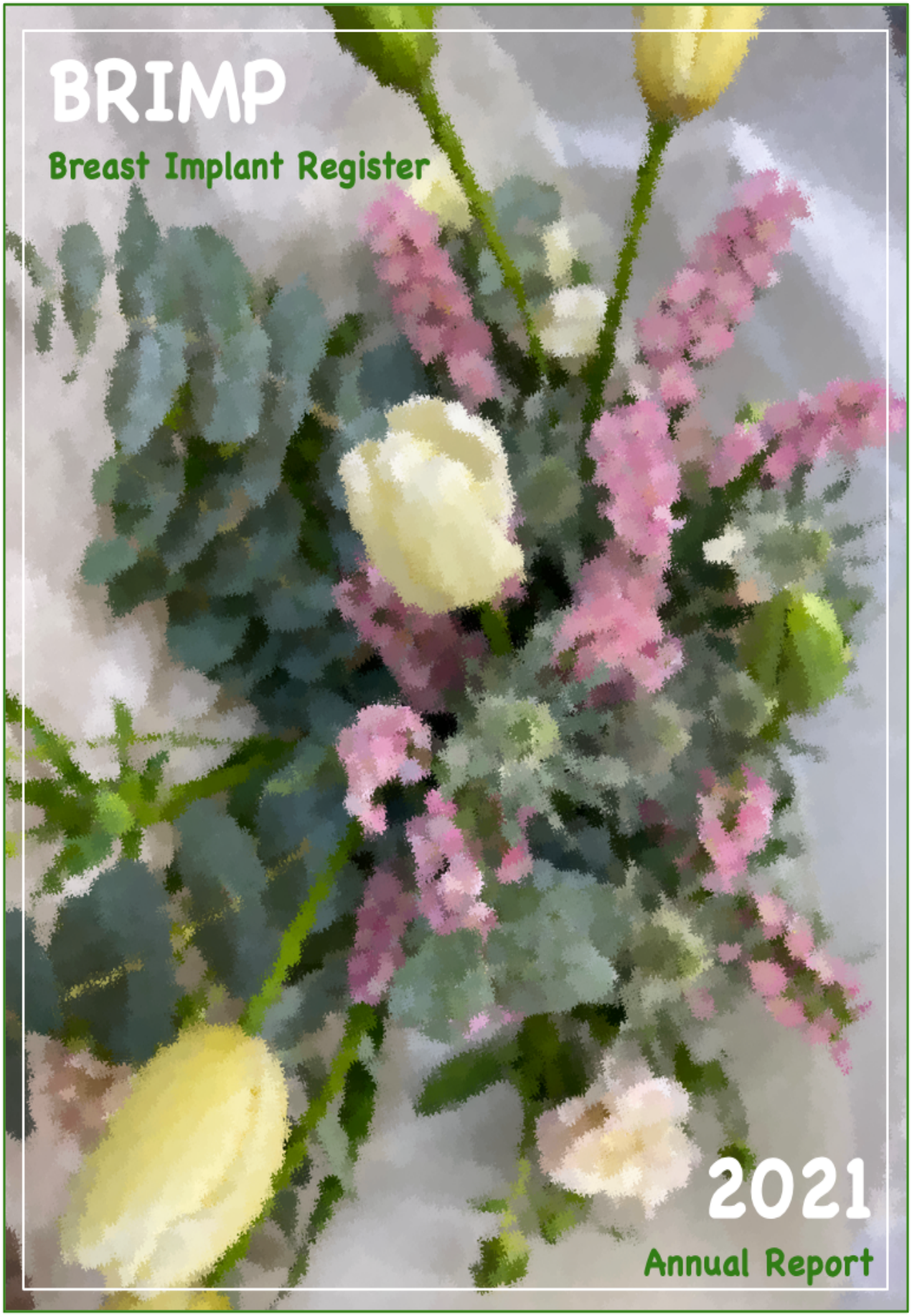
BRIMP
Breast Implant Register
2021
Annual Report

# CONTENT

# THOUGHTS FROM THE REGISTRY MANAGER

*Martin Halle, Associate Professor, Senior Physician in Plastic Surgery and Registry Manager for BRIMP*

It is an honour for me to take office as the new registry manager for BRIMP after Birgit Stark who created the registry and has run it since the start in 2014. The overarching aim with BRIMP is to inform patients, care professionals, authorities, and media about safety in using different breast implants. Specific goals are to objectively assess short- and long-term results in connection with implant-based operations after cancer and for benign breast conditions.

