# DUTCH BREAST IMPLANT REGISTRY (DBIR) ANNUAL REPORT 2015 – 2017

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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| Title | : | Annual Report DBIR 2015 – 2017 |
| Project | : | First extended report of the Dutch Breast Implant Registry |
| Date | : | November 2018 |
| Version | : | 2018.01 |
| Client | : | DBIR committee |
| Author(s) | : | Ms. B.E. Becherer MD, under the supervision of the DBIR committee |

# CONTENTS

# 1. FOREWORD

Dear reader,

Please find below the first annual report of the DBIR.

This report is the result of hard work, dedication, and input by all plastic surgeons in the Netherlands. After the first pilot phase in 2012, inclusion in DBIR started in April 2015. Today, we are slowly growing into a mature, opt-out registry.

In the Netherlands, approximately 3.3% of all mature women have breast implants. This means that one out of every 30 women has an implantable breast device. Since the start of their use in the 1960's, breast implants have been the most discussed medical devices in (social) media and the most investigated and debated devices in terms of safety. Today, breast implants are classified as safe, class III medical devices, which are used for cosmetic purposes in 75% and reconstructive indications in 25% of all cases.

The DBIR focuses on collecting both clinical and device related data. In addition, DBIR provides a way to recall implants and warn the recipients about the status of their device. One of the tools we developed to facilitate this, is the website www.implantaatcheck.nl where patients or healthcare providers can fill in the serial number of their implant to check whether or not this device has been registered and whether it is subject to a recall procedure.

Participation in our registry is a requirement for membership of the Netherlands Society for Plastic Surgery (NVPC), and compliance is a national quality indicator, which is surveyed by the Dutch Health and Youth Care Inspectorate.

We are grateful to the industry for their participation. In response to our desire for standardization in barcode systems, they have been actively involved in adopting a scannable GS-1 barcode on the boxes of their implants. Also, many of the implant companies have contributed to the registry, by uploading sales numbers per clinic combined with implant specific details. This is an essential aid to the validation of DBIR. Chapter 8 provides more information on this topic.

Finally, from the start, our registry has been the result of intense collaboration with our international partners through ICOBRA (International Collaboration of Breast Registry Activities), among which Australia and Sweden in particular. We are proud to say that Australia, Sweden, and The Netherlands are considered international leaders in the field of implant registries. Together we aim to improve the identification of adverse events associated with breast implants and to identify the best surgical strategies. (Chapter 8)

In line with this philosophy, this annual report aims to replicate as many tables and figures as we can from the Australian and Swedish registries, to facilitate easy comparisons between countries and implants within a large group of patients.

We hope the data we provide will further optimize patient care, patient safety, and implant development.

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

Hinne Rakhorst
*Chair DBIR committee*

# 2. REGISTRY PERSONNEL

The clinical content of DBIR is managed by a delegation of the medical society of plastic surgeons in the Netherlands, subdivided in 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 at November 2018)

- Mr. H.A. Rakhorst MD PhD, chairman, plastic surgeon at Medisch Spectrum Twente, Enschede & Ziekenhuis Groep Twente, Almelo.
- Mr. M.A.M. Mureau MD PhD, vice-chairman, plastic surgeon at Erasmus MC, University Medical Center Rotterdam, Rotterdam.
- Ms. J.E. Hommes MD PhD, secretary, plastic surgery resident, Maastricht University Medical Center +, Maastricht.

**DBIR Scientific Committee** (as at November 2018)

- Mr. H.A. Rakhorst MD PhD, chairman, plastic surgeon at Medisch Spectrum Twente, Enschede & Ziekenhuis Groep Twente, Almelo.
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- Ms. J.E. Hommes MD PhD, secretary, plastic surgery resident at Maastricht University Medical Center +, Maastricht.
- Ms. B.E. Becherer MD, Medical researcher at Dutch Institute for Clinical Auditing, Leiden & PhD candidate at Erasmus MC, University Medical Center Rotterdam, Rotterdam.
- Ms. M.J. Hoornweg MD PhD, plastic surgeon at Antoni van Leeuwenhoek hospital, Amsterdam.
- Mr. X.H.A. Keuter MD PhD, plastic surgeon at Viecuri, Venlo & Maastricht University Medical Center +, Maastricht.
- Ms. P.L.T. Liem MSc, staff member of the Netherlands Society for Plastic and Reconstructive Surgery, Utrecht.
- Ms. P.E.R. Spronk MD, plastic surgery resident at Erasmus Medical Center, Rotterdam.
- Mr. D.A. Young-Afat MD, plastic surgery resident at VU Medical Center, Amsterdam.

**Former members**

- Dr. M. Cromheecke, plastic Surgeon at Zipper Clinics, Apeldoorn, Enschede, Zwolle.
- Prof. dr. R.R.J.W. van der Hulst, plastic surgeon at Maastricht University Medical Center +, Maastricht.
- Prof. dr. I.M.J. Mathijssen, plastic surgeon at Erasmus MC, University Medical Center Rotterdam, Rotterdam.
- Dr. L. Moojen-Zaal, plastic surgeon at Velthuiskliniek, Hilversum.

# 3. HIGHLIGHTS OVER THE LAST YEARS

- *After a pilot phase starting in 2012, DBIR went live in April 2015.*

- *In 2016, 95% of the hospitals and 78% of the private clinics eligible for breast implant surgery participated in DBIR.*

- *In 2017, approximately 7,500 patients received one or two breast device(s) for either a reconstructive or aesthetic indication in the Netherlands, as registered in DBIR. This accounts for approximately 8,500 procedures and 15,000 devices.*

- *DBIR is a registry with three purposes, all aiming to improve health care quality and patient safety. Besides the benchmarking of health care provided, it contains data for recall purposes, and monitors the performance of registered devices.*

- *Clinicians are provided with a simple but extensive overview of the implant surgery one has done, including a benchmark for his or her performance versus the average plastic surgeon in the Netherlands.*

# 4. BACKGROUND

**Rationale for the registry**

Since April 2015, the Dutch Breast Implant Registry (DBIR) registers characteristics of patients, surgical procedures, and breast implants in order to provide benchmark information about breast implant surgery in the Netherlands and safeguard its quality. Furthermore, it can be used as a track and trace system for recall purposes.

By using feedback information, healthcare providers can gain insight into the quality of care (e.g., complications) and compare it anonymously to other centers in the Netherlands (i.e., benchmarking). In this way, the provided care can be evaluated and points of improvement identified. Every year a selection of quality indicators is published on the transparency portal, making these indicators available to other parties (Chapter 7). By now, participants in the registry can also use data from the registry for scientific research (www.dica.nl/dbir/onderzoek).

**Governance**

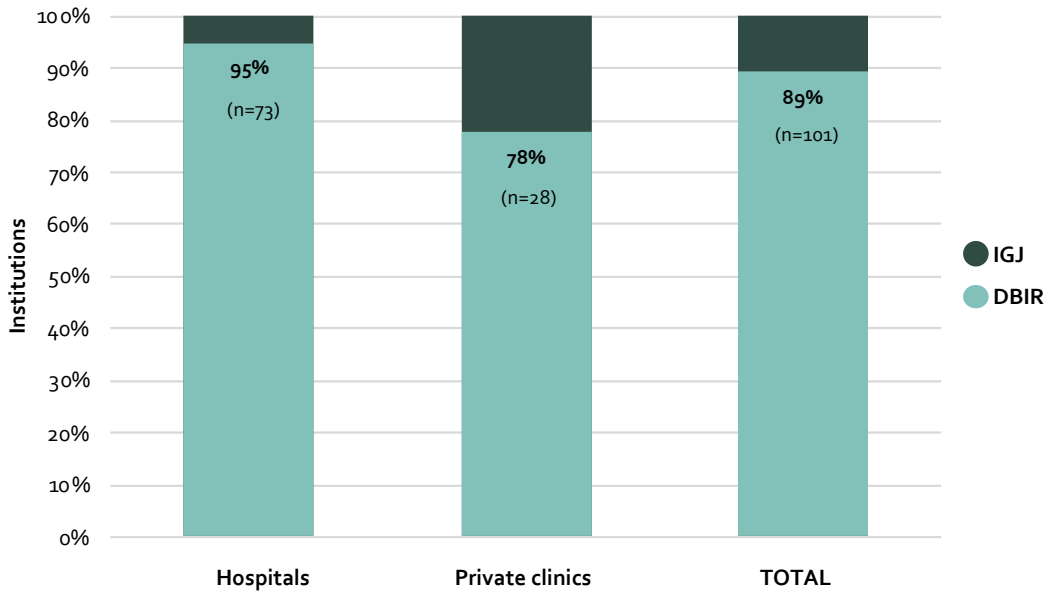
The DBIR was developed by commission of the Netherlands Society for Plastic Surgery (NVPC). A delegation of the NVPC, which is split into a Clinical Audit Board and a Scientific Committee, manages the content of the registry and safeguards the quality of the analyses and the interpretation of data.

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 health care. The DBIR is financially covered by a fixed fee per implant (EUR 25). This fee is paid either by the national health insurance (ZN) for patients receiving reconstructive breast implant surgery, or by private clinics in case of a cosmetic breast augmentation.

**Registry participation**

DBIR is a national, prospective, opt-out registry, with mandatory registration for all board-certified plastic surgeons in the Netherlands. In contrast to other countries, only board-certified plastic surgeons are allowed to perform breast implant surgery in the Netherland. Breast implant surgery can be performed in either a hospital or a private clinic. The number of participating institutions in the first full registration year was 101, of which 73 hospitals and 28 private clinics. This means an average coverage of 89% in 2016 relative to the eligible number of institutions known by the Dutch Health and Youth Care Inspectorate (IGJ) (95% of the hospitals, 78% of the private clinics) (Figure 1). The numbers of 2017 are not released by the IGJ, yet. Besides increasing our nationwide participation, another future step is to evaluate the completeness and quality of the data being entered by all participating institutions.

***Figure 1.*** *Coverage of DBIR in the Netherlands (2016)*




** IGJ: Dutch Health and Youth Care Inspectorate.*

**Methodology**

The dataset of the DBIR is based on a minimal data set developed by the International Collaboration of Breast Registry Activities (ICOBRA). All patients undergoing implantation or explantation of a breast implant are eligible for inclusion in DBIR. Health care institutions can register their data using an online module or via automated batches of the hospital system. A methodological council, consisting of statisticians, epidemiologists, and computer scientist, 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 the data points.

**Privacy**

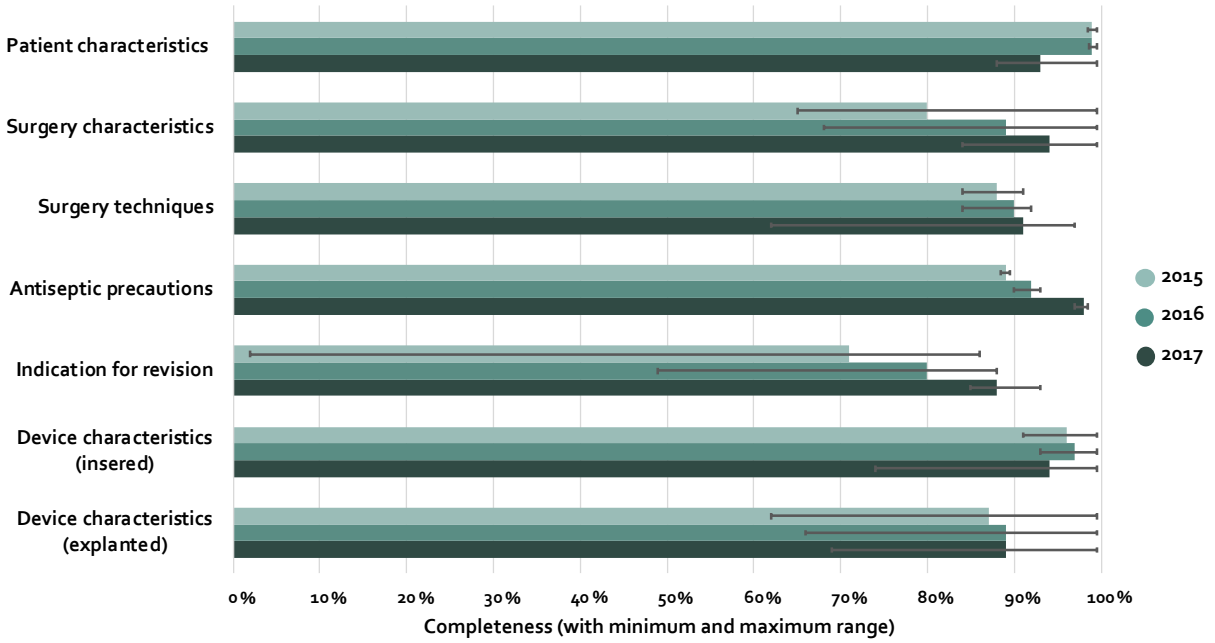
A certified third party (MRDM) appointed by the healthcare institutions and serving as an extension of the healthcare institutions, processes the data before they are forwarded to DICA. The data that DICA ends up receiving can no longer be traced back to individual patients. This process complies with the General Data Protection Regulation (AVG).

