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AUSTRALIAN BREAST DEVICE REGISTRY

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Data period

The data contained in this document were extracted from the ABDR database on 28 August 2025 and related to data that had been submitted from the initiation of the pilot ABDR on 19 January 2012 to 31 December 2024. As the Registry does not capture data in real time, there can be lag between occurrence of an event and capture in the ABDR. This work was supported by Monash eResearch capabilities, including Helix.

Funding

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abdr.org.au

Contents

Summary

Welcome to the 2024 Australian Breast Device Registry (ABDR) Annual Report, the Registry's **ninth.**

The ABDR continues to fulfil a critical national role in supporting the safety of breast devices and quality of breast device surgery. Through comprehensive data collection and robust analytical processes, the ABDR provides a firm evidence base that informs clinical practice, regulatory decision-making, and broader healthcare policy. This work remains essential to safeguard patient outcomes and maintain confidence in breast device safety in Australia.

Key findings of the 2024 ABDR Annual Report (as at 31st December, 2024):

Overall:

- 242 sites and 449 clinicians participated in the ABDR in 2024
- 73% of participating sites were private hospitals, and 27% were public
- 77% of reconstructive, and nearly all cosmetic procedures were performed in private hospitals
- The patient opt-out rate for the ABDR is 1% for 2024
- The ABDR procedure capture rate was 69% overall for 2023-24, and over 75% for all implant insertions (noting WA public hospitals have not participated to date)
- A total of 9,765 patients, 11,902 operations and 18,842 devices were captured in 2024
- Since commencement, the ABDR has information regarding 109,020 patients, 126,380 operations and 213,141 devices
- Reconstructive patients comprise 20.6% of total patients but 25.9% of total procedures
- Mentor and Motiva devices account for 96% of all new implants in 2024
- In 2024, the ABDR captured 740 removal of implants that had been inserted overseas
- No new confirmed reports of BIA-ALCL were made to the ABDR in 2024

Reconstructive Procedures:

- 3,166 reconstructive procedures were captured by the ABDR in 2024
- The median patient age for post-cancer implant insertion procedures was 50 years of age
- In 2024, the most common surgical trends were direct to implant (DTI) reconstruction (69%); inframammary incision site (41%); pre-pectoral plane for direct-to-implant (42%) and sub-pectoral plane for two-stage procedures (45%)
- In 2024, the most common implant type was smooth implants (67%)
- 65% of direct-to-implant and 31% of two-stage procedures used matrix or mesh
- In 2024, 66% of revisions were associated with a complication, while 18% were unrelated (patient preference); of complications, the most common were capsular contracture (54%), device malposition (35%) and device rupture/deflation (24%)
- The all-cause revision rate at 9 years for post-cancer reconstruction was 20%, and 13% due to complications
- The all-cause revision rates, as well as revisions due to complications at 9 years were very similar for procedures with and without mesh

Cosmetic Procedures:

- 7,281 cosmetic procedures were captured by the ABDR in 2024
- The median patient age for cosmetic implant insertion procedures was 31 years
- Explants have increased as a proportion of cosmetic procedures, from 0.5% in 2016 to 9.7% in 2024 (1,394 explant only procedures in 2024)
- In 2024, the most common implant type was smooth implants (67%)
- 2.5% of cosmetic revision procedures reported using matrix/mesh in 2024
- In 2024, 64% of revisions were associated with a complication, while 31% were unrelated (patient preference); of complications, the most common were capsular contracture (56%), device rupture/deflation (33%) and device malposition (29%)
- The all-cause revision rate at 9 years for cosmetic procedures was 7%, with 3% being due to complications

Clinical Quality Indicators:

- The proportion of ABDR procedures with reported intra-operative antibiotic use in 2024 was 89% for cosmetic procedures and 84% for reconstructive procedures, a slight increase since 2016
- Revision rates at 12 months post first breast implant insertion have decreased slightly over time for reconstructive procedures (3.9% in 2016 to 3.2% in 2024) and cosmetic procedures (0.6 to 0.4%)

Engagement:

- The ABDR disseminated its sixth annual set of clinician reports in 2024 to 311 clinicians
- Seven requests for data from the ABDR in 2024 were received and approved
- ABDR staff and Clinical leads participated in nine conferences in 2024, seven of which included oral presentations or posters. The ABDR produced two academic publications in 2024.

The continued success of the ABDR depends on the cooperation and dedication of clinicians, surgeons, hospital staff and most importantly the patients who consent to participate. We extend our sincere appreciation to all contributors for their enduring support. Their commitment ensures the Registry continues to strengthen the safety and quality of breast device surgery across Australia.

Professor Susannah Ahern, ABDR Chair and Academic Lead

Dr Yvonne Chow, Australian Society of Plastic Surgery

Dr Patrick Tansley, Australasian College of Cosmetic Surgery and Medicine

Dr Melanie Walker, Breast Surgeons of Australia and New Zealand

Acknowledgements

The ABDR acknowledges the Commonwealth Department of Health, Disability and Ageing under the National Clinical Quality Registry Program for funding the Registry. We also acknowledge the in-kind support of Monash University, which have strengthened the Registry's capacity and reach. The important work of the ABDR continues to be informed and supported by the respective craft groups: Australian Society and Plastic Surgeons, Australasian College of Cosmetic Surgery and Medicine and Breast Surgeons of Australia and New Zealand, whose collaboration has been instrumental in advancing the Registry's development.

We further acknowledge the cooperation and support of those undertaking surgery and contributing to data collection. In particular, we extend our gratitude to the clinicians/surgeons, clinician trainees, theatre staff, and hospital administration staff for their essential role in ensuring high quality and comprehensive data.

The Registry also acknowledges the ongoing support of hospitals across Australia, both public and private, that undertake breast device procedures. We are especially grateful to each hospital's nominated site Principal Investigator for their commitment and engagement. A complete list of participating hospitals is presented at the end of this report.

Finally, and most importantly, the ABDR expresses its sincere appreciation to all breast device recipients that have participated. Their willingness to contribute enables continuous improvement in breast device surgery outcomes nationally.

ABDR Chair and Academic Lead

Professor Susannah Ahern

ABDR Clinical Leads (during 2024)

Dr Yvonne Chow (Australian Society of Plastic Surgeons)

Dr Patrick Tansley (Australasian College of Cosmetic Surgery and Medicine)

Dr Melanie Walker (Breast Surgeons Australia and New Zealand)

ABDR Steering Committee (during 2024)

Ms Sally Rayner, Ms Kerry Brown and Ms Megan Phelan
(Commonwealth Department of Health, Disability and Ageing)

Dr Amanda Craig (Therapeutic Goods Administration)

Ms Jane Synnot (Consumer representative)

Dr Jasjit Baveja (Medical Technology Association of Australia)

Dr Deepali Poels (Trainee Representative, Breast Surgeons Australia and New Zealand)

Dr Kwok Hao Lie (Trainee Representative, Australasian College of Cosmetic Surgery and Medicine)

Dr Jieyun Zhou (Trainee Representative, Australian Society of Plastic Surgeons)

ABDR Clinical Leads (listed above)

ABDR Clinician-academics
(members of the Research and Data Sharing subcommittee, during 2024)

Associate Professor Joseph Dusseldorp

Associate Professor Gillian Farrell

Dr David Topchian

Associate Professor Simon Tsao

ABDR Clinical Leads (listed above)

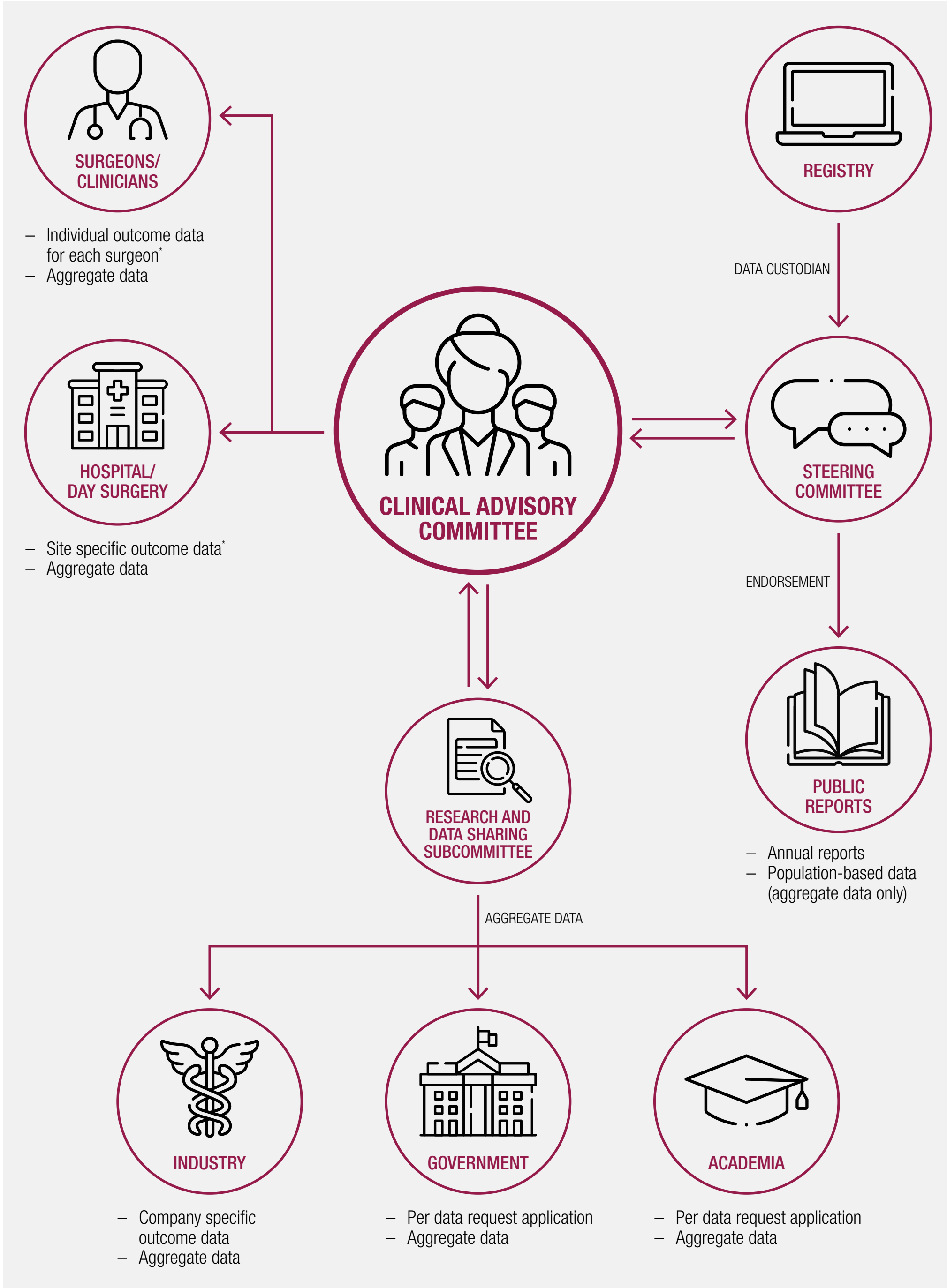
Introduction

Registry objectives

The ABDR aims to monitor the long-term safety and performance of breast devices, to identify and report on possible trends and complications and the quality of surgery involving breast implants, breast tissue expanders and acellular dermal matrices and other meshes associated with breast devices.

Reporting/registry output

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



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

Methods

Outcome assessment

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

Definitions:

- Revision surgery includes the replacement, repositioning or explant of an in-situ breast device. Time-to-revision is defined as the time from the insertion of the device of interest to the first subsequent revision procedure of the breast.
- All-cause revision incidence considers revisions captured by the Registry due to any reason, whether due to complication, patient preference or other unknown reasons (e.g. asymptomatic; breast cancer reported but no other issues).
- 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 (historically captured in the previous database), deep wound infection, seroma/ haematoma and BIA-ALCL).
- Primary breast implants are defined as those which are inserted into breasts which have no in-situ breast implant (i.e.: procedure is not a replacement of an implant) and also have no recorded history of prior procedures involving implants recorded in the Registry.
- Primary tissue expanders are defined as those which are inserted into breasts which have no in-situ device (i.e.: procedure is not replacement) and also have no recorded history of prior procedures involving tissue expanders or implants recorded in the Registry.

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

- If a revision follow-up procedure is captured, the end time of the interval is the time of the first revision. If this revision procedure involves the endpoint of interest (all-cause revision/ revision due to any complication/revision involving a specific complication), the interval is a time to event. Otherwise, the interval is a time to censoring.
- For tissue expander insertions, if a tissue expander removal and implant insertion procedure is the first follow-up procedure captured, this procedure is used as the end time for a censoring interval.
- If there are no follow-up procedures, 15 May 2025, is used as the end time for a censoring interval. This censoring date has been used for comparability with previous reports. The last procedure captured in previous extracts has typically been around this time of the year.

Cumulative revision incidence rates and hazard functions have been calculated based on the time intervals corresponding to primary devices inserted between 2012-2024 (inclusive).

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

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

A limitation with time-to-revision analysis data is the potential under-reporting of follow-up procedures, especially for explant only procedures which do not involve new devices. It should also be noted that long periods of time can elapse between when issues are first experienced and when the revision procedures occur. Furthermore, patients with complications may not necessarily undergo revision surgeries. Data collection forms are received by the Registry at any time following the procedure. Therefore, annually there are forms that are not received or entered into the registry until the following year.

Assessment of clinical variation

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

Key features of funnel plots include:

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

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

Presentation of this report

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

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

Patients whose records omitted the indication for surgery (not stated) were excluded from further analysis in this report (refer to Table 3.1 and Table 3.2). Within the two Registry output sections, reconstructive and cosmetic results have been analysed and presented across three types of procedural interventions where possible.

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

CHAPTER 1

Overview of the Australian Breast Device Registry

The history of breast implants has been shaped by a series of significant controversies that emphasise the importance of patient safety, regulatory oversight, and systematic monitoring. In the early 1990s, Dow Corning faced extensive litigation in the United States regarding alleged links between silicone breast implants and systemic illness.[1]

In 2010, the Poly Implant Prothèse (PIP) scandal in Europe further intensified global concerns, when industrial-grade silicone was fraudulently used in breast implants. The resulting device failures, recalls, and harm to patients prompted widespread regulatory reforms and renewed calls for international vigilance.[2] In Australia, these global events, together with local concerns, led to a Senate Inquiry into the risks associated with breast implants, which reinforced the need for national oversight and reliable outcome data.[3]

These events collectively provided the impetus for establishing the Australian Breast Device Registry. Its primary focus is on quality improvement activities and post-marketing surveillance of breast device safety, ensuring that clinical practice is guided by robust evidence and that patient outcomes remain central to ongoing monitoring. Today, the Registry is recognised internationally as a world-leading model for breast device surveillance and quality improvement.[4, 5]

Registry governance and reporting

The ABDR operates in accordance with the Australian Commission on Safety and Quality in Health Care's Framework for Australian clinical quality registries[6] and the National Clinical Quality Registry and Virtual Registry Strategy 2020-2030 (the Strategy)[7]. 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 are actively involved with ensuring that the Registry's activities align with this purpose, advises on policies and governance matters and monitors performance against agreed outcomes. The Steering Committee Chair is Professor Susannah Ahern and the membership are listed above (page 4). The committee meets three times a year.

The ABDR Clinical Advisory Committee is responsible for providing oversight of the Registry's daily operations and governance. It provides expert advice, develops recommendations and support better understanding clinical standards in practice. The committee is comprised of Dr's Yvonne Chow, Patrick Tansley and Melanie Walker and the Chair is Professor Susannah Ahern. The committee meet six times a year.

The ABDR Research and Data Sharing Subcommittee is responsible for reviewing all academic and industry data requests, as well as ABDR reports. It ensures that proposed research proposals demonstrate scientific merit and clearly defined objectives, and the methodology and statistical analysis plan are appropriately aligned with the research aims to generate meaningful impact. The subcommittee is comprised of Dr's Yvonne Chow, Patrick Tansley and Melanie Walker and additional clinician-academics representing the craft groups for further expertise in research review. The Chair is Professor Susannah Ahern. The committee meet six times a year.

1 Angell M. Shattuck Lecture — Evaluating the Health Risks of Breast Implants: The Interplay of Medical Science, the Law, and Public Opinion. *N Engl J Med. 1996;334(23):1513-8.*

2 Heneghan C, Langton D, Billingsley M. Poly Implant Prothèse breast implants: an overview of the evidence. *BMJ. 2012;344:e306.*

3 Senate Community Affairs References Committee. *The role of the Therapeutic Goods Administration regarding medical devices, particularly Poly Implant Prothèse (PIP) breast implants*. Canberra: Commonwealth of Australia; 2011.

4 Hopper I, Ahern S, Eager S, et al. The Australian Breast Device Registry: clinical quality registry for breast device surgery. *BMJ Open. 2017;7(5):e015246.*

5 Cooter RD, McNeil JJ, Walton TJ, et al. The Australian Breast Device Registry. *Plast Reconstr Surg Glob Open. 2015;3(5):e381*

6 Australian Commission on Safety and Quality in Health Care, Australian Framework for National Clinical Quality Registries 2024. Sydney. ACSQHC, 2024.

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

On an international level the ABDR was a prominent stakeholder in establishing the International Collaboration of Breast Registry Activities (ICOBRA). The countries that have committed to ICOBRA continues to work towards data harmonisation across registries. ICOBRA meet annually to discuss cross-collaboration in order to develop global best practice guide to inform international breast implant surgical practices. Member countries that are represented in ICOBRA include: Austria, Canada, France, Germany, Ireland, Italy, the Netherlands, New Zealand, South Africa, the United Kingdom and the United States.

Key milestones in the ABDR

OCTOBER 2011
Monash university engaged by Australasian Foundation for Plastic Surgery to establish pilot Breast Device Registry

JANUARY 2012
HREC approval received for pilot Breast Device Registry

MARCH 2012
First patient data entered into pilot Breast Device Registry

JULY 2014
Funding received from Commonwealth Government to establish the Australian Breast Device Registry

APRIL 2015
Alfred Health Human Research Ethics Committee Approval granted for the Australian Breast Device Registry

JUNE 2015
First patient data entered into the Australian Breast Device Registry

DECEMBER 2016
10,000 patients enrolled in the ABDR

MARCH 2017
ABDR launches Patient Reported Outcomes Measures

MARCH 2018
Publication of first ABDR Annual Report and first site and clinician reports

MARCH 2021
Almost 50,000 patients enrolled in the ABDR

2023
Granted Qualified Privilege under the Health Services Act (Commonwealth)

Captured more than 100,000 procedures in the Registry

2024/2025
Launch of the new ABDR database allowing clinicians direct data entry into the Registry

ABDR Case ascertainment

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

1. The ABDR compares **device insertions** reported to the Registry by participating clinicians against device sales data for that year provided by the **Therapeutics Good Administration** (TGA). For 2024, the TGA reported supply of 28,743 devices of which 18,842 were captured by the ABDR, resulting in an **65.6% device insertion capture rate.** Previously reported device insertion capture rates using this method have been 73% in 2019 and 2020, 94% in 2021, 76.3% in 2022 and 86.4% in 2023. The capture rate is variable over the last five years. It also has limited accuracy however as devices maybe sold to hospitals and clinicians but not implanted in the same calendar year.
2. The ABDR compares national breast implant operation numbers against publicly available Australian Institute of Health and Welfare (AIHW) data to verify procedure data capture. The ACHI (Australian Classification of Health Interventions) procedure codes used for this analysis mapped against ABDR operation types are shown in Figure 1.1

FIGURE 1.1 MAPPING OF ABDR OPERATION TYPES TO ACHI PROCEDURE CODES

ABDR-OPERATION TYPE	Block No.	Block Description	ACHI Code	ACHI Code Description
First implant insertion	1753	Augmentation mammoplasty Includes: insertion of a prosthesis Excludes: that by injection	45524-00	Augmentation mammoplasty, unilateral
			45528-00	Augmentation mammoplasty, bilateral
			45527-00	Augmentation mammoplasty, following mastectomy, unilateral
			45527-01	Augmentation mammoplasty, following mastectomy, bilateral
Tissue expander insertion	1756	Reconstruction procedures on breast	45539-00	Reconstruction of breast with insertion of tissue expander
Tissue expander revision, removal, or replacement	1758	Procedures involving removal or adjustment of breast prosthesis or tissue expander (note: performmed following breast reconstruction after mastectomy or previous augmentation mammoplasty)	45548-02	Adjustment of breast tissue expander Relocation of breast tissue expander
			45548-01	Removal of breast tissue expander
Tissue expander removal and implant insertion	1758	Procedures involving removal or adjustment of breast prosthesis or tissue expander (note: performmed following breast reconstruction after mastectomy or previous augmentation mammoplasty)	45542-00	Removal of breast tissue expander and insertion of permanent prosthesis
Implant revision, removal, or replacement	1758	Procedures involving removal or adjustment of breast prosthesis or tissue expander (note: performmed following breast reconstruction after mastectomy or previous augmentation mammoplasty)	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
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.

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

Table 1.1 and Figure 1.2 shows data the **ABDR operation capture rate overall** and **by procedure type** for the financial years 2017-2018 to 2023-2024. Overall, ABDR data capture rates have decreased from **73.9% in 2019-2020** to **68.7% in 2023-2024.** For 2024, the ABDR captured **over three quarters of implant insertions** – 77.5% for tissue expander removal and implant insertion and 76.0% for first implant insertion, and captured **approximately two-thirds** of tissue expander insertion (64.7%) and implant revisions, removal or replacement (62.2% procedures). Capture rate is lowest for tissue expander revision, removal or replacement, at 46.9%, however only 1,965 of these procedures were recorded by the AIHW between mid-2019 to mid-2024.

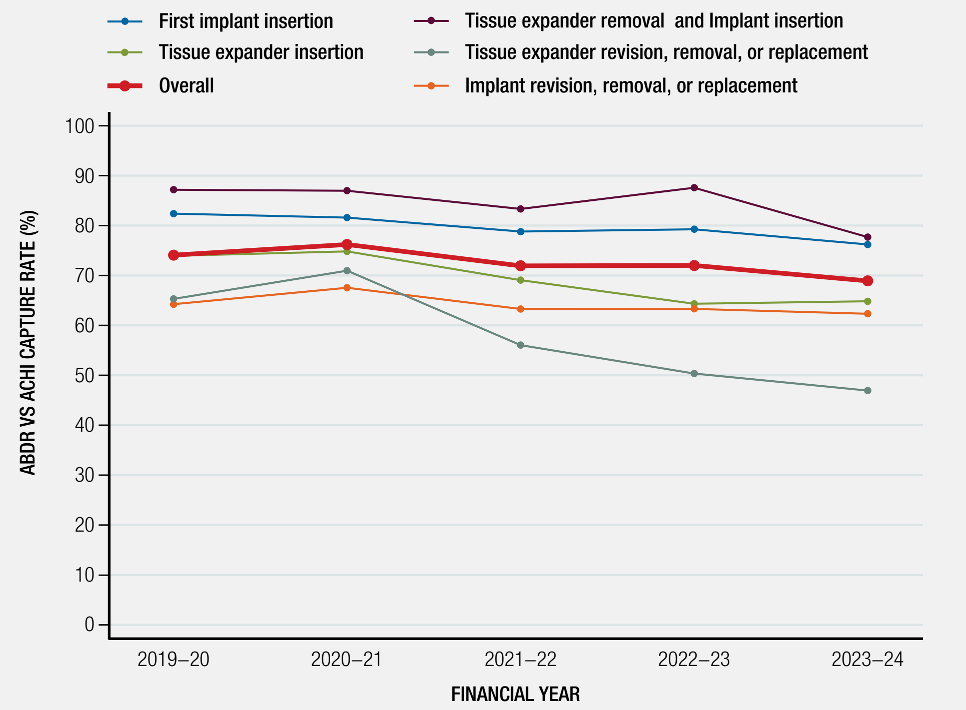
In relation to the ABDR capture rate, it is worth noting that the ABDR is unable to recruit participants in Western Australia due to state-based legislation. Additionally, the ABDR continues to report changes in clinical practice, such that an increasing proportion of first stage (tissue expander) procedures are not followed by a (second stage) breast implant. This has impacted the completeness of second stage procedures captured by the ABDR.

TABLE 1.1 CAPTURE RATE BY FINANCIAL YEAR BASED ON NUMBERS OF PROCEDURES CAPTURED BY ABDR AND AIHW (2018-2019 TO 2023-2024)

Operation Type	FY 2019-2020			FY 2020-2021			FY 2021-2022			FY 2022-2023			FY 2023-2024		
	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	12,229	14,891	82.1%	19,232	23,646	81.3%	14,498	18,455	78.6%	14,974	18,954	79.0%	11,648	15,329	76.0%
Tissue Expander insertion*	1,450	1,967	73.7%	1,489	1,996	74.6%	1,340	1,946	68.9%	1,094	1,705	64.2%	1,094	1,692	64.7%
Tissue Expander removal and Implant insertion	1,464	1,685	86.9%	1,400	1,615	86.7%	1,172	1,411	83.1%	1,119	1,282	87.3%	1,003	1,295	77.5%
Implant revision, removal, or replacement*	8,984	14,022	64.1%	10,587	15,720	67.3%	9,222	14,611	63.1%	9,336	14,788	63.1%	9,455	15,210	62.2%
Tissue Expander revision, removal, or replacement	226	347	65.1%	283	400	70.8%	213	381	55.9%	205	408	50.2%	201	429	46.9%
Total	**24,307**	**32,912**	**73.9%**	**32,954**	**43,377**	**76.0%**	**26,394**	**36,804**	**71.7%**	**26,663**	**37,137**	**71.8%**	**23,333**	**33,955**	**68.7%**

Note: Some of the decrease in capture rate in the most recent financial year may be explained by the delay between procedures and data collection forms being entered into the Registry.
*"Implant removal and tissue expander insertion" procedures were included in the ABDR counts of both "Tissue Expander insertion" and "Implant revision, removal, or replacement" device operation types. Refer to Figure 1.1 (Mapping of ABDR operation types to ACHI Procedure Codes).
Number of "Implant removal and tissue expander insertion" procedures in ABDR, by financial year: N=46 in 2019-20, N=37 in 2021-21, N=51 in 2021-22, N=65 in 2022-23, N=68 in 2023-24. In the total row, these types of procedures are counted only once (not double counted).

FIGURE 1.2 CAPTURE RATE BY FINANCIAL YEAR BASED ON NUMBERS OF PROCEDURES CAPTURED BY ABDR AND AIHW (2018-2019 TO 2023-2024)



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

CHAPTER 2

Registry Participation

Site participation

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

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

In 2024, the ABDR added an additional two private hospitals. The ABDR employ specific terminology to demonstrate site participation in the Registry. 'Contributing' site refers to a hospital that has submitted data to the Registry in previous years but may not have submitted data in the current reporting period. 'Participating' site refers to a hospital that has maintained reporting to the Registry including in the current reporting period. Differentiating 'contributing' and 'participating' sites has meant fewer participating sites, however, this provides a more accurate measure of which sites are regularly performing breast device surgery and submitting data collection forms.

In 2024 a total of **242 sites** were participating in the ABDR, specifically 177 (73.1%) private hospitals, clinics and day surgeries; and 65 (26.9%) public hospitals (Table 2.1).

TABLE 2.1 SITE PARTICIPATION BY STATE AND SITE TYPE (2024)

State	Total	%	Private	%	Public	%
NSW	80	33.1	56	31.6	24	36.9
VIC	56	23.1	37	20.9	19	29.2
QLD	51	21.1	40	22.6	11	16.9
SA	22	9.1	15	8.5	7	10.8
WA	17	7.0	17	9.6	0	0.0
ACT	7	2.9	6	3.4	1	1.5
TAS	6	2.5	4	2.3	2	3.1
NT	3	1.2	2	1.1	1	1.5
Total	**242**	**100**	**177**	**100**	**65**	**100**

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

TABLE 2.2 PROCEDURE BY STATE/TERRITORY, SURGERY INDICATION AND SITE TYPE (PUBLIC AND PRIVATE) 2012-2024

Site State	Cosmetic		Reconstructive		Indication Not stated/Not known		Total	
	Private	Public	Private	Public	Private	Public	Private	Public
NSW	24,774 (30.4%)	94 (22.7%)	6,523 (26.0%)	2,100 (27.5%)	2,837 (26.5%)	293 (30.8%)	34,134 (29.1%)	2,487 (27.6%)
QLD	24,454 (30.0%)	127 (30.7%)	4,595 (18.3%)	1,698 (22.2%)	3,610 (33.7%)	219 (23.0%)	32,659 (27.8%)	2,044 (22.7%)
VIC	17,098 (21.0%)	89 (21.5%)	5,291 (21.1%)	2,249 (29.4%)	1,862 (17.4%)	247 (26.0%)	24,251 (20.7%)	2,585 (28.7%)
WA	9,705 (11.9%)	0 (0.0%)	4,128 (16.4%)	0 (0.0%)	1,647 (15.4%)	0 (0.0%)	15,480 (13.2%)	0 (0.0%)
SA	4,257 (5.2%)	70 (16.9%)	3,292 (13.1%)	1,125 (14.7%)	505 (4.7%)	125 (13.1%)	8,054 (6.9%)	1,320 (14.7%)
TAS	704 (0.9%)	30 (7.2%)	590 (2.3%)	223 (2.9%)	157 (1.5%)	36 (3.8%)	1,451 (1.2%)	289 (3.2%)
ACT	417 (0.5%)	3 (0.7%)	531 (2.1%)	202 (2.6%)	38 (0.4%)	25 (2.6%)	986 (0.8%)	230 (2.6%)
NT	142 (0.2%)	1 (0.2%)	173 (0.7%)	47 (0.6%)	41 (0.4%)	6 (0.6%)	356 (0.3%)	54 (0.6%)
Total (Site type)	**81,551 (99.5%)***	**414 (0.5%)***	**25,123 (76.7%)***	**7,644 (23.3%)***	**10,697 (91.8%)***	**951 (8.2%)***	**117,371 (92.9%)***	**9,009 (7.1%)***
Total	**81,965**		**32,767**		**11,648**		**126,380**	

Note: Public hospitals in Western Australia are unable to contribute to the Registry due to state legislation.
*Percentage of procedures that are private/public out of those with the indication specified at the top of the table.

As at 31 December, 2024, 126,380 procedures had been recorded by the ABDR since commencement. Indication for surgery (cosmetic augmentation, reconstruction post-cancer, reconstruction benign/prophylactic or congenital deformity) was not stated in the data collection form for 9.2% of these procedures (N=11,648). As the remainder of the report is stratified into reconstructive and cosmetic procedures, those procedures with unknown indication have been excluded from further analysis.

A total of 99.5% of cosmetic procedures were performed in private hospitals, and 76.7% of reconstructive procedures were also performed in private hospitals (Table 2.2).

Clinician participation

All clinicians affiliated with the three craft groups represented in the ABDR are encouraged to contribute data to the Registry. In 2024, 44 new clinicians joined the Registry. Table 2.3 represents the total number of clinicians (N=462) participating (defined as those who have submitted at least one data collection form) in the ABDR during 2024, based on clinical specialty and state/territory. Plastic surgeons are the highest contributing craft group (N=293; 63% of total). The greatest number of clinicians contributing data to the ABDR mainly operate in New South Wales (N=150) and Queensland (N=103).

TABLE 2.3 CLINICIAN/SURGEON PARTICIPATION BY STATE/TERRITORY AND CLINICAL SPECIALTY (2024)

State	Plastic Surgeons	General/Breast Surgeons	Cosmetic Clinicians	Total
NSW	85	57	8	150
QLD	61	37	5	103
VIC	78	19	3	100
WA	31	15	3	49
SA	22	12	1	35
ACT	5	6	0	11
TAS	9	2	0	11
NT	2	1	0	3
Total	**293**	**149**	**20**	**462**

Note: Clinicians who have performed procedures in more than one jurisdiction have been allocated to the one in which they performed the most procedures during 2024.

Accumulation of clinician participation

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

Figure 2.1 shows in the 11 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.

FIGURE 2.1 CUMULATIVE PARTICIPATING ABDR CLINICIANS BY CLINICAL SPECIALTY

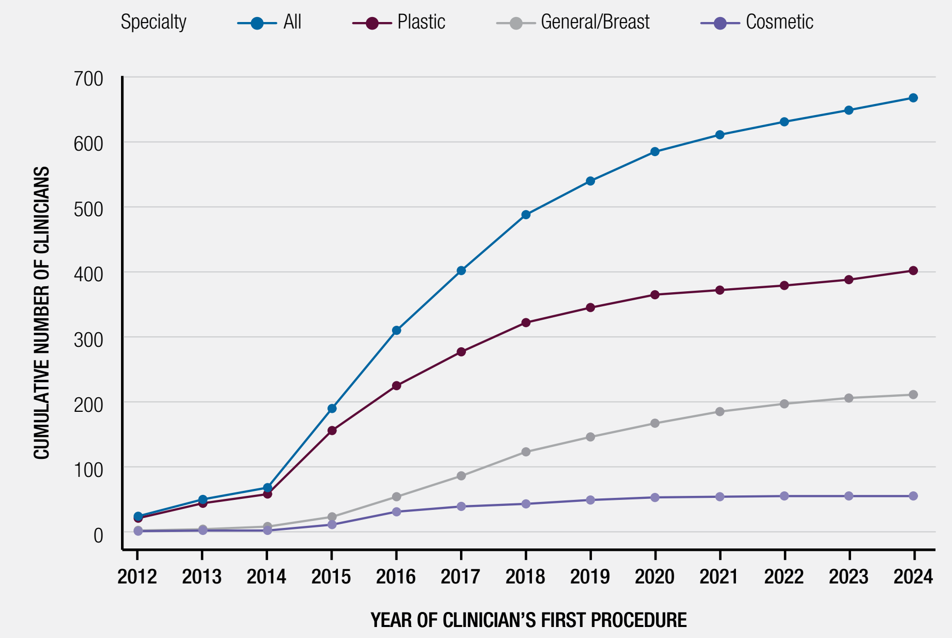


Table 2.4 provides insight into the numbers of reconstructive and cosmetic procedures undertaken by individual clinicians. Of the total of 462 clinicians, 13 clinicians did not have any procedure in 2024 with indication reported, thus **449 clinicians are captured in this data.** This is an increase of 11 clinicians compared with the previous year.

A majority of participating clinicians in 2024 (54%) performed both cosmetic and reconstructive procedures, with 23% performing only cosmetic procedures and 23% performing only reconstructive procedures. Of clinicians that perform both cosmetic and reconstructive procedures, they most commonly (55%) performed 11-50 procedures per year with 2% performing greater than 200 procedures, and 7% performing no more than five procedures. Of those clinicians that only perform cosmetic or reconstructive procedures, they most commonly performed no more than 5 procedures per year.

This data highlights that the vast majority of participating ABDR clinicians (86%) undertake 50 procedures or fewer a year (no more than one breast device procedure per week), and as such, are not high-volume clinicians. This has implications for engagement of clinicians in the ABDR, and indicates that the data reported back to individual hospitals and clinicians has the statistical limitations associated with being low volume.

TABLE 2.4 RECONSTRUCTIVE AND COSMETIC PROCEDURES PER CLINICIAN (2024) (N=449)

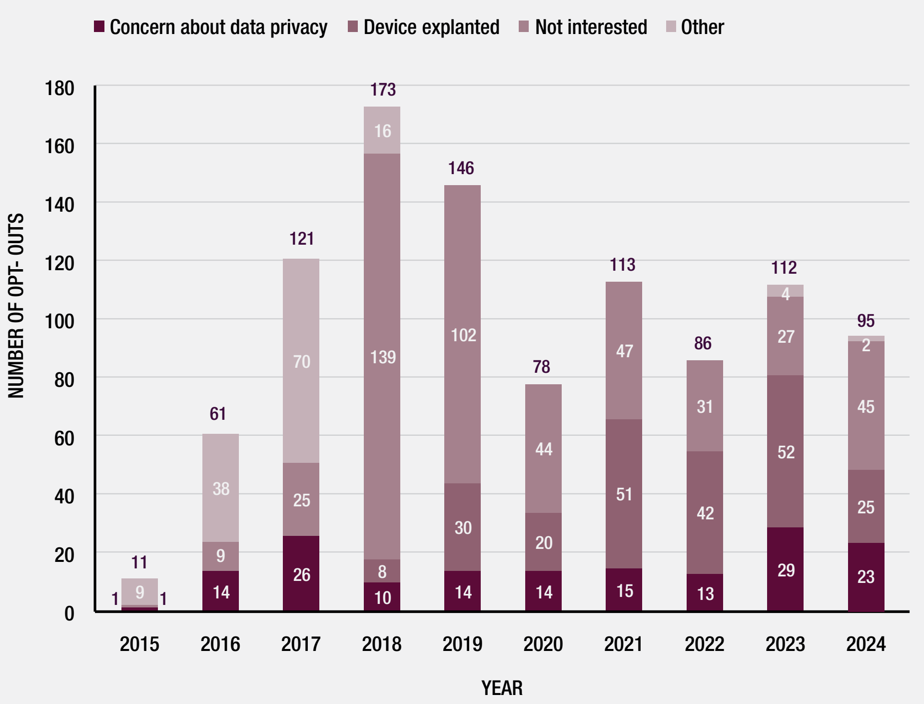
Procedures per clinician/surgeon	Clinician/surgeon performed only cosmetic procedures	Clinician/surgeon performed only reconstructive procedures	Clinician/surgeons who performed both cosmetic and reconstructive procedures
	N (%)	N (%)	N (%)
>200	2 (2%)	0 (0%)	6 (2%)
101-200	3 (3%)	0 (0%)	5 (2%)
51-100	6 (6%)	1 (1%)	38 (16%)
11-50	38 (37%)	18 (17%)	134 (55%)
6-10	9 (9%)	24 (23%)	42 (17%)
≤5	45 (44%)	61 (59%)	17 (7%)
Total	**103 (23%*)**	**104 (23%*)**	**242 (54%*)**

Note: Excludes 13 clinicians who only submitted DCFs with indication not stated in 2024
*Percentage of all clinicians who have submitted at least one DCF with indication stated.

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=1,020 for 2012-2024) are not included in the analysis for the reported figures and tables. Figure 2.2 shows the number of opt-outs per year by reason for opting out during 2015-2024 (inclusive). In order of frequency, the reasons for opting out during this reporting period were: patients not being interested (N=470; 47%), having devices explanted (N=228; 23%), other (N=139; 14%), and being concerned about data privacy (N=159; 16%).

FIGURE 2.2 NUMBER OF OPTED-OUT PATIENTS BY REASON FOR OPT-OUT (2015-2024) (N=996)



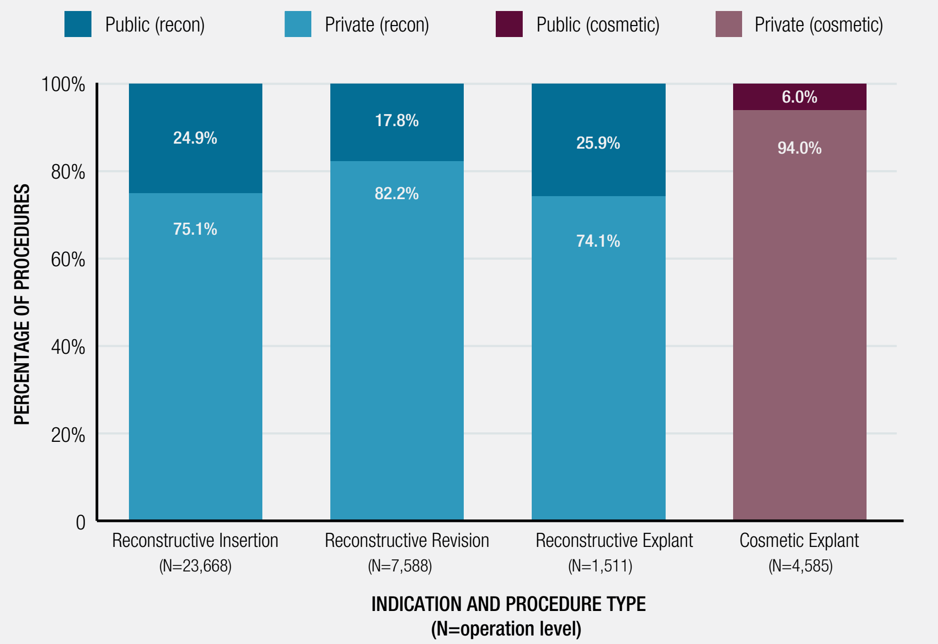
Clinician and site reporting

The ABDR disseminated its sixth annual set of clinician reports (for procedures up to 31 Dec 2023) in 2024 to 280 clinicians. All clinicians with a minimum case load (five or more data collection forms) who submitted data in the reporting year received an individualised clinician report regarding their ABDR activity and outcomes. The ABDR also provided 107 sites with an annual site report (for procedures up to 31 Dec 2023), having done so since 2020. These sites met the minimum requirements of three participating clinicians and the submission of 20 data collection forms within the reporting period. If a site does not meet these criteria then they are able to request a report by contacting the ABDR. These threshold numbers are being reviewed by the ABDR for 2025 reports.