The year 2021 has been marked by both a continued pandemic, but also increased patient unease around potential negative effects of breast implants. This development has taken place against the background of the emergence of several important aspects regarding the medical safety when using breast implants in both public as well as private healthcare. The lymphoma disease Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) has received wide attention in both media and in the scientific community. The same can be said of the symptom complex Breast Implant Illness, BII, also called ASIA syndrome, Autoimmune/inflammatory Syndrome Induced by Adjuvants. Whether these conditions are related to different types of breast implants is so far not clear. Furthermore, implant surgery is today not so seldomly combined with other techniques, such as fat grafting and net insertion. The register is therefore continuously working with the aim of improving the data quality and to adjust BRIMP's variables to relevant questions concerning breast implants. BRIMP has an important function by providing objective and scientific data as a counterweight to the subjective information the patients receive via social media. Against the background of this I have therefore, together with the steering group's section for the annual report, chosen to look closer into how patient-experienced worry has formed the basis for surgical procedures and chosen to illustrate trends over time regarding the use of different implants.

The Swedish and English version of BRIMP's annual report is published yearly on BRIMP's web site, www.brimp.se, and is distributed free of charge to all members of the professional associations. All units that report to BRIMP receive a benchmarking summary of their own results. Each unit's own data in relation to aggregated data in BRIMP can be followed online using the unit's login.

To provide statistically based answers, large data is needed, which is why the registry managers have an intense cooperation with other international breast implant registries within ICOBRA (International Collaboration of Breast Registry Activities). The advantage of this collaboration to compare large amounts of data is that we can get answers to different questions in connection with breast implants in a much shorter time. The contribution from BRIMP to the collaboration is substantial as we during 2021 passed 50 000 registered implants.

MARTIN HALLE
Registry Manager BRIMP
2022-08-01

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Kirurgkliniken - Västervik

Kirurgkliniken - Falun

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VO Kirurgi - Bröst och plastikenheten - Kristianstad

VO spec. kir, Sektion för plastikkirurgi - Malmö

# SUMMARY

During 2021 it could be noted that more than 50 000 breast implants had been registered. For cancer operations mainly the Mentor make has been used and for benign breast conditions Mentor's and Motiva's products dominated in Sweden. During 2021 a certain increase of the number of reoperations could be noted in private healthcare, but not in public healthcare. A clear increase has been noted for permanent extractions of implants, so called explantation. An unexpectedly high frequency of extensive capsule resection "en bloc" could also be noted. This can possibly be explained, but not medically motivated by, a concurrent increased worry about breast implants as indication before reoperation. The number of primarily registered patients in both private and public healthcare was stable compared with 2020, as well as for primary operations of both reconstructions and benign conditions. A tendency towards increased use of implants with a smooth surface has been noted in public healthcare, where implants with a textured surface however still dominate. This trend with an increased proportion of smooth implants has during several years been noted in the private healthcare but appears to have swung back during 2021. The proportion of smooth and textured implants was essentially evenly distributed in the private healthcare in 2021. In general, the risk of reoperation within 60 days and after 5.5 years was very low. Patients treated with radiation had a considerably higher risk for reoperation compared with non-radiation treated cancer patients. Data in BRIMP has shown a very low risk for reoperation due to implant rupture within 5.5 years. No differences could be seen between implant brands. With an increased amount of data, the hope is that future analyses will give patients and care providers information on which specific risk factors are coupled to an increased reoperation frequency. Furthermore, BRIMP is the only quality registry that considers implant-specific data and can put these in relation to the symptom complex Breast Implant Illness (BII) and Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). The Swedish National Breast Cancer Registry NKBC does not approach these questions. A linkage of the BRIMP and NKBC registries during the past year has however shown that the coverage rate of breast cancer cases in BRIMP can be improved, but at the same time it has shown that both registries are needed as they complement each other in several ways.

In BRIMP we process and analyse our data continuously and to improve the registry content. BRIMP is an extremely important tool for our patients that makes it possible for them to become informed about specific implants regarding complications. We can improve the statistical relevance of our analyses and help the decision makers to choose the right implant for the right patient. Our international collaboration with Australia, Holland, Germany, the UK, Switzerland and Italy in ICOBRA aims at defining quality parameters for healthcare on an international level.

# ACTIVITIES 2021

## Activities and main projects

At the turn of the year 2021-2022 the earlier registry manager Birgit Stark passed on the responsibility to Martin Halle who took office in BRIMP's steering group in the Autumn of 2021. The affiliation rate to BRIMP is still around 85% of the private practitioners in the country and at the end of 2021 the steering group has discussed different strategies to increase the affiliation rate. Among other things a certificate has been designed, which several units now use to inform patients and clients of their active participation. The participation in BRIMP is however not mandatory, neither for regionally funded care nor for private care, as opposed to the situation in the Netherlands, the UK and Australia. The affiliation rate is therefore completely dependent on goodwill on the part of the colleagues in the country. In cooperation with Registercentrum Västra Götaland we manage data from more than 50 000 implants. The work in 2021 mainly focused on four projects.

