence at 7 years post insertion was 8.5% for polyurethane, 6.1% for textured and 6.0% for smooth implants.

FIGURE 4.16: ALL-CAUSE REVISION INCIDENCE BY SHELL – COSMETIC PRIMARY BREAST IMPLANT



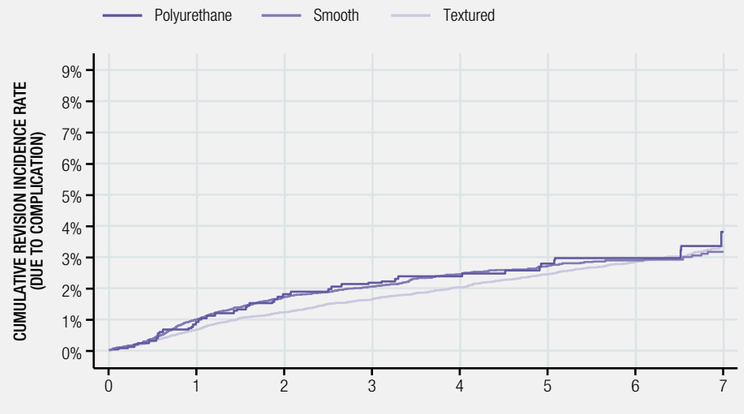
Number at risk

49,283	45,804	40,906	34,705	30,414	23,758	13,643	4,975	Textured
43,688	37,953	30,079	19,546	14,131	8,745	4,163	1,288	Smooth
2,525	2,487	2,452	2,428	2,265	1,758	1,111	421	Polyurethane

Notes: Revision incidence (all-cause) is based on reconstructive primary breast implants inserted from 2012 to 2022.
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 4.17 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 7 years post insertion was 3.8% for polyurethane, 3.3% for textured and 3.2% for smooth implants (Appendix 10).

FIGURE 4.17: REVISION INCIDENCE DUE TO COMPLICATION BY SHELL – COSMETIC PRIMARY BREAST IMPLANTS



Number at risk

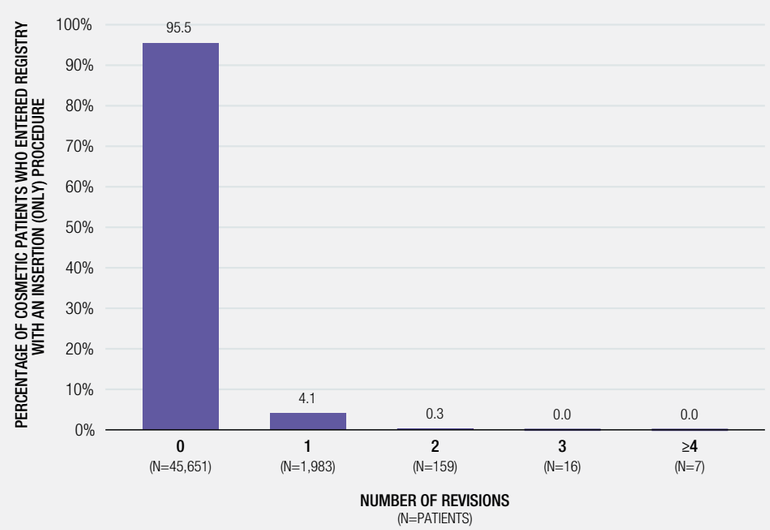
49,283	45,804	40,906	34,705	30,414	23,758	13,643	4,975	Textured
43,688	37,953	30,079	19,546	14,131	8,745	4,163	1,288	Smooth
2,525	2,487	2,452	2,428	2,265	1,758	1,111	421	Polyurethane

Notes: Revision incidence (due to complication) is based on reconstructive primary breast implants inserted from 2012 to 2022.
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.

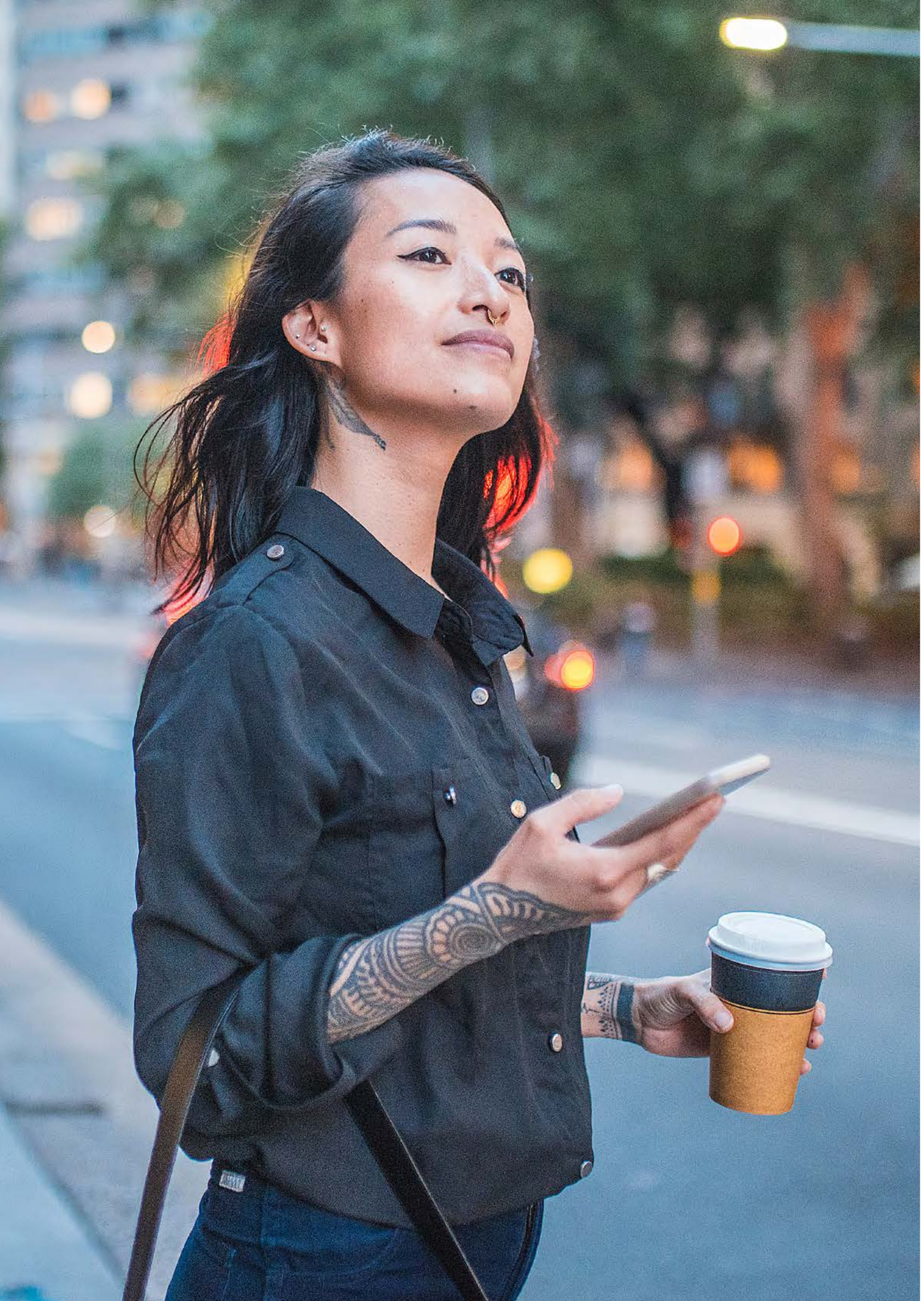
Multiple revision procedures

Figure 4.18 shows the percentages and counts of patients by the number of revisions they had. Only the 47,816 patients who enter the Registry with cosmetic insertions are included (since those entering the Registry with other procedures may have had prior revisions that were not possible to capture). Out of the 47,816 patients considered, 95.5% had no revisions (45,651) while 4.1% had one revision (1,983), and 0.3% had two revisions (182).

FIGURE 4.18: 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.



CHAPTER 5: REGISTRY OUTCOMES

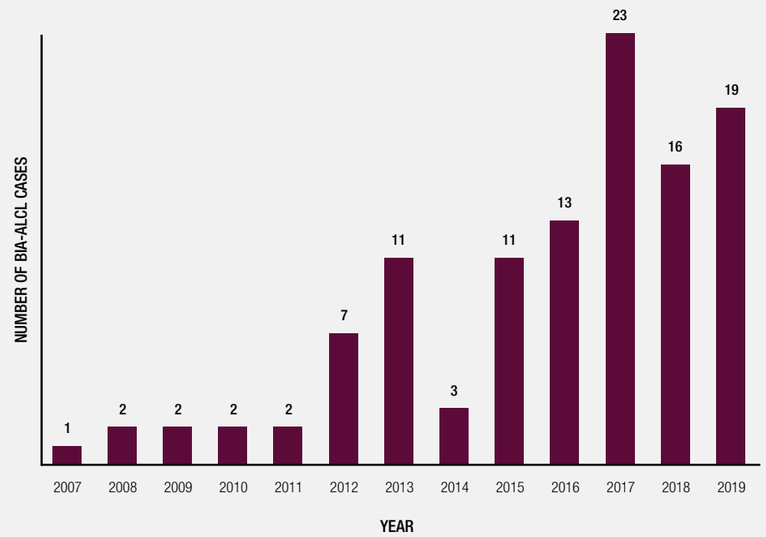
Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

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 is able to provide additional data relating to operation category, associated complications, and explanted device details.