Procedures by facility/site type

The majority of both cosmetic and reconstructive breast device procedures (operation level) recorded in the ABDR are performed in private facilities (Figure 2.3; 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 (82.2%), but also insertions (75.1%) and explants (74.1%). Cosmetic explants are the only cosmetic procedure that may be reimbursed to be undertaken in a public hospital. Approximately 6% of cosmetic implants are explanted in public hospitals.

FIGURE 2.3 PROCEDURES BY SITE TYPE FOR RECONSTRUCTION (BY DEVICE OPERATION TYPE) AND COSMETIC (EXPLANT ONLY) PROCEDURES DURING (2012-2024)



Note: Insertion, revision and explant procedures for any indication have been analysed independently. Both unilateral and bilateral procedures are included. A procedure indication hierarchy has been applied for bilateral procedures with different indication and procedure type per breast.

CHAPTER 3

Patients, Procedures and Devices

Of the **109,020 patients** in the ABDR until 31 December 2024, 70.7% had a cosmetic indication for surgery and 20.6% had a reconstructive indication (15.3% post-cancer reconstruction, 3.1% risk reducing reconstruction, and 2.2% for correction of developmental deformity) (Table 3.1). Approximately 8.7% of patients did not have an indication for surgery noted on their form.

From 2012 to 2024, the ABDR had 109,020 patients registered. A patient is considered to be participating in the ABDR from the date of their earliest ABDR recorded surgery. Due to the lag of data transfer from the site to the ABDR, additional patients may have had surgery in this timeframe but are yet to be included in the database.

The total number of **procedures** captured at operation level by the Registry is **126,380** indicating that some patients have more than one procedure captured by the Registry, particularly reconstructive patients who comprise **20.6%** of total **patients** but **25.9%** of total **procedures**. The ABDR has recorded **235,474** procedures at breast level, and **213,141 device insertions** (Table 3.1). The number of devices is fewer than the number of procedures (at breast level) because some procedures may not result in a new device insertion i.e.: explantation and reposition procedures. Furthermore, the number of procedures (at breast level) accounts for all procedures recorded by the ABDR and thus a specific breast may be included in this total more than once.

TABLE 3.1 TOTAL NUMBER AND PERCENTAGE OF REGISTERED PATIENTS, PROCEDURES PER PATIENT, PROCEDURES PER BREAST, AND TOTAL DEVICES CAPTURED BY CLINICAL INDICATION FOR SURGERY (2012-2024)

	Patients*		Procedures (operation level) **		Procedures (breast level) ***		Devices captured by Registry #	
	N	(%)	N	(%)	N	(%)	N	(%)
Reconstructive								
Post-cancer reconstruction	16,689	15.3	24,947	19.7	31,616	13.4	30,044	14.1
Risk-reducing reconstruction	3,431	3.1	5,092	4.0	14,571	6.2	13,819	6.5
Developmental deformity	2,357	2.2	2,728	2.2	4,635	2.0	4,413	2.1
Total reconstructive	**22,477**	**20.6**	**32,767**	**25.9**	**50,822**	**21.6**	**48,276**	**22.6**
Total cosmetic	**77,023**	**70.7**	**81,965**	**64.9**	**162,728**	**69.1**	**153,056**	**71.8**
Not stated	9,520	8.7	11,648	9.2	21,924	9.3	11,809	5.5
Total	**109,020**	**100**	**126,380**	**100**	**235,474**	**100**	**213,141**	**100**

Note: The indication of each operation was assigned based on the four-tier hierarchy beginning with post-cancer reconstruction, followed by risk-reducing reconstruction, developmental deformity and then cosmetic augmentation.

* Patients were assigned to the indication for their first procedure recorded in the ABDR.

** The number of procedures at the operation level have been reported, where the primary reason for the procedure determines the classification by indication.

*** The number of procedures at breast level have been reported.

\# Breast level procedures involving device insertions (breast implants/tissue expanders). Includes 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: 753 device insertion procedures reported as cosmetic but with the opposite breast reported as reconstructive.

A total of **9,765 patients, 11,902 procedures** (operation level) and **18,842 devices** were captured in 2024 (Table 3.2). The Registry recognises that the "not stated" category has increased in the current reporting period. It is exploring the reasons for this discrepancy and ways that the Registry can encourage sites and clinicians to identify the indication for surgery for all procedures.

TABLE 3.2 TOTAL NUMBER AND PERCENTAGE OF REGISTERED PATIENTS, PROCEDURES PER PATIENT, PROCEDURES PER BREAST, AND TOTAL DEVICE CAPTURED BY CLINICAL INDICATION FOR SURGERY (2024)

	Patients*		Procedures (operation level) **		Procedures (breast level) ***		Devices captured by Registry #	
	N	(%)	N	(%)	N	(%)	N	(%)
Reconstructive								
Post-cancer reconstruction	1,592	16.3	2,451	20.6	3,121	14.1	2,897	15.4
Risk-reducing reconstruction	299	3.1	462	3.9	1,353	6.1	1,250	6.6
Developmental deformity	212	2.2	253	2.1	468	2.1	436	2.3
Total reconstructive	**2,103**	**21.5**	**3,166**	**26.6**	**4,942**	**22.3**	**4,583**	**24.3**
Total cosmetic	**6,525**	**66.8**	**7,281**	**61.2**	**14,425**	**65.2**	**12,955**	**68.8**
Not stated	1,137	11.6	1,455	12.2	2,749	12.4	1,304	6.9
Total	**9,765**	**100**	**11,902**	**100**	**22,116**	**100**	**18,842**	**100**

Note: The indication of each operation was assigned based on the four-tier hierarchy beginning with post-cancer reconstruction, followed by risk-reducing reconstruction, developmental deformity and then cosmetic augmentation.
* Patients were assigned to the indication for their first procedure recorded in the ABDR.
** The number of procedures at the operation level have been reported, where the primary reason for the procedure determines the classification by indication.
*** The number of procedures at breast level have been reported.
\# Breast level procedures involving device insertions (breast implants/tissue expanders). Includes device operation types: first implant insertion; tissue expander insertion; tissue expander removal and implant insertion; implant revision – with revision type: replacement; tissue expander revision – with revision type: replacement; implant removal and tissue expander insertion.
Procedures with marked as cosmetic augmentation but with clashes against this indication: concurrent mastectomy/previous radiotherapy/procedures involving tissue expander have been moved to the "Not stated" group.
Cosmetic device count includes: 38 device insertion procedures reported as cosmetic but with the opposite breast reported as reconstructive.

Breast Devices Captured

The ABDR records and reports data on breast devices including implants and tissue expanders, by procedure (at breast level). Of the 235,474 procedures reported at breast level, 85.0% of procedures involved insertion of a new breast implant (including for an implant replacement), 5.5% involved insertion of a new tissue expander and the remaining procedures involved only explants or repositions (Table 3.3). Information regarding matrix/mesh use is reported later in Chapter 4.

TABLE 3.3 PROCEDURE TYPES CAPTURED BY THE ABDR (2012-2024)

Procedure Type	N	%
Implant inserted: (incl. replacement)	200,174	85.0
Implant reposition only	1,051	0.4
Implant explant only	20,259	8.6
TE inserted: (incl. replacement)	12,967	5.5
TE reposition only	22	<0.1
TE explant only	1,001	0.4
Total	**235,474**	**100**

Note: Counts are at the breast level. Procedures involving implant insertions include those with device operation types: first implant insertion; tissue expander removal and implant insertion; implant revision – with revision type: replacement. Procedures involving tissue expander insertions include those with device operation types: Tissue expander insertion; tissue expander revision – with revision type: replacement; implant removal and tissue expander insertion.

Breast Device Procedure Information by Manufacturer

Breast implant insertions by manufacturer

The following tables identify the manufacturers of inserted breast implants. Data is reported at breast level and shows data completeness. Table 3.4 and Figure 3.1 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 **as well as data relating to 2024 only (new analysis)**. Comparison of the aggregate vs 2024 data highlights that usage of Motiva implants has increased significantly in recent years, and that Mentor and Motiva devices account for 98% of all new implants in 2024. In 2024, small numbers of implants from Polytech and Nagor were also used.

Similar tables based on reconstruction and cosmetic indication for surgery can be found in their respective chapters.

TABLE 3.4 BREAST IMPLANTS INSERTED BY MANUFACTURER

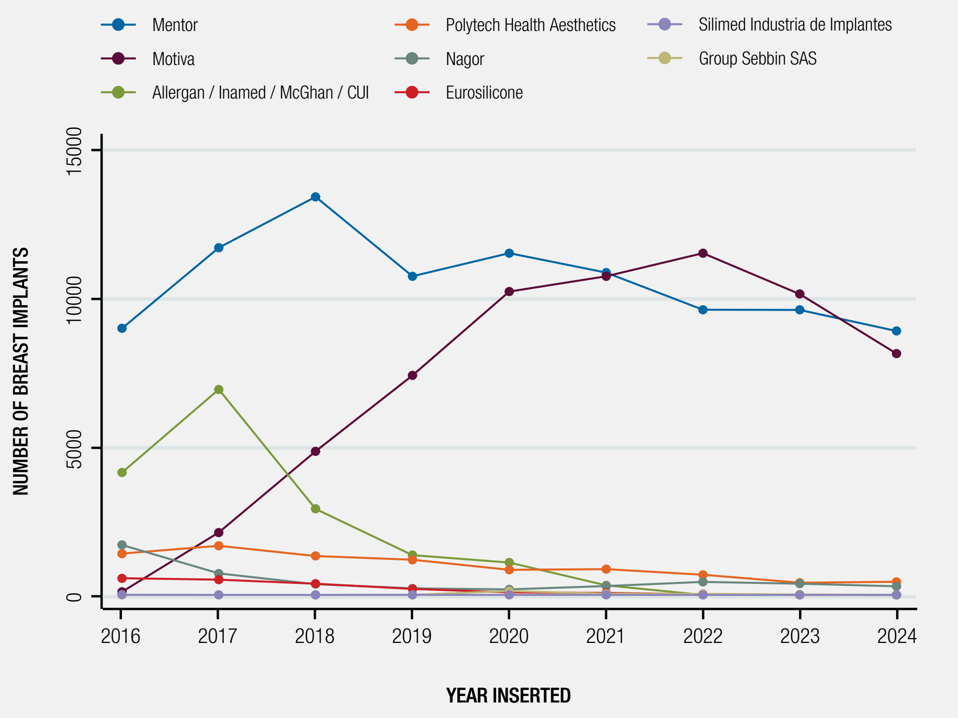
Manufacturer	2012–2024		2024	
	N	%	N	%
Mentor	97,954	48.9	8,857	50.0
Motiva	64,934	32.4	8,099	45.7
Allergan/Inamed/McGhan/CUI	19,888	9.9	0	0.0
Polytech Health & Aesthetics	8,958	4.5	441	2.5
Nagor	5,400	2.7	289	1.6
Eurosilicone	1,972	1.0	0	0.0
Silimed Industria de Implantes	594	0.3	0	0.0
Group Sebbin SAS	225	0.1	2	<0.1
Cereplas	44	<0.1	0	0.0
Not Stated	**205**	**0.1**	**32**	**0.2**
Total	**200,174**	**100**	**17,720**	**100**

Note: Counts are at the breast level. Includes procedures with device operation types: first implant insertion; tissue expander removal and implant insertion; implant revision - with revision type: replacement.

Table 3.4 provides the breakdown of **breast implants inserted** by manufacturer from any surgical indication as reported to the Registry. From 2012-2024, a total of 200,174 implant devices were inserted of which **99.9% had manufacturer details provided.** The most frequently inserted devices by manufacturer were Mentor, Motiva and Allergan/Inamed/McGhan/CUI which together contribute to 91.3% of the implants inserted. In contrast in 2024, a total of 17,720 devices were inserted of which 99.8% had manufacturer details provided.

Figure 3.1 shows the change in the number of breast implants inserted by manufacturer 2016-2024 (data collected during the pilot program 2012-2015 is omitted from this figure due to the low capture rate reported during this time). Mentor implants were the most commonly used devices in 2024, followed by Motiva. Of note, all Allergan macro-textured implants were withdrawn from use in Australia in 2019.

FIGURE 3.1 BREAST IMPLANTS INSERTED BY MANUFACTURER (2016-2024)



Note: Counts are at the breast level. Includes 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 2012-2024 by manufacturer were: Allergan/Inamed/McGhan/CUI and Mentor devices which together comprised 47.3% of devices (Table 3.5). 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 53,447 implant replacement procedures recorded in the ABDR, **61.3% had explant manufacturer information** reported to the Registry.

TABLE 3.5 EXPLANTED DEVICES FROM IMPLANT REPLACEMENT PROCEDURES BY MANUFACTURER (NOT INCLUDING TISSUE EXPANDERS) (2012-2024)

Manufacturer	N	%
Allergan/Inamed/McGhan/CUI	13,377	25.0
Mentor	9,506	17.8
Silimed Industria de Implantes	2,375	4.4
Nagor	2,237	4.2
Motiva	2,016	3.8
Eurosilicone	1,066	2.0
PIP	906	1.7
Polytech Health & Aesthetics	880	1.6
Dow Corning	209	0.4
Cereplas	138	0.3
Group Sebbin SAS	66	0.1
LifeSil	4	<0.1
Not Stated	**20,667**	**38.7**
Total	**53,447**	**100**

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

Breast devices explanted only

The most frequently **explanted devices from explant only procedures (of breast implants)** between 2012-2024 by manufacturer were: Allergan/Inamed/McGhan/CUI and Mentor devices which together comprised 48.5% of the explanted devices (Table 3.6). Of the total 20,259 explants only procedures reported to the Registry, **72.6%** had manufacturer information provided.

TABLE 3.6 EXPLANTED DEVICES FROM EXPLANT ONLY PROCEDURES BY MANUFACTURER (NOT INCLUDING TISSUE EXPANDERS) (2012-2024)

Manufacturer	N	%
Allergan/Inamed/McGhan/CUI	5,546	27.4
Mentor	4,281	21.1
Silimed Industria de Implantes	1,356	6.7
Nagor	1,034	5.1
Motiva	506	2.5
Eurosilicone	500	2.5
Polytech Health & Aesthetics	388	1.9
PIP	362	1.8
Dow Corning	170	0.8
Cereplas	106	0.5
Group Sebbin SAS	38	0.2
LifeSil	4	<0.1
Not Stated	**5,968**	**29.5**
Total	**20,259**	**100**

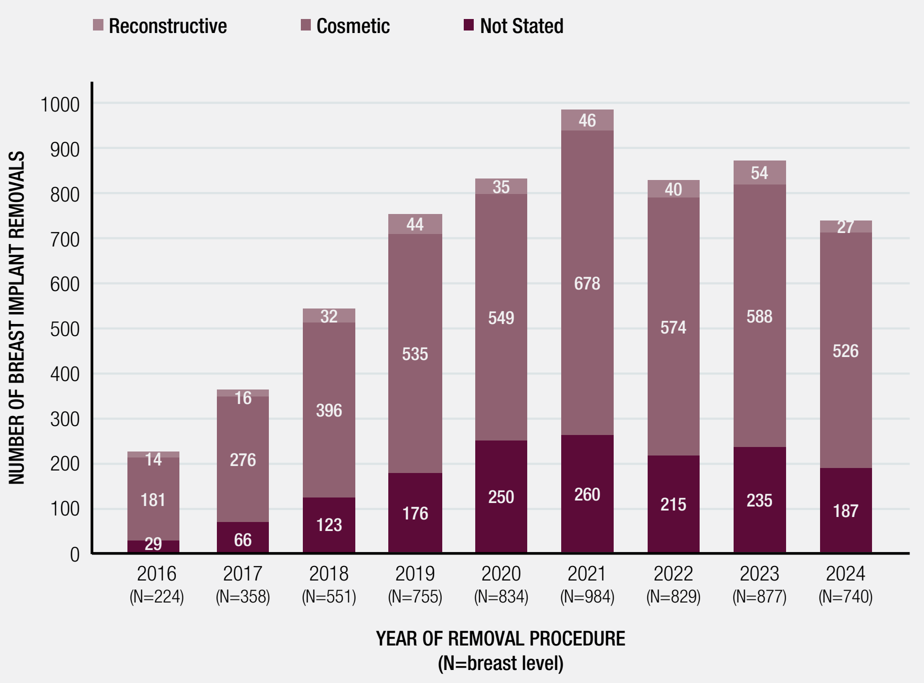
Note: Counts are at the breast level. Includes implant revision procedures with revision type: explant. Proportions are not reflective of device performance (typical times of insertion and volumes of devices inserted vary across manufacturers). The LifeSil implants were all inserted overseas.

Removal of implants from overseas

The ABDR collects information regarding when an implant is **removed** whether the outgoing device was **originally inserted overseas**. Patients with procedures involving removals of devices originating from overseas may consist of: medical tourists returning to Australia, patients who had a breast device insertion procedure before permanently migrating to Australia, and visitors to Australia. A total of **6,287 procedures** were captured from 2012-2024 which involved removal of devices originally inserted overseas.

The annual numbers of such procedures peaked in 2021 at nearly 1,000 procedures, but has declined since then, in line with procedures performed in Australia (see Chapter 6, Figure 6.1). In 2024, there were 740 implants inserted overseas with subsequent revisions performed in Australia. In 2024, 71.1% of implants inserted overseas and revised in Australia were for cosmetic indications, 25.3% were not stated and 3.6% were for reconstructive indication (Figure 3.2).

FIGURE 3.2 REMOVAL OF IMPLANTS INSERTED OVERSEAS (2016-2024) (N=6,152)



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

CHAPTER 4

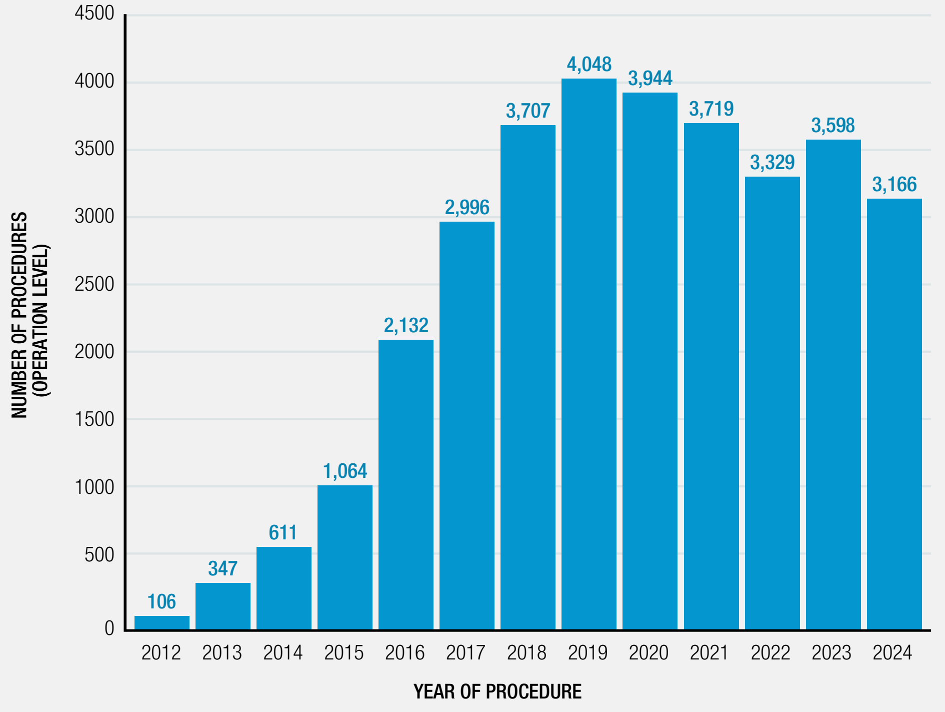
Reconstructive Breast Procedures

Reconstructive procedure numbers

The ABDR has captured a **total of 32,767 procedures** involving breast devices for reconstructive surgery, where the reasons for reconstructive surgery included post-cancer reconstruction, risk-reducing reconstruction and developmental deformity.

Figure 4.1 shows the annual number of reconstructive procedures captured from 2012 to 2024. In 2024 there were **3,166 reconstructive procedures** captured by the ABDR, a slight decrease on 2023 procedures, and lower than the peak of over 4,048 procedures captured in 2019.

FIGURE 4.1 REGISTERED PROCEDURES – RECONSTRUCTIVE PROCEDURES (2012-2024)

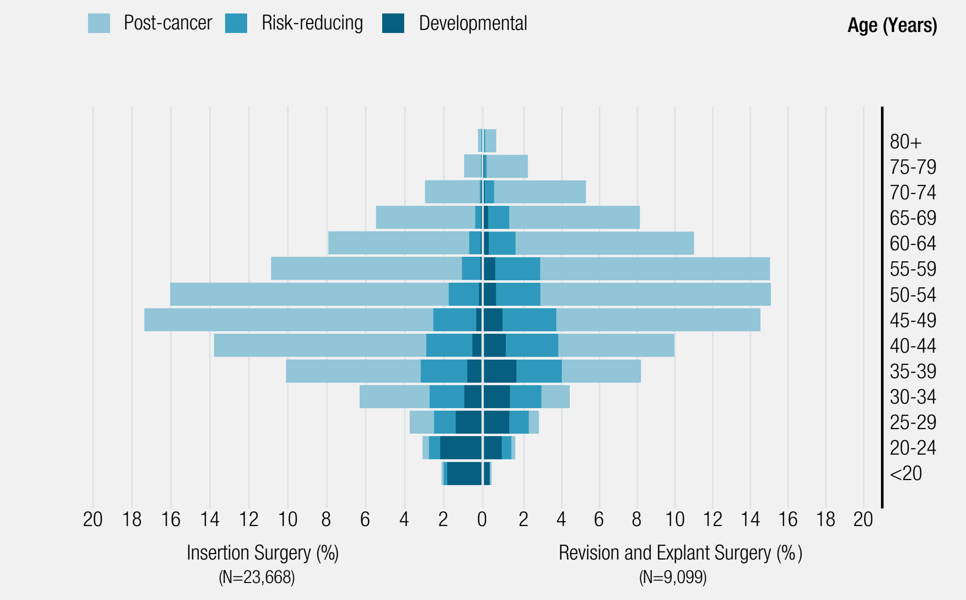


Patient age at reconstructive procedure

The age distribution at the time of reconstructive procedure is shown in Figure 4.2 and Table 4.1. Age differences can be seen by procedure indication and type: insertion, revision or explant.

In 2012-2024, the **median patient age for post-cancer reconstruction** insertion, revision and explant procedures were approximately 50, 55 and 55 years respectively. **Risk-reducing procedure patients had a median age of 42, 47 and 45 years respectively. For patients undergoing reconstruction surgery for developmental deformity the median age was 25 years for insertions**, 38 for revisions and 37 years for explants.

FIGURE 4.2 AGE DISTRIBUTION AT TIME OF PROCEDURE – RECONSTRUCTIVE PROCEDURES (2012-2024)



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 four-tier hierarchy has been applied for bilateral procedures with different indication and procedure type details per breast.

TABLE 4.1 SUMMARY STATISTICS FOR AGE AT TIME OF PROCEDURE – RECONSTRUCTIVE PROCEDURES (2012-2024)

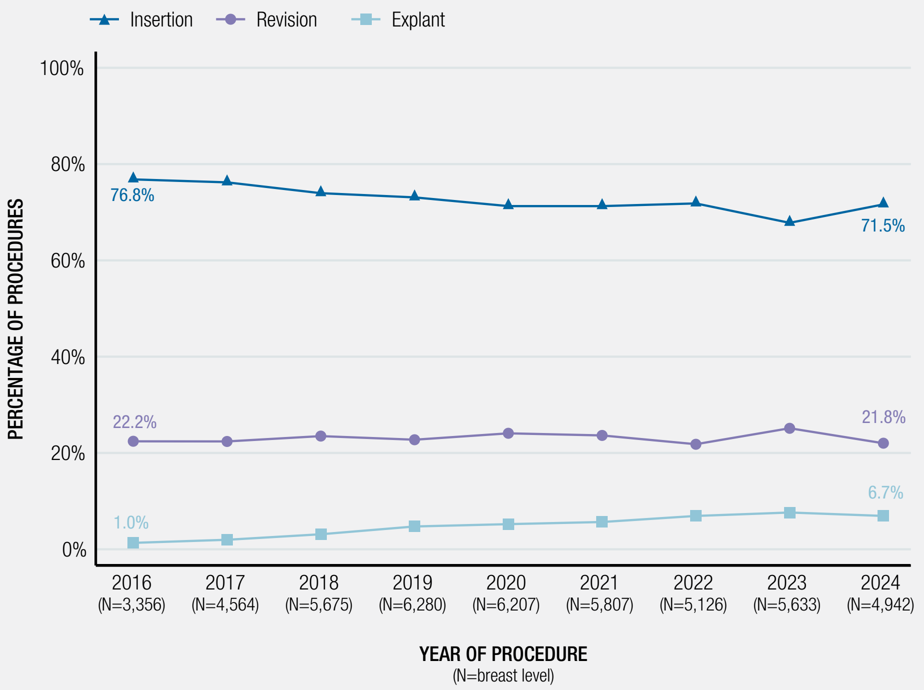
	Insertion Surgery		Revision Surgery		Explant Only	
	N	Median Age (IQR)	N	Median Age (IQR)	N	Median Age (IQR)
Post-cancer	18,465	50.4 (43.5, 58.1)	5,389	55.0 (47.6, 62.9)	1,093	55.5 (48.1, 63.7)
Risk-reducing	3,348	42.1 (34.7, 49.9)	1,447	47.5 (39.0, 57.0)	297	45.2 (36.2, 55.8)
Developmental	1,855	25.1 (20.4, 33.8)	752	37.1 (29.2, 46.8)	121	38.0 (30.6, 46.2)
Total	**23,668**		**7,588**		**1,511**	

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. The interquartile range reports observed patient age at the 25th and 75th percentiles.

ABDR Procedures – insertion, revision and explantation

Figure 4.3 and Table 4.2 show the percentage and counts of reconstructive breast procedures classified as device insertion, revision and explant of the procedures entering the Registry in the reporting period (2016-2024). During 2024 a total of 3,536 (71.5%) breasts entered the Registry with a reconstructive insertion procedure; 1,077 (21.8%) with a reconstructive revision procedure; and 329 (6.7%) with a reconstructive explant procedure (total of 4,942 reconstructive procedures). During the last nine years, the proportion of device insertion procedures at breast level have decreased by 5.3% and revision procedures have remained stable. The proportion of procedures which are explant only continues to increase, from 1.0% in 2016 to 6.7% in 2024. The absolute number of explants captured has increased year-on-year up to 2023.

FIGURE 4.3 INSERTION, REVISION AND EXPLANT PROCEDURES OVER TIME – RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2016-2024)



Note: First implant insertion; tissue expander removal and implant insertion; tissue expander insertion procedures are classified as insertions. The revision category includes breast implant/tissue expander revisions with device replacement/reposition (not explant only procedures).

TABLE 4.2 INSERTION, REVISION AND EXPLANT PROCEDURES OVER TIME – RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2016-2024)

Procedure type	Year of procedure								
	2016	2017	2018	2019	2020	2021	2022	2023	2024
Insertion	2,576 (76.8%)	3,475 (76.1%)	4,193 (73.9%)	4,585 (73.0%)	4,419 (71.2%)	4,134 (71.2%)	3,678 (71.8%)	3,814 (67.7%)	3,536 (71.5%)
Revision	745 (22.2%)	1,012 (22.2%)	1,321 (23.3%)	1,415 (22.5%)	1,481 (23.9%)	1,360 (23.4%)	1,107 (21.6%)	1,404 (24.9%)	1,077 (21.8%)
Explant	35 (1.0%)	77 (1.7%)	161 (2.8%)	280 (4.5%)	307 (4.9%)	313 (5.4%)	341 (6.7%)	415 (7.4%)	329 (6.7%)
Total	**3,356 (100.0%)**	**4,564 (100.0%)**	**5,675 (100.0%)**	**6,280 (100.0%)**	**6,207 (100.0%)**	**5,807 (100.0%)**	**5,126 (100.0%)**	**5,633 (100.0%)**	**4,942 (100.0%)**

Reconstructive procedures manufacturer details

Implants used in reconstructive procedures

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

Table 4.3 shows the breakdown of breast implants inserted by manufacturer for **reconstructive procedures** as reported to the Registry. From 2012-2024 a total of **35,886 reconstructive breast implants were inserted** of which 99.9% had manufacturer details provided. The most frequently inserted breast implants by manufacturer were: Mentor and Motiva, which combined comprised 86.0% of reconstructive breast implants inserted. In 2024 a total of 3,526 reconstructive breast implants were inserted of which 99.8% had manufacturer details provided. The most frequently inserted breast implants by manufacturer in 2024 were: Mentor and Motiva which combined comprised of 99.1% of reconstructive breast implants inserted.

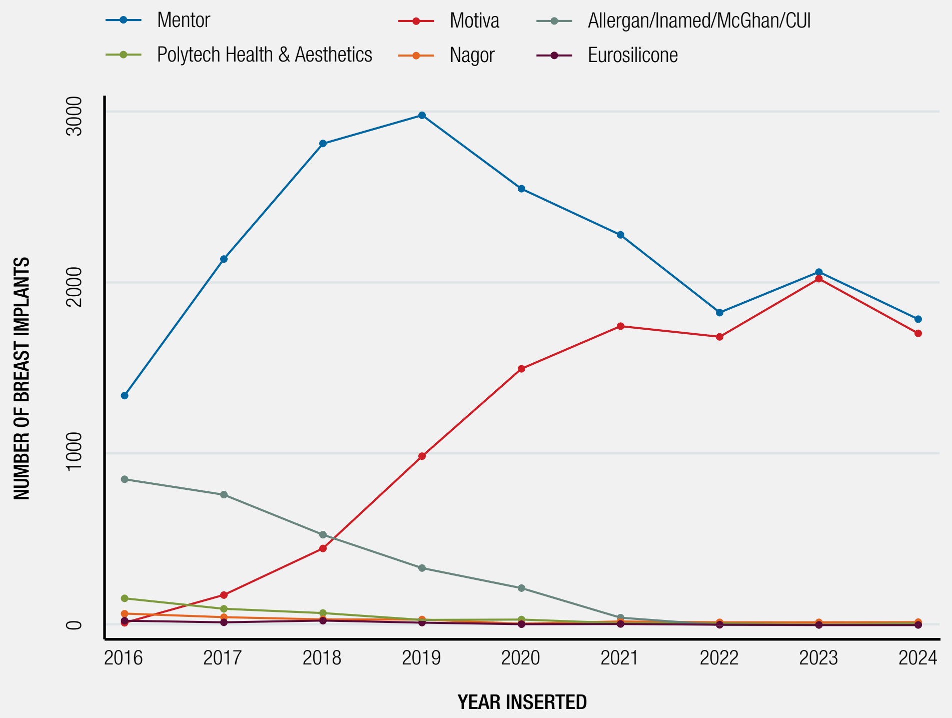
TABLE 4.3 BREAST IMPLANTS INSERTED BY MANUFACTURER – RECONSTRUCTIVE PROCEDURES

Manufacturer	2012–2024		2024	
	N	%	N	%
Mentor	20,563	57.3	1,788	50.7
Motiva	10,283	28.7	1,705	48.4
Allergan/Inamed/McGhan/CUI	4,049	11.3	0	0.0
Polytech Health & Aesthetics	433	1.2	10	0.3
Nagor	311	0.9	17	0.5
Eurosilicone	98	0.3	0	0.0
Silimed Industria de Implantes	92	0.3	0	0.0
Cereplas	11	<0.1	0	0.0
Not Stated	**46**	**0.1**	**6**	**0.2**
Total	**35,886**	**100**	**3,526**	**100**

Note: Counts are at the breast level. Includes procedures with device operation types: first implant insertion; tissue expander removal and implant insertion; implant revision - with revision type: replacement.

Figure 4.4 shows the annual **numbers of implant devices inserted by manufacturer 2016-2024** (data collected during the pilot program 2012-2015 are omitted from this figure due to the low capture rate of procedures reported during this time). Mentor has manufactured the majority of implants used for reconstruction procedures in the Registry, but the proportion of devices from Motiva has been steadily increasing. Allergan/Inamed/McGhan/CUI device use continued to decrease over this time period. Of note, all Allergan macro-textured implants were withdrawn from use in Australia in 2019.

FIGURE 4.4 BREAST IMPLANTS INSERTED BY MANUFACTURER – RECONSTRUCTIVE PROCEDURES (2016-2024)



Note: Counts are at the breast level. Includes procedures with device operation types: first implant insertion; tissue expander removal and implant insertion; implant revision - with revision type: replacement.

Tissue expanders in reconstructive procedures

Table 4.4 shows the breakdown of **tissue expanders** inserted by manufacturer for reconstructive procedures as reported to the Registry. From 2012-2024 a total of 12,390 tissue expanders were inserted, of which 99.8% had manufacturer details provided. The most frequently inserted tissue expanders by manufacturer were: Mentor and Allergan/Inamed/McGhan/CUI which combined comprised 93.9% of tissue expanders inserted. In 2024 a total of 1,057 tissue expanders were inserted, of which 99.8% had manufacturer details provided. The majority of tissue expanders inserted in 2024 (97.5%) were manufactured by Mentor and 2.3% were from Motiva.

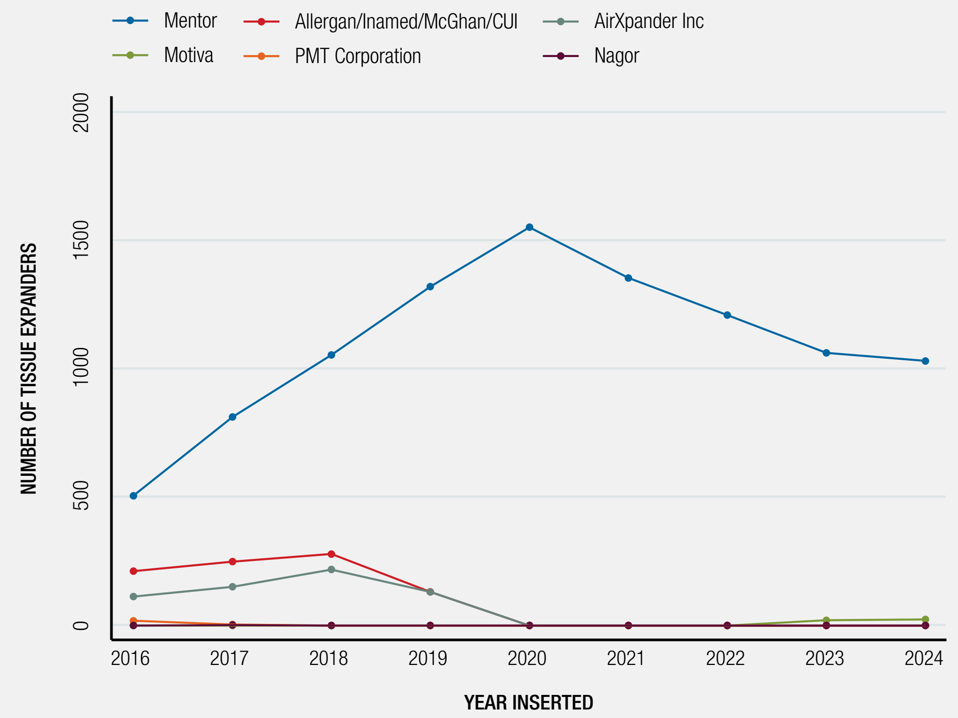
TABLE 4.4 TISSUE EXPANDERS INSERTED BY MANUFACTURER – RECONSTRUCTIVE PROCEDURES

Manufacturer	2012–2024		2024	
	N	%	N	%
Mentor	10,183	82.2	1,031	97.5
Allergan/Inamed/McGhan/CUI	1,454	11.7	0	0.0
AirXpander Inc	632	5.1	0	0.0
Motiva	45	0.4	24	2.3
PMT Corporation	35	0.3	0	0.0
Silimed Industria de Implantes	10	0.1	0	0.0
Nagor	2	<0.1	0	0.0
Not Stated	**29**	**0.2**	**2**	**0.2**
Total	**12,390**	**100**	**1,057**	**100**

Note: Counts are at the breast level. Includes 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= 12,967 tissue expanders have been inserted overall between 2012-2024)

Figure 4.5 shows the annual number of tissue expanders inserted by manufacturer 2016-2024 (data collected during the pilot program 2012-2015 are omitted from this figure due to the low case ascertainment rates reported during this time). Mentor tissue expanders were the most commonly used since 2020. Of note, Allergan tissue expanders were withdrawn in 2019.

FIGURE 4.5 TISSUE EXPANDERS INSERTED BY MANUFACTURER – RECONSTRUCTIVE PROCEDURES (2016-2024)



Note: Counts are at the breast level. Includes 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 used in reconstructive procedures

Table 4.5 shows the breakdown of matrix/mesh devices inserted by manufacturer for reconstructive procedures as reported to the Registry. From 2012-2024 a total of **11,465 matrix/mesh** were inserted, of which **98.6% had manufacturer details provided.** The most common matrix/mesh devices by product group were: TiLOOP, Flex and Veritas which combined comprised 95.1% of matrix/mesh inserted for reconstructive procedures.

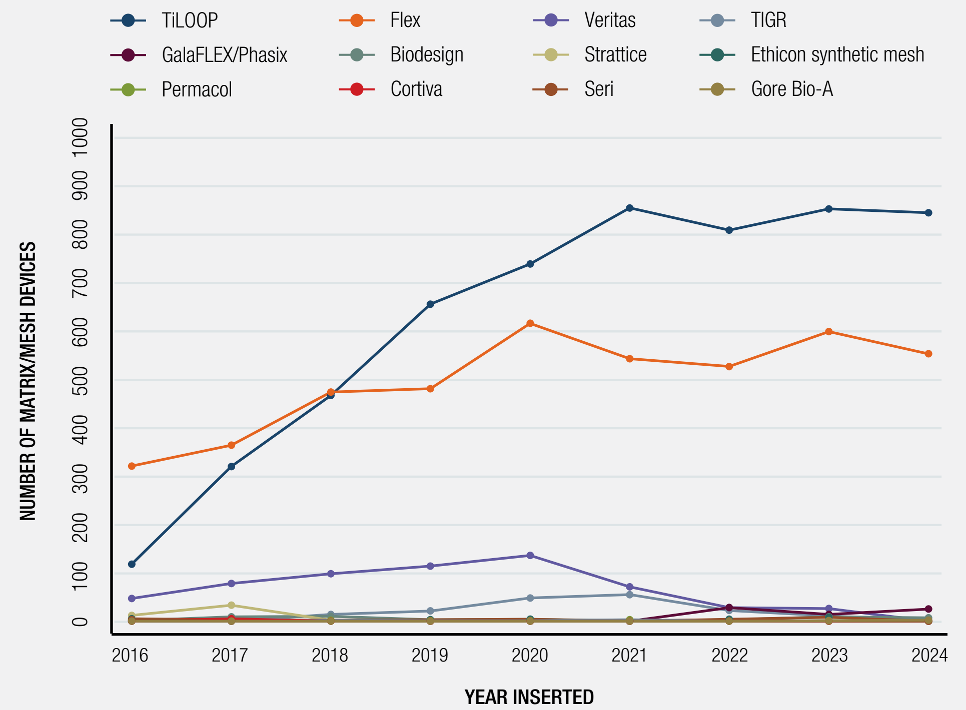
TABLE 4.5 MATRIX/MESH DEVICES INSERTED BY PRODUCT – RECONSTRUCTIVE PROCEDURES

Manufacturer	2012–2024		2024	
	N	%	N	%
TiLOOP	5,685	49.6%	845	59.0%
Flex	4,610	40.2%	553	38.6%
Veritas	609	5.3%	0	0.0%
TIGR	171	1.5%	0	0.0%
GalaFLEX/Phasix	67	0.6%	25	1.7%
Biodesign	53	0.5%	7	0.5%
Strattice	47	0.4%	0	0.0%
Ethicon synthetic mesh	33	0.3%	0	0.0%
Permacol	16	0.1%	0	0.0%
Cortiva	5	<0.1%	0	0.0%
Seri	4	<0.1%	0	0.0%
Gore Bio-A	3	<0.1%	2	0.1%
Not Stated	**162**	**1.4%**	**0**	**0.0%**
Total	**11,465**		**1,432**	

Note: Counts are at the breast level. Includes procedures with reported use of matrix/mesh devices. Only breast procedures recorded as having reconstructive indications are included (N=12,613 matrix/mesh have been inserted overall between 2012-2024).