### 1. Out-data Functions as Support for Clinical Care

Feedback to participating units is an important function in a quality registry. In cooperation with the project management at Registercentrum Västra Götaland two online web modules for participating units have been prepared. All registering units can sign in and obtain aggregated benchmarking data in BRIMP. A new web-accounting of statistical data for affiliated units is under preparation. The registry manager has submitted a proposal of accounting of data in real-time. The concept needs to be discussed in the steering group for implementation in the Spring of 2023.

### 2. Improved Registry Content

A critical analysis of the meaning of the BRIMP-variables for clinical care has been taking place continuously and has resulted in an update of the relevant data. Participation and quality of the reports are other factors that were evaluated in the past year. In 2021 the registry manager has carried out a new critical analysis of data quality regarding newly added/especially observed implant-related problems in addition to newly added variables in BRIMP. Data from the annual report of 2020 with national and regional data outcomes have made it clear that some variables probably were misinterpreted. A clarification of specific data was made and sent to all users. An improved registry content is also created by an analysis of the completeness rate.
We experience an increased understanding of the value and the importance of BRIMP. More national units are asking for information about BRIMP. The current total rate of complete data sets in BRIMP amounts to around 65%. Credible sales data from the industry that the registry manager has taken part of shows that we register 65% of all sold implants in Sweden. The registry manager has together with representatives of the industry discussed how we together can improve coverage. An agreement has been made with the company Mentor that sells around 50% of the implants in Sweden in which Mentor actively encourages their sales partner's participation in. By matching BRIMP's customers, which are public on their web site, the registry's coordinator can see which units perform breast implant surgery but are not in contact with BRIMP. The aim is to initiate active work for these unit's participation in BRIMP.
A critical analysis of outcome data in BRIMP during the years 2015-2021 shows stable statistical results. In consultation with our statisticians at Registercentrum we concluded in the annual reports of 2019 and 2020 that these accounted results are Swedish standard. However, breast implants are used in cases within other overlapping specialities where we so far have not been able to convince all breast surgeons to participate in BRIMP. We are therefore hoping for a closer cooperation between the National Breast Cancer Registry (NKBC) and BRIMP, which hopefully will increase the completeness rate by channelling data from NKBC to BRIMP. Data transmission started in the Fall of 2021.

### 3. Facilitate Everyday Routines for Reporting Units

In a first process the possibility of linking BRIMP to an industry database. i.e. a digital transmission of data based on the implant specification was investigated. The advantage would be that data in BRIMP is transmitted correctly with the aim of decreasing missing data in the long run. The consequence analysis showed that BRIMP for the moment does not dispose over the necessary economical basis to run such a project.
Furthermore, we evaluated in a questionnaire on how registering units perceived of the daily work with BRIMP and their potential problems. The overriding aim was to improve the communication between BRIMP and care providers. Against the background of the given data from the questionnaire a webinar was held in November 2021. Thirty-three persons from different personnel categories participated in the webinar. The initiative was appreciated and digital exchanges between registry management and registering units will also be used in the future in order to

encourage interactivity and communication. These activities aim to contribute to increasing the completeness rate of reports to BRIMP.

### 4. Industry Database

In cooperation with the project management at Registercentrum BRIMP has created different report models for an industry database. Data regarding complications and reason for reoperation of the company's products are compared with aggregated data in BRIMP. The implant companies Motiva and Mentor have obtained this industry report from BRIMP in 2021. Registercentrum has developed suitable collaboration agreements with the implant-producing companies Motiva and Mentor regarding industry report 2021. The commission to Registercentrum comprises the de facto cost of the creation of industry reports.

## The work of the Steering Group and the Registry Manager in 2021

**Registry Work 2021**

The steering group has gathered for four video conference calls during the year. The registry manager has had a little more than 30 digital meetings and current contacts by phone and mail. The contacts with project management and statisticians have been very intense during the first six months of 2021 until the work with the annual report 2020 was completed. Furthermore, the registry manager has held several separate meetings per term with the registry coordinator to plan the continuous registry work with the units. The registry coordinator has been in continuous contact with the units for support and help with the registry work.

The registry manager has had the main responsibility for the work with the annual report and has gathered relevant data and written a script and arranged for an English version of the annual report. The registry manager has participated in the national and international work group with around 10 digital meetings for the BIA-ALCL task force-group in Europe and ICOBRA. The registry manager has presented BRIMP at national and international meetings and has ensured economy for 2022 by several written applications to the Swedish Association of Local Authorities and Regions in the past year.

**Collaboration with Industry**

During the past year the creation of an industry report has demanded several meetings and working time where the registry manager has been in contact with representatives from industry and project management from Registercentrum.

