MONASH University

AUSTRALIAN BREAST DEVICE REGISTRY

2018 REPORT

AUSTRALIAN Breast Device REGISTRY

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Data Period

The data contained in this document were extracted from the ABDR on 19 March 2019 and pertains to data that had been submitted from the initiation of the pilot ABDR on 19 January 2012 to 31 December 2018. As the registry does not capture data in real time, there can be a lag between occurrence of an event and capture in the ABDR.

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

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FOREWORD

It is our pleasure to introduce the Australian Breast Device Registry (ABDR) Annual Report for 2018.

Since its inception in 2015, the ABDR has grown steadily in geographic coverage, contributing sites and surgeons and, most importantly, patients. It is exciting to see the continued progress of the registry and we look forward to reaching a phase of consolidation and ongoing growth in following reporting periods.

This is the third annual report released by the ABDR. The structure of the report follows previous years but includes key changes to reflect the evolution of the registry and improve usefulness of data for clinicians and other key stakeholders. The most important of these is the separation of reconstructive and aesthetic indications for surgery, in recognition of the fact that patients with these indications for surgery follow distinct surgical pathways.

Significant initiatives implemented in 2018 included the release of the registry's first clinician and site reports. All clinicians received a report and site reports were released to the top 80% high volume sites. Site reports followed a pilot project to ascertain the registry's case capture rate using ICD-10-AM coding data, while clinician reports focused on activity-based indicators such as number and type of patients contributed, across which healthcare facilities, and completeness of data. Feedback received will inform future reporting initiatives.

Another significant initiative undertaken in 2018 was the rollout of the registry's patient reported outcomes measures (PROMs), the Breast-Q Implant Surveillance module (Breast-Q IS). The ABDR is one of the first clinical registries to utilise text messaging technology to collect feedback from patients and we have been excited to share our progress with other research groups.

International collaboration continued to strengthen in 2018 with focus on an internationally harmonised dataset to potentially identify safety issues earlier, work towards a standardised system of barcoding and unique device identifiers to aid in implant tracking, and research into the emerging issue of breast implant associated anaplastic large cell lymphoma (BIA-ALCL).

We are pleased to see the registry gain traction in the surgical community and with patient advocacy groups and we look forward to seeing the ABDR further mature and achieve its aims.

We thank everyone involved in developing this annual report; from the project team led by Dr Ingrid Hopper, to members of the governance committees overseen by the Steering Committee Chair, Professor John McNeil, to the surgeons and sites contributing data. As always, the biggest thanks goes to the patients who allow the registry to retain their data and use it to monitor device performance and quality of breast device surgery.

Australian Society *of* Plastic Surgeons

Breast Surgeons of Australia & New Zealand

Associate Professor Elisabeth Elder, PhD, FRACS, BreastSurgANZ

Associate Professor Colin Moore, FRACS, ACCS

Miss Gillian Farrell, FRACS, ASPS

ACKNOWLEDGEMENTS

The ABDR was originally funded by the Australasian Foundation for Plastic Surgery and receives ongoing funding from the Commonwealth Department of Health with in-kind support from Monash University. The registry is operated by the Department of Epidemiology and Preventive Medicine, Monash University, and is endorsed by major surgical societies in Australia.

We are grateful for the contributions made by the ABDR steering committee, ABDR clinical quality committee, and ABDR management committee. We acknowledge the leadership of Professor John McNeil who is the chair of the steering committee, and Dr Ingrid Hopper who is project lead and data custodian. We would like to acknowledge the contributions of the ABDR project team (Full list on page 58) and the Registry Science and Research (RSR) team including Associate Professor Susannah Ahern, Associate Professor Arul Earnest and Ms Breanna Pellegrini.

We also gratefully acknowledge the dedication of the steering committee members, including the clinical leads Associate Professor Elisabeth Elder, Breast Surgeons of Australia and New Zealand Inc. (BreastSurgANZ) and Associate Professor Colin Moore, Australasian College of Cosmetic Surgery (ACCS) and Miss Gillian Farrell representing Australian Society of Plastic Surgeons (ASPS). Also Pamela Carter, Therapeutic Goods Administration (TGA), Cindy Schultz Ferguson, Consumers Health Forum of Australia (CHF), Andrea Kunca and Sandra Marjanovic, Medical Technology Association of Australia (MTAA), Suzanna Henderson, Australian Commission on Safety and Quality in Healthcare (ACSQHC) and Dr Supriya Budala, Australian Government Department of Health (as observer only).

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

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

This report was subject to critical review prior to publication. We thank the members of the committee who were involved in the review meeting and subsequent draft review, including individuals representing Monash University (ABDR and RSR), the three surgical societies (ACCS, ASPS, BreastSurgANZ), TGA, CHF and Australian Government Department of Health.

We also acknowledge our international collaborators through the International Collaboration of Breast Registry Activities (ICOBRA), including Babette Becherer, Andy Crosbie, Howard Klein, David Lumenta, Danica Marinac-Dabic, Marc Mureau, Graeme Perks, Andrea Pusic, Hinne Rakhorst, Pauline Spronk, Birgit Stark and Uwe von Fritschen.

We are pleased to see the registry gain traction in the surgical community and with patient advocacy groups.

EXECUTIVE SUMMARY

The ABDR's continuing mission is to improve patient outcomes by identifying and reporting on possible trends and complications associated with breast device surgery; tracking the long-term safety and performance of implantable breast devices; and identifying best surgical practice and optimal patient health outcomes.

In response to comments on previous years' reports, and on advice of the ABDR Clinical Quality Committee, the format of this third annual report has been updated to separate the reconstructive and aesthetic indications for surgery. This recognises the fundamental differences underlying these groups in terms of patient risk profile and surgical pathways. In addition, some key terminology has been amended from previously to bring the report in line with other international breast device registries, including the Dutch Breast Implant Registry.[1] This includes the sub-analysis by two types of surgical interventions (insertion surgery and revision surgery), and reference to devices rather than breasts.

As at December 2018, the ABDR has collected data on 37,603 patients having 41,921 procedures involving 78,024 devices. Australia-wide, 514 surgeons operating at 280 hospitals and day surgeries have contributed data. The opt out rate remained low with only 1.1% of patients choosing to opt out of participating in the ABDR.

The first registry output section of the 2018 annual report presents data on patients having reconstructive surgery; including post-cancer, risk-reducing mastectomy and surgery to correct for developmental deformity. The second registry output section of the report presents data on patients having surgery for aesthetic reasons, namely cosmetic augmentation (augmentation mammoplasty). Both sections present data on patient demographics, procedure and device details, surgical technique, complications and revision incidence.

The third section of the report presents data on registry outcomes. This includes clinician and site reporting, international collaboration, breast implant associated anaplastic large cell lymphoma (BIA-ALCL) and the rollout of the registry's patient reported outcomes measures (PROM), the Breast-Q Implant Surveillance module (Breast-Q IS) which utilises five questions extracted from the larger Breast-Q tool, selected specifically to provide an early signal of potential device problems.

The key findings and highlights from the 2018 Annual Report are presented below.

Key findings and highlights from the 2018 Annual Report.

- The format of the 2018 report has been updated to report reconstructive and aesthetic procedures in separate sections, including more detailed analysis for each cohort.
- National rollout of the registry was nearing completion in 2018 with all eligible sites and surgeons having been approached. The registry has now progressed to a maintenance phase.
- The total number of procedures captured by ABDR in 2018 was 13,718, including 3,544 reconstructive and 9,337 aesthetic procedures.
- At the end of 2018, 37,603 patients had procedures captured by the ABDR, an addition of 11,990 in 2018.
- The ABDR 2018 data capture rate for implant procedures was 74%, ascertained from sales data provided by the Therapeutic Goods Administration (up from 65% in 2017 and 44 % in 2016).
- Collection of PROMs was rolled out nationally, showing at 1-year follow up a 78% response rate in patients with breast reconstruction, and 61% response rate in patients with breast augmentation.
- The ABDR released individualised, activity-based surgeon reports and individualised case ascertainment site reports for the first time in 2018.

If you are having a breast device inserted, I urge you to ensure that your surgeon registers your device with the ABDR.

Cindy Schultz-Ferguson, Consumer Representative

INTRODUCTION

The Australian Breast Device Registry (ABDR) is a clinical quality registry designed to monitor the performance of breast implants and breast tissue expanders, and the quality and safety of breast device related surgery. It was established in 2015 with funding from the Commonwealth Department of Health[2]. This is the third annual report released by the ABDR in its four years of operation.

The ABDR is tasked with collecting, analysing and reporting data on all breast device surgery taking place across Australia.[3] This type of surgery takes place in a wide variety of clinical settings and the ABDR captures data from public hospitals, private hospitals and private day surgeries nationwide.

REGISTRY GOVERNANCE AND STRUCTURE

Governance

As a clinical quality registry, the ABDR adheres to the Australian Commission on Safety and Quality in Health Care (ACSQHC) Framework for Australian Clinical Quality Registries (2014)[4] and Operating Principles and Technical Standards for Clinical Quality Registries (2008)[5]. It complies with all relevant standards of data security and protection and privacy.

Steering Committee

The ABDR Steering Committee (SC) operates in an advisory capacity to the registry custodian, Monash University. SC members represent organisations from across government, industry, clinical craft groups, consumer groups and academia (see Registry Personnel). In 2018 the SC provided guidance on issues of data quality, data reporting and stakeholder engagement.

Clinical Quality Committee

The ABDR Clinical Quality Committee (CQC) advises the SC on clinical matters arising from ABDR data. CQC members represent each of the three clinical craft groups (Australian Society of Plastic Surgeons (ASPS), Australasian College of Cosmetic Surgery (ACCS), Breast Surgeons of Australia and New Zealand Inc. (BreastSurgANZ) and Monash University. In 2018 the CQC provided guidance on templates for the analysis, presentation and distribution of registry data, review of the minimum dataset and development of clinical quality indicators. The CQC evaluated potential risk adjustment factors for future analysis.

Management Committee

The ABDR Management Committee (MC) meets monthly to discuss and resolve issues associated with day to day running of the ABDR. It provides a link between operational stakeholders (sites, surgeons, patients) and advisory stakeholders (SC members). In 2018 the MC provided practical assistance with site and surgeon engagement, and review of the registry's minimum dataset and communication strategy.

REGISTRY PARTICIPATION (2012-2018)

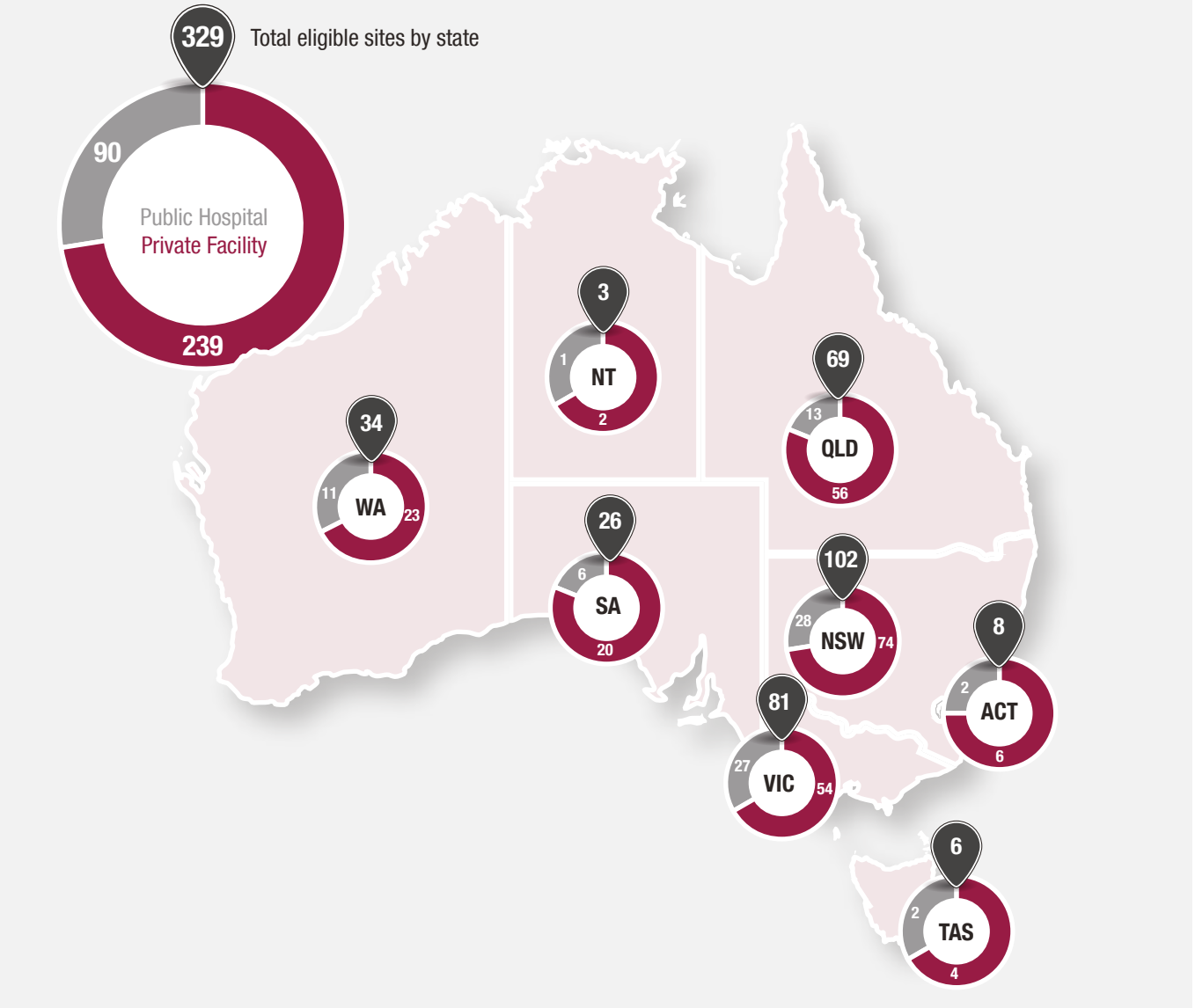
Site Participation

The ABDR continues to engage eligible sites Australia-wide to contribute data to the registry. An **eligible** site is defined as a site currently undertaking breast device surgery as identified by ICD-10-AM† coding data provided by the Australian Government Department of Health (data provided Oct 2015) or as reported by external sources (internet search, surgeons or site staff).

Figure 1 shows the number and classification of eligible sites per state. The total number of currently eligible sites is estimated at 329, increasing by 12 from 2017. Approximately 77% of eligible sites are located in New South Wales, Queensland and Victoria and 73% of eligible sites are Private Facilities.

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

FIGURE 1: NUMBER OF SITES ELIGIBLE FOR ABDR PARTICIPATION



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

TABLE 1: SITE ENGAGEMENT BY STATE AT 31ST DECEMBER 2018

State/ Territory	Number of Closed/No Device Sites	Number of Eligible Sites	Participating Sites	Sites in Progress	Engagement of Eligible Sites *
NSW	5	102	78	24	76%
VIC	5	81	65	16	80%
QLD	8	69	55	14	80%
WA	1	34	23	11	68%
SA	3	26	22	4	85%
ACT	0	8	6	2	75%
TAS	0	6	6	0	100%
NT	0	3	3	0	100%
TOTAL	**22**	**329**	**258**	**71**	**78%**

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

A **participating** site is defined as any site that has committed to contribute data to the ABDR (implemented) or is represented by a surgeon that contributes data to the ABDR. As of 31 December 2018, 78% (258) of eligible sites were participating in the ABDR (Table 1). The total number of participating sites throughout 2018 was 280, including 22 sites that by the end of 2018 were classified as closed or no device sites.

New South Wales, Queensland and Victoria continue to have the greatest number of participating sites (77%), reflecting the higher concentration of providers in these states (Table 1 and Figure 2). Data have been collected predominantly from private facilities (79%) (Figure 3), comprising 157 private overnight and 63 private same day facilities. Of the 280 participating sites, 267 are actively contributing data. The remaining 13 have received ethics and governance approval but have either not contributed data in the reporting period or are considered to not routinely perform breast device surgery.

FIGURE 2: SITE PARTICIPATION BY STATE

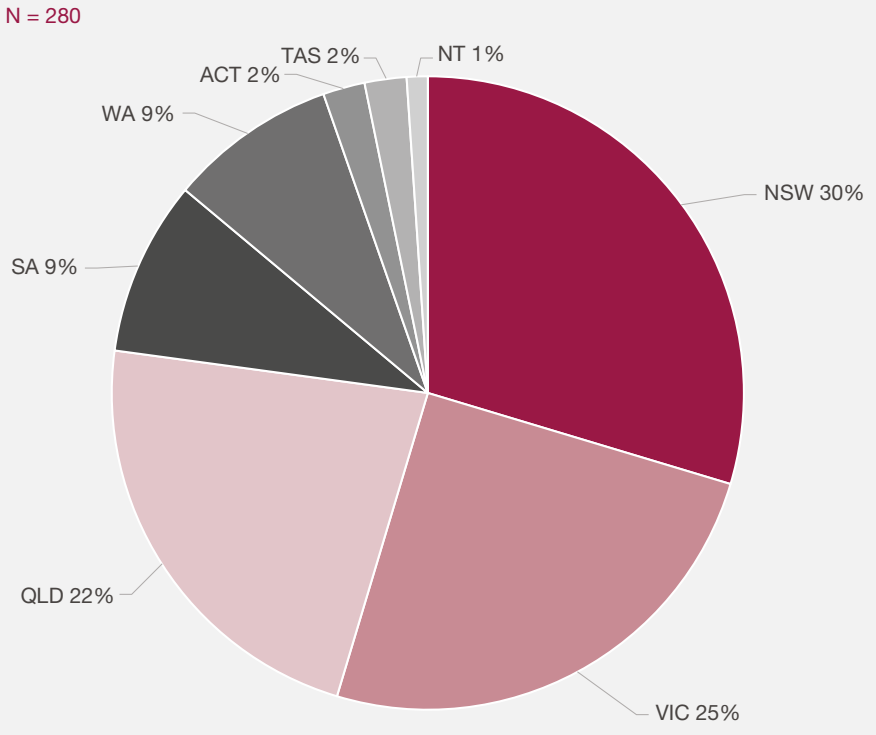
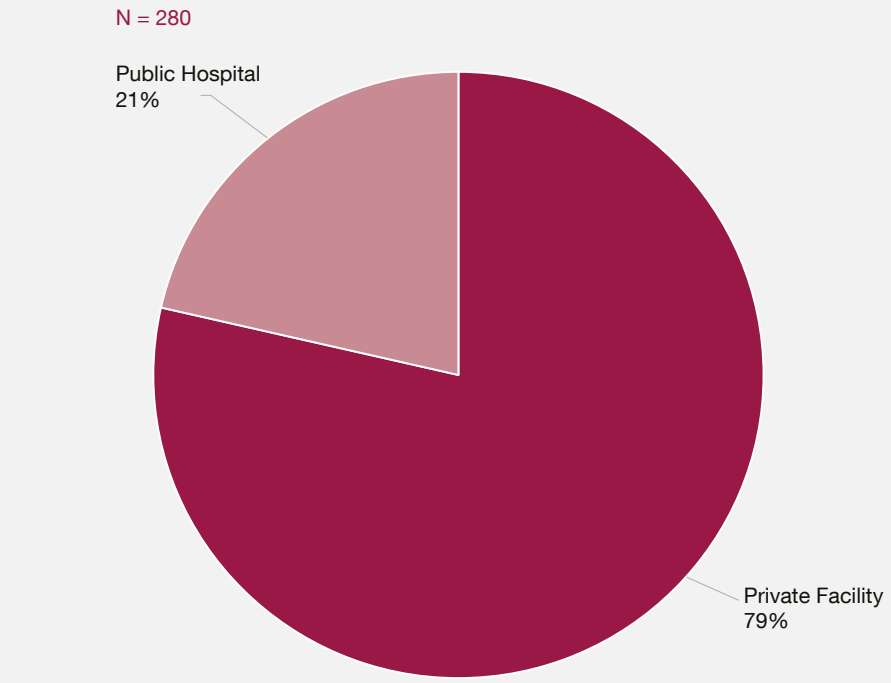


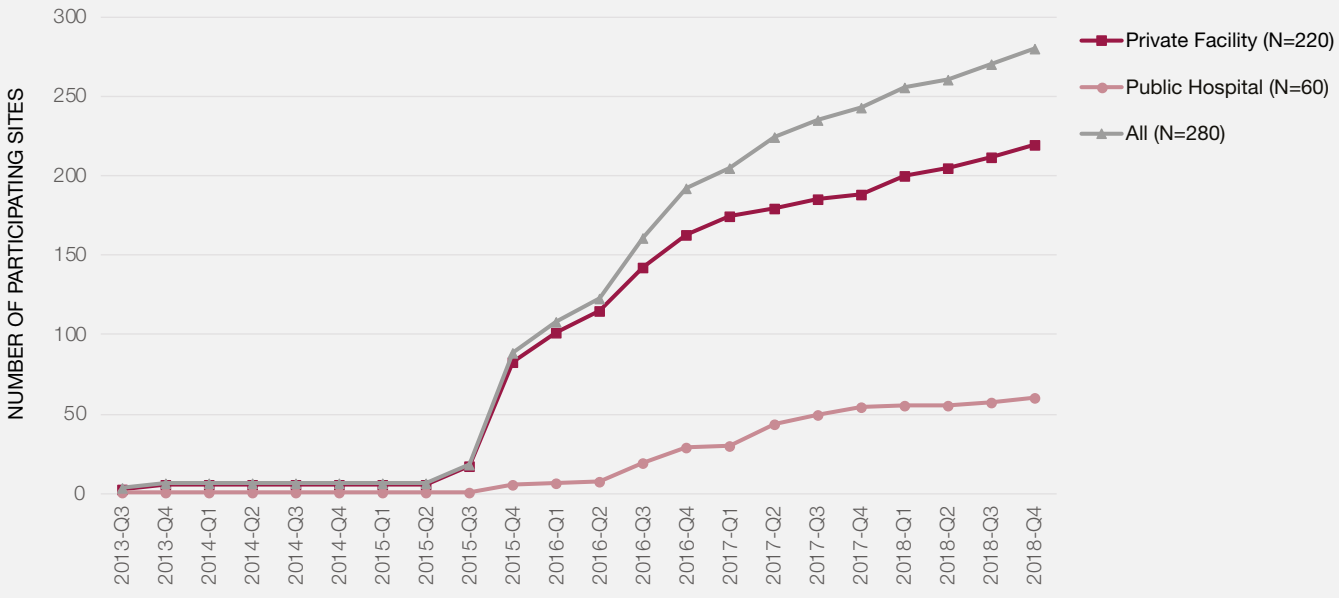
FIGURE 3: SITE PARTICIPATION BY SITE TYPE



Timeline of Site Participation

The number of participating sites continues to increase steadily since inception of the ABDR in April 2015 (Figure 4) after a pilot study was conducted involving seven sites (2013-2015). At the end of 2018, a total of 280 sites were participating, steadily increasing from the seven pilot sites in April 2015.

