DUTCH BREAST IMPLANT REGISTRY (DBIR) ANNUAL REPORT 2021

DBIR

DUTCH BREAST IMPLANT REGISTRY

DICA
DUTCH INSTITUTE FOR CLINICAL AUDITING

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

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Author(s)	:	Ms. J.J. Vrolijk, MD and Ms. P.E. Melse, BSc under the supervision of the DBIR committee

CONTENTS

1. FOREWORD

Dear reader,

The scientific committee of DBIR is proud to present the 2021 annual report. We are thankful for all plastic surgeons and residents who endorse and collaborate with the registry daily. You are actively registering all cases where 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 Dutch hospitals and 93% of the private clinics are registering in DBIR today. Furthermore, we value our plastic surgeons' and residents' gift of time and energy.

The scientific board of the DBIR believes that properly designed clinical quality registries can provide essential evidence and play an important role in patient and implant safety. In addition, these registries facilitate quality monitoring and improve ways to innovate, measure, and reduce adverse events.

DBIR is independent of industry and is funded by patients and healthcare insurance. Industry's independence is vital to our existence and will always remain one of our core values. On the other hand, registry data are increasingly important to support innovation and adverse event reporting as required by the new Medical Device Regulation (MDR) that came into effect in May 2021. In other words, our registry data are becoming of vital importance to our patients to ensure breast implants remain on the market. Therefore, in 2021 we collaborated with industry and notified bodies to study today's required data. DBIR reports on all the listed items required by MDR and notified bodies. Moreover, registries are considered validated sources for MDR as pre-approval and post-approval data.

Over the coming years, we will focus on the data completeness of explanted implants. To investigate implant safety, it is necessary to trace all inserted implants and collect reports of all removed implants, including the reasons for removal. The industry collects data on removed implants by an opt-in system where surgeons return the removed implants to their manufacturer together with an extensive questionnaire to be filled out by the surgeon. DBIR collects data on removed implants more robustly and as part of its core tasks. This results in a more complete numerator and denominator, which is of vital importance to study the incidence of adverse events.

In the Netherlands, breast implant safety is being studied on a larger scale than DBIR, thanks to the Dutch government's funding, distributed and monitored by the National Institute for Public Health and the Environment (RIVM). In addition to DBIR, three ongoing projects focus on Breast Implant-Associated Illness (BII) and do this by combining three different perspectives. One does this from a big data perspective and combines DBIR data with the national GP database NIVEL. The second uses a questionnaire perspective by the AREOLA study collecting questionnaire data from breast cancer patients with and without implants. Finally, the Amsterdam UMC group runs a clinic collecting all data of BII patients presented to them. The results of these studies will be published from 2023 onward.

1. FOREWORD

The debate on breast implant safety will remain in the public domain where many patients, journalists, and professionals were vocal and conclusive with or without scientific evidence. Patients and journalists around the world keep showing there is a need for independent and reliable data that objectively represents what is actually happening regarding several implantable medical devices. The DBIR annual reports are important in this debate, and we are happy that the reports are found by journalists, patient advocacy groups, legislators, and producers worldwide.

It remains our vision that patients should be able to be followed across different registries with respect to the patients' privacy. Linking registries is a major challenge within the Dutch ethical and legal environment. DBIR remains 'ready to connect' and prepared to link data in an ethical and legal way according to the FAIR principles. The GDPR needs to provide us with the way forward. The first registries of interest to connect to DBIR include the NABON Breast Cancer Audit (NBCA) and the National Implant Registry (LIR).

Let's keep improving the quality and safety of breast implant surgery for our patients. Let's keep on reducing our administrative burdens to a minimum. Let's keep aiming to connect to other registries to increase our knowledge and to serve our patients better every 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
X.H.A. Keuter, MD, PhD
Prof. H.M. Verkooijen, MD, PhD
J.E. Hommes, MD, PhD
A.C.M. van Bommel, MD, PhD
P.L.T. Liem, MSc
J.J. Vrolijk, MD
M.J. Hoornweg, MD, PhD
P.E. Melse, BSc
D.A. Young-Afat, 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 Clinical Audit Board (as of November 2022)

- 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 at Erasmus MC Cancer Institute, University Medical Center Rotterdam, Rotterdam;
- J.E. Hommes, MD, PhD, secretary, plastic surgeon at Zuyderland Medical Center, Heerlen.

DBIR Scientific Committee (as of November 2022)

- 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 Zuyderland Medical Center, Heerlen;
- B.E. Becherer, MD, PhD
- 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, BSc, clinical researcher at the Dutch Institute for Clinical Auditing, Leiden and PhD candidate at Erasmus MC Cancer Institute, University Medical Center Rotterdam, Rotterdam;
- 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, clinical researcher at the Dutch Institute for Clinical Auditing, Leiden and PhD candidate at Maastricht University Medical Center Grow, Maastricht;
- D.A. Young-Afat, MD, PhD, epidemiologist and plastic surgery resident at Amsterdam University Medical Center, Amsterdam.

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 Ziekenhuis, Leiderdorp.

3. FACT SHEET (NL)

DUTCH BREAST IMPLANT REGISTRY

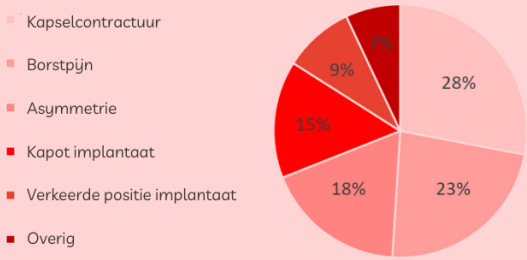
FACT SHEET JAARRAPPORT 2021

In 2021 zijn **13.941 patiënten**, **14.639 operaties** en **28.629 implantaten** geregistreerd in DBIR. Dit zijn cosmetische borstvergrotingen en reconstructies na bijvoorbeeld borstkanker.

Van alle geplaatste implantaten in 2021, is ongeveer 70% geplaatst vanwege een **cosmetische borstvergroting** en 30% vanwege een **reconstructie**.

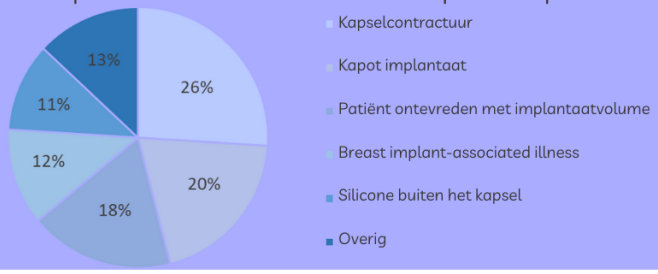
TOP 5 REDENEN VOOR HEROPERATIE

Na een reconstructie aan één of beide borsten werden in het jaar 2021 1.171 patiënten opnieuw geopereerd na het plaatsen van een permanent borstimplantaat. Hieronder een top 5 van redenen waarom er opnieuw geopereerd werd.



TOP 5 REDENEN VOOR HEROPERATIE

In 2021 zijn 4.451 patiënten opnieuw geopereerd nadat zij eerder in hun leven een cosmetische borstvergroting ondergingen. Hieronder ziet u de top 5 redenen waarom deze heroperaties plaatsvonden.



DISCLAIMER

De aantallen in dit fact sheet kunnen verschillen ten opzichte van het jaarrapport omdat het fact sheet data op patiëntniveau toont en het jaarrapport op implantaatniveau.

Voor meer algemene informatie over borstimplantaten:
www.igj.nl/onderwerpen/borstimplantaten

DUTCH BREAST IMPLANT REGISTRY

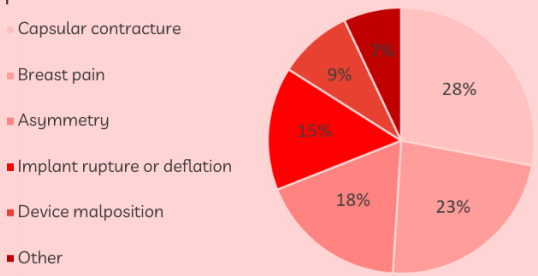
FACT SHEET ANNUAL REPORT 2021

In 2021, **13,941 patients**, **14,639 surgeries** and **28,629 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 2021, approximately 70% were inserted because of **cosmetic breast augmentation**, and 30% because of **breast reconstruction**.

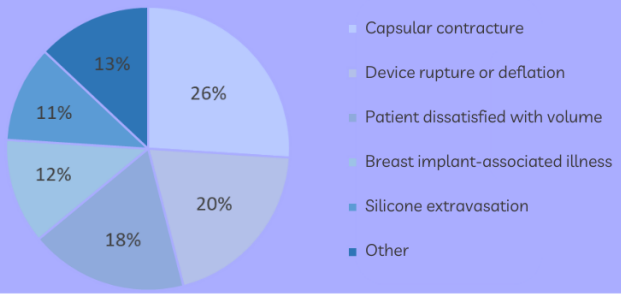
TOP 5 REASONS FOR REOPERATION

After single- or double-sided breast reconstruction with a permanent implant, 1,171 patients underwent reoperation in 2021. The top 5 reasons for reoperation are mentioned below.



TOP 5 REASONS FOR REOPERATION

In 2021, 4,451 patients underwent reoperation after a previous cosmetic breast augmentation. The top 5 reasons for reoperation are mentioned below.



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

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. Every year a selection of quality indicators is published on the Transparency Calendar, making this information publicly available (*Chapter 7*). Additionally, 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). DICA is an independent institution founded 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 25). 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.