## International and National Collaboration

BRIMP has experienced growing national and international attention. The English versions of the annual reports of 2017-2020 are published at EASAPS (European Association of Aesthetic Plastic Surgery Societies) web site and were given to international members of the ICOBRA (International Collaboration of Breast Registry Activities). Reports were also distributed to all members of SFEP (Swedish Association of Aesthetic Plastic Surgery) and SPKF (Swedish Association of Plastic Surgery), and to European specialists in plastic surgery. In addition to the annual report, all units that report to BRIMP receive a special summary of their own results, which are sent by mail twice per year. The units' own benchmarking data in relation to aggregated data in BRIMP can also be followed online after login. The registry manager Birgit Stark planned an international meeting with ICOBRAs collaboration partners in Stockholm in June 2020, but the meeting was cancelled due to the Covid pandemic. A new international meeting with the same content has been planned by registry manager Birgit Stark together with ICOBRAs representatives in Lima, Peru at ICOPLASTs meeting in May 2022, but even this meeting was adjourned due to the Covid pandemic. The collaboration with ICOBRA has resulted in a research publication in 2021.

## Economy

BRIMP has so far mainly been funded by allocations from the Swedish Association of Local Authorities and Regions, which we have applied for annually in competition with the other, approximately 100 quality registries in the country. No privately run unit or professional association has contributed to BRIMPs expenses. No fee has been paid for annual reports or specific units' reports, which are sent twice annually to participants. BRIMP has been reimbursed for an industry report to the implant-producing companies Motiva and Mentor. The reimbursement only covers the production cost for the report. The registry manager has reconciled budget for BRIMP with the management of Registercentrum and has participated regularly in follow-up meetings that are held four times per year.

In summary it can be stated that BRIMPs economy is in balance with budget for 2021.

# Data Quality and Sample Controls for the Annual Report of 2021

**Aim**

The main goal is to present BRIMP's data for primary implant-based operations and reoperations and to present a risk analysis for specific parameters against the background of reported data in the registry. Prior to the current work a control of data quality in BRIMP's current registry was carried out. This is performed automatically when generating the R-data layer. Patients that have more than one primary operation per side are identified, and these patients are removed from both datasets (primary operation and reoperation). Patients who are reoperated before primary operation are identified and removed from the dataset reoperation. Their primary operations are kept in the Primary Operation dataset. For risk analyses we included all patients with primary operations. The outcome of the risk analysis is based on the patients that have a registered reoperation in BRIMP. Data extraction for the annual report was carried out in March 2021. Registrations made after this date were therefore not part of any analyses. The time that passes until a registration is done after the operation differs between different units and periods. In some cases, registrations are carried out several months after the operation date. After the data extraction was made there has been more registrations for 2021 that therefore have not been part of the analyses.

**Improvement Proposals**

The main future aim is that most units should register intraoperatively without delay. This however demands that personnel with the right to register is available in the operating room. In the long run one should also be able to add a warning that appears when a user tries to input a new primary operation for a patient that is already operated. It could suffice if the system only prints the date for the registration of the first primary operation, in order not to infringe on the patient secrecy. The same applies if a reoperation is registered with an earlier date than the primary operation.

**The Annual Report 2021**

In this annual report data from patients with breast reconstruction and risk-reducing mastectomies were evaluated separated from implant-based operations for benign conditions. We have chosen to present data for 2021 both in relation to all previous years and in some cases in relation to the aggregated patient cohort with primary operations in 2014-2020. It is worth mentioning that some variables have been added between 2014-2020, therefore a value of zero in earlier years may mean that this variable is new and a low value the first year may reflect that the variable has been added during that year. Patient-reported reason for revision, intraoperative findings and measure are accounted for. Furthermore, the reoperations in BRIMPs database are evaluated at 60 days, one and six years after operation. A general summary of the most important outcome data is presented in connection with the annual report. The total number of registered operations in 2021 was 6403, divided into 4094 primary operations and 2309 reoperations. In total, this is an increase by 3%, where an increase was seen for reoperations with 14% with a concurrent decrease by 2% for primary operations. Therefore, although the current pandemic has not resulted in any major difference between 2020 and 2021 in total, a continuously lower level of operations was observed compared with previous years. (Figure 1). An analysis on a regional level show that the total number of registered primary operations, as well as primary operations, performed at private units, is the largest in the Västra Götaland-region (figure 2 and 4), while the number of registered primary operations in public care is the largest in Stockholm. (Figure 3). It seems likely that there is a certain underreporting of the number of primary operations in the Stockholm region, since some major private clinics do not report to BRIMP yet.

# STATISTICS

Below the total number of operations regardless of diagnosis is presented, whereafter data is presented based on the indication of the primary operation (red: cancer or risk reduction and blue: benign conditions) and thereafter in common (purple: regardless of indication) for reoperations and risk analysis.

