DUTCH BREAST IMPLANT REGISTRY (DBIR)
ANNUAL REPORT 2022

DICA DBIR
Dutch Breast Implant Registry

NVPC
Nederlandse Vereniging voor Plastische Chirurgie
handchirurgie, reconstructieve en esthetische chirurgie

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1. FOREWORD

Dear reader,

The scientific committee of DBIR is proud to present the 2022 annual report. We are thankful to all plastic surgeons and residents who actively endorse and collaborate with the registry on a daily basis. You are actively registering all cases in which breast implants and tissue expanders are used, while administrative work is a major challenge in our everyday practice. Being aware of this, we are proud to show that 100% of the hospitals and 93% of the private clinics are actively registering in DBIR today. We value the gift of time and energy from our plastic surgeons and residents.

The commitment of our plastic surgeons and residents, demonstrated through the investment of their valuable time and energy, remains the cornerstone of our success. The DBIR scientific board firmly believes that well-designed clinical quality registries play a pivotal role in providing essential evidence for patient and implant safety. These registries, independent of industry influence and funded by patients and healthcare insurance, not only facilitate quality monitoring but also drive innovation, measurement, and the reduction of adverse events.

Looking ahead, our focus in the upcoming years will center on improvement of the registry in terms of automation of data input, and the data completeness of explanted implants. Investigating methods for more automated data registry is a focus, since it leads to improvement of data quality, and reduces the administrative burden for clinical practices. Data completeness of explanted implants is important, it is necessary to record all cases of explanted implants, including reasons for removal, to monitor and investigate the safety of breast implants.

Having established an institutional annual report this year, we are committed to its ongoing enhancement through evaluation and continuous improvement. Recognizing the value of our annual reports, we are dedicated to refining and advancing them in the years to come.
In the broader context of breast implant safety research in the Netherlands, DBIR collaborates with government-funded initiatives monitored by the National Institute for Public Health and the Environment (RIVM). Three ongoing projects, complementing DBIR's efforts, delve into Breast Implant-Associated Illness (BII) from varying perspectives, promising valuable insights to be unveiled from 2023 onwards.

Amidst the ongoing discourse on breast implant safety, characterized by impassioned voices of patients, journalists, and professionals, the demand for independent and reliable data persists. The DBIR annual reports hold a significant position in this dialogue, garnering attention from journalists, patient advocacy groups, legislators, and producers globally.

1. FOREWORD

Our enduring vision remains rooted in patient-centered care, advocating for the ability to trace patients across different registries while upholding their privacy. Despite the challenges posed by the Dutch ethical and legal environment, DBIR stands 'ready to connect', committed to linking data ethically and legally according to the FAIR principles, awaiting guidance from the GDPR. The first registries earmarked for connection include the NABON Breast Cancer Audit (NBCA) and the National Implant Registry (LIR).

In conclusion, let us persist in our collective endeavor to enhance the quality and safety of breast implant surgery for our patients. May we continue to streamline administrative processes and let the spirit of collaboration drive us to connect with other registries, thereby advancing our knowledge and better serving our patients each day.

Best regards,
on behalf of the DBIR Clinical Audit Board & DBIR Scientific Committee,

Hinne Rakhorst, MD, PhD, chairman DBIR committee

Prof. M.A.M. Mureau, MD, PhD
B.E. Becherer, MD, PhD
M.J. Hoornweg, MD, PhD
P.E. Melse, MD
J.J. Vrolijk, MD
J.E. Hommes, MD, PhD
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A.C.M. van Bommel, MD, PhD
P.L.T. Liem, MSc
Prof. H.M. Verkooijen, MD, PhD

2. REGISTRY PERSONNEL

The clinical content of DBIR is managed by a delegation of plastic surgeons from the Netherlands Society of Plastic Surgery, subdivided into a Clinical Audit Board and a Scientific Committee. Daily management of the registry is facilitated and administered by DICA, the Dutch Institute for Clinical Auditing.

DBIR Scientific Committee

- H.A. Rakhorst, MD, PhD, chairman, plastic surgeon at Medisch Spectrum Twente, Enschede and Ziekenhuis Groep Twente, Almelo and Hengelo;
- Prof. M.A.M. Mureau, MD, PhD, vice-chairman, Professor of Oncological Reconstructive Surgery, Erasmus MC Cancer Institute, University Medical Center Rotterdam, Rotterdam;
- J.E. Hommes, MD, PhD, secretary, plastic surgeon at Isala Hospital, Zwolle;
- B.E. Becherer, MD, PhD, consultant at Allegro Medical, Hilversum;
- M. de Boer, MD, PhD, plastic surgery resident at Maastricht University Medical Center +, Maastricht;
- A.C.M. van Bommel, MD, PhD, plastic surgeon at Antoni van Leeuwenhoek hospital, Amsterdam;
- M.J. Hoornweg, MD, PhD, plastic surgeon at Antoni van Leeuwenhoek hospital, Amsterdam;
- X.H.A. Keuter, MD, PhD, plastic surgeon at VieCuri Medical Center, Venlo and Maastricht University Medical Center +, Maastricht;
- P.L.T. Liem, MSc, director of the Netherlands Society of Plastic Surgery, Utrecht;
- P.E. Melse, MSc, clinical researcher at the Dutch Institute for Clinical Auditing, Leiden and PhD candidate at Erasmus MC Cancer Institute, University Medical Center Rotterdam, Rotterdam;
- I. Moes, MSc, data scientist at the Dutch Institute for Clinical Auditing, Leiden;
- Prof. H.M. Verkooijen, MD, PhD, Professor of Evaluation of Image-Guided Treatment at Division of Imaging and Cancer, University Medical Center Utrecht, Utrecht;
- J.J. Vrolijk, MD, PhD candidate at Maastricht University Medical Center Grow, Maastricht;
- D.A. Young-Afat, MD, PhD, epidemiologist and plastic surgeon at Amsterdam University Medical Center, Amsterdam.

DBIR Audit Committee

- B.O. Verwer, MD, PhD, plastic surgeon at Isala hospital, Zwolle;
- C. Schouten, MD, PhD, plastic surgeon at Rijnstate hospital, Arnhem;
- N.M.A. Krekel, MD, PhD, plastic surgeon at Alrijne hospital, Leiderdorp.

Former members

- M. Cromheecke, MD, PhD, plastic Surgeon at Zipper Clinics, Apeldoorn and Enschede, Zwolle;
- Prof. R.R.J.W. van der Hulst, MD, PhD, Professor of Plastic and Reconstructive Surgery at Maastricht University Medical Center Grow, Maastricht;
- Prof. I.M.J. Mathijssen, MD, PhD, plastic surgeon at Erasmus MC, University Medical Center Rotterdam, Rotterdam;
- L. Moojen-Zaal, MD, PhD, plastic surgeon at Velthuiskliniek, Hilversum;
- P.E.R. Spronk, MD, PhD, general surgery resident at Alrijne hospital, Leiderdorp.

3. FACT SHEET (NL)

DUTCH BREAST IMPLANT REGISTRY

Fact sheet annual report

2022

In 2022 zijn **10.823** patiënten, **11.455** operaties en **25.290** implantaten geregistreerd in DBIR. Dit zijn cosmetische borstvergrotingen en reconstructies na bijvoorbeeld borstkanker.

Van alle geplaatste implantaten in 2022, is ongeveer 70% geplaatst vanwege een **cosmetische borstvergroting** en 30% vanwege een **reconstructie**.

Top 5 redenen voor heroperatie (Reconstructief)

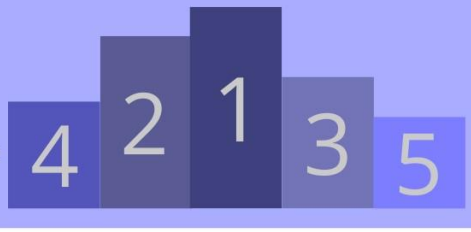
Na een reconstructie aan één of beide borsten werden in het jaar 2022 **1.623** patiënten ongepland opnieuw geopereerd na het plaatsen van een permanent borstimplantaat. Hieronder een top 5 van redenen waarom er opnieuw geopereerd werd.

1. Kapselcontractuur
2. Borstpijn
3. Kapot implantaat
4. Asymmetrie
5. Patiënt ontevreden met implantaatvolume

Top 5 redenen voor heroperatie (Cosmetisch)

In 2022 zijn **3.871** patiënten opnieuw geopereerd nadat zij eerder in hun leven een cosmetische borstvergroting ondergingen. Hieronder ziet u de top 5 redenen waarom deze heroperaties plaatsvonden.

1. Kapselcontractuur
2. Kapot implantaat
3. Borstpijn
4. Patient ontevreden met implantaatvolume
5. Breast implant-associated illness



Disclaimer

Numbers in this fact sheet may differ from the annual report because the fact sheet shows data at patient level and the annual report at implant level.
For general information about breast implants:
www.igj.nl/onderwerpen/borstimplantaten

DUTCH BREAST IMPLANT REGISTRY

Fact sheet annual report

2022

In 2022, **10,823** patients, **11,455** surgeries, and **25,290** implants were registered in DBIR. These breast implants were used for cosmetic breast augmentations and reconstructions (for example, after breast cancer).

Of all breast implants registered in 2022, approximately 70% were inserted because of **cosmetic augmentation**, and 30% because of **breast reconstruction**.

Top 5 reasons for reoperation (Reconstruction)

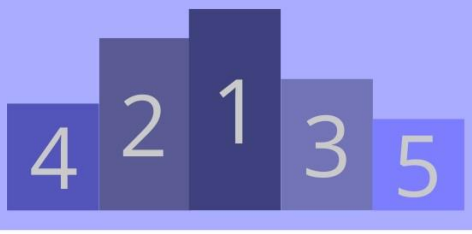
After single- or double-sided breast reconstruction with a permanent implant, **1,623** patients underwent an unplanned reoperation in 2022. The top 5 reasons for reoperation are mentioned below.

1. Capsular contracture
2. Breast pain
3. Device rupture or deflation
4. Asymmetry
5. Dissatisfied with size

Top 5 reasons for reoperation (Cosmetic)

In 2022, **3,871** patients underwent reoperation after a previous cosmetic breast augmentation. The top 5 reasons for reoperation are mentioned below.

1. Capsular contracture
2. Device rupture or deflation
3. Breast pain
4. Dissatisfied with size
5. Breast implant-associated illness



Disclaimer

Numbers in this fact sheet may differ from the annual report because the fact sheet shows data at patient level and the annual report at implant level.
For general information about breast implants:
www.igj.nl/onderwerpen/borstimplantaten

DICA DBIR
Dutch Breast Implant Registry

4. BACKGROUND

Rationale for the registry

Since April 2015, the Dutch Breast Implant Registry (DBIR) has registered characteristics of patients, surgical procedures, and breast implants to monitor, benchmark, and improve the quality of breast implant surgery in the Netherlands. Additionally, DBIR can be used as a track and trace system for recall purposes. Healthcare providers can gain insight into their quality of care and complications by anonymously comparing the results of their clinic to other centers in the Netherlands (i.e., benchmarking). In this way, the provided care can be evaluated and points for improvement may be identified. Annually, a selection of quality indicators is published on the Transparency Calendar, making this information publicly available (***Chapter 7***). Furthermore, participants of the registry can also use data from the registry for scientific research purposes (***Chapter 11*** or ***www.dica.nl/dbir/onderzoek***).

Governance

The DBIR was developed by commission of the Netherlands Society of Plastic Surgery (NVPC). A delegation of the NVPC, which is split into a Clinical Audit Board and a Scientific Committee, manages the content of the registry and safeguards the quality of the analyses and the interpretation of data. The daily management of the registry is facilitated by the Dutch Institute for Clinical Auditing (DICA), an independent institution established in 2009. DICA manages and supports clinical outcome registries in the Netherlands, aiming at quality improvement, transparency, and cost savings in healthcare. The DBIR is financially covered by a fixed fee per implant (EUR 28). This fee is paid by the national health insurance (ZN) for patients receiving reconstructive breast implant surgery and by healthcare institutions in case of cosmetic breast augmentation.

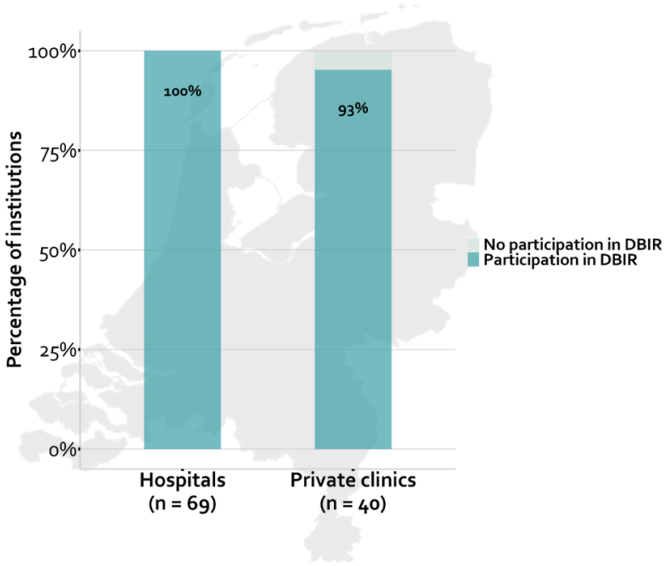
Patients are involved

Patients can check whether their plastic surgeon has registered their breast implant(s) in the DBIR. On the website ***implantaatcheck.nl***, patients may enter the unique combination of the manufacturer's name and the serial number of their implant. Patients can find this information on the implant card provided after breast implant surgery. The website subsequently provides information on the registration status of the device and refers to reliable sources containing information about breast implants. Additionally, the website serves as an information tool for patients during an implant recall, stating whether the breast implant is involved in the recall or not.