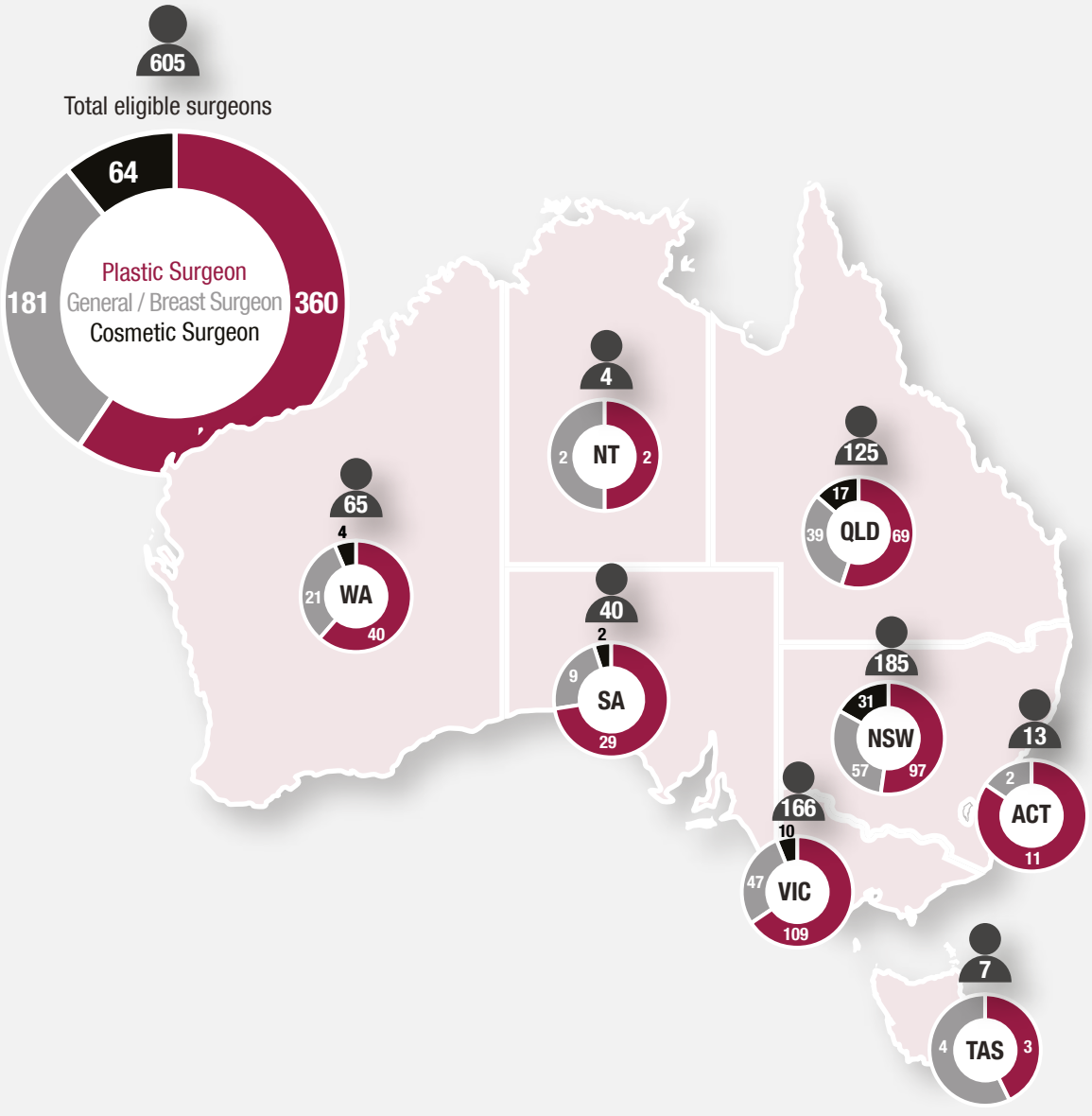
FIGURE 4: CUMULATIVE PARTICIPATING ABDR SITES BY SITE TYPE



Surgeon Participation

Surgeons eligible to participate in the ABDR were initially identified through the ASPS, ACCS and BreastSurgANZ. Each society supports the ABDR and provides an up to date list of surgeons who have reported breast device work. Surgeons are also identified through site contacts at hospitals where breast device procedures are undertaken, and further confirmed through internet search engines and networking sites. At 31 December 2018, a total of 605 surgeons were identified as undertaking breast device procedures (Figure 5). An additional 80 surgeons were identified not currently undertaking breast device procedures but having capacity to do so in the future. The ABDR communicates with these 'no device' surgeons regularly to confirm their status. The objective of the ABDR is to have all surgeons who insert or explant breast devices participate in the registry.

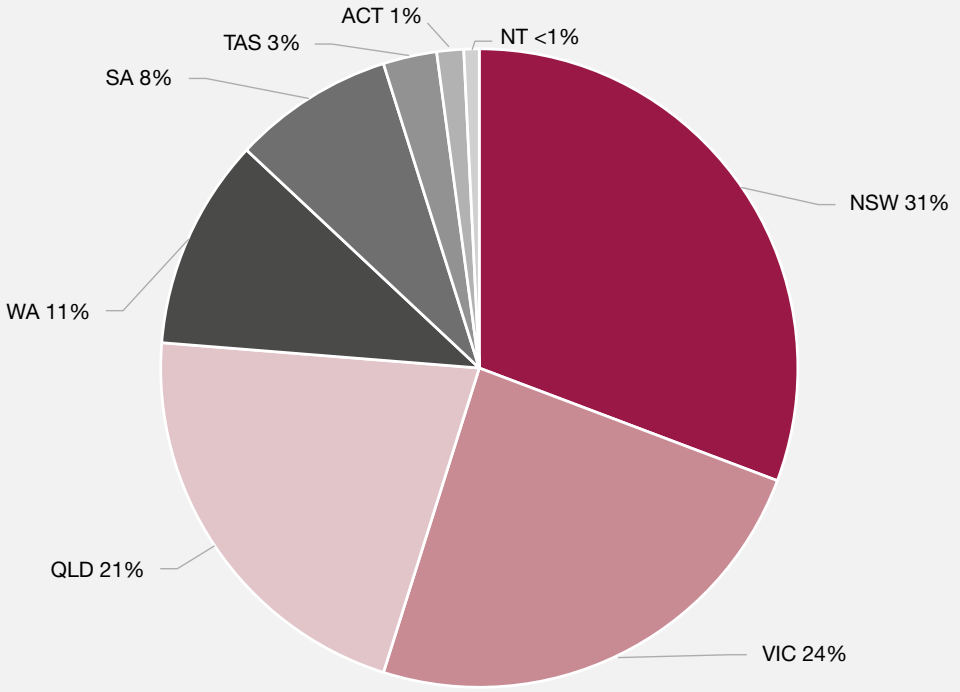
FIGURE 5: NUMBER OF SURGEONS ELIGIBLE FOR ABDR PARTICIPATION



A wide-ranging group of clinicians participate in the ABDR. At 31 December 2018, 514 individual surgeons were participating in the ABDR including 336 plastic surgeons, 131 general/breast surgeons and 47 cosmetic surgeons. This totals to 85% of eligible surgeons. Participating surgeons were principally from New South Wales, Victoria, and Queensland (Figure 6). Plastic surgeons are the largest participating group, comprising 65% of participating surgeons (Figure 7). Of the 514 participating surgeons, 484 currently contribute data on a regular basis with the remaining 30 surgeons awaiting final ethics or governance approval for their operating sites.

FIGURE 6: SURGEON PARTICIPATION BY STATE

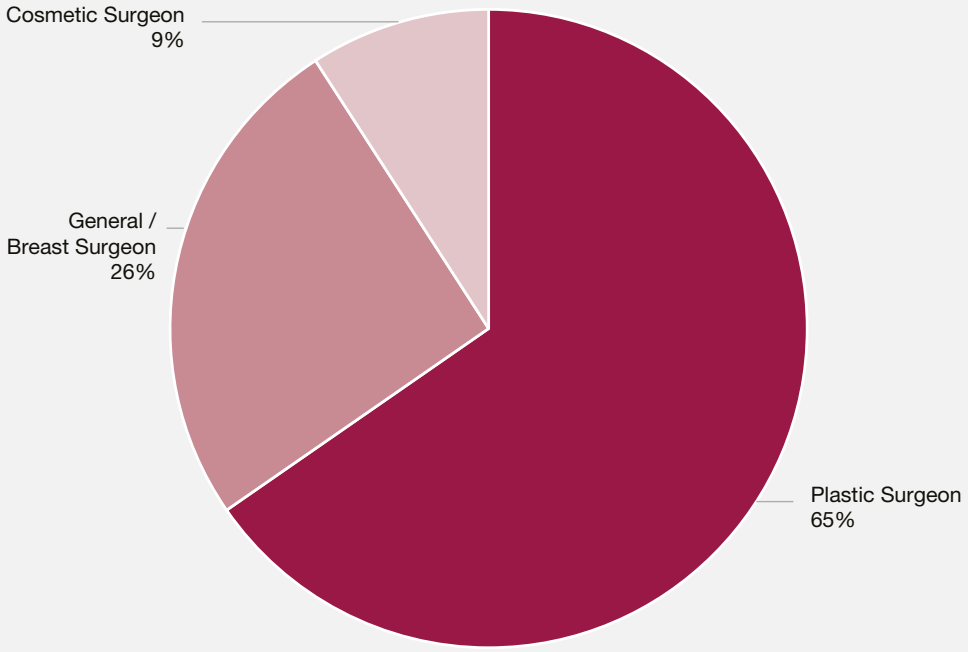
N = 514



Notes: The number of participating surgeons includes surgeons that contributed data to the ABDR but are now retired. These surgeons are not included in figures for 'surgeons eligible for ABDR participation' (Figure 5) resulting in a greater number of surgeons participating than eligible in some states.

FIGURE 7: SURGEON PARTICIPATION BY CRAFT GROUP

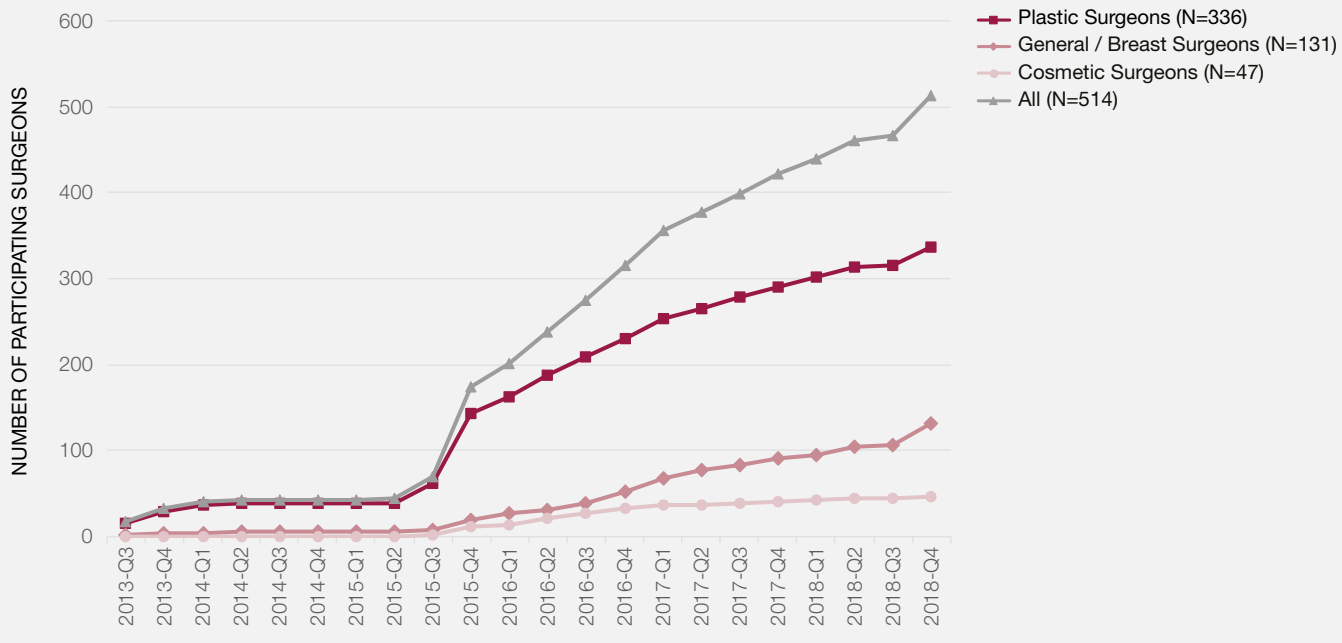
N = 514



Timeline of Surgeon Participation

Figure 8 shows the timeline for recruitment of surgeons into the pilot BDR and ABDR. Prior to April 2015, the pilot study included accredited sites with plastic surgeons and general/breast surgeons only. In late 2014 the registry became an initiative of the Australian Government Department of Health and the scope was broadened to include all medical professionals performing breast device surgery. Members of the Australasian College of Cosmetic Surgery began participating in October 2015.

FIGURE 8: CUMULATIVE PARTICIPATING ABDR SURGEONS BY CRAFT GROUP



Patient, Procedure, Device Numbers (2012 – 2018)

As at December 2018, 37,603 patients were participating in the ABDR, an addition of 11,990 in 2018. The patient opt out rate was 1.1%. A patient is considered to be participating in the ABDR from the date of their earliest ABDR recorded surgery. Due to the lag of data transfer from the surgeon to the ABDR, additional patients may have had surgery in this timeframe but are yet to be included in the database. Data from patients who chose to opt out and patients who did not have a procedure date listed are not included in the reported figures.

Table 2 presents the number of patients, number of procedures at patient level and number of procedures at breast/device level (excluding acellular dermal/synthetic matrix) by indication for surgery. Indication was assigned based on a four-tier hierarchy beginning with post-cancer reconstruction, followed by risk-reducing reconstruction, developmental deformity and then cosmetic augmentation. Patients were assigned to the indication for their first procedure as recorded on the data collection form submitted by surgeons and subsequently recorded in the ABDR database. Where the first operation was bilateral but different procedures were undertaken on each breast, the four-tier hierarchy was applied. For example, a patient with a bilateral first procedure with post-cancer reconstruction on one side, and cosmetic augmentation on the other side would be allocated to the post-cancer reconstruction indication based on the hierarchy. The hierarchy was also used to assign indication to procedures (at patient level) when bilateral differences were seen.

Of the 37,603 patients in the ABDR, 75% entered the registry for cosmetic augmentation, 15% for post-cancer reconstruction, 3% for risk-reducing reconstruction, 2% to correct for developmental deformity and 4% entered the registry with an indication for surgery not stated on the data collection form.

The ABDR received breast implant sales data from the TGA in 2018 for the purpose of case ascertainment calculations. The data capture rate for implant procedures in 2018 was 74%, increased from 65% in 2017 and 44% in 2016.

TABLE 2. REGISTERED PATIENTS, PROCEDURES AND DEVICES BY INDICATION FOR SURGERY (2012 – 2018)

	Patients*		Procedures**		Devices***	
	N	(%)	N	(%)	N	(%)
Reconstructive						
Post-cancer reconstruction	5,677	(15.1%)	7,968	(19.0%)	10,121	(13.0%)
Risk-reducing reconstruction	1,292	(3.4%)	1,761	(4.2%)	4,731	(6.1%)
Developmental deformity	901	(2.4%)	1,033	(2.5%)	1,690	(2.2%)
Aesthetic						
Cosmetic augmentation	28,090	(74.7%)	29,206	(69.7%)	57,952	(74.3%)
Not Stated	1,643	(4.4%)	1,953	(4.7%)	3,530	(4.5%)
TOTAL	**37,603**	**(100%)**	**41,921**	**(100%)**	**78,024**	**(100%)**

Notes: Indication was assigned based on a four-tier hierarchy beginning with post-cancer reconstruction, followed by risk-reducing reconstruction, developmental deformity and then cosmetic augmentation.

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

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

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

Figures 9 and 10 show a steady rise in the accumulation of both reconstructive and aesthetic patients and procedures captured by the ABDR over the last three years. A total of 7,870 reconstructive patients, 10,762 reconstructive procedures (patient level) and 16,542 reconstructive procedures (breast/device level) have been captured by the ABDR since registry commencement until December 2018 (Figure 9). A total of 28,090 aesthetic patients, 29,206 aesthetic procedures (patient level) and 57,952 aesthetic procedures (breast/device level) have been captured by ABDR as at December 2018 (Figure 10). Patients with a reconstructive indication were more likely to undergo multiple procedures compared to patients with aesthetic indication. Patients with aesthetic indication were more likely to undergo bilateral procedures compared to patients with reconstructive indication.