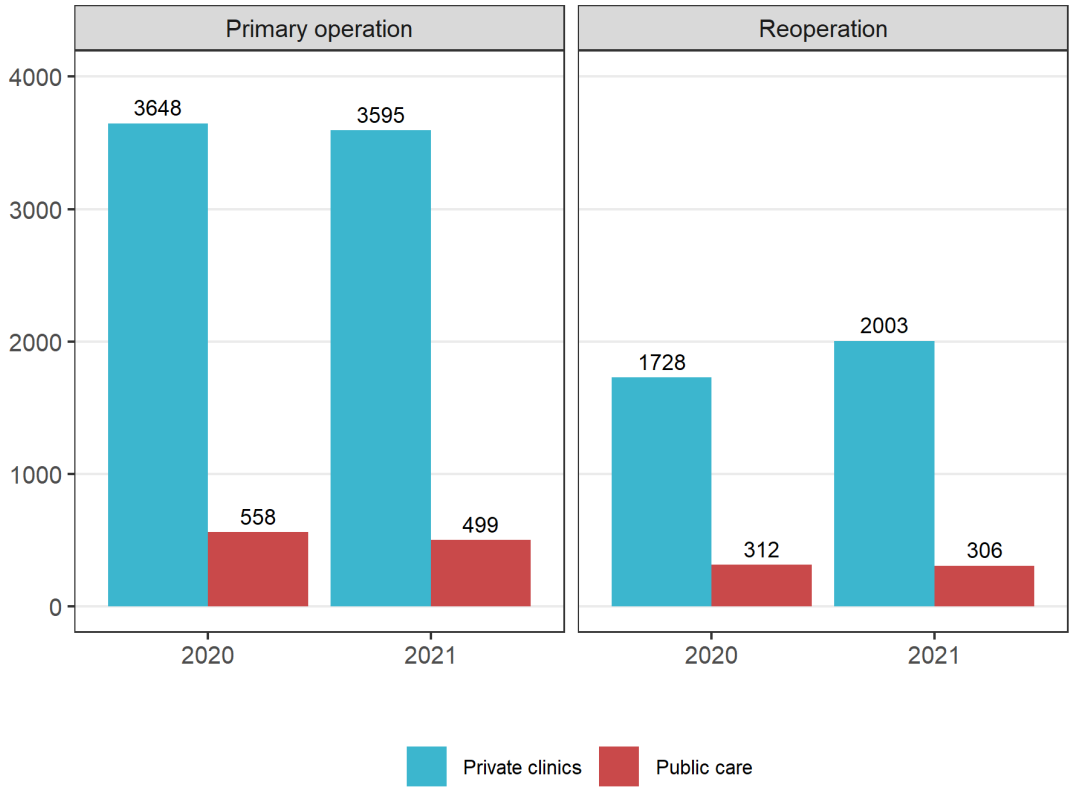



Figure 1. Registered operations in 2020 and 2021 regardless of diagnosis.

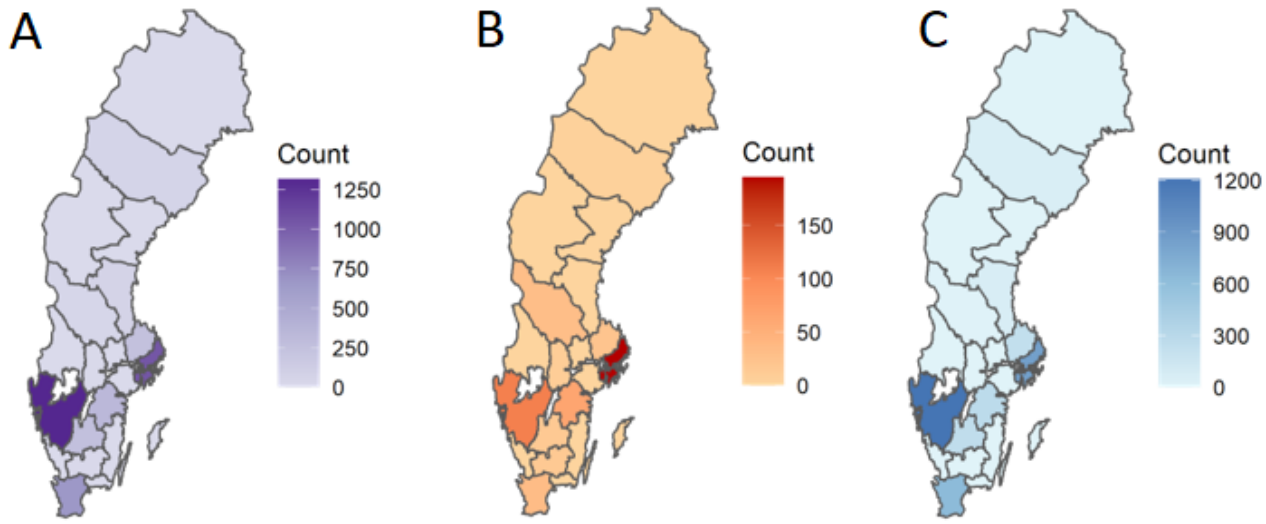



Figure 2. A) Registered primary operations in 2021, all units. B) Registered primary operations in 2021, public care. C) Registered primary operations in 2021, private units.