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

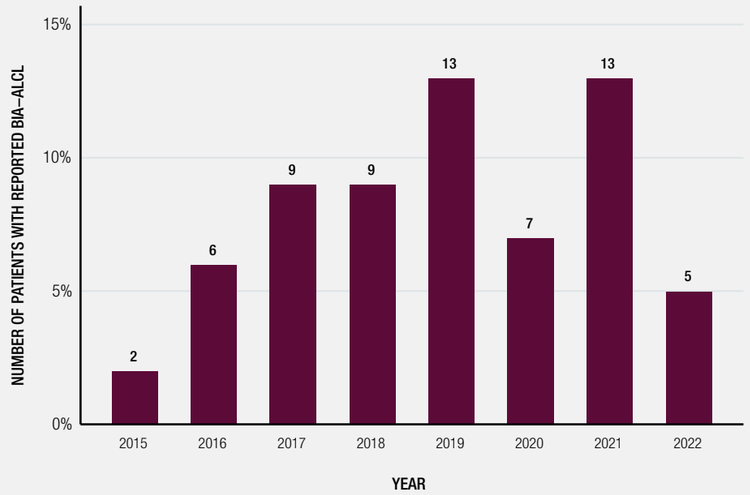
FIGURE 5.1: NUMBER OF BIA-ALCL CASES 2007-2019 MACQUARIE UNIVERSITY (N=112)



ABDR data

The methodology to report positive cases of BIA-ALCL to the ABDR is twofold: (1) initially, the clinician reports suspected BIA-ALCL to the ABDR via the data collection form; and (2) the ABDR requests the clinician to provide confirmation via the pathology/histology report. The lymphoma could either be the reason that the patient has returned to surgery for a revision procedure or may be discovered incidentally. In 2022, there have been 5 new cases of BIA-ALCL reported to and confirmed by the Registry. There are a total of 64 patients reported with BIA-ALCL recorded in the ABDR (Figure 5.2). Of the 64 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 (2015-2022)



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 AND SITE TYPE ABDR (2015-2022)

State	Private	Public	Total
QLD	18	4	22
NSW	9	5	14
VIC	9	4	13
WA	7	0	7
Other/unknown	7	1	8
Total	**50**	**14**	**64**

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=36), followed by reconstruction following breast cancer (N=15) and reconstruction for risk-reduction and developmental deformity (N=6). There was one reported reconstructive procedure where the specific surgery indication was unknown. Furthermore, for 8 cases, the indication for surgery was not stated.

TABLE 5.2: NUMBER OF BIA-ALCL CASES (AT BREAST LEVEL) BY INDICATION FOR SURGERY ABDR (2015-2022)

Indication for Surgery	N	%
Cosmetic augmentation	36	55%
Reconstruction post cancer	15	23%
Reconstruction benign/prophylactic	6	9%
Reconstruction*	1	2%
Not stated	8	12%
Total	**66**	**100%**

Notes: Includes 64 patients. 2 of these patients have bilateral BIA-ALCL.
*Specific type of reconstructive indication was not reported for 1 breast.

Figure 5.3 shows the duration between the insertion of the breast implant and the date of revision/explantation of that same implant (where this data is reported to the ABDR). The date of implant insertion is recorded in 50 of the 66 (breast level) cases of BIA-ALCL reported to the Registry. In most cases, the device remained in-situ 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 (2015-2022)

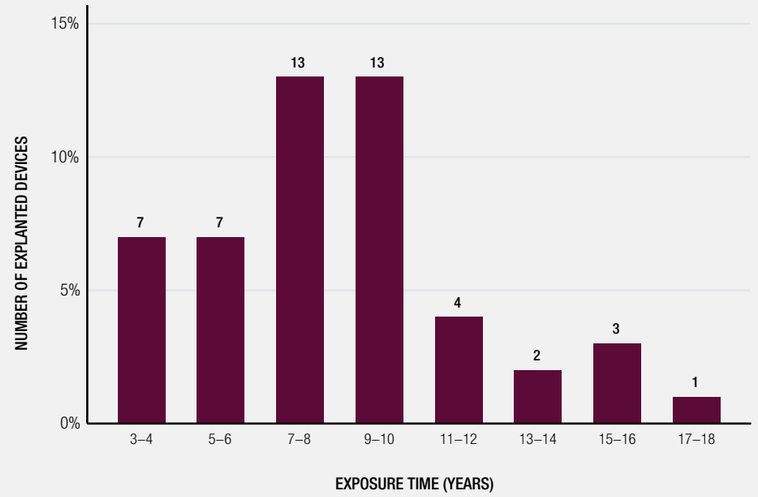


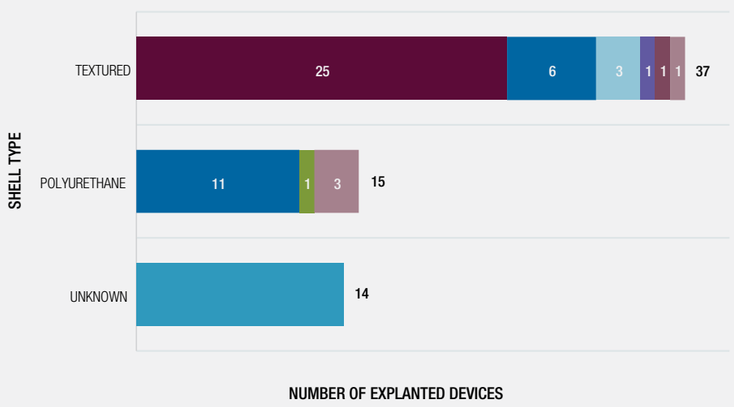
Table 5.3 demonstrates the number of BIA-ALCL cases at breast level by revision type; of the 66 procedures at breast level, 46 were recorded as device explant only procedures, and 20 as device replacement procedures. A full capsulectomy was performed in 43 of the explant only procedures, and 10 of the replacement procedures. Partial capsulectomy was performed in 3 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 (2015-2022)

Revision Type	Capsulectomy Type				Total
	Full	Partial	None	Not stated/Null	
Explant only	43	0	0	3	**46**
Replacement	10	3	4	3	**20**
Total	**53**	**3**	**4**	**6**	**66**

Figure 5.4 shows the explanted devices by shell type. Of the 66 breast implants in the Registry, 37 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, 25 were identified as Allergan/Inamed/McGhan/CUI. Of note, the foam-covered implants from Silimed Industria de Implantes had a manufacturing defect identified that caused surface delamination.

FIGURE 5.4: EXPLANTED DEVICES BY SHELL TYPE ABDR (2015-2022)



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 18 cases, one other clinical issue was reported, and in 10 patients, there were at least two clinical issues reported.

TABLE 5.4: NUMBER OF CLINICAL ISSUES ASSOCIATED WITH BIA-ALCL CASES IDENTIFIED AT REVISION ABDR (2015-2022)

Clinical issues reported	N
Only BIA-ALCL reported	35
One clinical issue reported	18
Two clinical issues reported	8
Three clinical issues reported	2
Asymptomatic	3
Total	**66**

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 (2015-2022)

Issue identified at revision	Reason for revision	Found incidentally
Seroma/haematoma	15	5
Capsular contracture	4	5
Device malposition	3	2
Device rupture/deflation	5	0
Skin Scarring problems	1	0
Deep wound infection	0	0
Breast cancer	0	0

Data requests

The ABDR continued to experience an increase of enquiries from patients during this reporting period. Patients contacting the ABDR are interested in learning their device details, changing their postal address, opting out of the Registry, and various other reasons In 2022, the ABDR was contacted via email by 224 patients. The ABDR also received approximately 194 calls during 2022.

Fourteen requests were made by surgeons for their patients' device details. Lists of patients and/or devices were only supplied if the request was made directly by the surgeon, or by an appropriately delegated hospital Quality Manager.

Data requests, including post-market clinical follow-up and information on long-term safety and performance of devices, were also received from one major industry company (Establishment Lab 'Motiva') that supplies breast devices to the Australian market. No identifiable data is ever included in these reports.

The ABDR also encourages the secondary uses of its data for research and related purposes. One formal research data access request was approved by the ABDR in 2022 for a PhD project.