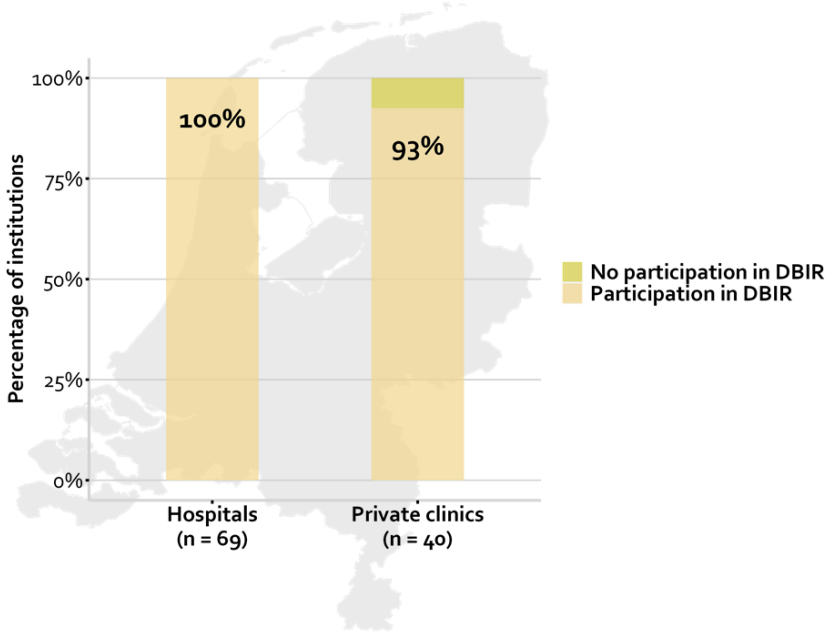
Patients are involved

Patients can check whether their plastic surgeon has registered their breast implant(s) in the DBIR. On the website *www.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. 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. Breast implant surgery is performed in either a hospital or 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 (2021)*



(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

[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.*

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 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*

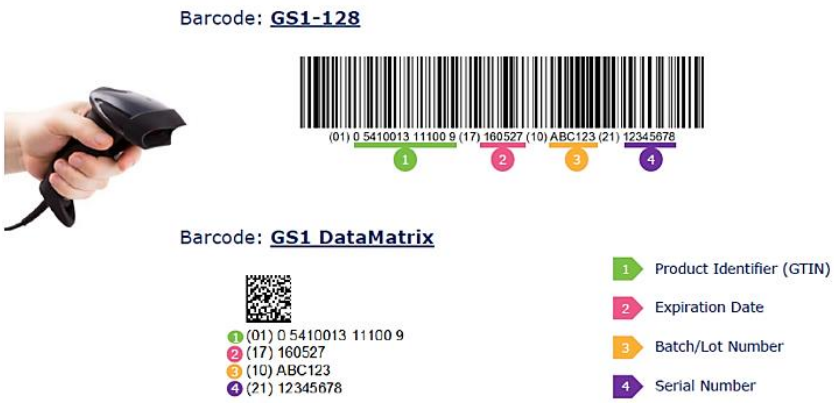


Table 1. *Participation GS1 and DBIR SUPPLIERS (2021)*

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.*

DBIR SUPPLIERS registry

The DBIR has a unique feature: the DBIR SUPPLIERS. The DBIR SUPPLIERS is a separate registry for the industry, created to serve different goals that will be explained below in more detail. *Figure 3* illustrates the relationship between the DBIR and DBIR SUPPLIERS registries. Currently, 4 of the 7 suppliers that distribute implants in the Netherlands (5 of the 8 brands) participate in this registry (*Table 1*).

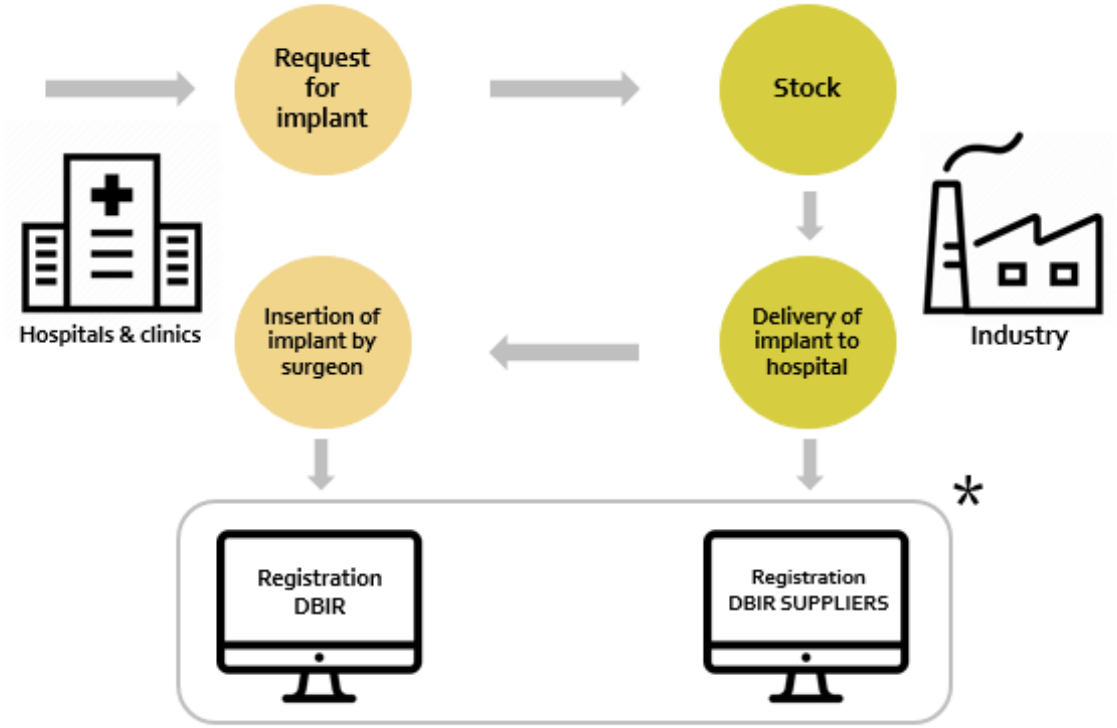
The DBIR SUPPLIERS is a system in which vendors of breast implants in the Netherlands register the number of implants sold per healthcare institution. Additionally, the vendors register several specific data points of each implant being shipped, such as implant characteristics (e.g., texture or coating), and the Unique Device Identifier (UDI), consisting of a Global Trade Item Number (GTIN), serial number, batch/lot number, and expiration date. Only breast tissue expanders and permanent breast implants are registered. Sizers are not registered nor are implants and expanders for other purposes than breast surgery.

In practice, a surgeon orders more than one implant for a patient. Often, various types and volumes of implants are ordered and the surgeon selects the final implant during the surgery. Subsequently, the unused implants are returned to the vendor.

Therefore, the vendor first registers all the shipped implants in DBIR SUPPLIERS. After receiving the returned implants, the vendor deregisters the unused implants. Deducting the returned implants from the total number of shipped implants leads to the number of implants that have actually been sold. The result is an overview of how many breast implants and which types were delivered per healthcare institution, per year. However, some healthcare institutions also keep some implants in stock. The DBIR committee currently investigates how many this concerns.

Once the DBIR SUPPLIERS contains sufficient and valid data of each brand, this system can be used to validate the devices registered in DBIR, provide suppliers with objective and reliable results of their devices in vivo with results from the DBIR (post-market surveillance), and help to minimalize the registration burden for the clinicians registering in DBIR by prefilling implant characteristics. Research on the potential of prefilling these implant characteristics is currently being conducted (*Chapter 8*).

Figure 3. *Relationship between the DBIR and DBIR SUPPLIERS registries*



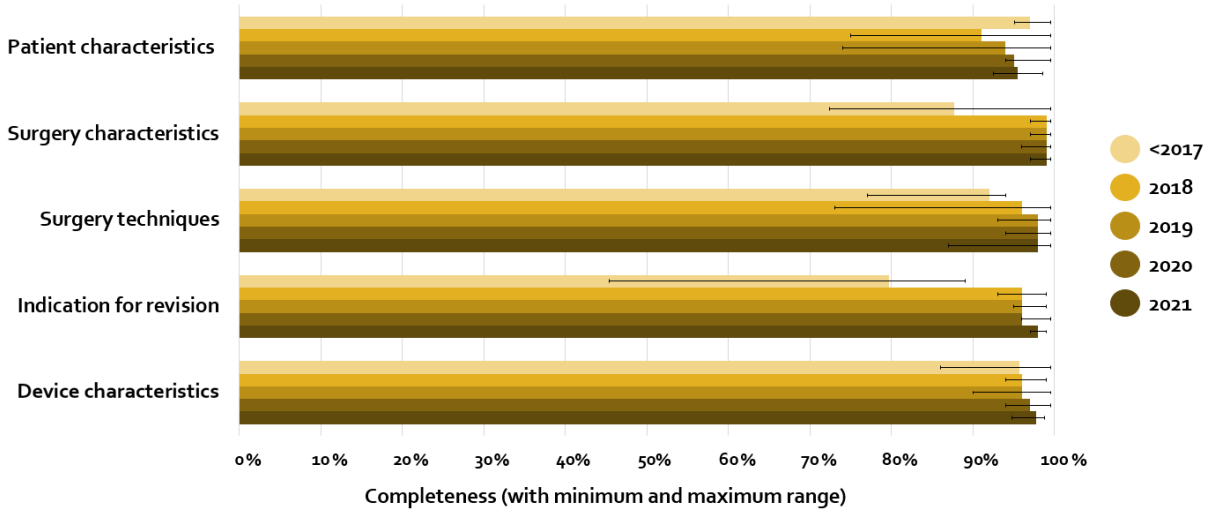
**The vendors register the number of devices that they deliver to healthcare institutions and the number that they receive in return in the DBIR SUPPLIERS registry. The net number of devices is calculated from these deliveries and returns. This number should in theory be equal to the number of inserted devices as registered by plastic surgeons in DBIR.*

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 - 2021)*



In general, the completeness of most variables was more than 95% in 2021, which is still increasing since the start of the registry (*Figure 4* and *Table 2*). Particularly the data on patient characteristics, indication for revisions, and device characteristics showed increasing completeness. This is mainly caused by higher percentages of records with 'Smoking status', 'Planned TE-to-autologous tissue replacement', and 'Texture'. Additionally, in 2020, 'project CLEAN-UP' was performed, in which the clinical relevance and completeness of all variables were critically reviewed. This resulted in the removal of several variables from the registry, decreasing registration burden and improving data completeness. More details of this project can be found in the annual report 2020. Furthermore, as a result of technical improvements, manual registration of device characteristics of explanted devices is no longer needed. This information is now re-used from the registered implantation records known in DBIR. Therefore, from 2021, separate information on data completeness of explanted devices is no longer reported.