Registry participation

DBIR is a national, prospective, opt-out registry with mandatory registration for all plastic surgeons in the Netherlands who are members of the Netherlands Society of Plastic Surgery (NVPC). In contrast to other countries, only board-certified plastic surgeons are allowed to perform breast implant surgery in the Netherlands, whether in a hospital or a private clinic. Every year, the nationwide coverage of DBIR participation is calculated, relative to the eligible number of institutions known by the Dutch Health and Youth Care Inspectorate (IGJ). With special thanks to all plastic surgeons and other collaborators who have contributed to the registry, the DBIR has matured into a registry with nationwide coverage of 97% (100% participation of the hospitals and 93% of the private clinics) (***Figure 1***).

Figure 1. *Coverage of DBIR in the Netherlands (2022)*



(n) represents the total number of healthcare institutions eligible for breast implant surgery in the Netherlands.

Methodology

The dataset of the DBIR is based on a core dataset developed by the International Collaboration of Breast Registry Activities (ICOBRA).[1] All patients undergoing implantation, replacement, or explantation of a breast implant (including tissue expanders) are eligible for inclusion in DBIR. Healthcare institutions may register their data using an online data entry portal or via automated batches extracted from electronic patient records. A methodological council, consisting of statisticians, epidemiologists, physicians, and data scientists, develops and secures the statistical methods used for analyses. To remain up to date, the quality registries of DICA undergo yearly updates, including removal, adjustment, or modification of data points.

Privacy

A certified Trusted Third Party (MRDM), appointed by the healthcare institutions and serving as an extension of the healthcare institutions, processes the data before they are forwarded to DICA. The data which DICA receives can no longer be traced back to individual patients. This process complies with the General Data Protection Regulation (GDPR, or AVG in Dutch).

GS1 standards in DBIR

Since the start of DBIR, the industrial partners who distribute breast implants in the Netherlands have been actively invited to embrace standardized barcodes and product identifiers. According to European regulations, GS1 is one of the two techniques to provide a Unique Device Identifier (UDI) to a medical device. This UDI is unique for every single implant and contains information about the Global Trade Item Number (GTIN), serial number, batch/lot number, and expiration date. With the

[1] Spronk PER, Begum H, Vishwanath S, Crosbie A, Earnest A, Elder E, et al. Toward international harmonization of breast implant registries: International Collaboration of Breast Registry Activities global common data set. *Plast Reconstr Surg. 2020;146(2):255–67.*

support of GS1, DBIR has incorporated barcode scanning technology for data entry in the online data entry portal. By scanning the standardized GS1-barcode, the GTIN, serial number, batch/lot number, and expiration date are automatically registered (***Figure 2***). In the future, this GS1 barcode will also be used to automatically register implant-specific details such as texture, fill, and shape. Therefore, this technology is crucial for the reduction of the administrative burden and typing errors in our registry. Currently, 4 of the 7 suppliers that distribute implants in the Netherlands (5 of the 8 brands) have embraced our joint choice for GS1 and have actively started adding GS1 barcodes to the boxes of their breast implants (***Table 1***). We thank GS1 and all industrial parties that have included a GS1-compatible barcode on their implant boxes, and we hope the remaining parties will follow this example in the near future.

Figure 2. *By scanning the GS1 barcode or matrix, important device identifiers are prefilled in the registry*

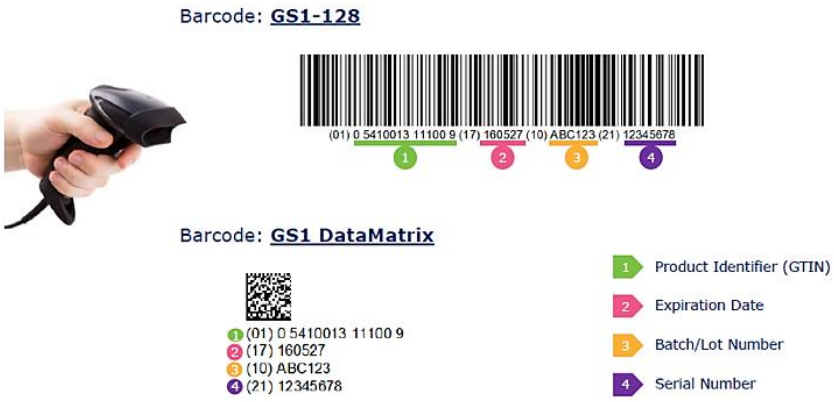


Table 1. *Participation GS1 and DBIR SUPPLIERS (2022)*

Supplier	Brand	Implementation GS1 barcode on implant box	Registration in DBIR SUPPLIERS*
Allergan	Allergan (Natrelle)	Yes	No
Aleamed	Polytech	Yes	Yes
BlooMEDical	Mentor	Yes	Yes
Contourion	Arion Laboratoires (Monobloc)	No	No
EmdaPlast	Eurosilicone	Yes	Yes
	Nagor	Yes	Yes
Groupe Sebbin	Sebbin	No	No
Motiva Benelux	Motiva	Yes	Yes

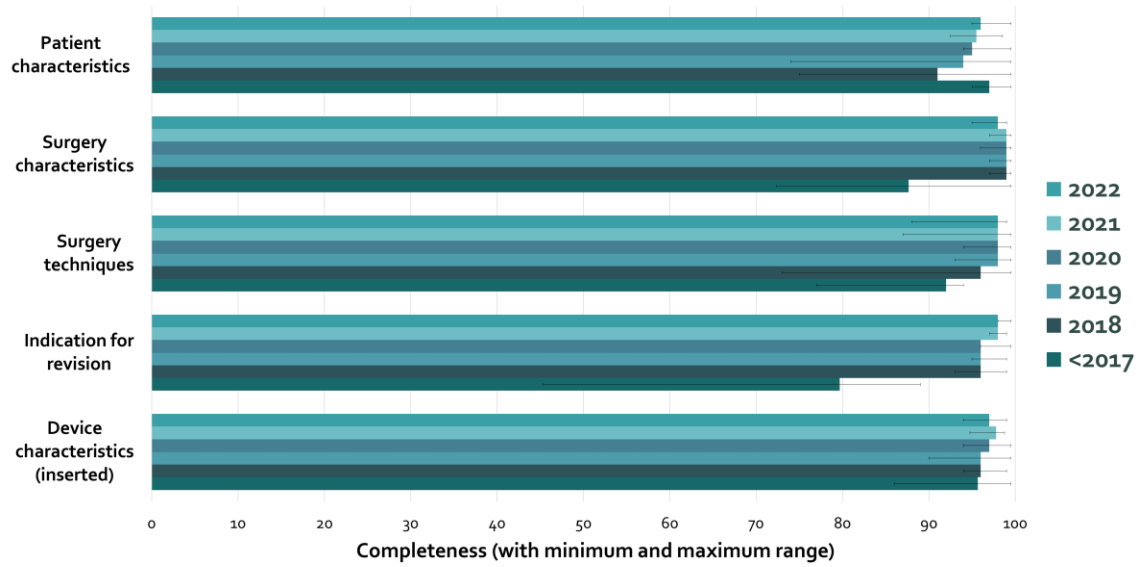
**The suppliers who do not register in DBIR SUPPLIERS are responsible for less than 1% of the breast implants sold on the Dutch market.*

5. DATA COMPLETENESS

To improve data completeness and data quality, DBIR uses an opt-out structure. Additionally, three quality control mechanisms have been incorporated:

- In the online registration interface ('Data Entry'), immediate feedback is provided on missing, erroneous, or unlikely data.
- After data entry, all remaining patients with missing or erroneous data are collected and appear on an institution-specific and surgeon-specific signaling list, which can be used to rectify these records.
- A weekly updated online platform is available for all participating institutions, presenting their outcomes compared to a Dutch benchmark to facilitate the clinical auditing process (*Chapter 10*).
- In case of data entry via batch upload, a validation report is sent to the healthcare institutions. If errors are found, the batch upload may be adjusted accordingly.

Figure 4. *Data completeness (2015 - 2022)*



In 2022, the majority of variables exhibited a completeness rate exceeding 95%, a trend that has persisted since the inception of the registry, as illustrated in *Figure 4* and *Table 2*. Notably, the average data completeness of the surgery characteristics in 2022 is only around 98%, representing a decrease compared to previous years. This decline is primarily attributed to the recording of preoperative radiotherapy, which was documented in only 88% of the records. Additionally, there was a marginal decrease in the data completeness of device characteristics compared to 2021.

5. DATA COMPLETENESS

Table 2. *Data completeness 2022*

	Complete (%)
	2022
Patient characteristics (patient level)	
Valid BSN	95%
Date of birth	98%
ASA classification	100%
Smoking	96%
Length	95%
Weight	95%
Body Mass Index	95%
Surgery characteristics (breast level)	
Date of surgery	100%
Healthcare institution	100%
Laterality	100%
Intervention	100%
Indication	99%
Timing reconstruction	100%
Primary implant surgery	100%
Preoperative radiotherapy	88%
Surgery techniques (breast level)	
Incision site	97%
Plane	97%
Capsulectomy	98%
Mastopexy	97%
Autologous flap cover	97%
Fat grafting	97%
Drains	97%
ADM/mesh use	97%
ADM/mesh manufacturer	96%
Sleeve/funnel	100%
Nipple guards	100%
Systemic antibiotics (preoperatively)	97%
Systemic antibiotics (postoperatively)	94%
Antiseptic rinse of implant	100%
Antiseptic rinse type	99%
Glove change	100%

	Complete (%)
	2022
Indication for revision (breast level)	
Planned TE to implant	100%
Planned TE for autologous tissue	100%
Flap problem	98%
Skin necrosis	98%
Deep wound infection	98%
Seroma	98%
Hematoma	98%
Capsular contracture	98%
Capsular contracture grade	99%
Breast cancer	98%
Suspicion of BIA-ALCL	100%
Breast implant-associated illness	100%
Breast pain	98%
Asymmetry	98%
Dissatisfaction with volume	98%
Device rupture/deflation	98%
Silicone extravasation	98%
Silicone extravasation type	99%
Device malposition	98%
Recall	98%
Device characteristics (device level, inserted)	
Device type	98%
Texture	94%
Coating	94%
Fill	94%
Shape	94%
Maximum volume/weight TE or implant	96%
Manufacturer	99%
Using barcode scanner	99%
Re-insertion of the same device	99%

Abbreviations: ASA: American Society of Anesthesiologists, ADM: Acellular Dermal Matrix, BIA-ALCL: Breast Implant-Associated Anaplastic Large Cell Lymphoma, TE = Tissue Expander.

N.B. See previous annual reports for data completeness in 2015 – 2021.

In this report, breast implants or breast devices are defined as both tissue expanders as well as permanent breast implants. When analyses were performed for either subgroup, this is indicated in the titles of figures and tables or explanatory notes.

Clinical differences were found between patients who opted for cosmetic breast augmentation and patients who received an implant for reconstructive indications. Therefore, the results in this report are presented separately for these two groups on the odd (reconstructive) and even (aesthetic) pages.

- **Odd pages - Reconstructive procedures,** includes the indications:
  - Reconstruction after mastectomy for cancer (surgery to recreate a breast after one or both breasts were removed as a treatment for breast cancer).
  - Reconstruction after prophylactic mastectomy (surgery to recreate a breast after one or both breasts were removed to reduce the risk of developing breast cancer).
  - Reconstruction benign (surgery to restore or create shape and symmetry in patients with loss or absence of all or some breast tissue due to congenital deformity, benign breast conditions, or gender reassignment surgery).

- **Even pages - Aesthetic procedures,** includes solely:
  - Cosmetic augmentations (cosmetic surgery for breast enlargement).

Table 3. *Indications for insertion only, replacement, and explantation only procedures with permanent breast implants and tissue expanders (2022)*

	Patients*		Procedures*		Devices†	
	n	(%)	n	(%)	n	%
Reconstructive						
Reconstruction after mastectomy for cancer	2,879	(27%)	3,274	(29%)	5,730	(23%)
Reconstruction after prophylactic mastectomy	554	(5%)	678	(6%)	1,687	(7%)
Reconstruction benign‡	159	(2%)	169	(2%)	382	(2%)
Aesthetic						
Cosmetic augmentation	7,168	(66%)	7,260	(63%)	17,414	(69%)
Not stated	62	(1%)	64	(1%)	76	(<1%)
TOTAL	**10,823**	**(100%)**	**11,455**	**(100%)**	**25,290**	**(100%)**

N.B. Due to rounding of percentages, added rows may exceed 100%.
**Patients and procedures are presented as unique patients and unique procedures. Some patients had multiple surgeries.*
†Devices are measured on breast level, i.e., bilateral insertion of a device equals two device registrations. Additionally, unilateral implantation and explantation of one device equals two device registrations as well.
‡Including congenital deformity and gender reassignment surgery.

Records for which the indication was not stated, were excluded from further analyses in this report (62 patients, 64 procedures, and 76 devices). In total, from the start of the registry in April 2015 until the end of 2022, information of 80,343 patients, 85,419 procedures, and 174,650 breast implants have been registered in DBIR (***Figures 5 and 6***). This includes insertion only procedures, replacement surgeries, and explantation only procedures with both tissue expanders and permanent implants, of which the indication was known (reconstructive or aesthetic). ***Figure 5*** illustrates that patients with a reconstructive indication are more likely to undergo multiple surgeries compared to patients with a cosmetic breast augmentation. Generally, the majority of aesthetic patients received breast implants bilaterally and reconstructive patients unilaterally.