# 5. DATA COMPLETENESS

In order to improve data completeness and data quality, DBIR uses an opt-out structure. Additionally, 3 quality control mechanisms have been incorporated:

- During the online registration process, 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 a hospital specific signaling list, that can be used to rectify these records.
- A weekly updated, online report is provided to all participating institutions, presenting their outcomes compared to a Dutch benchmark to facilitate the clinical auditing process. This report also includes an overview of the completeness of the data.

***Figure 2.*** *Data completeness (2015 - 2017)*




In general, completeness of all variables has increased over the last three years (Figure 2 & Table 1). In 2017, the average completeness level was >90% for five of the seven variable groups (Figure 2). Furthermore, the range of completeness of most variables in each variable group has decreased. This means that every single variable in the concerning variable group is increasingly being filled in.
However, the registry underwent a major update in September 2017, including the addition of new variables, the mutation of some variable conditions, and a change in the data structure. As a result, the completeness rates are lower for a selection of variables and their corresponding variable group, such as "Length" and "Weight" (BMI), "Postoperative radiotherapy", "Manufacturer of ADM/Mesh", and the group with "Device characteristics".

# 5. DATA COMPLETENESS

***Table 1.*** *Data completeness (2015 - 2017)*

| | Complete (%) | | |
|---|---|---|---|
| | **2015** | **2016** | **2017** |
| Total number of records | n = 12,016 | n = 17,956 | n = 18,521 |
| **Patient characteristics** (Patient level) | | | |
| Date of birth | 99% | 100% | 99% |
| ASA classification | 99% | 99% | 100% |
| Smoking | | | 95% |
| Length | | | 88% |
| Weight | | | 88% |
| BMI | | | 88% |
| **Surgery characteristics** (Breast level) | | | |
| Operation date | 100% | 100% | 100% |
| Hospital | 100% | 100% | 100% |
| Surgeon | 96% | 88% | 92% |
| Laterality | 100% | 100% | 100% |
| Intervention | 100% | 100% | 100% |
| Indication | 65% | 68% | 84% |
| Timing reconstruction | 75% | 72% | 85% |
| RTx (preop) | 83% | 87% | 93% |
| RTx (postop) | | | 88% |
| **Surgery techniques** (Breast level) | | | |
| Incision site | 91% | 92% | 97% |
| Plane | 84% | 84% | 88% |
| Capsulectomy | 89% | 90% | 94% |
| Mastopexy | 88% | 90% | 95% |
| Autologous flap cover | 88% | 90% | 95% |
| Fat grafting | 88% | 90% | 95% |
| Drains | 90% | 91% | 98% |
| ADM/Mesh use | 88% | 92% | 95% |
| ADM/Mesh manufacturer | | | 62% |
| **Antiseptic precautions** (Breast level) | | | |
| Systemic AB (preop) | 89% | 93% | 98% |
| Systemic AB (postop) | 89% | 91% | 97% |
| Antiseptic rinse of implant | 89% | 93% | 98% |
| Sleeve/Funnel | 88% | 92% | 98% |
| Nipple guards | 88% | 90% | 98% |
| Glove change | 88% | 90% | 98% |

| | Complete (%) | | |
|---|---|---|---|
| | **2015** | **2016** | **2017** |
| Total number of records | n = 12,016 | n = 17,956 | n = 18,521 |
| **Indication for revision** (Breast level) | | | |
| Change TE for implant | | | 91% |
| Flap problem | 83% | 85% | 89% |
| Skin necrosis | 3% | 49% | 85% |
| Skin scarring | 84% | 85% | 89% |
| Deep wound infection | 84% | 85% | 89% |
| Seroma/Hematoma | 83% | 85% | 88% |
| Capsular contracture | | | 93% |
| Capsular contracture grade | 77% | 81% | 85% |
| Breast cancer | 82% | 84% | 88% |
| BIA-ALCL | 79% | 82% | 85% |
| ASIA | 78% | 82% | 85% |
| Breast pain | 81% | 84% | 88% |
| Asymmetry | 80% | 84% | 89% |
| Dissatisfaction with volume | 2% | 49% | 86% |
| Device rupture/deflation | 86% | 88% | 92% |
| Silicone extravasation | | | 91% |
| Silicone extravasation type | 82% | 84% | 89% |
| Device malposition | 84% | 86% | 89% |
| **Device characteristics** (Device level, inserted) | | | |
| Device type | 100% | 100% | 100% |
| Texture | 91% | 93% | 95% |
| Coating | 96% | 97% | 97% |
| Fill | 95% | 94% | 96% |
| Shape | 95% | 96% | 98% |
| Volume/Weight | | | 97% |
| Max. volume TE | | | 95% |
| Intraoperative volume TE | | | 74% |
| Manufacturer | 98% | 99% | 94% |
| **Device characteristics** (Device level, explanted) | | | |
| Device type | 100% | 100% | 100% |
| Texture | | | 88% |
| Coating | | | 88% |
| Fill | | | 90% |
| Shape | | | 91% |
| Manufacturer | 62% | 66% | 69% |
| Inserted abroad | 100% | 100% | 98% |

** ASA: American Society of Anesthesiologists, ADM: Acellular Dermal Matrix, AB: antibiotics, RTx: radiotherapy, Preop: preoperatively, Postop: postoperatively, TE: tissue expander, BIA-ALCL: Breast Implant Associated - Anaplastic Large Cell Lymphoma, ASIA: Autoimmune Syndrome Induced by Adjuvants.*

# 6. REGISTRY OUTPUT

Indications for breast implant surgery

In this report, breast implants are defined as both tissue expanders as well as permanent implants.

Clinical differences were found between patients who opted for a cosmetic breast augmentation and patients who received an implant for a reconstructive indication. Therefore, the results in this report are presented separately for these two groups, with each their corresponding chapter.

- **Part 1 - Reconstructive procedures,** includes the indications:
  - *Reconstruction post mastectomy for cancer (surgery to recreate a breast after one or both breasts are removed as a treatment for breast cancer).*
  - *Reconstruction post prophylactic mastectomy (surgery to recreate a breast after one or both breasts are 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 benign breast conditions or gender reassignment surgery).*
  - *Congenital deformity (surgery to restore or create shape and symmetry in patients with loss or absence of all or some breast tissue due to a congenital deformity, such as tuberous breasts).*

- **Part 2 - Aesthetic procedures,** includes solely:
  - *Cosmetic augmentations (cosmetic surgery for enlarging breasts).*

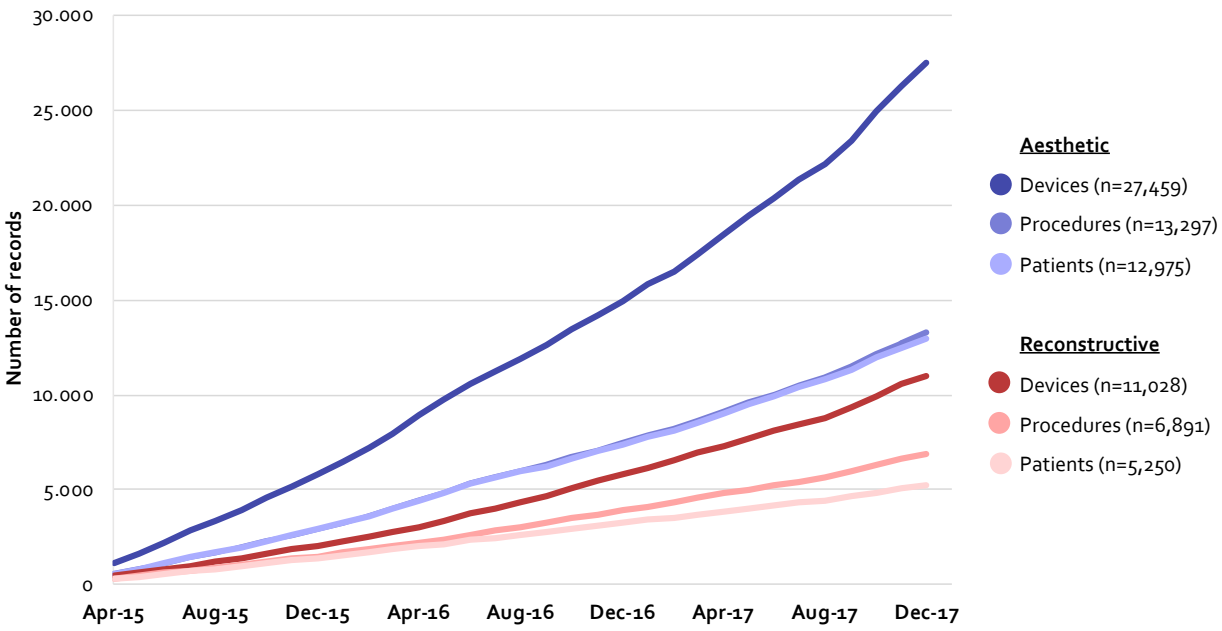
***Table 2.*** *Indications for breast implant surgery (2015 – 2017)*

| | Patients | | Procedures | | Devices | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | % |
| **Reconstructive** | | | | | | |
| Reconstruction post mastectomy for cancer | 4,628 | (19.1%) | 6,061 | (21.5%) | 9,301 | (15.2%) |
| Reconstruction post prophylactic mastectomy | 63 | (0.3%) | 108 | (0.4%) | 265 | (0.4%) |
| Reconstruction benign | 455 | (1.9%) | 611 | (2.2%) | 1270 | (2.1%) |
| Congenital deformity | 104 | (0.4%) | 111 | (0.4%) | 192 | (0.3%) |
| **Aesthetic** | 12,975 | (53.6%) | 13,297 | (47.3) | 27,459 | (44.8%) |
| **Not stated** | 5,975 | (24.7%) | 7,940 | (28.2%) | 22,856 | (37.3%) |
| **TOTAL** | 24,200 | (100%) | 28,128 | (100%) | 61,343 | (100%) |

** Patients and procedures are presented as unique patients and unique procedures. Some patients had multiple surgeries.*
** Devices are measured on breast level.*

Records in which the indication was not stated, were excluded from further analysis in this report.
In total, information on approximately 18,000 patients, 20,000 procedures, and 38,000 breasts implants has been registered in the DBIR database since the start of the registry in April 2015, until the end of 2017 (Figure 3). This includes primary procedures, revision surgeries, and explantations, of both tissue expanders and permanent implants, of which the indication is known (aesthetic vs. reconstructive). Most of the procedures were performed in the light of an aesthetic breast augmentation.
Figure 3 also illustrates that patients with a reconstructive indication are more likely to undergo multiple operations when compared to patients with an aesthetic breast augmentation. Generally, the majority of aesthetic patients received bilateral breast implants and reconstructive patients unilateral.

***Figure 3.*** *Cumulative number of registered patients, procedures and devices (2015 – 2017)*




In the two following chapters (i.e., reconstructive indications and aesthetic indications), results will be presented 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 in situ device and insertion of the same or new device.
  - Replacement of TE with an implant.
  - Replacement with autologous tissue.

- **Explantation only** includes:
  - Explantation of an in situ device without replacement of the device.

# PART 1 – RECONSTRUCTIVE INDICATIONS

# 6. REGISTRY OUTPUT

Part 1 – Reconstructive indications

A total of 6,891 operations (measured on patient level) were performed for a reconstructive indication, of which 4,601 patients underwent an insertion only procedure (5,041 operations), 583 replacement surgery (1,708 operations), and 62 an explantation only procedure (142 operations). The relatively low number of registered replacements and revisions is most likely explained by the fact that healthcare providers are legally required to register each inserted medical device. The registration of explanted devices, however, has not yet been mandatory but will be soon. Nevertheless, there is an increasing trend of replacement and explantation procedures being entered in DBIR, which is indispensable for reliable analysis of the quality of care and devices.