FIGURE 9. REGISTERED PATIENTS, PROCEDURES AND DEVICES – RECONSTRUCTIVE (2012 – 2018)

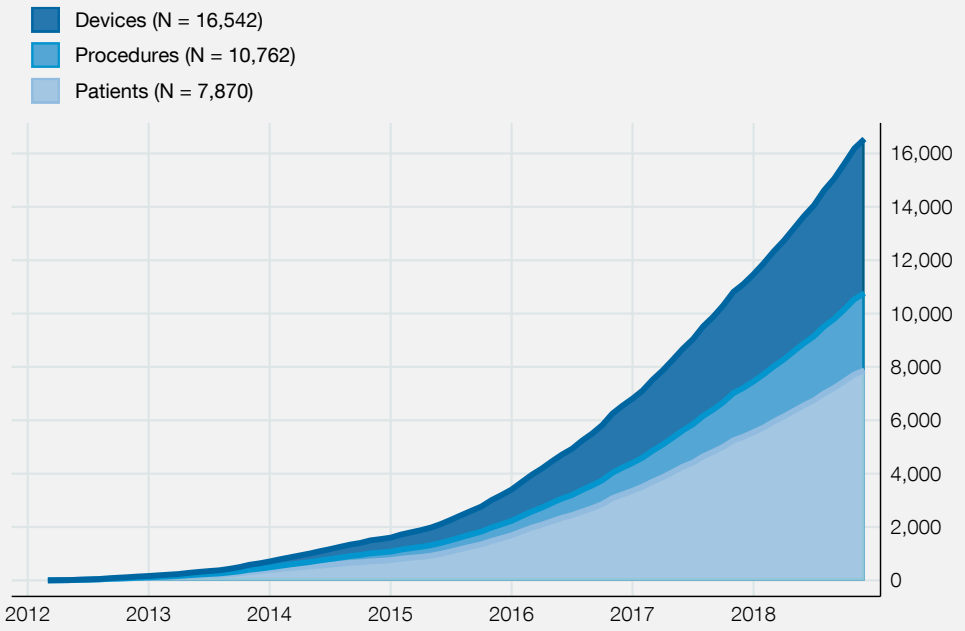
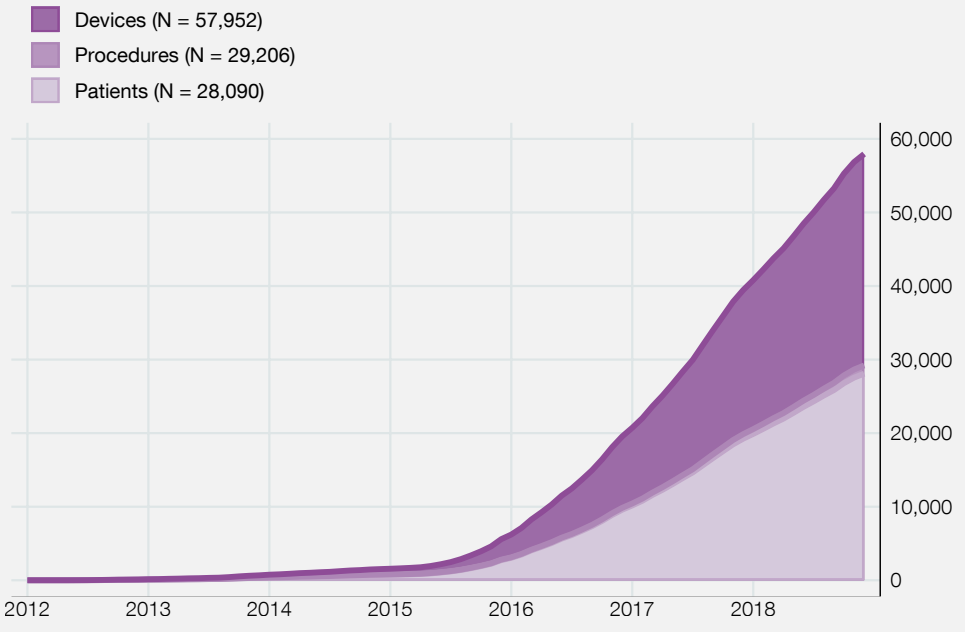
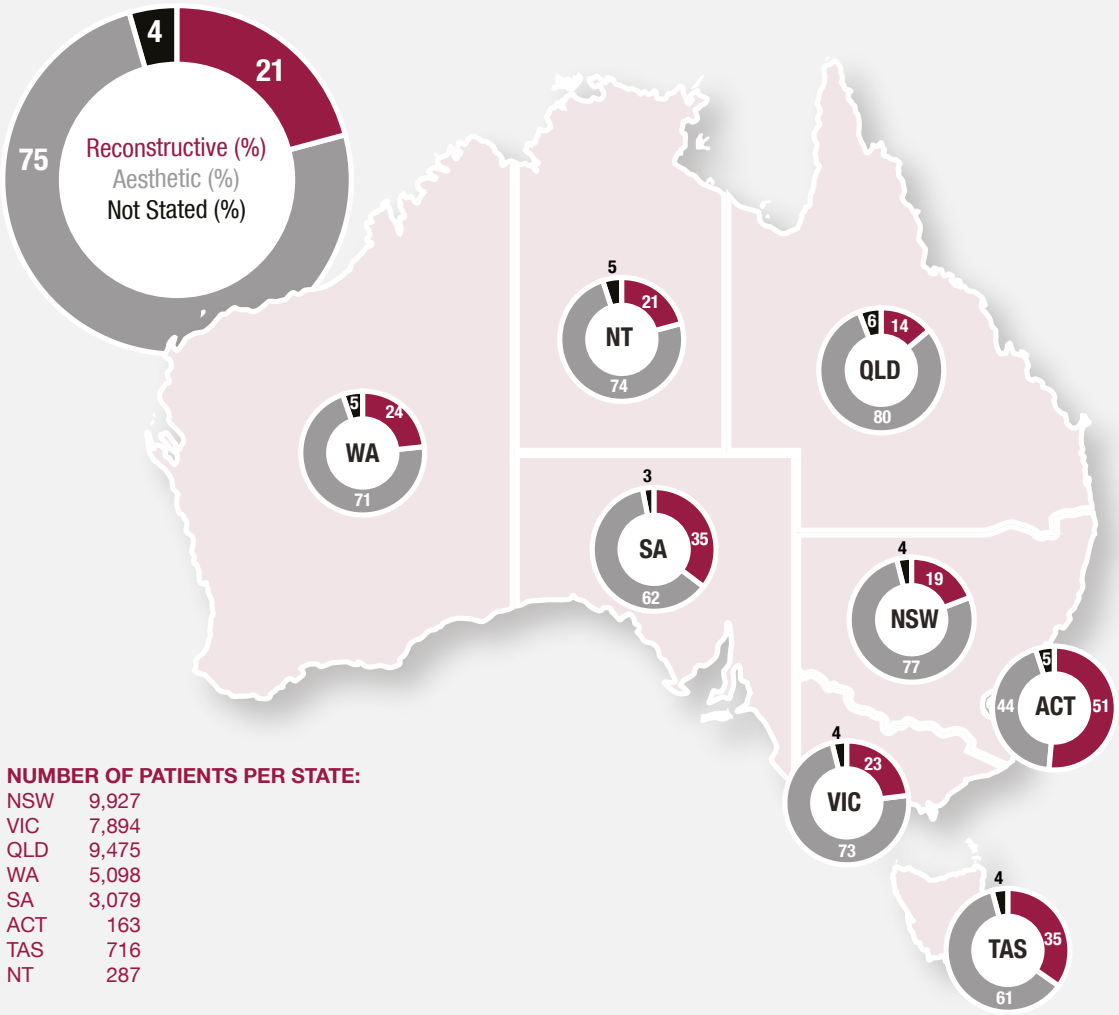


FIGURE 10. REGISTERED PATIENTS, PROCEDURES AND DEVICES – AESTHETIC (2012 – 2018)



Patient residency and indication at the time of entry to the registry are presented in Figure 11. Most states have a similar 75% and 20% breakdown of aesthetic and reconstructive patients captured. A higher 80% of Queensland residents entered the registry for aesthetic breast surgery. Also, a higher 51% of ACT residents and 35% of South Australian and Tasmanian residents entered the registry for reconstructive breast surgery. Registry participation for sites and surgeons in these states is still growing. Almost all overseas residents captured by the registry had aesthetic breast surgery in Australia.

FIGURE 11. PATIENT RESIDENCY BY INDICATION (2012 – 2018)



NUMBER OF PATIENTS PER STATE:

NSW	9,927
VIC	7,894
QLD	9,475
WA	5,098
SA	3,079
ACT	163
TAS	716
NT	287

Notes: N = 37,603 patients. This includes 189 overseas residents and 775 individuals with unknown residency. Patients with unknown residency are those who have elected email as the form of correspondence.

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

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

Records for which the indication was not stated were excluded from further analysis in this report (Table 2). Within the two registry output sections, results have been presented for two types of surgical/ procedure intervention:

- **Insertion Surgery** which includes insertion of a new device, either a 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
- **Revision Surgery** which includes unplanned replacement, reposition or explant of an in-situ device, either a tissue expander or breast implant. The initial device insertion may or may not have also been captured by the registry

REGISTRY OUTPUTS: RECONSTRUCTIVE INDICATIONS

Reconstructive Procedure Numbers

The ABDR has captured a total of 10,762 surgical procedures involving breast devices for reconstructive surgery, including post-cancer reconstruction, risk-reducing reconstruction and developmental deformity. Figure 12 shows a steady rise in the annual number of reconstructive procedures captured in each year since registry commencement. In 2018, 3,544 reconstructive procedures were captured. Of these 37% were unilateral post-cancer reconstruction, 20% were bilateral post-cancer reconstruction, 17% were bilateral with post-cancer reconstruction on one side and risk-reducing reconstruction on the other side, and 12% were bilateral risk-reducing reconstruction on both sides (Table 3).

FIGURE 12. REGISTERED PROCEDURES – RECONSTRUCTIVE (2012 – 2018)

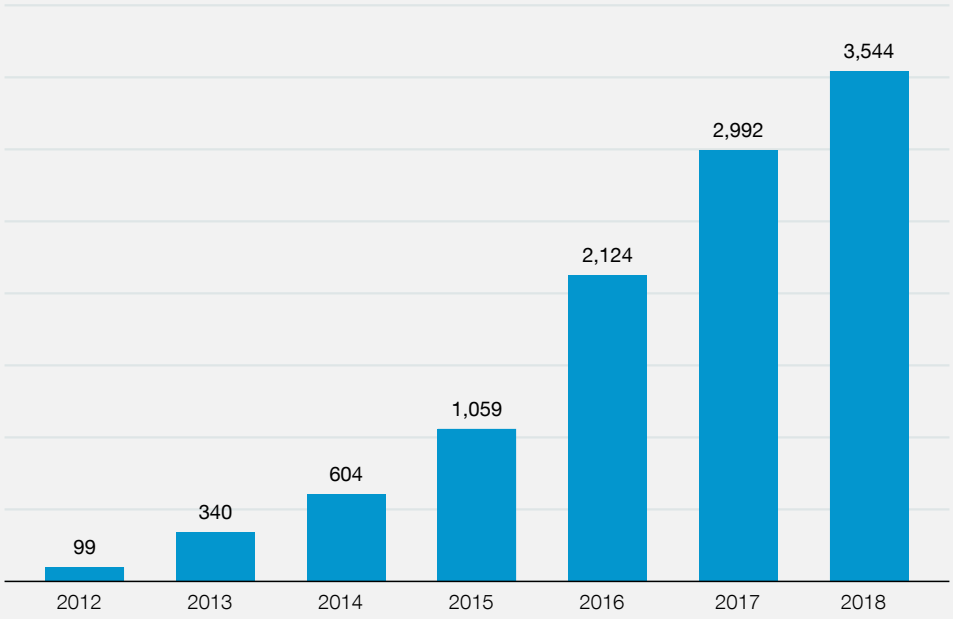


TABLE 3. PROCEDURE TYPE – RECONSTRUCTIVE

	2012-2018		2017		2018	
	N	(%)	N	(%)	N	(%)
Unilateral						
Post-cancer	3,902	(36.3%)	1,116	(37.3%)	1,317	(37.2%)
Risk-reducing	417	(3.9%)	115	(3.8%)	148	(4.2%)
Developmental	274	(2.5%)	84	(2.8%)	78	(2.2%)
Bilateral						
Post-cancer | Post-cancer	2,153	(20.0%)	594	(19.9%)	692	(19.5%)
Post-cancer | Risk-reducing	1,654	(15.4%)	462	(15.4%)	593	(16.7%)
Risk-reducing | Risk-reducing	1,316	(12.2%)	356	(11.9%)	439	(12.4%)
Developmental | Developmental	655	(6.1%)	159	(5.3%)	165	(4.7%)
Post-cancer | Aesthetic	238	(2.2%)	70	(2.3%)	71	(2.0%)
Developmental | Aesthetic	103	(1.0%)	21	(0.7%)	23	(0.6%)
Other	50	(0.5%)	15	(0.5%)	18	(0.5%)
TOTAL RECONSTRUCTIVE PROCEDURES	**10,762**	**(100%)**	**2,992**	**(100%)**	**3,544**	**(100%)**

Patient Age at Reconstructive Procedures

The age distribution at the time of reconstructive procedure is shown in Table 4 and Figure 13. Age differences can be seen by the indication for procedure and whether the procedure involved device insertion or revision. In 2018, median age at post-cancer reconstruction was 50 years for insertion surgery and 55 years for revision surgery. Patient age was lower for risk-reducing reconstruction and lowest for developmental deformity. Median age at risk-reducing reconstruction was 41 years for insertion surgery and 48 years for revision surgery. The median age at procedures to correct for developmental deformity was 22 for insertion surgery compared to 37 years for revision surgery.

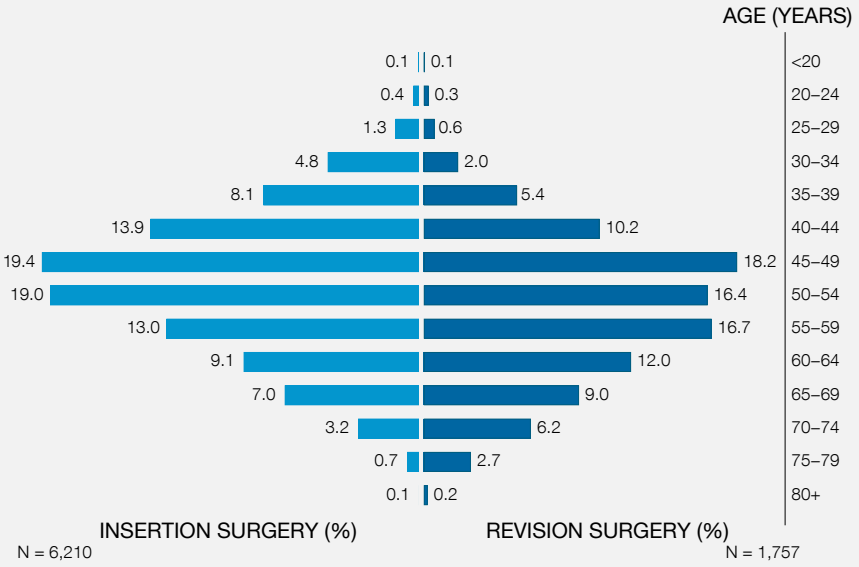
TABLE 4. SUMMARY STATISTICS FOR AGE AT TIME OF RECONSTRUCTIVE PROCEDURES

	Insertion Surgery			Revision Surgery		
	2012-2018	2017	2018	2012-2018	2017	2018
Post-cancer						
N	6,210	1,753	2,054	1,757	495	626
Mean Age (Standard deviation)	50.9 (10.5)	50.8 (10.7)	50.7 (11.0)	54.5 (10.9)	54.3 (11.4)	55.4 (11.1)
Median Age (Interquartile range)	50.6 (43.8, 58.0)	50.4 (43.6, 57.5)	50.0 (43.1, 57.8)	54.0 (46.9, 62.0)	53.8 (46.4, 62.9)	55.3 (47.2, 63.2)
Risk-reducing						
N	1,191	338	399	570	142	199
Mean Age (Standard deviation)	42.2 (10.9)	42.4 (11.1)	42.1 (11.0)	47.7 (13.0)	48.0 (13.0)	48.2 (13.0)
Median Age (Interquartile range)	41.6 (34.9, 49.0)	41.6 (35.4, 49.0)	40.9 (34.9, 49.0)	47.3 (38.4, 57.8)	47.0 (38.8, 58.4)	48.4 (38.5, 58.1)
Developmental						
N	725	177	158	308	87	108
Mean Age (Standard deviation)	27.2 (9.2)	27.9 (9.6)	25.2 (8.1)	36.8 (12.2)	35.7 (11.7)	38.3 (13.0)
Median Age (Interquartile range)	24.6 (20.3, 32.1)	24.9 (20.3, 33.4)	22.3 (19.2, 28.0)	35.3 (27.0, 44.6)	34.5 (26.5, 41.9)	37.2 (27.9, 47.0)

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

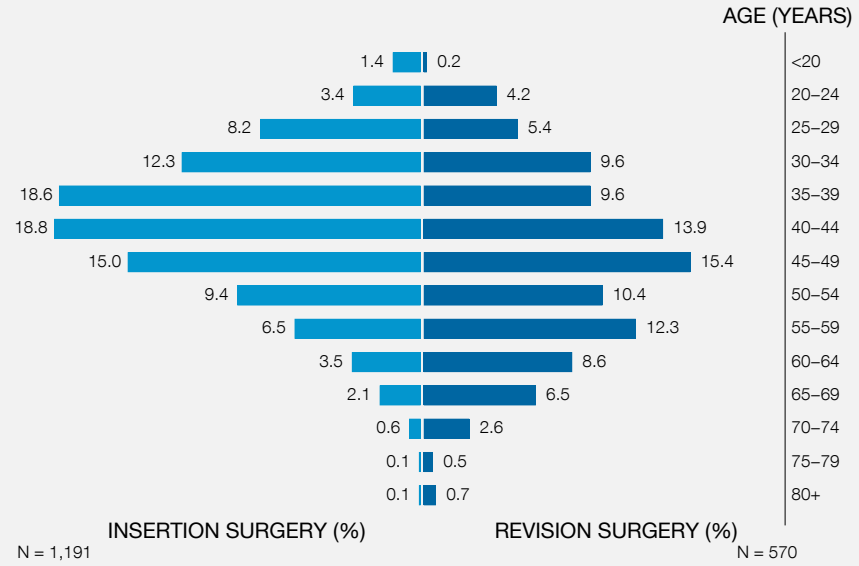
FIGURE 13. AGE DISTRIBUTION FOR RECONSTRUCTIVE PROCEDURES (2012 – 2018)

POST–CANCER RECONSTRUCTON



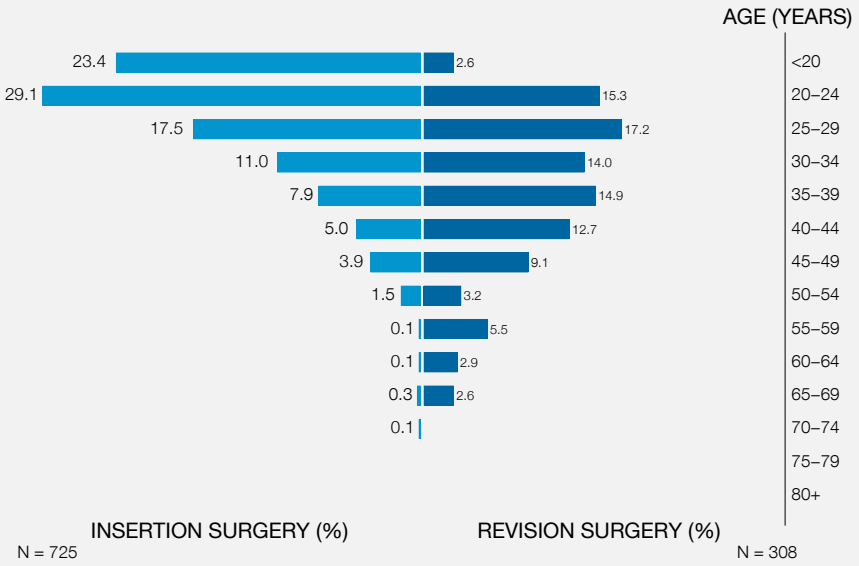
N = 6,210 N = 1,757

RISK–REDUCING RECONSTRUCTION



N = 1,191 N = 570

DEVELOPMENTAL DEFORMITY



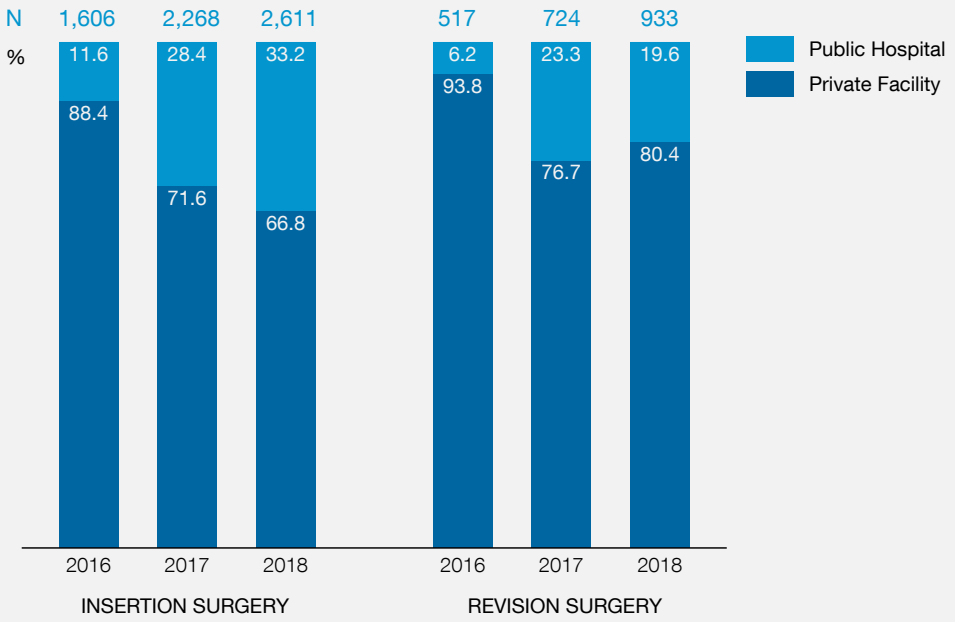
N = 725 N = 308

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

Site Type for Reconstructive Procedures

Over the last three years (2016 – 2018) the capture of procedures in public hospitals and private facilities has evolved as registry participation for sites and surgeons continues to grow (Figure 14). Reconstructive procedures captured by the registry in 2016 were predominately reported in private facilities, 88% for insertion surgery and 94% for revision surgery. In 2018, 67% of reconstructive procedures involving breast device insertion were reported in private facilities and 33% in public hospitals. However, breast device revision surgery was more often reported in private facilities. In 2018, 80% of reconstructive procedures involving breast device revision were reported in private facilities and 20% in public hospitals.

FIGURE 14. SITE TYPE FOR RECONSTRUCTIVE PROCEDURES (2016 – 2018)



Notes: Insertion and revision procedures have been analysed independently. Both unilateral and bilateral procedures have been included. A procedure indication hierarchy has been applied for bilateral procedures with different indication and procedure type details per breast.