Figure 5. *Cumulative number of registered patients, procedures, and devices for reconstructive indications (2015 – 2022)*

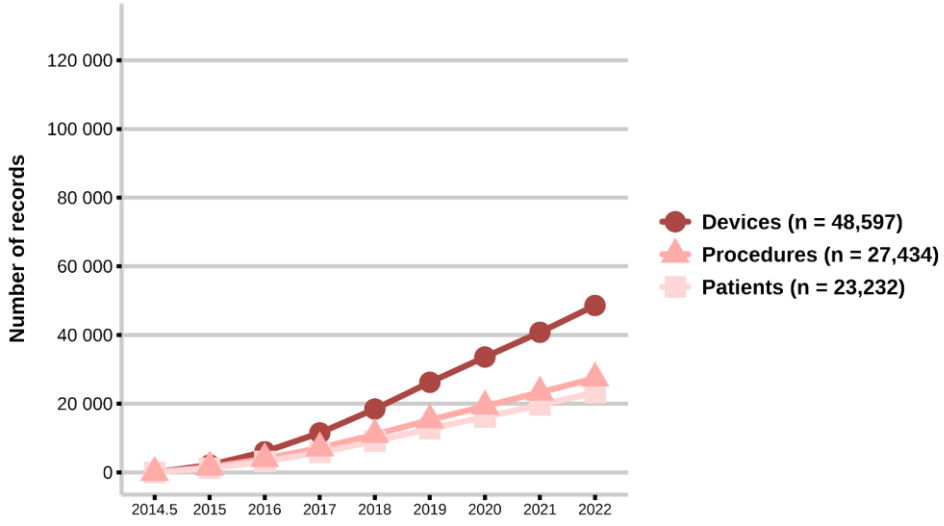
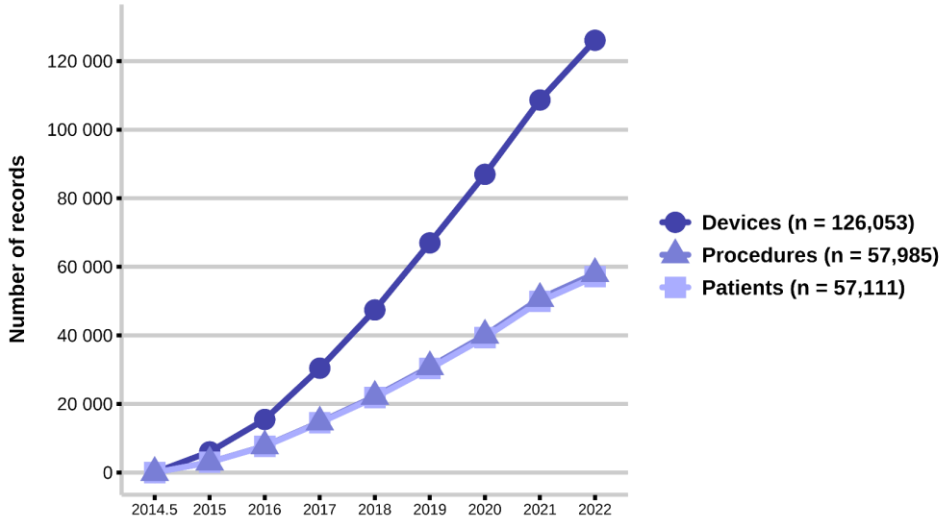


Figure 6. *Cumulative number of registered patients, procedures, and devices for aesthetic indications (2015 – 2022)*



Inserted devices per manufacturer and brand (*Figures 7 and 8*)

Almost all reconstructive procedures were undertaken in hospitals (92%, 89%, and 93% for insertion only, replacement, and explantation procedures, respectively). For aesthetic indications, most "insertion only" procedures were performed in private clinics (73%). While most aesthetic replacement and explantation only procedures still took place in hospitals (52% and 54%, respectively).

***Figure 7**. Healthcare institution type by intervention type for reconstructive indications, breast level (2022)*

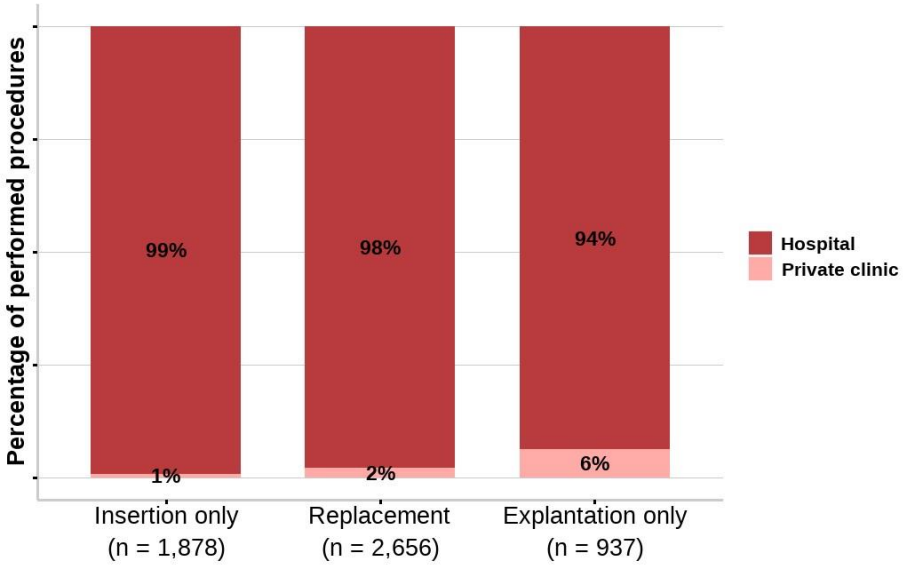
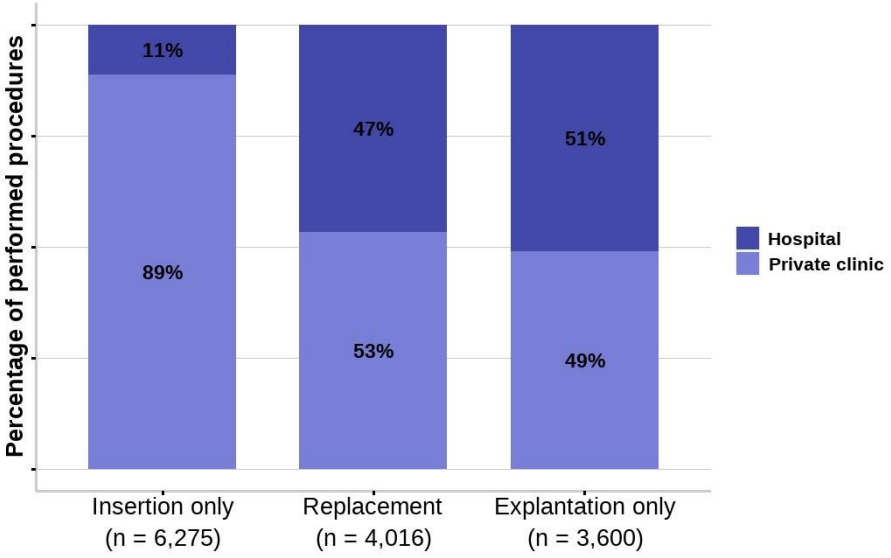


***Figure 8**. Healthcare institution type by intervention type for aesthetic indications, breast level (2022)*



Inserted devices per manufacturer and brand

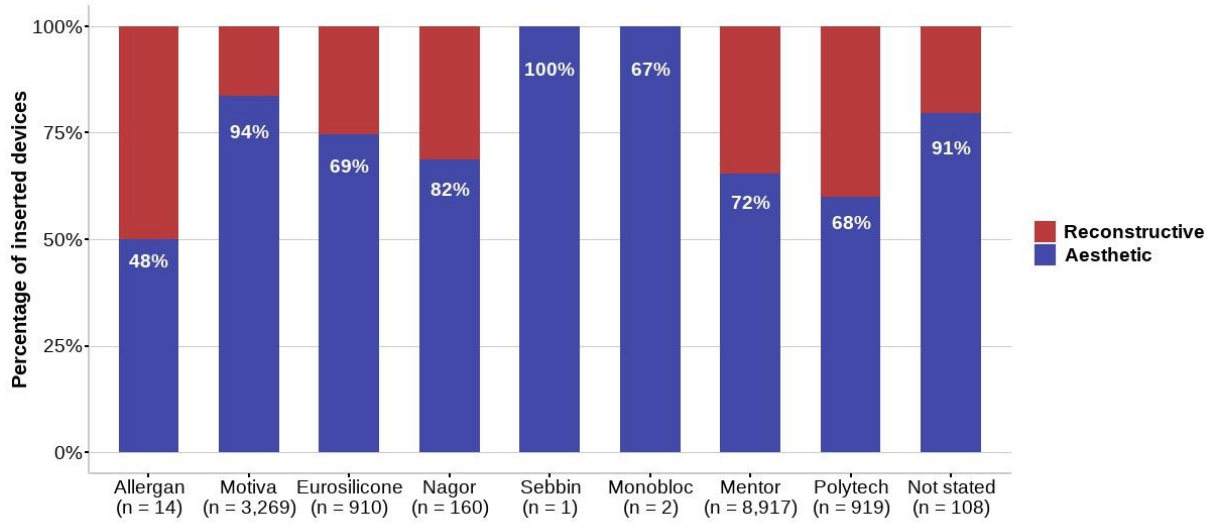
In 2022, permanent implants, and tissue expanders from 9 different brands (8 different manufacturers) were inserted. Most of these devices were manufactured by Mentor. *Figure 7* provides an overview of the distribution between reconstructive and aesthetic devices that have been inserted per manufacturer and brand.

Table 4. *Number of devices inserted per manufacturer and brand (2022)*

	Reconstructive*		Aesthetic†		Total	
	N	(%)	n	(%)	n	%‡
Manufacturer (brand)						
Allergan (Natrelle)	<10	(<1%)	<10	(<1%)	14	(<1%)
Establishment Labs (Motiva)	536	(12%)	2,733	(27%)	3,269	(23%)
GC Aesthetics (Eurosilicone)	230	(5%)	680	(7%)	910	(6%)
GC Aesthetics (Nagor)	50	(1%)	110	(1%)	160	(1%)
Groupe Sebbin		-	<10	(<1%)	<10	(<1%)
Laboratoires Arion (Monobloc)		-	<10	(<1%)	<10	(<1%)
Mentor	3,086	(72%)	5,831	(58%)	8,917	(62%)
Polytech	367	(9%)	552	(6%)	919	(6%)
Not stated	22	(<1%)	86	(<1%)	108	(1%)
TOTAL	**4,298**	**(100%)**	**10,002**	**(100%)**	**14,300**	**(100%)**

N.B. Due to rounding of percentages, added rows may exceed 100%.

Figure 9. *Percentage of reconstructive vs. aesthetic devices inserted per brand (2022)*



In the two following chapters, results for reconstructive and aesthetic indications are presented on separate pages, side by side to facilitate comparison. Both chapters describe the results for three types of interventions.

- **Insertion only** includes:
  - Initial insertion of a new device.
  - Insertion of a new device in a patient who has had previous implant surgery.
- **Replacement surgery** includes:
  - Removal of a device and insertion of the same or new device.
  - Replacement of TE with an implant.
  - Replacement of a device with autologous tissue.
- **Explantation only** includes:
  - Explantation of a device without replacement of a new device or autologous tissue.

ODD PAGES – RECONSTRUCTIVE INDICATIONS

EVEN PAGES – AESTHETIC INDICATIONS

6. REGISTRY OUTPUT

Reconstructive indications

Types of procedures (*Tables 5 - 7 on page 21*)

In 2022, a total of 4,123 reconstructive procedures were registered in DBIR. The following procedures were most often performed: unilateral insertion only surgery after mastectomy for cancer (1,043 procedures), unilateral replacement surgery after mastectomy for cancer (1,089 procedures), and unilateral explantation only surgery after mastectomy for cancer (438 procedures).

Patient characteristics (*Table 11 on page 27*)

Age

The mean age of patients undergoing an insertion only procedure was 49 years (SD 12), the mean age of patients undergoing a replacement procedure was 53 years (SD 12), and the mean age of patients undergoing an explantation only procedure was 57 years (SD 12).

ASA classification

For insertion only, replacement, and explantation only, most patients scored ASA class 2 (58%, 59%, and 61%, respectively), followed by ASA class 1 (38%, 33%, and 26%, respectively). In all intervention groups, ASA classification was missing in 2% of the records or less.

Smoking status

At the time of reconstructive surgery, the percentage of smokers was 10% for all types of procedures. In 13% to 19% of the cases, the smoking status was not recorded or was unknown.

Body Mass Index (BMI)

For insertion only, replacement, and explantation only procedures, most of the patients had a BMI between 18.5 and 24.9 kg/m^2 (46%, 50%, and 42%, respectively) followed by a BMI of 25.0 and 29.9 kg/m^2 (26%, 28%, and 33%, respectively). A BMI $\geq$30 kg/m^2 was registered in respectively 13%, 13%, and 17% of the cases, and <18.5 kg/m^2 in 1% of the cases for all types of procedures. In respectively 14%, 8%, and 7% of the records the patient's BMI was not registered.

Types of procedures (*Tables 8 - 10 on page 26*)

In 2022, a total of 7,241 aesthetic procedures were registered in DBIR. Of these procedures, 3,220 were insertions only procedures, 2,140 were replacement procedures, and 1,881 were explantation procedures. The procedures performed most often included bilateral insertion only surgery (3,153 procedures), bilateral replacement of implants (2,015 procedures), and bilateral explantation (1,808 procedures).