Table 2. *Data completeness (2021)*

	Complete (%)
	2021
Patient characteristics (patient level)	
Date of birth	99%
ASA classification	99%
Smoking	96%
Length	93%
Weight	93%
Body Mass Index	93%
Surgery characteristics (breast level)	
Date of surgery	100%
Healthcare institution	100%
Laterality	99%
Intervention	99%
Indication	99%
Timing reconstruction	99%
Primary implant surgery	99%
Preoperative radiotherapy	97%
Surgery techniques (breast level)	
Incision site	97%
Plane	97%
Capsulectomy	98%
Mastopexy	98%
Autologous flap cover	87%
Fat grafting	98%
ADM/mesh use	97%
ADM/mesh manufacturer	93%
Systemic antibiotics (preoperatively)	99%
Systemic antibiotics (postoperatively)	97%
Antiseptic rinse of implant	99%
Antiseptic rinse type	99%
Sleeve/funnel	99%
Nipple guards	99%
Glove change	99%
Drains	99%
Indication for revision (breast level)	
Planned TE-to-implant	98%
Planned TE-to-autologous tissue	97%
Flap problem	98%

	Complete (%)
	2021
Indication for revision (breast level) *continued*	
Skin necrosis	98%
Skin scarring	98%
Deep wound infection	98%
Seroma	98%
Hematoma	98%
Capsular contracture	98%
Capsular contracture grade	99%
Breast cancer	98%
Suspicion of BIA-ALCL	98%
Breast implant-associated illness	98%
Breast pain	98%
Asymmetry	98%
Dissatisfaction with volume	98%
Device rupture/deflation	98%
Silicone extravasation	98%
Silicone extravasation type	98%
Device malposition	98%
Recall	98%
Device characteristics (device level, inserted)	
Device type	99%
Texture	98%
Coating	97%
Fill	97%
Shape	97%
Maximum volume/weight TE or implant	95%
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 – 2020.

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 (2021)*

	Patients*		Procedures*		Devices†	
	n	(%)	n	(%)	n	%
Reconstructive						
Reconstruction after mastectomy for cancer	2,807	(20%)	3,226	(22%)	5,368	(19%)
Reconstruction after prophylactic mastectomy	504	(4%)	598	(4%)	1,445	(5%)
Reconstruction benign‡	160	(1%)	172	(1%)	372	(1%)
Aesthetic						
Cosmetic augmentation	10,426	(75%)	10,596	(72%)	21,376	(75%)
Not stated	44	(<1%)	47	(<1%)	68	(<1%)
TOTAL	**13,941**	**(100%)**	**14,639**	**(100%)**	**28,629**	**(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 (47 patients, 49 procedures, and 68 devices). In total, from the start of the registry in April 2015 until the end of 2021, information of 69,622 patients, 73,822 procedures, and 148,950 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 – 2021)*

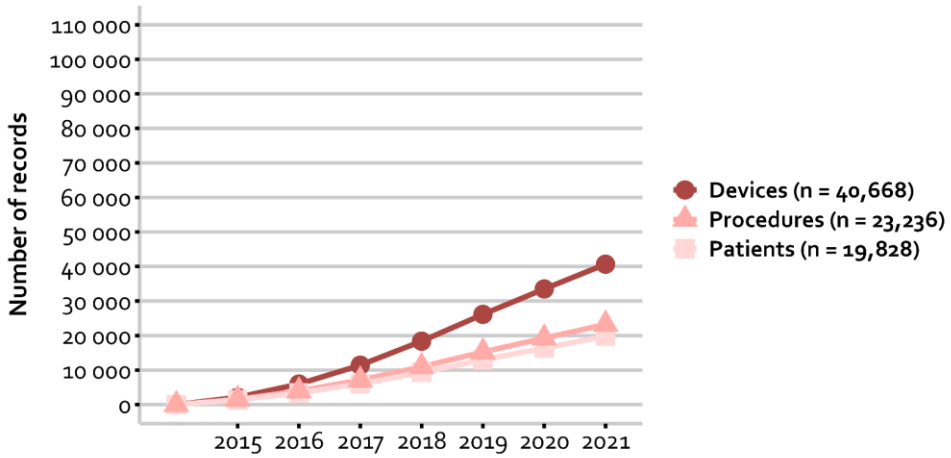
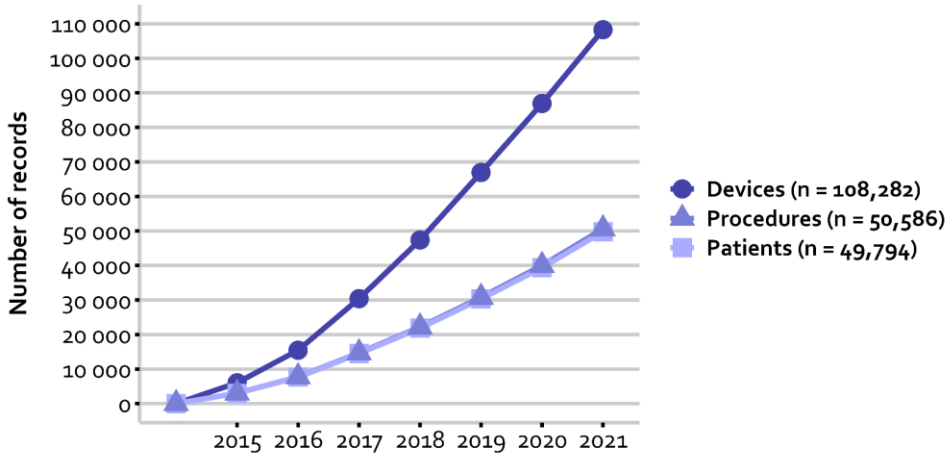


Figure 6. *Cumulative number of registered patients, procedures, and devices for aesthetic indications (2015 – 2021)*



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

Almost all reconstructive procedures were undertaken in hospitals (93%, 89%, and 88% for insertion only, replacement, and explantation procedures, respectively). For aesthetic indications, most insertion only procedures were performed in private clinics (72%). Although most aesthetic replacement and explantation only procedures still took place in private clinics, these percentages were considerably lower compared to insertion only procedures (62% and 57%, respectively).

***Figure 7**. Healthcare institution type by intervention type for reconstructive indications, breast level (2021)*

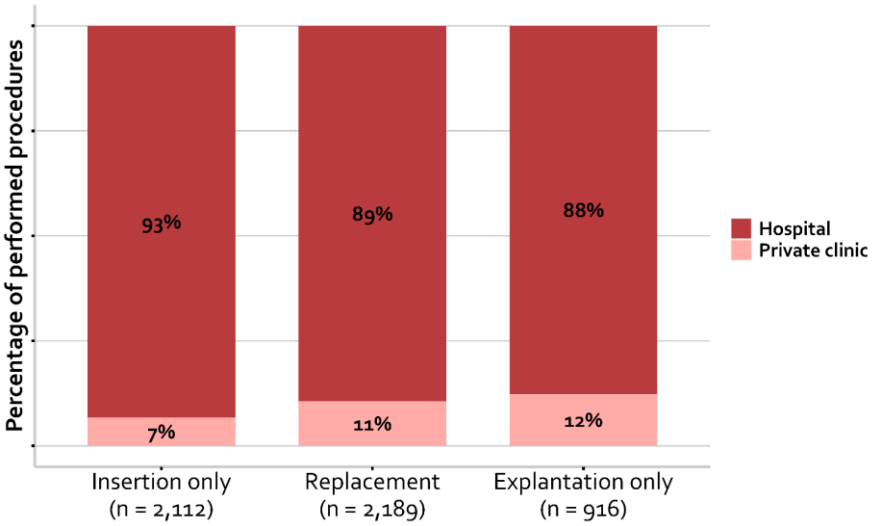
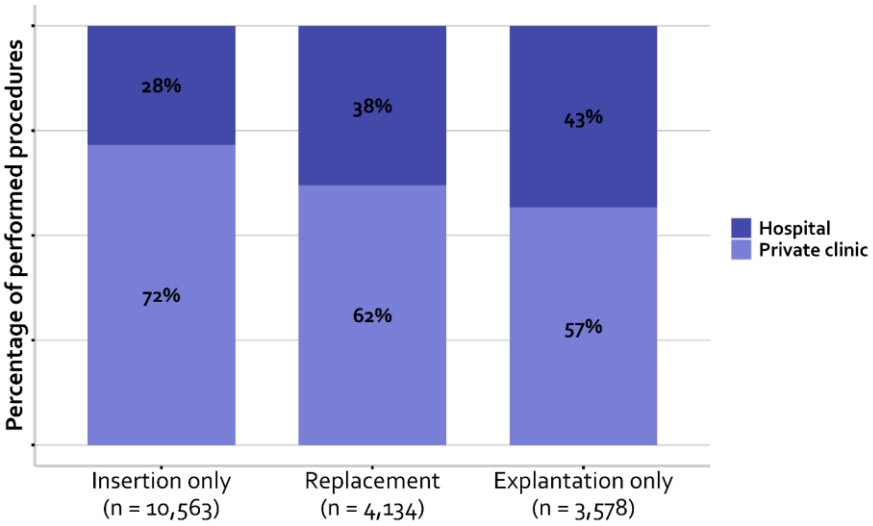


***Figure 8**. Healthcare institution type by intervention type for aesthetic indications, breast level (2021)*



Inserted devices per manufacturer and brand

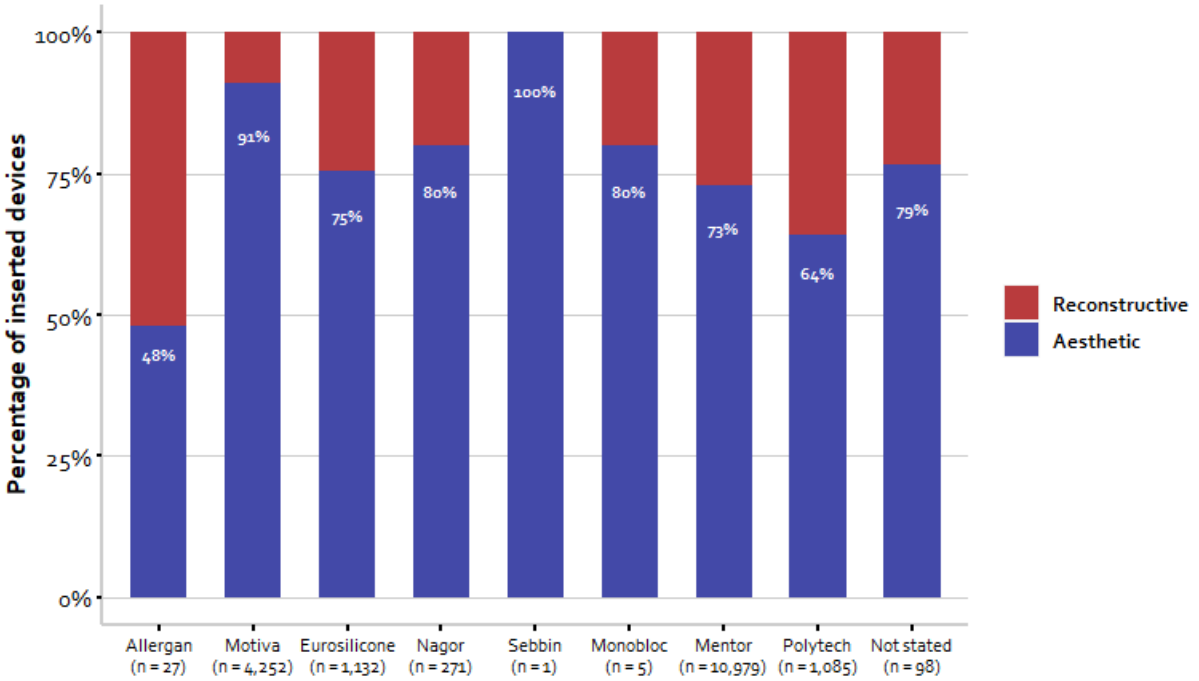
In 2021, permanent implants and tissue expanders from 8 different brands (7 different manufacturers) were inserted. Most of these devices were manufactured by Mentor. *Figure 7* provides an overview of the distribution between reconstructive and aesthetic devices that have been inserted per manufacturer and brand.