Date of approval	Name/organisation	Title of project
07/02/2022	Ms Michelle Merenda, PhD Student, Monash University	Using Patient Reported Outcome Measures as a predictor and outcome measure for Australian Breast Device Registry data
24/03/2022	Kahye Lee, Establishment Labs	Motiva Implants® Industry Report

CHAPTER 6: PATIENT REPORTED OUTCOME MEASURES (PROMs)

In collaboration with Dr Andrea Pusic and her team at the Memorial Sloan-Kettering Cancer Centre in New York (USA), the ABDR created the 5-item Breast-Q Implant Surveillance (IS) patient-reported measure in 2017. From 2017 to 2021 the Breast-Q IS was administered to all patients at 1-, 2-, and 5- years following device implantation via various methods including SMS, email, follow up phone call and mail. The use of the Breast-Q IS was paused in 2022 due to declining participant response rates and high costs associated with administration of the survey to large numbers of participants (approximately 20,000 per year). By 2021, response rates were in the low to mid 40% for reconstructive patients and in the low 30% for cosmetic patients. The ABDR was concerned about the validity of the responses, given these response rates.

Further review showed that patients over the age of 60 years were more likely to complete the survey. Considered together with clinical data in the Registry, it was identified that reconstruction patients are on average between 40-59 years, and generally experienced more complications and revisions following surgery.

Relaunching the PROMs, the ABDR decided to focus instead on participants' lived experience and satisfaction following breast reconstruction surgery. The ABDR approached Dr Pusic again to discuss alternative Breast-Q tools that could be used to address this new objective. The Breast-Q Reconstruction module comprising of 25 scales was specifically developed for patients following reconstruction procedures. In order to reduce the time commitment required to complete several scales, the ABDR, in consultation with the Clinical Leads, selected six-scales based on those that were related to the device after surgery.

An Acceptability study was conducted to determine which two of the six scales was most 'acceptable' to patients and their clinicians to be implemented into the ABDR, including the timepoints for delivering the scales. The study revealed that the scales relating to Satisfaction with Breasts and Psychosocial wellbeing were the most acceptable and that they should be delivered at 6, 12- and 24-months. The ABDR will implement the new PROMs for patients undergoing breast reconstruction for primary implant insertion in late 2023/early 2024.

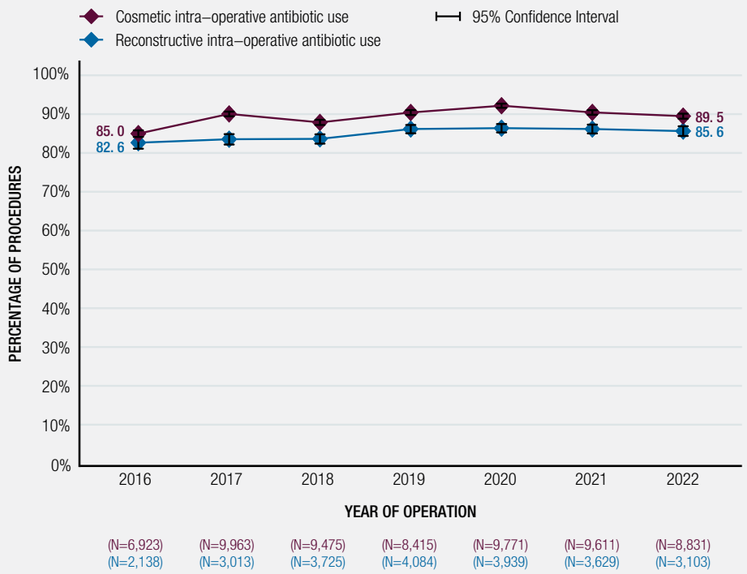
CHAPTER 7: CLINICAL QUALITY INDICATORS (CQIs)

The ABDR has reported on three Clinical Quality Indicators (CQIs) developed by the International Consortium of Breast Registry Activities (ICOBRA) for the last few years. These are derived from data elsewhere in the report.

CQI 1 Intra-operative antibiotics use

The proportion of intra-operative antibiotics provided before skin incision to reduce complications post-surgery is presented in Figure 7.1. There has been an increasing use of reported intra-operative antibiotic use for both reconstructive and cosmetic groups from 2016-2022 (all procedures regardless of device operation type are included).

FIGURE 7.1: PROPORTION OF PROCEDURES WITH REPORTED INTRA-OPERATIVE ANTIBIOTICS USE

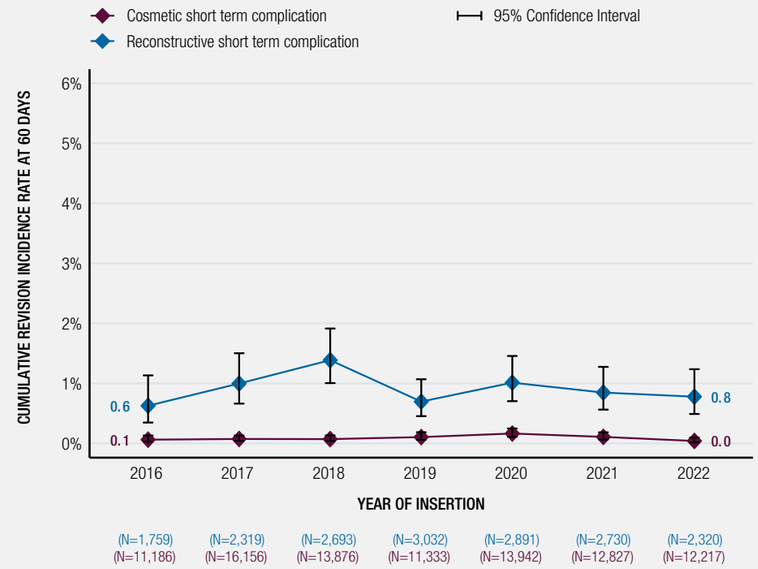


Note: Data was recorded at the operation level, and procedure hierarchy was applied to determine indication.

CQI 2 Revision due to short-term complications

The reoperation rate at 60 days post operation due to short term complications for the reconstructive and cosmetic cohorts are provided in Figure 7.2. In this section, a revision is considered to be due to short term complications if it 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 is very low with a slight fluctuating trend for reconstructive procedures, and has been consistently low over time for the cosmetic groups.

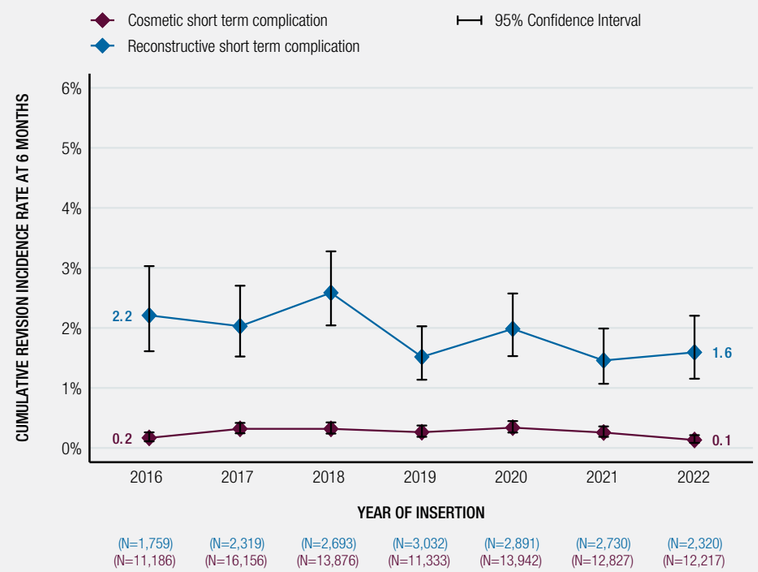
FIGURE 7.2: CUMULATIVE REVISION INCIDENCE RATE AT 60 DAYS POST PRIMARY BREAST IMPLANT INSERTION DUE TO SHORT TERM COMPLICATIONS BY INSERTION YEAR



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

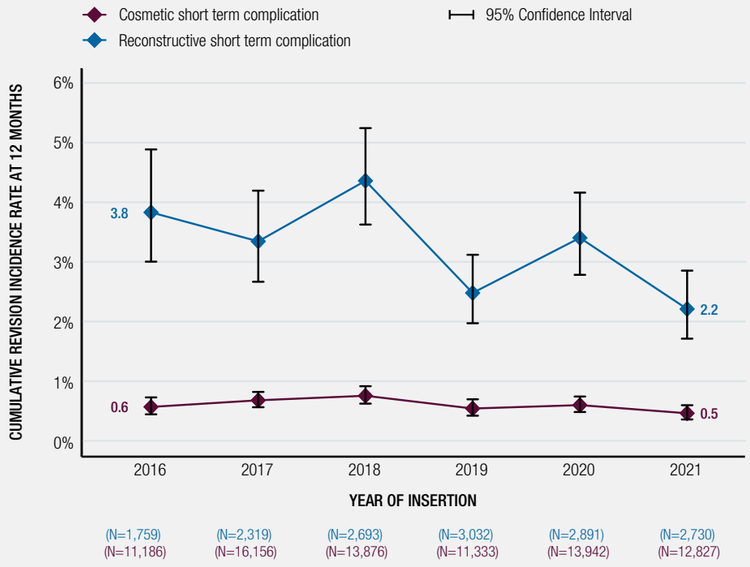
Figure 7.3 and Figure 7.4 consider the cumulative revision incidence at 6 and 12 months, respectively. It is notable that at 6 and 12 months post insertion there is a clear reduction in the revision rate for reconstructive procedures noted. At 12 months in particular, the revision rate for reconstructive procedures has decreased from 3.8% in 2016 to 2.2% in 2022.