Figure 4.6 shows the annual number of matrix/mesh devices inserted by manufacturer 2016-2024 (data collected during the pilot program 2012-2015 are omitted from this figure due to low case ascertainment of procedures reported during this time). Since 2018, TiLOOP has been the most frequently used matrix/mesh in reconstructive breast procedures.

FIGURE 4.6 MATRIX/MESH DEVICES INSERTED BY PRODUCT – RECONSTRUCTIVE PROCEDURES (2016-2024)



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

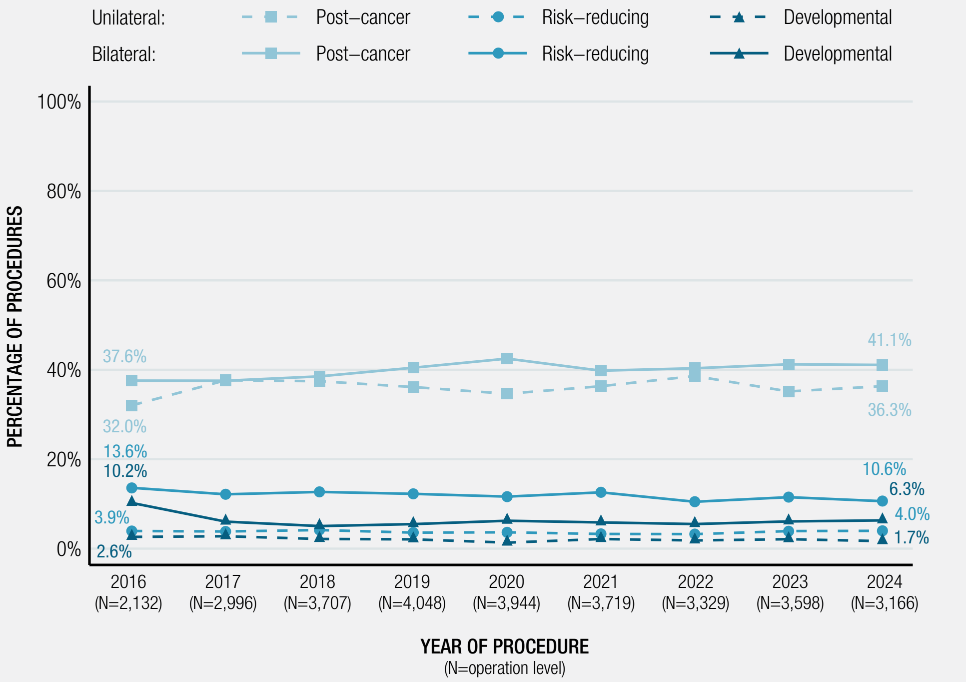
Reconstructive procedural types

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

Bilateral and unilateral procedures

Reconstructive procedures are most commonly undertaken following mastectomy for breast cancer. Procedures may be **unilateral or bilateral. In 2024, of a total of 3,166 reconstructive procedures** were undertaken. Of these, 1,301 (41.1%) were bilateral and 1,150 (36.3%) were unilateral **post-cancer procedures**. A further 10.6% of reconstructive procedures were **bilateral risk-reducing procedures**. Less common reconstructive procedures were bilateral procedures for developmental deformity (6.3% of procedures in 2024); unilateral risk reducing procedures (4.0%), and unilateral developmental deformity procedures (1.7%). Overall, the proportion of reconstructive surgery for post-cancer indications has slightly increased since 2016 whereas reconstructive surgery for other indications has slightly decreased over time (Figure 4.7).

FIGURE 4.7 PROCEDURE INDICATION AND LATERALITY – RECONSTRUCTIVE PROCEDURES (2016-2024)

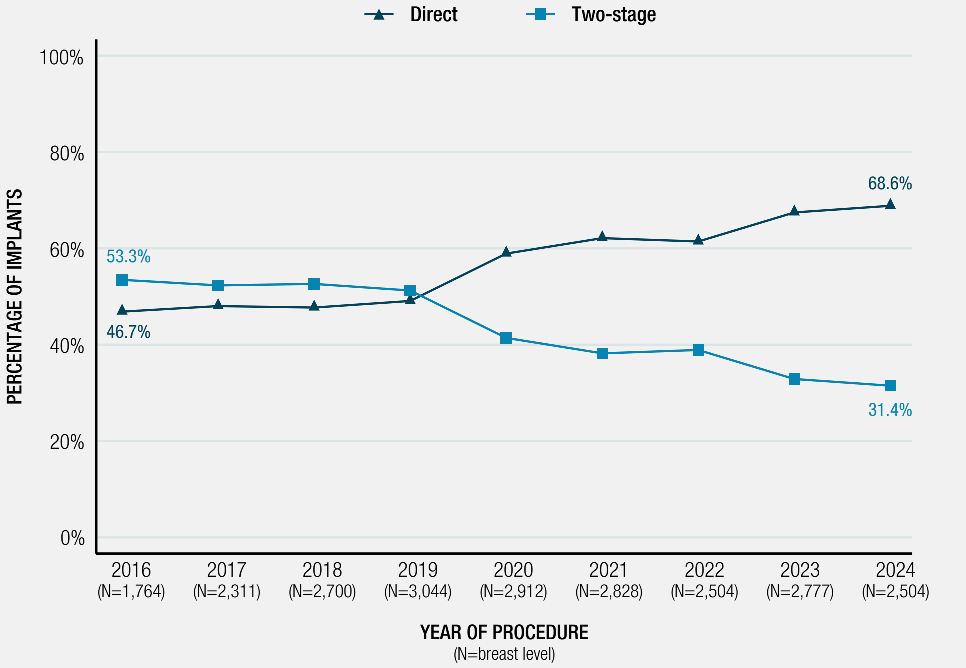


Note: Counts are at the operation level. A procedure indication hierarchy has been applied to bilateral procedures with different indication and procedure type details per breast. Primary reason for procedure has been applied for all patients.

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

Since 2016, the proportion of one-stage (direct-to-implant) procedures has increased, overtaking 2-stage procedures (tissue expander followed by an implant) from 2019 (Figure 4.8). In 2024, 68.6% of reconstructive procedures were direct-to-implant, and 31.4% were two-stage procedures.

FIGURE 4.8 PROPORTION OF DIRECT-TO-IMPLANT VS TWO-STAGE INSERTION PROCEDURES PERFORMED DURING 2016-2024

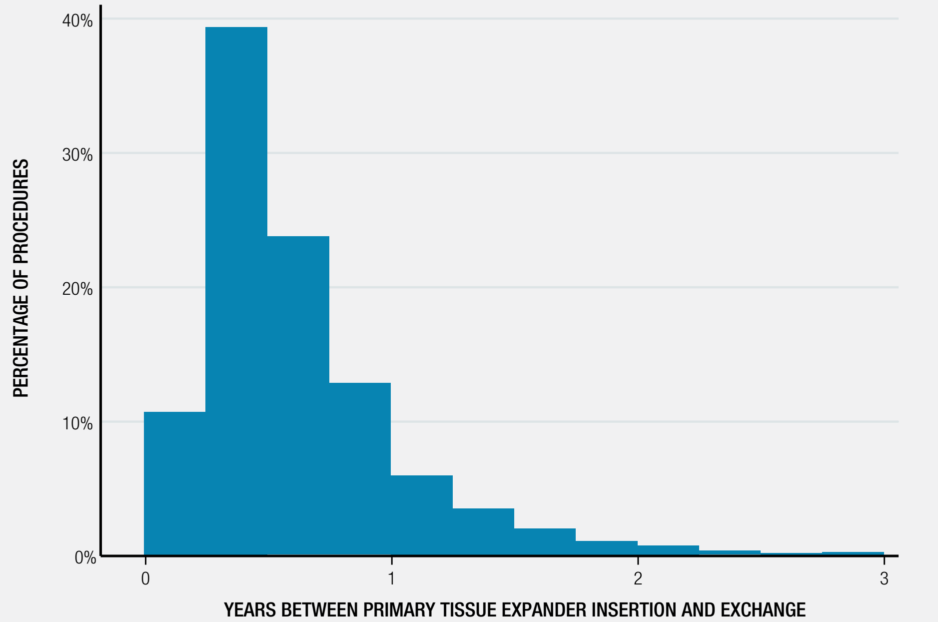


Note: Data was collected at the breast level for (direct) implant insertion or TE removal and implant insertion procedures. All other device operation types (revisions, explants, tissue expander insertions) and procedures involving breasts with recorded history of previous in situ breast implants are not considered here.

Capture of procedures after tissue expander insertion

Figure 4.9 shows the distribution in times to exchange of 7,788 primary tissue expander insertions. They include breasts which entered the Registry with a primary tissue expander insertion procedure and also have exchange to second stage implant as the next procedure captured in the Registry. The majority (86.0%) of exchanges occurred within 12 months, with very few (1.8%) occurring after 24 months (Appendix 2).

FIGURE 4.9 TIME BETWEEN PRIMARY TISSUE EXPANDER INSERTION AND EXCHANGE TO IMPLANT PROCEDURE (2012-2024)



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

Table 4.6 includes breasts which entered the Registry with primary reconstructive tissue expander insertion procedures from 2016-2023. It shows what type of procedure was next captured by the ABDR (if any) for each breast. The number of tissue expander insertions has been relatively stable at over 900 from 2017 to 2023.

The proportion of tissue expander insertion procedures that are followed by exchange to implant procedures has declined since 2016 from 81.4% to 59.9% in 2023 (the 2024 year is not included due to many exchanges not occurring within the same calendar year as the initial tissue expander insertion). At the same time, the proportion of TEs having no reported subsequent procedure has increased from 13.7% in 2016 to 28.0% in 2023. This may be due to delay in second stage procedures or data entry into the ABDR, or it may reflect changes in practice, such as first stages of TE not progressing to second stage and being replace with an autologous flap (such as TE being replaced with autologous flap in place of breast implants).

TABLE 4.6 PROCEDURE CAPTURED AFTER PRIMARY TISSUE EXPANDER INSERTION (2016-2023)

Next captured procedure following primary TE	Year of Primary TE insertion								
	2016	2017	2018	2019	2020	2021	2022	2023	Total (2016-2023)
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
None	109 (13.7%)	167 (15.1%)	201 (14.3%)	231 (15.8%)	276 (19.6%)	314 (25.7%)	249 (23.0%)	269 (28.5%)	1,816 (19.3%)
TE revision/explant	26 (3.3%)	57 (5.1%)	68 (4.8%)	76 (5.2%)	93 (6.6%)	98 (8.0%)	95 (8.8%)	85 (9.0%)	598 (6.3%)
Exchange to implant	646 (81.4%)	861 (77.6%)	1,098 (78.0%)	1,137 (77.6%)	996 (70.9%)	780 (63.9%)	706 (65.2%)	562 (59.5%)	6,786 (72.0%)
Other	13 (1.6%)	24 (2.2%)	40 (2.8%)	21 (1.4%)	40 (2.8%)	29 (2.4%)	33 (3.0%)	29 (3.1%)	229 (2.4%)
Total	**794 (100.0%)**	**1,109 (100.0%)**	**1,407 (100.0%)**	**1,465 (100.0%)**	**1,405 (100.0%)**	**1,221 (100.0%)**	**1,083 (100.0%)**	**945 (100.0%)**	**9,429 (100.0%)**

Reconstructive procedure intra-operative techniques

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

Table 4.7, Figure 4.10, Figure 4.11, and Appendix 3 show the intra-operative techniques used during breast reconstruction surgery. Overall, the use of intra-operative techniques has increased (post-operative antibiotics, antiseptic rinse, antibiotic rinse and sleeve/funnel) or remained stable over time (intra-operative antibiotics, drain use and nipple guard)

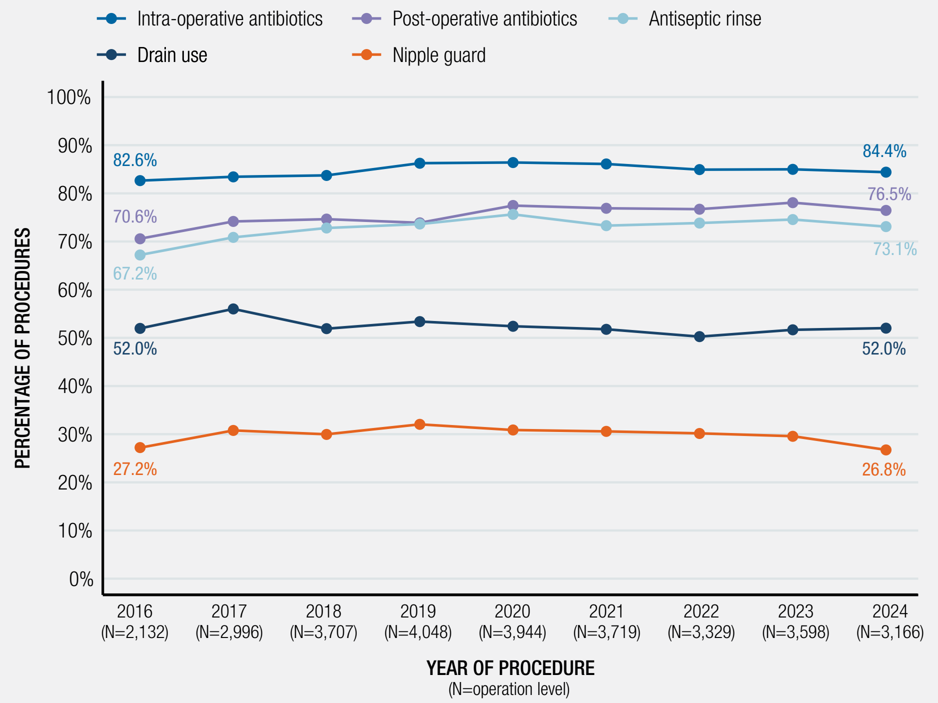
TABLE 4.7 INTRA-OPERATIVE TECHNIQUES – RECONSTRUCTIVE PROCEDURES (2012-2024)

	2012-2024		
	N	(%)	Total eligible
Intra-op/post-op antibiotics[1]	28,270	86.3	32,767
Antiseptic rinse[1]	23,875	72.9	32,767
Drain use[1]	17,238	52.6	32,767
Nipple guard[2]	5,563	29.1	19,145
Glove change for insertion[3]	24,249	77.6	31,246
Antibiotic dipping solution[3]	15,883	50.8	31,246
Sleeve/funnel[4]	7,778	34.0	22,849

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 2012-2024 because the data fields were not collected separately until 2015. Denominator for percentage calculation: [1]all procedures; [2]procedures where at least one breast has nipple absent not reported; [3]excludes explant only procedures; [4]only includes device operation types: first implant insertion; tissue expander removal and implant insertion; implant revision – with revision types: replacement/reposition.

Out of the 3,166 reconstructive operations in 2024, 2,672 used intra-operative antibiotics, 2,421 used post-operative antibiotics and 2,314 involved antiseptic rinse, and 1,647 used drain (Figure 4.10).

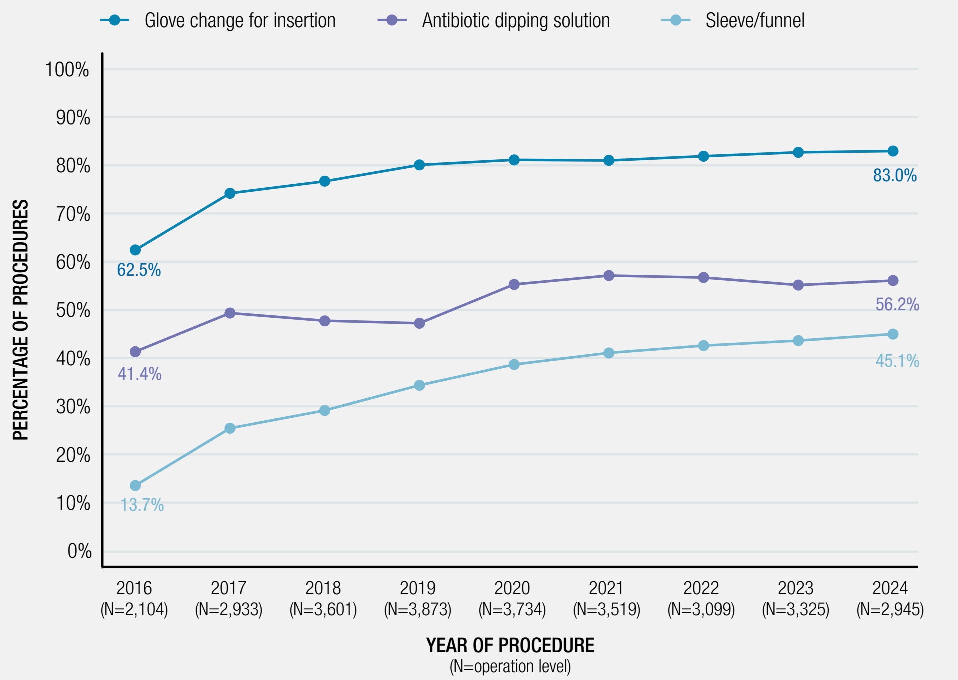
FIGURE 4.10 INTRA-OPERATIVE TECHNIQUES RELEVANT FOR RECONSTRUCTIVE PROCEDURES OF ANY DEVICE OPERATION TYPE (2016-2024)



Note: Information regarding intra-operative and post-operative antibiotics have been collected separately since 2015. A procedure indication hierarchy has been applied for bilateral procedures with different indication and procedure type details per breast. Procedures where at least one breast has nipple absent not reported is used as the denominator for nipple guard.

Out of the 2,945 reconstructive insertion and revision operations (not explant only) in 2024; 2,444 involved changing gloves for insertion and 1,654 used antibiotic dipping solution. 1,006 used a sleeve/funnel out of 2,231 procedures involving insertion of new implant or replacement/ reposition of an implant. 523 out of 1,955 procedures where at least one breast has nipple absent not reported involved use of nipple guards (Figure 4.11). Use of glove change for insertion, dipping solution and sleeve/funnel use has increased overtime and plateaued at 83%, 56% and 45% respectively.

FIGURE 4.11 INTRA-OPERATIVE TECHNIQUES RELEVANT FOR RECONSTRUCTIVE INSERTION AND REVISION (NOT EXPLANT ONLY) PROCEDURES (2016-2024)



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

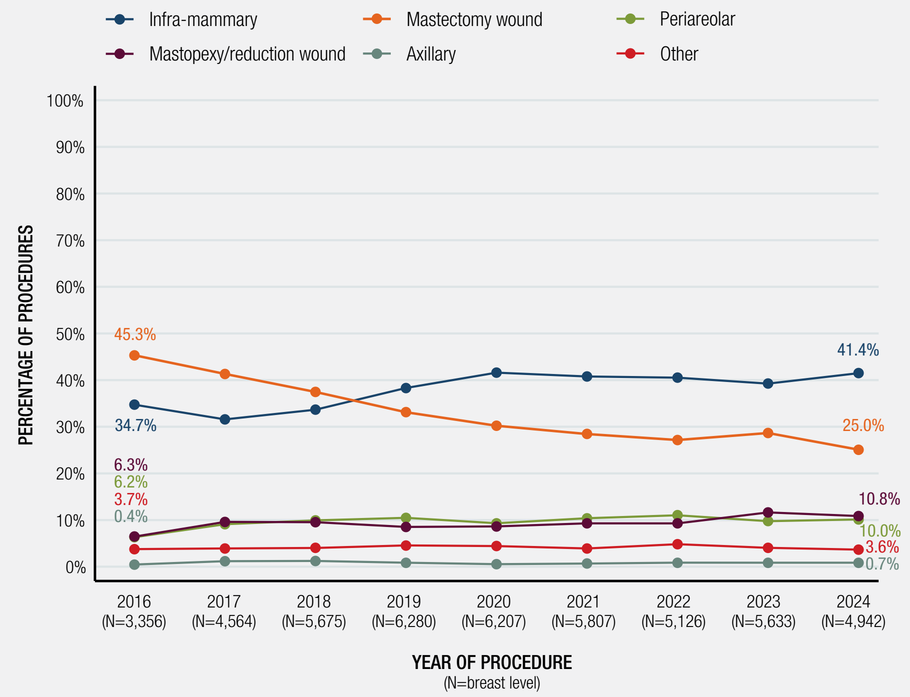
Reconstructive procedure surgical elements

Trends in surgical elements over time are shown in Figures 4.13-4.16 and further details can be found in Appendix 4.

Surgical incision site

Over the last six years, the most common surgical incision site used has changed from previous mastectomy wound incisions in favour of infra-mammary incisions (41.4%) with previous mastectomy wound used in 25.0% of procedures (Figure 4.12).

FIGURE 4.12 SURGICAL ELEMENTS – INCISION SITE – RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2016-2024)

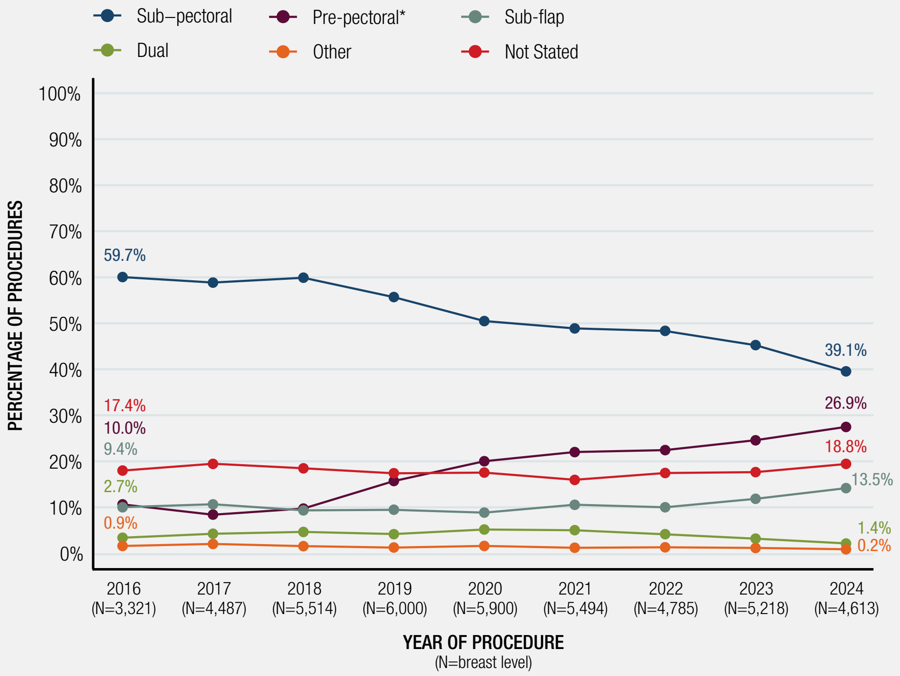


Note: More than one incision site can be recorded.

Surgical plane

The most commonly used surgical plane in 2024 remains sub-pectoral (39.1%), although use of the pre-pectoral plane continues to increase (26.9% in 2024) (Figure 4.13).

FIGURE 4.13 SURGICAL ELEMENTS – SURGICAL PLANE – RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2016-2024)

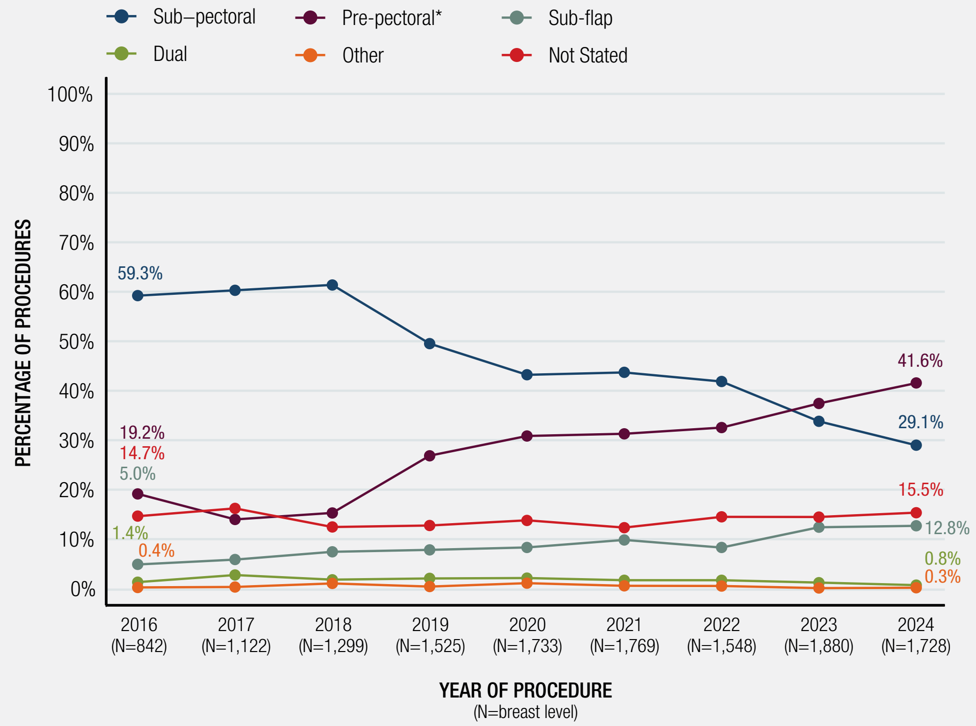


Note: Only insertion and revision procedures (which are not explant only) are included.
*A procedure is reported as having pre-pectoral plane if sub-glandular/sub-fascial has been ticked for plane or if "pre-pectoral"/"sub-cutaneous" has been written on the DCF.

The plane of device insertion has been analysed separately for primary direct-to-implant procedures and (the tissue expander insertion part of) primary two-stage procedures (new analysis).

For direct-to-implant procedures, use of pre-pectoral plane (41.6%) has recently overtaken use of sub-pectoral plane (29.1%) (Figure 4.14).

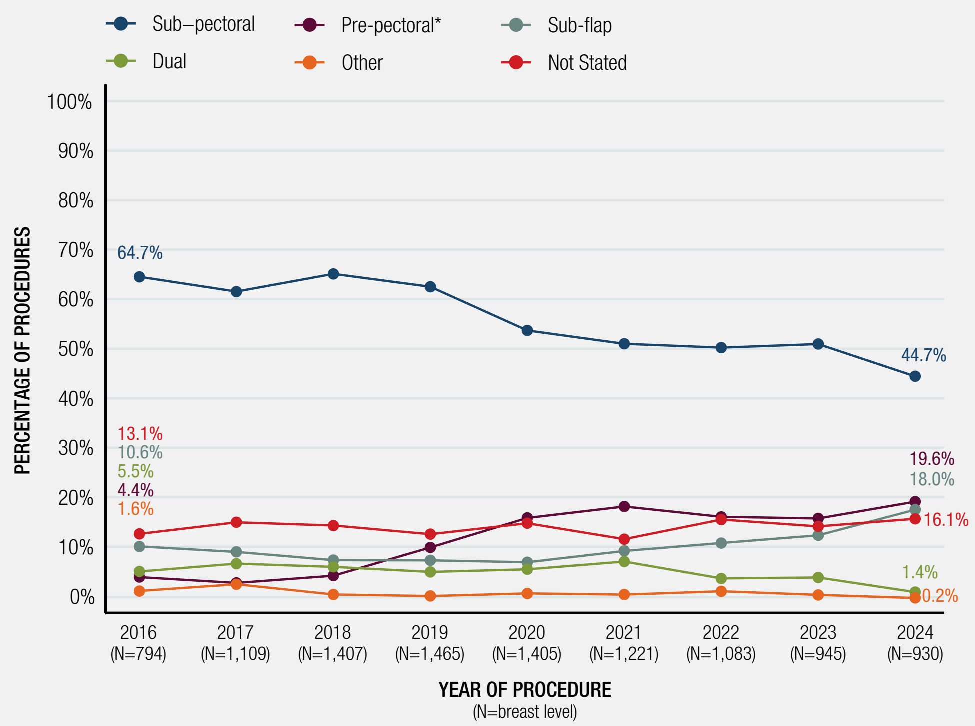
FIGURE 4.14 SURGICAL ELEMENTS – SURGICAL PLANE – DIRECT-TO-IMPLANT RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2016-2024)



Note: Only primary direct-to-implant procedures are included.
*A procedure is reported as having pre-pectoral plane if sub-glandular/sub-fascial has been ticked for plane or if "pre-pectoral"/"sub-cutaneous" has been written on the DCF.

For two-stage procedures (tissue expander insertion part), the sub-pectoral plane remains the most common (44.7%), however use of other planes including pre-pectoral (19.6%) and others are increasing (Figure 4.15).

FIGURE 4.15 SURGICAL ELEMENTS – SURGICAL PLANE (AT TISSUE EXPANDER INSERTION PART) – TWO-STAGE RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2016-2024)

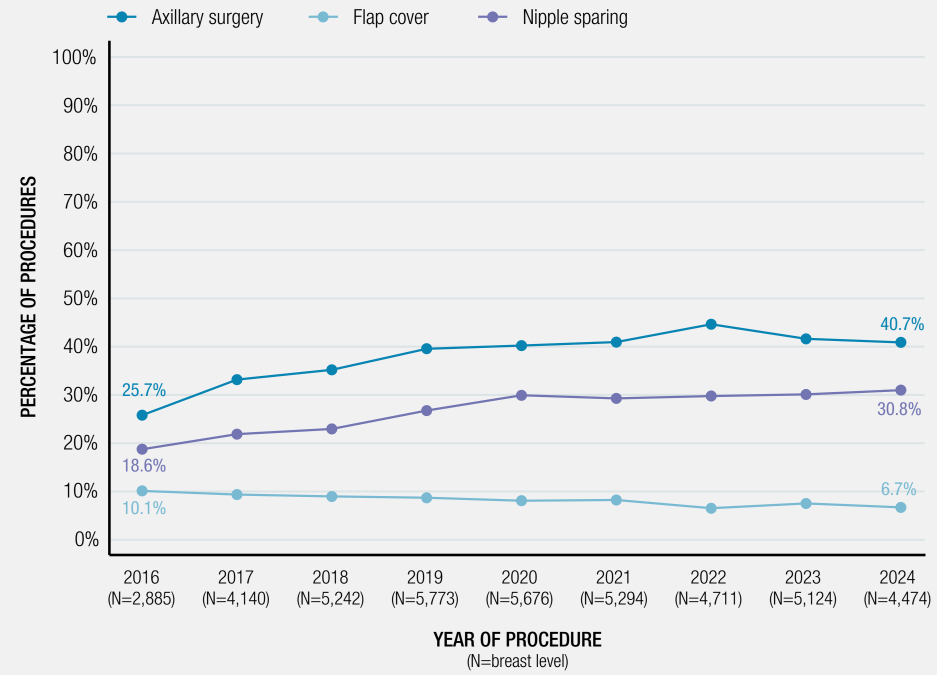


Note: Only primary tissue expander insertion procedures (first part of two-stage procedures) are included.
*A procedure is reported as having pre-pectoral plane if the "Sub-glandular/Sub-fascial" option has been selected for the plane field or if "pre-pectoral"/"sub-cutaneous" has been written on the DCF.

Other surgical elements

Over the last nine years the frequency of axillary surgery and nipple sparing has increased (40.7% and 30.8% respectively in 2024) and flap cover has decreased (6.7%) in 2024.

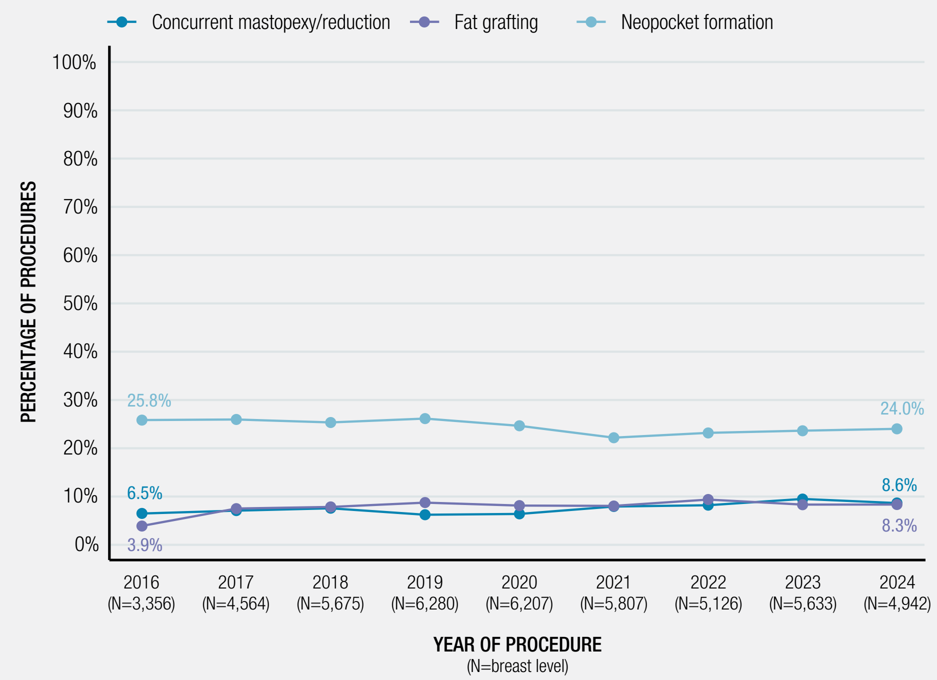
FIGURE 4.16 SURGICAL ELEMENTS RELEVANT FOR CANCER RELATED PROCEDURES – RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2016-2024)



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

Other surgical techniques (concurrent mastopexy, fat grating and neopocket formation) have remained relatively stable over time (Figure 4.17).

FIGURE 4.17 OTHER SURGICAL ELEMENTS - RECONSTRUCTIVE BREAST LEVEL PROCEDURES (2016-2024)



Note: The denominator for neo pocket formation includes only revision (not explant only) procedures.

Device characteristics for breast reconstruction procedures

The ABDR collects data on breast devices including breast implants, tissue expanders and matrix/mesh. Table 4.8 reports characteristics of **implants and tissue expanders** (shell/texture, shape and fill) used for breast reconstruction procedures.

The most common device characteristics for breast implants from 2012-2024 are textured shell type (49.7%), round shape (57.7%), and silicone filled (97.8%). The most common device characteristics for tissue expanders over the same period are textured shell type (99.3%), anatomical shape (99.6%) and saline fill (94.7%). Of note, carbon dioxide is no longer used in tissue expanders although during this reporting period 5.1% were recorded with this type of fill.

TABLE 4.8 DEVICE CHARACTERISTICS – RECONSTRUCTIVE BREAST DEVICES (2012-2024)

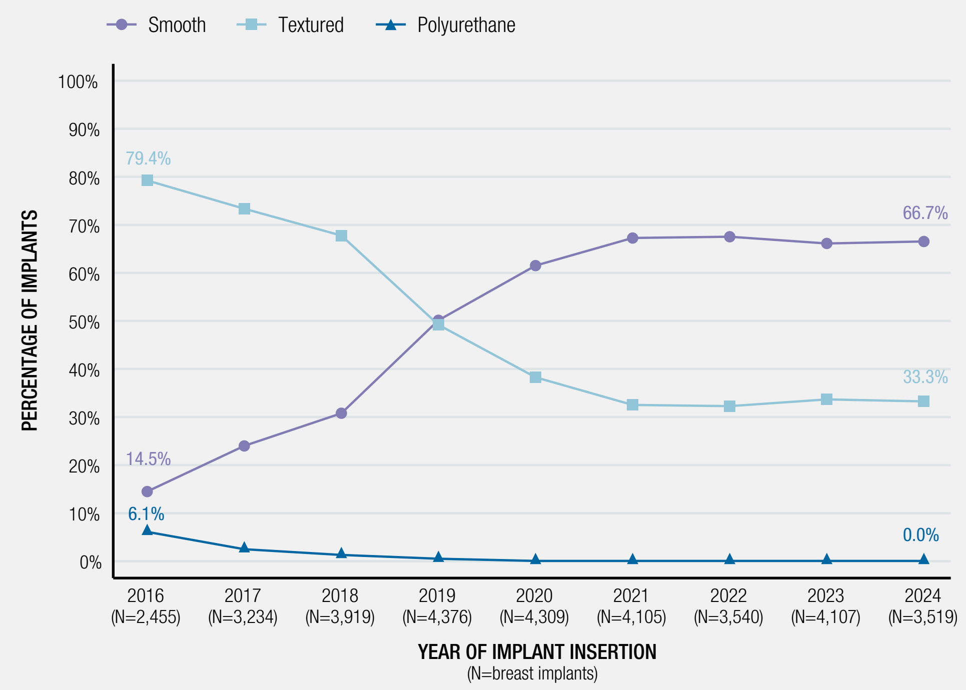
	Implant		Tissue Expander	
	N	(%)	N	(%)
Shell/Texture				
Textured	17,839	49.7	12,303	99.3
Smooth	17,616	49.1	57	0.5
Polyurethane	379	1.1	-	-
Not stated	52	0.1	30	0.2
Shape				
Round	20,724	57.7	18	0.1
Shaped/anatomical	15,110	42.1	12,342	99.6
Not stated	52	0.1	30	0.2
Fill				
Silicone	35,102	97.8	-	-
Silicone/Saline	470	1.3	-	-
Saline	262	0.7	11,729	94.7
Carbon dioxide	-	-	631	5.1
Not stated	52	0.1	30	0.2
Total	35,886		12,390	

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

Implant shell

Figure 4.18 shows the pattern of device shell used in reconstructive procedures (2016-2024). The most commonly used breast implant shell type has changed from textured breast implants 1,950 (79.4%) in 2016 to 1,172 (33.3%) in 2014; to smooth breast implants 356 (14.5%) in 2016 to 2,347 (66.7%) in 2024. From 2019 onwards, smooth implants were inserted more frequently than textured implants. Of note, 2019 marks the point in time that various textured and polyurethane devices were voluntary removed by the manufacturer or recalled by the TGA due to safety concerns.

FIGURE 4.18 DEVICE SHELL – RECONSTRUCTIVE IMPLANTS (2016-2024)

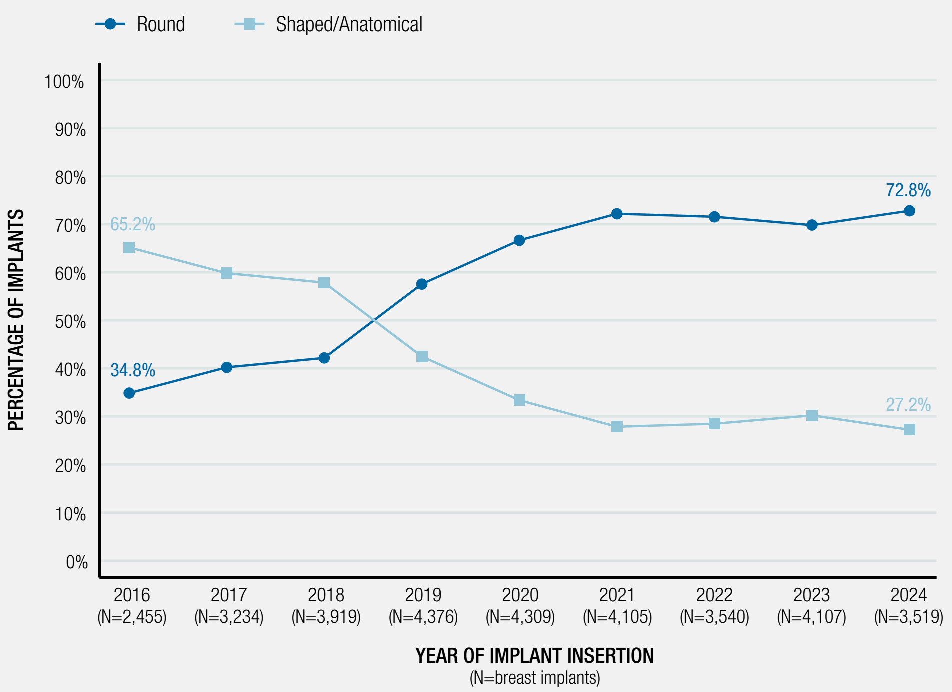


Note: Device texture is reported for newly inserted implants during an insertion procedure or a replacement revision procedure. Implants with an unknown shell type have not been included.