Table 4. *Number of devices inserted per manufacturer and brand (2021)*

	Reconstructive*		Aesthetic†		Total	
	n	(%)	n	(%)	n	%‡
Manufacturer (brand)						
Allergan (Natrelle)	14	(<1%)	13	(<1%)	27	(<1%)
Establishment Labs (Motiva)	384	(9%)	3,868	(28%)	4,252	(23%)
GC Aesthetics (Eurosilicone)	279	(7%)	853	(6%)	1,132	(6%)
GC Aesthetics (Nagor)	54	(1.%)	217	(2%)	271	(2%)
Groupe Sebbin		-	1	(<1%)	1	(<1%)
Laboratoires Arion (Monobloc)	1	(<1%)	4	(<1%)	5	(<1%)
Mentor	2,967	(72%)	8,012	(58%)	10,979	(61%)
Polytech	390	(10%)	695	(6%)	1,085	(6%)
Not stated	23	(<1%)	75	(<1%)	98	(<1%)
TOTAL	**4,112**	**(100%)**	**13,738**	**(100%)**	**17,850**	**(100%)**

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

Figure 9. *Percentage of reconstructive vs. aesthetic devices inserted per brand (2021)*



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 an in situ device and insertion of the same or new device.
  - Replacement of TE with an implant.
  - Replacement of an in situ device with autologous tissue.
- **Explantation only** includes:
  - Explantation of an in situ 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 25*)

In 2021, the following reconstructive procedures were most often performed: unilateral insertion only surgery after mastectomy for cancer (1,200 procedures), unilateral replacement surgery after mastectomy for cancer (982 procedures), and unilateral explantation only surgery after mastectomy for cancer (416 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 52 years (SD 12), and the mean age of patients undergoing an explantation only procedure was 56 years (SD 11).

ASA classification

For insertion only, replacement, and explantation only, most patients scored ASA class 2 (56%, 58%, and 57%, respectively), followed by ASA class 1 (39%, 34%, and 32%, 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 reconstructive surgery was between 9% and 10%. %. In 5% to 9% of the cases, it was recorded that the plastic surgeon did not know whether the patient smoked. In 7% to 14% of the cases, the variable 'Smoking' was not registered at all. The reasons for these missing values are unclear, but they are higher compared to other variables.

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 (45%, 48%, and 45%, respectively) or 25.0 and 29.9 kg/m^2 (26%, 30%, and 30%, respectively), followed by a BMI $\geq$30 kg/m^2 (14%, 12%, and 15%, respectively), and <18.5 kg/m^2 (2%, 1%, and 2%, respectively). In respectively 14%, 9%, and 8% of the records BMI was missing.

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

In 2021, the following aesthetic procedures were most often performed: bilateral insertion only surgery (5,887 procedures), bilateral replacement of implants (2,349 procedures), or bilateral explantation only surgery (1,984 procedures).

Patient characteristics (*Table 12 on page 28*)

Age

The mean age of patients undergoing an insertion only procedure was 32 years (SD 10), the mean age of patients undergoing a replacement procedure was 47 years (SD 12), and the mean age of patients undergoing an explantation only procedure was 49 years (SD 13).

ASA classification

For insertion only, replacement, and explantation only, most patients scored ASA class 1 (84%, 61%, and 50%, respectively), followed by ASA class 2 (15%, 36%, and 44%, respectively). In all intervention groups, ASA classification was missing in 2% of the records or less.

Smoking status

The percentage of smokers at the time of aesthetic surgery was between 11% and 18%. In 11% to 20% of the cases, it was recorded that the plastic surgeon did not know whether the patient smoked. In 1% to 2% of the cases, the variable 'Smoking' was not registered at all. 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 (73%, 72%, and 51%, respectively) or 25.0 and 29.9 kg/m^2 (14%, 18%, and 20%, respectively), followed by a BMI $\geq$30 kg/m^2 (2%, 3%, and 6%, respectively), and <18.5 kg/m^2 (5%, 4%, and 3%, respectively). In respectively 6%, 2%, and 10% of the records BMI was missing.

Table 5. *Number of reconstructive procedures, , insertion only* (2021)*

	n	(%)
Unilateral		
Reconstruction after mastectomy for cancer	1202	(69)
Reconstruction after prophylactic mastectomy	73	(4)
Reconstruction benign†	13	(1)
Bilateral		
Post-cancer & post-cancer	138	(8)
Post-cancer & prophylactic	125	(7)
Prophylactic & prophylactic	115	(9)
Benign & benign	21	(1)
Post-cancer & aesthetic	15	(1)
Benign & aesthetic	1	(<1)
Other	7	(<1)
Total	**1,710**	**(100)**

Table 6. *Number of reconstructive procedures, replacement* (2021)*

	n	(%)
Unilateral		
Reconstruction after mastectomy for cancer	925	(59)
Reconstruction after prophylactic mastectomy	65	(4)
Reconstruction benign†	26	(2)
Bilateral		
Post-cancer & post-cancer	234	(15)
Post-cancer & prophylactic	117	(8)
Prophylactic & prophylactic	136	(9)
Benign & benign	35	(2)
Post-cancer & aesthetic	23	(1)
Benign & aesthetic	5	(<1)
Other		(1)
Total	**1,577**	**(100)**

Table 7. *Number of reconstructive procedures, explantation only* (2021)*

	n	(%)
Unilateral		
Reconstruction after mastectomy for cancer	416	(61)
Reconstruction after prophylactic mastectomy	30	(4)
Reconstruction benign†	11	(2)
Bilateral		
Post-cancer & post-cancer	104	(15)
Post-cancer & prophylactic	30	(4)
Prophylactic & prophylactic	46	(7)
Benign & benign	31	(5)
Post-cancer & aesthetic	10	(2)
Benign & aesthetic	0	(<1)
Other		(1)
Total	**681**	**(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* (2021)*

	n	(%)
Cosmetic augmentation		
Unilateral	107	(2)
Bilateral	5,881	(98)
Total	**5,988**	**(100)**

Table 9. *Number of aesthetic procedures, replacement* (2021)*

	n	(%)
Cosmetic augmentation		
Unilateral	178	(7)
Bilateral	2,362	(93)
Total	**2,540**	**(100)**

Table 10. *Number of aesthetic procedures, explantation only* (2021)*

	n	(%)
Cosmetic augmentation		
Unilateral	88	(4)
Bilateral	1,976	(96)
Total	**2,064**	**(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 (2021)*

	Insertion only	Replacement	Explantation only
Number of unique patients	**(n = 1,465)**	**(n = 1,397)**	**(n = 609)**
Number of unique surgeries*	**(n = 1,697)**	**(n = 1,602)**	**(n = 697)**
Age in years, mean ± SD	49 ± 12	52 ± 12	56 ± 11
ASA classification			
I	39%	34%	32%
II	56%	58%	57%
III+	6%	7%	10%
Not stated	*<1%*	*1%*	*1%*
Smoking†			
Yes	9%	10%	9%
Unknown	5%	5%	10%
Not stated	*14%*	*9%*	*7%*
Body Mass Index			
< 18.5	2%	1%	2%
18.5 – 24.9	45%	48%	45%
25 – 29.9	26%	30%	30%
≥ 30	14%	12%	15%
Not stated	*14%*	*9%*	*8%*

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 (2021)*

	Insertion only	Replacement	Explantation only
Number of unique patients	**(n = 5,905)**	**(n = 2,460)**	**(n = 2,041)**
Number of unique surgeries*	**(n = 5,992)**	**(n = 2,528)**	**(n = 2,064)**
Age in years, mean ± SD	32 ± 10	47 ± 12	49 ± 13
ASA classification			
I	84%	61%	50%
II	15%	36%	44%
III+	<1%	2%	4%
Not stated	*<1%*	*1%*	*2%*
Smoking†			
Yes	17%	18%	11%
Unknown	20%	11%	18%
Not stated	*2%*	*1%*	*1%*
Body Mass Index			
< 18.5	5%	4%	3%
18.5 – 24.9	73%	72%	61%
25 – 29.9	14%	18%	20%
≥ 30	2%	3%	6%
Not stated	*6%*	*2%*	*10%*

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 2021, most reconstructive permanent 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 (25%). Notably, direct-to-implant procedures were the most frequently registered, while the literature generally describes two-stage reconstructions as the most commonly performed procedures. Particularly, the number of direct-to-implant procedures after prophylactic mastectomy increased compared to previous years (9% to 18%). In general, most reconstructive tissue expanders were used after mastectomy for cancer (82%).