FIGURE 7.3: 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 7.4: 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

In 2022, the ABDR reached a significant milestone reporting over 100,000 procedures. The growing number of procedures in the Registry strengthens our data analysis to demonstrate emerging trends in breast device surgery. It also supports more patients wishing to access their device details when they require it in the future.

The ABDR are continuing to build a new database that will replace, to a large part, paper-based data collection. It is a complex project that requires transferring several manual processes into an automated system. The value that the database will provide to clinicians and sites is immense, they will be able to access their own patient records and view aggregated reports on demand for quality improvement and audit purposes. As a registry, the data recorded in the database will be robust further supporting our analytical projects.

We look forward to relaunching the PROMs program for patients undergoing reconstruction procedures. The program will allow the ABDR to learn more about the experiences of these patients and the impact that reconstruction surgery with a breast device has on their lives. The PROMs program will be implemented as part of the new database. It is capable of identifying eligible patients and delivering the PROMs based on operation date using a multi-modal communication method.

Work is also continuing to identify new Clinical Quality Indicators and reviewing the device listings reported to the Registry. The TGA's Unique Device Identifier (UDI) project is another significant piece of work that the ABDR are contributing to and we hope will be launched very soon, it will facilitate accurate tracking and reporting of breast devices.

CHAPTER 9: ACADEMIC OUTPUTS 2022

The ABDR produced 4 academic publications in 2022:

Ahern, Susannah, Gabbe, Belinda J, Green, Sally, Hodgson, Carol L, Wood, Erica M, Zalcberg OAM, John R, & Zazryn, Tsharni. (2022). Realising the potential: leveraging clinical quality registries for real world clinical research. Medical Journal of Australia, 216(6), 273–277. https://doi.org/10.5694/mja2.51443

Hansen, Jessy, Ahern, Susannah, Gartoulla, Pragya, Khu, Ying, Elder, Elisabeth, Moore, Colin, Farrell, Gillian, Hopper, Ingrid, & Earnest, Arul. (2022). Identification of Predictive Factors for Patient-Reported Outcomes in the Prospective Australian Breast Device Registry. Aesthetic Surgery Journal, 42(5), 470–480. https://doi.org/10.1093/asj/sjab314

Jayasinghe, Randi T, Ruseckaite, Rasa, Gartoulla, Pragya, Elder, Elisabeth, & Hopper, Ingrid. (2022). Patient Reported Outcome Measures After Breast Augmentation–Using the BREAST-Q IS. Patient Related Outcome Measures, 13, 1–8. https://doi.org/10.2147/PROM.S330163

Ng, Sze, Parker, Emily, Pusic, Andrea, Farrell, Gillian, Moore, Colin, Elder, Elisabeth, Cooter, Rodney D, McNeil, John, & Hopper, Ingrid. (2022). Lessons Learned in Implementing Patient-Reported Outcome Measures (PROMs) in the Australian Breast Device Registry (ABDR). Aesthetic Surgery Journal, 42(1), 31–37. https://doi.org/10.1093/asj/sjaa376

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 2022, abstracts were accepted: for an oral and poster presentations at the Australasian International Breast Congress (Brisbane); and oral presentation at the Australian Clinical Trials Alliance Annual Scientific Meeting including Australian Registry Annual Scientific Meeting. There were several seminars conducted with clinicians and site theatre staff in person and via video-conferencing.

GLOSSARY

Capsular contacture	The scar tissue that forms around implant causes the implant to feel firm.
Contributing site	Any site that is currently contributing data to the ABDR
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.
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 Indicator
CQR	Clinical Quality Registry
The Department	Department of Health and Aged Care
HREC	Human Research Ethics Committee
MTAA	Medical Technology Association of Australia
TGA	Therapeutics Goods Administration
UDI	Unique Device Identifiers

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APPENDIX 1: DATA COMPLETENESS

Patient characteristics (patient level)	2020	2021	2022
	14,711	14,430	12,809
Name	100.0%	100.0%	100.0%
Surname	100.0%	100.0%	100.0%
Medicare number	89.8%	92.0%	91.6%
Date of birth	100.0%	100.0%	100.0%
Address	97.6%	97.7%	97.6%
Telephone	86.4%	87.2%	89.3%
Surgery characteristics (procedure level)	**15,390**	**15,000**	**13,286**
Operation date	100.0%	100.0%	100.0%
Hospital	100.0%	100.0%	100.0%
Surgeon	100.0%	100.0%	100.0%
Intra-operative techniques	88.2%	86.5%	86.8%
Surgery characteristics (breast level)	**28,833**	**28,081**	**24,901**
Side of breast	100.0%	100.0%	100.0%
Indication for surgery	89.0%	88.2%	89.7%
Surgery type	100.0%	100.0%	100.0%
Previous radiotherapy if reconstruction	89.2%	87.7%	89.3%
Incision site	87.9%	85.7%	86.1%
Plane	84.9%	84.4%	84.6%
Concurrent mastectomy	91.5%	90.6%	90.2%
Axillary surgery	91.5%	90.6%	90.2%
Concurrent mastopexy/reduction	91.6%	90.6%	90.3%
Concurrent flap cover	91.5%	90.6%	90.2%
Previous mastopexy/reduction	91.4%	90.6%	90.2%
Fat grafting	91.5%	90.1%	89.7%
Fat graft vol if fat grafting is selected	91.7%	92.0%	91.1%
Intra-op fill volume if tissue expander	64.7%	64.8%	66.0%
Revision characteristics (breast level)	**9,613**	**10,454**	**8,489**
Revision surgery type	100.0%	100.0%	100.0%
Indication for revision surgery	94.3%	95.5%	94.6%
Capsulectomy	87.5%	88.1%	87.7%
Neo pocket formation	72.9%	73.3%	73.2%
Neo pocket formation details	83.8%	85.5%	87.5%
Revision overseas implant	82.3%	82.7%	81.7%
Breast cancer	94.1%	95.6%	94.7%
Device rupture	94.0%	95.4%	94.3%
Device deflation	94.1%	95.4%	94.5%

Patient characteristics (patient level)	2020	2021	2022
	14,711	14,430	12,809
Capsular contracture	94.1%	95.4%	94.6%
Device malposition	94.1%	95.5%	94.7%
Skin scarring problems	94.1%	95.5%	94.6%
Deep wound infection	94.1%	95.6%	94.7%
Seroma/haematoma	94.1%	95.6%	94.7%
BIA-ALCL	94.1%	95.6%	94.6%
Device characteristics (breast level, inserted)	**25,645**	**24,370**	**22,022**
Implant/tissue expander device ID	99.8%	99.8%	99.9%
Matrix/mesh used	97.1%	99.6%	99.9%
Matrix/mesh device ID if matrix/mesh used	99.0%	98.4%	95.6%
Device characteristics (breast level, explanted)	**9,466**	**10,312**	**8,350**
Explanted device details	89.8%	89.8%	88.6%
Explanted device ID	10.2%	10.2%	11.4%
Patient opt-out rate	**0.9%**	**0.7%**	**0.8%**