Implant shape

Figure 4.19 demonstrates the **device shape** used in reconstructive surgery (2016-2024). The most commonly used breast implant shape has changed from anatomical 1,600 (65.2%) in 2016 to 957 (27.2%) in 2024; to round 855 (34.8%) in 2016 to 2,562 (72.8%) in 2024. This change occurred from 2018-19. This aligns with most smooth implants also being of round shape.

FIGURE 4.19 DEVICE SHAPE – RECONSTRUCTIVE IMPLANTS (2016-2024)



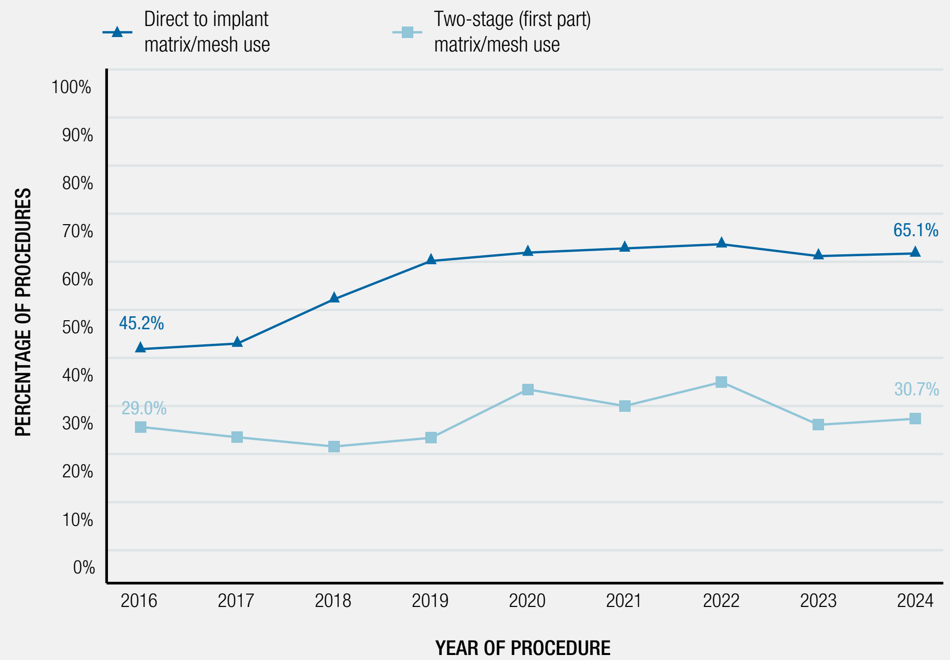
Note: Device shape is reported for new implants during an insertion procedure or a replacement revision procedure. Implants with an unknown shape have not been included.

Matrix/mesh use in reconstructive procedures

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

Appendix 5 shows the frequency of matrix/mesh use by device operation type and specific type of reconstructive indication. Use of matrix/mesh is highest for first implant insertion (e.g. direct-to-implant procedures) and tissue expander insertion (e.g. first part of two-stage procedures) device operation types and for post-cancer/risk-reducing indications. 65.1% of direct-to-implant procedures use matrix/mesh and 30.7% of two-stage procedures (TE insertion part) used matrix/mesh in 2024 (Figure 4.20, primary procedures with post-cancer/ risk-reducing indications only).

FIGURE 4.20 MATRIX/MESH USE IN PRIMARY DIRECT-TO-IMPLANT AND TWO-STAGE PROCEDURES (TISSUE EXPANDER INSERTION PART) (POST-CANCER AND RISK-REDUCING INDICATIONS, 2016-2024)



Primary and legacy breast devices

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

Table 4.9 shows the number of inserted implants classified as **primary** or **legacy**. An implant is classified based on the available history of the breast it is inserted in. Primary implants are defined as those which are inserted into breasts which have no in-situ breast implant (i.e.: procedure is not a replacement of an implant) and also have no recorded history of prior procedures involving implants recorded in the Registry. Legacy implants are defined as those that are inserted into breasts which have an in-situ implant or a prior history of one.

Of the 35,886 reconstructive breast implant insertions recorded in the ABDR between 2012-2024, 25,019 (69.7%) were primary breast implants and 10,867 (30.3%) were legacy breast implant insertions. **Only the primary breast implants are included in the following revision rate analyses.**

TABLE 4.9 BREAST IMPLANT INSERTIONS BY PRIMARY/LEGACY STATUS (2012-2024)

Breast implant insertion type	N	%
Primary	25,019	69.7
Legacy	10,867	30.3
Total	**35,886**	**100.0**

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

The ABDR has recorded 11,222 (90.6%) primary tissue expanders and 1,168 (9.4%) legacy tissue expanders (Table 4.10). In total 12,390 tissue expanders were inserted for reconstructive reasons. **Analysis to assess device performance-based time to event analysis uses primary devices only.**

TABLE 4.10 TISSUE EXPANDER INSERTIONS BY PRIMARY/LEGACY STATUS (2012-2024)

Tissue expander insertion type	N	%
Primary	11,222	90.6
Legacy	1,168	9.4
Total	**12,390**	**100.0**

Revision of reconstructive breast implants and complications

Revision surgery is described as a procedure for the unplanned replacement, reposition or explant of an in-situ breast device. A revision may be classified as being due to complication (complication selected as reason for revision or at least one issue reported at revision, as explained in Methods) or other reasons. Table 4.11 shows the breakdown of reasons for reconstructive implant revisions (revisions are included regardless of whether or not the corresponding initial implant insertion procedure was captured in the Registry). In 2024, 66.3% of reconstructive breast implant revisions were due to complication.

TABLE 4.11 REASONS FOR REVISION OF RECONSTRUCTIVE BREAST IMPLANTS

Reason for revision	2011–2024		2024	
	N	(%)	N	(%)
Complication	9,095	70.6	863	66.3
Asymptomatic	406	3.2	43	3.3
Patient preference	2,103	16.3	240	18.4
Breast Cancer	261	2.0	22	1.7
Not stated	1,021	7.9	134	10.3
Total number of revision procedures	**12,886**		**1,302**	

Note: The crude percentage shown for each reason for revision is an observational proportion that has not accounted for censoring and patient follow-up time so cannot be interpreted as a revision rate. A revision is classified as being due to complication if the reason for revision is reported as complication and/or at least one complication was reported. Refer to Methods.

The Registry captures data relating to specific issues found at revision surgery. These complications include capsular contracture, device malposition, device rupture/deflation, seroma/haematoma and deep wound infection. Table 4.12 reports the frequency of issues out of all reconstructive breast implant revision procedures which are due to complication. Please note, this table does not represent complication rates. Complication rates are described in the following section using Kaplan-Meier (event) curves. This table indicates only the most common complications that are reported to the Registry.

TABLE 4.12 SPECIFIC ISSUES AT REVISION (DUE TO COMPLICATION) OF RECONSTRUCTIVE BREAST IMPLANTS

Complications and Issues Identified at Revision (N.B. Not complication rates)	2012–2024		2024	
	N	(%)	N	(%)
Capsular contracture	4,711	51.8	464	53.8
Device malposition	3,485	38.3	299	34.6
Rupture/deflation	2,278	25.0	211	24.4
Seroma/haematoma	527	5.8	43	5.0
Deep wound infection	395	4.3	44	5.1

Note: Listed in order of frequency are issues identified during reconstructive breast implant revision procedures which are due to complication: Total N=9,095 (2012-2024); N=863 (2024). 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 shown for 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.

Multiple issues and complications can be reported at the time of revision surgery. In 2024, capsular contracture was the most common issue reported to the Registry at 53.8% of reconstructive breast implant revisions that were due to complication, followed by device malposition at 34.6% and device rupture/deflation at 24.4%.

Issues identified with reconstructive tissue expander revision procedures

Table 4.13 shows the breakdown of reasons for tissue expander revisions (revisions are included regardless of whether or not the corresponding tissue expander insertion procedure was captured in the Registry). In 2024, 71.2% of reconstructive tissue expander revisions were due to complication.

TABLE 4.13 REASONS FOR REVISION OF RECONSTRUCTIVE TISSUE EXPANDERS

Reason for revision	2012–2024		2024	
	N	(%)	N	(%)
Complication	657	67.8	74	71.2
Asymptomatic	12	1.2	0	0.0
Patient preference	146	15.1	23	22.1
Breast Cancer	29	3.0	3	2.9
Not stated	125	12.9	4	3.8
Total number of revision procedures	**969**		**104**	

Note: The crude percentage shown for each reason for revision is an observational proportion that has not accounted for censoring and patient follow-up time so cannot be interpreted as a revision rate.

Table 4.14 shows the frequency of issues for reconstructive tissue expander revision procedures which are due to complication. Please note, this table does not represent complication rates.

TABLE 4.14 SPECIFIC ISSUES AT REVISION (DUE TO COMPLICATION) OF RECONSTRUCTIVE TISSUE EXPANDERS

Complications and Issues Identified at Revision (N.B. Not complication rates)	2012–2024		2024	
	N	(%)	N	(%)
Deep wound infection	210	32.0	21	28.4
Device rupture/deflation	193	29.4	23	31.1
Seroma/haematoma	144	21.9	19	25.7
Capsular contracture	117	17.8	11	14.9
Device malposition	90	13.7	8	10.8

Note: Listed in order of frequency are issues identified during reconstructive tissue revision procedures which are due to complication: N=657 (2012-2024); N=74 (2024). 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 tissue expander in 2024 include most commonly device rupture/deflation (31.1% of tissue expander revisions due to complication) and deep wound infection (28.4%), followed by seroma/haematoma and capsular contracture (25.7% and 14.9% respectively).

CHAPTER 5

Reconstructive Breast Procedure Outcomes

Revision incidence – breast implants for reconstructive procedures

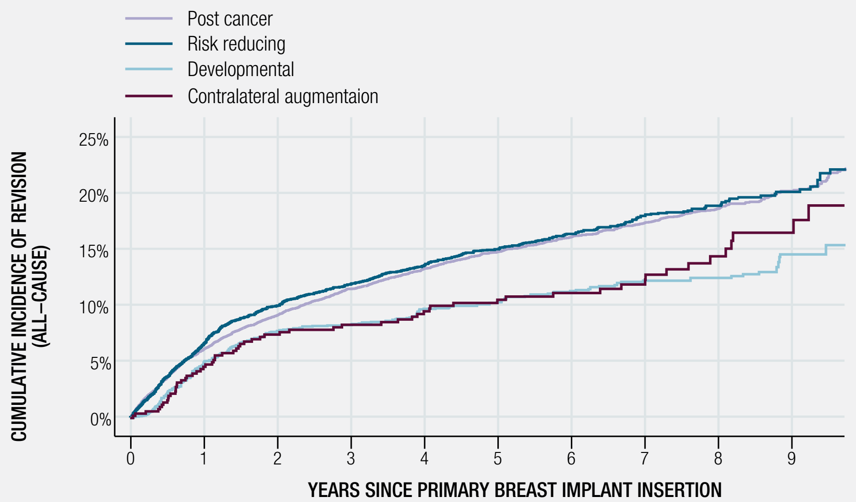
The issues identified at revision data collected by the Registry includes: device rupture/deflation, capsular contracture, device malposition, deep wound infection, seroma/haematoma, BIA-ALCL and skin scarring problems (historically captured in the previous database). All-cause revision incidence includes revisions reported as being due to complication/having the above listed issues as well as revisions due to patient preference, asymptomatic revisions, and revisions involving only breast cancer reported as an issue.

Revision incidence by reconstructive indication

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

Figure 5.1 demonstrates the **all-cause revision incidence curve** based on the indications for surgery. The all-cause cumulative revision incidence 9 years after primary implant insertion is **20.4% for post-cancer reconstruction, 20.3% for risk-reducing reconstruction, 14.7% for developmental deformity and 16.6% for contralateral augmentation**, which is higher than the cosmetic revision rate of 7.3% seen in Figure 7.1 (refer to Appendix 6 relating to Figures 5.1-5.3). The revision profile of contralateral augmentation procedures aligns closely with that of the developmental deformity cohort. The diversion at seven years maybe due to various factors including but not limited to patient factors to remove both breast implants.

FIGURE 5.1 ALL-CAUSE REVISION INCIDENCE BY INDICATION–RECONSTRUCTIVE PRIMARY BREAST IMPLANTS

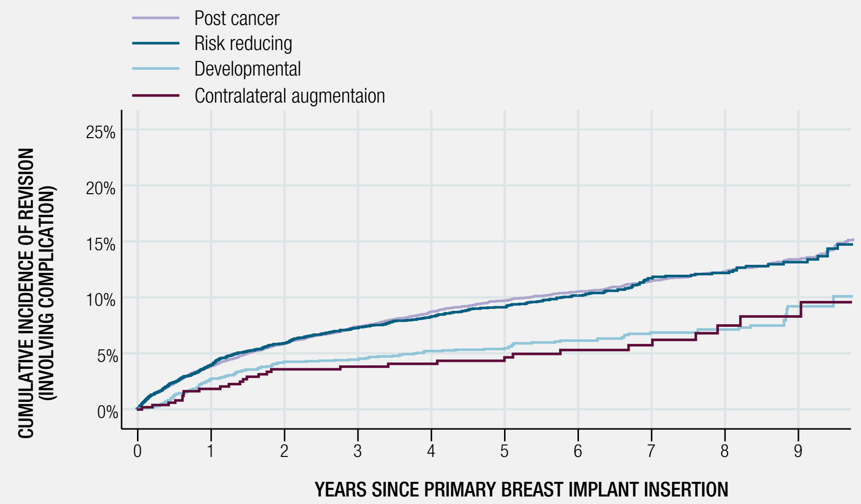


Number at risk

	0	1	2	3	4	5	6	7	8	9
Post cancer	14,829	12,946	11,041	9,328	7,759	6,136	4,599	3,127	1,872	997
Risk reducing	7,178	6,257	5,221	4,423	3,641	2,820	2,079	1,353	798	383
Developmental	3,012	2,670	2,301	2,035	17,03	1,322	1,062	816	591	328
Contralat. aug.	504	468	433	397	368	314	263	197	129	73

Note: Revision incidence (all–cause) is based on reconstructive primary breast implants inserted from 2012 to 2024. 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 5.2 REVISION INCIDENCE DUE TO COMPLICATION BY INDICATION–RECONSTRUCTIVE PRIMARY BREAST IMPLANTS



Number at risk

	0	1	2	3	4	5	6	7	8	9
Post cancer	14,829	12,946	11,041	9,328	7,759	6,136	4,599	3,127	1,872	997
Risk reducing	7,178	6,257	5,221	4,423	3,641	2,820	2,079	1,353	798	383
Developmental	3,012	2,670	2,301	2,035	1,703	1,322	1,062	816	591	328
Contralat. aug.	504	468	433	397	368	314	263	197	129	73

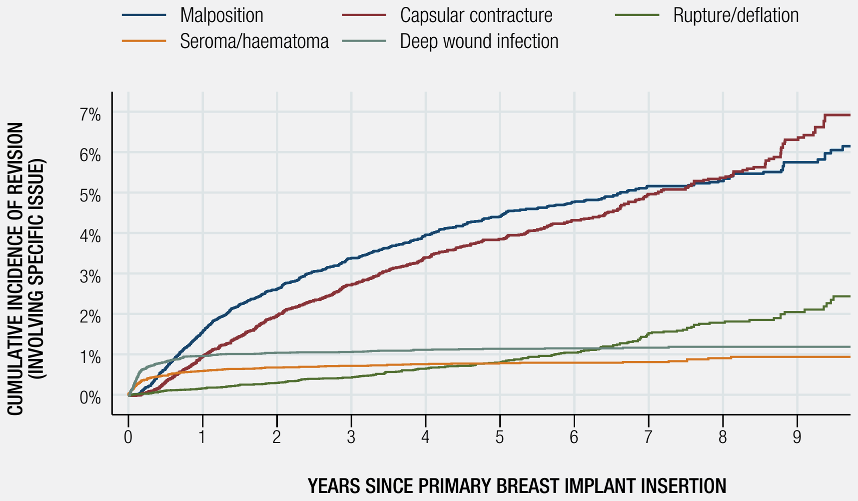
Note: Revision incidence (due to complication) is based on reconstructive primary breast implants inserted from 2012 to 2024. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary implant insertion date to the first revision procedure. The accompanying table provides the number of breasts at risk of revision, following from the initial implant procedure at Year=0.

Figure 5.2 provides **revision incidence due to complication** by indication. At 9 years after primary implant insertion, revision incidence due to complication was **13.2% for post-cancer, 13.0% for risk reducing reconstruction, 9.1% for developmental deformity and 8.2% contralateral augmentation**, which is higher than the cosmetic revision rate of 3.4% seen in Figure 7.2.

Revision incidence of specific complications

Figure 5.3 shows **the cumulative revision incidence rates by complication type up to 9 years** after the date of primary implant insertion. It shows that over time capsular contracture and malposition have higher incidence compared to other outcomes. At **9 years post implant insertion**, the revision incidence was 6.3% for capsular contracture, 5.7% for device malposition, 2.1% for device rupture/deflation, 1.2% for deep wound infection, and 1.0% for seroma/haematoma.

FIGURE 5.3 CUMULATIVE REVISION INCIDENCE RATE BY COMPLICATION TYPE – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS



Number at risk

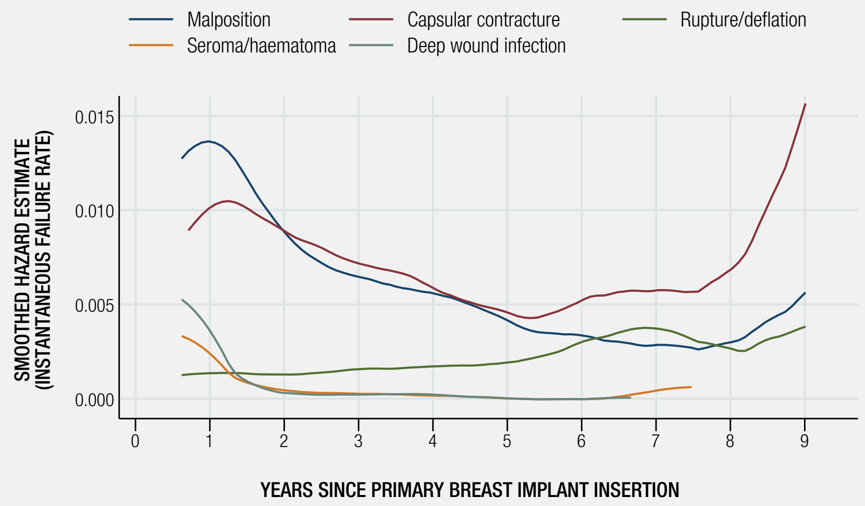
25,019	21,873	18,563	15,786	13,103	10,278	7,740	5,296	3,261	1,708
0	1	2	3	4	5	6	7	8	9

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

FIGURE 5.4 HAZARD BY COMPLICATION TYPE – REVISIONS OF RECONSTRUCTIVE PRIMARY BREAST IMPLANTS

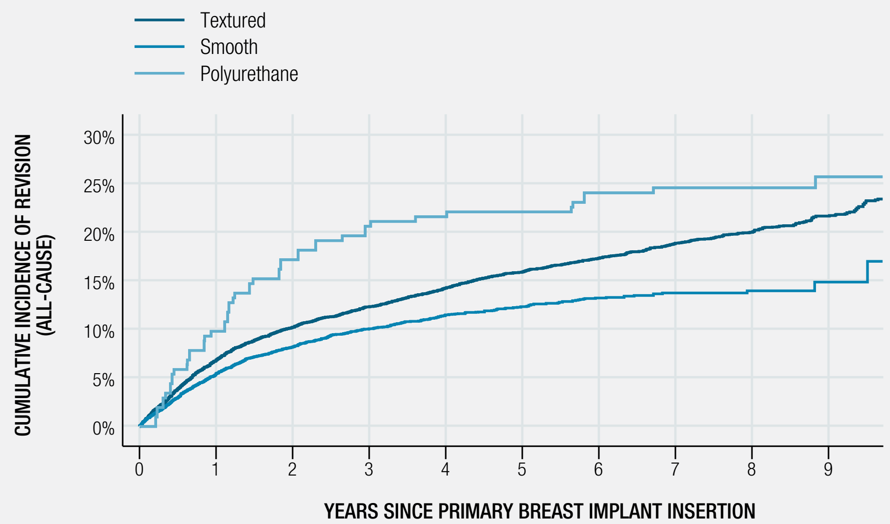


Note: Curves are truncated when smoothed estimates of hazard cannot be calculated (shortly after the start and when case numbers for the complication of interest are low). Experience of complications may not necessarily lead to a revision procedure. There may be long periods of time between when complications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

Revision incidence by device characteristics

Figure 5.5 provides the **all-cause revision incidence** for reconstructive implants based on device shell characteristics. The all-cause revision incidence rate at **9 years** since primary implant insertion was **25.6% for polyurethane implants, 21.6% for textured implants and 14.8% for smooth implants**.

FIGURE 5.5 ALL-CAUSE REVISION INCIDENCE BY SHELL – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS



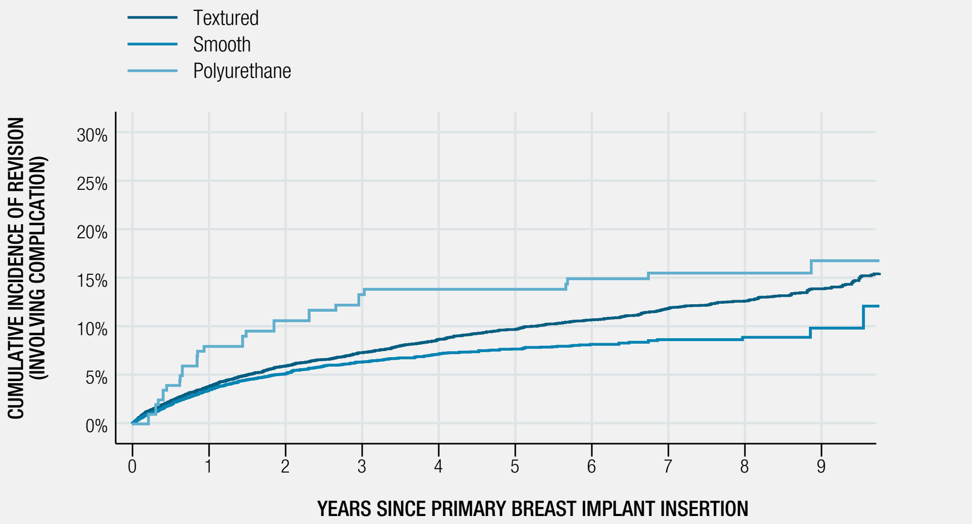
Number at risk

	0	1	2	3	4	5	6	7	8	9
Textured	13,164	11,696	10,419	9,399	8,408	7,172	5,973	4,286	2,781	1,487
Smooth	11,623	9,967	7,954	6,207	4,519	2,935	1,606	866	373	158
Polyurethane	205	184	169	162	160	159	155	139	104	60

Note: Revision incidence (all-cause) is based on reconstructive primary breast implants inserted from 2012 to 2024. 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 5.6 provides the **revision incidence due to complication** for reconstructive primary implants by device shell characteristics. The revision due to complication incidence rate at 9 years since primary implant insertion was 16.7% for polyurethane implants, 13.8% for textured implants and 9.8% for smooth implants. The revision incidence rates for specific complications can be found in Appendix 7.

FIGURE 5.6 REVISION INCIDENCE DUE TO COMPLICATION BY SHELL – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS



Number at risk

	0	1	2	3	4	5	6	7	8	9
Textured	13,164	11,696	10,419	9,399	8,408	7,172	5,973	4,286	2,781	1,487
Smooth	11,623	9,967	7,954	6,207	4,519	2,935	1,606	866	373	158
Polyurethane	205	184	169	162	160	159	155	139	104	60

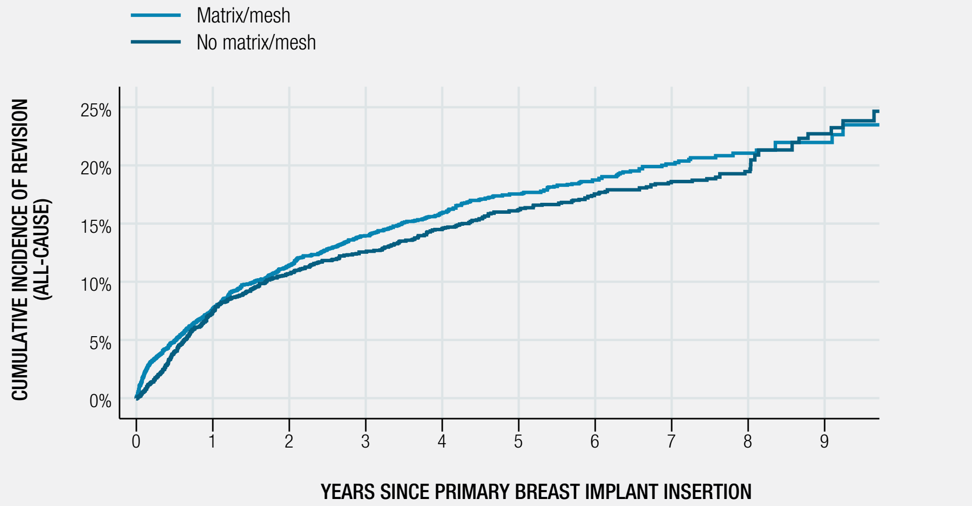
Note: Revision incidence (due to complication) is based on reconstructive primary breast implants inserted from 2012 to 2024. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary implant insertion date to the first revision procedure. The accompanying table provides the number of breasts at risk of revision, following from the initial implant procedure at Year=0. Implants with unknown shell have not been included.

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

The ABDR collects details of issues and complication that are found at the time of revision procedures for primary implants inserted with vs without matrix/mesh. Only breasts which enter the Registry with a direct-to-implant insertion procedure are included in the following figures. Very few developmental deformity procedures involved matrix/mesh. To keep the matrix/mesh use groups comparable, only post-cancer and risk-reducing procedures have been included here (Figures 5.7-5.8). Procedures with matrix/mesh use not stated have been excluded.

Figure 5.7 provides the **all-cause revision incidence curve** for reconstructive **direct-to-implant** primary breast implants **by matrix/mesh use**. The all-cause revision incidence **9 years** after insertion was **21.9% for the implants with matrix/mesh and 22.6% without matrix/mesh**.

FIGURE 5.7 ALL-CAUSE REVISION INCIDENCE BY MATRIX/MESH USE – RECONSTRUCTIVE PRIMARY DIRECT-TO-IMPLANT PROCEDURES (FOR POST-CANCER/RISK-REDUCING INDICATIONS)



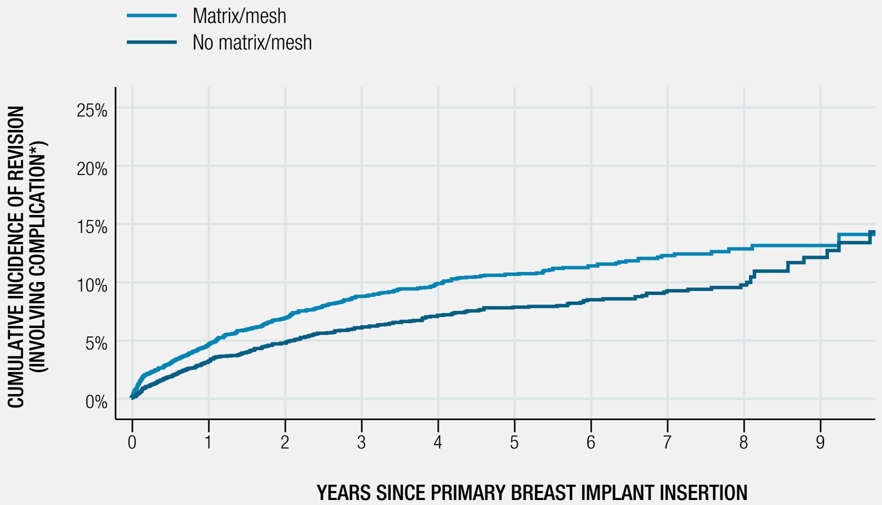
Number at risk

	0	1	2	3	4	5	6	7	8	9
Matrix/mesh	6,717	5,647	4,443	3,514	2,655	1,857	1,172	665	325	134
No matrix/mesh	4,338	3,658	3,012	2,542	2,059	1,585	1,196	826	413	162

Note: Revision incidence (all-cause revision) is based on reconstructive primary direct-to-implant procedures (for post-cancer/risk-reducing indications) beginning from 2012 to 2024. 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. Procedures with matrix/mesh use not stated have been excluded.

Figure 5.8 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 **9 years** after insertion was **13.0% for the implants with matrix/mesh and 12.0% without matrix/mesh**. The revision incidence rates for specific issues are found in the Appendix 8.

FIGURE 5.8 REVISION DUE TO COMPLICATION INCIDENCE BY MATRIX/MESH USE – RECONSTRUCTIVE PRIMARY DIRECT-TO-IMPLANT PROCEDURES (FOR POST-CANCER/RISK-REDUCING INDICATIONS)



Number at risk

	0	1	2	3	4	5	6	7	8	9
Matrix/mesh	6,717	5,647	4,443	3,514	2,655	1,857	1,172	665	325	134
No matrix/mesh	4,338	3,658	3,012	2,542	2,059	1,585	1,196	826	413	162

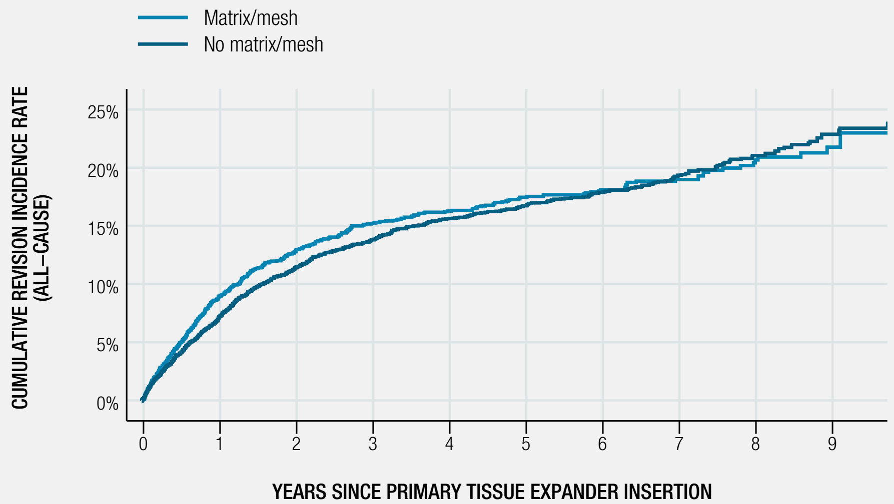
Note: Revision incidence (involving complication*) is based on reconstructive primary direct-to-implant procedures (for post-cancer/risk-reducing indications) beginning from 2012 to 2024. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary implant insertion 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.
Procedures with matrix/mesh use not stated have been excluded.

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

The following analysis is based on **two-stage** reconstructive procedures. Subsequent procedures after tissue expander insertion have often not been captured in the Registry (Table 4.6). Therefore, only breasts which entered the Registry with a tissue expander insertion procedure and also have a subsequent procedure captured in the Registry are included in Figures 5.9-5.10. Very few developmental deformity procedures involved matrix/mesh. In order to keep matrix/mesh use groups comparable, only post-cancer and risk-reducing procedures have been included here (Figures 5.9-5.10). Procedures with matrix/mesh use not stated have been excluded. Breasts with matrix/mesh inserted with the second stage breast implant are excluded from the following analysis due to small volume. The first revision is used as the endpoint (whether this is a revision of the tissue expander or the following implant).

The all-cause revision incidence **9 years** after tissue expander insertion was **21.8% for two-stage procedures with matrix/mesh and 22.9% for those without matrix/mesh** (Figure 5.9).

FIGURE 5.9 ALL-CAUSE REVISION INCIDENCE BY MATRIX/MESH USE – RECONSTRUCTIVE PRIMARY TWO-STAGE PROCEDURES (FOR POST-CANCER/RISK-REDUCING INDICATIONS)



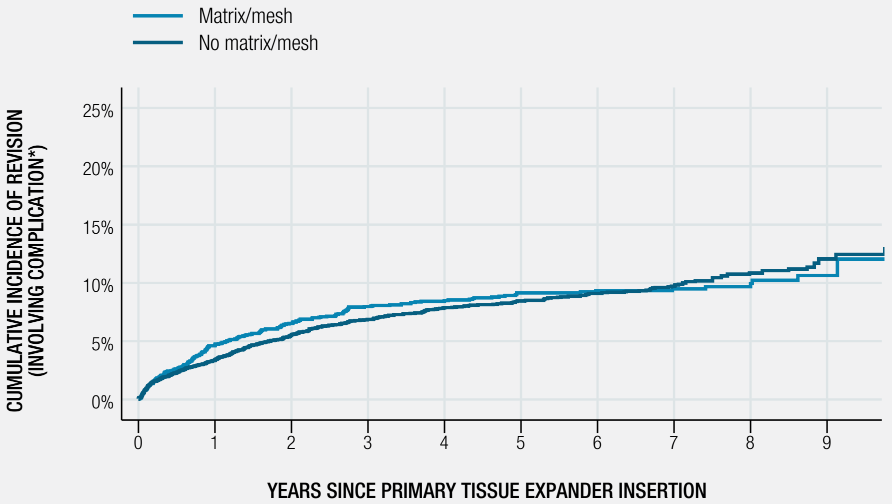
Number at risk

	0	1	2	3	4	5	6	7	8	9
Matrix/mesh	3,171	2,706	2,352	1,997	1,628	1,216	898	575	325	136
No matrix/mesh	7,320	6,396	5,536	4,866	4,153	3,384	2,582	1642	932	457

Note: Revision incidence (all-cause revision) is based on reconstructive primary two-stage procedures (for post-cancer/risk-reducing indications) beginning from 2012 to 2024. 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 tissue expander insertion procedure at Year=0. Procedures with matrix/mesh use not stated have been excluded. Procedures with matrix/mesh inserted with the second stage breast implant are excluded.

The revision due to **complication incidence for two-stage procedures by matrix/ mesh** use and non-use is shown in Figure 5.10. The outcome of interest here is any one of: malposition, capsular contracture, seroma/haematoma, or deep wound infection. The cumulative revision incidence at **9 years for two-stage procedures** with matrix/mesh is **10.5% while it is 11.9%** for procedures without matrix/mesh. The revision incidence rates for specific issues are found in Appendix 9.

FIGURE 5.10 REVISION DUE TO COMPLICATION INCIDENCE BY MATRIX/MESH USE – RECONSTRUCTIVE PRIMARY TWO-STAGE PROCEDURES (FOR POST-CANCER/RISK-REDUCING INDICATIONS)



Number at risk

	0	1	2	3	4	5	6	7	8	9
Matrix/mesh	3,171	2,706	2,352	1,997	1,628	1,216	898	575	325	136
No matrix/mesh	7,320	6,396	5,536	4,866	4,153	3,384	2,582	1642	932	457

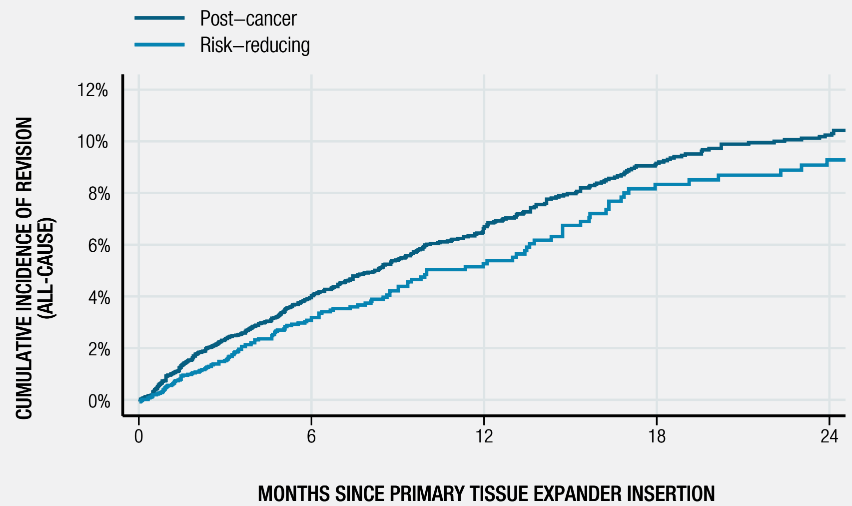
Note: Revision incidence (involving complication*) is based on reconstructive primary two-stage procedures (for post-cancer/risk-reducing indications) beginning from 2012 to 2024. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary tissue expander insertion date to the first revision procedure. The accompanying table provides the number of breasts at risk of revision, following from the initial tissue expander insertion procedure at Year=0.
*Involves at least one of: malposition, capsular contracture, seroma/haematoma, or deep wound infection.
Procedures with matrix/mesh use not stated have been excluded. Procedures with matrix/mesh inserted with the second stage breast implant are excluded.

Revision incidence for tissue expanders

The **all-cause revision incidence for primary reconstructive tissue expanders** is presented in Figure 5.11. Revision incidence is only shown up to **24 months** because tissue expanders are only used temporarily before being replaced, and ABDR data shows only 1.8% of tissue expanders are replaced after two years. In **post-cancer** reconstruction the cumulative revision incidence rate 24 months after insertion is **10.3%**, with revision incidence for risk reducing procedures at 9.3%. Reconstruction for developmental deformity is not presented in this figure because there are only a small number of reported cases in this cohort (there were 149 primary tissue expanders inserted for developmental deformity).

Please refer to Appendix 10.

FIGURE 5.11 ALL-CAUSE REVISION INCIDENCE – PRIMARY RECONSTRUCTIVE TISSUE EXPANDERS



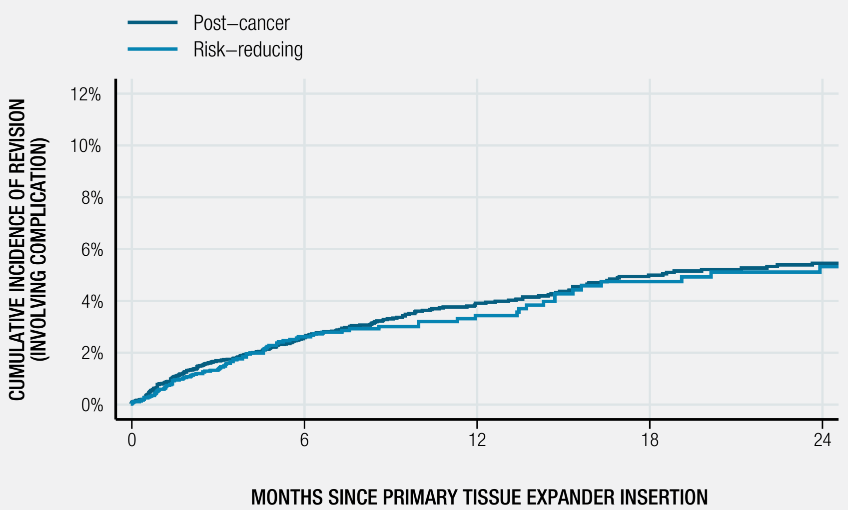
Number at risk

	0	6	12	18	24
Post–cancer	7,725	4,922	2,579	1,816	1,495
Risk–reducing	3,348	1,789	795	539	447

Note: Revision incidence (all-cause) is based on reconstructive primary tissue expanders inserted from 2012 to 2024. 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** is presented in Figure 5.12. The revision incidence at 24 months is **5.5%** for post-cancer and 5.3% 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 5.12 REVISION INCIDENCE DUE TO COMPLICATION – PRIMARY RECONSTRUCTIVE TISSUE EXPANDERS



Number at risk

	0	6	12	18	24
Post–cancer	7,725	4,922	2,579	1,816	1,495
Risk–reducing	3,348	1,789	795	539	447

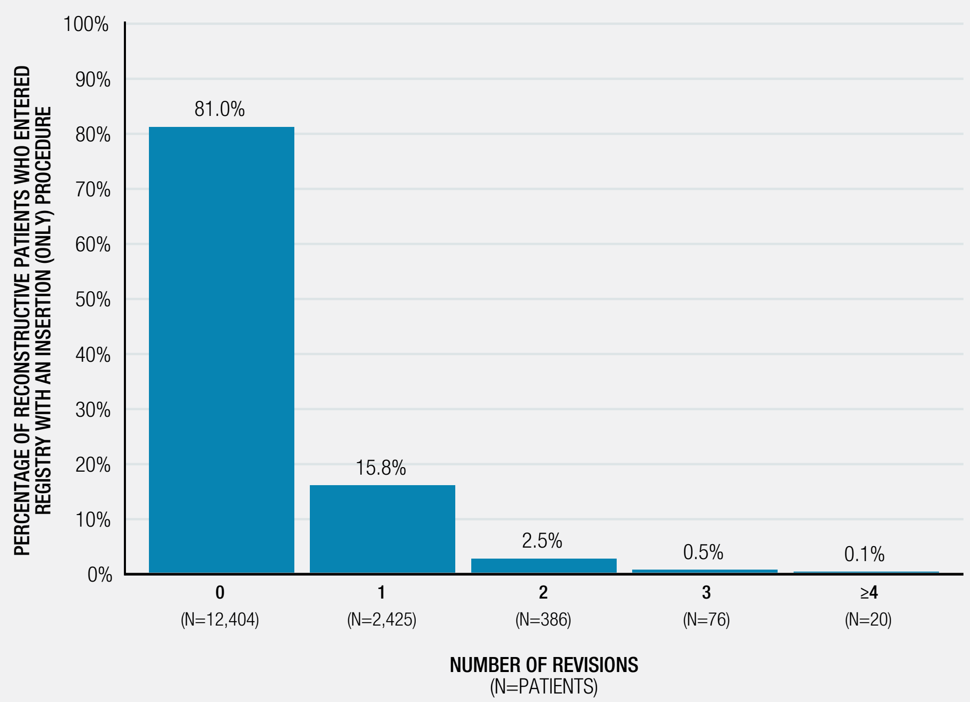
Note: Revision incidence (due to complication) is based on reconstructive primary tissue expanders inserted from 2012 to 2024. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary tissue expander insertion date to the first revision procedure. The accompanying table provides the number of breasts at risk of revision, following from the initial implant procedure at Year=0.