Table 13. *Timing of reconstructive procedures, per indication (2015 – 2021)*

	2015 - 2020		2021	
	n	%	n	%
NUMBER OF PERMANENT IMPLANTS	**(n = 11,705)**		**(n = 3,010)**	
Direct-to-implant insertion surgery				
Post-cancer	6,133	(52%)	1,430	(48%)
Prophylactic	1329	(11%)	478	(16%)
Benign	361	(3%)	105	(3%)
Two-stage insertion surgery				
Post-cancer	3,069	(26%)	767	(25%)
Prophylactic	647	(6%)	200	(7%)
Benign	166	(1%)	30	(1%)
NUMBER OF TISSUE EXPANDERS	**(n = 9,169)**		**(n = 1,505)**	
Insertion surgery				
Post-cancer	7,502	(82%)	1,192	(79%)
Prophylactic	986	(11%)	288	(19%)
Benign	681	(7%)	25	(2%)

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 31 shows that, in 2021, the most common incision site was a (previous) non-nipple-sparing-mastectomy scar (45% insertion only, and 44% replacement surgery). The most common surgical plane used for insertion was a dual plane or partial cover with PM (38% insertion only, 41% replacement surgery). Interestingly, ADM/mesh is used relatively less in breast reconstructions in the Netherlands (6%) when compared to annual reports from other international breast implant 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 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 9***). For other techniques, however, no consensus has been reached yet and insights into current practices are extra useful. ***Table 15*** on page 32 shows that, in 2021, the most common incision site was the inframammary fold (97% for insertion only, and 96% for replacement procedures). The most common surgical plane used for insertion was a dual plane (61% insertion only, 55% replacement surgery).

Table 14. *Intraoperative techniques in reconstructive procedures, per breast (2021)*

		Insertion only	Replacement	Explantation only
Total number of breasts		**(n = 2,112)**	**(n = 2,189)**	**(n = 916)**
Incision site	Inframammary	13%	30%	
	Mastectomy scar (NNS)	45%	44%	
	Mastectomy scar (NS)	17%	10%	
	Periareolar	5%	3%	
	Other	8%	7%	
	Not stated	*11%*	*7%*	
Plane*	Subglandular	2%	4%	
	Subfascial	1%	1%	
	Sub flap	6%	8%	
	Subcutaneous	12%	9%	
	Subpectoral	29%	30%	
	Dual plane or partial cover with PM	38%	41%	
	Not stated	*13%*	*7%*	
Mastopexy	Yes	6%	2%	5%
	Not stated	*11%*	*6%*	*4%*
Capsulectomy†	Partial capsulectomy		43%	38%
	Full capsulectomy		9%	23%
	Not stated		*7%*	*3%*
Autologous flap cover	Yes	8%	8%	
	Not stated	*12%*	*7%*	
Fat grafting	Yes	1%	7%	5%
	Not stated	*11%*	*6%*	*4%*
Drains	Yes	88%	56%	
	Not stated	*5%*	*3%*	
Mesh/ADM use*	Yes	6%	<1%	
	Not stated	*13%*	*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 (2021)*

		Insertion only	Replacement	Explantation only
Total number of breasts		**(n = 10,563)**	**(n = 4,134)**	**(n = 3,578)**
Incision site	Inframammary	97%	96%	
	Mastectomy scar (NNS)	<1%	1%	
	Mastectomy scar (NS)	<1%	<1%	
	Periareolar	1%	1%	
	Other	1%	3%	
	Not stated	*<1%*	*<1%*	
Plane*	Subglandular	23%	33%	
	Subfascial	12%	3%	
	Sub flap	-	<1%	
	Subcutaneous	1%	1%	
	Subpectoral	3%	7%	
	Dual plane or partial cover with PM	61%	55%	
	Not stated	*1%*	*1%*	
Mastopexy	Yes	4%	10%	15%
	Not stated	*<1%*	*<1%*	*<1%*
Capsulectomy†	Partial capsulectomy		41%	40%
	Full capsulectomy		23%	29%
	Not stated		*1%*	*1%*
Autologous flap cover	Yes	<1%	1%	
	Not stated	*11%*	*19%*	
Fat grafting	Yes	<1%	2%	16%
	Not stated	*<1%*	*1%*	*<1%*
Drains	Yes	5%	24%	
	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.*

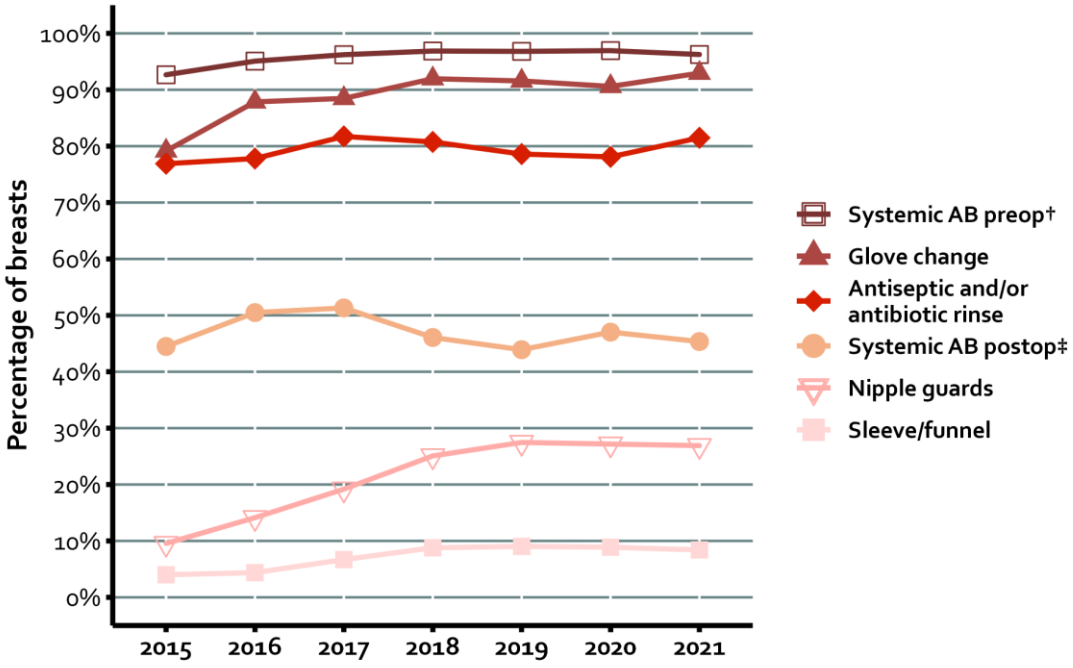
†The variable 'Capsulectomy' was only registered for replacement and explantation only procedures.

Infection control measures *(Figure 10)*

Most infection control measures (ICMs) were only registered for the insertion of an implant. Therefore, only the insertion only and replacement procedures are included in ***Figure 10***. Results are presented per breast. The use of ICMs increased over the years (2015 - 2021). However, the percentage of records with information on the use of ICMs also increased over the years from ~93% in 2016 to ~99% in 2021 (***Table 2***). This has to be kept in mind when interpreting these results.

The most frequently used ICMs for reconstructive indications in 2021 were preoperative systemic antibiotic prophylaxis, glove change, and antiseptic rinse of the pocket. Since 2015, the use of these ICMs has continued to increase from 93% to 96%, 79% to 93%, and 78% to 81%, respectively. Since the start of the registration, the use of postoperative antibiotic prophylaxis has been varying (range 44% to 51%). The use of nipple guards or a sleeve/Keller funnel has been used in less than a third of the cases (27% and 8%, respectively).

Figure 10. *Infection control measures for every reconstructive implant insertion, per breast* (2015 – 2021)*



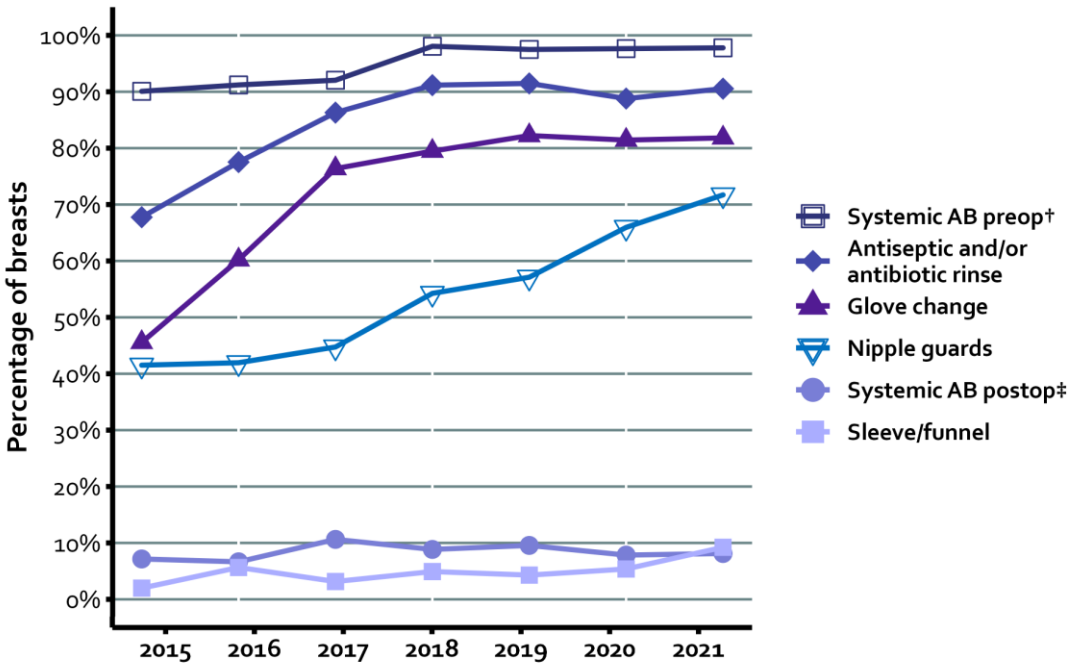
**Infection control measures were only registered for insertion only and replacement procedures.*
†Systemic AB preop: systemic antibiotics preoperatively (use of intravenous antibiotics within 60 minutes before incision).
‡Systemic AB postop: systemic antibiotics postoperatively (use of intravenous antibiotics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

Infection control measures *(Figure 11)*

Most infection control measures (ICMs) were registered during the insertion of an implant. Therefore, only the insertion only and replacement procedures are included in ***Figure 11***. Results are presented per breast. The use of ICMs increased over the years (2015 - 2021). However, the percentage of records with information on the use of ICMs also increased slightly over the years from ~93% in 2016 to ~99% in 2021 (***Table 2***). This has to be kept in mind when interpreting these results.