**Laterality** *(Table 3 & Figure 4)*

The majority of the reconstructive procedures were unilateral (72%). This is best explained by the vast majority of reconstructive procedures being performed after a mastectomy for breast cancer, which occurred mostly unilateral (77%). When looking at table 3 in more detail, it is clear that the other indications were more often performed bilaterally.

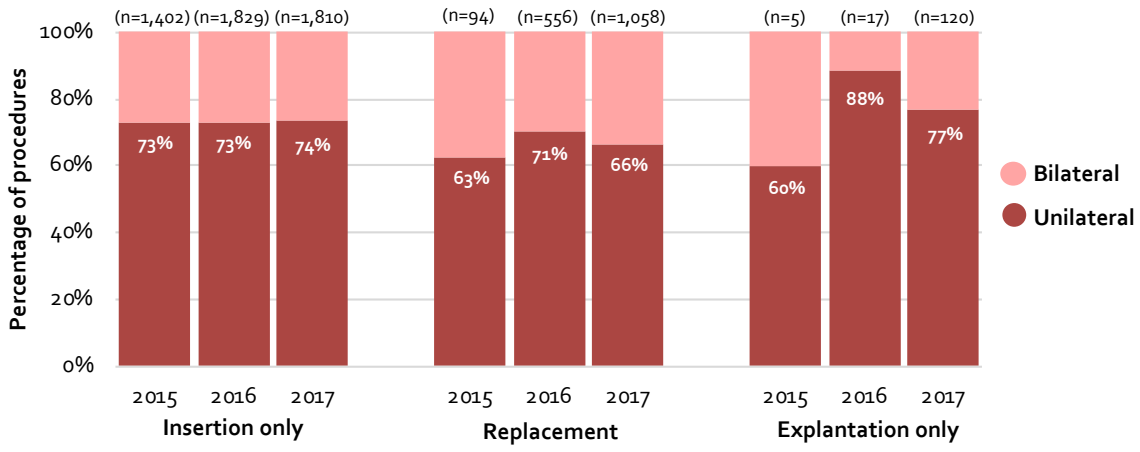
A more detailed trend over time is illustrated in figure 4. The proportion of unilateral vs. bilateral procedures did not change for insertion only and replacement procedures but has changed over the years for explantations only. The latter might best be explained by the simultaneous increase in the number of registrations as explained above.

***Table 3.*** *Laterality of reconstructive procedures (2015 – 2017)*

| | Unilateral | | Bilateral | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | % |
| **Reconstructive procedures** | **4,957** | **(72%)** | **1,934** | **(28%)** | **6,891** | **(100%)** |
| Reconstruction post mastectomy for cancer | 4,686 | (77%) | 1,375 | (23%) | 6,061 | (100%) |
| Reconstruction post prophylactic mastectomy | 32 | (30%) | 76 | (70%) | 108 | (100%) |
| Reconstruction benign | 193 | (32%) | 418 | (68%) | 611 | (100%) |
| Congenital deformity | 46 | (41%) | 65 | (59%) | 111 | (100%) |

** Presented as procedures on patient level. Some patients had multiple operations.*

***Figure 4.*** *Laterality of reconstructive procedures over time (2015 – 2017)*




** n is the total number of procedures per year.*

**Age** *(Table 4)*
Over time, not much difference existed between the mean age of patients who underwent an insertion only procedure (49 years) and patients with a replacement operation (51 years). The mean age of patients who underwent an explantation only procedure increased over the years, although this might be best explained by the increasing number of registrations per year.

***Figure 5.*** *Distribution of patient age at time of reconstructive surgery (2015 – 2017)*

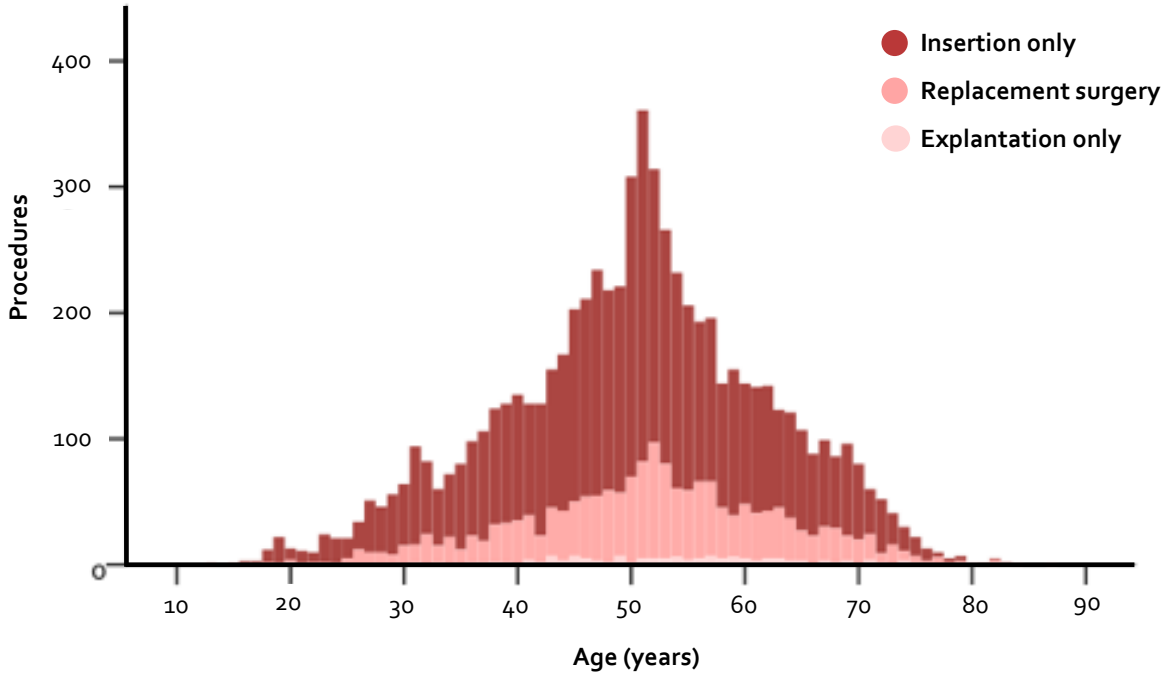


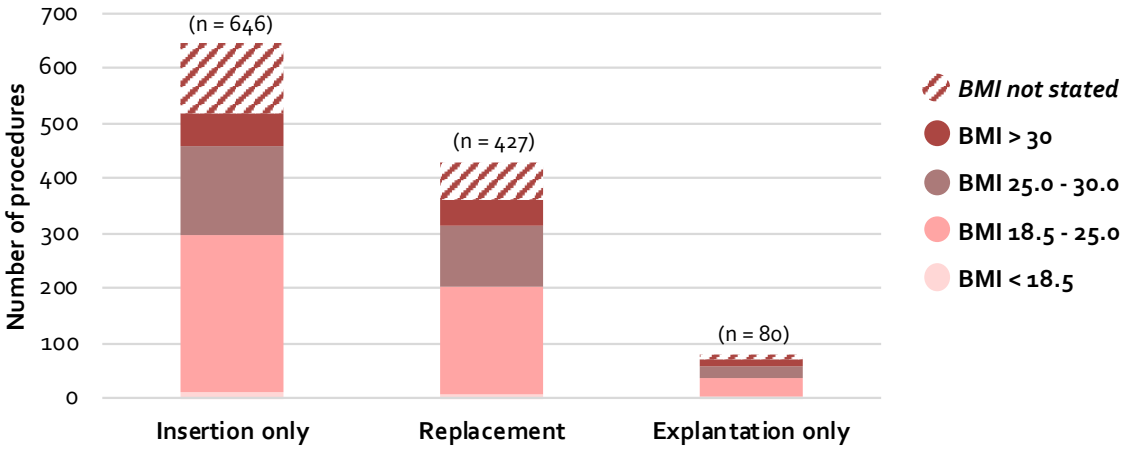

***Table 4.*** *Patient age at time of reconstructive surgery (2015 – 2017)*

| | Insertion only | | | Replacement | | | Explantation only | | |
|---|---|---|---|---|---|---|---|---|---|
| | 2015 | 2016 | 2017 | 2015 | 2016 | 2017 | 2015 | 2016 | 2017 |
| **n (procedures)** | **1,402** | **1,829** | **1,810** | **94** | **556** | **1,058** | **5** | **17** | **120** |
| **Mean** | **49.9** | **49.8** | **49.5** | **50.5** | **50.5** | **52.0** | **44.0** | **53.5** | **55.5** |
| SD | 11.6 | 11.8 | 11.7 | 11.8 | 11.2 | 11.4 | 13.6 | 14.9 | 9.9 |
| **Median** | **51.0** | **51.0** | **50.0** | **52.0** | **51.0** | **52.0** | **39.0** | **52.0** | **55.0** |
| IQR | 43-58 | 43-57 | 42-57 | 43-59 | 43-57 | 45-60 | 32-59 | 43-63 | 48-62 |

** SD: standard deviation, IQR: interquartile range.*

**Body Mass Index (BMI)** *(Figure 6)*
BMI has been registered as a case-mix variable since the DBIR update in September 2017. Therefore, BMI is analyzed for a smaller population. For insertion only, replacement, and explantation only procedures, most of the patients had a BMI between 18.5 and 25.0 (45%, 46%, and 44%, respectively), followed by 25.0 – 30.0 (25%, 26%, and 25%, respectively), >30 (9%, 11%, and 18%, respectively), and <18.5 (1%, 1%, and 2%, respectively). In respectively 20%, 16%, and 11% of the records BMI was missing.

***Figure 6.*** *Patient BMI at time of reconstructive surgery (Sept – Dec 2017)*




**Intra-operative techniques** *(Table 5)*
To improve the quality of care provided for breast implant surgery in the Netherlands, DBIR provides benchmark information on several topics, such as intra-operative infection control measures and technical operation details. For some techniques and measures, there is scientific evidence it has a positive effect on surgical outcomes, such as the preoperative use of prophylactic systemic antibiotics. For other techniques, however, no consensus has been reached, yet. Therefore, DBIR aims to identify best practices by collecting nationwide, patient-based data and surgical outcomes.
Over the years, the number of records with missing information on the intra-operative techniques decreased from ±12% in 2015 to ±5% in 2017 (Table 1). Except for the manufacturer (brand) of each ADM/Mesh, which only has been registered since September 2017.
No substantial alterations in the operation techniques used were seen over the years. Therefore, the trend over time was not described for this particular topic. Per type of intervention, however, most variation was observed in the plane of implant insertion, the type of capsulectomy that was performed, and the use of drains.

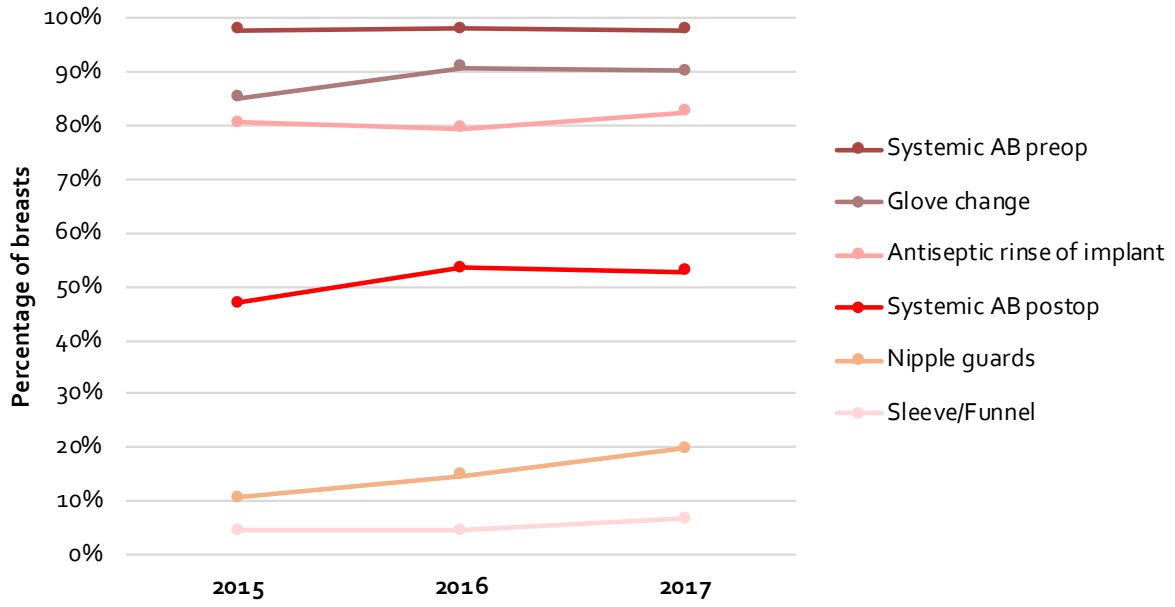
***Table 5.*** *Intra-operative techniques in reconstructive procedures, per breast (2015 – 2017)*