APPENDIX 2: TABLES SUPPORTING IN TEXT FIGURES

Surgical elements (2016-2022) – reconstructive breast level procedures

	2016	2017	2018	2019	2020	2021	2022
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Incision site*							
Previous mastectomy scar	1,521 (45.2%)	1,903 (41.4%)	2,130 (37.3%)	2,085 (32.9%)	1,870 (30.2%)	1,606 (28.3%)	1,312 (27.4%)
Inframammary	1,166 (34.6%)	1,444 (31.4%)	1,927 (33.8%)	2,427 (38.4%)	2,575 (41.5%)	2,307 (40.7%)	1,929 (40.3%)
Areola	209 (6.2%)	414 (9.0%)	558 (9.8%)	656 (10.4%)	567 (9.1%)	571 (10.1%)	501 (10.5%)
Mastopexy/reduction scar	217 (6.4%)	434 (9.4%)	536 (9.4%)	529 (8.4%)	527 (8.5%)	529 (9.3%)	448 (9.4%)
Axillary	12 (0.4%)	49 (1.1%)	66 (1.2%)	47 (0.7%)	27 (0.4%)	33 (0.6%)	36 (0.8%)
Other	123 (3.7%)	176 (3.8%)	222 (3.9%)	281 (4.4%)	271 (4.4%)	218 (3.8%)	225 (4.7%)
Not stated	189 (5.6%)	317 (6.9%)	406 (7.1%)	470 (7.4%)	560 (9.0%)	601 (10.6%)	502 (10.5%)
Surgical plane							
Sub-pectoral/dual plane	2,083 (62.5%)	2,812 (62.3%)	3,525 (63.6%)	3,547 (58.7%)	3,217 (54.6%)	2,847 (53.0%)	2,322 (51.8%)
Sub-flap	311 (9.3%)	450 (10.0%)	480 (8.7%)	538 (8.9%)	481 (8.2%)	529 (9.8%)	416 (9.3%)
Sub-glandular/sub-fascial**	328 (9.8%)	339 (7.5%)	447 (8.1%)	673 (11.1%)	835 (14.2%)	871 (16.2%)	759 (16.9%)
Other	32 (1.0%)	67 (1.5%)	105 (1.9%)	265 (4.4%)	359 (6.1%)	301 (5.6%)	239 (5.3%)
Not stated	577 (17.3%)	849 (18.8%)	988 (17.8%)	1,020 (16.9%)	1,003 (17.0%)	827 (15.4%)	744 (16.6%)
Axillary surgery							
Yes	355 (12.3%)	708 (17.0%)	943 (17.9%)	1,136 (19.5%)	1,202 (21.2%)	1,155 (22.4%)	1,050 (23.9%)
Concurrent mastectomy							
Yes	826 (28.5%)	1,409 (33.8%)	1,824 (34.6%)	2,159 (37.1%)	2,140 (37.7%)	2,067 (40.0%)	1,805 (41.1%)
Concurrent mastopexy							
Yes	219 (6.5%)	322 (7.0%)	432 (7.6%)	390 (6.2%)	393 (6.3%)	455 (8.0%)	396 (8.3%)
Flap cover							
Yes	292 (10.1%)	382 (9.2%)	470 (8.9%)	496 (8.5%)	457 (8.1%)	439 (8.5%)	317 (7.2%)
Previous mastopexy							
Yes	119 (3.5%)	217 (4.7%)	225 (3.9%)	229 (3.6%)	252 (4.1%)	254 (4.5%)	222 (4.6%)
Fat grafting							
Yes	132 (3.9%)	342 (7.4%)	448 (7.8%)	552 (8.7%)	506 (8.2%)	461 (8.1%)	459 (9.6%)
Drain use							
Yes	1,730 (51.4%)	2,524 (54.9%)	2,914 (51.1%)	3,292 (52.0%)	3,166 (51.1%)	2,817 (49.7%)	2,360 (49.3%)
Nipple guard							
Yes	482 (27.3%)	708 (30.3%)	873 (29.3%)	1,118 (31.6%)	1,166 (32.0%)	1,095 (31.9%)	860 (30.6%)
Nipple absent							
Yes	1,601 (55.3%)	2,258 (54.2%)	2,723 (51.7%)	2,790 (47.9%)	2,553 (45.0%)	2,238 (43.3%)	1,977 (45.1%)
Nipple sparing							
Yes	538 (18.6%)	901 (21.6%)	1,202 (22.8%)	1,538 (26.4%)	1,684 (29.7%)	1,495 (29.0%)	1,289 (29.4%)
Total procedures	**3,367**	**4,594**	**5,708**	**6,328**	**6,201**	**5,669**	**4,788**

Notes: Details are at the breast procedure level.
Procedures with unknown procedure type (insertion, revision or explant) have not been included.
*More than one incision site can be recorded
**This includes sub-cutaneous placement after mastectomy per data reported to the Registry.
The totals used to calculate the percentages for surgical plane are based on the number of insertion/revision procedures (not explant only) (2016: N=3,331; 2017: N =4,517; 2018: N=5,545; 2019: N=6,043; 2020: N=5,895; 2021: N=5,375; 2022: N=4,480)
The totals used to calculate the percentages for nipple guard are based on the number of procedures where nipple absent is not selected. (2016: N=1,764; 2017: N = 2,335; 2018: N=2,983; 2019: N=3,537; 2020: N=3,648; 2021: N=3,429; 2022: N=2,808)
The totals used to calculate the percentages for nipple absent, concurrent mastectomy, nipple sparing, axillary surgery and flap cover are based on the number of post-cancer and risk-reducing procedures.
(2016: N=2,896; 2017: N = 4,169; 2018: N=5,267; 2019: N=5,820; 2020: N=5,669; 2021: N = 5,163; 2022: N=4,387).

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
Post-cancer	11,495	9,846	8,126	6,399	4,782	3,244	1,950	1,043
Risk-reducing	5,536	4,698	3,816	2,943	2,166	1,422	835	401
Developmental	2,393	2,104	1,735	1,349	1,078	834	600	338
Total	19,424	16,648	13,677	10,691	8,026	5,500	3,385	1,782

	N Revised	Cumulative revision incidence						
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7
All-cause revision								
Post-cancer	1,467	6.5%	9.8%	12.5%	14.5%	16.5%	18.2%	20.0%
Risk-reducing	746	7.1%	10.9%	13.4%	15.5%	17.2%	18.9%	21.9%
Developmental	250	5.4%	8.9%	9.7%	11.6%	12.4%	13.7%	14.9%
Total	2,463	6.5%	10.0%	12.4%	14.4%	16.1%	17.8%	19.8%
Revision due to complication								
Post-cancer	1,019	4.4%	6.8%	8.6%	10.2%	11.4%	12.6%	13.8%
Risk-reducing	482	4.5%	6.7%	8.6%	10.1%	11.0%	12.3%	15.1%
Developmental	136	2.7%	4.8%	5.1%	6.1%	6.5%	7.7%	8.5%
Total	1,637	4.2%	6.5%	8.2%	9.7%	10.7%	11.9%	13.4%
Revision due to device malposition								
Post-cancer	421	1.6%	2.7%	3.6%	4.3%	4.9%	5.3%	6.0%
Risk-reducing	216	1.9%	3.1%	4.3%	4.8%	5.1%	5.5%	5.9%
Developmental	67	1.2%	2.5%	2.6%	3.1%	3.4%	3.9%	4.1%
Total	704	1.7%	2.8%	3.6%	4.3%	4.7%	5.2%	5.7%
Revision due to capsular contracture								
Post-cancer	402	1.1%	2.3%	3.3%	4.1%	4.8%	5.6%	6.4%
Risk-reducing	154	1.0%	1.8%	2.4%	3.2%	3.8%	4.4%	5.9%
Developmental	59	1.0%	2.0%	2.1%	2.8%	2.8%	3.4%	4.0%
Total	615	1.1%	2.1%	2.9%	3.7%	4.3%	5.0%	5.9%
Revision due to rupture/deflation								
Post-cancer	77	0.2%	0.3%	0.5%	0.7%	0.9%	1.2%	1.5%
Risk-reducing	36	0.2%	0.3%	0.4%	0.6%	0.8%	1.1%	2.2%
Developmental	12	0.1%	0.3%	0.4%	0.6%	0.6%	0.8%	0.8%
Total	125	0.2%	0.3%	0.4%	0.7%	0.8%	1.1%	1.6%
Revision due to skin scarring								
Post-cancer	130	0.7%	0.8%	1.1%	1.3%	1.4%	1.5%	1.7%
Risk-reducing	74	0.9%	1.2%	1.4%	1.5%	1.5%	1.6%	1.8%
Developmental	11	0.0%	0.4%	0.4%	0.5%	0.5%	0.8%	0.8%
Total	215	0.7%	0.9%	1.1%	1.3%	1.3%	1.5%	1.6%
Revision due to seroma/haematoma								
Post-cancer	85	0.6%	0.7%	0.7%	0.8%	0.8%	0.9%	0.9%
Risk-reducing	43	0.6%	0.7%	0.8%	0.9%	0.9%	0.9%	0.9%
Developmental	8	0.3%	0.3%	0.3%	0.3%	0.4%	0.4%	0.4%
Total	136	0.6%	0.6%	0.7%	0.8%	0.8%	0.8%	0.8%
Revision due to deep wound infection								
Post-cancer	131	1.0%	1.1%	1.1%	1.2%	1.3%	1.3%	1.3%
Risk-reducing	54	0.9%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%
Developmental	7	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%
Total	192	0.9%	1.0%	1.0%	1.1%	1.1%	1.1%	1.1%