The most frequently used ICMs for aesthetic indications in 2021, were preoperative systemic antibiotic prophylaxis, antiseptic rinse of the pocket, and glove change. Since 2015, the use of these ICMs has continued to increase from 90% to 98%, 68% to 91%, and 46% to 82%, respectively. Interestingly, the use of nipple guards especially increased over the last few years by up to 72%. The use of a sleeve/Keller funnel and postoperative antibiotic prophylaxis has remained low (9% and 11%, respectively).

Figure 11. *Infection control measures for every aesthetic implant insertion, per breast* (2015 – 2021)*



**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 2021, most of the permanent breast implants were anatomically shaped (57%), textured (69%), silicone coated (77%), silicone filled (84%), and had a volume between 200 and 399 cc (36%). The inserted tissue expanders were in 2021 predominantly anatomically shaped (96%), textured (94%), silicone coated (98%), filled with saline (95%), and had a volume between 400 and 599 cc (53%).

Table 16. *Characteristics of inserted devices for reconstructive indications, per year (2015 - 2021)*

	Permanent implants		Tissue expanders	
	2015 - 2020	**2021**	**2015 – 2020**	**2021**
Inserted devices	n = 13,152	n = 2,606	n = 9,167	n = 1,505
Device shape				
Round	19%	30%	1%	2%
Shaped/Anatomical	73%	57%	96%	96%
Not stated	*9%*	*14%*	*3%*	*2%*
Device texture				
Textured	84%	69%	97%	94%
Smooth	7%	18%	<1%	5%
Not stated	*9%*	*13%*	*3%*	*1%*
Device coating				
Silicone	83%	77%	97%	98%
Polyurethane	9%	9%	<1%	<1%
Not stated	*9%*	*14%*	*3%*	*2%*
Device fill				
Silicone	89%	84%	2%*	1%*
Saline	1%	3%	95%	95%
Hydrogel	1%	-	-	-
Air	-	-	-	3%
Other	1%	<1%	1%	-
Not stated	*9%*	*14%*	*3%*	*1%*
Device volume/weight† volume in cc				
<199	3%	2%	-	-
200 - 399	35%	36%	23%	25%
400 – 599	37%	35%	51%	53%
≥600	17%	13%	20%	19%
Not stated	13%	15%	5%	4%

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 2021, most of the permanent breast implants were round (72%), textured (70%), silicone coated (96%), silicone filled (99%), and had a volume between 200 and 399 cc (56%). The inserted tissue expanders were in 2021 predominantly anatomically shaped (90%), textured (90%), silicone coated (100%), filled with saline (84%), and had a volume between 400 and 599 cc (53%).

Table 17. *Characteristics of inserted devices for aesthetic indications, per year (2015 - 2021)*

	Permanent implants		Tissue expanders	
	2015 - 2020	**2021**	**2015 - 2020**	**2021**
Inserted devices	n = 71,323	n = 13,716	n = 150	n = 19
Device shape				
Round	68%	72%	3%	11%
Shaped/Anatomical	32%	28%	95%	90%
Not stated	*1%*	*<1%*	*2%*	-
Device texture				
Textured	82%	70%	99%	90%
Smooth	18%	30%	-	11%
Not stated	*2%*	*<1%*	*1%*	-
Device coating				
Silicone	96%	96%	98%	100%
Polyurethane	3%	3%	-	-
Other	-	-	1%	-
Not stated	*1%*	*1%*	*1%*	-
Device fill				
Silicone	98%	99%	4%*	5%*
Saline	<1%	1%	95%	84%
Hydrogel	1%	<1%	-	-
Air	-	-	-	11%
Other	<1%	-	1%	-
Not stated	*1%*	*1%*	-	-
Device volume/weight† volume in cc or grams				
<199	2%	1%	-	-
200 - 399	65%	56%	20%	42%
400 – 599	29%	33%	65%	53%
≥600	3%	5%	15%	5%
Not stated	*2%*	*3%*	*1%*	-

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

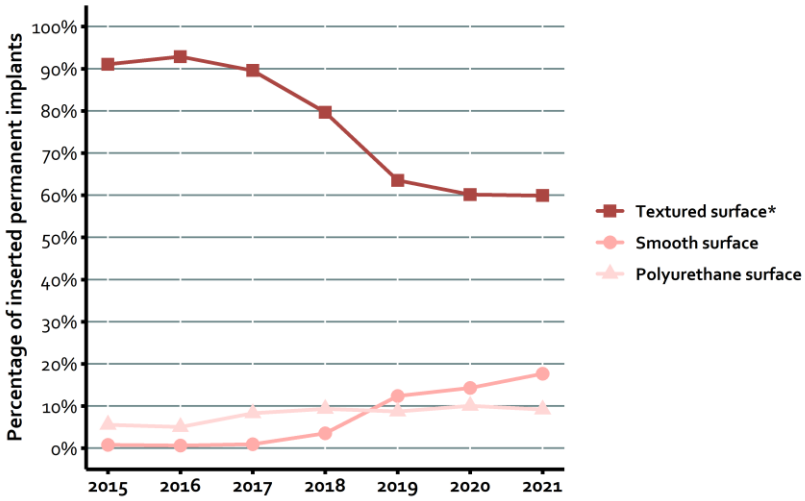
**This category describes tissue expanders that are filled with both silicone and saline.*

†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 made by the patient and the surgeon together and is based on the indication for surgery. However, breast implants have been frequently discussed in the media 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 European market by the manufacturer. Although no scientific basis has been found for a complete ban on these implants, the percentage of inserted smooth and polyurethane implants seems to be increasing at the expense of textured implants (***Figure 12***). Furthermore, because anatomically shaped implants appear to be preferred in breast reconstructions (***Table 16 on page 35***), 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 – 2021)*



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

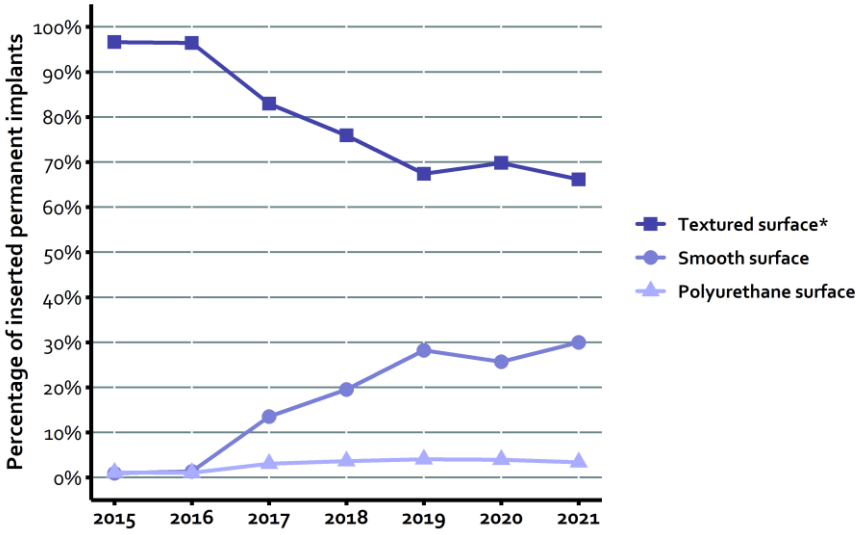
The DBIR collects details of issues and complications that are found at the time of a revision procedure involving breast devices. Revision surgery includes planned and unplanned replacement, repositioning, or explantation of an in-situ breast device.

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.*

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

The choice of implant type is made by the patient and the surgeon together and is based on the indication for surgery. However, breast implants have been frequently discussed in the media 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 European market by the manufacturer. Although no scientific basis has been found for a complete ban on these implants, the percentage of inserted smooth implants seems to be increasing at the expense of textured implants (***Figure 13***).

Figure 13. *Trends in characteristics of implants inserted for aesthetic indications (2015 – 2021)*



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. Percentages represent observational proportions, not actual complication rates. In 2021, the most commonly reported reasons for unplanned revision of reconstructive permanent implants were capsular contracture (28%), followed by breast pain (23%), and other (19%). The total number of revision procedures in 2021 illustrates the upward trend of more replacement and explantation procedures being registered in DBIR throughout the years. In addition, it is striking that in 2021 a sharply increasing number of breast implants were revised as a result of breast implant-associated illness (89 cases in 2021 vs. 110 cases in all previous years).

Table 18. *Indications for revision & perioperative findings, reconstructive permanent implants*

	2015 – 2020		2021	
TOTAL REVISION PROCEDURES (PER BREAST)	**(n = 5,428)**		**(n = 1,740)**	
	n	**%**	**n**	**%**
Capsular contracture	1,879	(35%)	484	(28%)
Breast pain	1,154	(21%)	395	(23%)
Other‡	649	(12%)	326	(19%)
Asymmetry	1,178	(22%)	304	(18%)
Device rupture or deflation	742	(14%)	252	(15%)
Device malposition	608	(11%)	165	(9%)
Patient dissatisfied with volume	687	(13%)	153	(9%)
Silicone extravasation*	392	(7%)	114	(7%)
Breast implant-associated illness	110	(2%)	89	(5%)
Breast cancer recurrence	268	(5%)	87	(5%)
Seroma or hematoma	241	(4%)	72	(4%)
Deep wound infection	240	(4%)	69	(4%)
Skin necrosis or dehiscence	223	(4%)	67	(4%)
Skin scarring	188	(4%)	37	(2%)
BIA-ALCL (suspicion)*	61	(1%)	19	(1%)
Flap problem	98	(2%)	12	(1%)
BIA-ALCL (PA proven)*§	10	(<1%)	5	(<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 2021 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 2021, the most commonly reported reasons for unplanned revision of aesthetic permanent implants were capsular contracture (26%), device rupture or deflation (20%), and patients' dissatisfaction with volume (18%). The total number of revision procedures in 2021 illustrates the upward trend of more replacement and explantation procedures being registered in DBIR throughout the years. In addition, it is striking that in 2021 a sharply increasing number of breast implants were revised as a result of breast implant-associated illness (885 cases in 2021 vs. 629 cases in all previous years).