Patient characteristics (*Table 12 on page 28*)

Age

The mean age of patients undergoing an insertion only procedure was 34 years (SD 10), the mean age of patients undergoing a replacement procedure was 48 years (SD 12), and the mean age of patients undergoing an explantation only procedure was 51 years (SD 14).

ASA classification

For insertion only, replacement, and explantation only, most patients scored ASA class 1 (81%, 58%, and 49%, respectively), followed by ASA class 2 (19%, 37%, and 44%, respectively). In all intervention groups, ASA classification was missing in 1% of the records or less.

Smoking status

The percentage of smokers at the time of aesthetic surgery was between 11% and 22%. In 12% to 18% of the cases, the smoking status was not recorded or was unknown. The reasons for these missing values are unclear, but they are higher compared to other variables.

Body Mass Index

For insertion only, replacement, and explantation only procedures, most of the patients had a BMI between 18.5 and 24.9 kg/m^2 (75%, 74%, and 57%, respectively) or 25.0 and 29.9 kg/m^2 (16%, 18%, and 23%, respectively), followed by a BMI < 18.5 kg/m^2 (6%, 3%, 3%), and $\geq$30 kg/m^2 (2%, 4%, and 7%, respectively). In respectively 1%, 1%, and 11% of the records the patient's BMI was not registered.

Table 5. *Number of reconstructive procedures, insertion only* (2022)*

	n	(%)
Unilateral		
Reconstruction after mastectomy for cancer	1,043	(68%)
Reconstruction after prophylactic mastectomy	55	(4%)
Reconstruction benign†	13	(1%)
Bilateral		
Post-cancer & post-cancer	107	(7%)
Post-cancer & prophylactic	136	(9%)
Prophylactic & prophylactic	120	(8%)
Benign & benign	11	(1%)
Post-cancer & aesthetic	36	(2%)
Benign & aesthetic	<10	(<1%)
Other	<10	(<1%)
Total	**1,527**	**(100%)**

Table 6. *Number of reconstructive procedures, replacement* (2022)*

	n	(%)
Unilateral		
Reconstruction after mastectomy for cancer	1,089	(57%)
Reconstruction after prophylactic mastectomy	70	(4%)
Reconstruction benign†	23	(1%)
Bilateral		
Post-cancer & post-cancer	274	(15%)
Post-cancer & prophylactic	149	(8%)
Prophylactic & prophylactic	188	(10%)
Benign & benign	43	(2%)
Post-cancer & aesthetic	30	(2%)
Benign & aesthetic	<10	(<1%)
Other	17	(1%)
Total	**1,886**	**(100%)**

Table 7. *Number of reconstructive procedures, explantation only* (2022)*

	n	(%)
Unilateral		
Reconstruction after mastectomy for cancer	438	(62%)
Reconstruction after prophylactic mastectomy	19	(3%)
Reconstruction benign†	18	(3%)
Bilateral		
Post-cancer & post-cancer	97	(14%)
Post-cancer & prophylactic	28	(4%)
Prophylactic & prophylactic	48	(7%)
Benign & benign	41	(6%)
Post-cancer & aesthetic	11	(2%)
Benign & aesthetic	<10	(<1%)
Other	<10	(1%)
Total	**710**	**(100%)**

N.B. Due to rounding of percentages, added rows may exceed 100%.

**Although all tables on this page represent reconstructive procedures, for bilateral surgery, a small number of aesthetic indications have been included for descriptive purposes.*

†Including congenital deformity and gender reassignment surgery.

Table 8. *Number of aesthetic procedures, insertion only* (2022)*

	n	(%)
Cosmetic augmentation		
Unilateral	67	(2%)
Bilateral	3,153	(98%)
Total	**3,220**	**(100%)**

Table 9. *Number of aesthetic procedures, replacement* (2022)*

	n	(%)
Cosmetic augmentation		
Unilateral	125	(6%)
Bilateral	2,015	(94%)
Total	**2,140**	**(100%)**

Table 10. *Number of aesthetic procedures, explantation only* (2022)*

	n	(%)
Cosmetic augmentation		
Unilateral	73	(4%)
Bilateral	1,808	(96%)
Total	**1,881**	**(100%)**

**All tables on this page represent aesthetic procedures. Both unilateral, as well as bilateral procedures, were performed for aesthetic purposes only.*

Table 11. *Patient characteristics, reconstructive procedures (2022)*

	Insertion only	Replacement	Explantation only
Number of unique patients	**(n = 1,125)**	**(n = 1,775)**	**(n = 692)**
Number of unique surgeries*	**(n = 1,497)**	**(n = 1,911)**	**(n = 713)**
Age in years, mean ± SD	49 ± 12	53 ± 12	57 ± 12
ASA classification			
I	38%	33%	26%
II	58%	59%	61%
III+	4%	6%	11%
Not stated	*1%*	*2%*	*2%*
Smoking†			
No	71%	75%	77%
Yes	10%	*10%*	10%
Not stated	*19%*	*15%*	*13%*
Body Mass Index			
< 18.5	1%	1%	1%
18.5 – 24.9	46%	50%	42%
25 – 29.9	26%	28%	33%
≥ 30	13%	13%	17%
Not stated	*14%*	*8%*	*7%*

Abbreviations: ASA: American Society of Anesthesiologists, SD = Standard Deviation.

N.B. Due to rounding of percentages, added rows may exceed 100%.

**The patient characteristics in this table are extracted from unique surgeries. Therefore, information on for example changes in Body Mass Index or smoking behavior remains preserved in patients that have had multiple surgeries during one calendar year.*

†Smoking at time of reconstructive insertion only, replacement, or explantation only procedure.

Table 12. *Patient characteristics, aesthetic procedures (2022)*

	Insertion only	Replacement	Explantation only
Number of unique patients	**(n = 3,184)**	**(n = 2,108)**	**(n = 1,876)**
Number of unique surgeries*	**(n = 3,230)**	**(n = 2,144)**	**(n = 1,886)**
Age in years, mean ± SD	34 ± 10	48 ± 12	51 ± 14
ASA classification			
I	81%	58%	49%
II	19%	37%	44%
III+	1%	4%	6%
Not stated	*<1%*	*1%*	*1%*
Smoking†			
No	64%	70%	71%
Yes	22%	19%	11%
Not stated	14%	12%	18%
Body Mass Index			
< 18.5	6%	3%	3%
18.5 – 24.9	75%	74%	57%
25 – 29.9	16%	18%	23%
≥ 30	2%	4%	7%
Not stated	*1%*	*1%*	*11%*

Abbreviations: ASA: American Society of Anesthesiologists, SD = Standard Deviation.

N.B. Due to rounding of percentages, added rows may exceed 100%.

**The patient characteristics in this table are extracted from unique surgeries. Therefore, information on for example changes in Body Mass Index or smoking behavior remains preserved in patients that have had multiple surgeries during one calendar year.*

†Smoking at time of aesthetic insertion only, replacement, or explantation only procedure.

Timing of reconstructive procedures ***(Table 13)***

In 2022, the majority of registered reconstructive permanent breast implants were inserted after mastectomy for cancer, either as part of a direct-to-implant procedure (48%) or as part of a two-stage reconstruction (23%). Notably, direct-to-implant procedures were the most frequently registered, while literature generally describes two-stage reconstructions as the most commonly performed procedures. In general, most reconstructive tissue expanders were used after mastectomy for cancer (76%) in 2022.

Table 13. *Timing of reconstructive procedures, per indication (2015 – 2022)*

	2015 – 2021		2022	
	n	%	n	%
NUMBER OF PERMANENT IMPLANTS	**(n = 14,810)**		**(n = 3,281)**	
Direct-to-implant insertion surgery				
Post-cancer	7,648	(52%)	1,584	(48%)
Prophylactic	1,816	(12%)	592	(18%)
Benign	465	(3%)	76	(2%)
Two-stage insertion surgery				
Post-cancer	3,838	(26%)	754	(23%)
Prophylactic	847	(6%)	257	(8%)
Benign	196	(1%)	18	(1%)
NUMBER OF TISSUE EXPANDERS	**(n = 10,576)**		**(n = 1,376)**	
Insertion surgery				
Post-cancer	8,600	(81%)	1,045	(76%)
Prophylactic	1,274	(12%)	316	(23%)
Benign	702	(7%)	15	(1%)

N.B. Due to rounding of percentages, added rows may exceed 100%.

Intraoperative techniques (*Table 14*)

DBIR collects data on intraoperative techniques used by plastic surgeons to identify best practices and to evaluate surgical outcomes. Benchmark information on these topics is provided to healthcare institutions to improve their quality of care (*read more in **Chapter 7***). For some surgical techniques, there is scientific evidence it has a positive effect on surgical outcomes, such as the preoperative use of prophylactic systemic antibiotics (***Figure 10***). For other techniques, however, no consensus has been reached yet and insights into current practices are extra useful. ***Table 14*** on page 29 shows that, in 2022, the most common incision site was a (previous) non-nipple-sparing mastectomy scar (47% for insertion only, and 46% for replacement procedures). The most common surgical plane used for insertion was a dual plane or partial cover with PM (36% for insertion only, and 42% for replacement procedures). Notably, in the Netherlands ADMs/meshes were used less (5%) in breast reconstructions compared to reported values in annual reports of other international registries.[2,3]

[2] *Australian Breast Device Registry (ABDR) Annual Report 2020. https://www.abdr.org.au/wp-content/uploads/2021/01/2019-ABDR-Annual-Report_web_V1.1.pdf*

[3] *The National Breast Implant Registry (NBIR) Annual Report 2020. https://www.thepsf.org/documents/Research/Registries/NBIR/NBIR-Annual-Report-2021.pdf*

Intraoperative techniques (*Table 15*)

The DBIR collects data on intraoperative techniques used by plastic surgeons to identify best practices and assess surgical outcomes. Benchmark information on these topics is provided to healthcare institutions to improve their quality of care (*read more in **Chapter 7***). For some surgical techniques, there is scientific evidence it has a positive effect on surgical outcomes, such as the preoperative use of prophylactic systemic antibiotics (***Figure 9***). For other techniques, however, no consensus has been reached yet and insights into current practices are extra useful. ***Table 15*** on page 30 shows that, in 2022, the most common incision site was the inframammary fold (99% for insertion only, and 96% for replacement procedures). The most common surgical plane used for insertion was a dual plane (52% for insertion only, and 51% for replacement procedures).

Table 14. *Intraoperative techniques in reconstructive procedures, per breast (2022)*

		Insertion only	Replacement	Explantation only
Total number of breasts		**(n = 1,878)**	**(n = 2,656)**	**(n = 937)**
Incision site	Inframammary	11%	30%	
	Mastectomy scar (NNS)	47%	46%	
	Mastectomy scar (NS)	21%	11%	
	Peri-areolar	<1%	<1%	
	Other	9%	6%	
	Not stated	*11%*	*7%*	
Plane*	Subglandular	2%	4%	
	Subfascial	1%	1%	
	Sub flap	6%	8%	
	Subcutaneous	14%	11%	
	Subpectoral	29%	29%	
	Dual plane or partial cover with PM	36%	42%	
	Not stated	*12%*	*8%*	
Mastopexy	Yes	5%	1%	7%
	Not stated	*10%*	*6%*	*5%*
Capsulectomy†	Partial capsulectomy		46%	38%
	Full capsulectomy		9%	24%
	Not stated		*7%*	*5%*
Autologous flap cover	Yes	8%	6%	
	Not stated	*10%*	*7%*	
Fat grafting	Yes	<1%	6%	5%
	Not stated	*10%*	*7%*	*5%*
Drains	Yes	86%	52%	
	Not stated	*7%*	*4%*	
Mesh/ADM use*	Yes	5%	1%	
	Not stated	*12%*	*7%*	

Abbreviations: ADM: Acellular Dermal Matrix, NS = Nipple-Sparing, NNS = Non-Nipple-Sparing.
N.B. Due to rounding of percentages, added rows may exceed 100%.
**The variables 'Plane', 'Autologous flap cover', 'Drains', and 'Mesh/ADM use' were only registered for insertion only and replacement procedures.*
†The variable 'Capsulectomy' was only registered for replacement and explantation only procedures.

Table 15. *Intraoperative techniques in aesthetic procedures, per breast (2022)*

		Insertion only	Replacement	Explantation only
Total number of breasts		**(n = 6,275)**	**(n = 4,016)**	**(n = 3,600)**
Incision site	Inframammary	99%	96%	
	Mastectomy scar (NNS)	-	-	
	Mastectomy scar (NS)	-	-	
	Peri-areolar	<1%	1%	
	Other	1%	4%	
	Not stated	*<1%*	*1%*	
Plane*	Subglandular	26%	37%	
	Subfascial	16%	4%	
	Sub flap	<1%	<1%	
	Subcutaneous	1%	1%	
	Subpectoral	5%	6%	
	Dual plane or partial cover with PM	52%	51%	
	Not stated	*1%*	*1%*	
Mastopexy	Yes	6%	10%	20%
	Not stated	*<1%*	*<1%*	*<1%*
Capsulectomy†	Partial capsulectomy		42%	39%
	Full capsulectomy		27%	30%
	Not stated		*<1%*	*<1%*
Autologous flap cover	Yes	<1%	1%	
	Not stated	*2%*	*4%*	
Fat grafting	Yes	<1%	4%	16%
	Not stated	*<1%*	*<1%*	*<1%*
Drains	Yes	7%	29%	
	Not stated	*<1%*	*<1%*	
Mesh/ADM use*	Yes	<1%	<1%	
	Not stated	*<1%*	*<1%*	

Abbreviations: ADM: Acellular Dermal Matrix.