Multiple revision procedures

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

Patients may have multiple revision procedures. Figure 5.13 shows the percentages and counts of patients by the number of revisions they had (the breast with the most revisions is used for the count). Patients whose first operation involved only tissue expander insertions or direct-to-implant insertions are included (since those who enter the Registry with other operation types could potentially have had prior revisions that cannot not be counted). Of the 15,311 patients included, 81.0% had no revisions (12,404), 15.8% had one revision (2,425), 2.5% (386) had two revisions, 0.5% had 3 revisions and 0.1% had 4 or more revisions.

FIGURE 5.13 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 entered the Registry with tissue expander insertions or direct-to-implant insertions.

Clinicians conducting revision procedures

Revision procedures are not necessarily conducted by the same clinician who performed prior insertions. The frequency of revisions being conducted by a different clinician has been investigated using breasts with both a primary implant insertion procedure and implant revision procedure captured. Of the 3,474 breasts included, 2,811 (80.9%) had both procedures conducted by the same clinician while 663 (19.1%) had insertion and revision procedures conducted by different clinicians.

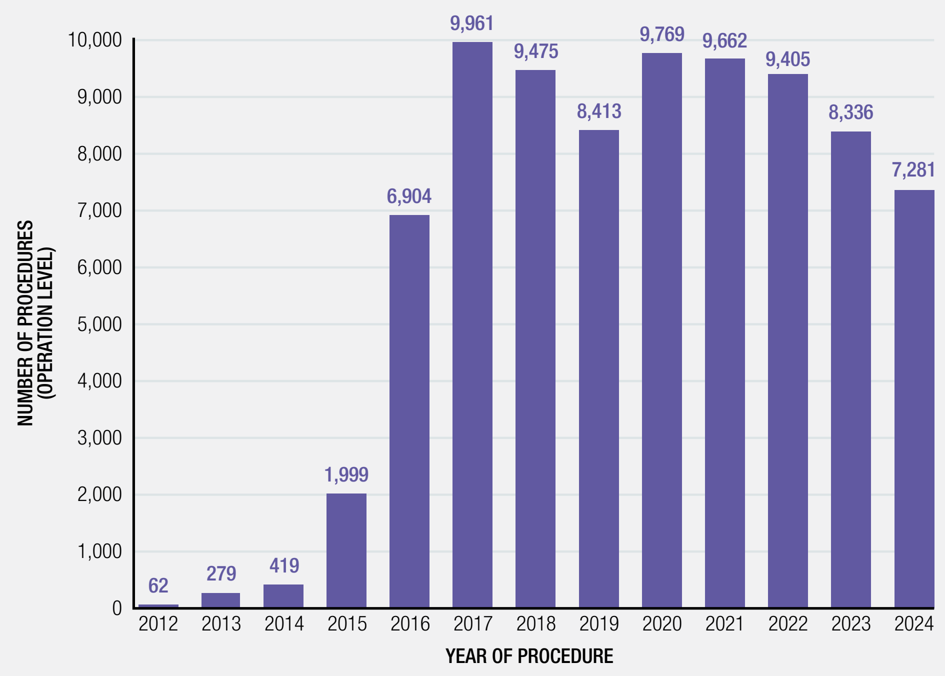
CHAPTER 6
Cosmetic Breast Procedures

Cosmetic procedure numbers

At the end of the 2024 calendar year, the ABDR had recorded a total of **81,965** 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 6.1 shows that in 2024 the total number of cosmetic procedures was **7,281** the lowest number since 2016. Given that case ascertainment of ABDR procedures has been fairly steady over this period, it is likely that this reflects a true reduction in the number of cosmetic procedures undertaken. This may be due to a reduction in cosmetic breast procedures and/or a reduction in implant-based cosmetic breast procedures being performed in Australia. As occurs every year, a few hundred 2024 procedures are likely to have delayed entry into the Registry, and these procedures will be captured and reported in the 2025 report.

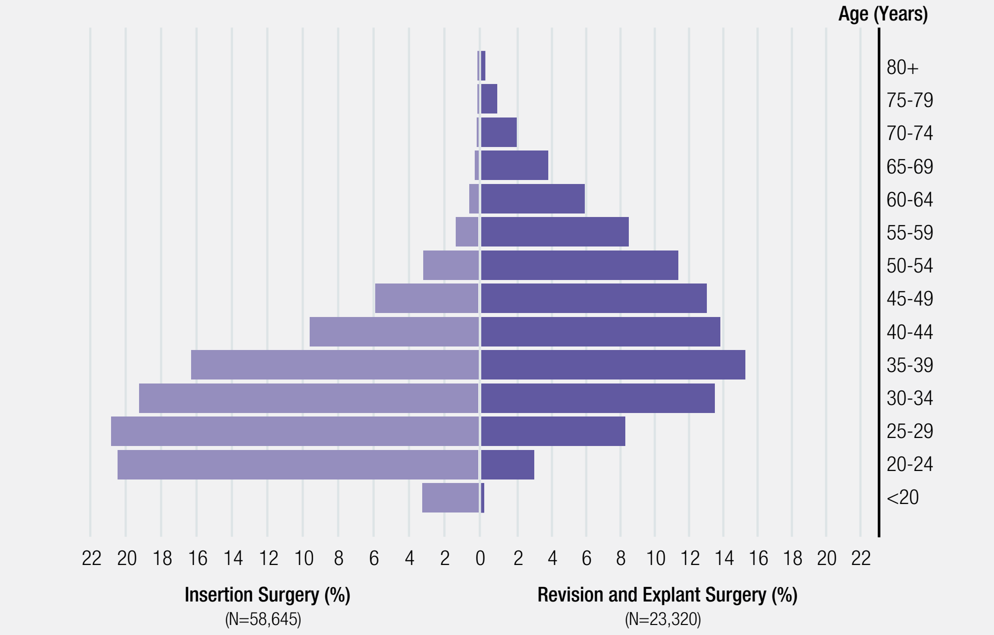
FIGURE 6.1 REGISTERED PROCEDURES – COSMETIC PROCEDURES (2012-2024)



Patient age at cosmetic procedure

The distribution of age at the time of cosmetic procedure is depicted in Figure 6.2 and Table 6.1. 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 groups for insertion procedures overall were the 25-29-year and 20-24-year age groups (20.7% and 20.3% of procedures respectively). 3.2% of the cosmetic insertion procedures captured by the Registry were performed on patients under 20 years old.

FIGURE 6.2: AGE DISTRIBUTION AT TIME OF PROCEDURE – COSMETIC PROCEDURES (2012-2024)



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 four-tier hierarchy has been applied for bilateral procedures with different indication and procedure type details per breast.

TABLE 6.1 SUMMARY STATISTICS FOR AGE AT TIME OF PROCEDURE – COSMETIC PROCEDURES (2012-2024)

Cosmetic	Insertion surgery	Revision surgery	Explant only
N	58,645	18,735	4,585
Median Age (Interquartile range)	31.5 (25.4, 38.5)	43.2 (35.0, 52.6)	44.8 (34.8, 56.4)

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 four-tier hierarchy has been applied for bilateral procedures with different indication and procedure type details per breast.The interquartile range reports observed patient age at the 25th and 75th percentiles.

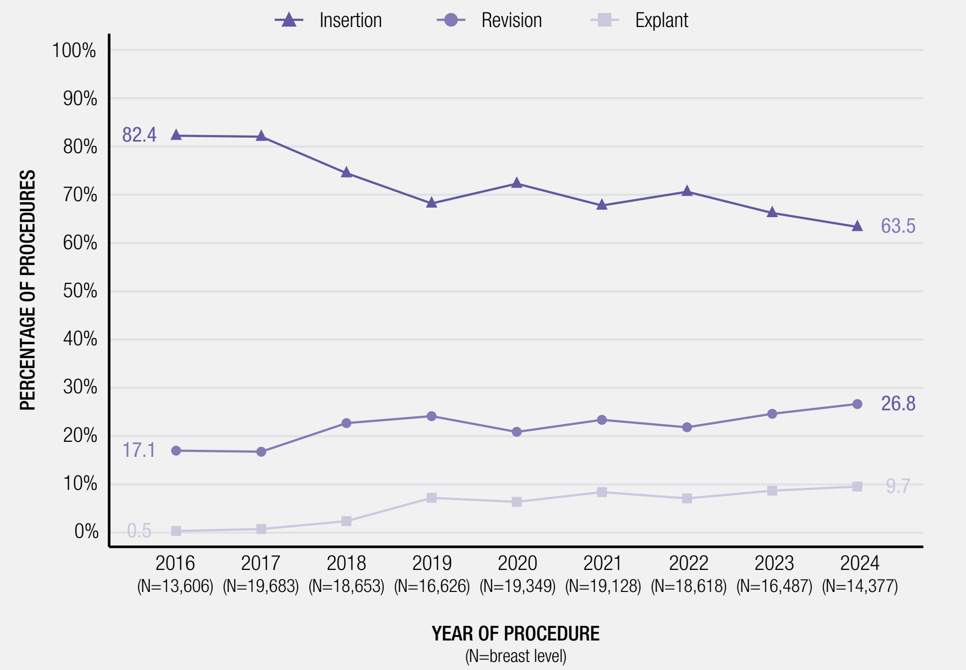
ABDR Procedures – insertion, revision and explantation

The number of procedures classified as insertion, revision and explant per breast are presented in Figure 6.3. They provide nine years of data for cosmetic initial procedures at breast level.

During 2024 a total of 9,129 (63.5%) breasts entered the Registry with a cosmetic insertion procedure; with 3,854 (26.8%) having a cosmetic revision procedure and 1,394 (9.7%) having a cosmetic explant procedure (total of 14,377 cosmetic procedures).

Figure 6.3 and Table 6.2 show the percentages and counts of cosmetic breast procedures classified as insertion, revision and explant during the reporting period. The percentage of device insertion procedures at breast level decreased by 18.9% during this nine-year period. In contrast, revision procedures increased by 9.7% and device explant only procedures increased from 0.5% in 2016 to 9.7% of procedures in 2024. The absolute count of explant only procedures has peaked in 2021.

FIGURE 6.3 INSERTION, REVISION AND EXPLANT PROCEDURES OVER TIME – COSMETIC BREAST LEVEL PROCEDURES (2016-2024)



Note: First implant insertion procedures are classified as insertions. The revision category includes breast implant revisions with device replacement/reposition (not explant only procedures).

TABLE 6.2: INSERTION, REVISION AND EXPLANT PROCEDURES OVER TIME – COSMETIC BREAST LEVEL PROCEDURES (2016-2024)

Procedure type	2016	2017	2018	2019	2020	2021	2022	2023	2024
Insertion	11,210 (82.4%)	16,178 (82.2%)	13,922 (74.6%)	11,366 (68.4%)	14,021 (72.5%)	12,995 (67.9%)	13,179 (70.8%)	10,945 (66.4%)	9,129 (63.5%)
Revision	2,331 (17.1%)	3,330 (16.9%)	4,260 (22.8%)	4,038 (24.3%)	4,066 (21.0%)	4,499 (23.5%)	4,091 (22.0%)	4,085 (24.8%)	3,854 (26.8%)
Explant	65 (0.5%)	175 (0.9%)	471 (2.5%)	1,222 (7.3%)	1,262 (6.5%)	1,634 (8.5%)	1,348 (7.2%)	1,457 (8.8%)	1,394 (9.7%)
Total	**13,606 (100.0%)**	**19,683 (100.0%)**	**18,653 (100.0%)**	**16,626 (100.0%)**	**19,349 (100.0%)**	**19,128 (100.0%)**	**18,618 (100.0%)**	**16,487 (100.0%)**	**14,377 (100.0%)**

Cosmetic procedure – manufacturer details

Table 6.3 shows the frequency of inserted cosmetic breast implants in the Registry by manufacturer. Since 2012-2024 a total of 152,303 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, Motiva and Allergan/Inamed/McGhan/CUI which together account for 89.9% of the implants inserted. In 2024, a total of 12,917 breast implants for cosmetic indication were inserted, of which 99.9% had manufacturer details provided. The implants were mostly manufactured by Mentor and Motiva which accounts for 95.1% of the implants inserted.

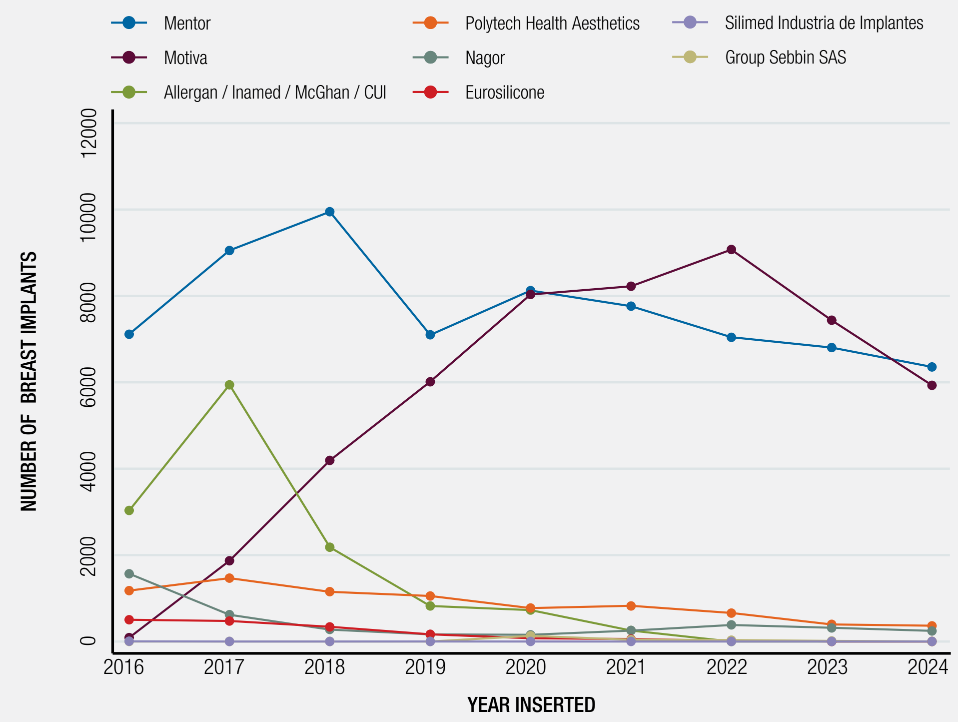
TABLE 6.3: BREAST IMPLANTS INSERTED BY MANUFACTURER – COSMETIC PROCEDURES

Manufacturer	2012-2024		2024	
	N	%	N	%
Mentor	71,375	46.9	6,356	49.2
Motiva	50,864	33.4	5,931	45.9
Allergan/Inamed/McGhan/CUI	14,688	9.6	0	0.0
Polytech Health & Aesthetics	8,050	5.3	366	2.8
Nagor	4,718	3.1	246	1.9
Eurosilicone	1,777	1.2	0	0.0
Silimed Industria de Implantes	467	0.3	0	0.0
Group Sebbin SAS	223	0.1	2	<0.1
Cereplas	26	<0.1	0	0.0
Not Stated	115	0.1	16	0.1
Total	**152,303**	**100**	**12,917**	**100**

Note: Counts are at the breast level. Includes procedures with device operation types: first implant insertion; implant revision – with revision type: replacement.

In Figure 6.4, the **numbers of cosmetic breast implants inserted annually between 2016-2024** by manufacturer 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 2018 the most common devices used by manufacturer for cosmetic procedures were Mentor and Motiva.

FIGURE 6.4 BREAST IMPLANTS INSERTED BY MANUFACTURER – COSMETIC PROCEDURES (2016-2024)



Note: Counts are at the breast level. Includes procedures with device operation types: first implant insertion; implant revision - with revision type: replacement.

Cosmetic procedure intra-operative techniques

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

TABLE 6.4 INTRA-OPERATIVE TECHNIQUES – COSMETIC PROCEDURES (2012-2024)

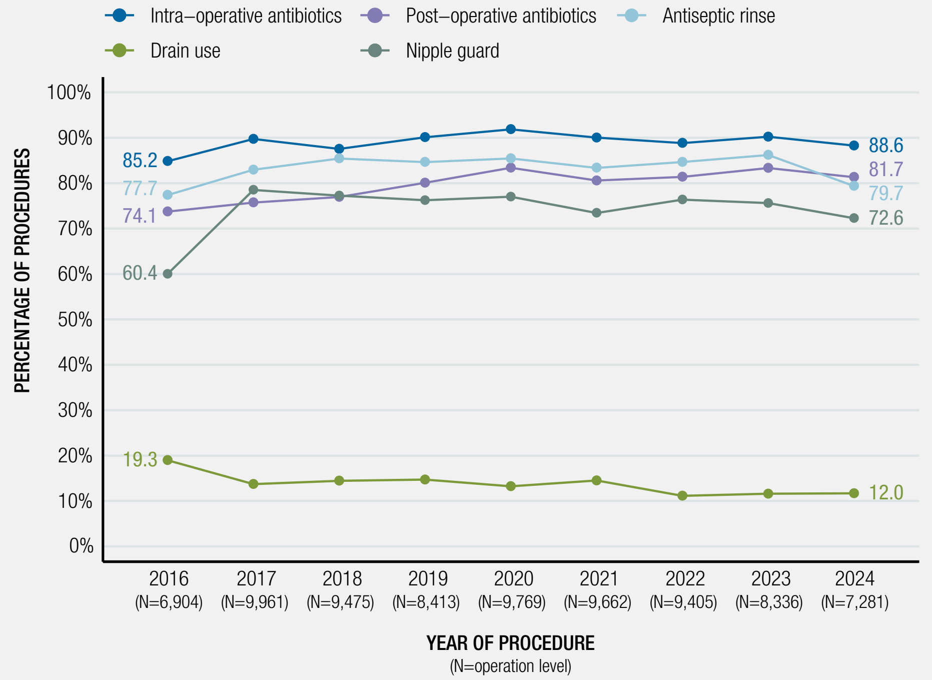
	2012-2024		
	N	(%)	Total eligible
Intra-op/post-op antibiotics[1]	74,264	90.6	81,965
Antiseptic rinse[1]	68,521	83.6	81,965
Drain use[1]	12,009	14.7	81,965
Occlusive nipple shields[1]	60,684	74.0	81,965
Glove change for insertion[2]	57,722	74.6	77,372
Antibiotic dipping solution[2]	47,148	60.9	77,372
Sleeve/funnel[2]	40,178	51.9	77,372

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 2012-2015 because the data fields were not collected separately until 2015. Denominator for percentage calculation: [1]all procedures; [2]excludes explant only procedures.

Table 6.4 shows that intra-operative/post-operative antibiotics are used in 90.6% of cosmetic procedures while antiseptic rinse is used in 83.6% of these. Glove change was reported in 74.6% of cosmetic insertion/revision procedures (not explant only).

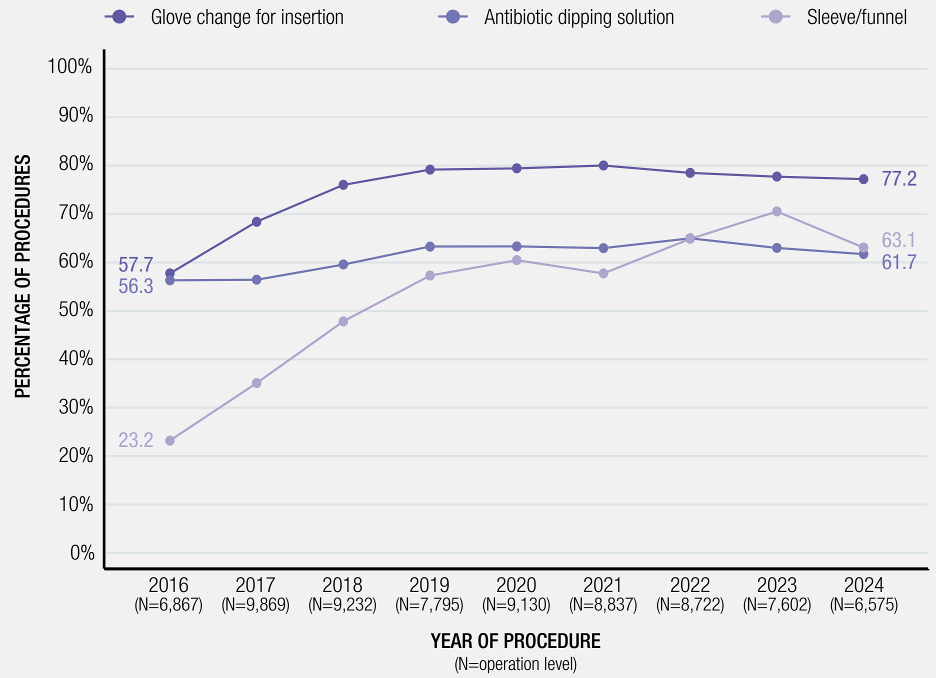
Figures 6.5, 6.6 and Appendix 11 demonstrate that intra-operative technique use has increased for cosmetic procedures. Intra-operative antibiotics, post-operative antibiotics and antiseptic rinse is applicable for all device operation types. Since 2016, occlusive nipple shield has increased by 12.2% (Figure 6.5). The greatest increase has been in the utilisation of sleeve/funnel, increasing by 39.9% since 2016 (Figure 6.6) in cosmetic insertion and revision procedures (excluding explant only procedures).

FIGURE 6.5 INTRA-OPERATIVE TECHNIQUES RELEVANT FOR COSMETIC PROCEDURES OF ANY DEVICE OPERATION TYPE (2016-2024)



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

FIGURE 6.6: INTRA-OPERATIVE TECHNIQUES RELEVANT FOR COSMETIC INSERTION AND REVISION (NOT EXPLANT ONLY) PROCEDURES (2016-2024)



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

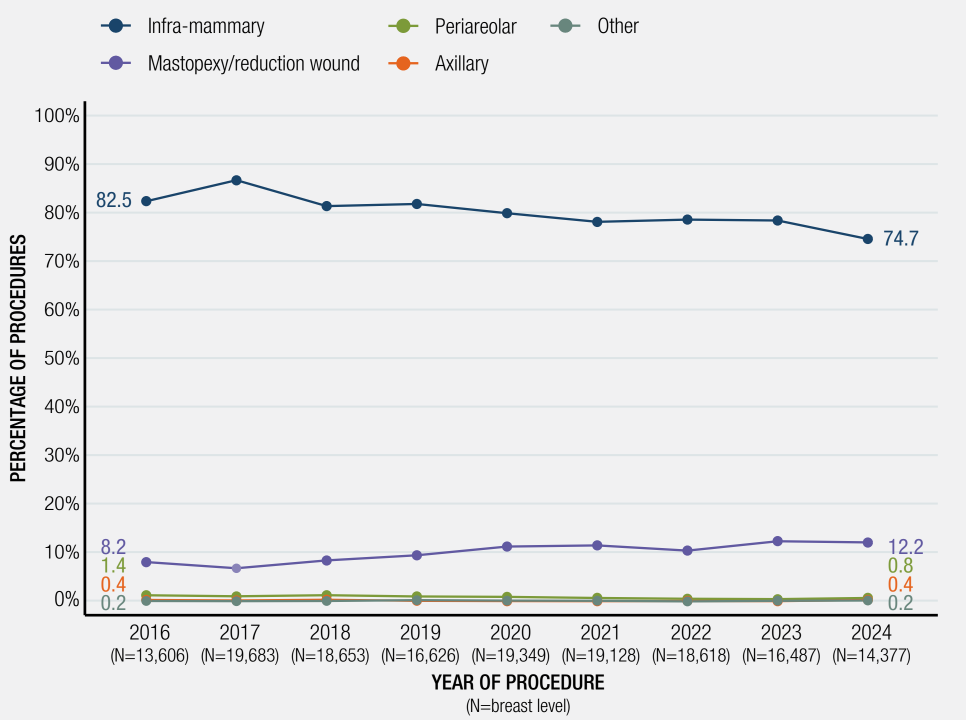
Cosmetic procedure surgical elements

Trends in surgical techniques over time are shown in Figure 6.7-6.9 and further details can be found in Appendix 12.

Surgical incision site

The most common surgical incision site for cosmetic procedures in 2024 is infra-mammary (74.7%). The next most common is incision site is mastopexy/reduction wound (12.2%) (Figure 6.7). Please refer to Appendix 12 for more detail.

FIGURE 6.7 SURGICAL ELEMENTS – INCISION SITE – COSMETIC BREAST LEVEL PROCEDURES (2016-2024)

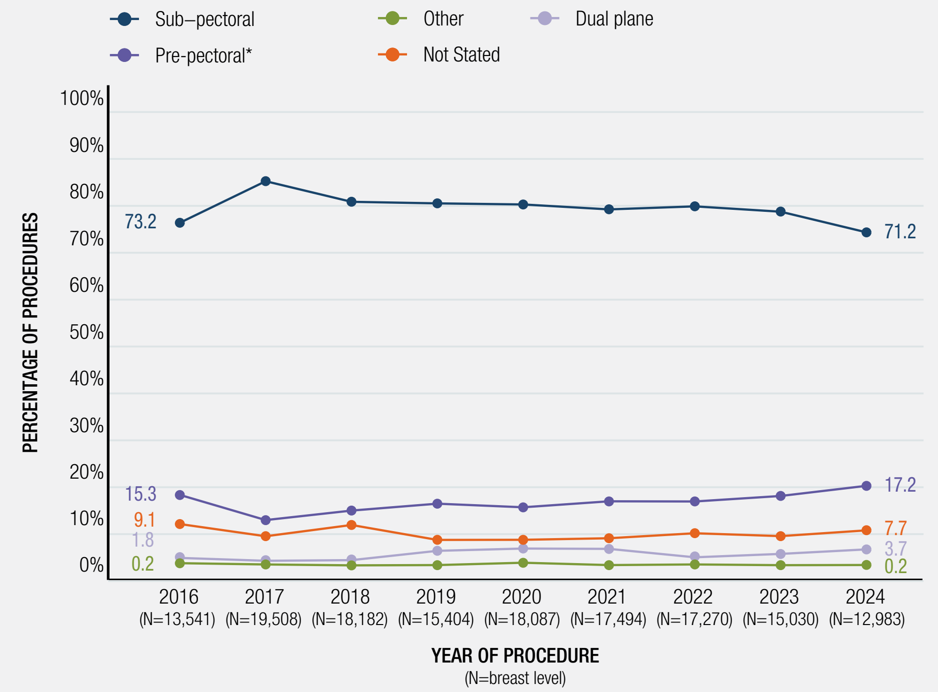


Note: More than one incision site can be recorded.

Surgical plane

Figure 6.8 demonstrates that the most common surgical plane for cosmetic procedures is the sub-pectoral plane 71.2%, followed by the pre-pectoral plane 17.2% (in 2024).

FIGURE 6.8 SURGICAL ELEMENTS – SURGICAL PLANE – COSMETIC BREAST LEVEL PROCEDURES (2016-2024)

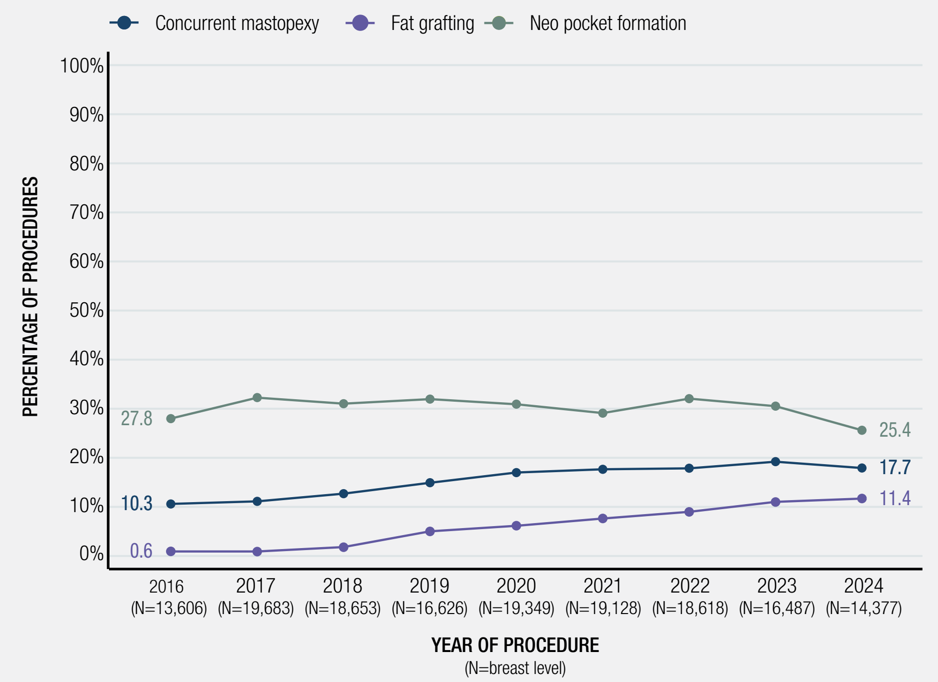


Note: Only insertion and revision procedures (which are not explant only) are included.
*A procedure is reported as having pre-pectoral plane if sub-glandular/sub-fascial has been ticked for plane or if "pre-pectoral" has been written on the DCF.

Other surgical elements

In other surgical techniques, increases over time (2016-2024) are observed in the use of fat grafting (0.6% to 11.4%) and concurrent mastopexy (10.3% to 17.7%) (Figure 6.9).

FIGURE 6.9 OTHER SURGICAL ELEMENTS – COSMETIC BREAST LEVEL PROCEDURES (2016-2024)



Note: The denominator for neo pocket formation includes only revision (not explant only) procedures.

Device characteristics for breast cosmetic procedures

Device characteristics are ascertained by the Registry from manufacturer catalogues. The ABDR characterises these according to implant shell/texture, shape and fill. A total of 152,497 devices used in cosmetic procedures have been recorded by the ABDR since 2012.

TABLE 6.5 DEVICE CHARACTERISTICS – COSMETIC BREAST IMPLANTS (2012-2024)

	Implant	
	N	(%)
Shell/Texture		
Smooth	79,148	52.0
Textured	69,452	45.6
Polyurethane	3,575	2.3
Not stated	128	0.1
Shape		
Round	114,581	75.2
Shaped/anatomical	37,594	24.7
Not stated	128	0.1
Fill		
Silicone	151,131	99.2
Saline	1,022	0.7
Silicone/Saline	22	<0.1
Not stated	128	0.1
Total	**152,303**	

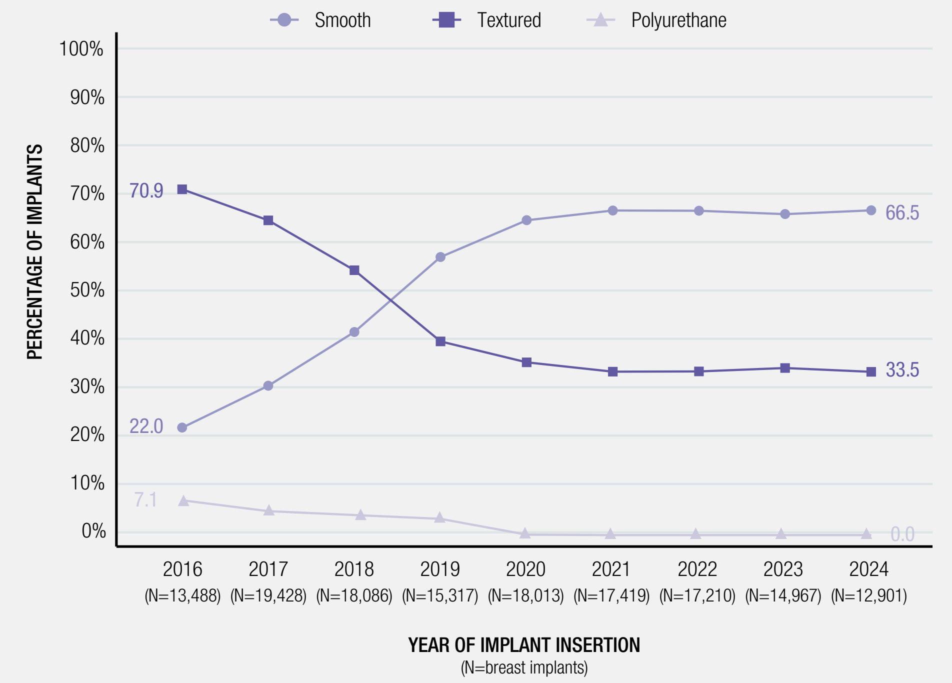
Note: Counts are at the breast level. Includes procedures with device operation types: first implant insertion; implant revision – with revision type: replacement.

Table 6.5 demonstrates that there are more smooth devices (52.0%) in the Registry for cosmetic procedures, compared to textured devices (45.6%). Round devices (75.2%) continue to be used often compared to shaped/anatomical devices (24.7%). Of note, smooth devices tend to also be round. The majority of implants have silicone fill (99.2%).

Implant shell

The Registry is able to show the trends in use of breast implants by shell and shape respectively over time. Figure 6.10 demonstrates that the proportion of smooth and textured devices has plateaued during 2021-2024. In 2024 there were 8,585 (66.5%) smooth devices and 4,316 (33.5%) textured devices.

FIGURE 6.10 DEVICE SHELL – COSMETIC IMPLANTS (2016-2024)

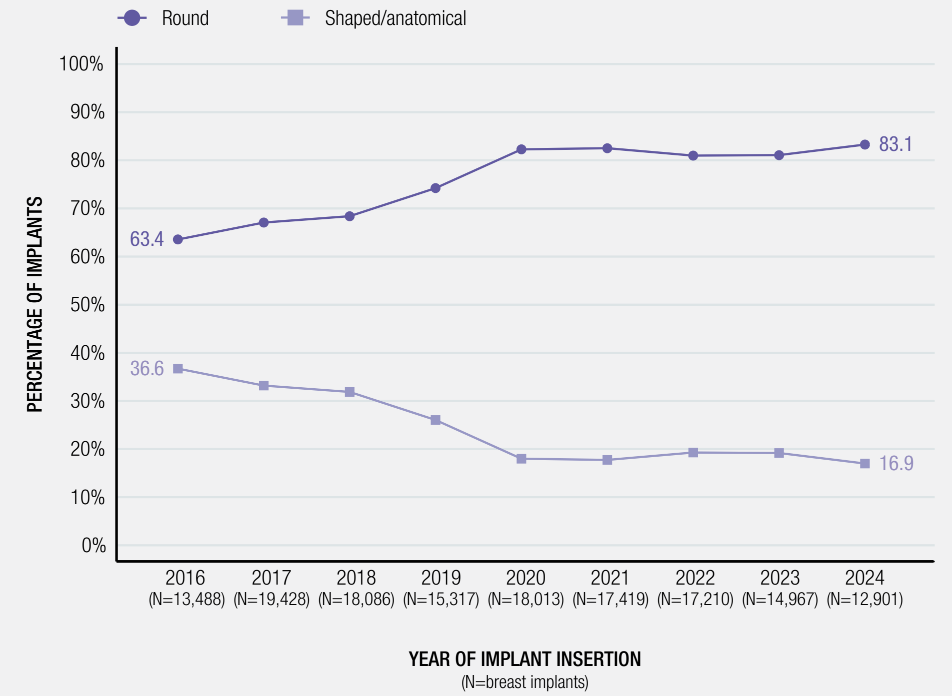


Note: Device texture is reported for newly inserted implants during an insertion procedure or a replacement revision procedure. Implants with an unknown shell type have not been included.

Implant shape

Figure 6.11 highlights the continued trends in the use of round breast implants in cosmetic surgery. Round implants have increased from 8,551 (63.4%) in 2016 to 10,719 (83.1%) 2024 while shaped/anatomical implants decreased from 4,937 (36.6%) in 2016 to 2,182 (16.9%) in 2024.

FIGURE 6.11 DEVICE SHAPE – COSMETIC IMPLANTS (2016-2024)



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

Matrix/mesh use in cosmetic procedures

Matrix/mesh devices use used much less frequently in cosmetic procedures compared to reconstructive ones. Matrix/mesh use for insertion procedures remains below 1% but has increased over the years. In 2024, matrix/mesh use rose to 2.5% for revision procedures.

TABLE 6.6: MATRIX/MESH USE BY YEAR – COSMETIC BREAST IMPLANT INSERTION PROCEDURES

	2016	2017	2018	2019	2020	2021	2022	2023	2024	Total (2012-2024)
Matrix/mesh used	4 (0.0%)	4 (0.0%)	1 (0.0%)	3 (0.0%)	8 (0.1%)	13 0.1%)	23 (0.2%)	29 (0.3%)	46 (0.5%)	134 (0.1%)
Total	**11,210**	**16,178**	**13,922**	**11,366**	**14,021**	**12,995**	**13,179**	**10,945**	**9,129**	**117,000**

TABLE 6.7: MATRIX/MESH USE BY YEAR – COSMETIC BREAST IMPLANT REVISION PROCEDURES (EXCLUDING EXPLANT ONLY)

	2016	2017	2018	2019	2020	2021	2022	2023	2024	Total (2012-2024)
Matrix/mesh used	30 (1.3%)	49 (1.5%)	58 (1.4%)	59 (1.5%)	38 (0.9%)	40 (0.9%)	69 (1.7%)	56 (1.4%)	96 (2.5%)	525 (1.5%)
Total	**2,331**	**3,330**	**4,260**	**4,038**	**4,066**	**4,499**	**4,091**	**4,085**	**3,854**	**35,870**

Primary and legacy breast devices

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

TABLE 6.8: BREAST IMPLANTS INSERTED BY PRIMARY/LEGACY STATUS (2012-2024)

Breast implant insertion type	N	%
Primary	116,378	76.4
Legacy	35,925	23.6
Total	**152,303**	**100**

Table 6.8 shows the number of implants classified as primary or legacy. An implant is classified based on the available history of the breast it is inserted in. Primary implants are defined as those which are inserted into the breast area with no in-situ breast implant (i.e.: procedure is not a replacement of an implant) and also no recorded history of prior procedures involving implants in the Registry. The ABDR has recorded 152,303 breast implant insertion procedures, where 116,378 (76.4%) are **cosmetic primary breast implants** and 35,925 (23.6%) **legacy implants**. Analysis to assess device performance based on time to event analysis i.e.: revision incidence, uses **primary devices only.**

Revision of cosmetic breast implants and complications

Revision surgery is described as a procedure for the unplanned replacement, reposition or explant of an in-situ breast device. A revision may be classified as being due to complication (complication selected as reason for revision or at least one issue reported at revision, as explained in Methods) or other reasons. Table 6.9 shows the breakdown of reasons for cosmetic implant revisions (revisions are included regardless of whether or not the corresponding initial implant insertion procedure was captured in the Registry). In 2024, 64.0% of cosmetic breast implant revisions were due to complication.