| | | Insertion only | Replacement | Explantation only |
|---|---|---|---|---|
| **Total number of breasts** | | **(n=6,386)** | **(n=2,268)** | **(n=173)** |
| **Incision site** | Inframammary | 12% | 21% | 17% |
| | Mastectomy scar | 62% | 63% | 62% |
| | Axillary | 0% | 0% | 0% |
| | Areolar | 10% | 3% | 2% |
| | Latissimus Dorsi | 4% | 5% | 10% |
| | Other | 6% | 5% | 5% |
| | *Not stated* | *6%* | *4%* | *2%* |
| **Plane** | Subglandular | 2% | 3% | |
| | Subfascial | 1% | 0% | |
| | Sub flap | 7% | 9% | |
| | Subcutaneous | 1% | 2% | |
| | Full pectoral muscle | 56% | 36% | |
| | Dual plane | 25% | 36% | |
| | *Not stated* | *8%* | *13%* | |
| **Mastopexy** | Yes | 5% | 2% | 3% |
| | *Not stated* | *11%* | *10%* | *4%* |
| **Capsulectomy** | Partial capsulectomy | | 43% | 24% |
| | Full capsulectomy | | 7% | 26% |
| | *Not stated* | | *14%* | *8%* |
| **Autologous flap cover** | Yes | 1% | 5% | 4% |
| | *Not stated* | *11%* | *9%* | *5%* |
| **Fat grafting** | Yes | 0% | 3% | 1% |
| | *Not stated* | *11%* | *9%* | *5%* |
| **Drains** | Yes | 93% | 69% | 75% |
| | *Not stated* | *2%* | *1%* | *4%* |
| **Mesh/ADM use** | Yes | 7% | 1% | |
| | *Not stated* | *6%* | *10%* | |

** ADM: Acellular Dermal Matrix.*
** The variables 'Plane' and 'Mesh/ADM use' were only registered for Insertion only & Replacement procedures.*
** The variable 'Capsulectomy' was only registered for Replacement & Explantation only procedures.*

**Infection control measures** *(Figure 6)*
Most of these variables were only registered for the insertion of an implant. Therefore, only the groups 'insertion only' and 'replacement' are included in figure 6. Results are presented per breast.
The extent to which infection control measures were applied remained pretty stable over the years, except for the use of nipple guards, which doubled.
Frequently applied measures for reconstructive indications, were the use of preoperative systemic antibiotics (±98%), glove change before the insertion of a breast implant (±89%), and an antiseptic rinse of the implant (±81%). Postoperative systemic antibiotics were provided in ±51% of the cases. Nipple guards or a sleeve/Keller funnel were not used commonly (±15% and ±5%, respectively). The number of records with missing information on the use of infection control measures decreased from ±12% in 2015 to ±2% in 2017. (Table 1)

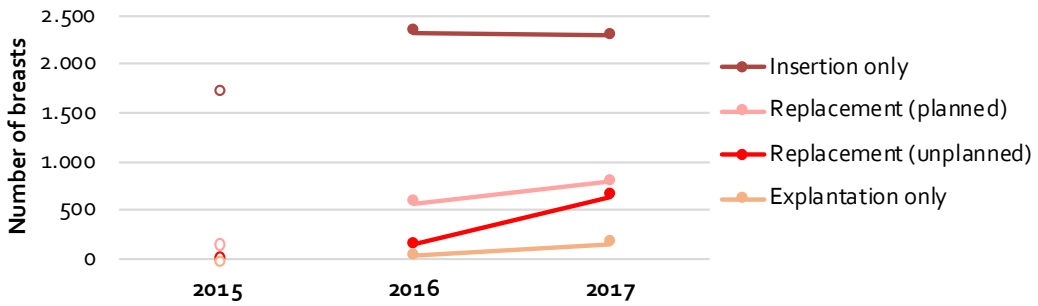
***Figure 6.*** *Infection control measures for every reconstructive implant insertion, per breast (2015 – 2017)*




** Infection control measures were only registered for Insertion only & Replacement procedures.*
** AB: antibiotics, Preop: preoperatively, Postop: postoperatively.*

**Revision surgery** *(Figure 7)*
Indications for revision surgery were categorized as unplanned or planned. Numbers presented in Figure 7 are composed of new implants as well as breast implants inserted (and/or explanted) prior to and after the start of the registry. The increasing trends represent an increasing number of registrations over time, rather than an increased revision rate.

***Figure 7.*** *Distribution of registered reconstructive procedures over time, per breast (2015 – 2017)*



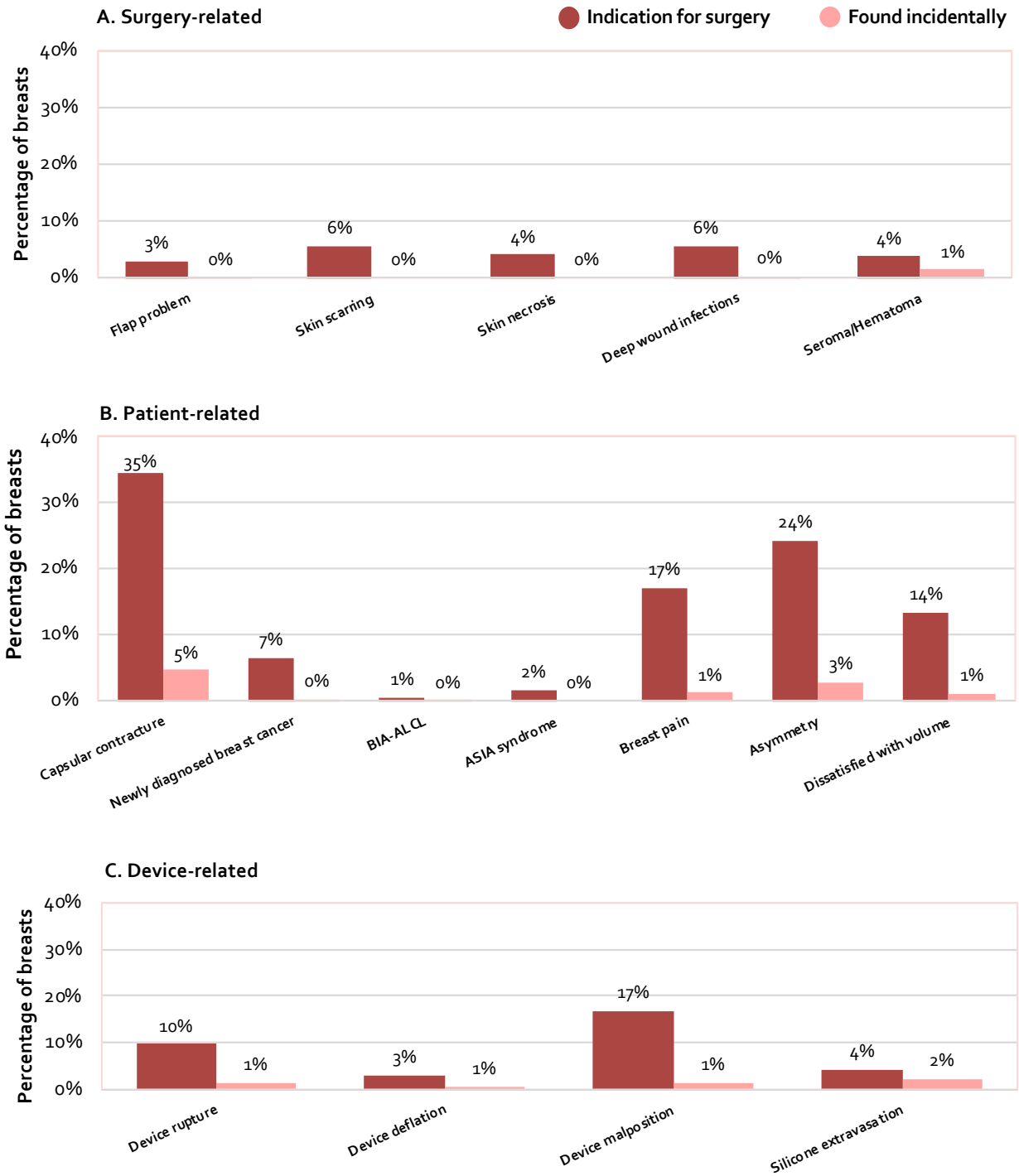

| | 2015 | 2016 | 2017 | Total |
|---|---|---|---|---|
| **Insertion only** | **1,771** | **2,321** | **2,294** | **6,386** |
| **Replacement (planned)** | **126** | **569** | **785** | **1,480** |
| TE to Implant | | | | |
| **Replacement (unplanned)** | **6** | **141** | **641** | **788** |
| Implant to Implant | 5 | 73 | 505 | 583 |
| Implant to TE | 1 | 32 | 47 | 80 |
| Implant to Autologous tissue | 0 | 15 | 35 | 50 |
| TE to TE | 0 | 21 | 39 | 60 |
| *Not stated* | *0* | *0* | *15* | *15* |
| **Explantation only** | **7** | **20** | **146** | **173** |

** 2015 was not a full registration year and is therefore not included in the trend line.*
** TE: tissue expander.*

**Indications for revision surgery & Incidental findings** *(Figure 8)*
Of the women with an unplanned breast implant replacement or explantation, the indication for revision was stated in 93.9% of the records. Of these, most revisions were done due to patient-related indications (2-35%), followed by device-related (3-17%), and surgery-related indications (3-6%).
All reported issues could also have been found incidentally during a revision procedure, not being the indication for revision. Nevertheless, these incidentally found issues were hardly reported. It is not known, however, whether they were less often encountered or that surgeons less frequently registered these issues.

***Note**: It is not known how many of the replacement and explantation procedures in the Netherlands were registered in DBIR (national denominator), as there is no gold standard for the validation of explantations, yet. Second, the numbers presented in Figure 8 comprise revisions and explantations of both breast implants inserted before and after the start of the registry. Therefore, the presented results should be interpreted with caution.*

***Figure 8.*** *Indications for replacement or explantation after reconstructive surgery, per breast (2015 – 2017)*




**Multiple indications could be reported per procedure.*
** These results should be interpreted carefully (See Note on page 19).*