N.B. Due to rounding of percentages, added rows may exceed 100%.

**The variables 'Plane', 'Autologous flap cover', 'Drains', and 'Mesh/ADM use' were only registered for insertion only and replacement procedures.*

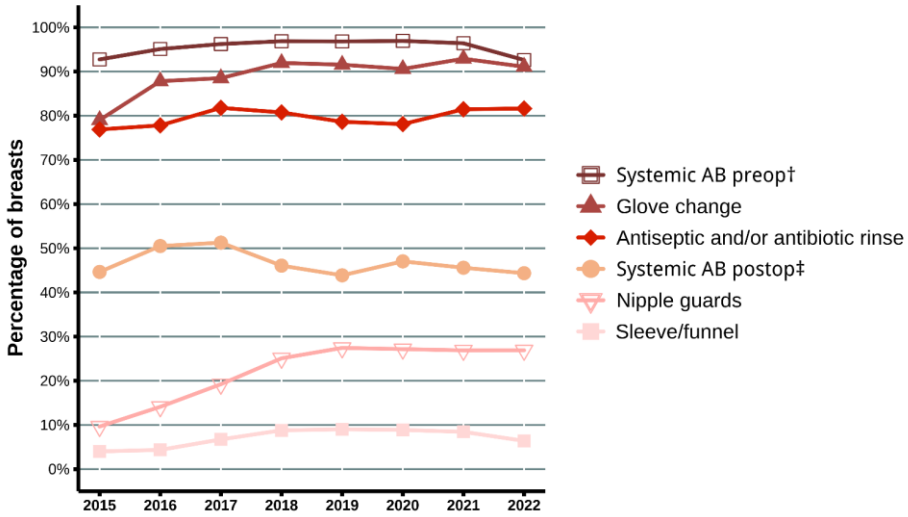
†The variable 'Capsulectomy' was only registered for replacement and explantation only procedures.

Infection control measures *(Figure 10)*

Most infection control measures (ICMs) were registered solely for the insertions of an implant. Therefore, only the insertion only and replacement procedures are included in ***Figure 10***. The results are presented per breast. Over the years (2015 - 2022), there has been an increase in the use of ICMs. However, also the percentage of records containing information about ICMs increased over this period, from approximately 93% in 2016 to about 99% in 2022 (***Table 2***). This is an important consideration when interpreting these results.

In 2022, the most frequently used ICMs for reconstructive indications were preoperative systemic antibiotic prophylaxis, glove change, and antiseptic pocket rinse. Since 2015, the use of these ICMs ranged from 93% to 98%. Glove change increased from 79% to 91%, and antiseptic pocket rinse increased from 78% to 81%. However, the use of postoperative antibiotic prophylaxis has varied over the years, ranging from 44% to 51%. In 2022, nipple guards and sleeve/Keller funnel has been used in less than a third of the cases (28% and 8%, respectively).

Figure 10. *Infection control measures for every reconstructive implant insertion, per breast* (2015 – 2022)*



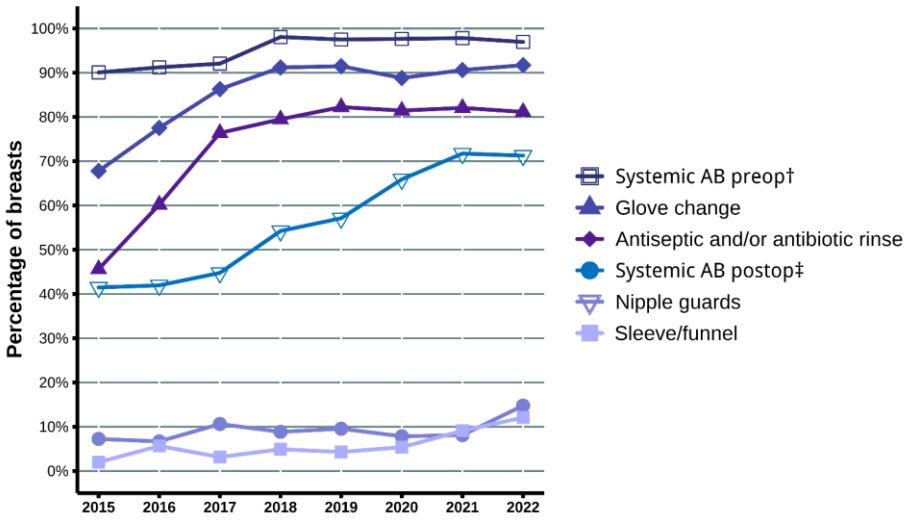
**Infection control measures were only registered for insertion only and replacement procedures.*
†Systemic AB preop: systemic antibiotics preoperatively (use of intravenous antibiotics within 60 minutes before incision).
‡Systemic AB postop: systemic antibiotics postoperatively (use of intravenous antibiotics at any time after 3 hours post-surgery).

Infection control measures *(Figure 11)*

Most infection control measures (ICMs) were registered solely for insertion of an implant. Therefore, only the insertion only and replacement procedures are included in ***Figure 11***. The results are presented per breast. Over the years (2015 - 2022), there has been an increase in the use of ICMs. However, also the percentage of records containing information about ICMs increased slightly over this period, from approximately 93% in 2016 to about 99% in 2022 (***Table 2***). This is an important consideration when interpreting these results.

In 2022, the most frequently used ICMs for aesthetic indications were preoperative systemic antibiotic prophylaxis, antiseptic pocket rinse, and glove change. Since 2015, the use of these ICMs has continued to increase from 90% to 98%, 68% to 92%, and 46% to 81%, respectively. Notably, the use of nipple guards showed an increase of up to 71% in the last years. The use of a sleeve/Keller funnel and postoperative antibiotic prophylaxis has remained low (12% and 15%, respectively).

Figure 11. *Infection control measures for every aesthetic implant insertion, per breast* (2015 – 2022)*



**Infection control measures were only registered for insertion only and replacement procedures.*
†Systemic AB preop: systemic antibiotics preoperatively (use of intravenous antibiotics within 60 minutes before incision).
‡Systemic AB postop: systemic antibiotics postoperatively (use of intravenous antibiotics at any time after 3 hours post-surgery).

Device characteristics ***(Table 16)***

The majority of devices inserted for reconstructive indications were permanent breast implants. In 2022, the most frequently registered permanent breast implant was anatomically shaped (56%), micro textured (62%), silicone coated (75%), silicone filled (78%), and had a volume ranging between 400 and 599 cc (37%). Tissue expanders inserted in 2022 were predominantly anatomically shaped (93%), micro textured (83%), silicone coated (95%), filled with saline (94%), and had a volume ranging between 400 and 599 cc (50%).

Table 16. *Characteristics of inserted devices for reconstructive indications, per year (2015 - 2022)*

	Permanent implants		Tissue expanders	
	2015 - 2021	**2022**	**2015 – 2022**	**2022**
Inserted devices	n = 15,916	n = 2,921	n = 10,574	n = 1,376
Device shape				
Round	20%	27%	4%	2%
Shaped/Anatomical	70%	56%	92%	93%
Not stated	*11%*	*18%*	*4%*	*5%*
Device texture				
Textured	20%	-	29%	-
Nano textured	3%	6%	1%	8%
Micro textured	54%	62%	58%	83%
Macro textured	7%	1%	9%	2%
Smooth	5%	14%	1%	3%
Not stated	*12%*	*17%*	*4%*	*5%*
Device coating				
Silicone	80%	75%	96%	95%
Polyurethane	9%	9%	-	-
Other	-	-	<1%	-
Not stated	*11%*	*17%*	*4%*	*5%*
Device fill				
Silicone	83%	79%	6%*	2%*
Saline	2%	2%	87%	94%
Hydrogel	1%	-	-	-
Air	-	-	<1%	<1%
Other	<1 %	<1%	3%	1%
Not stated	*13%*	*19%*	*4%*	*4%*
Device volume/weight† volume in cc				
<199	5%	14%	<1%	1%
200 - 399	34%	34%	24%	28%
400 – 599	35%	37%	51%	50%
≥600	12%	11%	19%	18%
Not stated	*14%*	*4%*	*6%*	*3%*

N.B. Due to rounding of percentages, added rows may exceed 100%.

**This category describes tissue expanders that are filled with both silicone and saline.*

†The variable 'Maximum volume/weight of device' has been registered since September 2017.

Device characteristics ***(Table 17)***

The majority of devices inserted for aesthetic indications were permanent breast implants. In 2022, most of the permanent breast implants were round (70%), micro textured (70%), silicone coated (95%), silicone filled (96%), and had a volume between 200 and 399 cc (59%). The inserted tissue expanders were in 2022 predominantly anatomically shaped (82%), micro textured (77%), silicone coated (100%), filled with saline (77%), and had a volume between 400 and 599 cc (64%).

Table 17. *Characteristics of inserted devices for aesthetic indications, per year (2015 – 2022)*

	Permanent implants		Tissue expanders	
	2015 – 2021	**2022**	**2015 - 2021**	**2022**
Inserted devices	n = 85,275	n = 9974	n = 174	n = 22
Device shape				
Round	67%	70%	7%	18%
Shaped/Anatomical	32%	28%	90%	82%
Not stated	*1%*	*2%*	*3%*	-
Device texture				
Textured	11%	-	6%	-
Nano textured	6%	17%	1%	18%
Micro textured	70%	70%	78%	77%
Macro textured	4%	1%	10%	-
Smooth	8%	9%	2%	5%
Not stated	*1%*	*2%*	*2%*	-
Device coating				
Silicone	96%	95%	97%	100%
Polyurethane	3%	3%	1%	-
Other	-	<1%	1%	-
Not stated	*1%*	*2%*	*2%*	-
Device fill				
Silicone	98%	96%	14%*	18%*
Saline	<1%	1%	84%	77%
Hydrogel	1%	<1%	-	-
Air	-	-	-	-
Other	-	<1%	1%	5%
Not stated	*1%*	*2%*	*2%*	-
Device volume/weight† volume in cc or grams				
<199	2%	1%	-	-
200 - 399	62%	59%	23%	27%
400 – 599	29%	32%	62%	64%
≥600	4%	5%	13%	9%
Not stated	*2%*	*4%*	*2%*	-

N.B. Due to rounding of percentages, added rows may exceed 100%.

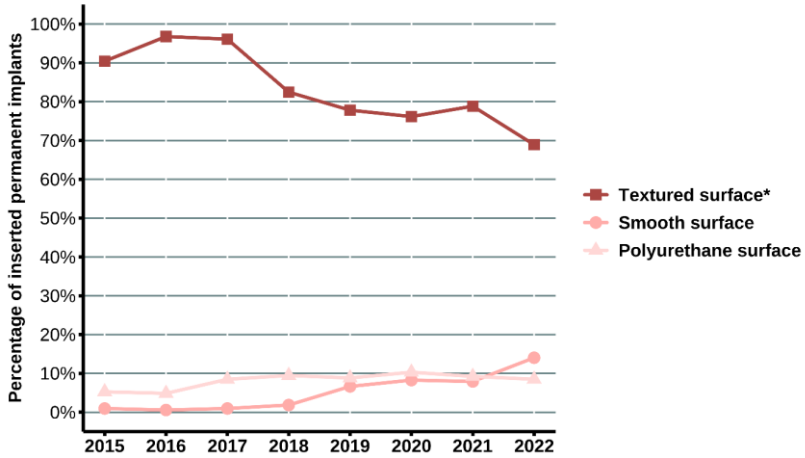
**This category describes tissue expanders that are filled with both silicone and saline.*

†The variable 'Maximum volume/weight of device' has been registered since September 2017.

Trends in characteristics of permanent implants *(Figure 12)*

The choice of implant type is a joint decision made by the patient and the surgeon and is based on the surgical indication. However, breast implants have been frequently discussed in the medica during the last few years. A ban on the use of some types of textured breast implants in France, due to a possible link with a rare form of lymph node cancer (BIA-ALCL), has raised concerns among patients and healthcare providers and led to the withdrawal of these breast implants from the global market by the manufacturer. Although no unequivocal scientific evidence has been found to substantiate a complete ban on textured implants, the percentage of inserted smooth and polyurethane implants seems to be increasing at the expense of textured implants (see ***Figure 12***). Furthermore, because anatomically shaped implants appear to be preferred in breast reconstruction (***Table 16 on page 31***), polyurethane implants as an alternative to textured implants also have the advantage that they are less likely to rotate or become displaced compared to smooth implants.

Figure 12. *Trends in characteristics of implants inserted for reconstructive indications (2015 – 2022)*



N.B. Percentages per year may not add up to 100% due to records in which the variable 'implant surface' was missing.
**Before September 2017, 'Surface texture' was defined as textured or smooth. After September 2017, these answer options were queried in more detail: macro-textured, micro-textured, nano-textured, or smooth surfaces. To provide an overview for all registry years, 'Textured surface' includes all textured answer options in this figure.*

Complications and revision incidence for permanent breast implants

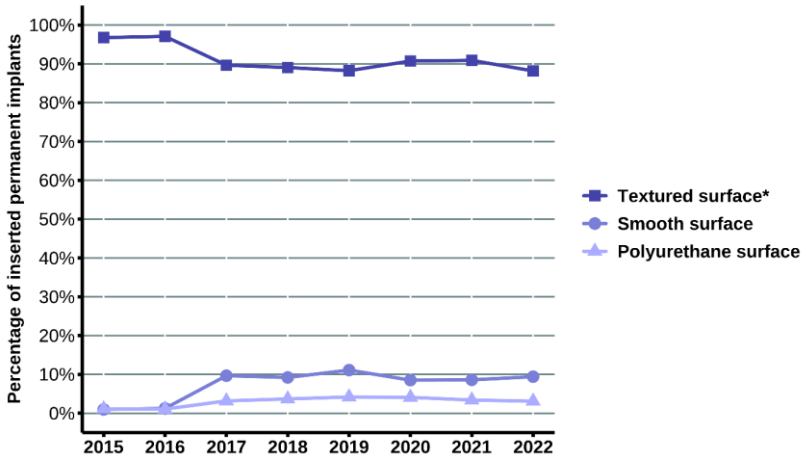
The DBIR collects details of issues and complications identified during revision procedures involving breast devices. Revision surgery includes both planned and unplanned replacement, repositioning, or explantation of an in-situ breast device.