TABLE 6.9: REASONS FOR REVISION OF COSMETIC BREAST IMPLANTS

Reason for revision	2012-2024		2024	
	N	(%)	N	(%)
Complication	30,220	67.3	3,360	64.0
Asymptomatic	892	2.0	73	1.4
Patient preference	11,746	26.1	1,612	30.7
Breast Cancer	27	0.1	9	0.2
Not stated	2,044	4.5	194	3.7
Total number of revision procedures	**44,929**		**5,248**	

Note: The crude percentage shown for each reason for revision is an observational proportion that has not accounted for censoring and patient follow-up time so cannot be interpreted as a revision rate. A revision is classified as being due to complication if the reason for revision is reported as complication and/or at least one complication was reported. Refer to Methods.

The Registry captures data relating to specific issues found at revision surgery. These complications include capsular contracture, device malposition, device rupture/deflation, seroma/haematoma and deep wound infection. Table 6.10 reports the frequency of issues out of all reconstructive breast implant revision procedures which are due to complication. Please note, this table does not represent complication rates. Complication rates are described in the following section using Kaplan-Meier (event) curves. This table indicates only the most common complications that are reported to the Registry.

TABLE 6.10: SPECIFIC ISSUES AT REVISION (DUE TO COMPLICATION) OF COSMETIC BREAST IMPLANTS

Complications and issues identified at revision (N.B. Not complication rates)	2012-2024		2024	
	N	(%)	N	(%)
Capsular contracture	16,425	54.4	1,871	55.7
Device rupture/deflation	10,398	34.4	1,122	33.4
Device malposition	9,095	30.1	991	29.5
Seroma/haematoma	1,088	3.6	93	2.8
Deep wound infection	268	0.9	26	0.8

Note: Listed in order of frequency are issues identified during cosmetic breast implant revision procedures which are due to complication: N=30,220 (2012-2024); N=3,360 (2024). 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 shown for 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 za complication rate.

Multiple issues and complications can be reported at the time of revision surgery. In 2024, capsular contracture (55.7%) was reported most often as a complication or issue identified at the time of revision surgery, followed by device rupture/deflation (33.4%) and device malposition (29.5%).

CHAPTER 7

Cosmetic Breast Procedure Outcomes

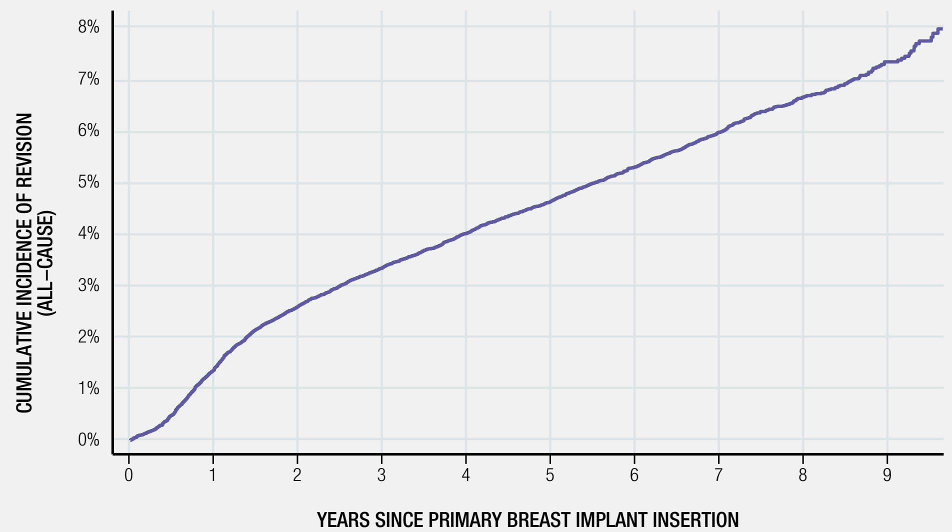
Revision incidence – breast implants for cosmetic procedures

The issues identified at revision data collected by the Registry includes: device rupture/deflation, capsular contracture, device malposition, deep wound infection, seroma/haematoma, BIA-ALCL and skin scarring problems (historically captured in the previous database). All-cause revision incidence includes revisions reported as being due to complication/having the above listed issues as well as revisions due to patient preference, asymptomatic revisions, and revisions involving only breast cancer reported as an issue.

Overall revision incidence for cosmetic procedures

Figure 7.1 and Figure 7.2 provides the **revision incidence** curve for cosmetic procedures. At 9 years after initial implant insertion, the all-cause cumulative revision incidence was 7.3% (Appendix 13).

FIGURE 7.1 ALL-CAUSE REVISION INCIDENCE – COSMETIC PRIMARY BREAST IMPLANTS



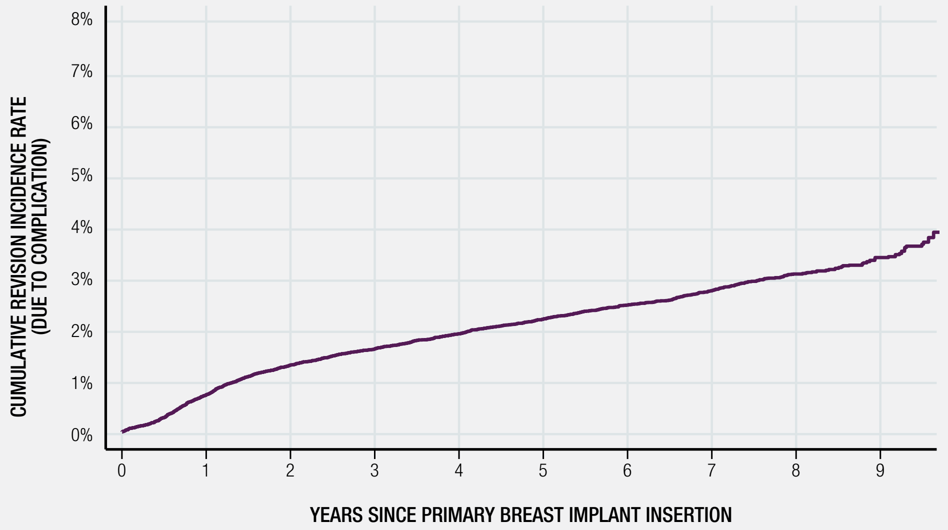
Number at risk

0	1	2	3	4	5	6	7	8	9
116,378	108,879	98,134	84,620	72,342	55,857	46,104	33,699	18,528	6,533

Note: Revision incidence (all-cause) is based on cosmetic primary breast implants inserted from 2012 to 2024. 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 9 years after insertion the revision incidence due to complication was 3.4 % (Figure 7.2).

FIGURE 7.2 REVISION INCIDENCE DUE TO COMPLICATION – COSMETIC PRIMARY BREAST IMPLANTS



Number at risk

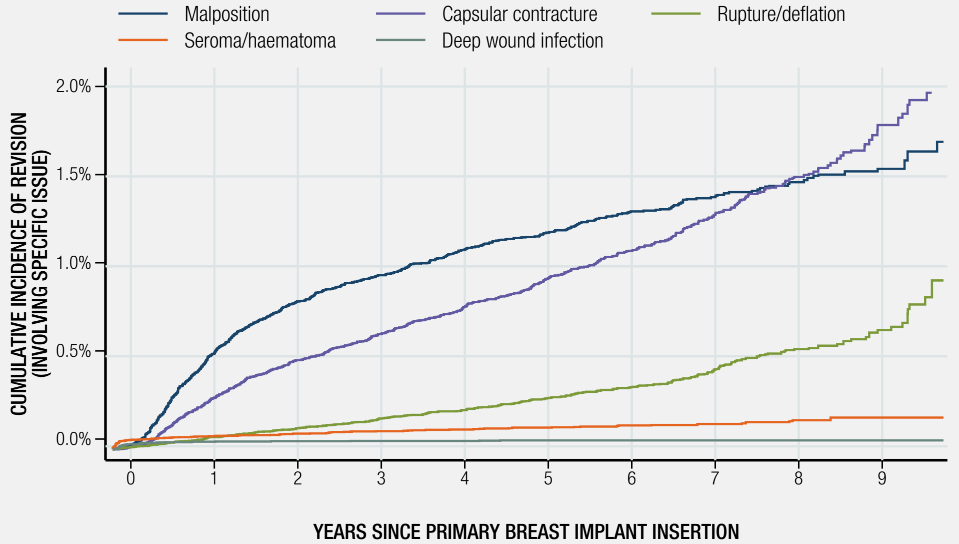
0	1	2	3	4	5	6	7	8	9
116,378	108,879	98,134	84,620	72,342	55,857	46,104	33,699	18,528	6,533

Note: Revision incidence (due to complication) is based on cosmetic primary breast implants inserted from 2012 to 2024. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary implant insertion date to the first revision procedure. The accompanying table provides the number of breasts at risk of revision following from the initial implant procedure at Year=0.

Revision incidence of specific complications

Figure 7.3 shows the cumulative revision incidence rates by type of complication up to 9 years after the date of primary implant insertion. At 9 years post implant insertion, the revision incidence was 1.8% for capsular contracture, 1.5% for device malposition, 0.7% for rupture/deflation, 0.2% for seroma/haematoma and <0.1% for deep wound infection.

FIGURE 7.3 CUMULATIVE REVISION INCIDENCE RATE BY COMPLICATION TYPE – COSMETIC PRIMARY BREAST IMPLANTS



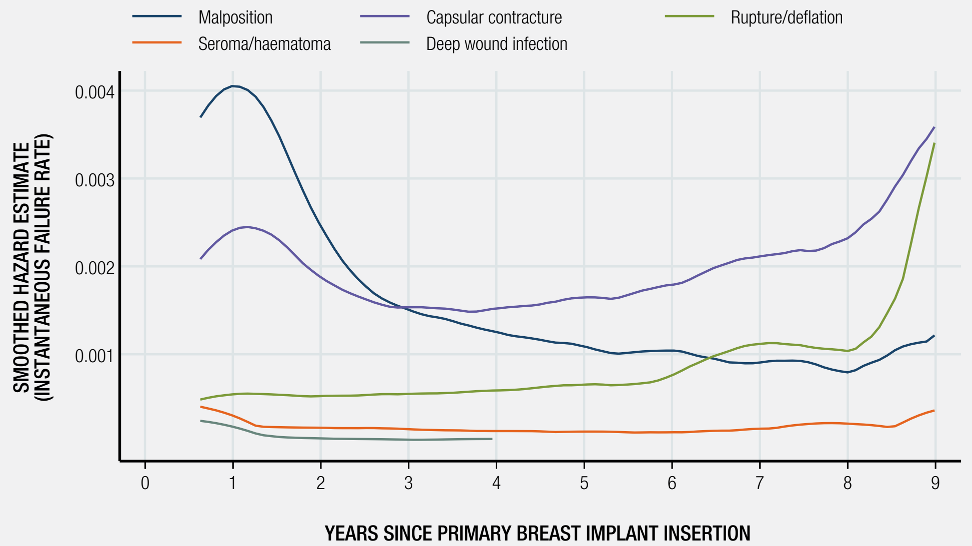
Number at risk

0	1	2	3	4	5	6	7	8	9
116,378	108,879	98,134	84,620	72,342	55,857	46,104	33,699	18,528	6,533

Concepts of hazard curves were introduced in the Methods section of Overview of the Australian Breast Device Registry and in the explanation for Figure 5.4 (page 57).

Hazard estimates over time for each type of complication are shown in Figure 7.4 and show the time points when revisions involving specific complications typically occur. Malposition appears to be an early failure outcome, having a distinct peak at around one year post insertion before rapidly decreasing. Rupture/deflation appears to be an outcome corresponding to wear out with its rate generally increasing as time elapses. Capsular contracture appears to have a peak at one year before decreasing then increasing again in later years. Risk of revision due to malposition and capsular contracture appears to be higher than that of other outcomes within 9 years post insertion in general.

FIGURE 7.4 HAZARD BY COMPLICATION TYPE – REVISIONS OF COSMETIC PRIMARY BREAST IMPLANTS

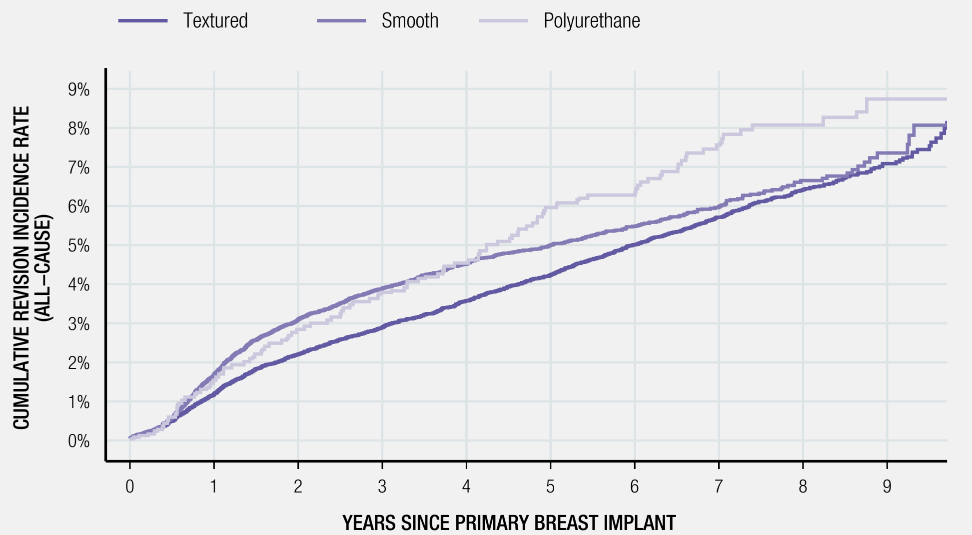


Note: Curves are truncated when smoothed estimates of hazard cannot be calculated (shortly after the start and when case numbers for the complication of interest are low). Experience of complications may not necessarily lead to a revision procedure. There may be long periods of time between when complications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

Revision incidence by implant characteristics

Figure 7.5 provides the **all-cause revision incidence by device shell type** for primary cosmetic breast implants. The all-cause cumulative revision incidence at 9 years post insertion was 8.6% for polyurethane, and 6.9% for smooth and 6.8% for textured implants.

FIGURE 7.5 ALL-CAUSE REVISION INCIDENCE BY SHELL – COSMETIC PRIMARY BREAST IMPLANTS



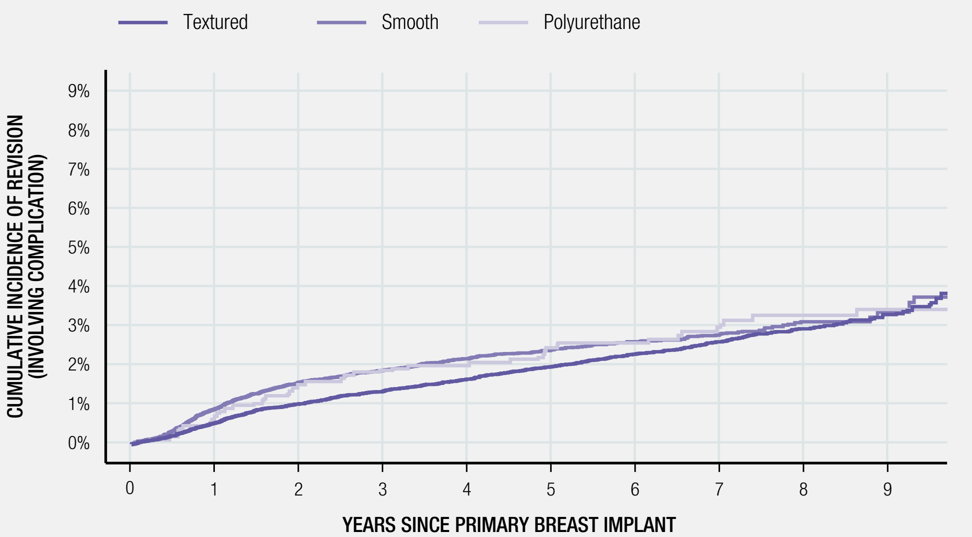
Number at risk

	0	1	2	3	4	5	6	7	8	9
Textured	56,842	54,062	50,111	45,032	40,300	34,183	29,898	23,316	13,346	4,850
Smooth	56,944	52,267	45,514	37,104	29,594	19,269	13,964	8,648	4,087	1,263
Polyurethane	2,531	2,493	2,458	2,434	2,411	2,374	2,223	1,723	1,084	413

Note: Revision incidence (all-cause) is based on cosmetic primary breast implants inserted from 2012 to 2024. 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 7.6 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 9 years post insertion was 3.3% for polyurethane, 3.1% for textured and 3.2% for smooth implants (Appendix 14).

FIGURE 7.6 REVISION INCIDENCE DUE TO COMPLICATION BY SHELL – COSMETIC PRIMARY BREAST IMPLANTS



Number at risk

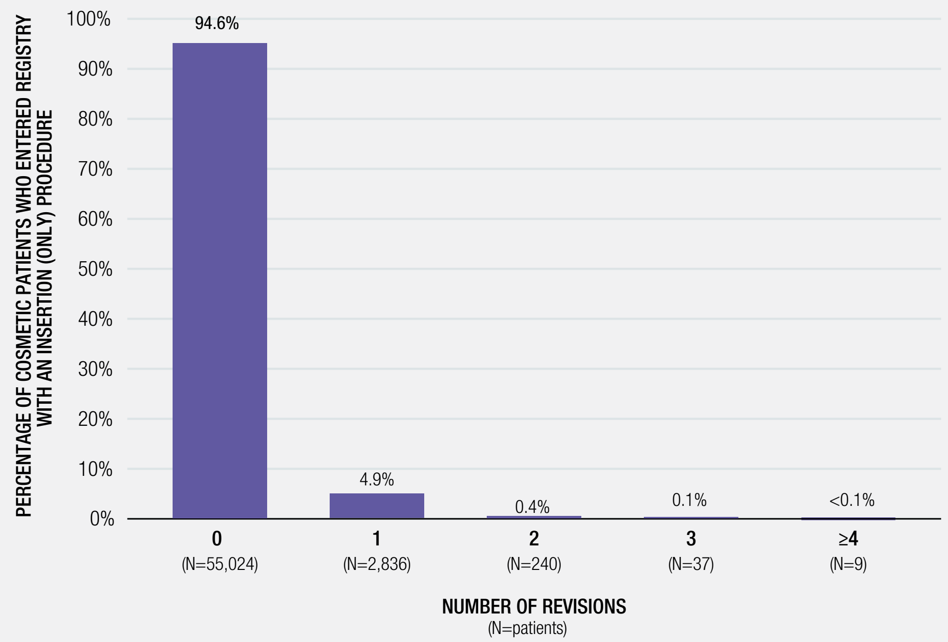
	0	1	2	3	4	5	6	7	8	9
Textured	56,842	54,062	50,111	45,032	40,300	34,183	29,898	23,316	13,346	4,850
Smooth	56,944	52,267	45,514	37,104	29,594	19,269	13,964	8,648	4,087	1,263
Polyurethane	2,531	2,493	2,458	2,434	2,411	2,374	2,223	1,723	1,084	413

Note: Revision incidence (due to complication) is based on cosmetic primary breast implants inserted from 2012 to 2024. 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.

Multiple revision procedures

Figure 7.7 shows the percentages and counts of patients by the number of revisions they had (the breast with the most revisions is used for the count). Patients whose first operation involved only insertions are included (since those who enter the Registry with other operation types could potentially have had prior revisions that cannot not be counted). Of the 58,146 patients included, 94.6% had no revisions (55,024), 4.9% had one revision (2,836) and 0.5% had two or more revisions.

FIGURE 7.7 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 entered the Registry with (direct-to-) implant insertions.

Clinician conducting revision procedures

The frequency of revisions being conducted by a different clinician has been investigated using breasts with both a primary implant insertion procedure and implant revision procedure captured. Of the 5,538 breasts included, **3,726 (67.3%) had both procedures conducted by the same clinician** and 1,812 (32.7%) had insertion and revision procedures conducted by different clinicians. The frequency of revisions being conducted by a different clinician is higher for the cosmetic cohort than for reconstructive (19.1%).

CHAPTER 8

Breast Implant Associated Anaplastic Large Cell Lymphoma

Clinicians are encouraged to report all new cases of Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) to the Registry. The ABDR are 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 Macquarie University (MQU) Research Group. MQU data comprised of 112 confirmed BIA-ALCL cases reported between 2007-2019.

The ABDR are notified by clinicians when their patient is suspected or confirmed to have BIA-ALCL. All cases of BIA-ALCL are followed-up by Registry. Clinicians are required to confirm via email if their records indicate that their patient is confirmed to have BIA-ALCL.

The lymphoma could either be the reason that the patient has returned to surgery for a revision procedure or may be discovered incidentally. In 2024 there have been no new cases of BIA-ALCL reported to the Registry. Therefore, there remains a total of 67 patients reported with BIA-ALCL recorded in the ABDR (Figure 8.1). Of the 67 cases, two patients were diagnosed with bilateral BIA-ALCL. One confirmed case reported in 2020 has since opted-out of the Registry.

FIGURE 8.1 PATIENTS REPORTED TO THE ABDR WITH BIA-ALCL BY YEAR (2015-2024)

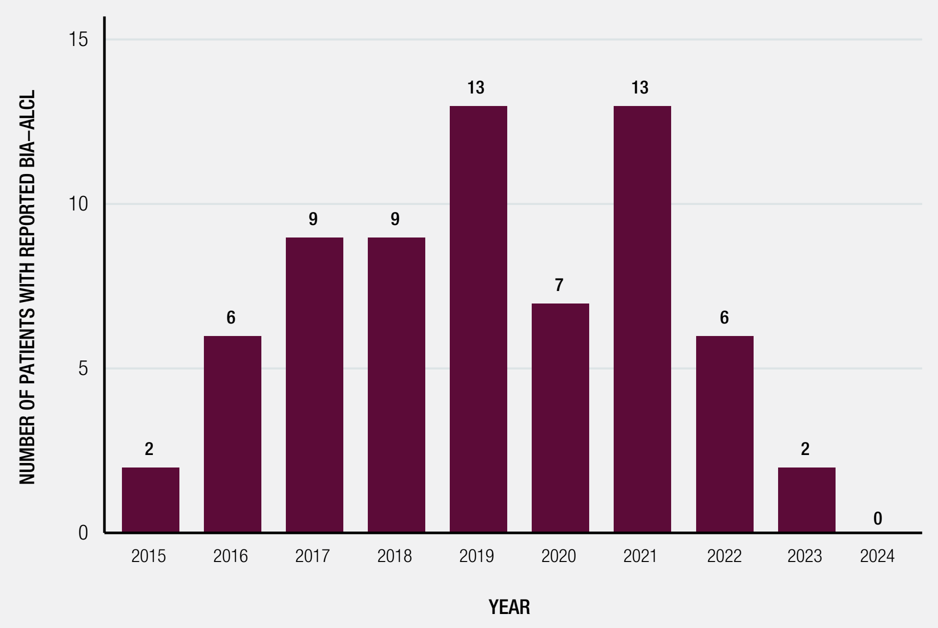


Figure 8.2 shows the duration between insertion of the breast implant and date of revision/explantation of that same implant (where this data is reported to the ABDR). The date of implant insertion is recorded in 52 of the 69 (breast level) cases of BIA-ALCL reported to the Registry. The most common number of years that an associated device remained in-situ was for 7-10 years before being explanted, with a range of 3-18 years.

FIGURE 8.2 NUMBER OF EXPLANTED DEVICES BY EXPOSURE TIME (YEARS) IN BIA-ALCL PATIENTS ABDR (2015-2024)

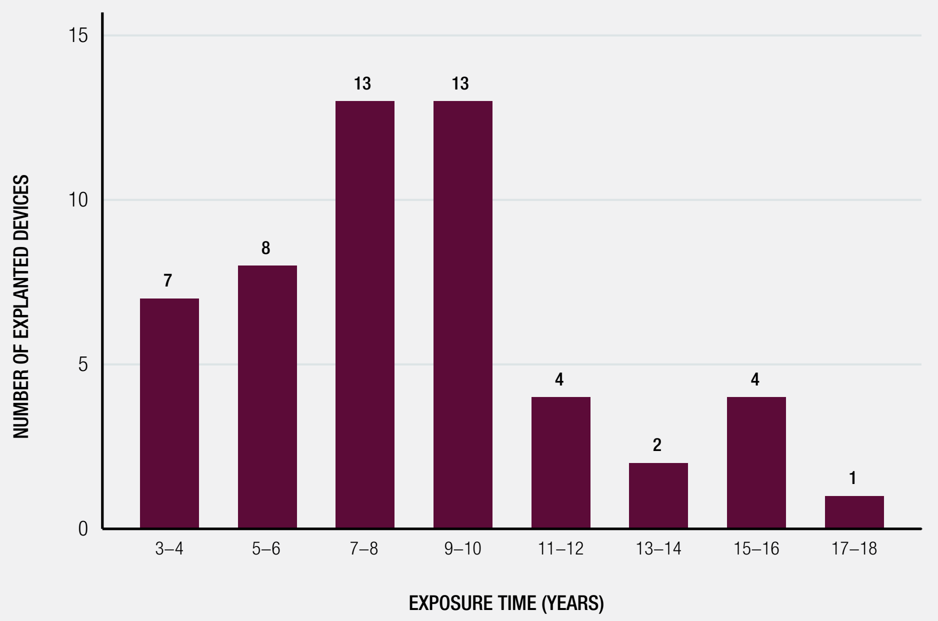
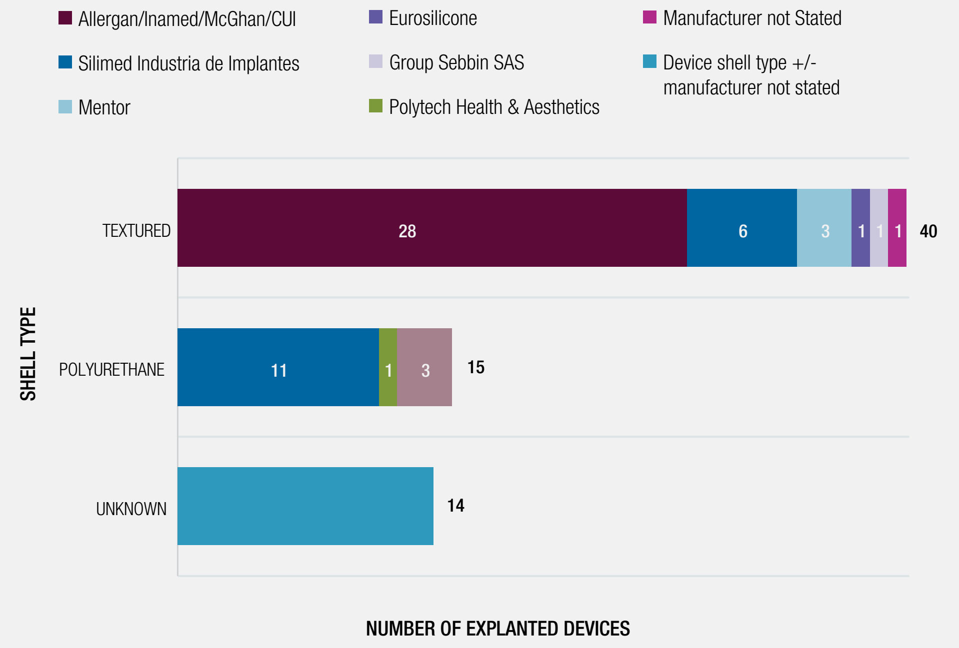


Figure 8.3 shows the explanted devices by shell type. Of the 69 breast implants in the Registry, 40 have the textured shell while 15 had polyurethane shell. There remain 14 devices that are of unknown shell type recorded in the Registry. Where device manufacturer information is available, 28 were identified as Allergan/inamed/McGhan/CUI. Of note, the Silimed Industria de Implantes foam covered implants had a manufacturing defect identified that caused surface delamination.[8]

FIGURE 8.3 EXPLANTED DEVICES BY SHELL TYPE ABDR (2015-2024)



Adjunct clinical issues reported in BIA-ALCL cases reported to the ABDR are presented in Table 8.1. The most common adjunct clinical issue reported was seroma/haematoma as the reason for revision in 16 cases and found incidentally in 5 cases.

TABLE 8.1: ADJUNCT CLINICAL ISSUES REPORTED IN BIA-ALCL CASES ABDR (2015-2024)

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

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

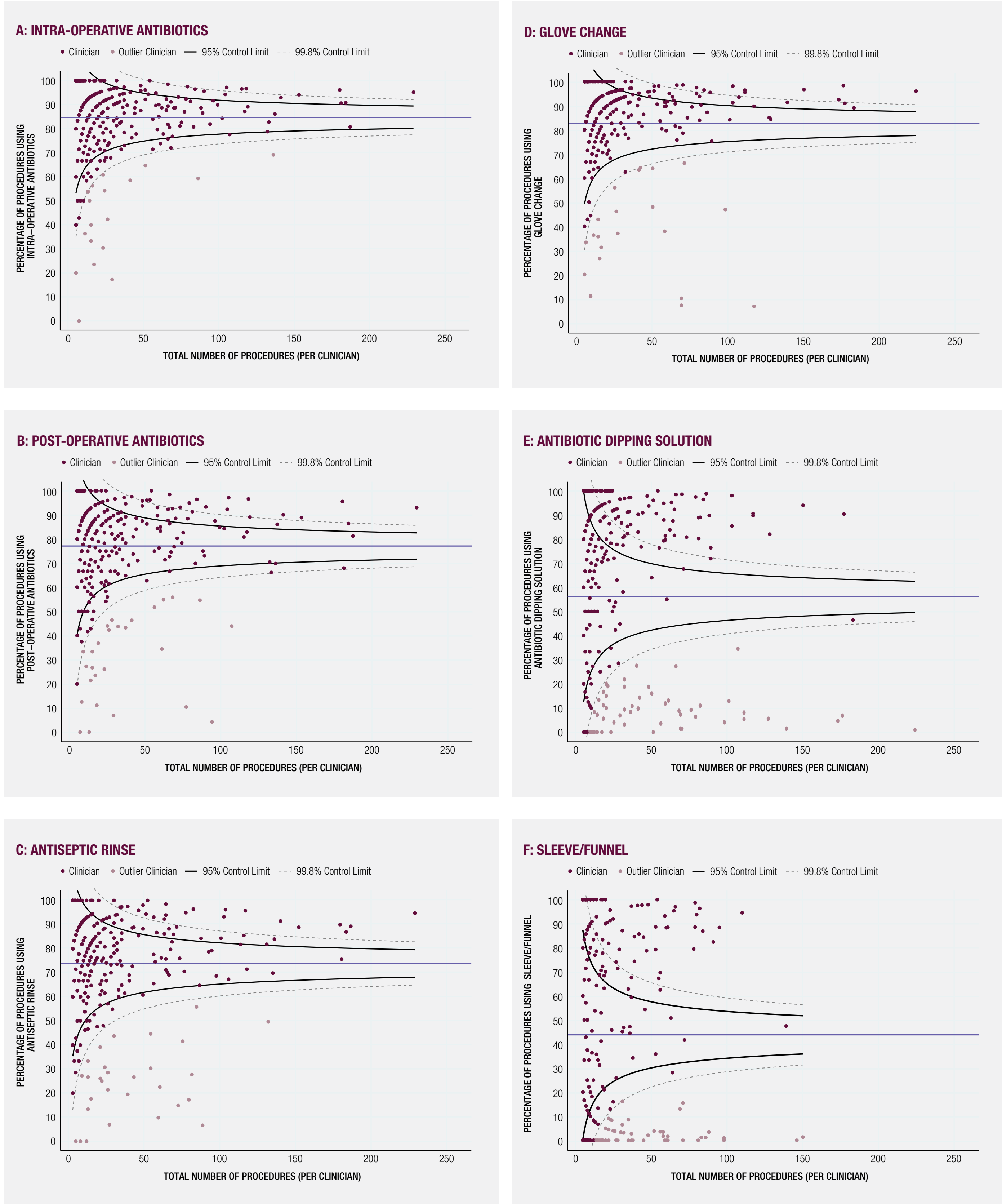
CHAPTER 9

Clinician Variation And Clinical Quality Indicators

Variation in intra-operative techniques

Funnel plots can be used to investigate variation in clinical practice. Figures 9.1 (A-F) and 9.2 (A-F) are funnel plots that show the number of clinicians using various intra-operative techniques (for reconstructive and cosmetic cohorts respectively). Funnel plots are described in more detail in the Methods section. In these plots, each point represents a clinician. The horizontal axes show the number of operations conducted by each clinician between 2022-2024 while the vertical axes show the frequency that each clinician reported the use of a specific intra-operative technique in this time period. Clinicians below the lower contour line may be considered as outliers having statistically below average use of an intra-operative technique. The funnel plots of both the reconstructive and cosmetic cohorts show lower levels of variation in the use of intra-operative antibiotics, post-operative antibiotics, antiseptic rinse and glove change; compared to the variation in the use of antibiotic dipping solution and a sleeve/funnel.

FIGURE 9.1 (A-F) INTRA-OPERATIVE TECHNIQUES FOR RECONSTRUCTIVE PROCEDURES (OPERATION LEVEL) – FUNNEL PLOTS COMPARING CLINICIANS (2022-2024)



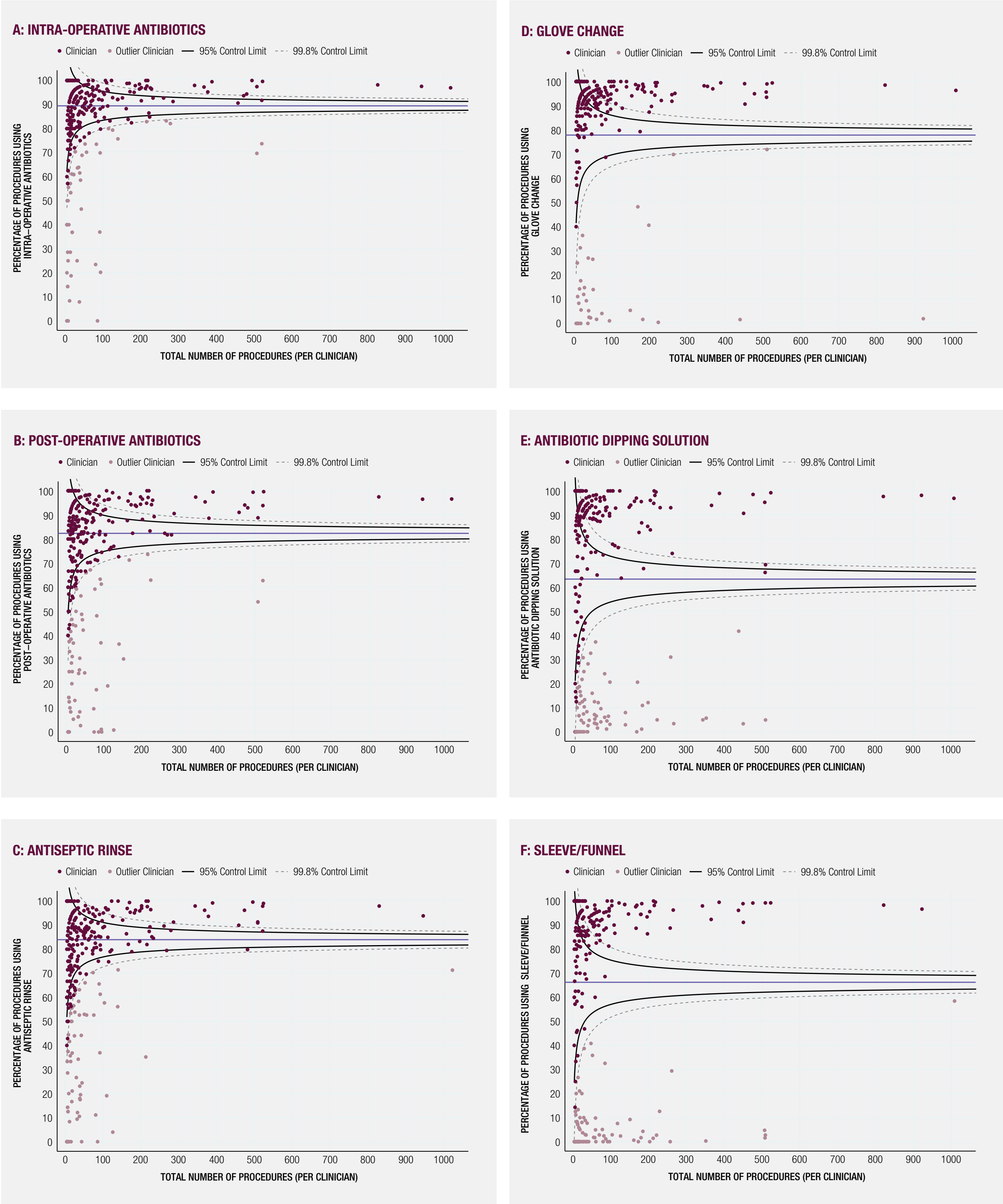
Note: Counts are at the operation level. Clinicians with less than five reconstructive procedures between 2022-2024 have been included for the calculation of the average use of each intra-operative technique but are not shown in the funnel plots.

Note A, B & C: 447 unique clinicians performed a total of 10,093 reconstructive procedures between 2022-2024.

Note D & E: 433 unique clinicians performed a total of 9,369 reconstructive procedures (which are not explant only procedures) between 2022-2024.

Note F: 422 unique clinicians performed a total of 7,096 reconstructive procedures (with device operation type being one of first implant insertion; tissue expander removal and implant insertion; implant revision – with revision types: replacement/reposition) between 2022-2024.

FIGURE 9.2 (A-F) INTRA-OPERATIVE TECHNIQUES FOR COSMETIC PROCEDURES (OPERATION LEVEL) – FUNNEL PLOTS COMPARING CLINICIANS (2022-2024)



Note: Counts are at the operation level. Clinicians with less than five cosmetic procedures between 2022-2024 have been included for the calculation of the average use of each intra-operative technique but are not shown in the funnel plots.

Note A, B & C: 433 unique clinicians performed a total of 25,022 cosmetic procedures between 2022-2024

Note D, E & F: 382 unique clinicians performed a total of 22,899 cosmetic procedures (which are not explant only procedures) between 2022-2024

Variation in revision rates

The Registry is reporting variation in **revision rates by hospital**, specifically **revision due to complication.**

Figures 9.3 and 9.4 show the variation in **rates of revision due to complication within 1 year** across hospitals, separately for reconstructive and cosmetic procedures. In these plots, each point represents a hospital. The horizontal axes show the number (at breast level) of primary implant insertion procedures conducted by a hospital over a 3-year period between 2021-2023. The inclusion of multiple years improves the robustness of the analysis where annual volumes per site are often low.

The vertical axes show the percentage of breasts with a subsequent revision due to complication procedure captured within 1 year of insertion. Hospitals above the contour line may be considered as outliers, having statistically above average revision rates. For the individual hospital reports associated with these funnel plots, each hospital will be identified within its own report, to allow it to compare itself with other hospitals undertaking reconstructive or cosmetic procedures.

Unadjusted rates of revision are presented. Surgical elements/intra-operative techniques may be related to clinical decisions so were not risk-adjusted for in the benchmarking of site-specific 1-year revision rates. In the reconstructive cohort, previous radiotherapy and indication for surgery (post-cancer/risk-reducing/developmental) were considered for risk adjustment of 1-year revision rates but they did not improve model fit. Risk-adjusting for age alone was not deemed appropriate as it was discussed that there are other factors (beyond clinical decisions/performance) which are associated with revisions. Plots risk-adjusting for age were quite similar to the crude unadjusted ones shown here.

The **average rate of revision within one year** (of insertion) for hospitals that have undertaken reconstructive breast implants is **3.2%** and for cosmetic implants is **0.5%** (for insertions between 2021-2023).