Note: Cumulative revision incidence is based on reconstructive primary breast implants inserted from 2012-2022.
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
Textured	11,229	9,942	8,778	7,476	6,206	4,461	2,896	1,553
Smooth	7,965	6,498	4,708	3,036	1,649	886	379	163
Polyurethane	207	186	171	164	162	146	107	63
Total	19,401	16,626	13,657	10,676	8,017	5,493	3,382	1,779

	N Revised	Cumulative revision incidence						
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7
All-cause revision								
Textured	1,673	6.9%	10.6%	13.0%	15.4%	17.4%	19.2%	21.3%
Smooth	742	5.9%	8.8%	11.1%	12.2%	12.8%	13.2%	14.9%
Polyurethane	48	10.1%	18.5%	22.7%	23.9%	24.5%	26.2%	27.5%
Total	2,463	6.6%	10.0%	12.4%	14.4%	16.2%	17.8%	19.8%
Revision due to complication								
Textured	1,080	4.3%	6.7%	8.3%	10.0%	11.1%	12.5%	14.0%
Smooth	524	4.1%	6.2%	7.8%	8.6%	9.1%	9.5%	11.2%
Polyurethane	33	8.1%	12.1%	15.6%	16.3%	16.3%	17.9%	19.3%
Total	1,637	4.2%	6.5%	8.2%	9.7%	10.7%	11.9%	13.4%
Revision due to device malposition								
Textured	435	1.5%	2.6%	3.4%	4.2%	4.7%	5.1%	5.6%
Smooth	251	1.8%	3.0%	3.8%	4.2%	4.5%	4.7%	5.2%
Polyurethane	18	4.0%	5.1%	8.1%	8.1%	8.1%	9.8%	11.1%
Total	704	1.7%	2.8%	3.6%	4.3%	4.7%	5.2%	5.7%
Revision due to capsular contracture								
Textured	472	1.3%	2.5%	3.3%	4.4%	5.0%	5.8%	6.8%
Smooth	132	0.7%	1.4%	2.2%	2.4%	2.5%	2.8%	3.1%
Polyurethane	11	2.6%	3.2%	4.4%	5.0%	5.0%	6.7%	6.7%
Total	615	1.1%	2.1%	2.9%	3.7%	4.3%	5.0%	5.9%
Revision due to rupture/deflation								
Textured	87	0.1%	0.3%	0.4%	0.7%	0.8%	1.2%	1.6%
Smooth	34	0.2%	0.3%	0.4%	0.7%	0.8%	0.8%	1.7%
Polyurethane	4	0.5%	1.6%	2.2%	2.2%	2.2%	2.2%	2.2%
Total	125	0.2%	0.3%	0.4%	0.7%	0.8%	1.1%	1.6%
Revision due to skin scarring								
Textured	122	0.6%	0.7%	1.0%	1.2%	1.3%	1.3%	1.4%
Smooth	88	0.8%	1.1%	1.2%	1.3%	1.3%	1.6%	2.3%
Polyurethane	5	1.0%	1.6%	1.6%	2.2%	2.2%	3.0%	3.0%
Total	215	0.7%	0.9%	1.1%	1.3%	1.3%	1.5%	1.6%
Revision due to seroma/haematoma								
Textured	80	0.5%	0.6%	0.7%	0.7%	0.8%	0.8%	0.8%
Smooth	48	0.6%	0.6%	0.6%	0.6%	0.6%	0.6%	0.6%
Polyurethane	8	3.1%	3.1%	4.3%	4.3%	4.3%	4.3%	4.3%
Total	136	0.6%	0.6%	0.7%	0.8%	0.8%	0.8%	0.8%
Revision due to deep wound infection								
Textured	121	1.0%	1.1%	1.1%	1.1%	1.2%	1.2%	1.2%
Smooth	69	0.8%	0.9%	0.9%	0.9%	0.9%	0.9%	0.9%
Polyurethane	2	0.5%	0.5%	0.5%	1.1%	1.1%	1.1%	1.1%
Total	192	0.9%	1.0%	1.0%	1.1%	1.1%	1.1%	1.1%

APPENDIX 5: TABLES SUPPORTING IN TEXT FIGURES

Cumulative revision incidence by matrix/mesh use – reconstructive primary direct-to-implant procedures

	N Primary Breast Implants	Number at risk						
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7
Matrix/mesh	4,653	3,751	2,815	1,966	1,240	695	334	137
No matrix/mesh	4,976	4,212	3,367	2,559	1,935	1,341	726	303
Not stated	471	438	411	372	357	348	339	259
Total	10,100	8,401	6,593	4,897	3,532	2,384	1,399	699

	N Revised	Cumulative revision incidence						
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7
All-cause revision								
Matrix/mesh	649	8.5%	12.6%	15.5%	18.0%	20.1%	21.9%	22.5%
No matrix/mesh	631	7.3%	10.8%	12.4%	14.7%	16.2%	18.0%	20.1%
Not stated	70	7.0%	10.3%	11.8%	14.0%	15.7%	16.0%	17.1%
Total	1,350	7.9%	11.6%	13.7%	16.1%	17.9%	19.4%	20.9%
Revision due to any of the below 4 complications								
Matrix/mesh	386	4.9%	7.3%	9.5%	11.2%	11.9%	13.1%	13.1%
No matrix/mesh	275	2.9%	4.6%	5.4%	6.4%	7.1%	7.9%	9.4%
Not stated	41	4.6%	6.5%	7.3%	8.6%	9.5%	9.5%	9.8%
Total	702	3.9%	5.9%	7.3%	8.6%	9.3%	10.1%	10.9%
Revision due to device malposition								
Matrix/mesh	161	1.7%	2.8%	4.2%	4.8%	5.3%	6.0%	6.0%
No matrix/mesh	146	1.3%	2.3%	2.9%	3.6%	3.9%	4.3%	5.0%
Not stated	14	0.9%	1.6%	2.1%	2.9%	3.2%	3.2%	3.6%
Total	321	1.5%	2.5%	3.4%	4.1%	4.5%	4.9%	5.3%
Revision due to capsular contracture								
Matrix/mesh	152	1.2%	2.5%	3.7%	5.1%	5.7%	6.8%	6.8%
No matrix/mesh	132	1.0%	2.2%	2.6%	3.1%	3.4%	4.0%	5.3%
Not stated	24	2.2%	3.4%	4.2%	5.5%	5.8%	5.8%	5.8%
Total	308	1.1%	2.4%	3.1%	4.0%	4.5%	5.1%	5.7%
Revision due to seroma/haematoma								
Matrix/mesh	67	1.3%	1.4%	1.5%	1.7%	1.7%	1.7%	1.7%
No matrix/mesh	25	0.4%	0.5%	0.5%	0.5%	0.6%	0.6%	0.6%
Not stated	10	1.5%	1.8%	2.0%	2.0%	2.3%	2.3%	2.3%
Total	102	0.9%	1.0%	1.1%	1.1%	1.2%	1.2%	1.2%
Revision due to deep wound infection								
Matrix/mesh	106	2.1%	2.4%	2.4%	2.5%	2.5%	2.5%	2.5%
No matrix/mesh	32	0.6%	0.7%	0.7%	0.7%	0.7%	0.7%	0.7%
Not stated	3	0.6%	0.6%	0.6%	0.6%	0.6%	0.6%	0.6%
Total	141	1.3%	1.4%	1.5%	1.5%	1.5%	1.5%	1.5%

Notes: Revision incidence is based on reconstructive direct-to-implant procedures with primary implants inserted from 2012 to 2022. 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

	N Primary Breast Procedures	Number at risk						
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7
Matrix/mesh	1,723	1,585	1,325	1,022	749	459	266	117
No matrix/mesh	4,355	4,057	3,519	2,897	2,236	1,446	861	429
Not stated	312	304	283	268	259	240	231	171
Total	6,390	5,946	5,127	4,187	3,244	2,145	1,358	717