***Note**: It is not known how many of the replacement and explantation procedures in the Netherlands have been registered in DBIR (national denominator), as there has been no gold standard for the validation of explantations yet. Therefore, the presented revision results should be interpreted with caution.*

Trends in characteristics of permanent implants *(Figure 13)*

The choice of implant type is a joint decision made by the patient and the surgeon and is based on the surgical indication. However, breast implants have frequently attracted media attention during the last few years. A ban on the use of some types of textured breast implants in France, due to a possible link with a rare form of lymph node cancer (BIA-ALCL), has raised concerns among patients and healthcare providers and led to the withdrawal of these breast implants from the global market by the manufacturer (*Figure 13*).

Figure 13. *Trends in characteristics of implants inserted for aesthetic indications (2015 – 2022)*



N.B. Percentages per year may not add up to 100% due to records in which the variable 'implant surface' was missing.
**Before September 2017, 'Surface texture' was defined as textured or smooth. After September 2017, these answer options were queried in more detail: macro-textured, micro-textured, nano-textured, or smooth surfaces. To provide an overview for all registry years, 'Textured surface' includes all textured answer options in this figure.*

Complications and revision incidence for permanent breast implants

The DBIR collects details of issues and complications that are found at the time of a revision procedure involving breast devices. Revision surgery includes planned and unplanned replacement, repositioning, or explantation of an in-situ breast device.

***Note**: It is not known how many of the replacement and explantation procedures in the Netherlands have been registered in DBIR (national denominator), as there has been no gold standard for the validation of explantations yet. Therefore, the presented revision results should be interpreted with caution.*

Indications for revision & perioperative findings *(**Table 18**)*

Table 18 shows issues identified during reconstructive breast implant revision procedures. Multiple indications may be registered per revision. The percentages in the table represent observational proportions rather than actual complication rates. In 2022, the most frequently reported reasons for unplanned revisions of reconstructive permanent implants were capsular contracture (30%), followed by breast pain (23%), and device rupture or deflation (18%).

Table 18. *Indications for revision & perioperative findings, reconstructive permanent implants (2015 – 2022)*

	2015 – 2021		2022	
TOTAL REVISION PROCEDURES (PER BREAST)	**(n = 7,204)**		**(n = 2,138)**	
	n	**%**	**n**	**%**
Capsular contracture	2,371	(33%)	631	(30%)
Breast pain	1,533	(22%)	494	(23%)
Device rupture or deflation	993	(14%)	375	(18%)
Asymmetry	1,488	(21%)	346	(17%)
Other‡	968	(13%)	246	(12%)
Patient dissatisfied with volume	845	(12%)	191	(9%)
Device malposition	755	(11%)	164	(8%)
Silicone extravasation*	506	(7%)	157	(7%)
Breast implant-associated illness	202	(3%)	89	(4%)
Breast cancer recurrence	360	(5%)	75	(4%)
Deep wound infection	309	(4%)	75	(4%)
Skin necrosis or dehiscence	290	(4%)	63	(3%)
Seroma or hematoma	312	(4%)	69	(3%)
BIA-ALCL (suspicion)*	80	(1%)	22	(1%)
Flap problem	111	(2%)	<10	(<1%)
BIA-ALCL (PA proven)*§	15	(<1%)	<10	(<1%)
Explantation due to a recall*	-	-	-	-

Abbreviations: BIA-ALCL: Breast Implant-Associated Anaplastic Large Cell Lymphoma, PA: pathology.
N.B. Numbers do not represent complication rates. This table includes devices that were inserted before and after the start of DBIR. Results should be interpreted carefully (see note on page 37) and it should be taken into consideration that explantations are being registered more thoroughly over the years. Issues are listed in order of frequency for 2022 and multiple issues could be reported per revision procedure.
‡Most commonly including 'Revision due to a contralateral problem' and 'Patient's request without health complaints'.
**These variables have not been registered from the start of the registry.*
§Please note that these cases still need to be validated with the Dutch pathology database (PALGA).

Indications for revision & perioperative findings *(Table 19)*

Table 19 shows issues identified during aesthetic breast implant revision procedures. Multiple indications may be registered per revision. Percentages represent observational proportions, not actual complication rates. In 2022, the most frequently reported reasons for unplanned revisions of aesthetic permanent implants were capsular contracture (29%), followed by device rupture or deflation (21%), and patient dissatisfaction with volume (14%). In the past 3 years, the number of revisions due to breast implant-associated illness has increased from 7% in 2020 to 11% in 2022.

Table 19. *Indications for revision & perioperative findings, aesthetic permanent implants (2015 – 2022)*

	2015 - 2021		2022	
TOTAL REVISION PROCEDURES (PER BREAST)	**(n = 23,020)**		**(n = 7,316)**	
	n	**%**	**n**	**%**
Capsular contracture*	8,112	(35%)	2,144	(29%)
Device rupture or deflation	5,146	(22%)	1,568	(21%)
Breast pain	3,091	(13%)	1,037	(14%)
Patient dissatisfied with volume	4,345	(19%)	1,023	(14%)
Other‡	3,214	(14%)	872	(12%)
Breast implant-associated illness	1,579	(7%)	801	(11%)
Silicone extravasation*	2,784	(12%)	679	(9%)
Asymmetry	2,289	(12%)	431	(6%)
Device malposition	1,490	(7%)	222	(3%)
BIA-ALCL (suspicion)*	341	(2%)	166	(2%)
Seroma or hematoma*	385	(2%)	92	(1%)
Deep wound infection	214	(1%)	37	(1%)
Breast cancer	115	(1%)	30	(<1%)
Skin necrosis or dehiscence	82	(<1%)	11	(<1%)
BIA-ALCL (PA proven)*§	25	(<1%)	<10	(<1%)
Explantation due to a recall¶	3	(<1%)	-	-
Flap problem	46	(<1%)	<10	(<1%)

Abbreviations: BIA-ALCL: Breast Implant-Associated Anaplastic Large Cell Lymphoma, PA: pathology.
N.B. Numbers do not represent complication rates. This table includes devices that were inserted before and after the start of DBIR. Results should be interpreted carefully (see note on page 38) and it should be taken into consideration that explantations are being registered more thoroughly over the years. Issues are listed in order of frequency for 2022 and multiple issues could be reported per revision procedure.
‡Most commonly including 'Revision due to a contralateral problem' and 'Patient's request without health complaints'.
**These variables have not been registered from the start of the registry.*
¶Registered since 2019. All explantations due to a recall involved a Poly Implant Prothèse (PIP) implant in this table.
§Please note that these cases still need to be validated with the Dutch pathology database (PALGA).

Revision incidence: all-cause vs. complication related (*Figures 14 – 15 and Table 20)*

The cumulative percentage of revised primary permanent implants was calculated per reconstructive indication. These analyses included all devices of which the insertion surgery was registered in DBIR since the start in April 2015. Breasts without a revision procedure captured by the registry had their follow-up time censored at the date of data extraction (March 21, 2023). Revision was defined as reinsertion of a new device, repositioning of the device, replacement with autologous tissue, or explantation without replacement with any device or autologous tissue. For all-cause revisions, all indications for revision were included, except planned replacement of a tissue expander for a permanent breast implant or autologous tissue. For complication-related revisions, included complications were deep wound infection, capsular contracture, device malposition or displacement, device rupture or deflation, seroma or hematoma, skin scarring (including skin necrosis or dehiscence), or BIA-ALCL. Only devices with a correct manufacturer and serial number registered during insertion surgery could be traced over time and could therefore be included in the calculations. The presented cumulative percentages are not adjusted for confounding factors.

Figure 14. *All-cause revision incidence - Reconstructive primary permanent breast implants*

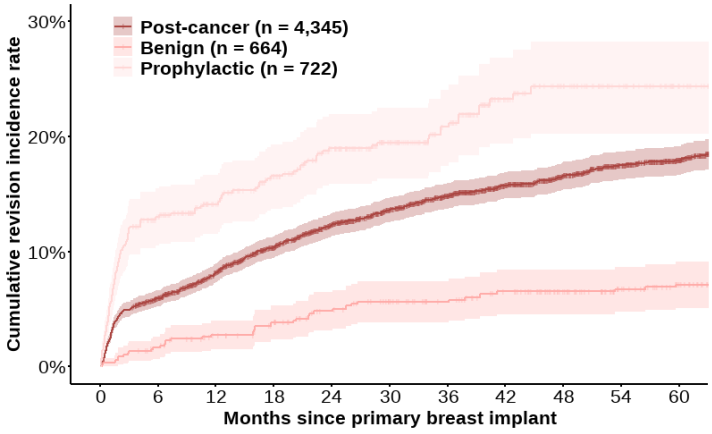
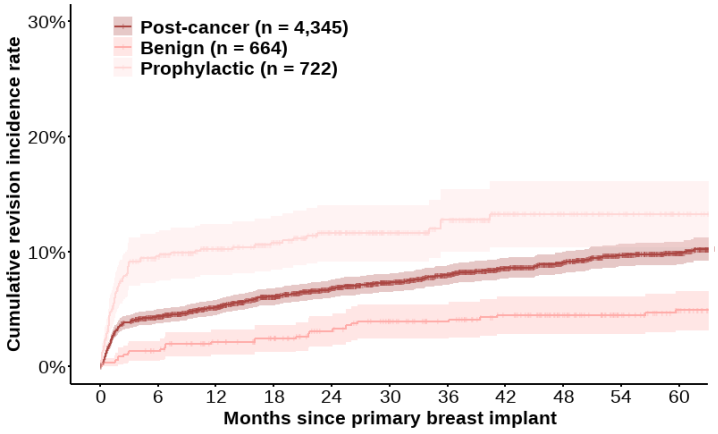


Figure 15. *Complication related revision incidence - Reconstructive primary permanent breast implants*



Revision incidence: all-cause vs. complication related (Figures 16 – 17 and Table 21)

The cumulative percentage of revised primary permanent implants was calculated per aesthetic indication. These analyses included all devices of which the insertion surgery was registered in DBIR since the start in April 2015. Breasts without a revision procedure captured by the registry had their follow-up time censored at the date of data extraction (March 21, 2023). Revision was defined as the reinsertion of a new device, repositioning of the existing device, replacement with autologous tissue, or explantation without replacement with any device or autologous tissue. For all-cause revisions, all indications for revision were included, except planned replacement of a tissue expander for a permanent breast implant or autologous tissue. For complication-related revisions, included complications were deep wound infection, capsular contracture, device malposition or displacement, device rupture or deflation, seroma or hematoma, skin scarring (including skin necrosis or dehiscence), or BIA-ALCL. Only devices with a correct manufacturer and serial number registered during insertion surgery could be traced over time and could therefore be included in the calculations. The presented cumulative percentages are not adjusted for confounding factors.

Figure 16. *All-cause revision incidence - Aesthetic primary permanent breast implants*

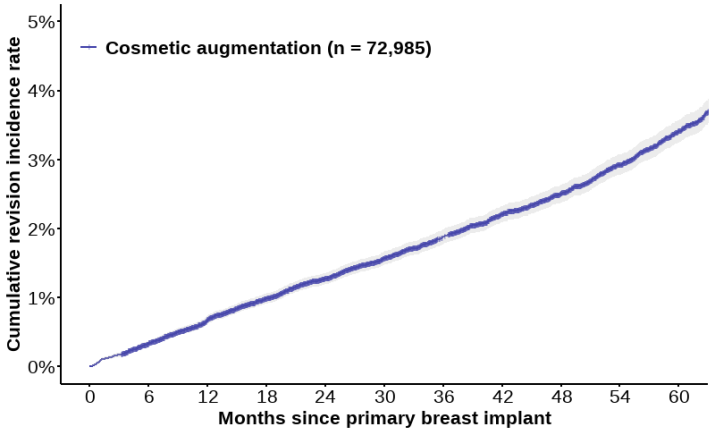
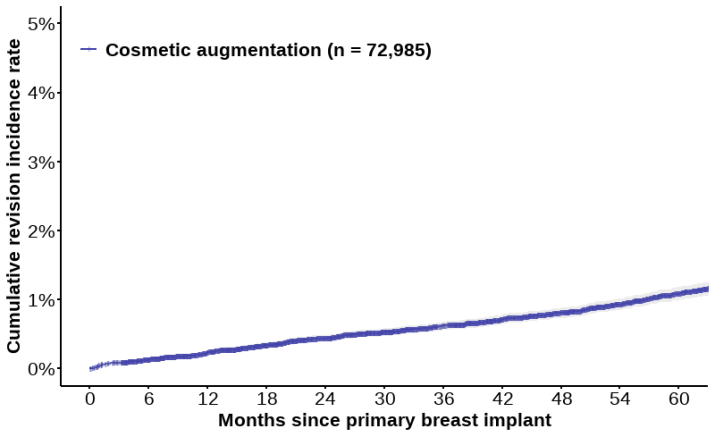


Figure 17. *Complication related revision incidence - Aesthetic primary permanent breast implants*



At 36 months after the date of primary implant insertion, 8.0% of the post-cancer implants had been revised due to complications, 3.9% of the implants inserted for benign reconstructions, and 12.7% of the implants that were inserted after prophylactic mastectomy. These revision incidences were 9.9%, 4.9%, and 13.3% after 60 months, respectively. Since most prophylactic mastectomies are performed bilaterally, the relatively high revision incidence in the all-cause and complication groups (25.8% and 13.3%) might be explained by the higher complication rate which is associated with bilateral breast implant reconstruction. Another explanation could be that a unilateral complication leading to a revision may also lead to a contralateral revision in the breast without a complication. Both breasts are included in the all-cause revision incidence curve. Moreover, a scientific paper is currently being written investigating which risk factors should be adjusted for to reliably compare the differences in the number of revisions between groups.