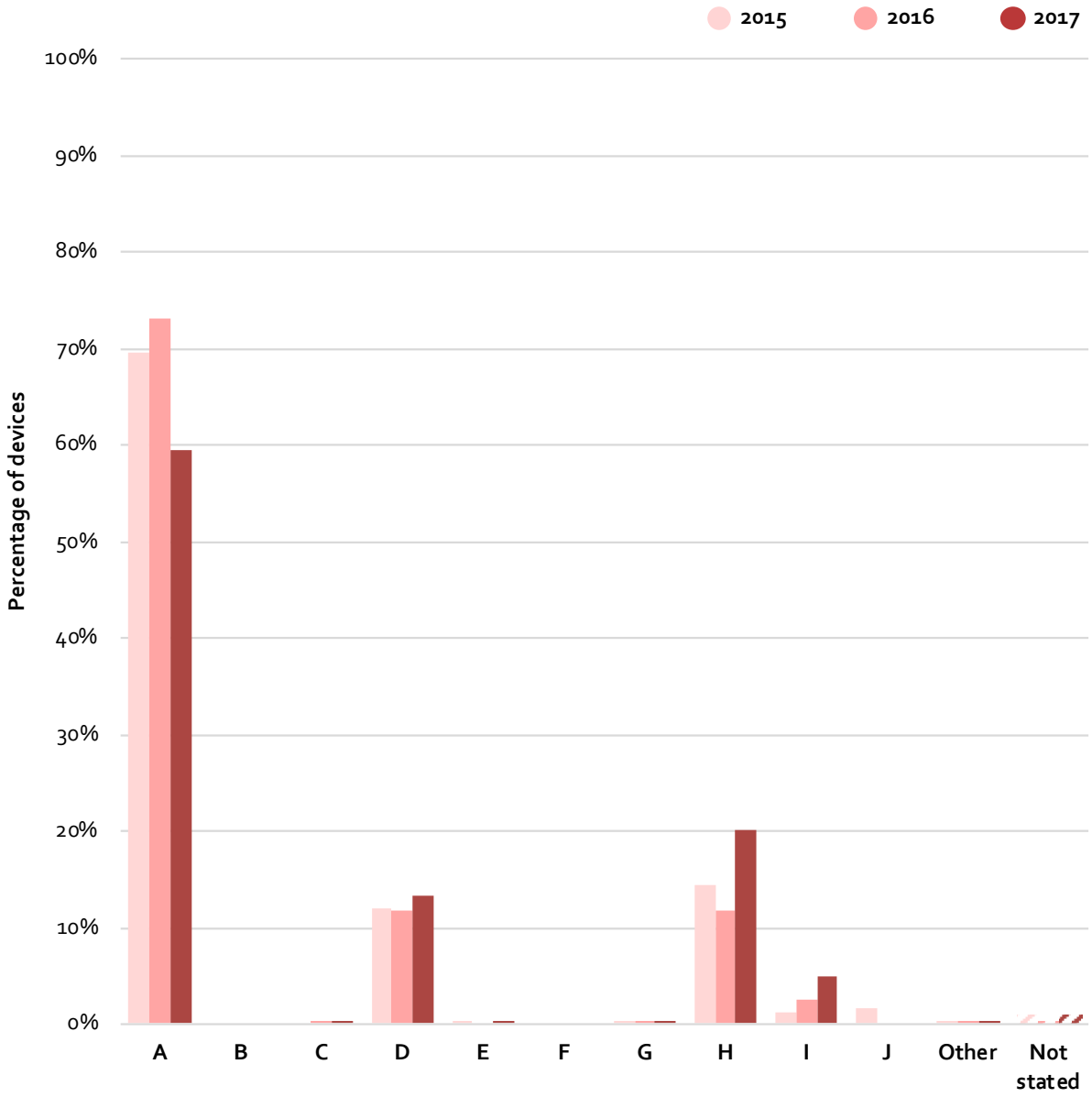
**Device characteristics** *(Table 6 & Figure 9)*
The majority of devices inserted for reconstructive indications were shaped, texturized, silicone coated, and silicone filled. The median volume of permanent implants was 415cc, the median volume of inserted tissue expanders was 450cc, and the median fill volume of tissue expanders per-operatively was 100cc.

***Table 6.*** *Device characteristics in reconstructive procedures, per device (2015 – 2017)*

| | INSERTED | | | EXPLANTED | | |
|---|---|---|---|---|---|---|
| | 2015 | 2016 | 2017 | 2015 | 2016 | 2017 |
| **Total number of records** | **n = 1,903** | **n = 3,016** | **n =3,668** | **n = 139** | **n = 730** | **n = 1,572** |
| Permanent implant | 41% | 51% | 59% | 8% | 18% | 44% |
| Tissue expander | 59% | 49% | 41% | 92% | 82% | 56% |
| **Device shape** | | | | | | |
| Round | 11% | 8% | 9% | | | 29% |
| Shaped/Anatomical | 83% | 88% | 88% | | | 61% |
| *Not stated* | *6%* | *4%* | *3%* | | | *10%* |
| **Device texture** | | | | | | |
| Textured | 91% | 94% | 92% | | | 83% |
| Smooth | 3% | 1% | 1% | | | 3% |
| *Not stated* | *6%* | *5%* | *7%* | | | *14%* |
| **Device coating** | | | | | | |
| Silicone | 94% | 95% | 91% | | | 84% |
| Polyurethane | 2% | 2% | 4% | | | 1% |
| *Not stated* | *4%* | *3%* | *5%* | | | *15%* |
| **Device fill** | | | | | | |
| Silicone | 42% | 47% | 56% | | | 70% |
| Saline | 47% | 37% | 33% | | | 16% |
| Hydrogel | 0% | 1% | 1% | | | 0% |
| Air | 0% | 0% | 0% | | | 0% |
| Other | 5% | 4% | 1% | | | 1% |
| *Not stated* | *6%* | *11%* | *9%* | | | *13%* |
| **Device volume** *Median volume in cc (IQR)* | | | | | | |
| Permanent implant | | | 415 (325-520) | | | |
| Tissue expander | | | 450 (400-550) | | | |
| Fill of tissue expander perop | 100 (100-150) | 100 (60-150) | 100 (60-160) | | | |

** Characteristics of explanted devices have been registered since September 2017 (n = 309 in 2017).*
** IQR: interquartile range, Perop: per-operatively.*

***Figure 9.*** *Percentage of inserted devices for reconstructive indications per manufacturer (x-axis), per year (2015 – 2017)*



# PART 2 – AESTHETIC INDICATIONS

# 6. REGISTRY OUTPUT

Part 2 – Aesthetic indications

A total of 13,297 operations (measured on patient level) were performed for an aesthetic indication, of which 12,371 patients underwent an insertion only procedure (12,581 operations), 501 patients replacement surgery (602 operations), and 103 an explantation only procedure (114 operations). Some patients had multiple surgeries. The relatively low number of registered replacements and revisions is most likely explained by the fact that healthcare providers are legally required to register each inserted medical device. The registration of explanted devices, however, has not yet been mandatory but will be soon. Nevertheless, there is an increasing trend of replacement and explantation procedures being entered in DBIR, which is indispensable for reliable analysis of the quality of care and devices.

**Laterality** *(Table 7 & Figure 10)*

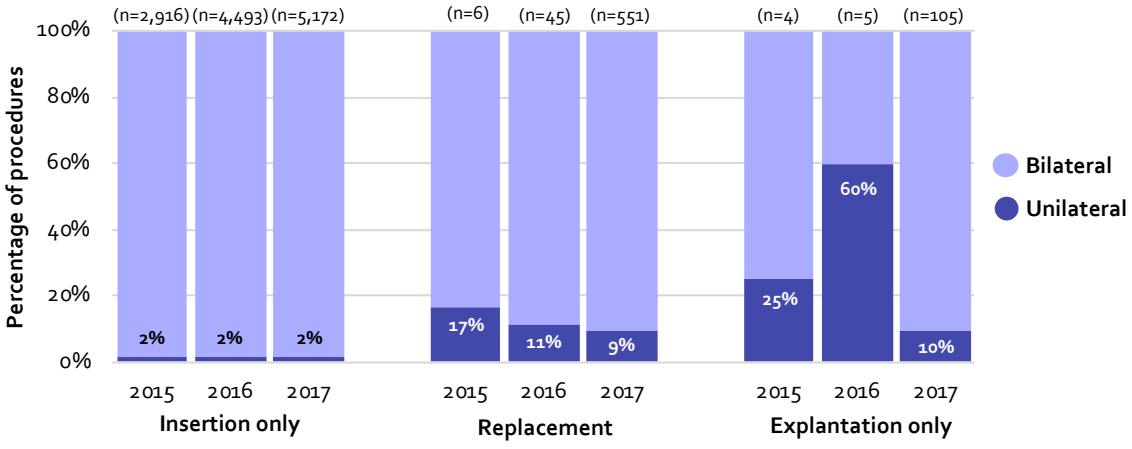
As expected, the majority of the aesthetic procedures were bilateral (98%). A more detailed trend over time is illustrated in figure 10. The proportion of unilateral vs. bilateral procedures did not change for insertions only. The proportion of bilateral procedures has changed slightly in replacement procedures, and major changes were seen in explantations only. However, the latter might best be explained by the simultaneous increase in the number of registrations as explained above.

***Table 7.*** *Laterality of aesthetic procedures (2015 – 2017)*

| | Unilateral | | Bilateral | | Total | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | % |
| **Cosmetic augmentation** | **287** | **(2%)** | **13,010** | **(98%)** | **13,297** | **(100%)** |

** Presented as procedures on patient level. Some patients had multiple operations.*

***Figure 10.*** *Laterality of aesthetic procedures over time (2015 – 2017)*




** n is the total number of procedures per year.*

**Age** (*Table 8)*
Over time, the mean age of patients undergoing an insertion only procedure was 31.5 years of age. The mean age of patients within the replacement group and patients undergoing an explantation only procedure varied over the years. Although, this might best be explained by the increasing number of registrations per year. Nevertheless, the mean age of the replacement and explantation only group was at least 10 years higher when compared to the insertion group.

***Figure 11.*** *Distribution of patient age at time of aesthetic surgery (2015 – 2017)*

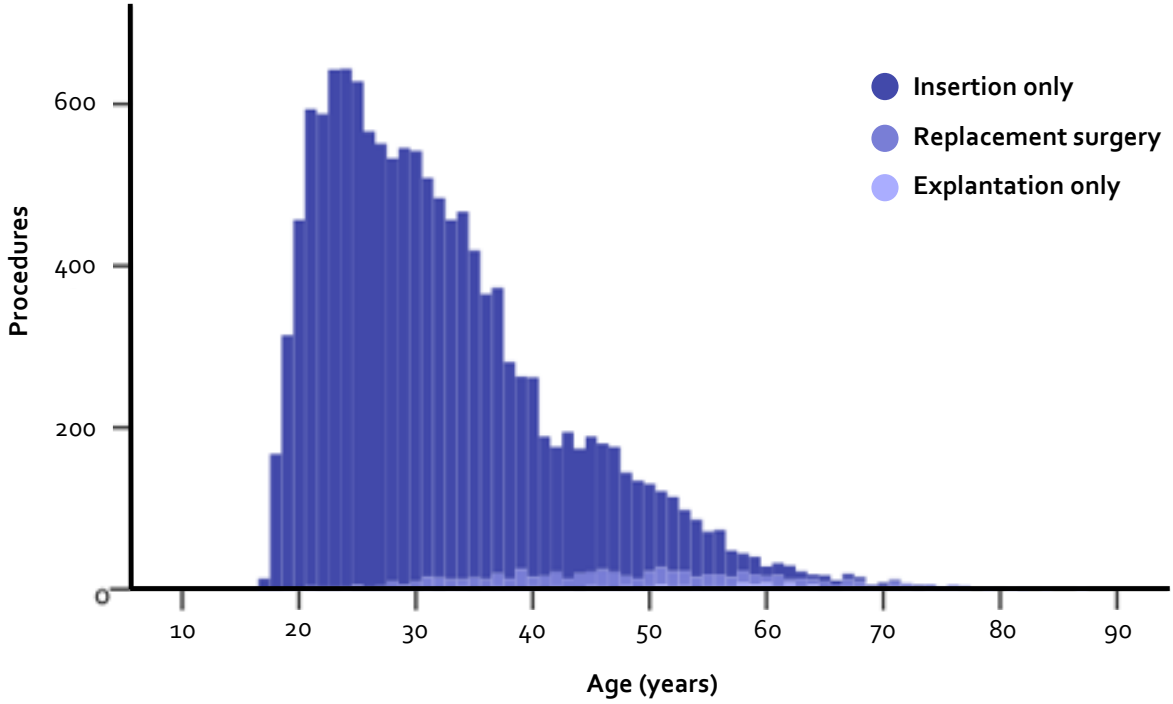


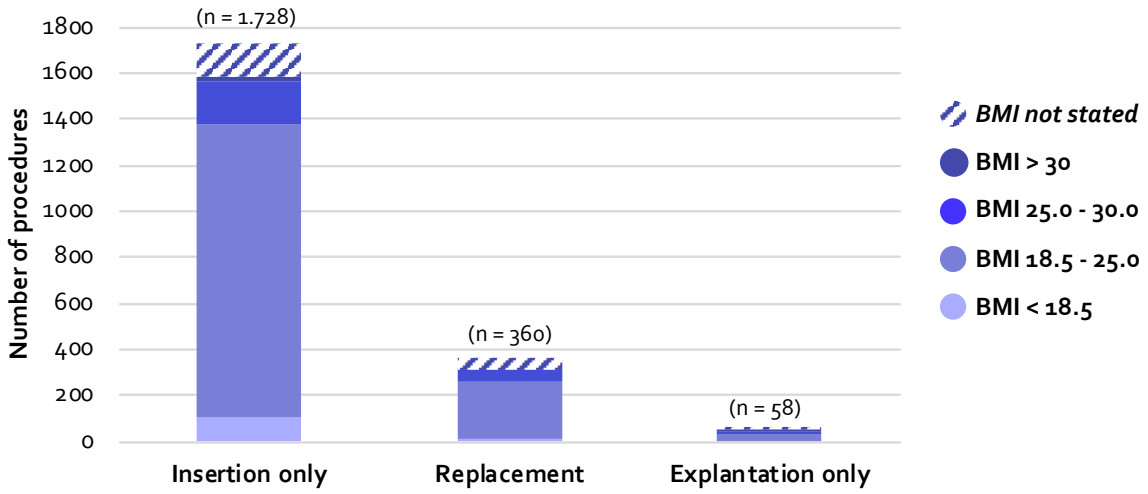

***Table 8.*** *Patient age at time of aesthetic surgery (2015 – 2017)*

| | Insertion only | | | Replacement | | | Explantation only | | |
|---|---|---|---|---|---|---|---|---|---|
| | 2015 | 2016 | 2017 | 2015 | 2016 | 2017 | 2015 | 2016 | 2017 |
| **N (procedures)** | **2,916** | **4,493** | **5,172** | **6** | **45** | **551** | **4** | **5** | **105** |
| **Mean** | **31.4** | **31.5** | **31.6** | **57.0** | **42.2** | **48.1** | **48.0** | **48.8** | **55.7** |
| SD | 9.3 | 9.4 | 9.6 | 12.5 | 12.8 | 12.2 | 8.0 | 11.1 | 12.6 |
| **Median** | **30.0** | **30.0** | **30.0** | **56.0** | **41.0** | **48.0** | **46.5** | **48.0** | **58.0** |
| IQR | 24-37 | 24-37 | 24-37 | 46-67 | 32-50 | 39-57 | 41-56 | 39-59 | 49-64 |