	N Revised	Cumulative revision incidence						
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7
All-cause revision								
Matrix/mesh	216	5.5%	9.8%	12.8%	14.2%	16.2%	16.7%	16.7%
No matrix/mesh	595	4.9%	9.2%	12.2%	14.6%	15.8%	17.8%	21.0%
Not stated	45	2.6%	8.7%	10.5%	12.3%	15.2%	15.2%	16.0%
Total	856	5.0%	9.4%	12.3%	14.4%	15.9%	17.4%	19.4%
Revision due to any of the below 4 complications								
Matrix/mesh	114	3.1%	5.1%	6.7%	7.5%	8.7%	9.0%	9.0%
No matrix/mesh	306	2.4%	4.6%	6.4%	7.6%	8.2%	9.0%	10.9%
Not stated	32	2.3%	7.0%	8.8%	9.5%	11.1%	11.1%	11.1%
Total	452	2.6%	4.9%	6.6%	7.7%	8.5%	9.1%	10.2%
Revision due to device malposition								
Matrix/mesh	67	1.5%	3.0%	4.0%	4.4%	5.2%	5.5%	5.5%
No matrix/mesh	159	1.0%	2.5%	3.4%	4.1%	4.4%	4.8%	5.3%
Not stated	15	1.0%	2.7%	3.8%	4.5%	5.3%	5.3%	5.3%
Total	241	1.1%	2.6%	3.6%	4.2%	4.7%	5.0%	5.3%
Revision due to capsular contracture								
Matrix/mesh	34	0.2%	0.8%	1.6%	2.2%	3.3%	3.7%	3.7%
No matrix/mesh	133	0.5%	1.3%	2.5%	3.3%	3.9%	4.3%	5.6%
Not stated	17	0.3%	4.4%	5.1%	5.1%	5.9%	5.9%	5.9%
Total	184	0.4%	1.3%	2.4%	3.1%	3.8%	4.2%	4.9%
Revision due to seroma/haematoma								
Matrix/mesh	16	0.8%	0.8%	0.9%	0.9%	1.1%	1.1%	1.1%
No matrix/mesh	36	0.7%	0.8%	0.8%	0.8%	0.9%	0.9%	0.9%
Not stated	3	0.6%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%
Total	55	0.8%	0.8%	0.9%	0.9%	0.9%	0.9%	0.9%
Revision due to deep wound infection								
Matrix/mesh	22	1.1%	1.2%	1.3%	1.3%	1.5%	1.5%	1.5%
No matrix/mesh	48	0.9%	1.1%	1.1%	1.1%	1.1%	1.1%	1.1%
Not stated	3	0.6%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%
Total	73	0.9%	1.1%	1.2%	1.2%	1.2%	1.2%	1.2%

Notes: Revision incidence is based on reconstructive direct-to-implant procedures with primary implants inserted from 2012 to 2022. 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; 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 a second stage implant insertion procedure recorded. Excludes breasts which have matrix/mesh inserted at second stage.

APPENDIX 7: TABLES SUPPORTING IN TEXT FIGURES

Cumulative revision incidence – primary reconstructive tissue expanders

	N Primary Tissue Expanders	Number at risk					
		6 Mo	12 Mo	18 Mo	24 Mo	30 Mo	36 Mo
Post-cancer	6,234	3,969	2,030	1,384	1,079	898	748
Risk-reducing	2,799	1,481	648	440	335	273	240
Developmental	133	81	52	28	17	15	11
Total	9,166	5,531	2,730	1,852	1,431	1,186	999

	N Revised	Cumulative revision incidence					
		6 Mo	12 Mo	18 Mo	24 Mo	30 Mo	36 Mo
All-cause revision							
Post-cancer	342	3.8%	6.2%	8.7%	9.4%	9.9%	10.7%
Risk-reducing	106	3.0%	4.8%	7.1%	7.9%	8.3%	8.3%
Developmental	3	0.0%	3.4%	3.4%	3.4%	9.3%	9.3%
Total	451	3.5%	5.8%	8.2%	8.9%	9.4%	10.0%
Revision due to complication							
Post-cancer	210	2.6%	3.9%	5.1%	5.4%	5.5%	5.6%
Risk-reducing	83	2.7%	3.4%	4.7%	5.3%	5.6%	5.6%
Developmental	3	0.0%	3.4%	3.4%	3.4%	9.3%	9.3%
Total	296	2.6%	3.8%	5.0%	5.3%	5.6%	5.6%

Notes: Revision incidence is based on reconstructive primary tissue expanders inserted from 2012 to 2022.
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).

APPENDIX 8: TABLES SUPPORTING IN TEXT FIGURES

Surgical elements (2012-2022) – cosmetic breast level procedures

	2016	2017	2018	2019	2020	2021	2022
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Incision site*							
Inframammary	11,235 (82.3%)	17,099 (86.9%)	15,206 (81.5%)	13,627 (81.9%)	15,468 (79.9%)	14,888 (78.2%)	13,774 (78.8%)
Mastopexy/reduction wound	1,117 (8.2%)	1,364 (6.9%)	1,593 (8.5%)	1,593 (9.6%)	2,200 (11.4%)	2,217 (11.7%)	1,882 (10.8%)
Areola	187 (1.4%)	226 (1.1%)	256 (1.4%)	185 (1.1%)	198 (1.0%)	153 (0.8%)	111 (0.6%)
Axillary	53 (0.4%)	56 (0.3%)	80 (0.4%)	36 (0.2%)	32 (0.2%)	24 (0.1%)	33 (0.2%)
Other	27 (0.2%)	31 (0.2%)	36 (0.2%)	59 (0.4%)	50 (0.3%)	42 (0.2%)	18 (0.1%)
Not stated	1,099 (8.1%)	996 (5.1%)	1,644 (8.8%)	1,228 (7.4%)	1,517 (7.8%)	1,787 (9.4%)	1,768 (10.1%)
Surgical plane							
Sub-pectoral/dual plane	10,171 (75.0%)	16,256 (83.3%)	14,376 (79.1%)	12,431 (80.7%)	14,633 (80.9%)	13,913 (79.9%)	12,705 (78.4%)
Sub-glandular/sub-fascial	2,065 (15.2%)	1,929 (9.9%)	2,165 (11.9%)	2,063 (13.4%)	2,272 (12.6%)	2,421 (13.9%)	2,317 (14.3%)
Other	81 (0.6%)	65 (0.3%)	28 (0.2%)	32 (0.2%)	130 (0.7%)	39 (0.2%)	53 (0.3%)
Not stated	1,244 (9.2%)	1,260 (6.5%)	1,605 (8.8%)	880 (5.7%)	1,052 (5.8%)	1,038 (6.0%)	1,129 (7.0%)
Concurrent mastopexy/reduction							
Yes	1,404 (10.3%)	2,136 (10.8%)	2,316 (12.4%)	2,433 (14.6%)	3,232 (16.7%)	3,323 (17.5%)	3,144 (18.0%)
Previous mastopexy/reduction							
Yes	229 (1.7%)	396 (2.0%)	447 (2.4%)	482 (2.9%)	476 (2.5%)	566 (3.0%)	579 (3.3%)
Fat grafting							
Yes	80 (0.6%)	114 (0.6%)	276 (1.5%)	783 (4.7%)	1125 (5.8%)	1395 (7.3%)	1,480 (8.5%)
Drain use							
Yes	2,560 (18.8%)	2,680 (13.6%)	2,686 (14.4%)	2,436 (14.6%)	2,568 (13.3%)	2,770 (14.6%)	1,968 (11.3%)
Nipple guard							
Yes	8,186 (60.0%)	1,5491 (78.7%)	14,412 (77.3%)	12,702 (76.4%)	14,954 (77.3%)	14,052 (73.8%)	13,460 (77.0%)
Total procedures	**13,644**	**19,687**	**18,654**	**16,629**	**19,351**	**19,029**	**17,487**

Note: Details are at the breast procedure level.
*More than one incision site can be recorded
The totals used to calculate the percentages for surgical plane are based on the number of insertion/revision procedures (not explant only) (2016: N=13,561; 2017: N = 19,510; 2018: N=18,174; 2019: N=15,406; 2020: N=18,087; 2021: N = 17,411; 2022: N=16,204).

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
	95,594	86,327	73,498	56,724	46,828	34,270	18,926	6,689

Issues at revision (/reason)	N Revised	Cumulative revision incidence						
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7
All-cause	3,759	1.4%	2.6%	3.4%	4.2%	4.9%	5.5%	6.3%
Complication	2,032	0.8%	1.5%	1.8%	2.2%	2.6%	2.9%	3.4%
Malposition	943	0.4%	0.8%	0.9%	1.1%	1.2%	1.3%	1.4%
Capsular Contracture	792	0.2%	0.5%	0.7%	0.8%	1.0%	1.2%	1.6%
Rupture/deflation	232	0.1%	0.1%	0.2%	0.2%	0.3%	0.4%	0.5%
Skin Scarring	120	0.1%	0.1%	0.1%	0.1%	0.2%	0.2%	0.2%
Seroma/haematoma	111	0.1%	0.1%	0.1%	0.1%	0.1%	0.2%	0.2%
Deep Wound Infection	43	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.1%

Notes: Cumulative revision incidence is based on cosmetic primary breast implants inserted from 2012 to 2022.
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
Textured	49,283	45,804	40,906	34,705	30,414	23,758	13,643	4,975
Smooth	43,688	37,953	30079	19,546	14,131	8,745	4,163	1,288
Polyurethane	2,525	2487	2452	2428	2265	1,758	1,111	421
Total	95,496	86,244	73,437	56,679	46,810	34,261	18,917	6,684