Table 20. *Revision incidence: all-cause vs. complication – Reconstructive primary permanent breast implants*

	Post-cancer	Benign	Prophylactic
Number of primary breast implants	**4,345**	**664**	**722**
Number revised: all-cause	**748**	**54**	**143**
Number revised: complication	**397**	**34**	**83**
All-cause revision incidence (95% confidence interval)			
12 months since primary breast implant	8.2% (7.3, 9.0)	2.7% (1.5, 4.0)	14.1% (11.5, 16.7)
24 months since primary breast implant	12.6% (11.6, 13.6)	4.8% (3.1, 6.4)	19.1% (16.1, 22.1)
36 months since primary breast implant	15.1% (14.0, 16.2)	5.6% (3.8, 7.)	21.3% (17.9, 24.6)
48 months since primary breast implant	16.9% (15.7, 18.1)	6.5% (4.6, 8.4)	24.8% (20.7, 28.7)
60 months since primary breast implant	18.2% (17.0, 19.5)	7.1% (5.1, 9.2)	25.8% (20.7, 28.7)
Revision incidence due to complication (95% confidence interval)			
12 months since primary breast implant	5.1% (4.5, 5.8)	2.1% (1.0, 3.2)	10.2% (7.9, 12.4)
24 months since primary breast implant	6.8% (6.0, 7.6)	3.1% (1.8, 4.4)	11.6% (9.1, 14.0)
36 months since primary breast implant	8.0% (7.1, 8.8)	3.9% (2.4, 5.4)	12.7% (10.0, 15.4)
48 months since primary breast implant	9.1% (8.2, 10.0)	4.5% (2.8, 6.1)	13.3% (10.3, 16.1)
60 months since primary breast implant	9.9% (8.9, 10.9)	4.9% (3.2, 6.6)	13.3% (10.3, 16.1)

N.B. Revision incidence is based on reconstructive primary breast implants inserted from April 2015 to 2022. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary implant insertion to the first revision procedure.

At 36 months after the date of primary implant insertion, 0.6% of the cosmetic augmentations had been revised due to complications. This revision incidence increased to 1.1% after 60 months

Table 21. *Revision incidence: all-cause vs. complication - Aesthetic primary permanent breast implants 1*

	Cosmetic augmentation
Number of primary breast implants	**72,985**
Number revised: all-cause	**2,185**
Number revised: complication	**688**
All-cause revision incidence (95% confidence interval)	
12 months since primary breast implant	0.7% (0.6, 0.7)
24 months since primary breast implant	1.3% (1.2, 1.4)
36 months since primary breast implant	1.9% (1.8, 2.0)
48 months since primary breast implant	2.5% (2.4, 2.6)
60 months since primary breast implant	3.4% (3.2, 3.6)
Revision incidence due to complication (95% confidence interval)	
12 months since primary breast implant	0.2% (0.2, 0.3)
24 months since primary breast implant	0.4% (0.4, 0.5)
36 months since primary breast implant	0.6% (0.5, 0.7)
48 months since primary breast implant	0.8% (0.7, 0.9)
60 months since primary breast implant	1.1% (1.0, 1.2)

N.B. Revision incidence is based on aesthetic primary breast implants inserted from April 2015 to 2022. Rates have not been adjusted for risk factors. Revision incidence relates to the time from primary implant insertion to the first revision procedure.

Complications and revision incidence for tissue expanders

Indications for revision & perioperative findings *(Table 24)*

Table 24 presents issues identified during revision procedures of reconstructive tissue expanders. Due to the limited number of revisions (n = 196) for aesthetic tissue expanders since the start of DBIR, there is no separate chapter dedicated to these. Multiple issues may be registered per revision, either as the primary reason for the revision or discovered incidentally during the procedure. The percentages are subject to inter-observer variability and therefore represent observational proportions rather than actual complication rates. The numbers consist of new tissue expanders as well as tissue expanders inserted (and/or explanted) prior to and after the start of the registry.
In 2022, the most frequently reported reasons for unplanned revisions of reconstructive tissue expanders were deep wound infection (7%), other (6%), and skin necrosis or dehiscence (5%).

Table 24. *Indications for revision & perioperative findings, reconstructive tissue expanders (2015 – 2022)*

	2015 – 2021		2022	
TOTAL REVISION PROCEDURES (PER BREAST)	**(n = 7,087)**		**(n = 1,362)**	
	n	**%**	**n**	**%**
TE to permanent implant* *(planned)*	4,394	(62%)	944	(69%)
TE to autologous tissue* (*planned*)	315	(4%)	118	(9%)
Deep wound infection	354	(5%)	98	(7%)
Other‡	439	(6%)	79	(6%)
Skin necrosis or dehiscence	192	(3%)	74	(5%)
Capsular contracture	464	(7%)	53	(4%)
Seroma or hematoma	295	(4%)	53	(4%)
Asymmetry	377	(5%)	50	(4%)
Breast pain	188	(3%)	44	(3%)
Device rupture or deflation	257	(4%)	37	(3%)
Device malposition	260	(4%)	19	(1%)
Dissatisfied with volume	122	(2%)	18	(1%)
Flap problem	79	(1%)	<10	(1%)
Breast cancer recurrence	86	(1%)	<10	(1%)
Breast implant-associated illness	<10	(<1%)	<10	(<1%)
BIA-ALCL (suspicion)	<10	(<1%)	<10	(<1%)
BIA-ALCL (PA proven)	-	(-)	<10	(<1%)

Abbreviations: BIA-ALCL = Breast Implant-Associated Anaplastic Large Cell Lymphoma, PA = pathology, TE = Tissue Expander.
N.B. Numbers do not represent complication rates. This table includes devices that were inserted before and after the start of DBIR. Results should be interpreted carefully (see note on page 37) and it should be taken into consideration that explantations are being registered more thoroughly over the years. Issues are listed in order of frequency for 2022 and multiple issues could be reported per revision procedure.
**These variables have not been registered from the start of the registry.*
‡Most commonly including 'Patient's request without health complaints'.

Revision incidence: all-cause and complication related (*Figures 22 – 23 and Table 25)*

The cumulative percentage of revised tissue expanders was calculated per reconstructive indication. These analyses included all tissue expanders of which the insertion surgery was registered in DBIR since the start in April 2015. For breasts without a revision procedure recorded in the registry, their follow-up time was censored as of the date of data extraction (April 7, 2022). Revision was defined as reinsertion of a new device, repositioning of the existing device, replacement with autologous tissue, or explantation without replacement with any device or autologous tissue (*see the next page for explanation on definitions in **Figures 22-23***).

Figure 22. *All-cause revision incidence - Reconstructive primary tissue expanders (2015 – 2022)*

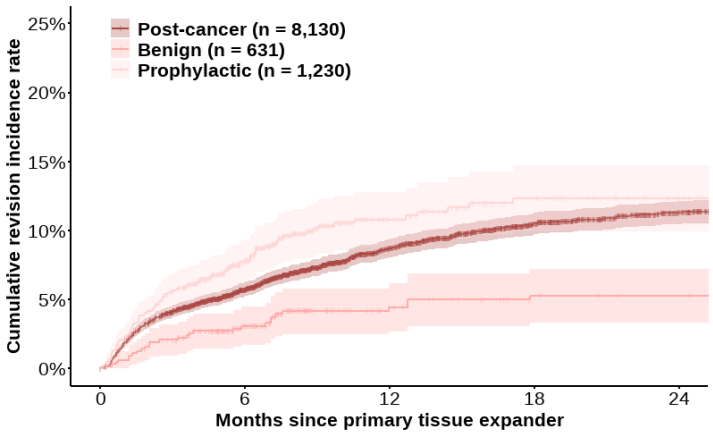
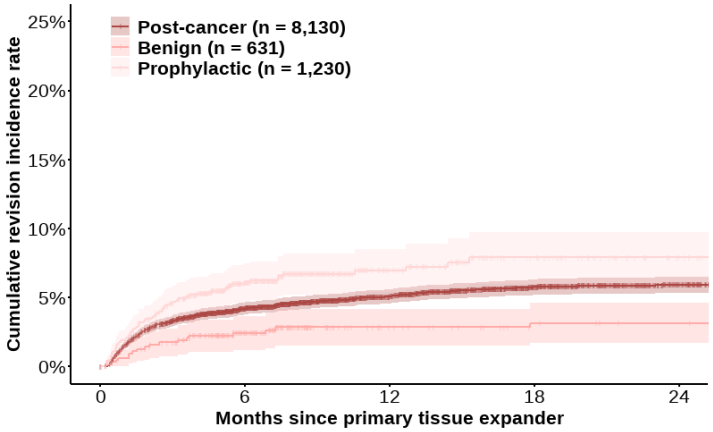


Figure 23. *Revision incidence due to complication - Reconstructive primary tissue expanders (2015 – 2022)*



For all-cause revisions, all indications for revision were included, except planned replacement of a tissue expander for a permanent breast implant or autologous tissue. For complication-related revisions, included complications were deep wound infection, capsular contracture, device malposition or displacement, device rupture or deflation, seroma or hematoma, skin scarring (including skin necrosis or dehiscence), or BIA-ALCL. Only devices with a correct manufacturer and serial number registered during insertion surgery could be traced over time and could therefore be included in the calculations. The presented cumulative percentages were not adjusted for confounding factors.

At 6 months after the date of primary tissue expander insertion, 4.2% of the post-cancer tissue expanders had been revised due to complications, 2.4% of the tissue expanders inserted for benign reconstructions, and 6.1% of the tissue expanders that were inserted after prophylactic mastectomy. These revision incidences increased to 5.9%, 3.2%, and 7.9% after 24 months, respectively. Since most prophylactic mastectomies are performed bilaterally, the relatively high revision incidence in this group could be explained by the higher complication rate that is associated with bilateral breast implant surgery.

Table 25. *Revision incidence: all-cause vs. complication - Reconstructive primary tissue expanders*

	Post-cancer	Benign	Prophylactic
Number of primary tissue expanders	**8,130**	**631**	**1,230**
Number revised: all-cause	**750**	**29**	**120**
Number revised: with complication	**426**	**18**	**81**
All-cause revision incidence (95% confidence interval)			
6 months since primary tissue expander	5.7% (5.2, 6.2)	3.1% (1.7, 4.5)	7.8% (6.3, 9.3)
12 months since primary tissue expander	8.7% (7.0, 9.4)	4.4% (2.7, 6.2)	10.8% (8.8, 12.8)
18 months since primary tissue expander	10.5% (9.7, 11.3)	5.3% (3.3, 7.2)	12.3% (9.9, 14.7)
24 months since primary tissue expander	11.3% (10.5, 12.1)	5.3% (3.3, 7.2)	12.3% (9.9, 14.7)
Revision incidence due to complication (95% confidence interval)			
6 months since primary tissue expander	4.2% (3.8, 4.6)	2.4% (1.2, 3.6)	6.1% (4.7, 7.5)
12 months since primary tissue expander	5.1% (4.6, 5.6)	2.9% (1.5, 4.2)	7.0% (5.0, 8.1)
18 months since primary tissue expander	5.8% (5.2, 6.3)	3.2% (1.7, 4.6)	7.9% (6.0, 9.8)
24 months since primary tissue expander	5.9% (5.4, 6.5)	3.2% (1.7, 4.6)	7.9% (6.0, 9.8)

QUALITY INDICATORS, PROJECTS, COLLABORATIONS, FUTURE PERSPECTIVES, AND RESEARCH

7. QUALITY INDICATORS

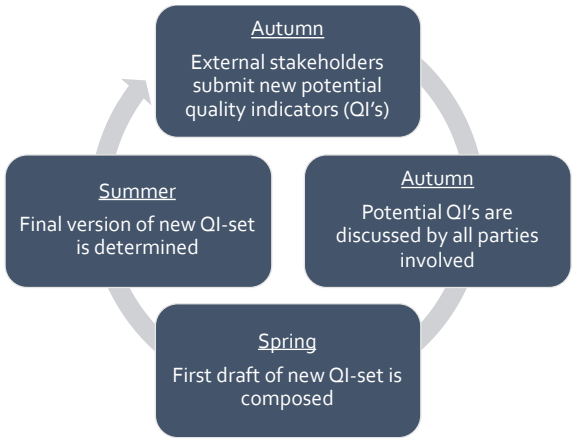
Quality indicators

According to Donabedian's model, there are three types of indicators: structure, process, and outcome indicators. Donabedian believed that structure measures affect process measures, which in turn affect outcome measures. Whether a healthcare institution registers in DBIR or not, is for example a structure indicator. Another example is the percentage of patients who receive antiseptic measures preoperatively (process), which might affect the complications after surgery (outcome). The DBIR quality indicators are defined by the Scientific Committee and constitute the basis for internal data mirroring.