FIGURE 9.3 VARIATION IN PERCENTAGE REVISED DUE TO COMPLICATION WITHIN 1 YEAR BY HOSPITAL – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS (INSERTED BETWEEN 2021-2023)

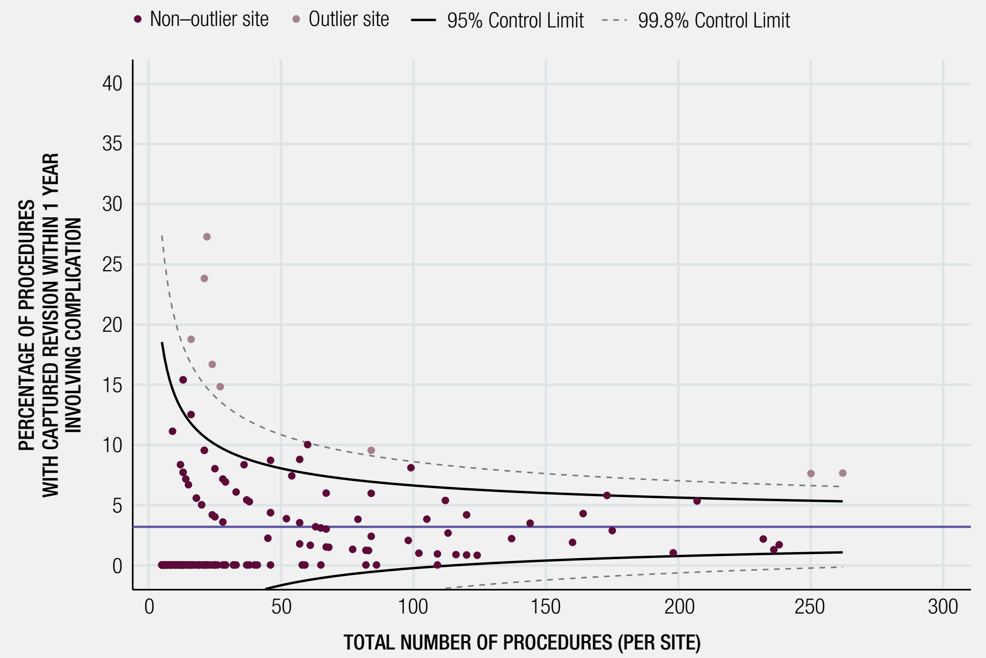
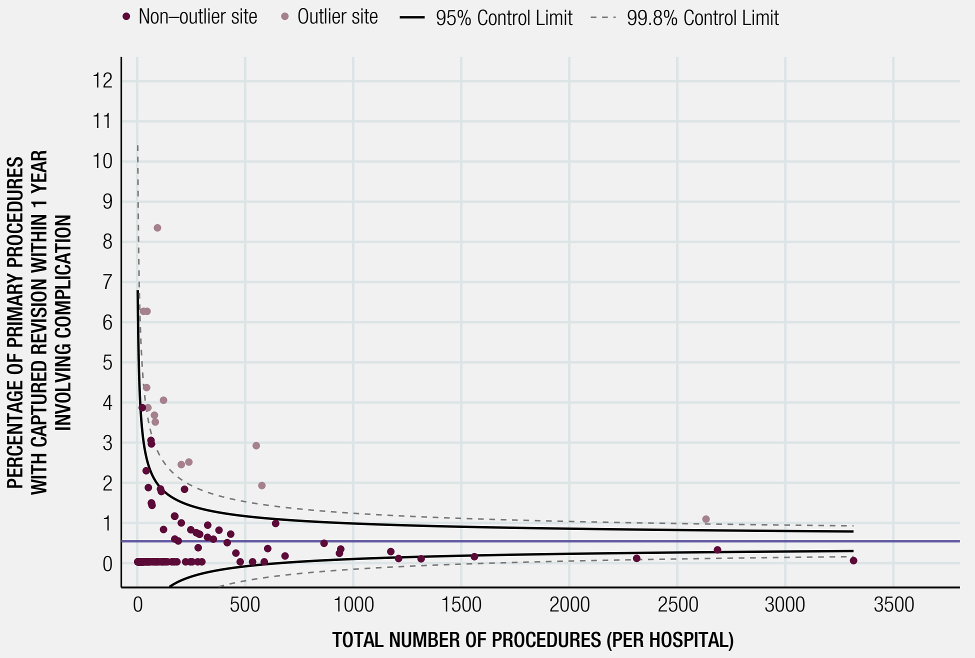


FIGURE 9.4 VARIATION IN PERCENTAGE REVISED DUE TO COMPLICATION WITHIN 1 YEAR BY HOSPITAL – COSMETIC PRIMARY BREAST IMPLANTS (INSERTED BETWEEN 2021-2023)



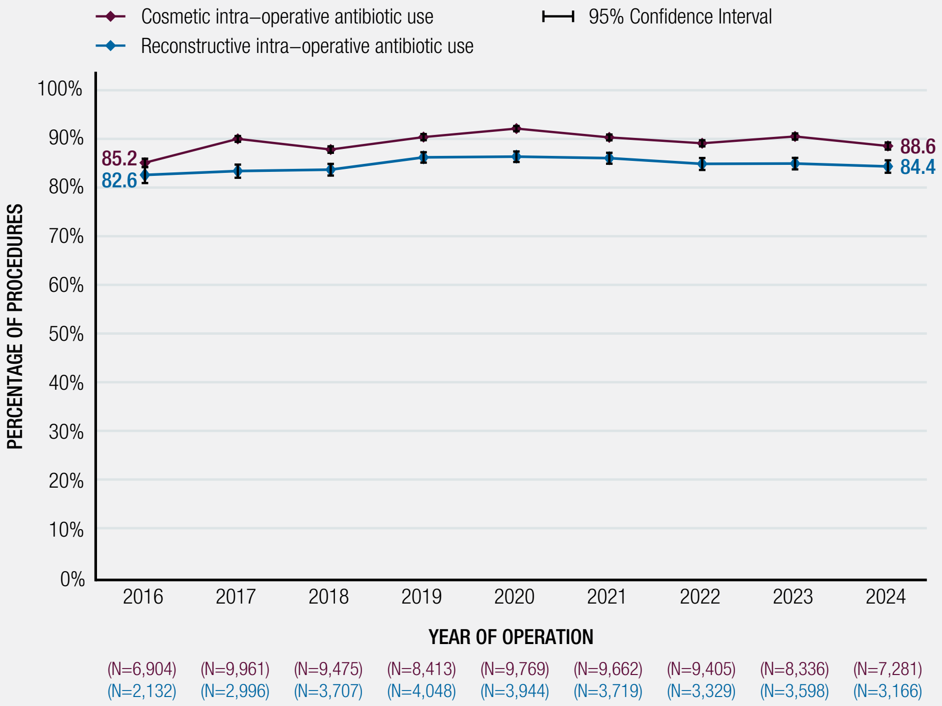
Clinical Quality Indicators

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

CQI 1 Intra-operative antibiotics use

The proportion of procedures that had intra-operative antibiotics provided before skin incision is presented in Figure 9.5. There has been consistent rate of reported use of intra-operative antibiotics for both reconstructive and cosmetic groups from 2016-2024 (all procedures).

FIGURE 9.5 PROPORTION OF PROCEDURES REPORTED INTRA-OPERATIVE ANTIBIOTICS USE



CQI 2: Revision due to short-term complications

Reoperation rates due to short term (within 60 days) complications for the reconstructive and cosmetic cohorts are provided in Figure 9.6, where the complication involves at least one of the following: deep wound infection, capsular contracture, device malposition, device rupture/deflation, seroma/haematoma, or implant loss. Although implant loss is not directly captured in the data collection form, it is defined as implant explantation (without replacement) for reasons other than patient preferences. The revision incidence rate at 60 days post operation due to short term complications has varied between 0.6-1.4% from 2016 to 2024 for reconstructive procedures, and has been consistently around 0.1% for cosmetic procedures.

FIGURE 9.6 CUMULATIVE REVISION INCIDENCE RATE AT 60 DAYS POST PRIMARY BREAST IMPLANT INSERTION DUE TO SHORT TERM COMPLICATIONS BY INSERTION YEAR

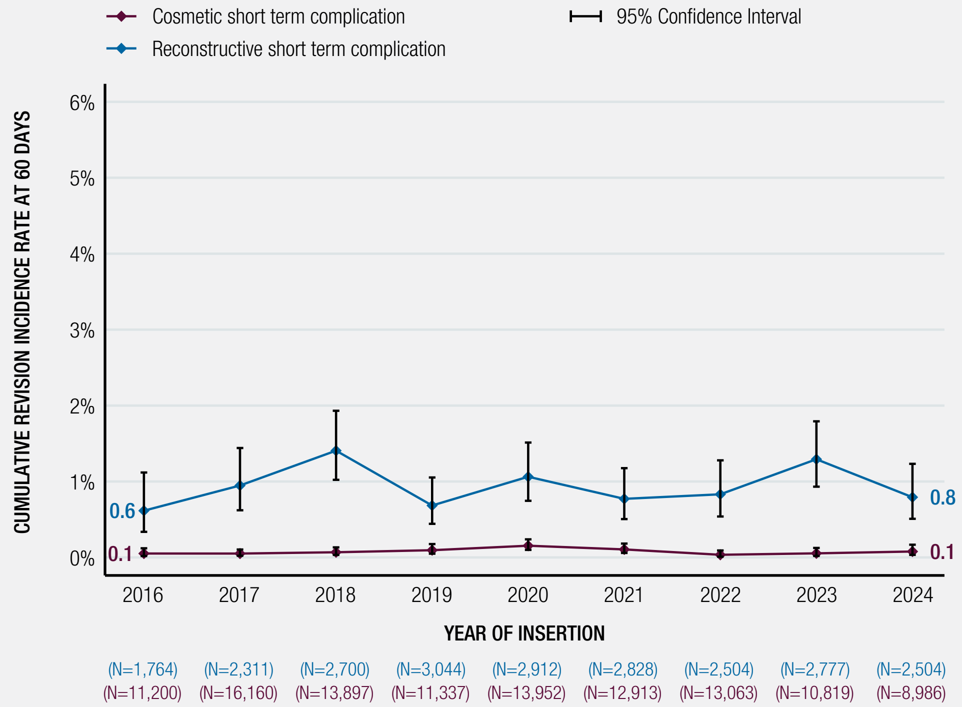


Figure 9.7 and Figure 9.8 consider the cumulative revision incidence at 6- and 12-months, respectively. Reconstructive revision rates have fluctuated between approximately 1.5-2.5% over the period from 2016-2024 for revision at 6 months, and fluctuated between 2.5-4.2% for revisions at 12 months. Cosmetic reconstructive procedures have varied little during this time, having revision rates of 0.1-0.3% at 6 months, and 0.5-0.8% at 12 months.

FIGURE 9.7 CUMULATIVE REVISION INCIDENCE RATE AT 6 MONTHS POST PRIMARY BREAST IMPLANT INSERTION DUE TO SHORT TERM COMPLICATIONS BY INSERTION YEAR

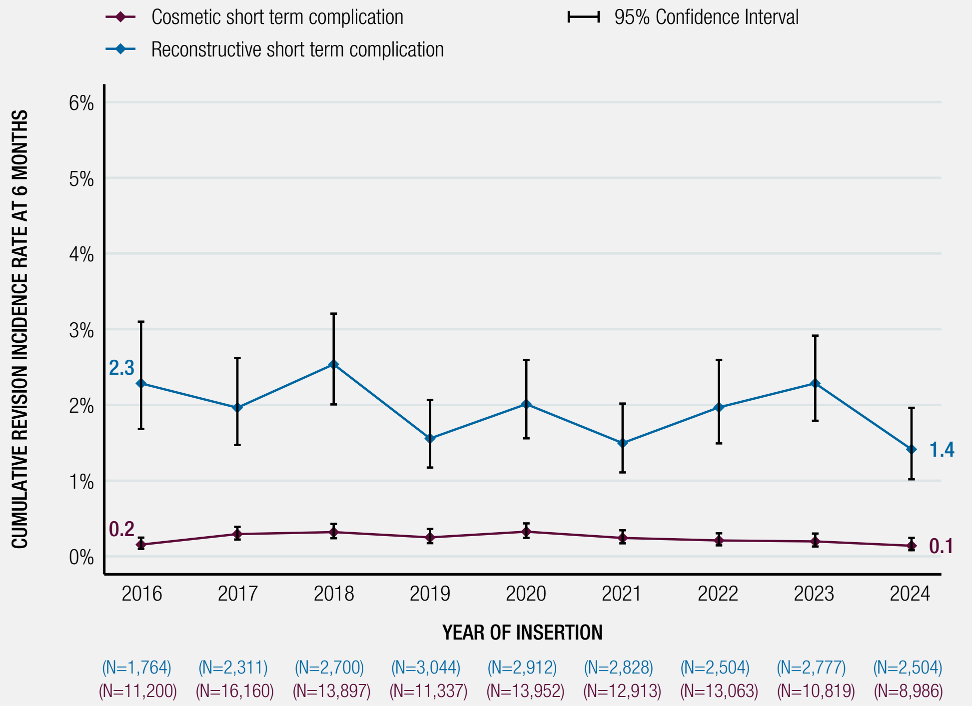
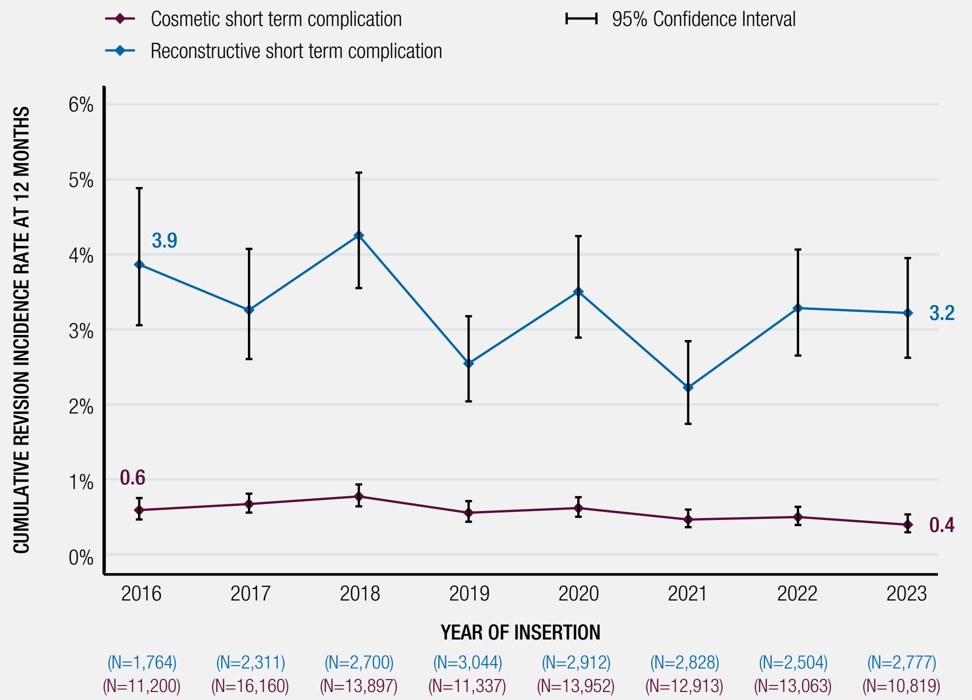


FIGURE 9.8 CUMULATIVE REVISION INCIDENCE RATE AT 12 MONTHS POST PRIMARY BREAST IMPLANT INSERTION DUE TO SHORT TERM COMPLICATIONS BY INSERTION YEAR



CHAPTER 10

Patient Reported Outcomes Measures

Patient-reported outcome measures, or PROMs, have become an essential component of contemporary clinical quality registries, including those focused on medical devices. Their development within device registries reflects the growing recognition that clinical indicators alone cannot fully describe the real-world performance of implanted devices or their impact on patients' quality of life. PROMs instruments, such as the BREAST-Q[9] is developed and validated using rigorous psychometric methods, allow breast device registries to systematically capture patients' perspectives on symptoms, function, satisfaction, and overall wellbeing following device implantation.

The ABDR is launching its new PROMs program as part of the rollout of the custom-built Registry database. An acceptability study[10] was undertaken to identify the most appropriate BREAST-Q scales for routine use, amongst patients having breast reconstruction surgery following cancer or for risk reducing reasons. The Registry has determined that the two selected scales will be psychosocial wellbeing and satisfaction with breasts. The study also confirmed that the following time points are acceptable for patient follow-up: 6-, 12- and 24-months. PROMs will be delivered to patients through multiple modes, including text message, email, and postal mail, to maximise accessibility and response rates.

9 Pusic AL, Klassen AF, Scott AM, Klok JA, Cordeiro PG, Cano SJ. Development of a new patient-reported outcome measure for breast surgery: the BREAST-Q. Plast Reconstr Surg. 2009 Aug;124(2):345-353. doi: 10.1097/PRS.0b013e3181aee807. PMID: 19644246.

10 Herbert D, Ahern S, Walker M, Farrell G, Hopper I, Ruseckaite R. Reconceptualizing Patient-reported Outcomes Measures in the Australian Breast Device Registry. Plast Reconstr Surg Glob Open. 2025 Apr 14;13(4):e6685. doi: 10.1097/GOX.0000000000006685. PMID: 40230468; PMCID: PMC11995982.

CHAPTER 11

ABDR Data Requests, Publications and Conferences

Data requests

The ABDR continued to experience an increase in enquiries from patients during this reporting period. Patients contacting the ABDR are interested to learn their device details, to change their postal address, to opt-out of the Registry and various other reasons. In 2024, the ABDR was contacted via email and phone by patients (N=172) and clinicians (N=14) specifically related to device inquiries, with 237 calls overall being received in 2024.

Data requests were received by industry, government and academic researchers (Table 11.1). The growing number of requests demonstrates the maturity of the Registry and its relevance to a broad range of stakeholders. All ABDR data reported to industry or government is via reports that are produced by the ABDR and reviewed by the ABDR's Research and Data Sharing Subcommittee (for further information please refer to 'Overview of the Australian Breast Device Registry'). No patient level or identifiable information is shared in these reports.

TABLE 11.1: DATA REQUESTS APPROVED IN 2024

Date of approval	Name	Organisation	Request type	Title of project
20/03/2024	Prof. Arul Earnest	Monash University	Research	Implementing machine learning techniques to predict device-related complications among women who have undergone breast implant surgeries- a large multi-centre study
20/08/2024	Ms Michelle Merenda	Monash University	Research (PhD project)	Investigating the interaction between surgical plane type with mesh/ADM on Patient Reported Outcome Measures (PROMs) in reconstructive patients
20/08/2024	Dr Puck Melse	Dutch Breast Implant Registry	Research (PhD project)	Outcomes after ADM or Mesh assisted implant breast operations in international combined breast implant registries
22/08/2024	–	Mentor Worldwide	Report	Mentor Breast Device Post-Market Clinical follow-up report 2024-2026
29/08/2024	Associate Professor Joe Dusseldorf	Chris O'Brian Lifehouse Hospital	Research	Complications and cost implications associated with the use of temporary tissue expander implants in delayed-immediate breast reconstruction for locally advanced breast cancer
15/10/2024	Dr Yvonne Chow and Dr Jieyun Zhou	Monash Health	Research	Breast device surgery and the growing trend in medical tourism
4/11/2024	–	Medical Specialties Australasia Pty Ltd (MSA)	Report	TiLOOP Device Industry Report

Publications

The ABDR produced 2 Academic publications in 2024:

– Merenda M, Earnest A, Ruseckaite R, Tse WC, Elder E, Hopper I, Ahern S. Patient-Reported Outcome Measures in High-Risk Medical Device Registries: A Scoping Review. Aesthetic Surgery Journal Open Forum, online March 16, 2024. https://doi.org/10.1093/asjof/ojae015.

– Leow, Sean Kwang Howe, and Robert John William Knight. "Contemporary Trends in Antiseptic Pocket Rinse in Primary Breast Implant Surgery." Aesthetic Surgery Journal 44, no. 8 (2024): 809–17. https://doi.org/10.1093/asj/sjad351.

Conferences

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 2024, abstracts were accepted: for an oral and poster presentations. The ABDR were also invited to speak at various meetings.

International meetings

PRS Korea 2024 (17-19 November 2024) Grand Intercontinental Seoul Parnas, Seoul Korea (accepted for two poster presentations Dr Yvonne Chow)

Breastanbul 2024 (10-12 October 2024) Wyndham Grand Istanbul Levent Turkiye (oral presented by Dr Melanie Walker)

Controversies in Breast Cancer (CoBrCa) 8th World Congress (11-13 September 2024) Edinburgh Scotland (Delegate Dr Melanie Walker)

ICOBRA and ICOPLAST Conference (11-12 September 2024) Gothenburg Sweden (oral presentation by Professor Susannah Ahern and Mr Patrick Garduce)

Royal Australian College of Surgeons 92nd Annual Scientific Congress (6-10 May 2024) Te Pae Christchurch Convention Centre, Ōtautahi Christchurch, Aotearoa New Zealand (oral presentation by Dr Melanie Walker)

National meetings

Australian Clinical Trials Alliance 2024 Clinical Trials and Registries Symposium (2-4 December 2024) The Pullman Albert Park Hotel Melbourne Victoria (oral presentation by Dr Dilinie Herbert)

Leura International Breast Cancer Conference (23-26 October 2024) Fairmont Resort Blue Mountains New South Wales (oral presentation by Dr Melanie Walker)

46th Annual Australasian Society of Aesthetic Plastic Surgeons Conference (18-20 October 2024) W Brisbane, Brisbane Queensland Australia (exhibitor Dr Yvonne Chow)

Cosmetex2024 (8-9 August 2024) Radisson Blu Sydney, New South Wales Australia (oral presentation by Professor Susannah Ahern)

CHAPTER 12

Future Initiatives

At the time of writing this report, the ABDR has commenced the external rollout of its new purpose-built online database. This system has been designed to support efficient and accurate data entry, provide clinicians with access to practice-level reports, and, in the near future, offer interactive dashboards that will enable real-time navigation and interpretation of registry data. As the database is progressively implemented, the complementary PROMs program is being rolled out in parallel, ensuring that patient-reported outcomes are integrated seamlessly with clinical data to enhance the depth and quality of information captured.

Work continues on the transfer of ethical oversight for the Registry, a change that will streamline amendment submissions, progress reporting, and overall governance processes. In addition, efforts are ongoing to support the onboarding of Western Australian public hospitals using an opt-in model administered through the hospital electronic medical records system, which will further expand national participation and improve data completeness.

Increasing consumer involvement will also be a priority, with initiatives designed to ensure that consumer perspectives help shape how the Registry responds to the needs of patients undergoing breast device surgery. Over the coming year, the Registry will strengthen its approach to consumer involvement by broadening the representation of consumers within advisory structures, expanding opportunities for patient input into Registry processes, and ensuring that consumer voices are embedded in decision-making around data collection, reporting, and quality improvement activities.

With nearly ten years of continuous data capture, the Registry is also well positioned to contribute more extensively to the scientific literature through publication of emerging trends, long-term outcomes, and device performance analyses. This maturing dataset provides a strong foundation for high-quality observational research that strengthens public health discourse. Registry-based studies offer several advantages, including large and diverse patient populations, real-world outcome data, longitudinal follow-up, and the ability to detect rare complications not easily identified in clinical trials. Such contributions support informed clinical decision-making, regulatory oversight, and broader quality improvement initiatives across the health system.

In 2026, the Registry will maintain its focus on improving case ascertainment by engaging new hospitals and strengthening participation across existing sites. These activities, together with deepened consumer involvement and an expanding analytical agenda, will ensure that the Registry continues to fulfil its purpose of advancing the safety, quality, and outcomes of breast device surgery for patients across Australia.

Glossary

Capsular contacture	The scar tissue that forms around implant causes the implant to feel firm.
Contributing site	Any site that has contributed data to the ABDR at any point in time.
Deep wound infection	Infection leading to explantation: An infection associated with a breast implant in place, which leads to its explantation. Usually involves redness, localised pain or tenderness, abscess or persistent serous liquid formation around the implant even with distinct clinical signs it might be culture-negative.
Device deflation	The occurrence of saline implant deflation.
Device malposition	Any instance in which the implant is outside its intended position.
Device rupture	Silicone implant that has ruptured.
Direct-to-implant	A breast reconstruction procedure whereby an implant is inserted at the time of the mastectomy.
Eligible site	A site undertaking breast device surgery as identified by ICD-10-AM code data.
Insertion surgery	Includes procedures that involve insertion of a new device, either a tissue expander or breast implant in a patient who has or has not had previous breast device surgery. Also included are tissue expander-to-implant exchanges and implant-to-tissue expander exchange.
Interquartile range	Quartiles divide a rank-ordered dataset into four equal parts. The values that divide each part are called the first, second and third quartiles. First, second and third quartiles correspond to the observation at the 25th, 50th and 75th percentiles, respectively. The observation from the 25th percentile to the 75th percentile is referred as the interquartile range. An observation at the 50th percentile corresponds to the median value in the dataset.
Participating site	A site that has contributed data in the current reporting period (2024).
Primary breast implant	A breast implant which is inserted into a breast which has no in-situ breast implant (i.e.: procedure is not a replacement of an implant) and also has no recorded history of prior procedures involving implants recorded in Registry.
Primary tissue expander	A tissue expander which is inserted into a breast which has no in-situ device (i.e.: procedure is not replacement) and also has no recorded history of prior procedures involving tissue expanders or implants recorded in Registry.
Revision surgery	A procedure involving unplanned replacement or reposition procedures. The initial device insertion may or may not have also been captured by the Registry. Also includes procedures involving the removal of an implant and insertion of a tissue expander.
Seroma/haematoma	An abnormal accumulation of serum around the device/a collection of blood adjacent to breast device.
Skin scarring	Unsightly scarring following reconstructive breast surgery.
Two-stage implant	A breast reconstruction procedure whereby the initial device insertion is a tissue expander, which is exchanged to a breast implant in a subsequent procedure.

Abbreviations

ABDR	Australian Breast Device Registry
ACCSM	Australasian College of Cosmetic Surgery and Medicine
ACHI	Australian Classification of Health Interventions
ACSQHC	Australian Commission on Safety and Quality in Health Care
ASPS	Australian Society of Plastic Surgeons
BIA-ALCL	Breast Implant Associated-Anaplastic Large Cell Lymphoma
BREAST-Q IS	BREAST-Q Implant Surveillance module
BreastSurgANZ	Breast Surgeons of Australia and New Zealand
CQI	Clinical Quality Indicators
CQR	Clinical Quality Registry
The Department	Department of Health, Disability and Ageing
HREC	Human Research Ethics Committee
MTAA	Medical Technology Association of Australia
TE	Tissue Expander
TGA	Therapeutics Goods Administration
UDI	Unique Device Identifiers

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APPENDIX 1

Data completeness

Patient characteristics (patient level)*	2020	2021	2022	2023	2024
	14,716	14,565	13,630	12,940	11,421
Name	100.0%	100.0%	100.0%	100.0%	100.0%
Surname	100.0%	100.0%	100.0%	100.0%	100.0%
Medicare number	89.9%	91.9%	91.4%	92.3%	92.5%
Date of birth	100.0%	100.0%	100.0%	100.0%	100.0%
Address	98.0%	97.7%	97.7%	97.9%	99.0%
Telephone	86.5%	87.2%	89.1%	89.2%	88.9%
Surgery characteristics (operation level)	**15,394**	**15,153**	**14,175**	**13,445**	**11,902**
Operation date	100.0%	100.0%	100.0%	100.0%	100.0%
Hospital	100.0%	100.0%	100.0%	100.0%	100.0%
Clinician	100.0%	100.0%	100.0%	100.0%	100.0%
Intra-operative techniques**	91.2%	89.7%	89.5%	89.4%	87.5%
Surgery characteristics (breast level)	**28,839**	**28,342**	**26,538**	**25,030**	**22,116**
Side of breast	100.0%	100.0%	100.0%	100.0%	100.0%
Indication for surgery	89.0%	88.2%	89.7%	88.6%	87.6%
Surgery type	100.0%	100.0%	100.0%	100.0%	100.0%
Incision site	87.9%	85.7%	85.9%	86.5%	83.1%
Plane, if not explant only	89.3%	89.3%	88.6%	88.3%	86.8%
Fat graft vol, if fat grafting is selected	91.9%	92.0%	91.0%	94.8%	94.9%
Intra-op fill volume, if tissue expander inserted	64.7%	65.0%	66.2%	67.2%	61.2%
Revision characteristics (breast level)	**9,619**	**10,559**	**9,003**	**9,754**	**9,028**
Revision surgery type	100.0%	100.0%	100.0%	100.0%	100.0%
Indication for revision surgery	94.1%	95.1%	94.1%	94.9%	93.9%
Device characteristics (breast level, involves device insertion)	**25,650**	**24,582**	**23,481**	**21,628**	**18,842**
Implant/tissue expander device ID	99.8%	99.8%	99.9%	99.9%	99.8%
Matrix/mesh device ID, if matrix/mesh used	99.3%	98.7%	98.0%	98.3%	98.6%
Device characteristics (breast level, involves device explant)	**9,510**	**10,454**	**8,903**	**9,658**	**8,902**
Explanted device ID	10.2%	10.4%	11.5%	10.9%	9.0%
Patient opt-out rate	**0.9%**	**0.7%**	**0.8%**	**0.9%**	**1.0%**

Note: *Each patient is counted once for each year that they have at least one procedure captured by the Registry.
**Considered as complete if at least one of: intra-operative antibiotics, post-operative antibiotics, antiseptic rinse, drain use, nipple guard, glove change for insertion, antibiotic dipping solution or sleeve/funnel is reported as being used.

Appendices 2-14: Tables supporting in text figures

APPENDIX 2

Time between primary tissue expander insertion and exchange to implant procedure (2012-2024) – reconstructive, breast level

Time between TE insertion and exchange to implant procedure	N	%
0 to <3 months	823	10.6
3 to <6 months	3,042	39.1
6 to <9 months	1,834	23.6
9 to <12 months	989	12.7
12 to <15 months	457	5.9
15 to <18 months	267	3.4
18 to <21 months	150	1.9
21 to <24 months	79	1.0
≥ 24 months	139	1.8
Total	**7,780**	**100**

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

APPENDIX 3

Intra-operative techniques (2016-2024) – reconstructive operation level procedures

	2016	2017	2018	2019	2020	2021	2022	2023	2024
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Intra-operative antibiotics[1]	1,762 (82.6%)	2,500 (83.4%)	3,104 (83.7%)	3,492 (86.3%)	3,408 (86.4%)	3,202 (86.1%)	2,827 (84.9%)	3,058 (85.0%)	2,672 (84.4%)
Post-operative antibiotics[1]	1,505 (70.6%)	2,222 (74.2%)	2,767 (74.6%)	2,991 (73.9%)	3,055 (77.5%)	2,860 (76.9%)	2,554 (76.7%)	2,809 (78.1%)	2,421 (76.5%)
Antiseptic rinse[1]	1,433 (67.2%)	2,123 (70.9%)	2,699 (72.8%)	2,980 (73.6%)	2,983 (75.6%)	2,726 (73.3%)	2,458 (73.8%)	2,683 (74.6%)	2,314 (73.1%)
Drain use[1]	1,108 (52.0%)	1,678 (56.0%)	1,924 (51.9%)	2,161 (53.4%)	2,067 (52.4%)	1,926 (51.8%)	1,673 (50.3%)	1,859 (51.7%)	1,647 (52.0%)
Nipple guard[2]	310 (27.2%)	474 (30.8%)	590 (30.0%)	737 (32.0%)	725 (30.9%)	681 (30.6%)	599 (30.2%)	642 (29.6%)	523 (26.8%)
Glove change for insertion[3]	1,315 (62.5%)	2,178 (74.3%)	2,763 (76.7%)	3,103 (80.1%)	3,031 (81.2%)	2,852 (81.0%)	2,539 (81.9%)	2,751 (82.7%)	2,444 (83.0%)
Antibiotic dipping solution[3]	872 (41.4%)	1,450 (49.4%)	1,723 (47.8%)	1,833 (47.3%)	2,068 (55.4%)	2,013 (57.2%)	1,760 (56.8%)	1,837 (55.2%)	1,654 (56.2%)
Sleeve/funnel[4]	212 (13.7%)	536 (25.6%)	747 (29.3%)	964 (34.5%)	1,052 (38.8%)	1,059 (41.2%)	970 (42.7%)	1,134 (43.7%)	1,006 (45.1%)
Denominators									
All procedures[1]	2,132	2,996	3,707	4,048	3,944	3,719	3,329	3,598	3,166
At least one breast operated on has nipple absent unticked[2]	1,140	1,540	1,968	2,300	2,349	2,227	1,985	2,170	1,955
Not explant only[3]	2,104	2,933	3,601	3,873	3,734	3,519	3,099	3,325	2,945
Procedure involves implant insertion[4]	1,546	2,095	2,552	2,795	2,712	2,571	2,272	2,593	2,231

Note: Details are at the operation level.
[1,2,3,4] Denominators used for each intra-operative technique are shown at the bottom of the table.

APPENDIX 4

Surgical elements (2016-2024) – reconstructive breast level procedures

	2016	2017	2018	2019	2020	2021	2022	2023	2024
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Incision site*[1]									
Infra-mammary	1,163 (34.7%)	1,438 (31.5%)	1,906 (33.6%)	2,402 (38.2%)	2,578 (41.5%)	2,364 (40.7%)	2,074 (40.5%)	2,207 (39.2%)	2,047 (41.4%)
Mastectomy wound	1,519 (45.3%)	1,883 (41.3%)	2,122 (37.4%)	2,075 (33.0%)	1,871 (30.1%)	1,647 (28.4%)	1,388 (27.1%)	1,610 (28.6%)	1,236 (25.0%)
Mastopexy/reduction wound	213 (6.3%)	434 (9.5%)	536 (9.4%)	529 (8.4%)	530 (8.5%)	534 (9.2%)	471 (9.2%)	650 (11.5%)	532 (10.8%)
Periareolar	209 (6.2%)	411 (9.0%)	558 (9.8%)	652 (10.4%)	572 (9.2%)	598 (10.3%)	560 (10.9%)	544 (9.7%)	496 (10.0%)
Axillary	12 (0.4%)	49 (1.1%)	64 (1.1%)	47 (0.7%)	27 (0.4%)	33 (0.6%)	39 (0.8%)	42 (0.7%)	37 (0.7%)
Other	123 (3.7%)	174 (3.8%)	222 (3.9%)	280 (4.5%)	268 (4.3%)	221 (3.8%)	242 (4.7%)	222 (3.9%)	176 (3.6%)
Plane[2]									
Sub-pectoral	1,984 (59.7%)	2,627 (58.5%)	3,286 (59.6%)	3,321 (55.4%)	2,957 (50.1%)	2,665 (48.5%)	2,294 (47.9%)	2,339 (44.8%)	1,805 (39.1%)
Pre-pectoral**	331 (10.0%)	346 (7.7%)	500 (9.1%)	905 (15.1%)	1,146 (19.4%)	1,178 (21.4%)	1,046 (21.9%)	1,254 (24.0%)	1,243 (26.9%)
Sub-flap	311 (9.4%)	449 (10.0%)	478 (8.7%)	527 (8.8%)	482 (8.2%)	544 (9.9%)	447 (9.3%)	584 (11.2%)	624 (13.5%)
Dual	89 (2.7%)	159 (3.5%)	218 (4.0%)	209 (3.5%)	264 (4.5%)	237 (4.3%)	164 (3.4%)	129 (2.5%)	66 (1.4%)
Other	29 (0.9%)	59 (1.3%)	46 (0.8%)	31 (0.5%)	52 (0.9%)	26 (0.5%)	28 (0.6%)	23 (0.4%)	7 (0.2%)
Not stated	577 (17.4%)	847 (18.9%)	986 (17.9%)	1,007 (16.8%)	999 (16.9%)	844 (15.4%)	806 (16.8%)	889 (17.0%)	868 (18.8%)

	2016	2017	2018	2019	2020	2021	2022	2023	2024
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Cancer related surgical elements									
Nipple sparing[3]	538 (18.6%)	901 (21.8%)	1,197 (22.8%)	1,537 (26.6%)	1,690 (29.8%)	1,542 (29.1%)	1,395 (29.6%)	1,535 (30.0%)	1,379 (30.8%)
Flap cover[4]	287 (10.1%)	379 (9.3%)	455 (8.9%)	478 (8.7%)	434 (8.0%)	411 (8.2%)	286 (6.5%)	356 (7.5%)	279 (6.7%)
Axillary surgery[5]	338 (25.7%)	658 (33.0%)	876 (35.0%)	1,062 (39.3%)	1,130 (40.0%)	1,108 (40.7%)	1,078 (44.4%)	1,067 (41.4%)	982 (40.7%)
Other surgical elements									
Fat grafting[1]	131 (3.9%)	342 (7.5%)	444 (7.8%)	547 (8.7%)	503 (8.1%)	467 (8.0%)	479 (9.3%)	468 (8.3%)	411 (8.3%)
Concurrent mastopexy/ reduction[1]	217 (6.5%)	322 (7.1%)	428 (7.5%)	390 (6.2%)	396 (6.4%)	459 (7.9%)	419 (8.2%)	534 (9.5%)	426 (8.6%)
Neopocket formation[6]	192 (25.8%)	262 (25.9%)	334 (25.3%)	369 (26.1%)	364 (24.6%)	301 (22.1%)	256 (23.1%)	331 (23.6%)	258 (24.0%)
Denominators									
All procedures[1]	3,356	4,564	5,675	6,280	6,207	5,807	5,126	5,633	4,942
Not explant only[2]	3,321	4,487	5,514	6,000	5,900	5,494	4,785	5,218	4,613
Post-cancer and risk-reducing[3]	2,885	4,140	5,242	5,773	5,676	5,294	4,711	5,124	4,474
Post-cancer and risk-reducing; not explant only[4]	2,851	4,069	5,092	5,517	5,394	5,014	4,395	4,756	4,177
Post-cancer and risk-reducing; first implant insertion or tissue expander insertion only[5]	1,317	1,994	2,502	2,699	2,824	2,720	2,428	2,577	2,415
Replacement/reposition revisions[6]	745	1,012	1,321	1,415	1,481	1,360	1,107	1,404	1,077

Note: Details are at the breast level.
[1,2,3,4,5,6] Denominators used for each surgical element are shown at the bottom of the table.
*More than one incision site can be recorded.
**A procedure is reported as having pre-pectoral plane if sub-glandular/sub-fascial has been ticked for plane or if "pre-pectoral"/"sub-cutaneous" has been written on the DCF.

APPENDIX 5

Matrix/mesh use – reconstructive breast level procedures (2012-2024)

	Number of procedures with matrix/mesh use (N)	Proportion of procedures with matrix/mesh use (%)	Total number of procedures (N)
Breast Implants			
Direct-to-implant insertion			
Post-cancer	4,106	60.9%	6,740
Risk-reducing	2,628	59.4%	4,421
Developmental	11	0.4%	2,825
Total	6,745	48.2%	13,986
Tissue expander removal and implant insertion			
Post-cancer	271	3.2%	8,427
Risk-reducing	73	2.5%	2,888
Developmental	0	0.0%	206
Total	344	3.0%	11,521
Revision (replacement/reposition, not explant only)			
Post-cancer	663	9.9%	6,685
Risk-reducing	353	11.4%	3,088
Developmental	40	3.2%	1,250
Total	1,056	9.6%	11,023
Tissue Expander			
Insertion			
Post-cancer	2,269	28.7%	7,908
Risk-reducing	993	29.2%	3,403
Developmental	2	1.3%	149
Total	3,264	28.5%	11,460
Revision (replacement/reposition, not explant only)			
Post-cancer	43	9.7%	443
Risk-reducing	13	11.7%	111
Developmental	0	0.0%	1
Total	56	10.1%	555
Total procedures	11,465	23.6%	48,545

Note: Details are at the breast procedure level.