	N Revised	Cumulative revision incidence						
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7
All-cause revision								
Textured	649	8.5%	12.6%	15.5%	18.0%	20.1%	21.9%	22.5%
Smooth	631	7.3%	10.8%	12.4%	14.7%	16.2%	18.0%	20.1%
Polyurethane	70	7.0%	10.3%	11.8%	14.0%	15.7%	16.0%	17.1%
Total	1,350	7.9%	11.6%	13.7%	16.1%	17.9%	19.4%	20.9%
Revision due to complication								
Textured	1,088	0.7%	1.2%	1.6%	2.0%	2.4%	2.8%	3.3%
Smooth	866	1.0%	1.7%	2.1%	2.4%	2.7%	2.9%	3.2%
Polyurethane	75	0.9%	1.8%	2.2%	2.4%	2.8%	3.0%	3.8%
Total	2,029	0.8%	1.5%	1.8%	2.2%	2.6%	2.9%	3.4%
Revision due to device malposition								
Textured	414	0.3%	0.5%	0.7%	0.9%	0.9%	1.1%	1.1%
Smooth	489	0.6%	1.0%	1.2%	1.4%	1.5%	1.6%	1.6%
Polyurethane	40	0.6%	1.2%	1.4%	1.5%	1.5%	1.6%	1.8%
Total	943	0.4%	0.8%	0.9%	1.1%	1.2%	1.3%	1.4%
Revision due to capsular contracture								
Textured	489	0.2%	0.5%	0.7%	0.9%	1.1%	1.3%	1.7%
Smooth	267	0.3%	0.5%	0.6%	0.8%	0.9%	1.0%	1.2%
Polyurethane	34	0.2%	0.5%	0.7%	0.8%	1.2%	1.3%	2.1%
Total	790	0.2%	0.5%	0.6%	0.8%	1.0%	1.2%	1.5%
Revision due to deflation/rupture								
Textured	140	0.0%	0.1%	0.2%	0.2%	0.3%	0.4%	0.5%
Smooth	87	0.1%	0.1%	0.2%	0.2%	0.3%	0.3%	0.5%
Polyurethane	5	0.0%	0.1%	0.1%	0.1%	0.2%	0.2%	0.2%
Total	232	0.1%	0.1%	0.2%	0.2%	0.3%	0.4%	0.5%
Revision due to skin scarring								
Textured	59	0.0%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Smooth	60	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%
Total	120	0.1%	0.1%	0.1%	0.1%	0.2%	0.2%	0.2%

APPENDIX 10: TABLES SUPPORTING IN TEXT FIGURES cont.

Cumulative revision incidence by device shell – cosmetic primary breast implant

	N Revised	Cumulative revision incidence						
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7
Revision due to seroma/haematoma								
Textured	68	0.1%	0.1%	0.1%	0.1%	0.2%	0.2%	0.2%
Smooth	35	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%
Total	110	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.2%
Revision due to deep wound infection								
Textured	27	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Smooth	16	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.1%
Polyurethane	0	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Total	43	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.1%

Note: Cumulative revision incidence is based on reconstructive primary breast implants inserted from 2012 to 2022.
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).

APPENDIX11: DATA COLLECTION FORM

AUSTRALIAN BREAST DEVICE REGISTRY FORM

AUSTRALIAN Breast Device REGISTRY

MONASH University Medicine, Nursing and Health Sciences

Australian Society of Plastic Surgeons

Breast Surgeons of Australia & New Zealand

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

Patient UR # :

Medicare # :

Surname :

First name: Middle Name:

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

Address :

State: P/code:

Telephone : - Home: Business:

Mobile :

Email :

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

SITE DETAILS:

Site Name:

Suburb: State:

Surgeon name:

Is this patient a medical tourist to Australia? Yes No

RETURN FORM:

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

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

Manufacturer:
Distributor:
Reference no:
Serial no:

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

Manufacturer:
Distributor:
Reference no:
Serial no:

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

MESH/DERMAL SHEET: Yes No

Manufacturer:
Reference no:
Serial no:

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

MESH/DERMAL SHEET: Yes No

Manufacturer:
Reference no:
Serial no:

PATIENT HISTORY:

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

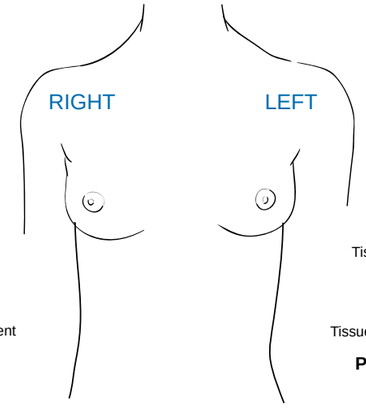
Category of operation
- Cosmetic augmentation
- Reconstruction - post cancer
- Reconstruction - benign / prophylactic
- Congenital deformity

Operation type

Initial (new device)
- Tissue Expander insertion
- First Implant insertion
- Tissue Expander removal & Implant insertion

Revision of in situ device
- Implant revision, removal or replacement
- Tissue Expander revision, removal, replacement

Previous Radiotherapy Yes No



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ELEMENTS OF OPERATION

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

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

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

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

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

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

Fat grafting Yes Volume.....mLs No

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

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

Fat grafting Yes Volume.....mLs No

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

INTRAOPERATIVE TECHNIQUES

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

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

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

FOR REVISION SURGERY ONLY

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

Revision Type:
Replacement Reposition existing implant Explant only

Capsulectomy ..... Full Partial None

Neo pocket formation ... Yes No Subglandular Submuscular

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

Reason for Revision
Complication Asymptomatic Patient Preference

Is the operation removing an implant inserted overseas Yes No

Details : .....

Device rupture?
Yes, reason for revision Yes, found incidentally No

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

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

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APPENDIX 12: ABDR STAFF

Professor Susannah Ahern, ABDR Steering Committee Chair/ABDR Academic Lead
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 Delphine Allan, Senior Project Officer
Ms Sally McInnes, Registry Operations Manager
Mr Patrick Garduce, Data Analyst, DEPM, Monash University
Professor Arul Earnest, Senior Biostatistician, DEPM, Monash University
Dr Pragya Gartoulla, Research Manager
Ms Ying Khu, PROMs Research Officer
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
Ms Chethana Mundanna, Data Entry
Mr Adriano Morandini, Data Entry
Ms Hazel Loo, Data Entry
Ms Renee Conroy, Data Entry
Mr Mudit Sharma, Data Entry

APPENDIX 13: LIST OF PARTICIPATING SITES AS AT END OF 2022

State	Site Name
ACT	Barton Private Hospital
ACT	Calvary Bruce Private Hospital
ACT	Calvary John James Hospital
ACT	Calvary Public Hospital ACT
ACT	Canberra Private Hospital
ACT	National Capital Private Hospital
ACT	Sole Vita Surgery
NSW	Aesthetic Day Surgery
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	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	Hurstville 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	Macquarie St Day Surgery
NSW	Macquarie University Hospital
NSW	Maitland Private Hospital
NSW	Mater Hospital Sydney
NSW	Mount Druitt Hospital
NSW	Nepean Hospital
NSW	Nepean Private Hospital
NSW	Newcastle 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	St George Hospital
NSW	St George Private Hospital
NSW	St Luke's Hospital
NSW	St Vincent's Private Community Hospital Griffith
NSW	St Vincent's Hospital (Darlinghurst)
NSW	St Vincent's Private Hospital (Darlinghurst)
NSW	St Vincent's Private Hospital (Lismore)
NSW	Strathfield Private Hospital
NSW	Surry Hills Day 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 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
QLD	Caboolture Private Hospital
QLD	Cairns Base Hospital
QLD	Cairns Private Hospital
QLD	Canossa Private Hospital

State	Site Name
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	Ipswich 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	Noosa 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	Rockhampton Base Hospital
QLD	Royal Brisbane & Women's Hospital
QLD	South Bank Day 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	Toowoomba Surgicentre
QLD	Varsity Lakes Day Hospital
QLD	Westside Private Hospital
SA	Adelaide Day Surgery
SA	Ashford Community Hospital
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

State	Site Name
SA	Modbury Hospital
SA	Noarlunga Health Service
SA	North Adelaide Day Surgery Centre
SA	North Eastern Community Hospital
SA	Norwood Day Surgery
SA	St Andrew's Hospital INC
SA	Stirling Hospital INC
SA	The Burnside War Memorial Hospital
SA	The Queen Elizabeth Hospital
SA	The Royal Adelaide Hospital
SA	Waverley House Plastic Surgery Centre
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

State	Site Name
VIC	South West Healthcare-Warrnambool Campus
VIC	Specialist Surgicentre Geelong
VIC	St John of God Ballarat Hospital
VIC	St John of God Bendigo Hospital
VIC	St John of God Berwick Hospital
VIC	St John of God Geelong 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 Hospital
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	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

Produced by Pidgeon Ward
CRICOS provider: Monash University 00008C, Monash College Pty Ltd 01857J.
395859 December 2023.