** SD: standard deviation, IQR: interquartile range.*

**Body Mass Index (BMI)** *(Figure 12)*
BMI has been registered as a case-mix variable since the DBIR update in September 2017. Therefore, BMI is analyzed for a smaller population. For insertion only, replacement, and explantation only procedures, most of the patients had a BMI between 18.5 and 25.0 (74%, 71%, and 48%, respectively), followed by 25.0 – 30.0 (10%, 12%, and 26%, respectively), >30 (2%, 2%, and 12%, respectively), and <18.5 (6%, 3%, and 4%, respectively). In respectively 8%, 12%, and 10% of the records BMI was missing.

***Figure 12.*** *Patient BMI at time of aesthetic surgery (Sept – Dec 2017)*




**Intra-operative techniques** *(Table 9)*
To improve the quality of care provided for breast implant surgery in the Netherlands, DBIR provides benchmark information on several topics, such as intra-operative infection control measures and technical operation details. For some techniques and measures, there is scientific evidence it has a positive effect on surgical outcomes, such as the preoperative use of prophylactic systemic antibiotics. For other techniques, however, no consensus has been reached, yet. Therefore, DBIR aims to identify best practices by collecting nationwide, patient-based data and surgical outcomes.
Over the years, the number of records with missing information on the intra-operative techniques decreased from ±12% in 2015 to ±5% in 2017. (Table 1). Except for the manufacturer (brand) of each ADM/Mesh, which only has been registered since September 2017.
No substantial alterations in the operation techniques used were seen over the years. Therefore, the trend over time was not described for this particular topic. Per type of intervention, however, most variation was observed in the plane of implant insertion, whether a mastopexy was performed, the type of capsulectomy, and the use of drains.

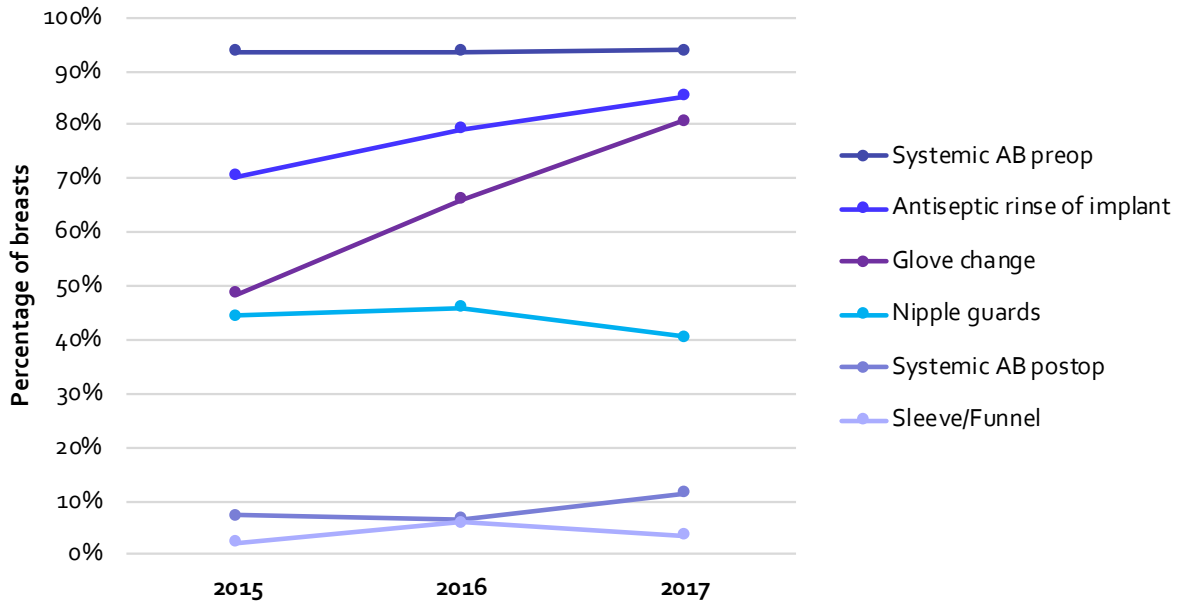
***Table 9.*** *Intra-operative techniques in aesthetic procedures, per breast (2015 – 2017)*

| | | Insertion only | Replacement | Explantation only |
|---|---|---|---|---|
| **Total number of breasts** | | **(n=24,940)** | **(n=1,159)** | **(n=215)** |
| **Incision site** | Inframammary | 94% | 95% | 84% |
| | Mastectomy scar | 1% | 1% | 0% |
| | Axillary | 0% | 0% | 1% |
| | Areolar | 0% | 1% | 0% |
| | Latissimus Dorsi | 0% | 0% | 0% |
| | Other | 4% | 2% | 12% |
| | *Not stated* | *1%* | *1%* | *2%* |
| **Plane** | Subglandular | 13% | 33% | |
| | Subfascial | 7% | 1% | |
| | Sub flap | 0% | 0% | |
| | Subcutaneous | 0% | 1% | |
| | Full pectoral muscle | 27% | 8% | |
| | Dual plane | 47% | 48% | |
| | *Not stated* | *5%* | *9%* | |
| **Mastopexy** | Yes | 3% | 6% | 23% |
| | *Not stated* | *2%* | *4%* | *2%* |
| **Capsulectomy** | Partial capsulectomy | | 39% | 23% |
| | Full capsulectomy | | 30% | 55% |
| | *Not stated* | | *5%* | *6%* |
| **Autologous flap cover** | Yes | 0% | 1% | 4% |
| | *Not stated* | *2%* | *4%* | *0%* |
| **Fat grafting** | Yes | 0% | 1% | 1% |
| | *Not stated* | *2%* | *4%* | *3%* |
| **Drains** | Yes | 13% | 55% | 67% |
| | *Not stated* | *4%* | *1%* | *0%* |
| **Mesh/ADM use** | Yes | 0% | 0% | |
| | *Not stated* | *2%* | *4%* | |

** ADM: Acellular Dermal Matrix.*
** The variables 'Plane' and 'Mesh/ADM use' were only registered for Insertion only & Replacement procedures.*
** The variable 'Capsulectomy' was only registered for Replacement & Explantation only procedures.*

**Infection control measures** *(Figure 13)*
Most of these variables were only registered for the insertion of an implant. Therefore, only the groups 'insertion only' and 'replacement' are included in figure 13. Results are presented per breast.
The extent to which infection control measures were applied varied over the years, except for the use of preoperative systemic antibiotics, which remained stable.
Frequently applied measures for aesthetic indications were the use of preoperative systemic antibiotics (94%), an antiseptic rinse of the implant (±79%), and glove change before the insertion of a breast implant (±66%). Nipple guards were used in ±44% of the breast augmentation procedures. Postoperative systemic antibiotics or a sleeve/Keller funnel were not used commonly (±9% and ±4%, respectively).
The number of records with missing information on the use of antiseptic precautions decreased from ±12% in 2015 to ±2% in 2017. (Table 1)

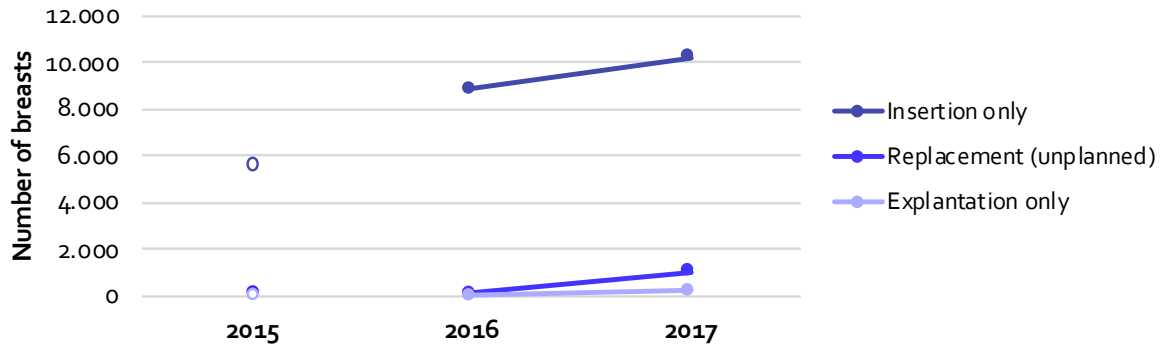
***Figure 13.*** *Infection control measures for every aesthetic implant insertion, per breast (2015 – 2017)*




** Infection control measures were only registered for Insertion only & Replacement procedures.*
** AB: antibiotics, Preop: preoperatively, Postop: postoperatively.*

**Revision surgery** *(Figure 14)*
Indications for revision surgery were categorized as unplanned or planned for reconstructive indications, such as the exchange of a tissue expander for a breast implant. For aesthetic augmentation procedures, however, every revision was considered unplanned. The numbers presented in figure 14 are composed of new implants as well as breast implants inserted (and/or explanted) prior to and after the start of the registry. The increasing trends represent an increasing number of registrations over time, rather than an increased revision rate.