Table 19. *Indications for revision & perioperative findings, aesthetic permanent implants*

	2015 - 2020		2021	
TOTAL REVISION PROCEDURES (PER BREAST)	**(n = 15,306)**		**(n = 7,598)**	
	n	**%**	**n**	**%**
Capsular contracture*	6,080	(40%)	2,007	(26%)
Device rupture or deflation	3,610	(24%)	1,510	(20%)
Patient dissatisfied with volume	2,965	(19%)	1,372	(18%)
Other‡	1,908	(13%)	1,243	(16%)
Breast implant-associated illness	629	(4%)	885	(12%)
Breast pain	2,226	(15%)	837	(11%)
Silicone extravasation*	2,011	(13%)	700	(9%)
Asymmetry	1,802	(12%)	476	(6%)
Device malposition	947	(10%)	271	(4%)
BIA-ALCL (suspicion)*	187	(1%)	146	(2%)
Seroma or hematoma*	305	(2%)	78	(1%)
Deep wound infection	161	(1%)	52	(1%)
Breast cancer	92	(1%)	23	(<1%)
Skin necrosis or dehiscence	61	(<1%)	20	(<1%)
Skin scarring	93	(1%)	15	(<1%)
Flap problem	40	(<1%)	4	(<1%)
BIA-ALCL (PA proven)*§	22	(<1%)	3	(<1%)
Explantation due to a recall¶	3	(<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 2021 and multiple issues could be reported per revision procedure.
**These variables have not been registered from the start of the registry.*
‡Most commonly including 'Revision due to a contralateral problem' and 'Patient's request without health complaints'.
¶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 (April 7, 2022). 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*

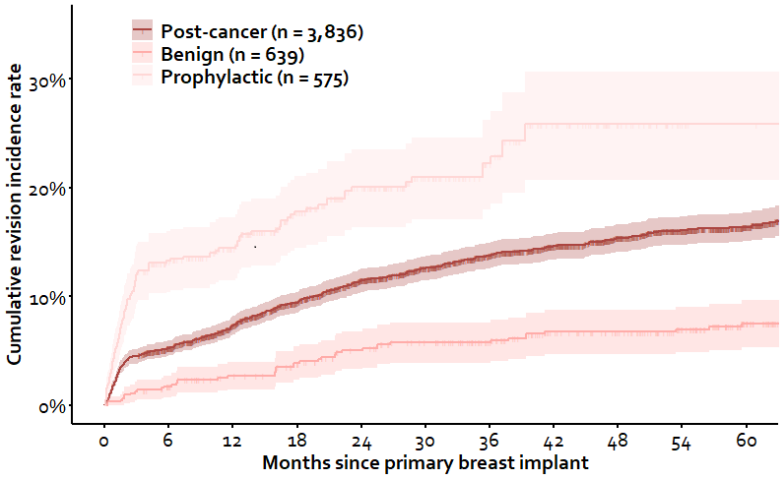
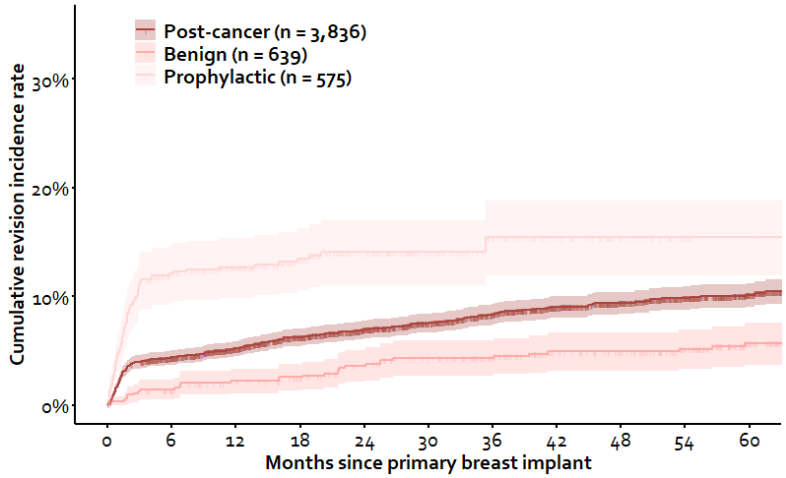


Figure 15. *Complication related revision incidence - Reconstructive primary permanent breast implants*



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

The cumulative percentage of revised primary permanent implants was calculated per 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 (April 7, 2022). 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 16. *All-cause revision incidence - Aesthetic primary permanent breast implants (please note different scale on y-axis)*

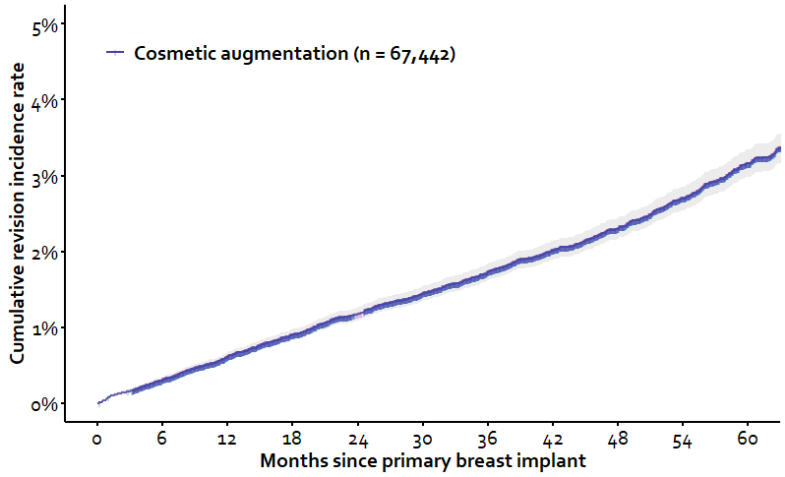
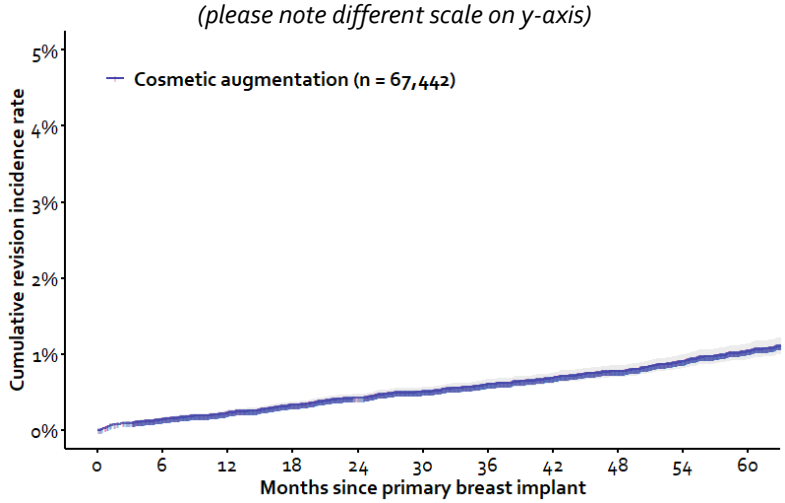


Figure 17. *Complication related revision incidence - Aesthetic primary permanent breast implants (please note different scale on y-axis)*



At 36 months after the date of primary implant insertion, 8.3% of the post-cancer implants had been revised due to complications, 4.3% of the implants inserted for benign reconstructions, and 15.4% of the implants that were inserted after prophylactic mastectomy. These revision incidences were 10.1%, 5.7%, and 15.4% 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 15.4%) 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	**3,836**	**639**	**575**
Number revised: all-cause	**546**	**50**	**112**
Number revised: complication	**335**	**34**	**79**
All-cause revision incidence (95% confidence interval)			
12 months since primary breast implant	7.3% (6.5, 8.2)	2.7% (1.4, 3.9)	14.4% (11.5, 17.3)
24 months since primary breast implant	11.5% (10.4, 12.5)	5.1% (3.3, 6.8)	20.0% (16.4, 23.5)
36 months since primary breast implant	13.8% (12.6, 14.9)	5.8% (3.9, 7.6)	22.2% (18.0, 26.2)
48 months since primary breast implant	15.4% (14.1, 16.6)	6.7% (4.7, 8.7)	25.8% (20.7, 30.7)
60 months since primary breast implant	16.4% (15.0, 17.7)	7.5% (5.3, 9.7)	25.8% (20.7, 30.7)
Revision incidence due to complication (95% confidence interval)			
12 months since primary breast implant	5.2% (4.5, 5.9)	2.2% (1.1, 3.4)	12.7% (9.9, 15.3)
24 months since primary breast implant	7.0% (6.1, 7.8)	3.6% (2.1, 5.1)	14.1% (11.1, 17.0)
36 months since primary breast implant	8.3% (7.4, 9.2)	4.3% (2.7, 5.9)	15.4% (11.9, 18.8)
48 months since primary breast implant	9.4% (8.4, 10.4)	4.9% (3.1, 6.6)	15.4% (11.9, 18.8)
60 months since primary breast implant	10.1% (9.0, 11.2)	5.7% (3.7, 7.6)	15.4% (11.9, 18.8)

N.B. Revision incidence is based on reconstructive primary breast implants inserted from April 2015 to 2021. 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 1.0% after 60 months.

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

	Cosmetic augmentation
Number of primary breast implants	**67,442**
Number revised: all-cause	**1,516**
Number revised: complication	**505**
All-cause revision incidence (95% confidence interval)	
12 months since primary breast implant	0.6% (0.5, 0.7)
24 months since primary breast implant	1.2% (1.1, 1.3)
36 months since primary breast implant	1.7% (1.6, 1.8)
48 months since primary breast implant	2.3% (2.2, 2.4)
60 months since primary breast implant	3.2% (3.0, 3.3)
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	1.0% (0.9, 1.1)

N.B. Revision incidence is based on aesthetic primary breast implants inserted from April 2015 to 2021. 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 shows issues identified during reconstructive tissue expander revision procedures. There is no separate chapter on aesthetic tissue expanders, due to the small number of revisions (n = 169 since the start of DBIR). Multiple issues may be registered per revision, either as the reason for revision or found incidentally during the revision procedure. Percentages are subject to inter-observer variability and therefore represent observational proportions, not 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 2021, the most commonly reported reasons for unplanned revision of reconstructive tissue expanders were deep wound infection (8%), other reasons (6%), and seroma or hematoma (6%).