Reconstructive Procedure Techniques and Elements

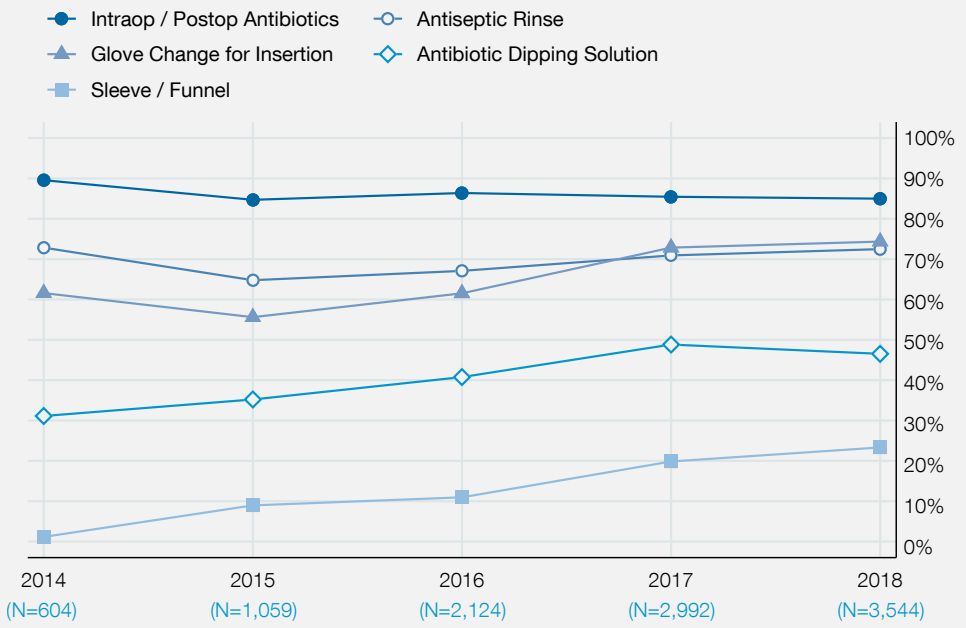
The ABDR collects data on intraoperative techniques used by contributing surgeons to identify current practice in surgical techniques and their association with patient outcomes. More than one intraoperative technique can be used and recorded per procedure. Table 5 and Figure 15 show the intraoperative techniques used during breast reconstruction surgery. In 2018, the use of intraoperative and/or postoperative antibiotics (85%), antiseptic rinse (72%) and glove change for insertion (74%) were commonly reported during breast reconstruction. Less frequently reported intraoperative techniques included antibiotic dipping solution (46%) and sleeve/funnel (23%) in 2018.

TABLE 5. INTRAOPERATIVE TECHNIQUES – RECONSTRUCTIVE PROCEDURES

	2012-2018		2017		2018	
	N	(%)	N	(%)	N	(%)
Intraop / Postop antibiotics*	9,238	(85.8%)	2,557	(85.5%)	3,012	(85.0%)
Antiseptic rinse	7,566	(70.3%)	2,122	(70.9%)	2,569	(72.5%)
Glove change for insertion	7,372	(68.5%)	2,180	(72.9%)	2,635	(74.4%)
Antibiotic dipping solution	4,629	(43.0%)	1,461	(48.8%)	1,649	(46.5%)
Sleeve / Funnel	1,761	(16.4%)	594	(19.9%)	827	(23.3%)
Not stated	1,249	(11.6%)	360	(12.0%)	473	(13.3%)
TOTAL	**10,762**		**2,992**		**3,544**	

Notes: More than one intraoperative technique can be used and recorded per procedure.
* Includes cases where intraoperative and/or postoperative antibiotics were administered.

FIGURE 15. INTRAOPERATIVE TECHNIQUES – RECONSTRUCTIVE PROCEDURES (2014 – 2018)



The registry reports details about other surgical elements and techniques used during each breast procedure. From 2012-2018 the most common surgical plane used during breast reconstruction surgery was a sub-pectoral plane, 63% when involving device insertion and 52% when involving device revision surgery (Table 6). A previous mastectomy scar or the inframammary fold were the most commonly used incision sites reported in reconstructive breast procedures during 2012 to 2018 (Table 6).

Table 7 details other surgical elements reported during breast reconstruction. Concurrent mastectomy occurred in 32% of breast reconstruction procedures involving device insertion. Axillary surgery (16%) and concurrent flap cover (10%) were other surgical elements reported during breast reconstruction procedures involving device insertion. Fat grafting occurred in 13% of reconstructive revision procedures. Drains were used in 55% of reconstructive insertion procedures and in 48% of reconstructive revision procedures. The nipple was absent during 48% of reconstructive insertion procedures and during 32% of reconstructive revision procedures. Nipple sparing was another technique used during breast reconstruction procedures, 19% when involving device insertion and 15% when involving device revision surgery.

TABLE 6. SURGICAL PLANE AND INCISION SITE – RECONSTRUCTIVE PROCEDURES

	Insertion Surgery 2012-2018		Revision Surgery 2012-2018	
	N	%	N	%
Plane				
Sub-pectoral	7,948	(62.7%)	1,997	(51.6%)
Sub-flap	1,152	(9.1%)	381	(9.8%)
Sub-glandular / Sub-fascial	973	(7.7%)	478	(12.4%)
Dual	409	(3.2%)	62	(1.6%)
Other	194	(1.5%)	14	(0.4%)
Not stated	1,996	(15.8%)	937	(24.2%)
Incision Site				
Previous mastectomy scar	5,698	(45.0%)	1,582	(40.9%)
Inframammary	3,654	(28.8%)	1,602	(41.4%)
Areolar	1,210	(9.5%)	138	(3.6%)
Mastopexy/reduction wound	1,060	(8.4%)	275	(7.1%)
Axillary	110	(0.9%)	21	(0.5%)
Other	538	(4.2%)	31	(0.8%)
Not stated	718	(5.7%)	309	(8.0%)
TOTAL	**12,672**		**3,869**	

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

TABLE 7. OTHER SURGICAL ELEMENTS – RECONSTRUCTIVE PROCEDURES

	Insertion Surgery 2012-2018		Revision Surgery 2012-2018	
	N	(%)	N	(%)
Axillary Surgery (incl. Sentinel Node Biopsy)				
Yes	1,982	(15.6%)	66	(1.7%)
No	8,116	(64.0%)	2,935	(75.9%)
Not stated	2,574	(20.3%)	868	(22.4%)
Concurrent Mastectomy				
Yes	4,122	(32.5%)	105	(2.7%)
No	6,097	(48.1%)	2,910	(75.2%)
Not stated	2,453	(19.4%)	854	(22.1%)
Concurrent Mastopexy/Reduction				
Yes	908	(7.2%)	259	(6.7%)
No	10,728	(84.7%)	3,147	(81.3%)
Not stated	1,036	(8.2%)	463	(12.0%)
Concurrent Flap Cover				
Yes	1,292	(10.2%)	156	(4.0%)
No	10,331	(81.5%)	3,235	(83.6%)
Not stated	1,049	(8.3%)	478	(12.4%)
Previous Mastopexy/Reduction				
Yes	363	(2.9%)	240	(6.2%)
No	9,658	(76.2%)	2,760	(71.3%)
Not stated	2,651	(20.9%)	869	(22.5%)
Fat Grafting				
Yes	512	(4.0%)	501	(12.9%)
No	10,541	(83.2%)	2,768	(71.5%)
Not stated	1,619	(12.8%)	600	(15.5%)
Drains Used				
Yes	6,917	(54.6%)	1,850	(47.8%)
No	5,755	(45.4%)	2,019	(52.2%)
Not stated	0	(0.0%)	0	(0.0%)
Nipple Guard/Shield				
Yes	1,758	(13.9%)	812	(21.0%)
No	10,914	(86.1%)	3,057	(79.0%)
Not stated	0	(0.0%)	0	(0.0%)
Nipple Absent				
Yes	6,103	(48.2%)	1,254	(32.4%)
No	5,944	(46.9%)	2,447	(63.2%)
Not stated	625	(4.9%)	168	(4.3%)
Nipple Sparing				
Yes	2,465	(19.5%)	591	(15.3%)
No	9,582	(75.6%)	3,110	(80.4%)
Not stated	625	(4.9%)	168	(4.3%)
TOTAL	**12,672**		**3,869**	

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

Device Characteristics For Breast Reconstruction

The registry captures information about breast devices used during procedures in Australia. Information is collected about breast implants, tissue expanders and acellular dermal/synthetic matrix. Table 8 and 9 provide device shell, fill and shape characteristics for breast implants and tissue expanders inserted for breast reconstruction during an insertion procedure or a replacement revision procedure. One device previously classified as textured was reclassified to smooth in accordance with their listing on the Australian Register of Therapeutic Goods. In 2018, 55% of the breast implants inserted in registry participants for breast reconstruction were silicone implants with textured shell and anatomical shape, and 30% were silicone implants with smooth shell and round shape (Table 8). Of the tissue expanders inserted in 2018 for breast reconstruction, 85% were saline expanders with textured shell and anatomical shape, and 14% were carbon dioxide expanders with textured shell and anatomical shape (Table 9).

TABLE 8. DEVICE CHARACTERISTICS – RECONSTRUCTIVE BREAST IMPLANTS

	2012-2018		2017		2018	
	N	(%)	N	(%)	N	(%)
Silicone Implants						
Textured | Anatomical	6,858	(58.8%)	1,807	(56.0%)	2,044	(54.6%)
Textured | Round	1,770	(15.2%)	512	(15.9%)	422	(11.3%)
Smooth | Round	2,427	(20.8%)	763	(23.6%)	1,132	(30.3%)
Polyurethane | Anatomical	273	(2.3%)	72	(2.2%)	42	(1.1%)
Polyurethane | Round	85	(0.7%)	9	(0.3%)	5	(0.1%)
Saline Implants						
Textured | Anatomical	12	(0.1%)	0	(0.0%)	5	(0.1%)
Textured | Round	5	(<0.1%)	0	(0.0%)	3	(0.1%)
Smooth | Round	38	(0.3%)	11	(0.3%)	18	(0.5%)
Silicone/Saline Implants						
Textured | Anatomical	175	(1.5%)	52	(1.6%)	67	(1.8%)
Textured | Round	3	(<0.1%)	1	(<0.1%)	2	(0.1%)
Not Stated	12	(0.1%)	0	(0.0%)	2	(0.1%)
TOTAL	**11,658**	**(100%)**	**3,227**	**100%**	**3,742**	**(100%)**

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

TABLE 9. DEVICE CHARACTERISTICS – RECONSTRUCTIVE TISSUE EXPANDERS

	2012-2018		2017		2018	
	N	(%)	N	(%)	N	(%)
Saline Expanders						
Textured | Anatomical	3,949	(88.5%)	1,066	(87.2%)	1,264	(85.3%)
Textured | Round	7	(0.2%)	0	(0.0%)	0	(0.0%)
Smooth | Anatomical	2	(<0.1%)	2	(0.2%)	0	(0.0%)
Smooth | Round	5	(0.1%)	3	(0.2%)	2	(0.1%)
Carbon Dioxide Expanders						
Textured | Anatomical	495	(11.1%)	151	(12.4%)	212	(14.3%)
Not Stated	4	(0.1%)	0	(0.0%)	4	(0.3%)
TOTAL	**4,462**	**(100%)**	**1,222**	**(100%)**	**1,482**	**(100%)**

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

Acellular dermal/synthetic matrices are most commonly used during reconstructive surgery. The registry captures the use of acellular dermal/synthetic matrices when used concurrently with a tissue expander or breast implant. Table 10 reports acellular dermal/synthetic matrix usage during reconstructive surgery involving breast implants and tissue expanders. In 2018, an acellular dermal/synthetic matrix was used during 51% of direct-to-implant insertions for post-cancer reconstruction and 58% for risk-reducing reconstruction. For patients undergoing surgery for developmental deformity, acellular dermal/synthetic matrices were only used at the time of revision surgery (3% in 2018). Additionally, in 2018 acellular dermal/synthetic matrix usage during reconstructive procedures involving the insertion of tissue expanders was 25% for both post-cancer and risk-reducing reconstruction.

TABLE 10. ACELLULAR DERMAL/SYNTHETIC MATRIX USE WITH DEVICES USED IN BREAST RECONSTRUCTION SURGERY

	2012-2018		2017		2018	
	N	(% with ADM)	N	(% with ADM)	N	(% with ADM)
BREAST IMPLANTS						
Direct-to-implant Insertion Surgery						
Post-cancer reconstruction	1,622	(44.3%)	502	(46.6%)	588	(51.0%)
Risk-reducing reconstruction	1,181	(48.2%)	377	(42.2%)	429	(58.0%)
Developmental deformity	1,035	(0.0%)	247	(0.0%)	230	(0.0%)
Two-stage Insertion Surgery						
Post-cancer reconstruction	3,336	(2.2%)	894	(2.7%)	1,005	(1.9%)
Risk-reducing reconstruction	1,109	(2.4%)	291	(2.7%)	361	(1.4%)
Developmental deformity	103	(0.0%)	25	(0.0%)	17	(0.0%)
Revision Surgery						
Post-cancer reconstruction	2,045	(7.6%)	576	(9.2%)	737	(7.3%)
Risk-reducing reconstruction	1,090	(8.3%)	270	(8.1%)	381	(8.1%)
Developmental deformity	482	(2.7%)	131	(4.6%)	174	(2.9%)
TISSUE EXPANDERS						
Insertion Surgery						
Post-cancer reconstruction	2,905	(24.3%)	805	(27.0%)	964	(25.4%)
Risk-reducing reconstruction	1,313	(24.8%)	348	(25.6%)	442	(25.3%)
Developmental deformity	68	(0.0%)	20	(0.0%)	8	(0.0%)
Revision Surgery						
Post-cancer reconstruction	212	(5.7%)	65	(1.5%)	78	(5.1%)
Risk-reducing reconstruction	38	(7.9%)	12	(8.3%)	17	(5.9%)
Developmental deformity	2	(0.0%)	0	(0.0%)	2	(0.0%)
Not Stated	1		0		0	
TOTAL DEVICES	**16,542**		**4,563**		**5,433**	

Notes: ADM includes acellular dermal and synthetic matrices.

Complications and Revision Incidence – Breast Implants for Reconstruction

The registry collects details of issues and complications that are found at the time of a revision procedure involving breast devices. Revision surgery includes the unplanned replacement, reposition or explant of an in-situ breast device. Table 11 reports issues identified during reconstructive breast implant revision procedures. Multiple issues can be recorded per revision and issues were either identified as a reason for the revision or found incidentally during the revision procedure. Table 11 reports the issues identified at all reconstructive breast implant revisions, including revisions for breasts where the insertion of the initial implant may or may not have also been captured by the registry. A more detailed revision and complication analysis follows for the primary breast implants for which the revision details can be linked to the initial inserted implant. In 2018, capsular contracture was the most common issue identified and reported for reconstructive breast implant revisions (39%), followed by device malposition (33%) and device rupture (17%). Please also refer to the BIA-ALCL reports in the Registry Outcomes section for information relating to cases of ALCL.

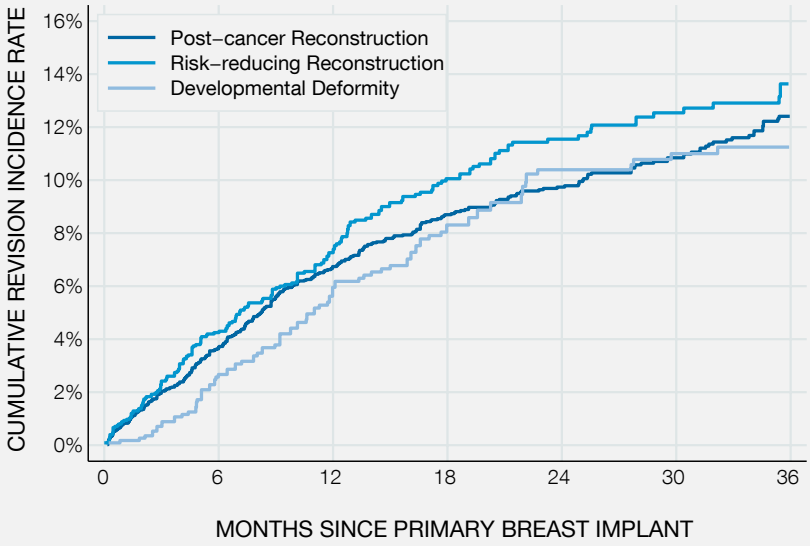
TABLE 11. ISSUES IDENTIFIED AT REVISION PROCEDURE –RECONSTRUCTIVE BREAST IMPLANTS

Complications and Issues Identified at Revision (N.B. Not complication rates)	2012-2018		2017		2018	
	N	(%)	N	(%)	N	(%)
Capsular contracture	1,422	(39.6%)	408	(42.0%)	498	(39.1%)
Device malposition	1,210	(33.7%)	356	(36.7%)	424	(33.3%)
Device rupture	538	(15.0%)	139	(14.3%)	215	(16.9%)
Device deflation	276	(7.7%)	73	(7.5%)	92	(7.2%)
Skin scarring problems	270	(7.5%)	77	(7.9%)	112	(8.8%)
Seroma/Haematoma	156	(4.3%)	44	(4.5%)	54	(4.2%)
Deep wound infection	106	(3.0%)	27	(2.8%)	44	(3.5%)
Breast cancer	68	(1.9%)	15	(1.5%)	38	(3.0%)
TOTAL REVISION PROCEDURES	**3,589**		**971**		**1,274**	

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

Time-to-revision analysis using survival analysis methods[6] was conducted to investigate revision incidence rates for primary reconstructive breast implants. Revision time was defined as the time from the insertion of the breast implant to the first subsequent revision procedure. Crude cumulative revision incidence rates were generated using Nelson-Aalen estimates for all primary reconstructive breast implants captured by the ABDR since 2012 to 2018. Figure 16 provides an all-cause revision incidence curve for the three reconstructive indications. All-cause revision incidence rates at time intervals after the date of implant insertion are also reported in Table 12. All-cause revision incidence considers all revisions captured by the registry, whether for complication reasons, patient preference or other unknown reasons. In this case, breasts without a revision procedure captured by the registry had their follow-up time censored at the date of data extraction (19 March, 2019). At 12 months after the date of primary implant insertion, 6.7% of implants for post-cancer reconstruction were revised for the first time, 7.3% of implants for risk-reducing reconstruction and 6.0% of primary implants inserted for developmental deformity were revised for the first time.

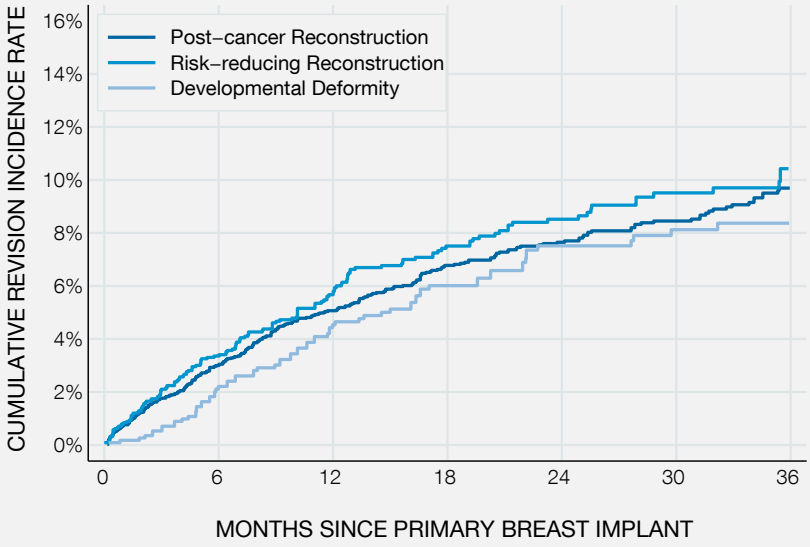
FIGURE 16. ALL-CAUSE REVISION INCIDENCE – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS



NUMBER AT RISK

4,853	4,229	3,393	2,607	1,959	1,429	1,034	Post–cancer
2,259	1,937	1,506	1,138	816	572	405	Risk–reducing
1,133	1,032	888	746	594	448	314	Developmental

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



NUMBER AT RISK

4,853	4,229	3,393	2,607	1,959	1,429	1,034	Post–cancer
2,259	1,937	1,506	1,138	816	572	405	Risk–reducing
1,133	1,032	888	746	594	448	314	Developmental

Figure 17 provides revision incidence due to complication curves for the three reconstructive indications. Revision incidence rates due to complication are also reported in Table 12. Revision incidence due to complication considers all revisions captured by the registry that occurred due to complication. A revision due to complication in this case was defined as revisions that stated complication as the reason for revision and/or an issue was identified at revision (issues included any of device rupture, device deflation, capsular contracture, device malposition, skin scarring problems, deep wound infection, seroma/haematoma and ALCL). Breasts without a revision procedure due to complication captured by the registry had their follow-up time censored at either the date of a revision procedure that occurred due to other reasons or the date of data extraction (19 March, 2019) if no revision was captured. At 12 months after the date of primary implant insertion, revision incidence due to complication was 5.1% for post-cancer reconstruction implants, 5.7% for risk-reducing reconstruction implants and 4.5% for primary implants inserted for developmental deformity.