Annual cycle ***(Figure 24)***

The cycle for developing quality indicators is a secure trajectory that involves close collaboration between external stakeholders and the Scientific Committee. A potential quality indicator undergoes two phases: internal and external transparency. During the first few years, only healthcare institutions receive feedback about this indicator (internal indicator) to further review and adjust the indicator where needed. After the agreement of all involved stakeholders, it is decided whether an indicator will become externally transparent (external indicator) in the annual Transparency Calendar of the Dutch National Healthcare Institute (ZiNL). At that time, the quality indicator should be sufficiently valid to be shared with external parties, such as patients and healthcare insurers.

Figure 24. *Annual DICA cycle for quality indicators*



Dutch Health and Youth Care Inspectorate (IGJ)

There are multiple parties in the Netherlands that request quality indicators to monitor the quality of care. One of these parties is the Dutch Health and Youth Care Inspectorate (IGJ). These indicators are legally required for healthcare institutions. For this reason, DBIR tries to collaborate closely with IGJ and other parties regarding the development of new quality indicators to prevent double requests or any ambiguities from the care providers' side.

External quality indicators 2023

No.	Description	Type
1.	Is this institution registering in DBIR? (yes/no)	Structure
2.	The percentage of registered breast devices in DBIR	Process
3.	The percentage of registered breast devices in DBIR with a complete record (including completely filled in recall variables)	Process
4.	The percentage of breast devices in DBIR for which the patient received preoperative intravenous antibiotic prophylaxis	Process
5.	The percentage of reoperation due to a short-term complication in DBIR	Outcome
6.	The percentage of reoperation due to long-term complication in DBIR	Outcome

Results of external quality indicators

The outcome indicators for 2023 have not changed compared to the set of 2022.
Although DBIR does not have access to the names of the healthcare institutions that show a delay in their registration for privacy reasons, the Netherlands Society of Plastic Surgery (NVPC) audit committee may ask these healthcare institutions for clarification (*Chapter 8*).

The following quality indicators are being internally tested for validity to assess whether they could be part of the DBIR indicator set in the future.

- The percentage of glove changes before inserting a breast device;
- The percentage of explanted breast devices for which a reason for revision has been entered;
- The percentage of reoperations due to patient dissatisfaction with volume;
- Median insertion-to-reoperation time due to patient dissatisfaction with implant volume.

8. PROJECTS

Automated data submission to the DBIR

Every year, the reduction of the administrative burden is one of the top priorities of DBIR. Therefore, DBIR co-operates in projects that invest in the registration of information uniformly, so that data can be extracted automatically from electronic patient records for various purposes, based on the FAIR principles (Findable, Accessible, Interoperable, Reusable). DBIR is currently working on a project which aims to easily reuse clinical data based on a standardized international language. The purpose is to record healthcare information only once and then reuse it for various purposes from the original source. As all the information is recorded unambiguously at the point of care, it becomes easier for healthcare professionals to supply the required information for quality assurance, research, and to other parties. See ***https://www.registratieaandebron.nl/videos/the-bigger-picture-english-instruction*** for more information.

Facilitating clinical information at the point of care

For the first time, all participating healthcare institutions in the DBIR received an annual report on hospital level. All results are presented compared to the national benchmark.

Netherlands Society of Plastic Surgery (NVPC) audit committee

In 2022, the NVPC set up an audit committee independent of DBIR to stimulate the quality of breast implant surgery in healthcare institutions whose results have been shown to lag significantly behind those of other healthcare institutions according to DBIR quality indicators (***Chapter 7***). To achieve this, the audit committee has been mandated to investigate which specific healthcare institutions score worse on these quality indicators ($p<0.05$) to subsequently conduct an audit which may lead to an advice to undertake improvement measures.

Implant characteristics prefill

The administrative burden can be reduced by registering implant data using a barcode scanner. By scanning the GS1 barcode on the packaging of an implant, the variables: GTIN, lot number, expiry data, and serial number can be automatically filled. For the future, we plan to implement automatic filling for additional variables.

9. COLLABORATIONS

DBIR collaborators

DBIR thanks all plastic surgeons, residents, and other contributors for registering, and believes that this annual report and the research resulting from the registry are a shared effort. Therefore, everyone who registers in DBIR since 2021 has been offered to become a collaborator on the DBIR annual reports that are published on PubMed. For the most recently published annual report, 134 plastic surgeons and residents have signed up as official collaborators. The DBIR reports will continue to be published annually on PubMed and the opportunity to become a collaborator will also return so that all aggregated DBIR data is public and easily accessible to everyone.

Industrial partners

Without compromising its organizational and financial independence, DBIR collaborates with various industrial partners (DBIR SUPPLIERS) to research and improve the safety and quality of breast implant surgery and to innovate within the registry.

International collaboration with ICOBRA

DBIR collaborates intensively with international partners through ICOBRA (International Collaboration of Breast Registry Activities) (***Figure 25***). ICOBRA was founded in 2012, at the initiative of the Australian Breast Device Registry (ABDR) and under the auspices of the Australasian Foundation for Plastic Surgery. At the heart of the ICOBRA concept resides the core ethic and commitment to improving health outcomes for patients with breast devices globally, in an atmosphere of transparency, and a non-profit setup. Contributing countries have been working towards an internationally agreed comparable core dataset and quality indicators, using standardized and epidemiologically sound data that reflect global best practices. By using harmonized datasets, ICOBRA hopes that future crises related to breast devices can be detected and averted in a timely fashion and that the best surgical strategies can be identified. The first global report with data on more than 200,000 implants was written in collaboration with Australia, Sweden, The United States, and the Netherlands.[4] The first steps in pooling anonymized data between the DBIR and ABDR have been explored and are expected to be field-tested in the near future.

Figure 25. Current partners of ICOBRA

[4] *Improving Breast Implant Safety through International Collaboration of National Registries – A Review of over 85000 Patients and 200000 Implants from Four Countries. Becherer BE, Hopper I, Cooter RD, Couturaud B, von Fritschen U, Mullen E, Perks AGB, Pusic AL, Stark B, Mureau MAM, Rakhorst HA. Plast Reconstr Surg, in press.*

10. FUTURE PERSPECTIVES

Linkage with other registries and databases

Currently, all breast cancer patients undergoing implant-based breast reconstruction are being registered in the NBCA (the NABON Breast Cancer Audit) and DBIR. The same applies to patients with Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL), who are registered in the Dutch nationwide pathology database PALGA and DBIR. Ideally, overlapping information between different registries is registered only once. Although DBIR tries to set up collaborations, current privacy issues must be considered and overcome. In 2021, a collaboration project started between DBIR, NIVEL (the Dutch primary healthcare database), and CBS (Statistics Netherlands) to further investigate breast implant-associated illness. The Medical Ethics Review Board has approved this study, showing that linking is possible in exceptional cases.

Codman Dashboard

Since the summer of 2019, all plastic surgeons participating in DBIR have access to an interactive dashboard: the Codman Dashboard (***https://apps.mrdm.nl/***). In this dashboard, the results of the external and internal quality indicators, together with an overview of the treated patients are provided. Participating plastic surgeons can zoom in on specific patient populations, inserted breast implants, or applied surgical techniques when they look for the results of their performed implant surgery. All results are presented compared to the national benchmark.

One million implants

The next major international step, following the first global report of 200,000 breast implants (***Chapter 9***), is to continue our collaboration with other nationwide breast implant registries to publish a paper on one million breast implants.

Patient-reported outcome measures (PROMs)

The opinion of patients about the performance of their breast implants is an important outcome measure in breast implant surgery. That is why international research is being conducted from different perspectives into the most optimal inquiry and implementation of PROMs within breast implant surgery. DBIR is currently investigating how these study results can be used within the current technical and privacy frameworks to implement PROMs in the near future.

Privacy issues in improving patient care

Sharing aggregated data with other registries nationally and internationally helps to identify areas of improvement for individual patient care. However, with the introduction of new privacy legislation, clinical quality registries are under pressure. The DBIR scientific committee notices differences in the interpretation of laws between healthcare institutions, legal advisors, and privacy officers within European countries as well as the rest of the world. These issues will be addressed and an open mind toward the use of data, with respect for the individual's privacy, will be essential for future quality improvement.

11. RESEARCH OUTPUT

The primary goal of DBIR is to enhance the quality of care and breast implants through benchmark information and quality indicators, with participants encouraged to submit research proposals for scientific research to contribute to improving care, identifying best practices, and evaluating device performance. Therefore, all participants of the registry (e.g., plastic surgeons) have the possibility to conduct research with the data and are encouraged to submit research proposals (***www.dica.nl/dbir/onderzoek***). These research proposals are managed by the Scientific Committee of DBIR and the statistical department of DICA, to check the validity and relevance of the proposal, and the availability of the requested data items. This chapter provides a chronological overview of the papers and articles that have been published with DBIR data so far.

1. Becherer BE, Hopper I, Cooter RD, et al. Comparing 200,000 breast implants and 85,000 patients over four national breast implant registries. Plast. Reconstr. Surg. 2023;152(2):307–318. doi: 10.1097/PRS.0000000000010208
2. Becherer BE, Heeg E, Young-Afat DA, et al. Revision incidence after immediate direct-to-implant versus two-stage implant-based breast reconstruction using national real-world data. Plast. Reconstr. Surg. 2023;151(4):693–702. doi: 10.1097/PRS.0000000000009979
3. Becherer BE, Marang-van de Mheen PJ, Young-Afat DA. Variation in the use of infection control measures and infection-related revision incidence after breast implant surgery in the Netherlands. JPRAS Open. 2022;34:226-238. doi: 10.1016/j.jpra.2022.10.004
4. Lieffering AS, Hommes JE, Ramerman L, et al. Prevalence of Local Postoperative Complications and Breast Implant Illness in women with Breast Implants. JAMA Netw Open. 2022;5(10):e2236519. Published 2022 Oct 3. doi:10.1001/jamanetworkopen.2022.36519
5. Blok YL, Plat VD, van der Hage JA, Krekel NMA, Mureau MAM. Nation-wide validation of a multicenter risk model for implant loss following implant-based breast reconstruction. J Plast Reconstr Aesthet Surg. 2022;75(12):4347-4353. doi:10.1016/j.bjps.2022.08.065
6. Barati N, Vrolijk JJ, Becherer BE, et al. Using a Digital Implant Catalog Improves Data Quality and Reduces Administrative Burden in the Dutch Breast Implant Registry. Aesthet Surg J. 2022;42(5):275-281. doi:10.1093/asj/sjab336
7. Bargon CA, Becherer BE, Young-Afat DA, et al. Moving breast implant registries forward: Are they FAIR and Functional?. J Plast Reconstr Aesthet Surg. 2021;74(1):4-12. doi:10.1016/j.bjps.2020.10.001
8. Spronk PER, Begum H, Vishwanath S, et al. Toward International Harmonization of Breast Implant Registries: International Collaboration of Breast Registry Activities Global Common Data Set. Plast Reconstr Surg. 2020;146(2):255-267. doi:10.1097/PRS.0000000000006969
9. Spronk PER, Becherer BE, Hommes J, et al. How to improve patient safety and quality of care in breast implant surgery? First outcomes from the Dutch Breast Implant Registry (2015-2017). J Plast Reconstr Aesthet Surg. 2019;72(10):1607-1615. doi:10.1016/j.bjps.2019.06.023
10. Becherer BE, de Boer M, Spronk PER, et al. The Dutch Breast Implant Registry: Registration of Breast Implant-Associated Anaplastic Large Cell Lymphoma-A Proof of Concept. Plast Reconstr Surg. 2019;143(5):1298-1306. doi:10.1097/PRS.0000000000005501
11. Rakhorst HA, Mureau MAM, Cooter RD, et al. The new opt-out Dutch National Breast Implant Registry - Lessons learnt from the road to implementation. J Plast Reconstr Aesthet Surg. 2017;70(10):1354-1360. doi:10.1016/j.bjps.2017.04.003
12. Hommes J, Mureau MA, Harmsen M, Rakhorst H. 'Welk borstimplantaat heb ik eigenlijk?'; het belang van de Dutch Breast Implant Registry ['Which breast implant do I have?'; the importance of the Dutch Breast Implant Registry]. Ned Tijdschr Geneeskd. 2015;160:A9728.

APPENDIX

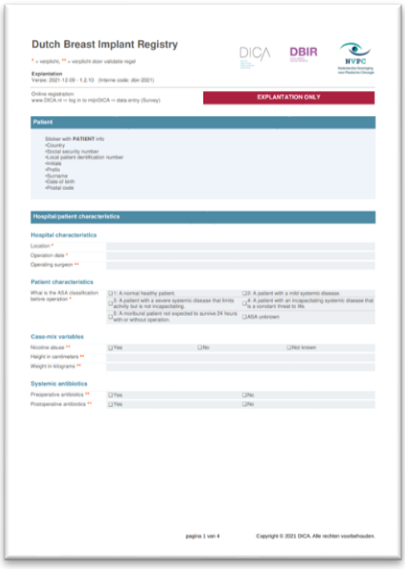
Case report forms

The paper Case Report Forms (CRF) are accessible by clicking one of the images below, or by visiting one of the websites:

- *https://dica.nl/dbir/about-dbir*
- *https://support.mrdm.com/nl/downloads/documenten/?org=dica&set=dbir*

IMPLANTATION ONLY

REPLACEMENT PROCEDURE



EXPLANTATION ONLY

Scan the QR-code to read the digital version of the DBIR Annual Reports

2015 - 2017

2018

2019

2020

2021

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