***Figure 14**. Distribution of registered aesthetic procedures over time, per breast (2015 – 2017)*



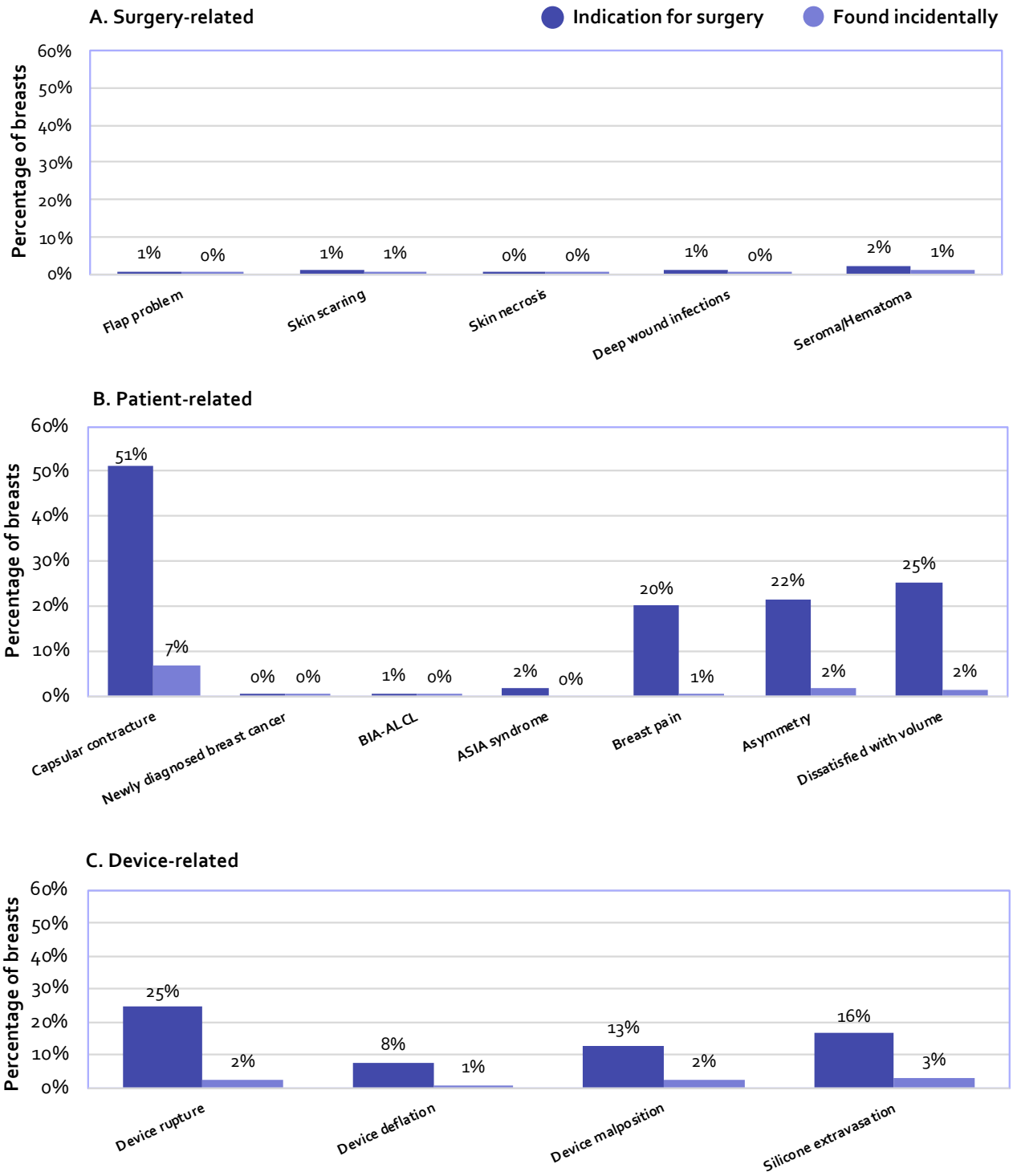

| | 2015 | 2016 | 2017 | Total |
|---|---|---|---|---|
| **Insertion only** | **5,783** | **8,909** | **10,248** | **24,940** |
| **Replacement (unplanned)** | **8** | **96** | **1,055** | **1,159** |
| Implant to Implant | 3 | 71 | 1,017 | 1,091 |
| Implant to TE | 0 | 0 | 1 | 1 |
| Implant to Autologous tissue | 0 | 0 | 2 | 2 |
| TE to Implant | 5 | 25 | 17 | 47 |
| *Not stated* | *0* | *0* | *18* | *18* |
| **Explantation only** | **6** | **7** | **202** | **215** |

** 2015 was not a full registration year and is therefore not included in the trend line.*
** TE: tissue expander.*

**Indications for revision surgery & Incidental findings** *(Figure 15)*
Of the women with an unplanned breast implant replacement or explantation, the indication for revision was stated in 87.9% of the records. Of these, most revisions were done due to patient-related indications (0-51%), followed by device-related (8-25%), and surgery-related indications (0-2%).
All reported issues could also have been found incidentally during a revision procedure, not being the indication for revision. Nevertheless, these incidentally found issues were hardly reported. It is not known, however, whether they were less often encountered or that surgeons less frequently registered these issues.

***Note**: It is not known how many of the replacement and explantation procedures in the Netherlands were registered in DBIR (national denominator), as there is no gold standard for the validation of explantations, yet. Second, the numbers presented in Figure 15 comprise revisions and explantations of both breast implants inserted before and after the start of the registry. Therefore, the presented results should be interpreted with caution.*

***Figure 15.*** *Indications for replacement or explantation after aesthetic surgery, per breast (2015 – 2017)*




** Multiple indications could be reported per procedure.*
** These results should be interpreted carefully (See Note on page 29).*

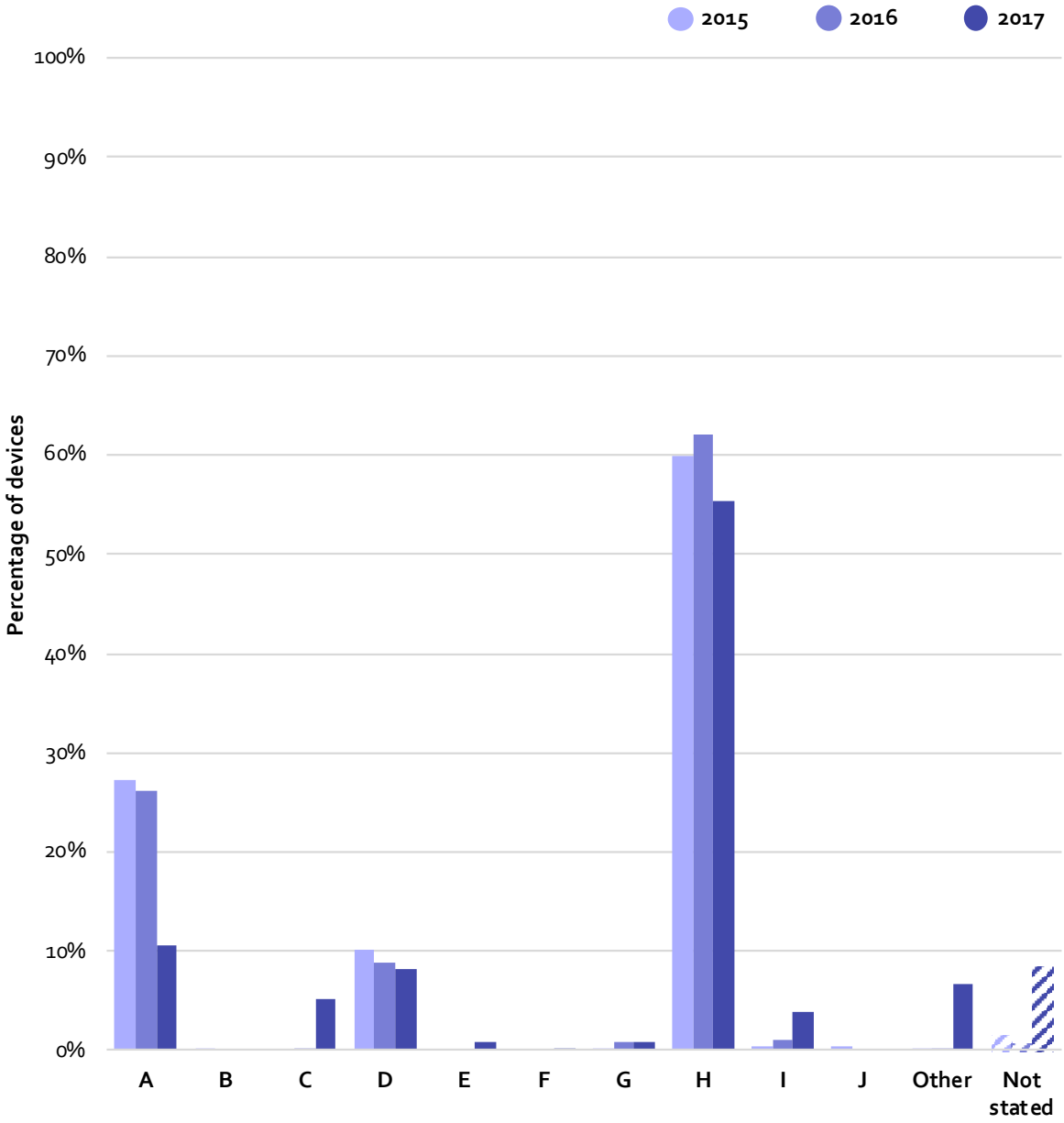
**Device characteristics** *(Table 10 & Figure 15)*
The majority of devices inserted for aesthetic indications were round, texturized, silicone coated, and silicone filled. The median volume of permanent implants was 350cc, the median volume of inserted tissue expanders was 450cc, and the median fill volume of tissue expanders per-operatively was 120cc.

***Table 10.*** *Device characteristics in aesthetic procedures, per device (2015 – 2017)*

| | INSERTED | | | EXPLANTED | | |
|---|---|---|---|---|---|---|
| | 2015 | 2016 | 2017 | 2015 | 2016 | 2017 |
| **Total number of records** | **n = 5,791** | **n = 9,005** | **n =11,293** | **n = 14** | **n = 103** | **n = 1,253** |
| Permanent implant | 100% | 100% | 99% | 64% | 76% | 98% |
| Tissue expander | 0% | 0% | 1% | 36% | 24% | 2% |
| **Device shape** | | | | | | |
| Round | 66% | 68% | 69% | | | 76% |
| Shaped/Anatomical | 32% | 30% | 30% | | | 20% |
| *Not stated* | *2%* | *2%* | *1%* | | | *4%* |
| **Device texture** | | | | | | |
| Textured | 96% | 97% | 89% | | | 79% |
| Smooth | 1% | 1% | 8% | | | 14% |
| *Not stated* | *3%* | *2%* | *3%* | | | *7%* |
| **Device coating** | | | | | | |
| Silicone | 97% | 97% | 95% | | | 93% |
| Polyurethane | 1% | 1% | 3% | | | 1% |
| *Not stated* | *2%* | *2%* | *2%* | | | *6%* |
| **Device fill** | | | | | | |
| Silicone | 98% | 97% | 97% | | | 91% |
| Saline | 0% | 0% | 0% | | | 2% |
| Hydrogel | 0% | 1% | 1% | | | 3% |
| Air | 0% | 0% | 0% | | | 0% |
| Other | 0% | 0% | 0% | | | 1% |
| *Not stated* | *2%* | *2%* | *2%* | | | *4%* |
| **Device volume** *Median volume in cc (IQR)* | | | | | | |
| Permanent implant | | | 350 (300-405) | | | |
| Tissue expander | | | 450 (400-650) | | | |
| Fill of tissue expander perop | *Not stated* | *Not stated* | 120 (100-300) | | | |

** Characteristics of explanted devices have been registered since September 2017 (n= 701 in 2017).*
** IQR: interquartile range, Perop: per-operatively.*

***Figure 15.*** *Percentage of inserted devices for aesthetic indications per manufacturer (x-axis), per year (2015 – 2017)*



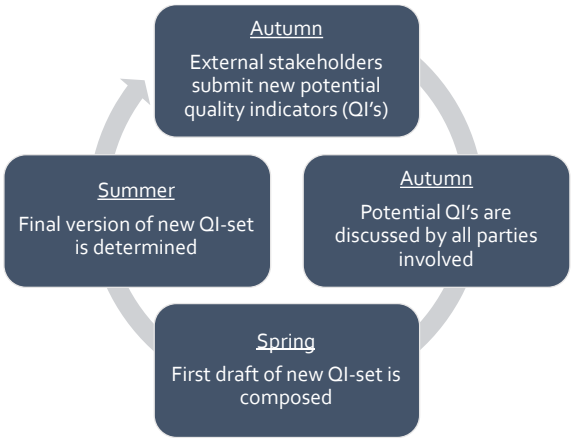
# QUALITY INDICATORS, COLLABORATIONS, FUTURE PERSPECTIVES, AND RESEARCH

# 7. QUALITY INDICATORS

**Quality indicators**
According to Donabedian's model, there are three types of indicators: structure, process and outcome indicators. The DBIR quality indicators are defined by the Scientific Committee and constitute the basis for internal data mirroring. After tripartite coordination with patient representatives and health care insurers, indicators can eventually become externally transparent, which means that hospitals make their results publicly available.

**Annual cycle** *(Figure 16)*
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: internally and externally transparent. Before a quality indicator is sufficiently valid to be shared (external indicator) with external parties (e.g., patients and health insurers), at first – for a few years – only hospitals receive feedback from this indicator and further develop it (internal indicator). After an agreement of all involved stakeholders it will be decided whether or not an indicator will be included in the yearly Transparency Calendar of the Dutch National Health Care Institute (ZiNL).

***Figure 16.*** *Annual DICA cycle for quality indicators*




**Dutch Health and Youth Care Inspectorate (IGJ)**
There are multiple parties in the Netherlands that request quality indicators. One of these parties is the Dutch Health and Youth Care Inspectorate (IGJ). These indicators are legally required for health care institutions and aim to monitor the quality of care. For this reason, when setting up its indicators, DBIR tries to collaborate closely with this party, among others, to prevent double requests or any ambiguities from the care providers' side.