# Implant-based reconstruction for breast cancer or risk reducing mastectomies

The Covid-19-pandemic has influenced all areas within Swedish healthcare also in 2021. We have therefore chosen, in this annual report, to show the number of implant-based primary operations for breast cancer or risk-reducing mastectomies from 2014-2020 compared with data for 2021. All patients were operated within the framework of the publicly funded healthcare in Sweden. In total 2969 patients that underwent a breast reconstruction with implants have been reported to BRIMP, of which 395 patients were operated in 2021. In region Stockholm and in the Västra Götaland-region most reconstructions were performed last year according to reported data in BRIMP. (Table 2). (Figure 3).

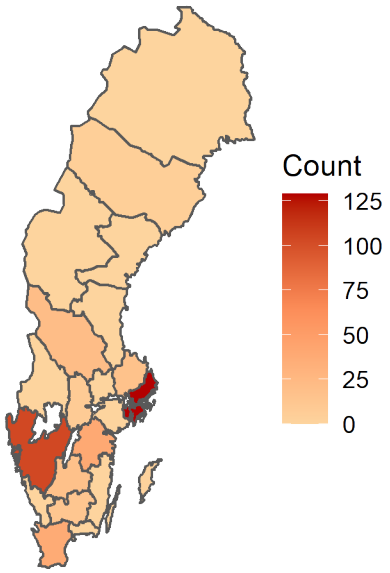



Figure 3. The number of registered reconstructions.

*Choice of implant*

There are no national recommendations or consensus regarding choice of implant make or type of implant in Sweden. Some care providers have advocated the use of smooth implants for this patient group, having in mind increased relative risk for BIA-ALCL when using textured implants. Data in BRIMP from 2014-2020 showed that 89.5% of the reconstructions were carried out with textured implants, mainly from the company Mentor. There has however been a decrease of textured implants for breast reconstructions from 89.5% to 55.4% together with an increase of smooth implants from 6.5% in 2014-2020 to 22% in 2021. (Figure 4.) It is worth to mention however that non-registered surface "unknown" increased from 3.7% to 22.3% during the corresponding comparison. Reconstructions with the products of Motiva were only performed in 1.3% of in total 395 documented cases, why data should be interpreted with a certain caution. The products of Mentor were predominantly used. (Figure 5)

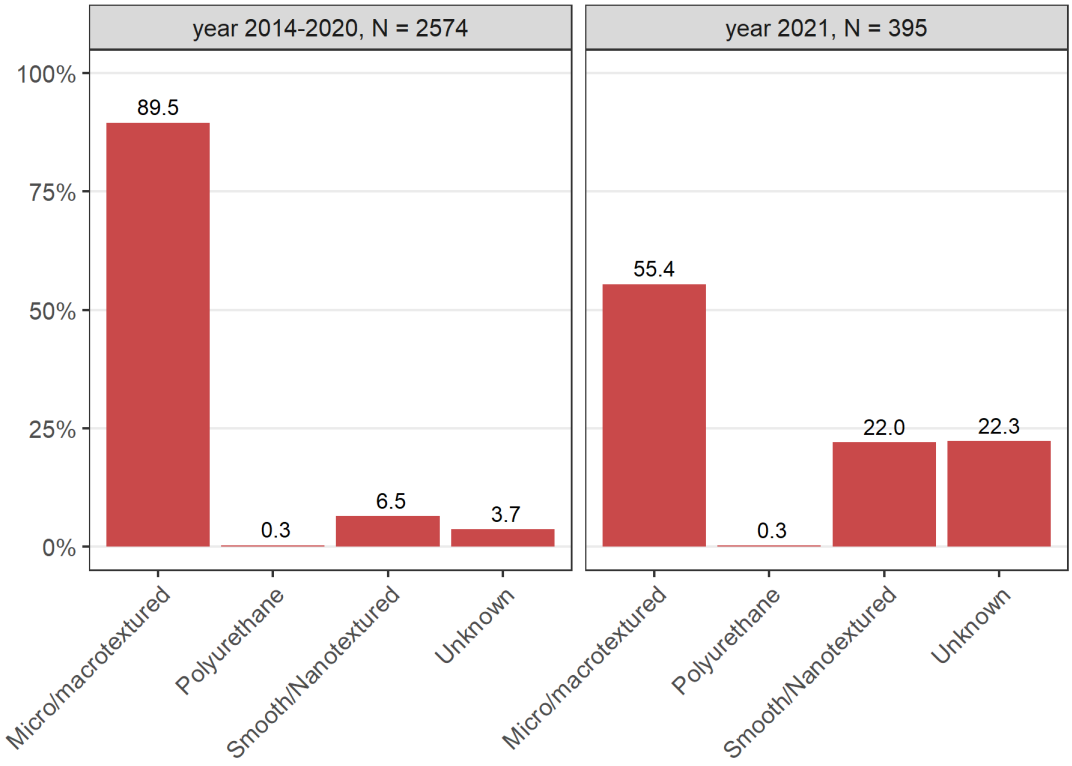



Figure 4. The implant surface for reconstructive primary operations.