TABLE 12. REVISION INCIDENCE: ALL-CAUSE AND WITH COMPLICATION – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS

	Post-cancer	Risk-reducing	Developmental
Number of Primary Breast Implants	4,853	2,259	1,133
Number Revised: All-cause	423	218	103
Number Revised: With Complication	329	163	76
All-cause Revision Incidence (95% Confidence Interval)			
6 months since primary breast implant	3.7% (3.2, 4.3)	4.3% (3.5, 5.2)	2.7% (1.9, 3.8)
12 months since primary breast implant	6.7% (6.0, 7.6)	7.3% (6.2, 8.6)	6.0% (4.6, 7.7)
18 months since primary breast implant	8.7% (7.8, 9.7)	10.1% (8.7, 11.7)	8.3% (6.7, 10.4)
24 months since primary breast implant	9.7% (8.8, 10.8)	11.6% (10.0, 13.4)	10.4% (8.5, 12.8)
30 months since primary breast implant	10.8% (9.8, 12.0)	12.5% (10.8, 14.5)	11.0% (9.0, 13.5)
36 months since primary breast implant	12.4% (11.1, 13.8)	13.6% (11.7, 15.9)	11.3% (9.2, 13.8)
Revision Incidence Due to Complication (95% Confidence Interval)			
6 months since primary breast implant	3.0% (2.5, 3.5)	3.4% (2.7, 4.2)	2.2% (1.5, 3.3)
12 months since primary breast implant	5.1% (4.4, 5.8)	5.7% (4.7, 6.8)	4.5% (3.4, 6.1)
18 months since primary breast implant	6.8% (6.0, 7.7)	7.5% (6.3, 8.9)	6.0% (4.6, 7.8)
24 months since primary breast implant	7.7% (6.8, 8.6)	8.5% (7.2, 10.1)	7.5% (5.9, 9.6)
30 months since primary breast implant	8.5% (7.5, 9.5)	9.5% (8.0, 11.3)	8.1% (6.4, 10.3)
36 months since primary breast implant	9.7% (8.6, 11.0)	10.4% (8.7, 12.4)	8.4% (6.6, 10.6)

Notes: Revision incidence is based on reconstructive primary breast implants inserted from 2012 to 2018. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary implant insertion date to the first revision procedure.

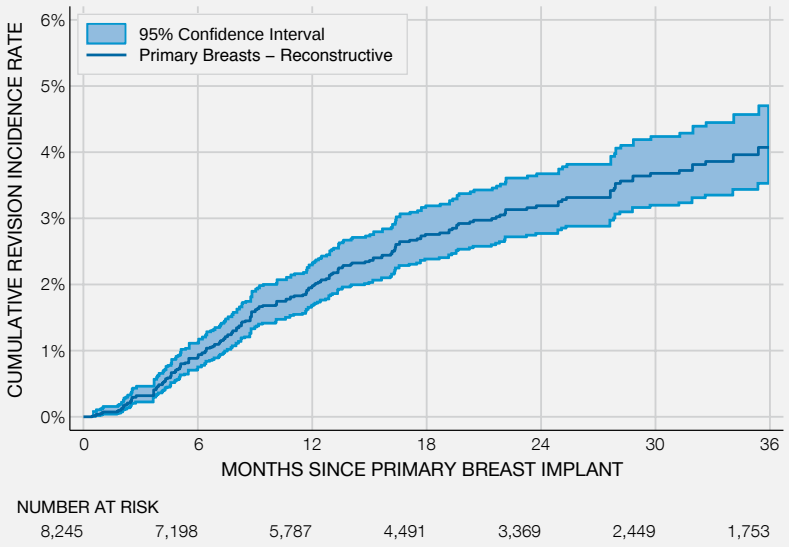
Revision incidence curves and rates for reconstructive primary breast implants were produced for revisions due to device malposition, capsular contracture and device rupture/deflation (Table 13 and Figures 18-20). Breasts without a revision procedure due to these issues were censored at either the date of a revision procedure that occurred due to other reasons or the date of data extraction (19 March, 2019) if no revision was captured. Revision incidence due to device malposition for reconstructive breast implants was 2.0% at 12 months and 4.1% at 36 months following the date of primary implant insertion. Revision incidence due to capsular contracture was 1.6% at 12 months and 3.7% at 36 months following the date of primary implant insertion. Revision incidence due to device rupture/deflation for reconstructive breast implants was 0.2% at 12 months and 0.5% at 36 months following the date of primary implant insertion.

TABLE 13. REVISION INCIDENCE: DEVICE ISSUES – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS

	Device Malposition	Capsular Contracture	Device Deflation/ Rupture
Number of Primary Breast Implants	8,245	8,245	8,245
Number Revised Due to Device Issues	224	200	28
Revision Incidence Due to Device Issues (95% Confidence Interval)			
6 months since primary breast implant	0.9% (0.7, 1.1)	0.6% (0.5, 0.8)	0.1% (0.1, 0.2)
12 months since primary breast implant	2.0% (1.7, 2.3)	1.6% (1.3, 1.9)	0.2% (0.1, 0.3)
18 months since primary breast implant	2.8% (2.4, 3.2)	2.3% (1.9, 2.7)	0.3% (0.2, 0.4)
24 months since primary breast implant	3.2% (2.8, 3.7)	2.9% (2.4, 3.3)	0.3% (0.2, 0.5)
30 months since primary breast implant	3.7% (3.2, 4.2)	3.0% (2.6, 3.5)	0.5% (0.3, 0.7)
36 months since primary breast implant	4.1% (3.5, 4.7)	3.7% (3.1, 4.3)	0.5% (0.3, 0.7)

Notes: Revision incidence is based on reconstructive primary breast implants inserted from 2012 to 2018. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary implant insertion date to the first revision procedure.

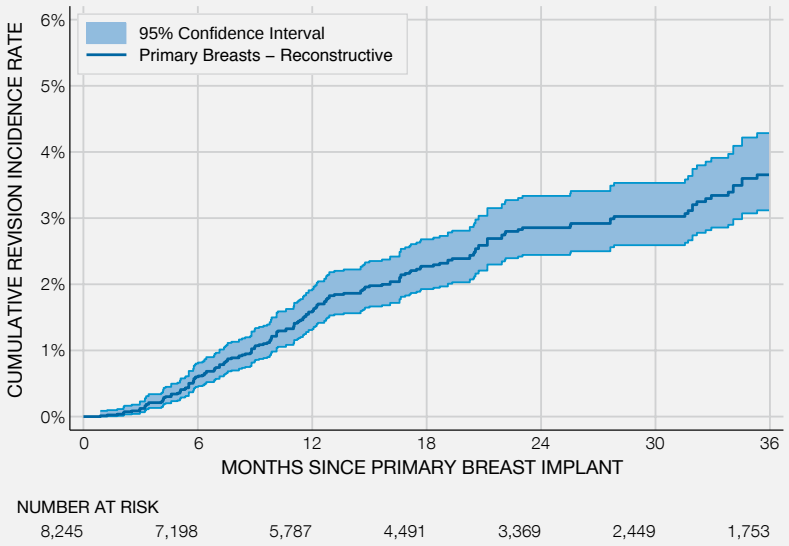
FIGURE 18. REVISION INCIDENCE DUE TO DEVICE MALPOSITION – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS



NUMBER AT RISK

8,245	7,198	5,787	4,491	3,369	2,449	1,753

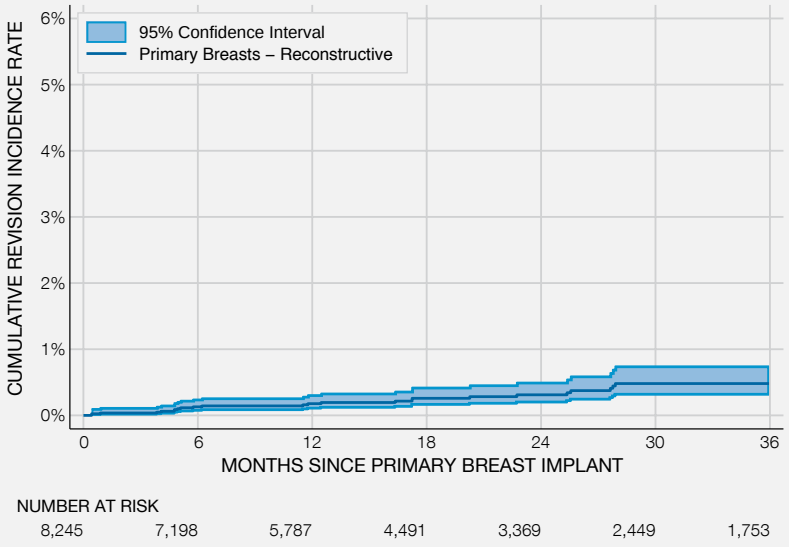
FIGURE 19. REVISION INCIDENCE DUE TO CAPSULAR CONTRACTURE – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS



NUMBER AT RISK

8,245	7,198	5,787	4,491	3,369	2,449	1,753

FIGURE 20. REVISION INCIDENCE DUE TO DEVICE RUPTURE/DEFLATION – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS



NUMBER AT RISK

8,245	7,198	5,787	4,491	3,369	2,449	1,753

Complication and Revision Incidence – Tissue Expanders for Reconstruction

The registry also collects details of issues and complications found at the time of unplanned revision procedures involving tissue expanders. Table 14 reports issues identified during reconstructive tissue expander revision procedures. Multiple issues can be recorded per revision and issues were either identified as a reason for the revision or found incidentally during the revision procedure. Table 14 reports the issues identified at all unplanned reconstructive tissue expander revisions, including revisions for breasts where the insertion of the initial tissue expander may or may not have also been captured by the registry. A more detailed revision analysis follows for the primary tissue expanders for which the revision details can be linked to the initial inserted tissue expander. In 2018, deep wound infection (19%), capsular contracture (18%), device rupture (18%), device deflation (18%), skin scarring problems (17%) and seroma/haematoma (16%) were commonly occurring issues identified and reported for unplanned reconstructive tissue expander revisions.

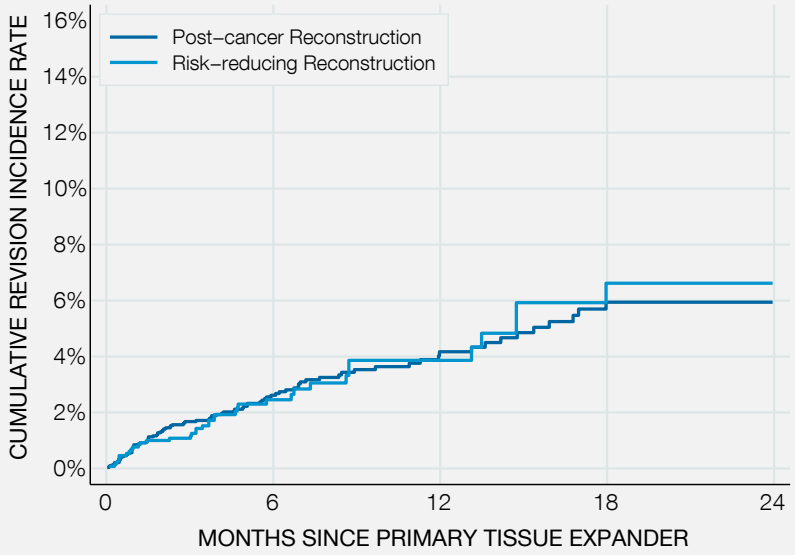
TABLE 14. ISSUES IDENTIFIED AT REVISION PROCEDURE – RECONSTRUCTIVE TISSUE EXPANDERS

Complications and Issues Identified at Revision	2012-2018		2017		2018	
(N.B. Not complication rates)	N	(%)	N	(%)	N	(%)
Deep wound infection	55	(21.9%)	20	(26.0%)	18	(18.8%)
Capsular contracture	43	(17.1%)	9	(11.7%)	17	(17.7%)
Device rupture	41	(16.3%)	13	(16.9%)	17	(17.7%)
Device deflation	41	(16.3%)	10	(13.0%)	17	(17.7%)
Seroma/Haematoma	39	(15.5%)	13	(16.9%)	15	(15.6%)
Device malposition	32	(12.7%)	10	(13.0%)	8	(8.3%)
Skin scarring problems	29	(11.6%)	3	(3.9%)	16	(16.7%)
Breast cancer	15	(6.0%)	5	(6.5%)	3	(3.1%)
TOTAL REVISION PROCEDURES	**251**		**77**		**96**	

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

Time-to-revision analysis using survival analysis methods[6] was conducted to investigate revision incidence rates for primary reconstructive tissue expanders. Revision time was defined as the time from the insertion of the tissue expander to the first subsequent unplanned revision procedure. Crude cumulative revision incidence rates were generated using Nelson-Aalen estimates for all primary reconstructive tissue expanders captured by the ABDR since 2012 to 2018. Figure 21 provides an all-cause revision incidence curve for post-cancer and risk-reducing reconstruction. All-cause revision incidence rates at time intervals after the date of tissue expander insertion are also reported in Table 15. All-cause revision incidence considers all revisions captured by the registry, whether for complication reasons, patient preference or other unknown reasons. In this case, breasts without a revision procedure captured by the registry had their follow-up time censored at the date of data extraction (19 March, 2019). At 12 months after the date of primary tissue expander insertion, 4.2% of tissue expanders for post-cancer reconstruction were revised for the first time; and 3.9% of tissue expanders for risk-reducing reconstruction were revised for the first time.

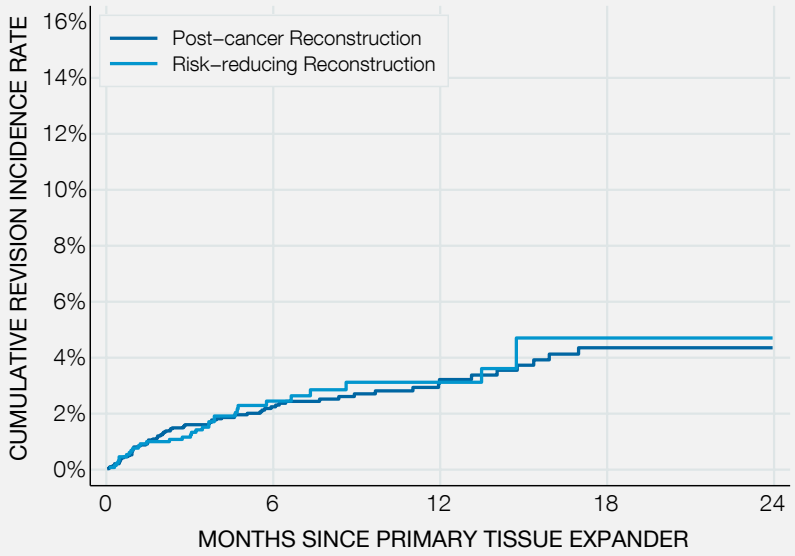
FIGURE 21. ALL-CAUSE REVISION INCIDENCE – RECONSTRUCTIVE PRIMARY TISSUE EXPANDERS



NUMBER AT RISK

2,851	1,610	697	408	287	Post–cancer
1,307	594	231	143	90	Risk–reducing

FIGURE 22. REVISION INCIDENCE DUE TO COMPLICATION – RECONSTRUCTIVE PRIMARY TISSUE EXPANDERS



NUMBER AT RISK

2,851	1,610	697	408	287	Post–cancer
1,307	594	231	143	90	Risk–reducing

Figure 22 provides revision incidence due to complication curves for post-cancer and risk-reducing reconstruction. Revision incidence rates due to complication are also reported in Table 15. Revision incidence due to complication considers all revisions captured by the registry that occurred due to complication. A revision due to complication in this case was defined as revisions that stated complication as the reason for revision and/or an issue was identified at revision (issues included any of device rupture, device deflation, capsular contracture, device malposition, skin scarring problems, deep wound infection, seroma/haematoma and ALCL). Breasts without a revision procedure due to complication captured by the registry had their follow-up time censored at either the date of a revision procedure that occurred due to other reasons or the date of data extraction (19 March, 2019) if no revision was captured. At 12 months after the date of primary tissue expander insertion, revision incidence due to complication was 3.2% for post-cancer reconstruction and 3.1% for risk-reducing reconstruction.

TABLE 15. REVISION INCIDENCE: ALL-CAUSE AND WITH COMPLICATION – RECONSTRUCTIVE PRIMARY TISSUE EXPANDERS

	Post-cancer	Risk-reducing
Number of Primary Tissue Expanders	2,851	1,307
Number Revised: All-cause	93	39
Number Revised: With Complication	75	33
All-cause Revision Incidence (95% Confidence Interval)		
6 months since primary tissue expander	2.6 (2.1, 3.3)	2.5 (1.7, 3.6)
12 months since primary tissue expander	4.2 (3.3, 5.3)	3.9 (2.6, 5.7)
18 months since primary tissue expander	5.9 (4.6, 7.7)	6.6 (4.3, 10.2)
24 months since primary tissue expander	5.9 (4.6, 7.7)	6.6 (4.3, 10.2)
Revision Incidence Due to Complication (95% Confidence Interval)		
6 months since primary tissue expander	2.3 (1.7, 2.9)	2.5 (1.7, 3.6)
12 months since primary tissue expander	3.2 (2.5, 4.2)	3.1 (2.1, 4.6)
18 months since primary tissue expander	4.4 (3.3, 5.8)	4.7 (3.0, 7.5)
24 months since primary tissue expander	4.4 (3.3, 5.8)	4.7 (3.0, 7.5)

Notes: Revision incidence is based on reconstructive primary tissue expanders inserted from 2012 to 2018. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary tissue expander insertion date to the first revision procedure.

REGISTRY OUTPUTS: AESTHETIC INDICATIONS

The ABDR has captured a total of 29,202 surgical procedures involving breast devices with aesthetic indication. The aesthetic procedures captured include procedures for cosmetic augmentation only, reported either unilaterally or bilaterally. Figure 23 shows a rise in the annual number of aesthetic procedures captured in each year since registry commencement until 2017, and then a slight drop in the number of procedures in 2018. In 2018, 9,337 aesthetic procedures were captured, 97% were bilateral cosmetic augmentations and 3% were unilateral cosmetic augmentation (Table 16).

Aesthetic Procedure Numbers

FIGURE 23. REGISTERED PROCEDURES – AESTHETIC (2012 – 2018)

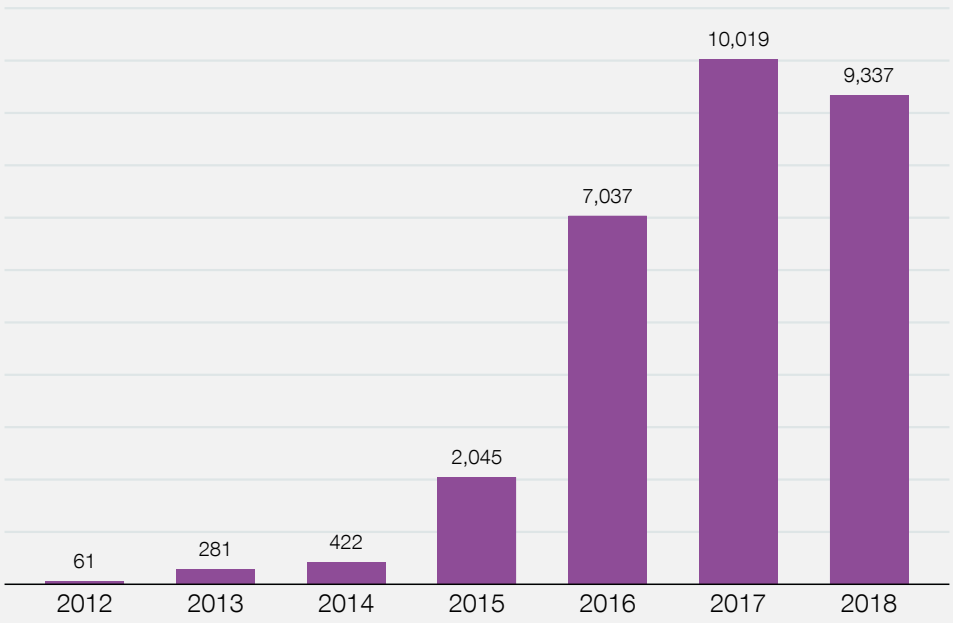


TABLE 16. PROCEDURE TYPE – AESTHETIC

	2012-2018		2017		2018	
	N	(%)	N	(%)	N	(%)
Cosmetic Augmentation						
Bilateral	28,382	(97.2%)	9,783	(97.6%)	9,055	(97.0%)
Unilateral	820	(2.8%)	236	(2.4%)	282	(3.0%)
TOTAL AESTHETIC PROCEDURES	**29,202**	**(100%)**	**10,019**	**(100%)**	**9,337**	**(100%)**

Patient Age at Aesthetic Procedures

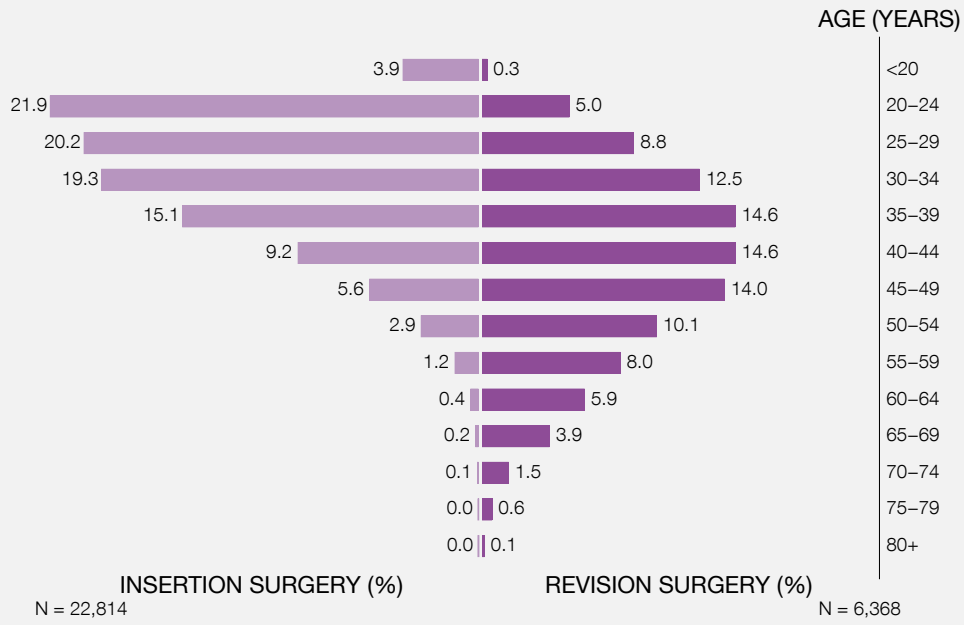
The age distribution at the time of aesthetic procedure is shown in Table 17 and Figure 24. A difference can be seen by whether the procedure involved device insertion or revision. In 2018, the median age at cosmetic augmentation was 31 years for insertion surgery and higher at 43 years for revision surgery.