APPENDIX 6

Cumulative revision incidence by indication – reconstructive primary breast implants

	N Primary breast implants	Number at risk								
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9
Post-cancer	14,829	12,946	11,041	9,328	7,759	6,136	4,599	3,127	1,872	997
Risk-reducing	7,178	6,257	5,221	4,423	3,641	2,820	2,079	1,353	798	383
Developmental	3,012	2,670	2,301	2,035	1,703	1,322	1,062	816	591	328
Above 3 combined	25,019	21,873	18,563	15,786	13,103	10,278	7,740	5,296	3,261	1,708
Contralateral augmentation	504	468	433	397	368	314	263	197	129	73

	N Revised	Cumulative incidence of revision								
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9
All-cause revision										
Post-cancer	2,082	6.2%	9.2%	11.6%	13.4%	14.9%	16.3%	17.6%	18.8%	20.4%
Risk-reducing	1,025	6.7%	10.1%	12.1%	13.7%	15.2%	16.5%	18.3%	19.1%	20.3%
Developmental	310	5.0%	7.8%	8.4%	9.8%	10.4%	11.4%	12.3%	12.6%	14.7%
Above 3 combined	3,417	6.2%	9.3%	11.3%	13.1%	14.5%	15.7%	17.1%	18.1%	19.7%
Contralateral augmentation	62	4.6%	7.5%	8.4%	9.6%	10.6%	11.2%	12.9%	14.5%	16.6%
Revision due to complication										
Post-cancer	1292	3.8%	5.8%	7.3%	8.6%	9.6%	10.4%	11.4%	12.2%	13.2%
Risk-reducing	606	3.9%	5.9%	7.2%	8.2%	9.0%	10.0%	11.7%	12.0%	13.0%
Developmental	167	2.7%	4.2%	4.4%	5.2%	5.4%	6.1%	6.8%	7.0%	9.1%
Above 3 combined	2,065	3.7%	5.6%	6.9%	8.1%	8.9%	9.8%	10.9%	11.5%	12.7%
Contralateral augmentation	28	1.8%	3.5%	3.8%	4.0%	4.6%	5.2%	6.1%	7.4%	8.2%
Revision due to device malposition										
Post-cancer	550	1.5%	2.4%	3.3%	3.9%	4.5%	4.7%	5.1%	5.3%	5.6%
Risk-reducing	298	1.8%	3.0%	3.9%	4.4%	4.8%	5.3%	5.7%	5.7%	6.0%
Developmental	95	1.5%	2.6%	2.7%	3.0%	3.2%	3.6%	3.8%	4.1%	5.1%
Above 3 combined	943	1.6%	2.6%	3.4%	3.9%	4.4%	4.7%	5.1%	5.3%	5.7%
Contralateral augmentation	16	1.4%	2.1%	2.3%	2.6%	2.6%	3.2%	3.2%	3.8%	4.7%
Revision due to capsular contracture										
Post-cancer	570	1.0%	2.2%	3.2%	3.9%	4.5%	5.0%	5.6%	6.1%	6.9%
Risk-reducing	203	0.8%	1.6%	2.2%	2.8%	3.2%	3.6%	4.6%	4.8%	5.6%
Developmental	73	1.0%	1.8%	1.8%	2.3%	2.3%	2.6%	2.9%	3.2%	4.7%
Above 3 combined	846	1.0%	2.0%	2.7%	3.4%	3.8%	4.3%	4.9%	5.3%	6.3%
Contralateral augmentation	11	0.4%	1.3%	1.3%	1.5%	1.8%	1.8%	2.3%	3.0%	3.8%

	N Revised	Cumulative incidence of revision								
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9
Revision due to rupture/deflation										
Post-cancer	133	0.2%	0.3%	0.5%	0.8%	1.0%	1.2%	1.5%	1.8%	2.0%
Risk-reducing	59	0.1%	0.3%	0.4%	0.5%	0.6%	1.0%	1.9%	2.1%	2.3%
Developmental	21	0.1%	0.3%	0.3%	0.6%	0.6%	0.7%	1.0%	1.3%	1.6%
Above 3 combined	213	0.2%	0.3%	0.4%	0.7%	0.8%	1.1%	1.5%	1.8%	2.1%
Contralateral augmentation	4	0.0%	0.0%	0.0%	0.3%	0.5%	0.5%	1.0%	1.8%	1.8%
Revision due to skin scarring										
Post-cancer	184	0.7%	0.9%	1.1%	1.3%	1.5%	1.6%	1.7%	1.7%	1.8%
Risk-reducing	95	0.9%	1.1%	1.3%	1.4%	1.4%	1.5%	1.7%	1.7%	1.7%
Developmental	13	0.0%	0.3%	0.3%	0.4%	0.4%	0.5%	0.7%	0.7%	0.8%
Above 3 combined	292	0.7%	0.9%	1.1%	1.2%	1.3%	1.4%	1.6%	1.6%	1.6%
Contralateral augmentation	2	0.0%	0.2%	0.2%	0.2%	0.2%	0.6%	0.6%	0.6%	0.6%
Revision due to seroma/haematoma										
Post-cancer	121	0.7%	0.7%	0.8%	0.8%	0.9%	0.9%	0.9%	1.0%	1.0%
Risk-reducing	60	0.6%	0.8%	0.8%	0.9%	0.9%	0.9%	0.9%	1.1%	1.1%
Developmental	8	0.2%	0.2%	0.2%	0.2%	0.3%	0.3%	0.3%	0.3%	0.3%
Above 3 combined	189	0.6%	0.7%	0.7%	0.8%	0.8%	0.8%	0.8%	0.9%	1.0%
Contralateral augmentation	1	0.0%	0.0%	0.0%	0.0%	0.3%	0.3%	0.3%	0.3%	0.3%
Revision due to deep wound infection										
Post-cancer	190	1.1%	1.2%	1.2%	1.3%	1.4%	1.4%	1.4%	1.4%	1.4%
Risk-reducing	75	0.9%	1.0%	1.1%	1.1%	1.1%	1.1%	1.1%	1.1%	1.1%
Developmental	8	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%
Above 3 combined	273	1.0%	1.1%	1.1%	1.1%	1.2%	1.2%	1.2%	1.2%	1.2%
Contralateral augmentation	2	0.2%	0.4%	0.4%	0.4%	0.4%	0.4%	0.4%	0.4%	0.4%

Note: Cumulative revision incidence is based on reconstructive primary breast implants inserted from 2012 to 2024. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary implant insertion date to the first revision procedure (censored if there are no recorded revision procedures before 15 May 2025).

APPENDIX 7

Cumulative revision incidence by device shell – reconstructive primary breast implants

	N Primary breast implants	Number at risk								
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9
Textured	13,164	11,696	10,419	9,399	8,408	7,172	5,973	4,286	2,781	1,487
Smooth	11,623	9,967	7,954	6,207	4,519	2,935	1,606	866	373	158
Polyurethane	205	184	169	162	160	159	155	139	104	60
Total	24,992	21,847	18,542	15,768	13,087	10,266	7,734	5,291	3,258	1,705

	N Revised	Cumulative incidence of revision								
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9
All-cause revision										
Textured	2,183	6.8%	10.2%	12.3%	14.2%	15.9%	17.3%	18.8%	19.9%	21.6%
Smooth	1,183	5.4%	8.2%	10.0%	11.5%	12.3%	13.2%	13.7%	13.9%	14.8%
Polyurethane	51	9.8%	17.1%	20.6%	21.5%	22.0%	24.0%	24.5%	24.5%	25.6%
Total	3,417	6.2%	9.3%	11.4%	13.1%	14.5%	15.8%	17.1%	18.1%	19.7%
Revision due to complication										
Textured	1,304	3.8%	5.9%	7.3%	8.7%	9.7%	10.7%	11.9%	12.6%	13.8%
Smooth	730	3.5%	5.2%	6.4%	7.2%	7.7%	8.1%	8.6%	8.9%	9.8%
Polyurethane	31	7.9%	10.6%	13.2%	13.8%	13.8%	14.9%	15.4%	15.4%	16.7%
Total	2,065	3.7%	5.6%	6.9%	8.1%	8.9%	9.8%	10.9%	11.5%	12.7%
Revision due to device malposition										
Textured	560	1.4%	2.5%	3.3%	4.0%	4.6%	5.0%	5.4%	5.5%	6.0%
Smooth	365	1.7%	2.7%	3.3%	3.7%	3.9%	4.1%	4.2%	4.4%	5.4%
Polyurethane	18	4.0%	5.1%	7.9%	7.9%	7.9%	9.1%	9.7%	9.7%	9.7%
Total	943	1.6%	2.6%	3.4%	4.0%	4.4%	4.8%	5.1%	5.3%	5.7%
Revision due to capsular contracture										
Textured	614	1.2%	2.4%	3.2%	4.1%	4.7%	5.2%	6.0%	6.5%	7.5%
Smooth	220	0.7%	1.4%	2.1%	2.4%	2.5%	2.7%	3.0%	3.0%	3.0%
Polyurethane	12	2.6%	3.2%	4.3%	4.9%	4.9%	6.1%	6.1%	6.1%	7.5%
Total	846	1.0%	2.0%	2.7%	3.4%	3.8%	4.3%	4.9%	5.3%	6.3%
Revision due to rupture/deflation										
Textured	135	0.1%	0.3%	0.4%	0.6%	0.7%	1.0%	1.5%	1.9%	2.1%
Smooth	73	0.2%	0.3%	0.5%	0.7%	0.9%	1.2%	1.3%	1.3%	1.3%
Polyurethane	5	0.5%	1.6%	2.2%	2.2%	2.2%	2.2%	2.2%	2.2%	3.7%
Total	213	0.2%	0.3%	0.4%	0.7%	0.8%	1.1%	1.5%	1.8%	2.1%

	N Revised	Cumulative incidence of revision								
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9
Revision due to skin scarring										
Textured	158	0.6%	0.8%	1.0%	1.2%	1.3%	1.4%	1.5%	1.5%	1.6%
Smooth	129	0.7%	1.0%	1.1%	1.3%	1.3%	1.4%	1.6%	1.6%	1.6%
Polyurethane	5	1.0%	1.6%	1.6%	2.2%	2.2%	2.8%	2.8%	2.8%	2.8%
Total	292	0.7%	0.9%	1.1%	1.2%	1.3%	1.4%	1.6%	1.6%	1.6%
Revision due to seroma/haematoma										
Textured	116	0.6%	0.8%	0.8%	0.9%	0.9%	0.9%	0.9%	1.0%	1.1%
Smooth	65	0.5%	0.6%	0.6%	0.6%	0.6%	0.6%	0.6%	0.6%	0.6%
Polyurethane	8	3.1%	3.1%	4.2%	4.2%	4.2%	4.2%	4.2%	4.2%	4.2%
Total	189	0.6%	0.7%	0.7%	0.8%	0.8%	0.8%	0.8%	0.9%	1.0%
Revision due to deep wound infection										
Textured	162	1.1%	1.2%	1.2%	1.2%	1.3%	1.3%	1.3%	1.3%	1.3%
Smooth	109	0.9%	0.9%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%
Polyurethane	2	0.5%	0.5%	0.5%	1.1%	1.1%	1.1%	1.1%	1.1%	1.1%
Total	273	1.0%	1.1%	1.1%	1.1%	1.2%	1.2%	1.2%	1.2%	1.2%

Note: Cumulative revision incidence is based on reconstructive primary breast implants inserted from 2012 to 2024. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary implant insertion date to the first revision procedure (censored if there are no recorded revision procedures before 15 May 2025). Implants with unknown shell have not been included.

APPENDIX 8

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

	N Primary direct-to-implant	Number at risk								
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9
Matrix/mesh	6,717	5,647	4,443	3,514	2,655	1,857	1,172	665	325	134
No matrix/mesh	4,338	3,658	3,012	2,542	2,059	1,585	1,196	826	413	162
Total	11,055	9,305	7,455	6,056	4,714	3,442	2,368	1,491	738	296

	N Revised	Cumulative incidence of revision								
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9
All-cause revision										
Matrix/mesh	994	7.7%	11.4%	13.9%	15.9%	17.5%	18.7%	20.1%	21.0%	21.9%
No matrix/mesh	635	7.5%	10.7%	12.5%	14.5%	16.2%	17.5%	18.6%	19.4%	22.6%
Total	1,629	7.6%	11.1%	13.4%	15.3%	17.0%	18.2%	19.4%	20.3%	22.5%
Revision due to any of the below 4 complications										
Matrix/mesh	582	4.5%	6.8%	8.7%	9.8%	10.6%	11.3%	12.2%	12.8%	13.0%
No matrix/mesh	292	3.1%	4.7%	6.0%	7.1%	7.8%	8.4%	9.2%	9.7%	12.0%
Total	874	4.0%	6.0%	7.6%	8.7%	9.5%	10.1%	11.0%	11.5%	12.9%
Revision due to device malposition										
Matrix/mesh	246	1.5%	2.7%	3.9%	4.4%	5.0%	5.4%	5.9%	5.9%	5.9%
No matrix/mesh	145	1.4%	2.1%	3.1%	3.9%	4.2%	4.4%	4.7%	4.7%	6.2%
Total	391	1.5%	2.5%	3.6%	4.2%	4.7%	5.0%	5.4%	5.4%	6.2%
Revision due to capsular contracture										
Matrix/mesh	244	1.0%	2.4%	3.6%	4.5%	4.9%	5.7%	6.4%	7.1%	7.4%
No matrix/mesh	128	0.8%	1.9%	2.5%	3.0%	3.4%	4.0%	4.7%	5.1%	6.8%
Total	372	0.9%	2.2%	3.2%	3.9%	4.3%	5.0%	5.7%	6.2%	7.3%
Revision due to seroma/haematoma										
Matrix/mesh	94	1.2%	1.4%	1.4%	1.5%	1.5%	1.5%	1.5%	1.8%	2.1%
No matrix/mesh	35	0.7%	0.7%	0.8%	0.8%	0.9%	0.9%	0.9%	1.0%	1.0%
Total	129	1.0%	1.1%	1.2%	1.3%	1.3%	1.3%	1.3%	1.5%	1.6%
Revision due to deep wound infection										
Matrix/mesh	146	2.0%	2.2%	2.2%	2.3%	2.3%	2.3%	2.3%	2.3%	2.3%
No matrix/mesh	47	1.0%	1.0%	1.0%	1.1%	1.1%	1.1%	1.1%	1.3%	1.3%
Total	193	1.6%	1.7%	1.8%	1.8%	1.8%	1.8%	1.8%	1.9%	1.9%

Note: Cumulative revision incidence is based on reconstructive primary direct-to-implant procedures (for post-cancer/risk-reducing indications) beginning from 2012 to 2024.Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary implant insertion date to the first revision procedure (censored if there are no recorded revision procedures before 15 May 2025). Procedures with matrix/mesh use not stated have been excluded.

APPENDIX 9

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

	N Primary two-stage	Number at risk								
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9
Matrix/mesh	3,171	2,706	2,352	1,997	1,628	1,216	898	575	325	136
No matrix/mesh	7,320	6,396	5,536	4,866	4,153	3,384	2,582	1,642	932	457
Total	10,491	9,102	7,888	6,863	5,781	4,600	3,480	2,217	1,257	593

	N Revised	Cumulative incidence of revision								
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9
All-cause revision										
Matrix/mesh	522	9.0%	12.8%	15.2%	16.3%	17.5%	18.1%	19.0%	20.7%	21.8%
No matrix/mesh	1210	7.1%	11.4%	13.8%	15.7%	16.8%	17.9%	19.4%	21.1%	22.9%
Total	1732	7.7%	11.8%	14.3%	15.9%	17.0%	18.0%	19.3%	21.0%	22.6%
Revision due to any of the below 4 complications										
Matrix/mesh	251	4.7%	6.5%	7.9%	8.4%	9.1%	9.2%	9.4%	10.1%	10.5%
No matrix/mesh	578	3.4%	5.5%	6.8%	7.8%	8.4%	9.0%	9.7%	10.7%	11.9%
Total	829	3.8%	5.8%	7.1%	8.0%	8.6%	9.1%	9.7%	10.6%	11.6%
Revision due to device malposition										
Matrix/mesh	92	1.2%	2.3%	3.1%	3.3%	3.7%	3.8%	3.8%	3.8%	4.2%
No matrix/mesh	253	0.9%	2.3%	2.9%	3.7%	4.0%	4.4%	4.7%	5.1%	5.3%
Total	345	1.0%	2.3%	3.0%	3.6%	3.9%	4.2%	4.5%	4.8%	5.0%
Revision due to capsular contracture										
Matrix/mesh	72	0.5%	1.3%	2.2%	2.5%	3.0%	3.2%	3.4%	4.0%	4.0%
No matrix/mesh	209	0.4%	1.2%	2.1%	2.8%	3.3%	3.6%	4.1%	4.9%	5.8%
Total	281	0.4%	1.3%	2.1%	2.7%	3.2%	3.5%	3.9%	4.6%	5.3%
Revision due to seroma/haematoma										
Matrix/mesh	62	1.8%	1.9%	1.9%	2.0%	2.2%	2.2%	2.2%	2.2%	2.2%
No matrix/mesh	104	1.2%	1.4%	1.4%	1.4%	1.5%	1.5%	1.5%	1.5%	1.7%
Total	166	1.4%	1.6%	1.6%	1.6%	1.7%	1.7%	1.7%	1.7%	1.8%
Revision due to deep wound infection										
Matrix/mesh	87	2.5%	2.7%	2.8%	2.8%	2.9%	2.9%	2.9%	3.1%	3.1%
No matrix/mesh	147	1.7%	2.0%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%	2.1%
Total	234	2.0%	2.2%	2.3%	2.3%	2.3%	2.3%	2.4%	2.4%	2.4%

Note: Cumulative revision incidence is based on reconstructive primary two-stage procedures (for post-cancer/risk-reducing indications) beginning from 2012 to 2024. 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 (censored if there are no recorded revision procedures before 15 May 2025). Procedures with matrix/mesh use not stated have been excluded. Procedures with matrix/mesh inserted with the second stage breast implant are excluded.

APPENDIX 10

Cumulative revision incidence – primary reconstructive tissue expanders

	N Primary tissue expanders	Number at risk			
		6 Mo	12 Mo	18 Mo	24 Mo
Post-cancer	7,725	4,922	2,579	1,816	1,495
Risk-reducing	3,348	1,789	795	539	447
Developmental	149	88	57	37	28
Total	11,222	6,799	3,431	2,392	1,970

	N Revised	Cumulative incidence of revision			
		6 Mo	12 Mo	18 Mo	24 Mo
All-cause revision					
Post-cancer	463	4.1%	6.7%	9.2%	10.3%
Risk-reducing	146	3.2%	5.3%	8.4%	9.3%
Developmental	2	0.0%	3.2%	3.2%	3.2%
Total	611	3.8%	6.3%	8.9%	9.9%
Revision due to complication					
Post-cancer	263	2.6%	3.9%	5.0%	5.5%
Risk-reducing	98	2.6%	3.4%	4.7%	5.3%
Developmental	2	0.0%	3.2%	3.2%	3.2%
Total	363	2.5%	3.8%	4.9%	5.4%

Note: Cumulative revision incidence is based on reconstructive primary tissue expanders inserted from 2012 to 2024. 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 (censored if there are no recorded revision procedures before 15 May 2025).

APPENDIX 11

Intra-operative techniques (2016-2024) – cosmetic operation level procedures

	2016	2017	2018	2019	2020	2021	2022	2023	2024
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Pre-operative antibiotics[1]	5,879 (85.2%)	8,971 (90.1%)	8,326 (87.9%)	7,608 (90.4%)	9,005 (92.2%)	8,731 (90.4%)	8,385 (89.2%)	7,549 (90.6%)	6,451 (88.6%)
Post-operative antibiotics[1]	5,114 (74.1%)	7,576 (76.1%)	7,323 (77.3%)	6,765 (80.4%)	8,178 (83.7%)	7,818 (80.9%)	7,685 (81.7%)	6,974 (83.7%)	5,945 (81.7%)
Antiseptic rinse[1]	5,365 (77.7%)	8,296 (83.3%)	8,125 (85.8%)	7,148 (85.0%)	8,379 (85.8%)	8,086 (83.7%)	7,993 (85.0%)	7,213 (86.5%)	5,803 (79.7%)
Drain use[1]	1,334 (19.3%)	1,402 (14.1%)	1,402 (14.8%)	1,268 (15.1%)	1,328 (13.6%)	1,437 (14.9%)	1,081 (11.5%)	997 (12.0%)	877 (12.0%)
Nipple guard[1]	4,167 (60.4%)	7,853 (78.8%)	7,351 (77.6%)	6,442 (76.6%)	7,556 (77.3%)	7,127 (73.8%)	7,214 (76.7%)	6,331 (75.9%)	5,287 (72.6%)
Glove change for insertion[2]	3,965 (57.7%)	6,753 (68.4%)	7,018 (76.0%)	6,172 (79.2%)	7,252 (79.4%)	7,072 (80.0%)	6,847 (78.5%)	5,908 (77.7%)	5,077 (77.2%)
Antibiotic dipping solution[2]	3,867 (56.3%)	5,569 (56.4%)	5,499 (59.6%)	4,934 (63.3%)	5,781 (63.3%)	5,564 (63.0%)	5,668 (65.0%)	4,789 (63.0%)	4,058 (61.7%)
Sleeve/funnel[2]	1,595 (23.2%)	3,463 (35.1%)	4,417 (47.8%)	4,466 (57.3%)	5,521 (60.5%)	5,102 (57.7%)	5,658 (64.9%)	5,362 (70.5%)	4,147 (63.1%)
Denominators									
All procedures[1]	6,904	9,961	9,475	8,413	9,769	9,662	9,405	8,336	7,281
Not explant only[2]	6,867	9,869	9,232	7,795	9,130	8,837	8,722	7,602	6,575

Note: Details are at the operation level.
[1,2] Denominators used for each intra-operative technique are shown at the bottom of the table.

APPENDIX 12

Surgical elements (2016-2024) – cosmetic breast level procedures

	2016	2017	2018	2019	2020	2021	2022	2023	2024
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Incision*[1]									
Infra-mammary	11,228 (82.5%)	17,097 (86.9%)	15,206 (81.5%)	13,627 (82.0%)	15,490 (80.1%)	14,974 (78.3%)	14,660 (78.7%)	12,952 (78.6%)	10,746 (74.7%)
Mastopexy/ reduction wound	1,115 (8.2%)	1,363 (6.9%)	1,593 (8.5%)	1,595 (9.6%)	2,204 (11.4%)	2,224 (11.6%)	1,965 (10.6%)	2,058 (12.5%)	1,761 (12.2%)
Periareolar	185 (1.4%)	226 (1.1%)	256 (1.4%)	185 (1.1%)	199 (1.0%)	153 (0.8%)	119 (0.6%)	93 (0.6%)	115 (0.8%)
Axillary	53 (0.4%)	56 (0.3%)	80 (0.4%)	36 (0.2%)	32 (0.2%)	27 (0.1%)	33 (0.2%)	25 (0.2%)	55 (0.4%)
Other	25 (0.2%)	29 (0.1%)	34 (0.2%)	59 (0.4%)	50 (0.3%)	42 (0.2%)	18 (0.1%)	35 (0.2%)	40 (0.3%)
Plane[2]									
Sub-pectoral	9,918 (73.2%)	16,015 (82.1%)	14,129 (77.7%)	11,919 (77.4%)	13,953 (77.1%)	13,312 (76.1%)	13,253 (76.7%)	11,363 (75.6%)	9,245 (71.2%)
Pre-pectoral**	2,067 (15.3%)	1,931 (9.9%)	2,168 (11.9%)	2,063 (13.4%)	2,284 (12.6%)	2,432 (13.9%)	2,394 (13.9%)	2,260 (15.0%)	2,233 (17.2%)
Dual	249 (1.8%)	238 (1.2%)	248 (1.4%)	516 (3.3%)	694 (3.8%)	659 (3.8%)	340 (2.0%)	405 (2.7%)	475 (3.7%)
Other	81 (0.6%)	65 (0.3%)	27 (0.1%)	32 (0.2%)	125 (0.7%)	36 (0.2%)	58 (0.3%)	28 (0.2%)	29 (0.2%)
Not stated	1,226 (9.1%)	1,259 (6.5%)	1,610 (8.9%)	874 (5.7%)	1,031 (5.7%)	1,055 (6.0%)	1,225 (7.1%)	974 (6.5%)	1,001 (7.7%)
Other surgical elements									
Fat grafting[1]	79 (0.6%)	114 (0.6%)	276 (1.5%)	782 (4.7%)	1,129 (5.8%)	1,401 (7.3%)	1,619 (8.7%)	1,770 (10.7%)	1,640 (11.4%)
Concurrent mastopexy/ reduction[1]	1,404 (10.3%)	2,134 (10.8%)	2,316 (12.4%)	2,435 (14.6%)	3,240 (16.7%)	3,330 (17.4%)	3,277 (17.6%)	3,126 (19.0%)	2,540 (17.7%)
Neopocket formation[3]	648 (27.8%)	1,068 (32.1%)	1,314 (30.8%)	1,283 (31.8%)	1,249 (30.7%)	1,301 (28.9%)	1,304 (31.9%)	1,239 (30.3%)	979 (25.4%)
Denominators									
All procedures[1]	13,606	19,683	18,653	16,626	19,349	19,128	18,618	16,487	14,377
Not explant only[2]	13,541	19,508	18,182	15,404	18,087	17,494	17,270	15,030	12,983
Replacement/ reposition revisions[3]	2,331	3,330	4,260	4,038	4,066	4,499	4,091	4,085	3,854

Note: Details are at the breast level.
[1,2,3] Denominators used for each surgical element are shown at the bottom of the table.
*More than one incision site can be recorded.
**A procedure is reported as having pre-pectoral plane if sub-glandular/sub-fascial has been ticked for plane or if “pre-pectoral” has been written on the DCF.

APPENDIX 13

Cumulative revision incidence – cosmetic primary breast implants

	N Primary breast implants	Number at risk								
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9
	116,378	108,879	98,134	84,620	72,342	55,857	46,104	33,699	18,528	6,533

Issue at revision (/reason)	N Revised	Cumulative incidence of revision								
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9
All-cause	5,489	1.4%	2.6%	3.4%	4.0%	4.6%	5.3%	6.0%	6.7%	7.3%
Complication	2,542	0.7%	1.3%	1.6%	1.9%	2.2%	2.5%	2.8%	3.1%	3.4%
Malposition	1,311	0.4%	0.8%	0.9%	1.1%	1.2%	1.3%	1.4%	1.5%	1.5%
Capsular contracture	1,114	0.2%	0.5%	0.6%	0.8%	0.9%	1.1%	1.3%	1.5%	1.8%
Rupture/deflation	360	0.1%	0.1%	0.2%	0.2%	0.3%	0.3%	0.4%	0.6%	0.7%
Skin scarring	141	0.0%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Seroma/haematoma	140	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.2%	0.2%
Deep wound infection	55	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Note: Cumulative revision incidence is based on cosmetic primary breast implants inserted from 2012 to 2024. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary implant insertion date to the first revision procedure (censored if there are no recorded revision procedures before 15 May 2025).

APPENDIX 14

Cumulative revision incidence by device shell – cosmetic primary breast implants

	N Primary breast implants	Number at risk								
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9
Textured	56,842	54,062	50,111	45,032	40,300	34,183	29,898	23,316	13,346	4,850
Smooth	56,944	52,267	45,514	37,104	29,594	19,269	13,964	8,648	4,087	1,263
Polyurethane	2,531	2,493	2,458	2,434	2,411	2,374	2,223	1,723	1,084	413
Total	116,317	108,822	98,083	84,570	72,305	55,826	46,085	33,687	18,517	6,526

	N Revised	Cumulative incidence of revision								
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9
All-cause revision										
Textured	2,751	1.2%	2.2%	2.9%	3.5%	4.2%	5.0%	5.7%	6.4%	7.1%
Smooth	2,529	1.7%	3.1%	3.9%	4.5%	5.0%	5.4%	6.0%	6.6%	7.3%
Polyurethane	200	1.5%	2.8%	3.8%	4.5%	5.9%	6.3%	7.5%	8.0%	8.7%
Total	5,480	1.4%	2.6%	3.4%	4.0%	4.6%	5.3%	6.0%	6.7%	7.3%
Revision due to complication										
Textured	1,256	0.5%	1.0%	1.3%	1.7%	2.0%	2.3%	2.6%	2.9%	3.3%
Smooth	1,204	0.9%	1.6%	1.9%	2.2%	2.4%	2.6%	2.8%	3.1%	3.4%
Polyurethane	78	0.7%	1.5%	1.9%	2.0%	2.4%	2.6%	3.0%	3.3%	3.4%
Total	2,538	0.7%	1.3%	1.6%	1.9%	2.2%	2.5%	2.8%	3.1%	3.4%
Revision due to device malposition										
Textured	522	0.3%	0.5%	0.6%	0.8%	0.9%	1.0%	1.1%	1.1%	1.2%
Smooth	745	0.6%	1.0%	1.2%	1.4%	1.5%	1.6%	1.7%	1.8%	1.8%
Polyurethane	44	0.6%	1.2%	1.4%	1.4%	1.5%	1.6%	1.7%	1.8%	1.8%
Total	1,311	0.4%	0.8%	0.9%	1.1%	1.2%	1.3%	1.4%	1.5%	1.5%
Revision due to capsular contracture										
Textured	661	0.2%	0.4%	0.6%	0.8%	1.0%	1.2%	1.4%	1.6%	1.9%
Smooth	406	0.3%	0.5%	0.6%	0.7%	0.8%	0.9%	1.0%	1.2%	1.4%
Polyurethane	44	0.2%	0.5%	0.7%	0.8%	1.2%	1.3%	1.7%	1.9%	2.1%
Total	1,111	0.2%	0.5%	0.6%	0.8%	0.9%	1.1%	1.3%	1.5%	1.8%
Revision due to rupture/deflation										
Textured	227	0.0%	0.1%	0.2%	0.2%	0.3%	0.4%	0.5%	0.6%	0.7%
Smooth	124	0.1%	0.1%	0.2%	0.2%	0.3%	0.3%	0.3%	0.4%	0.4%
Polyurethane	9	0.0%	0.1%	0.1%	0.1%	0.2%	0.2%	0.3%	0.4%	0.5%
Total	360	0.1%	0.1%	0.2%	0.2%	0.3%	0.3%	0.4%	0.6%	0.7%

	N Revised	Cumulative incidence of revision								
		Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9
Revision due to skin scarring										
Textured	63	0.0%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Smooth	77	0.0%	0.1%	0.1%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Polyurethane	1	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Total	141	0.0%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Revision due to seroma/haematoma										
Textured	90	0.1%	0.1%	0.1%	0.1%	0.1%	0.2%	0.2%	0.2%	0.2%
Smooth	42	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Polyurethane	7	0.2%	0.2%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%
Total	139	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.2%	0.2%
Revision due to deep wound infection										
Textured	32	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Smooth	23	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Polyurethane	0	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Total	55	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Note: Cumulative revision incidence is based on cosmetic primary breast implants inserted from 2012 to 2024. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary implant insertion date to the first revision procedure (censored if there are no recorded revision procedures before 15 May 2025). Implants with unknown shell have not been included.

APPENDIX 15
Data collection form

AUSTRALIAN Breast Device REGISTRY

MONASH University Medicine, Nursing and Health Sciences
Australian Society of Plastic Surgeons
Breast Surgeons of Australia & New Zealand

AUSTRALIAN BREAST DEVICE REGISTRY FORM

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

Patient UR # : ☐☐☐☐☐☐☐☐☐☐☐☐

Medicare # : ☐☐☐☐☐☐☐☐☐☐☐☐

Surname : ______

First name: ______ Middle Name: ______

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

Address : ______

______ State: ☐☐☐ P/code: ☐☐☐☐

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

Mobile : ☐☐☐☐☐☐☐☐☐☐

Email : ______

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

SITE DETAILS:

Site Name: ______

Suburb: ______ State: ______

Surgeon name: ______

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

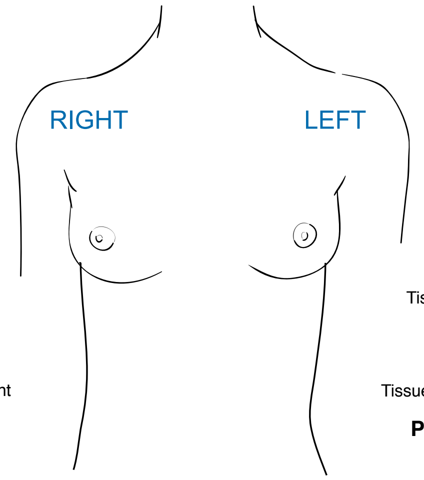
RETURN FORM:
Australian Breast Device Registry,
Monash University, DEPM,
553 St Kilda Road, Melbourne 3004
email: abdr@monash.edu **fax:** (03) 9903 0277
contact phone: (03) 9903 0205

AFFIX **RIGHT DEVICE** STICKER [COMPLETE IF NO DEVICE STICKER]	AFFIX **LEFT DEVICE** STICKER [COMPLETE IF NO DEVICE STICKER]
Manufacturer: ______	Manufacturer: ______
Distributor: ______	Distributor: ______
Reference no: ______	Reference no: ______
Serial no: ______	Serial no: ______

AFFIX **MESH/DERMAL SHEET** STICKER [COMPLETE IF NO DEVICE STICKER]	AFFIX **MESH/DERMAL SHEET** STICKER [COMPLETE IF NO DEVICE STICKER]
MESH/DERMAL SHEET: Yes ☐ No ☐	MESH/DERMAL SHEET: Yes ☐ No ☐
Manufacturer: ______	Manufacturer: ______
Reference no: ______	Reference no: ______
Serial no: ______	Serial no: ______

PATIENT HISTORY:

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



RIGHT	LEFT
Category of operation	**Category of operation**
☐ Cosmetic augmentation	Cosmetic augmentation ☐
☐ Reconstruction - post cancer	Reconstruction - post cancer ☐
☐ Reconstruction - benign / prophylactic	Reconstruction - benign / prophylactic ☐
☐ Congenital deformity	Congenital deformity ☐
Operation type	**Operation type**
Initial (new device)	***Initial (new device)***
☐ Tissue Expander insertion	Tissue Expander insertion ☐
☐ First Implant insertion	First Implant insertion ☐
☐ Tissue Expander removal & Implant insertion	Tissue Expander removal & Implant insertion ☐
Revision of in situ device	***Revision of in situ device***
☐ Implant revision, removal or replacement	Implant revision, removal or replacement ☐
☐ Tissue Expander revision, removal, replacement	Tissue Expander revision, removal, replacement ☐
Previous Radiotherapy ☐ Yes ☐ No	**Previous Radiotherapy** ☐ Yes ☐ No

PLEASE COMPLETE OVER PAGE

ABDR_Data Collection Form_v1.0_20150310

ELEMENTS OF OPERATION

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

RIGHT Incision site	RIGHT Plane	LEFT Plane	LEFT Incision site
☐ Axillary	☐ Sub-glandular / Sub-fascial	Subglandular / Sub-fascial ☐	Axillary ☐
☐ Areolar	☐ Sub-pectoral	Sub-pectoral ☐	Areolar ☐
☐ Infra-mammary	☐ Sub-flap	Sub-flap ☐	Infra-mammary ☐
☐ Previous mastectomy scar			Previous mastectomy scar ☐
☐ Mastopexy/reduction wound			Mastopexy/reduction wound ☐
☐			.... ☐

RIGHT	LEFT
Concurrent Mastectomy .... ☐ Yes ☐ No	☐ Yes ☐ No .... **Concurrent Mastectomy**
Axillary surgery incl. sentinel node biopsy .... ☐ Yes ☐ No	☐ Yes ☐ No .... **Axillary surgery incl. sentinel node biopsy**
Concurrent Mastopexy / Reduction .... ☐ Yes ☐ No	☐ Yes ☐ No .... **Concurrent Mastopexy / Reduction**
Concurrent Flap cover .... ☐ Yes ☐ No	☐ Yes ☐ No .... **Concurrent Flap cover**
Previous Mastopexy/Reduction .... ☐ Yes ☐ No	☐ Yes ☐ No .... **Previous Mastopexy/Reduction**
Fat grafting ☐ Yes Volume..............mLs ☐ No	**Fat grafting** ☐ Yes Volume..............mLs ☐ No
IF TISSUE EXPANDER, Intra Operative fill volume: ....mLs	**IF TISSUE EXPANDER,** Intra Operative fill volume: ....mLs

INTRAOPERATIVE TECHNIQUES

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

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

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

FOR REVISION SURGERY ONLY

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

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

☐ Tick if Same Bilateral

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

☐ Tick if Same Bilateral

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

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

ABDR_Data Collection Form_v1.0_20150310

APPENDIX 16

ABDR staff (During 2024)

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

APPENDIX 17

List of participating sites as at end of 2024

State	Site Name
ACT	Barton Private Hospital
ACT	Calvary Bruce Private Hospital
ACT	Calvary John James Hospital
ACT	Canberra Private Hospital
ACT	National Capital Private Hospital
ACT	North Canberra Hospital
ACT	Sole Vita Surgery
NSW	Aesthetic Day Surgery
NSW	Albury Wodonga Health- Albury Campus
NSW	Albury Wodonga Private Hospital
NSW	Auburn Hospital & Community Health Services
NSW	Bankstown-Lidcombe Hospital
NSW	Baringa Private Hospital
NSW	Bella Vista Day Hospital
NSW	Belmont Hospital
NSW	Bondi Junction Private Hospital
NSW	Brisbane Waters Private Hospital
NSW	Calvary Mater Newcastle
NSW	Calvary Riverina Hospital
NSW	Campbelltown Hospital
NSW	Campbelltown Private Hospital
NSW	Castlecrag Private Hospital
NSW	Charlestown Private Hospital
NSW	Chris O'Brien Lifehouse
NSW	City West Specialist Day Hospital
NSW	Coffs Harbour Base Hospital
NSW	Concord Repatriation Hospital
NSW	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	Liverpool Hospital
NSW	Macquarie St Day Surgery
NSW	Macquarie University Hospital
NSW	Maitland Private Hospital
NSW	Mater Hospital Sydney

State	Site Name
NSW	Mount Druitt Hospital
NSW	Nepean Hospital
NSW	Nepean Private Hospital
NSW	Newcastle Private Hospital
NSW	North Shore Private Hospital
NSW	North Shore Specialist Day Hospital
NSW	Northern Beaches Hospital
NSW	Norwest Private Hospital
NSW	Port Macquarie Private Hospital
NSW	Prince of Wales Hospital
NSW	Prince of Wales Private Hospital
NSW	Ramsay Surgical Centre Miranda
NSW	Riverina Day Surgery
NSW	Royal Hospital for Women
NSW	Royal North Shore Hospital
NSW	Shellharbour Private Hospital
NSW	Somerset Private Hospital
NSW	Southern Highlands Private Hospital
NSW	St George Hospital
NSW	St George Private Hospital
NSW	St Luke's Hospital
NSW	St Vincent's Hospital (Darlinghurst)
NSW	St Vincent's Private Community Hospital Griffith
NSW	St Vincent's Private Hospital (Darlinghurst)
NSW	St Vincent's Private Hospital (Lismore)
NSW	Strathfield Private Hospital
NSW	Swan Clinic for Plastic Surgery
NSW	Sydney Adventist Hospital
NSW	Sydney Children's Hospital
NSW	Sydney Day Hospital
NSW	Sydney Surgical Centre
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 Private Hospital
QLD	Buderim Private Hospital
QLD	Caboolture Private Hospital
QLD	Cairns Base Hospital

State	Site Name
QLD	Cairns Private Hospital
QLD	Canossa Private Hospital
QLD	Chermside Day Hospital
QLD	Far North Day Hospital
QLD	Gold Coast Private Hospital
QLD	Gold Coast University Hospital
QLD	Greenslopes Private Hospital
QLD	Herston Private Hospital
QLD	Hillcrest - Rockhampton Private Hospital
QLD	John Flynn Private Hospital
QLD	Kawana Private Hospital
QLD	Mater Adult Hospital
QLD	Mater Private Hospital (South Brisbane)
QLD	Mater Private Hospital Rockhampton
QLD	Mater Private Hospital Springfield
QLD	Mater Private Hospital Townsville
QLD	Mater Private Hospital Townsville (Hyde Park Campus)
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 Brisbane 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	St Vincent's Private Hospital Toowoomba
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	Calvary Adelaide Hospital
SA	Calvary North Adelaide Hospital
SA	Flinders Medical Centre
SA	Flinders Private Hospital

State	Site Name
SA	Glenelg Community Hospital
SA	Hamilton House Day Surgery
SA	Lyell McEwin Hospital
SA	Memorial Hospital
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	Western Hospital (SA)
SA	Windsor Gardens Day Surgery
SA	Womens and Childrens Hospital
TAS	Calvary - St John's Hospital
TAS	Calvary - St Vincent's Hospital
TAS	Hobart Private Hospital
TAS	Launceston General Hospital
TAS	North Tas Day Hospital
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

State	Site Name
VIC	Peninsula Private Hospital (VIC)
VIC	Peter MacCallum Cancer Centre
VIC	Ramsay Surgical Centre Glenferrie
VIC	Ringwood Private Hospital
VIC	Royal Melbourne Hospital - City Campus
VIC	Sir John Monash Private Hospital
VIC	South West Healthcare-Warrnambool Campus
VIC	Specialist Surgicentre Geelong
VIC	St John Of God Warrnambool Hospital
VIC	St John of God Bendigo Hospital
VIC	St John of God Berwick Hospital
VIC	St John of God Geelong Hospital
VIC	St Vincent's Hospital (Melbourne) LTD
VIC	St Vincent's Private Hospital East Melbourne
VIC	St Vincent's Private Hospital Fitzroy
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	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 Midland Public & Private Hospital
WA	St John of God Mt Lawley Hospital
WA	St John of God Murdoch Hospital
WA	Subiaco Private Hospital
WA	The Park Private Hospital
WA	Waikiki Private Hospital
WA	West Leederville Private Hospital
WA	Subiaco Private Hospital
WA	Sundew Day Surgery
WA	The Park Private Hospital
WA	Waikiki Private Hospital
WA	West Leederville Private Hospital

MONASH University

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