***Table 11.*** *External quality indicators DBIR 2017*

| 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. | Process |

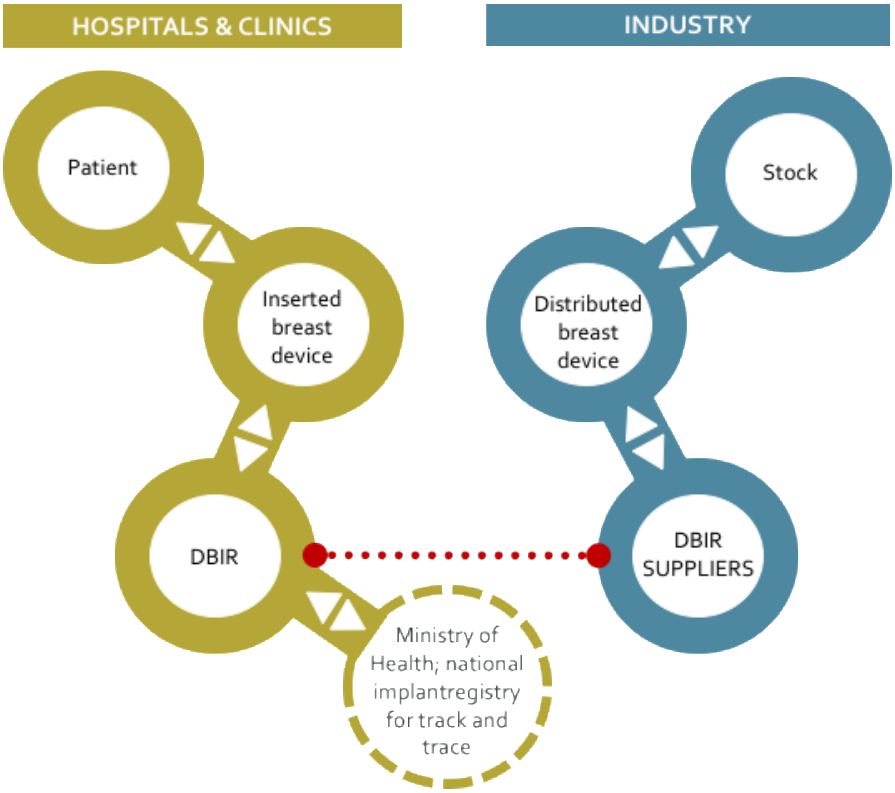
# 8. COLLABORATIONS

**National: DBIR SUPPLIERS**
Since the start of DBIR, the Scientific Committee collaborates closely with industrial partners that distribute breast implants in the Netherlands.

The industrial parties are actively involved in complying to European and Dutch agreements on the unique coding of medical devices, including implantable breast devices. With the support of GS1 Healthcare, DBIR has incorporated a feature in the online registration tool, through which GS1 barcodes on the breast implant box can be scanned and imported into the registry. In this way, device characteristics, such as the serial number and batch number are registered automatically, instead of manually. We thank 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.

Furthermore, the industrial partners started to register their distributed devices in our national industrial registry: the DBIR SUPPLIERS. Currently, the DBIR SUPPLIERS is in a start-up phase. However, once the DBIR SUPPLIERS is operational, this system can validate the devices registered in DBIR, provide suppliers with objective and reliable results of the quality of their devices in vivo, and help to minimalize the registration burden for the clinicians registering in DBIR. Figure 17 describes the relationship between the DBIR and DBIR SUPPLIERS in more detail.

***Figure 17.*** *Relationship between DBIR and DBIR SUPPLIERS*



**International: ICOBRA**

DBIR collaborates intensively with international partners through ICOBRA (International Collaboration of Breast Registry Activities). ICOBRA was founded in 2012, on 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 are working towards an internationally agreed comparable minimum data set and quality indicators, using standardized and epidemiologically sound data that reflect global best practice. Additionally, by using harmonized data sets, ICOBRA hopes that future crisis related to breast devices can be detected and averted in a timely fashion and that best surgical strategies can be identified.

As the first proof of concept, and in collaboration with the Australian and Swedish breast device registries, we have tried to reproduce as many tables and figures as possible from their annual reports in our annual report using data from DBIR.

During this collaboration, differences in data definitions, the rationale of data points, and experts' opinions on proper quality indicators have been identified. These differences found, highlighted the importance of ICOBRA's vision once more.

Currently, a first minimum data set has been defined, and a concept of the first set of quality indicators is in progress. Additionally, the first steps in pooling anonymized datasets between the DBIR and ABDR are being explored.

***Figure 18.*** *Current partners of ICOBRA*

# 9. FUTURE PERSPECTIVES

**Coverage and quality of the DBIR database**
A requirement for a valid registry is optimizing capture rates, the data quality, and preventing selection bias. The capture rate of DBIR has to be calculated more extensively for not only implant insertions but explantations as well, for both reconstructive and aesthetic indications. Various sources of validation are currently under review, including declaration data and the DBIR SUPPLIERS dataset.

**Quality Indicators**
For now, the DBIR has structural and process indicators that are externally transparent. Internally, however, the first outcome indicators are being developed, in line with the ICOBRA standards.

**Making registration easier**
Reduction of the administrative burden is one of the top priorities of DBIR and DICA. Strategies to achieve this, include the categorization of data points using the International Classification of Diseases (ICD) codes and SNOMED CT, in accordance with "Registratie aan de bron". This project aims to collect and register information in electronic patient records only once, in a uniform manner, so that data can be extracted automatically for various purposes, among which clinical registries.

**Scannable GS1 barcodes on all breast implant boxes**
In order to track and trace implants, device characteristics must be entered flawlessly. Manually, a typing error is easily made. Let alone the registration burden. Therefore, DBIR, together with the support of GS1 Healthcare, advocates for uniform, unique coding on all breast implant boxes.

**Link with other registries and databases**
Currently, all breast cancer patients undergoing an implant-based breast reconstruction, have to be 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 is registered once. Therefore, DBIR aims to set up new collaborations. However, in all these linking processes, current privacy issues have to be considered and overcome.

**Privacy issues in improving patient care**
Sharing aggregated data with other registries nationally and internationally helps to identify points 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 hospitals, legal advisors and privacy officers, within European countries as well as the rest of the world. These issues should be addressed and an open mind towards data sharing, with respect for the individual's privacy, is essential for future quality improvement.

**Patient Feedback**
In addition to measuring clinical outcomes, it is essential to incorporate the patient perspective. DBIR intents to measure these patient reported outcomes (PROs) with the Implant Surveillance Module of the BREAST-Q. Eventually, by linking these PROs to the clinical data, we can gain more insight into the quality of the provided care and all registered breast implants.

**International Perspectives**
Parallel to these nationwide initiatives, we will continue our teamwork with the partners of ICOBRA, regarding the minimum dataset, GS1 barcodes, combined analysis, lining up our data definitions, the development of quality indicators, and patient reported outcome measures (PROMs).

# 10. RESEARCH OUTPUT

The primary goal of DBIR is improving the quality of care using benchmark information and quality indicators, rather than providing a large database for research purposes. However, the Scientific Committee of DICA and the DBIR Committee believe that scientific research contributes to improving the quality of care and identifying best practices. Therefore, participants of the registry do have the possibility to conduct research with the data. Research proposals are managed by the Scientific Committee of DICA and the DBIR Committee, whom both check the validity of the proposal and the suitability of the requested data items.

**Previous research:**


- Becherer BE, Spronk PER, Mureau MAM, Mulgrew S, Perks AGB, Stark B, Pusic AL, Lumenta DB, Hopper I, Cooter RD, Rakhorst HA. High risk device registries: Global value, costs, and sustainable funding. J Plast Reconstr Aesthet Surg. 2018 Jun 12. Pii:S1748-6815(18)30203-1. *Epub ahead of print*
- Rakhorst HA, Mureau MAM, Cooter RD, McNeil J, van Hooff M, van der Hulst R, Hommes J, Hoornweg M, Moojen-Zaal L, Liem P, Mathijssen IMJ. The new opt-out Dutch Breast Implant Registry – Lessons learnt from the road to implementation. J Plast Reconstr Aesthet Surg. 2017;70(10):1354-60.
- Hommes J, Mureau MAM, Harsmen M, Rakhorst HA. 'Welk borstimplantaat heb ik eigenlijk?' Het belang van de Dutch Breast Implant Registry'. Ned Tijdschr Geneeskd. 2015;160:A9728.

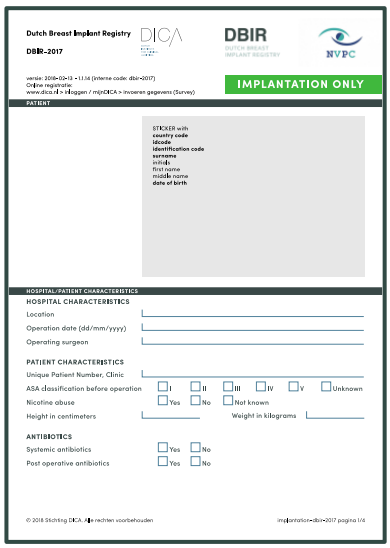
# APPENDIX

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://documents.mrdm.nl/showcase/downloaden

**IMPLANTATION ONLY**


Dutch Breast Implant Registry DICA DBIR NVPC
DBIR-2017
IMPLANTATION ONLY
PATIENT
STICKER with country code idcode identification code surname initials first name middle name date of birth
HOSPITAL/PATIENT CHARACTERISTICS
HOSPITAL CHARACTERISTICS
Location
Operation date (dd/mm/yyyy)
Operating surgeon
PATIENT CHARACTERISTICS
Unique Patient Number, Clinic
ASA classification before operation I II III IV V Unknown
Nicotine abuse Yes No Not known
Height in centimeters
Weight in kilograms
ANTIBIOTICS
Systemic antibiotics Yes No
Post operative antibiotics Yes No
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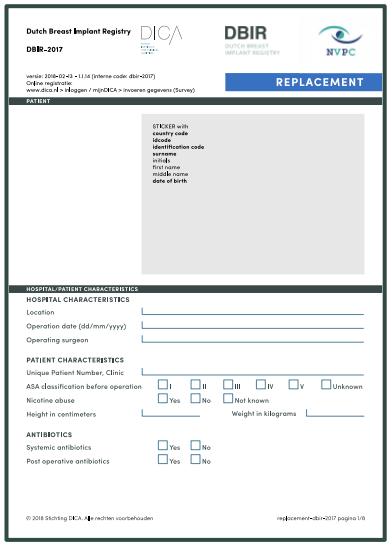
**REPLACEMENT PROCEDURE**


Dutch Breast Implant Registry DICA DBIR NVPC
DBIR-2017
REPLACEMENT
PATIENT
STICKER with country code idcode identification code surname initials first name middle name date of birth
HOSPITAL/PATIENT CHARACTERISTICS
HOSPITAL CHARACTERISTICS
Location
Operation date (dd/mm/yyyy)
Operating surgeon
PATIENT CHARACTERISTICS
Unique Patient Number, Clinic
ASA classification before operation I II III IV V Unknown
Nicotine abuse Yes No Not known
Height in centimeters
Weight in kilograms
ANTIBIOTICS
Systemic antibiotics Yes No
Post operative antibiotics Yes No
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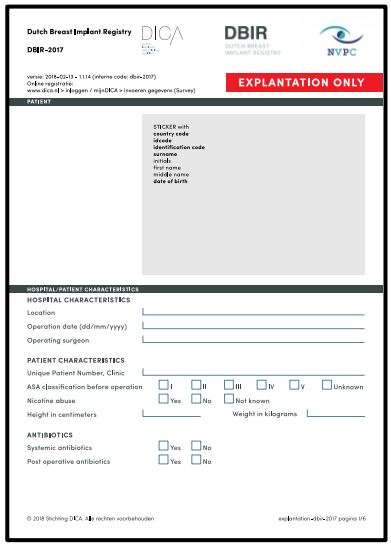
**EXPLANTATION ONLY**


Dutch Breast Implant Registry DICA DBIR NVPC
DBIR-2017
EXPLANTATION ONLY
PATIENT
STICKER with country code idcode identification code surname initials first name middle name date of birth
HOSPITAL/PATIENT CHARACTERISTICS
HOSPITAL CHARACTERISTICS
Location
Operation date (dd/mm/yyyy)
Operating surgeon
PATIENT CHARACTERISTICS
Unique Patient Number, Clinic
ASA classification before operation I II III IV V Unknown
Nicotine abuse Yes No Not known
Height in centimeters
Weight in kilograms
ANTIBIOTICS
Systemic antibiotics Yes No
Post operative antibiotics Yes No
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DICA MAKE CARE COUNT

Annual report DBIR 2015 - 2017