TABLE 17. SUMMARY STATISTICS FOR PATIENT AGE AT TIME OF AESTHETIC PROCEDURES

	Insertion Surgery			Revision Surgery		
	2012-2018	2017	2018	2012-2018	2017	2018
Cosmetic Augmentation						
N	22,814	8,145	6,892	6,368	1,873	2,440
Mean Age (Standard deviation)	32.4 (9.3)	32.0 (9.2)	32.4 (9.3)	43.9 (12.5)	43.6 (12.3)	44.4 (12.5)
Median Age (Interquartile range)	31.0 (24.8, 38.1)	30.5 (24.5, 37.6)	31.0 (24.8, 38.1)	43.0 (34.5, 52.4)	43.1 (34.4, 51.4)	43.3 (34.9, 52.9)

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

FIGURE 24. AGE DISTRIBUTION FOR AESTHETIC PROCEDURES (2012 – 2018)



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

Aesthetic Procedure Techniques and Elements

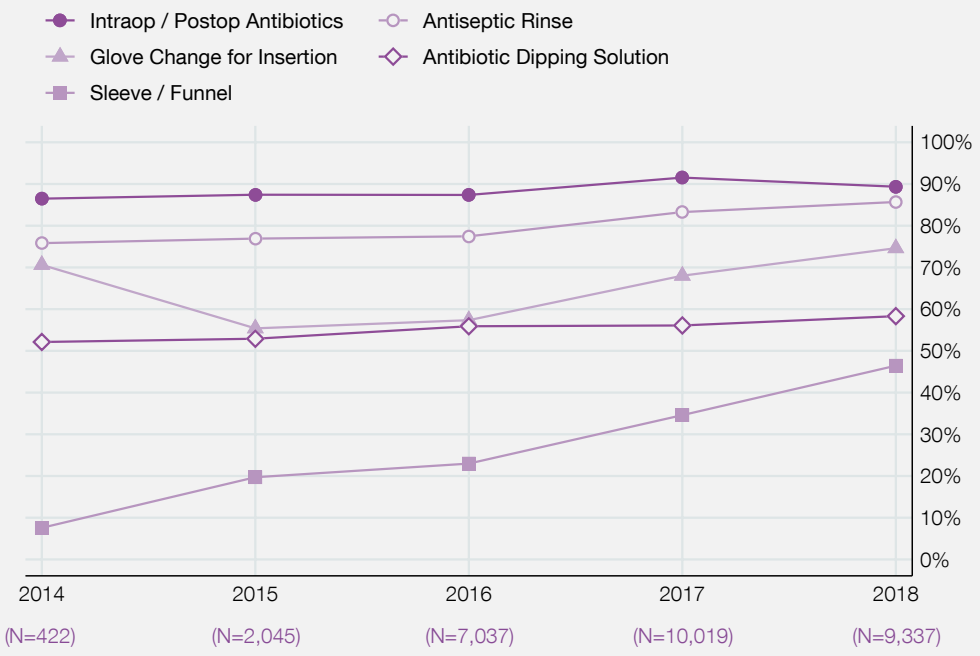
Aesthetic procedures captured by the registry in 2018 were predominately reported in private facilities, 99.8% (6,875) for insertion surgery and 98.1% (2,393) for revision surgery. Table 18 and Figure 25 show the intraoperative techniques used during aesthetic procedures. More than one intraoperative technique can be used and recorded per procedure. In 2018, the use of intraoperative and/or postoperative antibiotics (89%), antiseptic rinse (86%) and glove change for insertion (75%) were commonly reported for aesthetic procedures. Less frequently reported intraoperative techniques included antibiotic dipping solution (58%) and sleeve/funnel (46%) in 2018.

TABLE 18. INTRAOPERATIVE TECHNIQUES – AESTHETIC PROCEDURES

	2012-2018		2017		2018	
	N	(%)	N	(%)	N	(%)
Intraop / Postop antibiotics*	26,109	(89.4%)	9,172	(91.5%)	8,343	(89.4%)
Antiseptic rinse	23,942	(82.0%)	8,343	(83.3%)	8,001	(85.7%)
Glove change for insertion	19,503	(66.8%)	6,815	(68.0%)	6,967	(74.6%)
Antibiotic dipping solution	16,443	(56.3%)	5,620	(56.1%)	5,446	(58.3%)
Sleeve / Funnel	9,874	(33.8%)	3,466	(34.6%)	4,337	(46.4%)
Not stated	1,947	(6.7%)	510	(5.1%)	622	(6.7%)
TOTAL	**29,202**		**10,019**		**9,337**	

Notes: More than one intraoperative technique can be used and recorded per procedure.
* Includes cases were intraoperative and/or postoperative antibiotics were administered.

FIGURE 25. INTRAOPERATIVE TECHNIQUES – AESTHETIC PROCEDURES (2014 – 2018)



From 2012-2018 the most common surgical plane used during aesthetic procedures was a sub-pectoral plane, 80% when involving device insertion and 64% when involving device revision (Table 19). The inframammary fold was the most commonly used incision site reported for cosmetic augmentations during 2012 to 2018 (Table 19). Table 20 details other surgical elements reported during aesthetic breast procedures. Concurrent mastopexy/reduction occurred in 10% of cosmetic augmentations involving device insertion and 15% involving device revision. Drains were used in 12% of cosmetic augmentations involving device insertion and in 36% involving device revision. A nipple guard or shield was used during 75% of cosmetic augmentations involving device insertion and during 55% involving device revision.

TABLE 19. SURGICAL PLANE AND INCISION SITE – AESTHETIC PROCEDURES

	Insertion Surgery 2012-2018		Revision Surgery 2012-2018	
	N	(%)	N	(%)
Plane				
Sub-pectoral	36,422	(80.0%)	7,633	(63.6%)
Sub-glandular / Sub-fascial	5,192	(11.4%)	2,322	(19.4%)
Dual	688	(1.5%)	134	(1.1%)
Other	163	(0.4%)	48	(0.4%)
Not stated	3,080	(6.8%)	1,862	(15.5%)
Incision Site				
Infra-mammary	38,959	(85.5%)	9,027	(75.2%)
Mastopexy/reduction wound	3,081	(6.8%)	1,583	(13.2%)
Areolar	500	(1.1%)	282	(2.4%)
Axillary	183	(0.4%)	40	(0.3%)
Other	80	(0.2%)	61	(0.5%)
Not stated	2,939	(6.5%)	1,087	(9.1%)
TOTAL	**45,545**		**11,999**	

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

TABLE 20. OTHER SURGICAL ELEMENTS – AESTHETIC PROCEDURES

	Insertion Surgery 2012-2018		Revision Surgery 2012-2018	
	N	(%)	N	(%)
Concurrent Mastopexy/Reduction				
Yes	4,704	(10.3%)	1,804	(15.0%)
No	37,764	(82.9%)	8,822	(73.5%)
Not stated	3,077	(6.8%)	1,373	(11.4%)
Concurrent Flap Cover				
Yes	33	(0.1%)	49	(0.4%)
No	42,112	(92.5%)	10,424	(86.9%)
Not stated	3,400	(7.5%)	1,526	(12.7%)
Previous Mastopexy/Reduction				
Yes	402	(0.9%)	751	(6.3%)
No	40,848	(89.7%)	9,128	(76.1%)
Not stated	4,295	(9.4%)	2,120	(17.7%)
Fat Grafting				
Yes	303	(0.7%)	204	(1.7%)
No	38,844	(85.3%)	9,877	(82.3%)
Not stated	6,398	(14.0%)	1,918	(16.0%)
Drains Used				
Yes	5,448	(12.0%)	4,270	(35.6%)
No	40,097	(88.0%)	7,727	(64.4%)
Not stated	0	(0.0%)	2	(<0.1%)
Nipple Guard/Shield				
Yes	34,068	(74.8%)	6,559	(54.7%)
No	11,477	(25.2%)	5,438	(45.3%)
Not stated	0	(0.0%)	2	(<0.1%)
TOTAL	**45,545**		**11,999**	

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

Device Characteristics for Cosmetic Augmentation

Table 21 provides device shell, fill and shape characteristics for breast implants inserted for cosmetic augmentation during an insertion procedure or a replacement revision procedure. In 2018, 41% of the breast implants inserted in registry participants for cosmetic augmentation were silicone implants with smooth shell and round shape, 29% were silicone implants with textured shell and anatomical shape and 25% were silicone implants with textured shell and round shape.

TABLE 21. DEVICE CHARACTERISTICS – AESTHETIC BREAST IMPLANTS

	2012-2018		2017		2018	
	N	(%)	N	(%)	N	(%)
Silicone Implants						
Textured | Anatomical	16,942	(30.0%)	5,785	(29.6%)	5,195	(29.1%)
Textured | Round	19,232	(34.0%)	6,829	(34.9%)	4,538	(25.3%)
Smooth | Round	16,698	(29.5%)	5,799	(29.7%)	7,234	(40.6%)
Polyurethane | Anatomical	2,190	(3.9%)	675	(3.5%)	531	(3.0%)
Polyurethane | Round	871	(1.5%)	278	(1.4%)	215	(1.2%)
Saline Implants						
Textured | Round	17	(<0.1%)	4	(<0.1%)	10	(0.1%)
Smooth | Round	575	(1.0%)	167	(0.9%)	120	(0.7%)
Silicone/Saline Implants						
Textured | Anatomical	3	(<0.1%)	1	(<0.1%)	2	(<0.1%)
Textured | Round	3	(<0.1%)	3	(<0.1%)	0	(0.0%)
Not Stated	23	(<0.1%)	0	(0.0%)	8	(<0.1%)
TOTAL	**56,554**	**(100%)**	**19,541**	**(100%)**	**17,823**	**(100%)**

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

Complications and Revision Incidence – Aesthetic Breast Implants

Table 22 reports issues identified during aesthetic revisions of breast implants. Multiple issues can be recorded per revision and issues were either identified as a reason for the revision or found incidentally during the revision procedure. Table 22 reports the issues identified at all aesthetic revisions of breast implants, including revisions for breasts where the insertion of the initial implant may or may not have also been captured by the registry. A more detailed revision and complication analysis follows for the primary breast implants for which the revision details can be linked to the initial inserted implant. In 2018, capsular contracture was the most common issue identified and reported for aesthetic revisions of breast implants (42%), followed by device malposition (26%), device rupture (21%) and device deflation (10%). Please also refer to the BIA-ALCL reports in the Registry Outcomes section for information relating to cases of ALCL.

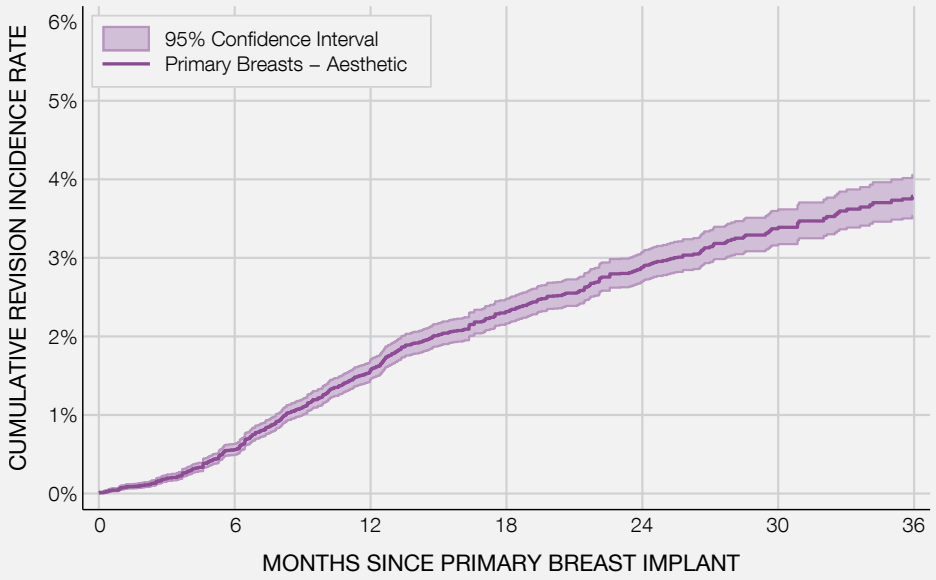
TABLE 22. ISSUES IDENTIFIED AT REVISION PROCEDURE – AESTHETIC BREAST IMPLANTS

Complications and Issues Identified at Revision (N.B. Not complication rates)	2012-2018		2017		2018	
	N	(%)	N	(%)	N	(%)
Capsular contracture	4,895	(40.9%)	1579	(44.8%)	1918	(41.6%)
Device malposition	2,879	(24.0%)	883	(25.0%)	1205	(26.1%)
Device rupture	2,442	(20.4%)	733	(20.8%)	993	(21.5%)
Device deflation	1,186	(9.9%)	370	(10.5%)	478	(10.4%)
Skin scarring problems	377	(3.1%)	132	(3.7%)	130	(2.8%)
Seroma/Haematoma	337	(2.8%)	127	(3.6%)	128	(2.8%)
Deep wound infection	96	(0.8%)	27	(0.8%)	35	(0.8%)
Breast cancer	8	(0.1%)	2	(0.1%)	3	(0.1%)
TOTAL REVISION PROCEDURES	**11,971**		**3,527**		**4,612**	

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

Time-to-revision analysis using survival analysis methods[6] was conducted to investigate revision incidence rates for primary aesthetic breast implants. Revision time was defined as the time from the insertion of the breast implant to the first subsequent revision procedure. Crude cumulative revision incidence rates were generated using Nelson-Aalen estimates for all primary aesthetic breast implants captured by the ABDR since 2012 to 2018. Figure 26 provides an all-cause revision incidence curve for cosmetic augmentation. All-cause revision incidence rates at time intervals after the date of breast implant insertion are also reported in Table 23. All-cause revision incidence considers all revisions captured by the registry, whether for complication reasons, patient preference or other unknown reasons. In this case, breasts without a revision procedure captured by the registry had their follow-up time censored at the date of data extraction (19 March, 2019). At 12 months after the date of primary breast implant insertion, 1.6% of cosmetic augmentations were revised for the first time; and 3.8% were revised for the first time at 36 months after the implant insertion.

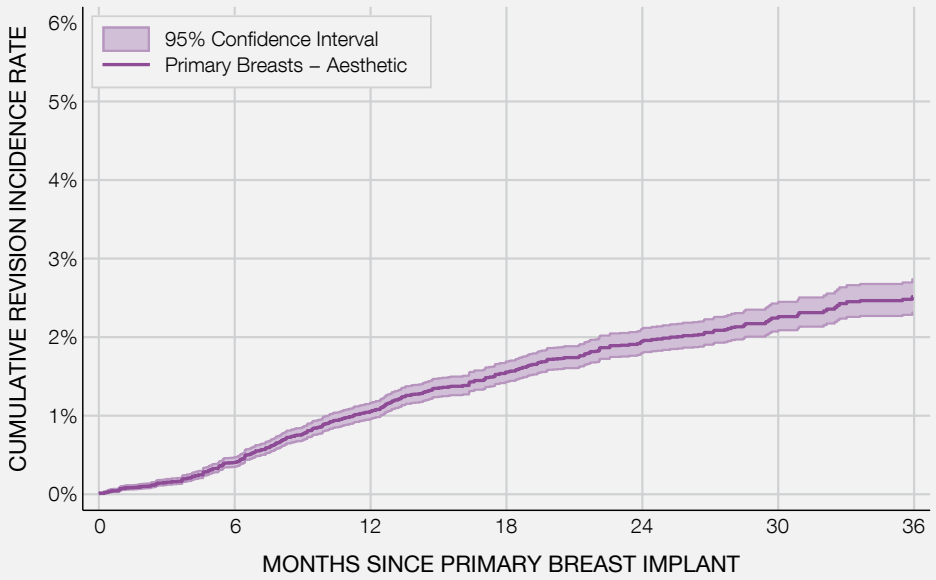
FIGURE 26. ALL-CAUSE REVISION INCIDENCE – AESTHETIC PRIMARY BREAST IMPLANTS



NUMBER AT RISK

45,455	41,367	33,949	25,709	17,668	10,725	5,662

FIGURE 27. REVISION INCIDENCE DUE TO COMPLICATION – AESTHETIC PRIMARY BREAST IMPLANTS



NUMBER AT RISK

45,455	41,367	33,949	25,709	17,668	10,725	5,662

Figure 27 provides revision incidence due to complication curves for cosmetic augmentation. Revision incidence rates due to complication are also reported in Table 23. A revision due to complication in this case was defined as revisions that stated complication as the reason for revision and/or an issue was identified at revision (issues included any of device rupture, device deflation, capsular contracture, device malposition, skin scarring problems, deep wound infection, seroma/haematoma and ALCL). Breasts without a revision procedure due to complication captured by the registry had their follow-up time censored at either the date of a revision procedure that occurred due to other reasons or the date of data extraction (19 March, 2019) if no revision was captured. Revision incidence due to complication for cosmetic augmentation was 1.1% at 12 months after the date of primary implant insertion and 2.5% at 36 months after implant insertion.

TABLE 23. REVISION INCIDENCE: ALL-CAUSE AND WITH COMPLICATION – AESTHETIC PRIMARY BREAST IMPLANTS

	All-cause	Due to complication
Number of Primary Breast Implants	45,455	45,455
Number Revised	1,115	747
Revision Incidence (95% Confidence Interval)		
6 months since primary breast implant	0.6% (0.5, 0.6)	0.4% (0.4, 0.5)
12 months since primary breast implant	1.6% (1.5, 1.7)	1.1% (1.0, 1.2)
18 months since primary breast implant	2.3% (2.2, 2.5)	1.6% (1.4, 1.7)
24 months since primary breast implant	2.9% (2.7, 3.1)	2.0% (1.8, 2.1)
30 months since primary breast implant	3.4% (3.2, 3.6)	2.3% (2.1, 2.5)
36 months since primary breast implant	3.8% (3.5, 4.1)	2.5% (2.3, 2.7)

Notes: Revision incidence is based on aesthetic primary breast implants inserted from 2012 to 2018. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary implant insertion date to the first revision procedure.

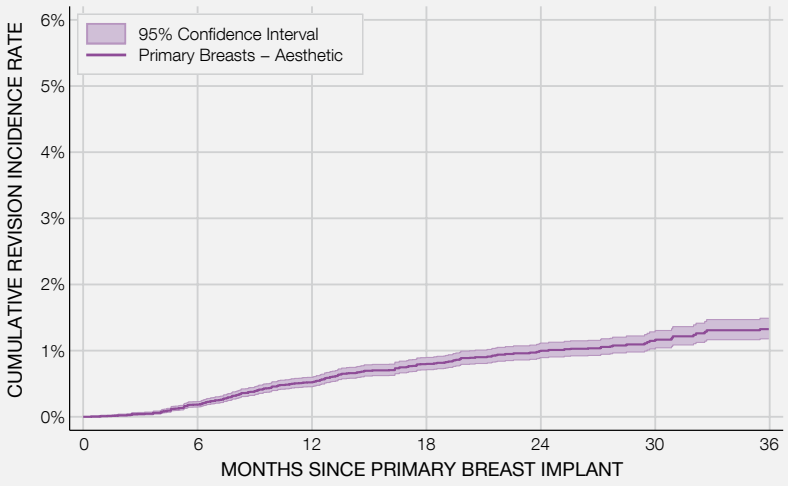
Revision incidence curves and rates for aesthetic primary breast implants were produced for revisions due to device malposition, capsular contracture and device rupture/deflation (Table 24 and Figures 28-30). Breasts without a revision procedure due to these issues were censored at either the date of a revision procedure that occurred due to other reasons or the date of data extraction (19 March, 2019) if no revision was captured. Revision incidence due to device malposition for breast implants inserted for cosmetic augmentation was 1.3% at 36 months following the date of primary implant insertion. Revision incidence due to capsular contracture for breast implants for cosmetic augmentation was 1.0% at 36 months following primary insertion. Revision incidence due to device rupture/deflation for breast implants inserted for cosmetic augmentation was 0.2% at 36 months following the date of primary insertion.