Table 24. *Indications for revision & perioperative findings, reconstructive tissue expanders*

	2015 - 2020		2021	
TOTAL REVISION PROCEDURES (PER BREAST)	**(n = 5,728)**		**(n = 1,332)**	
	n	**%**	**n**	**%**
TE to permanent implant* *(planned)*	3,452	(60%)	940	(71%)
Deep wound infection	245	(4%)	107	(8%)
Other‡	350	(6%)	85	(6%)
TE to autologous tissue* (*planned*)	237	(4%)	78	(6%)
Seroma or hematoma	213	(4%)	73	(6%)
Capsular contracture	396	(7%)	67	(5%)
Device rupture or deflation	196	(3%)	56	(4%)
Skin necrosis or dehiscence	137	(2%)	53	(4%)
Asymmetry	323	(6%)	48	(4%)
Breast pain	135	(2%)	48	(4%)
Device malposition	234	(4%)	23	(2%)
Flap problem	60	(1%)	20	(2%)
Dissatisfied with volume	108	(2%)	17	(1%)
Skin scarring	112	(2%)	15	(1%)
Breast cancer recurrence	73	(1%)	3	(<1%)
Breast implant-associated illness	9	(<1%)	1	(<1%)
BIA-ALCL (suspicion)	7	(<1%)	-	-
BIA-ALCL (PA proven)	-	-	-	-

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 2021 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. Breasts without a revision procedure captured by the registry had their follow-up time censored at the date of data extraction (April 7, 2022). 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 (*see next page for explanation on definitions in **Figures 22-23***).

Figure 22. *All-cause revision incidence - Reconstructive primary tissue expanders*

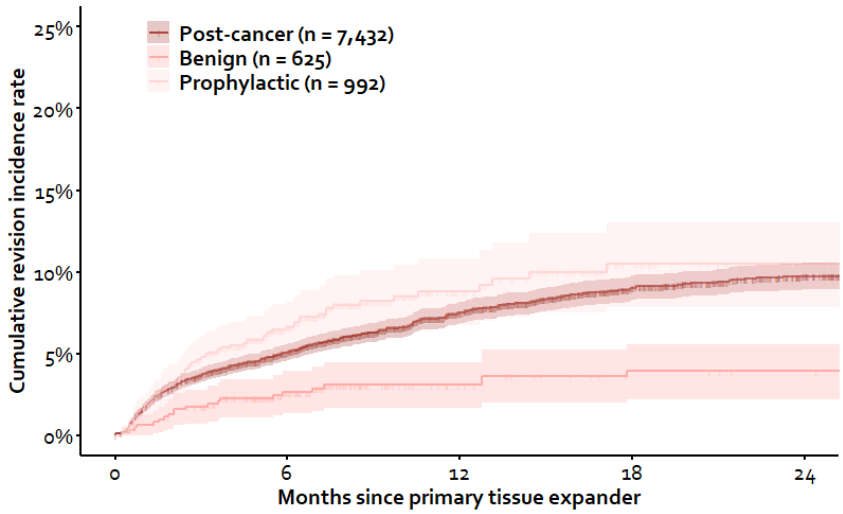
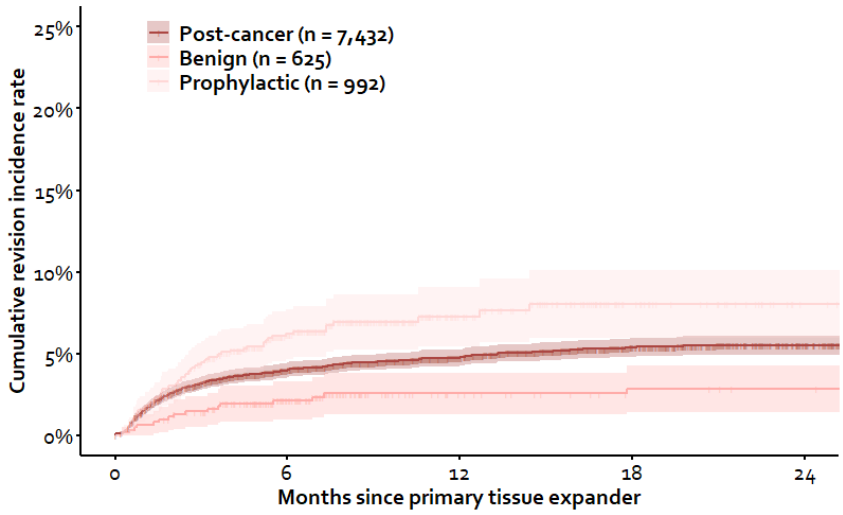


Figure 23. *Revision incidence due to complication - Reconstructive primary tissue expanders*



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, 3.4% of the post-cancer tissue expanders had been revised due to complications, 2.0% of the tissue expanders inserted for benign reconstructions, and 5.5% of the tissue expanders that were inserted after prophylactic mastectomy. These revision incidences increased to 4.7%, 2.4%, and 7.2% 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	**7,432**	**625**	**992**
Number revised: all-cause	**582**	**22**	**81**
Number revised: with complication	**364**	**16**	**66**
All-cause revision incidence (95% confidence interval)			
6 months since primary tissue expander	5.1% (4.6, 5.6)	2.6% (1.4, 3.9)	6.6% (5.0, 8.2)
12 months since primary tissue expander	7.5% (6.8, 8.2)	3.1% (1.7, 4.5)	8.8% (6.7, 10.8)
18 months since primary tissue expander	9.0% (8.3, 9.8)	3.9% (2.2, 5.6)	10.5% (7.9, 13.0)
24 months since primary tissue expander	9.7% (8.9, 10.5)	3.9% (2.2, 5.6)	10.5% (7.9, 13.0)
Revision incidence due to complication (95% confidence interval)			
6 months since primary tissue expander	3.9% (3.5, 4.4)	2.1% (1.0, 3.2)	6.0% (4.5, 7.5)
12 months since primary tissue expander	4.5% (4.0, 5.0)	2.4% (1.2, 3.6)	6.6% (5.0, 8.1)
18 months since primary tissue expander	4.8% (4.3, 5.3)	2.6% (1.3, 3.8)	6.8% (5.2, 8.4)
24 months since primary tissue expander	4.9% (4.4, 5.4)	2.6% (1.3, 3.8)	6.8% (5.2, 8.4)

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

7. QUALITY INDICATORS

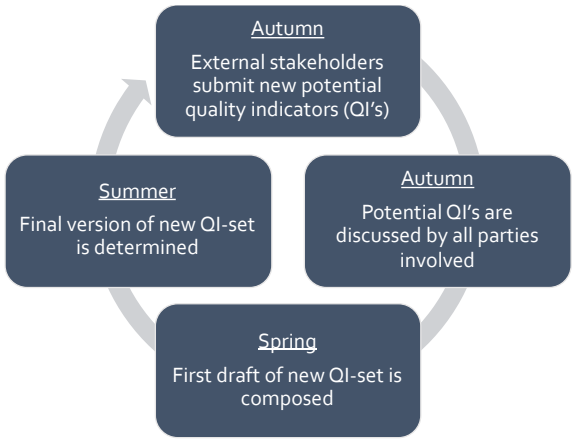
Quality indicators

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 or not 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 2022

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 registered breast devices in DBIR with completely filled in recall variables	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 indicators 'The percentage of registered breast devices in DBIR with a complete record' and 'The percentage of registered breast devices in DBIR with completely filled in recall variables' were combined into one. Three new quality indicators were made public in 2022. The new indicators are indicators for preoperative administration of systemic antibiotics, reoperation within 60 days due to a complication, and reoperation after 60 days up to a year due to a complication. These are the first outcome indicators for breast implant surgery in the Netherlands since the start of DBIR in 2015.

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 patients' dissatisfaction with volume;
- Median insertion-to-reoperation time due to patients' dissatisfaction with implant volume.

8. PROJECTS

Data verification

Verifying data quality and confirming that information provided by the clinical registries is reliable, is an essential part of a quality registry. To verify DBIR data, our Third Trusted Party (MRDM) developed and implemented a new automatic verification method in 2021. This method compared the information in the DBIR database with financial administrative data from participating healthcare institutions. With the help of this new method, it can be assessed whether variables have been entered correctly in the DBIR database. Additionally, this financial administrative data can also be used as a denominator population to determine the capture rate of implantations and explantations in DBIR. The results of this data verification process are currently being written down in a scientific paper.

Involvement patient advocacy groups

The growth of the DBIR database creates an important source of information for, for example, plastic surgeons, the government, breast implant manufacturers, and media, but in particular for patients. That is why the DBIR committee organized an introductory evening with various patient advocacy groups at the beginning of 2022 during which we explained what DBIR does, what our vision is for the future, and how we want to involve patients more in the registry. We listened to the thoughts and wishes of the patient advocacy groups with regard to DBIR and the provision of information to patients. As a result of this meeting, the fact sheets in *Chapter 3* were drawn up in collaboration with the participating patient advocacy groups.

Facilitating clinical information at the point of care

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.

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 ($p<0.05$) and subsequently can conduct an audit which may lead to an advice to undertake improvement measures.

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 have to 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.

First, 'Codman Connect' enables healthcare institutions to benchmark on a smaller scale. This means that healthcare institutions can, voluntarily, conclude an agreement with other healthcare institutions to compare results within their cluster. Second, DBIR has been chosen to participate in the pilot 'Codman Patients' together with the NABON Breast Cancer Audit (NBCA). This new dashboard is intended to facilitate shared decision-making in the consultation room. In the dashboard, patient characteristics such as age, Body Mass Index, or smoking behavior can be selected. Subsequently, an overview is then shown of the complication rates associated with different treatments based on the selected patient profile. Although the dashboard will not be available for use in the near future, the first steps were taken in 2021 by DBIR and the NBCA to realize a joint dashboard for patients undergoing reconstructive or cosmetic breast implant surgery.

International perspectives

Parallel to our nationwide initiatives, we will continue our teamwork with the partners of ICOBRA regarding the ICOBRA core dataset, GS1 barcodes, combined analysis, annual reports, lining up the development of quality indicators, and patient-reported outcome measures (PROMs).

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.

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.

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.

11. RESEARCH OUTPUT

The primary goal of DBIR is improving the quality of care and breast implants using benchmark information and quality indicators, rather than providing a large database solely for research purposes. However, the Scientific Committee of DICA and the DBIR Committee believe that scientific research contributes to improving the quality of 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. Improving Breast Implant Safety through International Collaboration of National Registries – A Review of over 85000 Patients and 200000 Implants from Four Countries. Plast Reconstr Surg, in press.
2. Becherer BE, Heeg E, Young-Afat DA, et al. Revision Incidence after Immediate Direct-To-Implant Versus Two-Stage Implant-Based Breast Reconstruction: Results from a Nationwide Breast Implant Registry. Plast Reconstr Surg, in press.
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, ISSN 2352-5878, https://doi.org/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):NP275-NP281. 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***

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