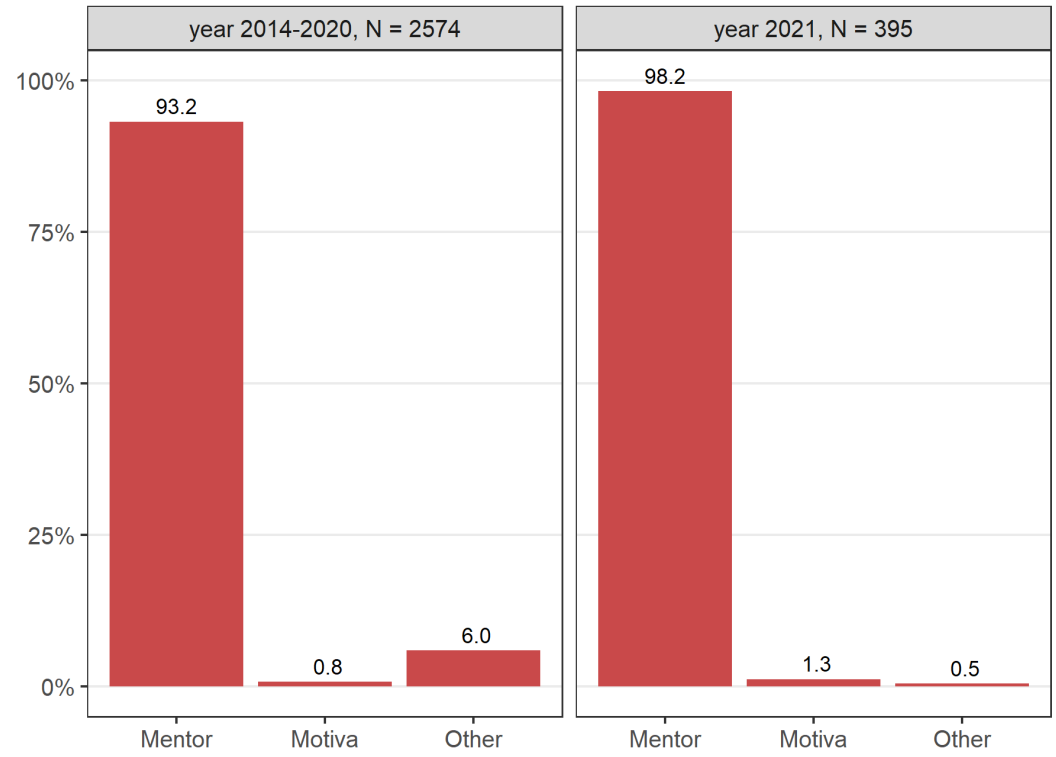



Figure 5. The implant make for reconstructive primary operations.

*Infection prophylaxis*

Per operative prophylactic antibiotics treatment is routine for reconstructive implant-based breast reconstruction. Data in BRIMP shows that 81.3% of the patients were given a prophylactic treatment. We have chosen to show pre- and per operative treatments together as the definitions can be unclear. In general, it can be said that the patients seem to be well-covered with antibiotics before insertion of implants. Intraoperative antibiotics irrigation of the prosthesis cavity or of the prosthesis before insertion was 4.1% and does not correspond to the accepted national care routines in connection with reconstructive operations. Antiseptic irrigations are to date not allowed in the public care. Interestingly, also a relatively large proportion of patients (38.5%) are given a postoperative treatment. (Figure 6.) Transcription of antibiotics and treatment length should be controlled with the medicine registry.