TABLE 24. REVISION INCIDENCE: DEVICE ISSUES – AESTHETIC PRIMARY BREAST IMPLANTS

	Device Malposition	Capsular Contracture	Device Deflation/ Rupture
Number of Primary Breast Implants	45,455	45,455	45,455
Number Revised	382	285	47
Revision Incidence Due to Device Issues (95% Confidence Interval)			
6 months since primary breast implant	0.19% (0.15, 0.23)	0.10% (0.07, 0.14)	0.03% (0.02, 0.05)
12 months since primary breast implant	0.52% (0.45, 0.60)	0.38% (0.32, 0.45)	0.05% (0.03, 0.08)
18 months since primary breast implant	0.80% (0.71, 0.90)	0.57% (0.50, 0.66)	0.08% (0.06, 0.12)
24 months since primary breast implant	1.00% (0.89, 1.11)	0.74% (0.65, 0.85)	0.12% (0.08, 0.17)
30 months since primary breast implant	1.17% (1.04, 1.30)	0.88% (0.77, 1.00)	0.15% (0.11, 0.21)
36 months since primary breast implant	1.32% (1.18, 1.49)	1.03% (0.90, 1.19)	0.17% (0.12, 0.23)

Notes: Revision incidence is based on aesthetic primary breast implants inserted from 2012 to 2018. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary implant insertion date to the first revision procedure.

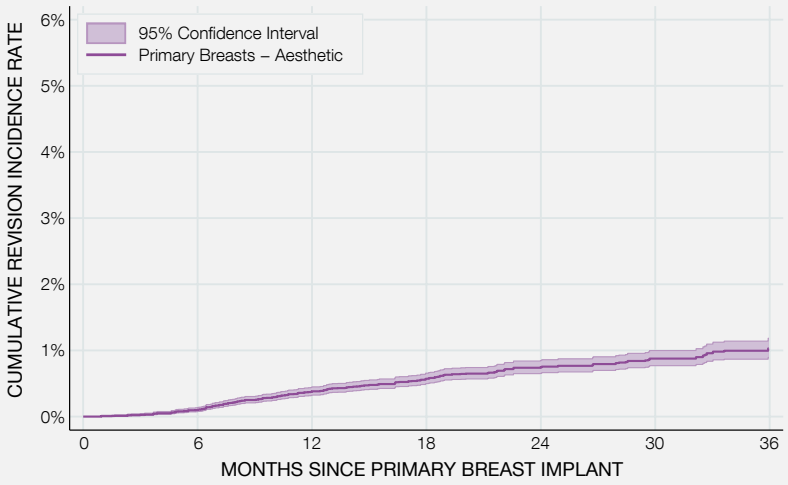
FIGURE 28. REVISION INCIDENCE DUE TO DEVICE MALPOSITION – AESTHETIC PRIMARY BREAST IMPLANTS



NUMBER AT RISK

45,455	41,367	33,949	25,709	17,668	10,725	5,662

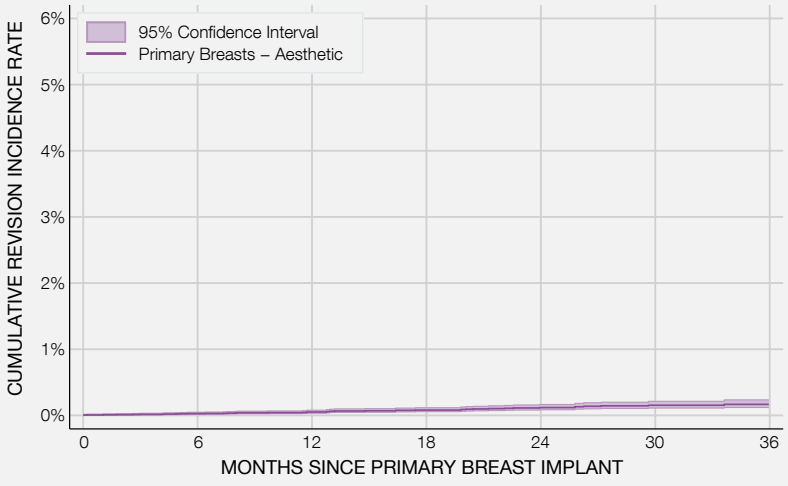
FIGURE 29. REVISION INCIDENCE DUE TO CAPSULAR CONTRACTURE – AESTHETIC PRIMARY BREAST IMPLANTS



NUMBER AT RISK

45,455	41,367	33,949	25,709	17,668	10,725	5,662

FIGURE 30. REVISION INCIDENCE DUE TO DEVICE RUPTURE/DEFLATION – AESTHETIC PRIMARY BREAST IMPLANTS



NUMBER AT RISK

45,455	41,367	33,949	25,709	17,668	10,725	5,662

REGISTRY OUTCOMES

Surgeon and Site Reporting

Surgeon

In July 2018 the ABDR released its first round of surgeon reports. These individualised, activity-based reports were sent to all surgeons who had contributed breast procedure data to the ABDR in the period to 31 December 2017 and reported data on the number of patients submitted, the number and type of procedures completed (broken down by site) and the completeness of submitted data, comparing the individual surgeon total to the ABDR aggregate total.

The surgeon reports did not provide benchmarked outcome data provided as it was recognised that data were not sufficiently mature. As the registry matures, surgeons will be invited to opt in to receive reports benchmarking their performance.[7]

Site

In September 2018 the ABDR released its first round of site reports to the top 80% of contributing sites. These site reports presented the case capture rate for the site in addition to a descriptive overview of each site's number of surgeries and use of intraoperative techniques. The reports classified sites based on case capture rate, with high capture rate >80%, medium capture rate 60-80%, and low capture rate <60%. This method of engagement enabled the ABDR to feedback to sites on their current case ascertainment and to provide suggestions on ways for sites to improve their data capture rates. Further information on the process of ascertaining the capture rate is outlined below.

International Minimum Dataset and Data Definitions

The ABDR continued to collaborate with the International Collaboration Of Breast Registry Activities (ICOBRA)[8] to progress the establishment of an international minimum dataset and data definitions. The data set and definitions were formatted into a pilot data collection form for multiple review rounds by clinicians. At the end of 2018, the modified minimum dataset and definitions were sent for final review and ratification. A peer-review manuscript was being drafted for submission in 2019.

BIA-ALCL Reports

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

At the end of 2018, 76 cases of BIA-ALCL in Australian women had been reported to the TGA.[9] The ABDR had received direct reports on 26 cases of confirmed BIA-ALCL at the end of 2018.

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

Case Ascertainment

A high-quality device registry is dependent on many factors, including ensuring that it captures a high percentage of device procedures being performed. As a national registry, it is important to ascertain the amount of data that is being captured. A pilot study was undertaken to determine an estimate on the current data capture rates across breast device surgeries in Australia utilising the standard ICD-10-AM (International Classification of Diseases 10th Revision – Australian Modification) codes. A total of ten codes were relevant for breast device related procedures (Table 25).

This pilot study was conducted over 8 months, across the top 80% of performing sites in Australia during the 2017 calendar year were counted (as calculated by the number of data collection forms submitted to the ABDR). A total of 50 sites contributed to 80% of all data captured by the ABDR. These data were then compared against the number of data collection forms received by the ABDR from that site in the same time period.

This study posed several challenges. Firstly, the process of manually collecting data from 45 sites was labour intensive and time consuming due to high staff turnover at the sites and site staff being unaware of the right person to extract data. Diverse types of complicated software systems used in the hospitals made it difficult for sites to extract the data fields required for the study. We undertook further investigation to identify reasons if there was low data capture, and we identified that miscoding of data at sites, multiple procedures filled in one data collection form, and lack of communication between site staff resulting in misplaced data collection forms were the main reasons of discrepancy in data capture rates.

Due to the labour-intensive process of collecting this data, we sought to collect aggregate non-identifiable data from state departments of health throughout Australia. This would enable the ABDR to have a rough aggregate data capture rate that could prompt the ABDR to re-engage with sites that have low data capture rates, and if required, request specific sites to give ICD-10-AM data for a particular time period to work through reasons for low capture rates specific to that site. Agreements had been put into place through departments of health in some states, with others refusing due to low numbers of procedures or not collecting these data. The ABDR also approached the Australian Institute of Health and Welfare (AIHW) as a universal one-stop destination to collect aggregate data on breast device procedures in Australia but due to cost and ethics barriers, this was not pursued further.

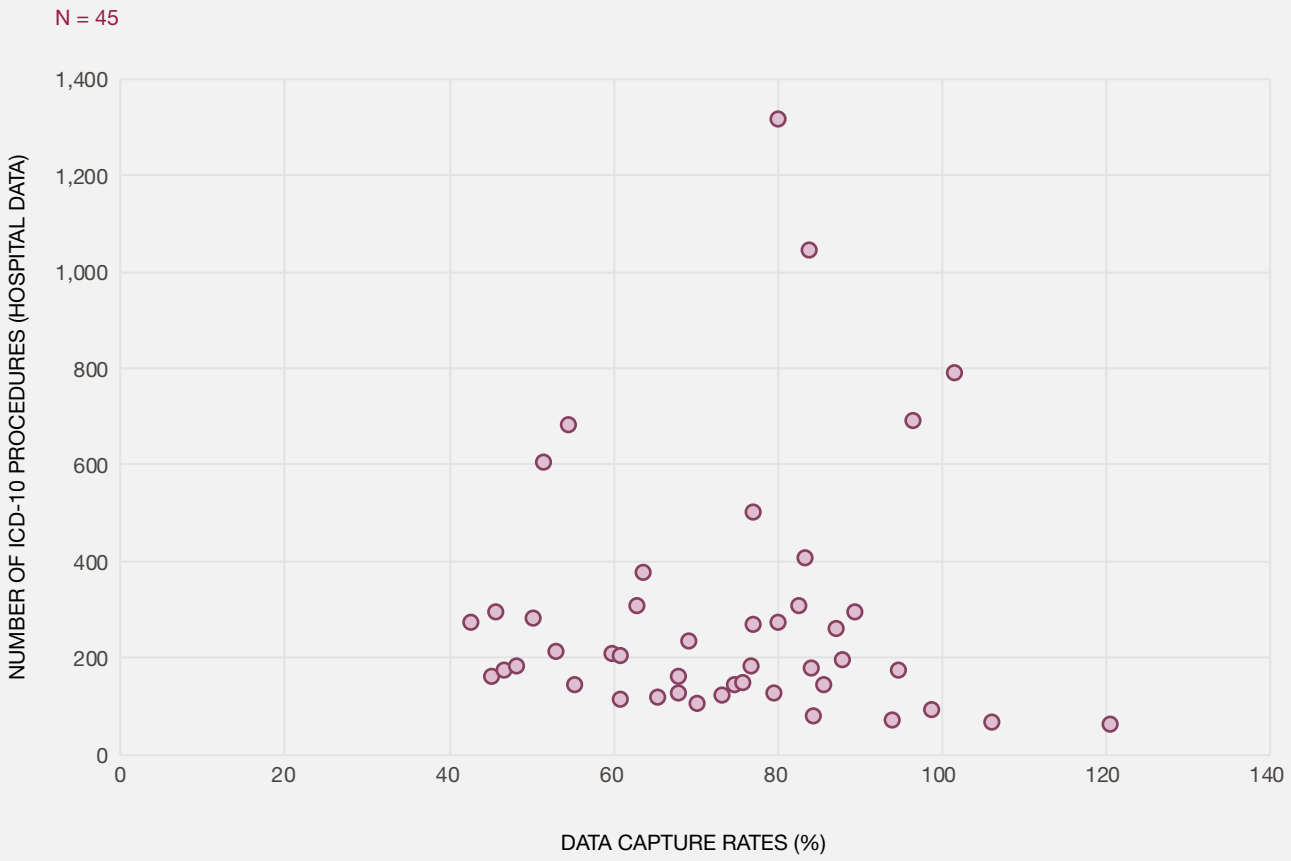
Lastly, six main hospital groups [Ramsay (36 sites for second quarter of 2018), Healthscope (20 sites), Epworth (6 sites), St John of God (12 sites), Cabrini (2 sites), Uniting Care (2 sites)] were approached to provide ICD-10-AM data for all their sites, and all groups provided data quickly and efficiently. Both high and low volume sites data were captured in this method and enabled us to report the case ascertainment directly to the hospital group.

In future, the ABDR hopes to re-engage with the state departments of health to acquire aggregate data for all breast device procedures performed in Australia.

TABLE 25: LIST OF ICD-10-AM CODES INVOLVING BREAST DEVICE PROCEDURES FOR AUGMENTATION AND RECONSTRUCTION USED IN THIS STUDY

Block No	ICD-10-AM Code	Description
1753	**Repair (Augmentation mammoplasty – insertion of a prosthesis)**	
	45524-00	Augmentation mammoplasty, unilateral
	45528-00	Augmentation mammoplasty, bilateral
	45527-00	Augmentation mammoplasty, following mastectomy, unilateral
	45527-01	Augmentation mammoplasty, following mastectomy, bilateral
1756	**Reconstruction procedures on breast**	
	45539-00	Reconstruction of breast with insertion of tissue expander
1758	**Procedures involving removal or adjustment of breast prosthesis or tissue expander**	
	45548-02	Adjustment of breast tissue expander Relocation of breast tissue expander
	45548-01	Removal of breast tissue expander
	45542-00	Removal of breast tissue expander and insertion of permanent prosthesis
	45548-00	Removal of breast prosthesis - Includes capsulotomy - Includes excision of fibrous capsule (capsulectomy) - Excludes that with replacement
	45552-00	Replacement of breast prosthesis - Includes capsulotomy - Includes excision of fibrous capsule - Includes formation of new pocket

FIGURE 31: DATA CAPTURE FOR TOP 80% CONTRIBUTING SITES



Notes: These data pertain to 2017. Four sites contributed more data to the ABDR than ICD-10-AM data recorded by the sites.

Patient Reported Outcome Measures

The ABDR implemented registry wide Patient Reported Outcome Measures (PROMs) in 2018 following a successful pilot.[10] Patients were contacted by text message at different time periods after their procedure (1, 2 and 5 years) and invited to answer a series of five questions relating to their breast device (BREAST-Q IS, Appendix 3). Patients were followed up with a reminder text message and then contacted by an alternative method including phone, email and regular post.

From October 2017 to December 2018, a total of 9,204 patients who had received breast augmentation were contacted and 1,413 who had received breast reconstruction were contacted. Of the patients contacted, 5,399 (59%) patients with breast augmentation and 1,082 (77%) patients with breast reconstruction responded to the follow up PROMs questions.

Of the patients in the breast reconstruction cohort, the following number of patients were contacted:
Year-1, 755 patients (606, 78% responded);
Year-2, 562 patients (420, 75% responded);
Year-5, 76 patients (56, 74% responded).

Of the patients in the breast augmentation cohort, the following number of patients were contacted:
Year-1, 5,372 patients (3,301, 61% response rate);
Year-2, 3,696 patients (2,032, 55% responded),
Year-5, 136 patients (67, 49% responded).

Mobile phone numbers proved to have the highest completion rates among all methods of contact and patient opt out of PROMs follow up was very low at 1% for breast augmentation patients and 0.8% for breast reconstruction patients.

The results of the Breast-Q IS are shown in Figures 32-35. Patients were contacted at Year-1, or Year-2 or Year-5 post-operatively, so the results cannot be interpreted as describing the patient journey over time. As the data matures we will be able to track PROMs over time. Overall for patients with breast reconstruction, satisfaction with look, feel and rippling were high for approximately three-quarters, with about one-quarter reporting dissatisfaction. A minority of patients with breast reconstruction experienced pain and tightness most or all of the time. Overall for patients with breast augmentation, satisfaction with look, feel and rippling was generally high, although with a small proportion of patients who were either dissatisfied or very dissatisfied. Over 60% of patients with breast augmentation experienced no pain or tightness.

The ABDR is working towards further validating the BREAST-Q IS PROMs tool and currently performing a test-retest reliability study on 200 registry patients.

FIGURE 32: SATISFACTION LEVEL OF BREAST RECONSTRUCTION PATIENTS AT 1, 2 AND 5 YEARS POSTOPERATIVE

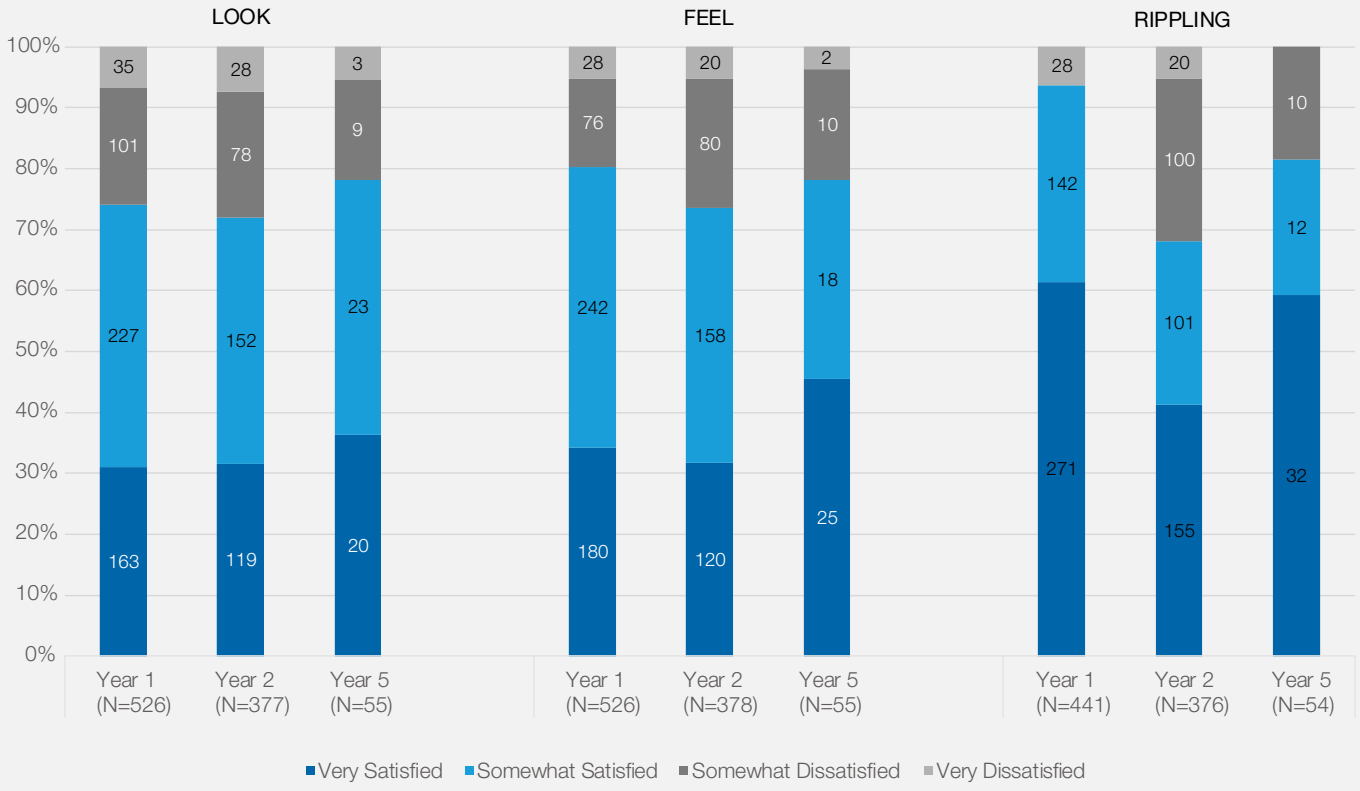


FIGURE 33: EXPERIENCE OF BREAST RECONSTRUCTION PATIENTS AT 1, 2 AND 5 YEARS POSTOPERATIVE

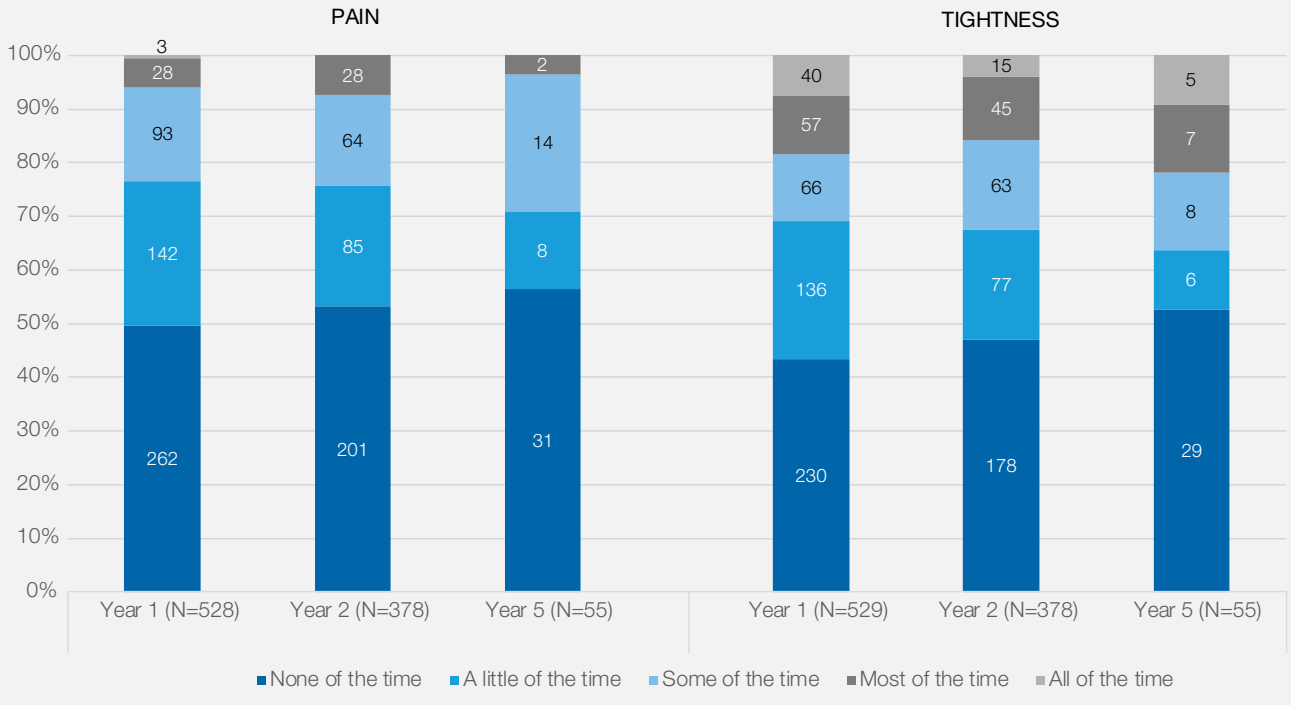


FIGURE 34: SATISFACTION LEVEL OF BREAST AUGMENTATION PATIENTS AT 1, 2 AND 5 YEARS POSTOPERATIVE.

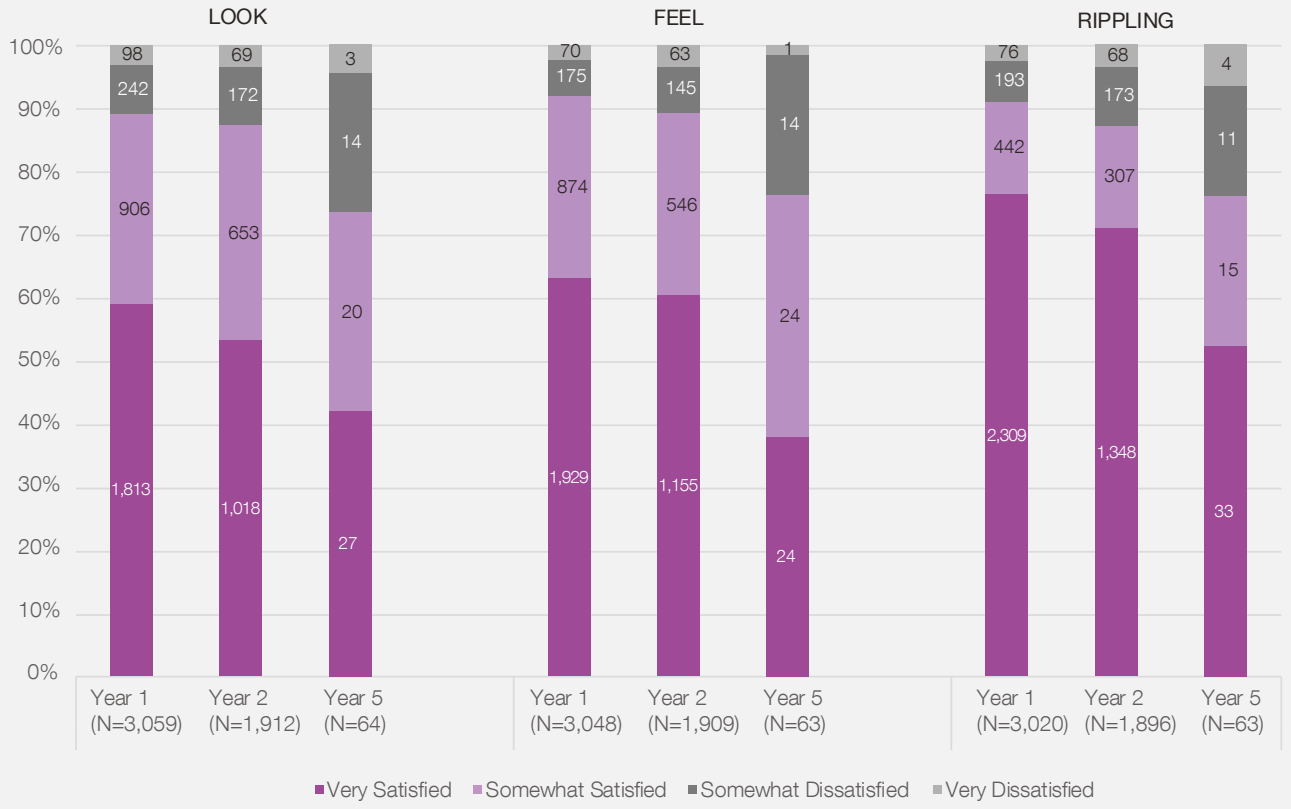
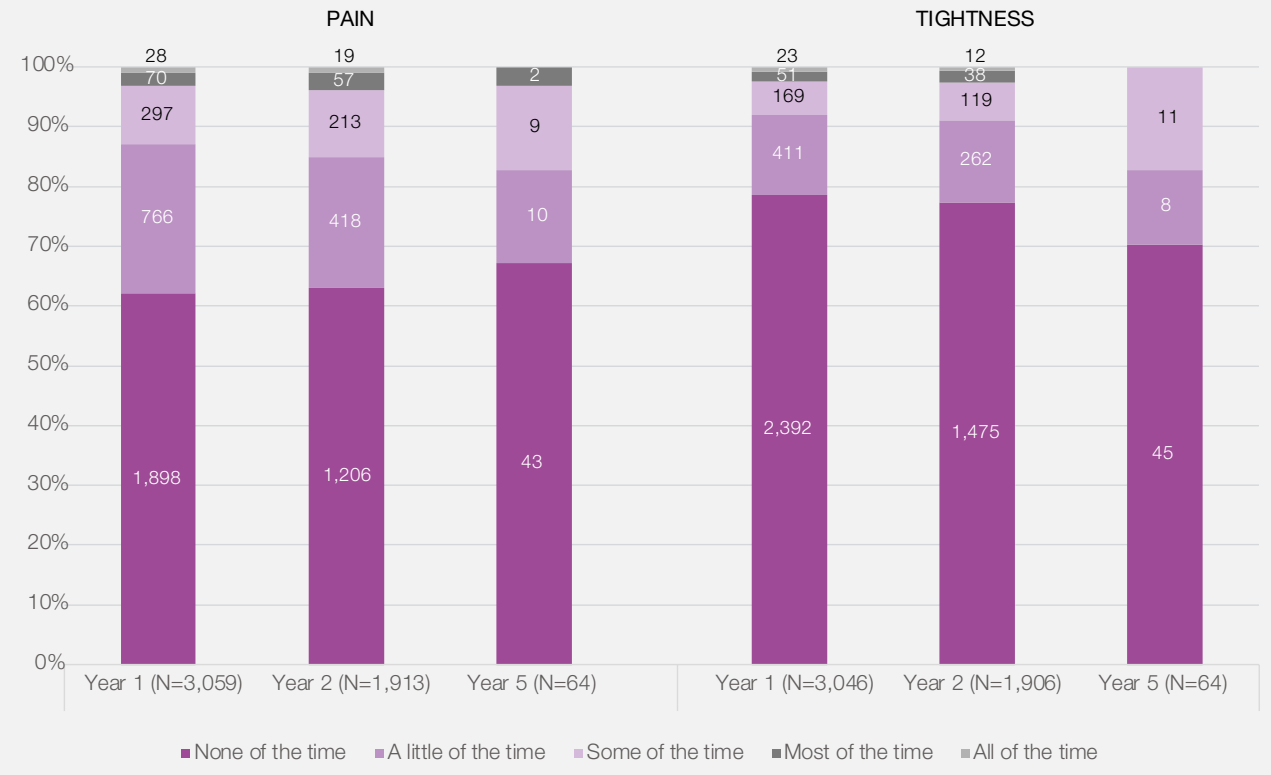


FIGURE 35: EXPERIENCE OF BREAST AUGMENTATION PATIENTS AT 1, 2 AND 5 YEARS POSTOPERATIVE.



FUTURE INITIATIVES

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

We anticipate that data from the ABDR will become increasingly important to drive continuous quality improvement in healthcare. We plan to provide more detailed reports back to surgeons' including their choice of process measures of care. The federal government has indicated its increasing commitment to continuous quality improvement. The Draft National Clinical Quality Registry Strategy sets out the blue print for clinical quality registries in the future. We will continue to work with relevant stakeholders to ensure that the ABDR data are appropriately protected, so surgeons can review their own performance and opt in benchmarked reports can be provided in due course.

We will continue to engage our stakeholders to ensure all Australians are offered the opportunity to have their breast device data recorded on the ABDR at the time of breast device surgery. In 2019 we will be undertaking a consumer engagement strategy to raise awareness about the registry and educate consumers to ask for a surgeon who contributes to the ABDR.

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

The ABDR will continue to work with other research collaborators. We will continue our work together with the TGA and Macquarie research group to address the important issue of breast implant associated anaplastic large cell lymphoma. We welcome further collaborations with researchers, and new areas of research and new collaborations will be engaged.

Work is being undertaken with the ICOBRA registries including Netherlands, Sweden, UK and US towards a combined annual report examining breast devices across these countries. Aggregate non-identifiable data will be analysed in the same manner by each of the countries, and it is planned that these analyses will be compared, and combined into a larger report. This will be the first time an international report on breast device surgery will be created, and will establish the foundation for further international reports in the future.

As part of efforts to establish the capacity of comparing breast devices between countries, we are working with ICOBRA registries, medical device regulators and representatives of industry on an international device library. This will ensure that when analyses of devices are undertaken in different countries devices will be compared to like devices. This includes consistent coding of characteristics such as surface texture, and we will be working with regulators internationally on surface texture standards.

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

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PUBLICATIONS 2018

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GLOSSARY

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

REGISTRY PERSONNEL

Steering Committee Representatives

Australasian College of Cosmetic Surgery (ACCS) - **www.accs.org.au**
Australian Commission on Safety and Quality in Health Care (ACSQHC) - **www.safetyandquality.gov.au**
Australian Society of Plastic Surgeons (ASPS) - **www.plasticsurgery.org.au**
Breast Surgeons of Australia and New Zealand (BreastSurgANZ) - **www.breastsurganz.com**
Consumers Health Forum of Australia (CHF) - **https://chf.org.au/**
Department of Health (Health) - **www.health.gov.au (observer only)**
Medical Technology Association of Australia (MTAA) - **www.mtaa.org.au**
Therapeutic Goods Administration (TGA) - **www.tga.gov.au**

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Mureau, Marc (Netherlands)
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LIST OF FIGURES

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APPENDIX 1– DATA COLLECTION FORM

AUSTRALIAN Breast Device REGISTRY

AUSTRALIAN BREAST DEVICE REGISTRY FORM

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

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

Patient UR # : ☐☐☐☐☐☐☐☐☐☐☐☐

Medicare # : ☐☐☐☐☐☐☐☐☐☐☐☐

Surname : _____

First name: _____ Middle Name: _____

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

Address : _____

_____ State: ☐☐☐ P/code: ☐☐☐☐

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

Mobile : ☐☐☐☐☐☐☐☐☐☐

Email : _____

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

SITE DETAILS:

Site Name: _____

Suburb: _____ State: _____

Surgeon name: _____

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

RETURN FORM:

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

AFFIX **RIGHT DEVICE** STICKER

[COMPLETE IF NO DEVICE STICKER]

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

AFFIX **LEFT DEVICE** STICKER

[COMPLETE IF NO DEVICE STICKER]

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

AFFIX **MESH/DERMAL SHEET** STICKER

[COMPLETE IF NO DEVICE STICKER]

MESH/DERMAL SHEET: Yes ☐ No ☐

Manufacturer: _____
Reference no: _____
Serial no: _____

AFFIX **MESH/DERMAL SHEET** STICKER

[COMPLETE IF NO DEVICE STICKER]

MESH/DERMAL SHEET: Yes ☐ No ☐

Manufacturer: _____
Reference no: _____
Serial no: _____

PATIENT HISTORY:

RIGHT BREAST

☐ Tick if Same Bilateral

Category of operation

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

Operation type

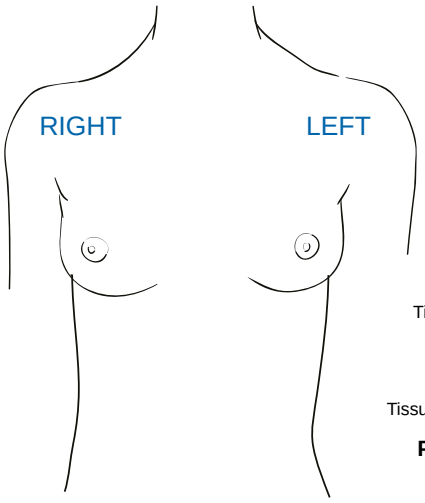
Initial (new device)

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

Revision of in situ device

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

Previous Radiotherapy ☐ Yes ☐ No



BREAST **LEFT**

Category of operation

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

Operation type

Initial (new device)

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

Revision of in situ device

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

Previous Radiotherapy ☐ Yes ☐ No

PLEASE COMPLETE OVER PAGE

ABDR_Data Collection Form_v1.0_20150310

ELEMENTS OF OPERATION

RIGHT BREAST

☐ Tick if Same Bilateral

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

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

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

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

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

BREAST LEFT

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

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

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

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

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

INTRAOPERATIVE TECHNIQUES

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

RIGHT BREAST

☐ Tick if Same Bilateral

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

BREAST LEFT

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

FOR REVISION SURGERY ONLY

RIGHT BREAST

☐ Tick if Same Bilateral

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

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

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

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

Reason for Revision
☐ Complication ☐ Asymptomatic ☐ Patient Preference

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

Details : .....

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

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

BREAST LEFT

☐ Tick if Same Bilateral

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

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

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

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

Reason for Revision
Complication ☐ Asymptomatic ☐ Patient Preference ☐

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

Details : .....

☐ Tick if Same Bilateral

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

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

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

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APPENDIX 2 – LIST OF PARTICIPATING SITES AS AT DECEMBER 2018

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

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

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

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

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

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

APPENDIX 3 – BREAST Q IMPLANT SURVEILLANCE

BREAST-Q IS AUGMENTATION ITEMS

Answer these questions thinking of the breast you are least satisfied with.

Please state which breast you are least satisfied with:

No Difference ◯ Right Breast ◯ Left Breast ◯

In the past week, how satisfied or dissatisfied have you been with:

	Very Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Very Satisfied
a. How do you look in the mirror unclothed?	1	2	3	4
b. How your breast(s) feel(s) to touch?	1	2	3	4
c. The amount of rippling (wrinkling) of your implant(s) that you can see?	1	2	3	4

In the past week, how often have you experienced:

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
a. Pain in your breast area?	1	2	3	4	5
b. Tightness in your breast area?	1	2	3	4	5

Would you like to add any comments?

BREAST-Q IS RECONSTRUCTION ITEMS

If you have had implant surgery of both breasts, answer these questions thinking of the breast you are least satisfied with.

Please state which breast you are least satisfied with:

No Difference ◯ Right Breast ◯ Left Breast ◯

In the past week, how satisfied or dissatisfied have you been with:

	Very Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Very Satisfied
a. How do you look in the mirror unclothed?	1	2	3	4
b. How your breast(s) feel(s) to touch?	1	2	3	4
c. The amount of rippling (wrinkling) of your implant(s) that you can **see**?	1	2	3	4

In the past week, how often have you experienced:

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
a. Pain in your reconstructed breast(s) area?	1	2	3	4	5
b. Tightness in your reconstructed breast(s) area?	1	2	3	4	5

Would you like to add any comments?

APPENDIX 4 – DATA COMPLETENESS

The ABDR is designed to collect information about surgical procedures involving breast implants, tissue expanders and acellular dermal/synthetic matrices if used. The current data collection process entails:

1. Surgeon performs an insertion procedure or revision procedure involving a breast implant or tissue expander and completes the ABDR data collection form (Appendix 1);
2. The surgeon or operating theatre staff return the completed form to the ABDR;
3. ABDR staff enter the data from the data collection form into the ABDR database;
4. ABDR staff perform data intuitive checks and data validation rules have been built into the ABDR database to ensure data quality before commencement of data analysis activities

A summary of the completeness of data elements captured within the ABDR database for procedures in 2016, 2017 and 2018 is presented below. Noticeable improvements in data completeness for procedures in 2017 were seen and this high level of data completeness was maintained for procedures in 2018. Regular review of incoming forms, imputation of missing data where possible and promptly following up with missing key data fields are strategies that have contributed to this attainment. Email addresses are not provided on the hospital patient label, so attempts are being made to capture these at the time of PROMs follow up. Explanted device characteristics are infrequently provided by surgeons, as these data are commonly not available to the explanting surgeon, however as the dataset matures, explanted device details will be present within the registry.

	2016	2017	2018
Patient Characteristics (Patient Level)	**9,143**	**12,977**	**13,050**
Name	100%	100%	100%
Surname	100%	100%	100%
Medicare number	91.0%	88.1%	87.9%
Date of birth	100%	100%	100%
Address	99.0%	98.9%	99.4%
Telephone	82.2%	82.7%	82.7%
Email	16.9%	15.1%	8.7%
Surgery Characteristics (Procedure Level)	**9,539**	**13,543**	**13,718**
Operation date	100%	100%	100%
Patient UR	100%	100%	100%
Hospital	100%	100%	100%
Surgeon	100%	100%	100%
Intraoperative Techniques	90.1%	92.1%	89.3%
Surgery Characteristics (Breast Level)	**17,989**	**25,423**	**25,457**
Side of breast	100%	100%	100%
Indication for surgery	96.2%	96.2%	94.0%
Surgery type (device insertion or revision)	99.7%	100%	99.9%
Previous radiotherapy (if indication = reconstruction)	90.5%	90.0%	90.4%
Incision site	91.7%	93.5%	89.5%
Plane	87.7%	89.1%	85.4%
Concurrent mastectomy	86.1%	94.1%	92.3%
Axillary surgery	85.7%	93.9%	92.2%
Concurrent mastopexy / reduction	87.1%	94.4%	92.3%
Concurrent flap cover	86.2%	93.8%	92.1%
Previous mastopexy / reduction	85.6%	93.8%	92.1%
Fat grafting	75.4%	89.7%	90.3%
Fat grafting volume (if fat grafting = yes)	77.4%	84.7%	88.9%
Intraoperative fill volume (if tissue expander)	67.1%	67.1%	67.4%
Revision Surgery Characteristics (Breast Level)	**3,782**	**5,531**	**7,458**
Revision surgery type	100%	100%	100%
Indication for revision surgery	85.5%	92.7%	94.5%
Capsulectomy	80.2%	85.1%	85.9%
Neo pocket formation	68.8%	73.5%	74.4%
Neo pocket formation details (if neo pocket formation = yes)	79.9%	82.6%	81.0%
Revision of an implant inserted overseas	79.7%	84.0%	84.2%
Breast cancer	73.9%	91.7%	94.0%
Device rupture	85.4%	92.5%	93.1%
Device deflation	74.6%	91.2%	94.0%
Capsular contracture	78.1%	92.6%	93.9%
Device malposition	75.2%	91.8%	93.9%
Skin scarring problems	74.0%	91.6%	94.1%
Deep wound infection	74.0%	91.8%	94.1%
Seroma / Haematoma	74.2%	91.9%	94.1%
Anaplastic Large Cell Lymphoma	73.3%	91.6%	93.9%
Device Characteristics (Breast Level, Inserted)	**17,635**	**24,725**	**23,986**
Breast implant/tissue expander Device ID	99.9%	100%	99.9%
ADM used	69.7%	99.2%	99.0%
ADM Device ID if (ADM = yes)	96.2%	100%	99.6%
Device Characteristics (Breast Level, Explanted)	**3,702**	**5,381**	**7,292**
Explanted device details provided	60.1%	77.1%	76.6%
Device ID (If device details provided)	12.5%	17.8%	8.3%

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