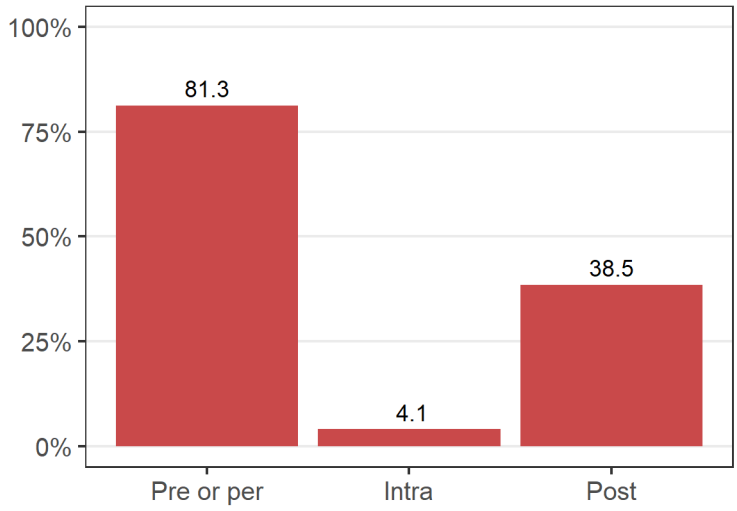
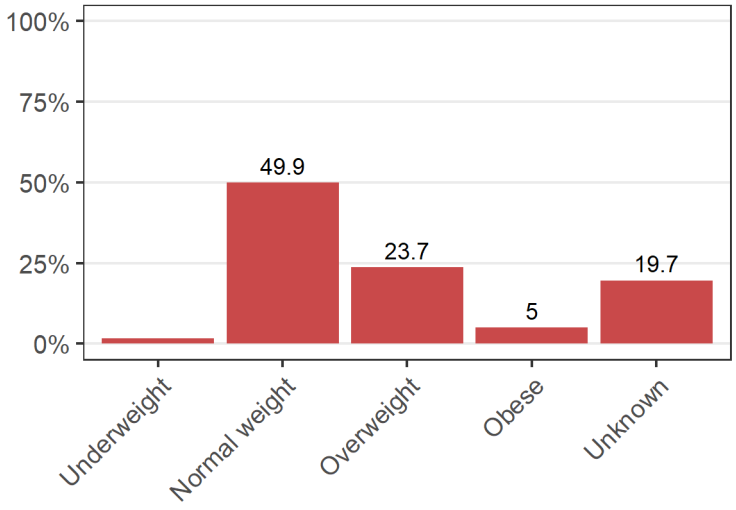



Figure 6. Infection prophylaxis for reconstructive primary operations.

*BMI stratified into weight groups*

This year we have chosen to report BMI in accepted weight groups, but in a fifth of the cases there was no registration of weight and length. It is therefore of importance that the units improve on the reporting of weight and length to BRIMP. Among other things BMI is an important variable that can influence the risk of a reoperation. In summary, BMI corresponding to normal weight is the dominating group in 2021. (Figure 7).

Figure 7. BMI in patients for reconstructive primary operations.



*Surgical approach and implant positioning*

34% of the reconstructions were performed in bi-dual implant position. Earlier years there has been a few questions about the definition of the variable bi-dual position. Information on how the variable should be registered has now been communicated to the colleagues via mail and in webinars. In connection with mastectomy or risk-reducing mastectomy no breast tissue is left in the lower pole of the breast. Implant in bi-dual position means a proximal coverage of the implant with the pectoralis muscle and a distal coverage with breast tissue. It is surprising that this large proportion has been reported to BRIMP. (Table 5.) Targeted efforts in this question have been made to the units concerned. Likewise sub glandular positioning of implant in connection with breast reconstructions has been an unclear variable as no breast tissue remains. In connection with the increase of breast reconstructions in front of the breast muscle one has chosen sub glandular positioning, which is logical. The questionnaire has therefore been updated with a clarifying addition "sub glandular/perpetually" for the same registration that is accounted for in 2022. The most chosen surgical approach in 2020 has as expected been via the old mastectomy scar or in the sub mammary fold. If one looks at the use of net in 2021 compared with the years 2014-2020 there is an increased proportion from 7.5% 2014-2020 to 25% in 2021 in BRIMP, which is an indication of an increased tendency towards hybrid operations in connection with breast reconstructions in the country. The use of fat transplantation in connection with primary insertion of implants in this patient group does not seem to be a first-hand indication. To be noted is that for hybrid procedures answers are missing for a considerable part of the patients. (Table 6.)

*Integration with data from National Quality registry for Breast Cancer*

Since 2021 we fetch data from National Quality registry for Breast Cancer (NKBC) twice per year and integrate it with BRIMPs data layer. National Quality registry for Breast Cancer started in 2008 and contains data on lead times, diagnostics, tumour characteristics, preoperative oncological treatment, breast and axilla surgery including oncoplastic/direct reconstruction, postoperative oncological treatment and follow-up. All NKBC-registrations are indicative of cancer, and most NKBC-registrations lack information on make, surface, implant related symptoms etc., therefore the proportion of missing data increases a lot when the data sets are aggregated. The hope was that NKBCs data would be more similar to what we have in BRIMP and thereby complement BRIMPs data, but when many parameters are missing in NKBC there will be a high proportion of missing/unknown/other for those patients that are only registered in NKBC. (Figure 8.) This leads to an unclear and difficult to interpret outcome, but at the same time illustrates that both registries are needed each in its own right. NKBCs data should therefore be accounted for separately in the future on a whole year basis.

Furthermore, a larger number of cases in several regions when integrating NKBC and BRIMP data is noted, compared with when only BRIMP-data is presented. (Figure 9.) This illustrates well that there are several regions that can increase their registration in BRIMP when it comes to mastectomies after cancer and possible also risk-reducing mastectomies.

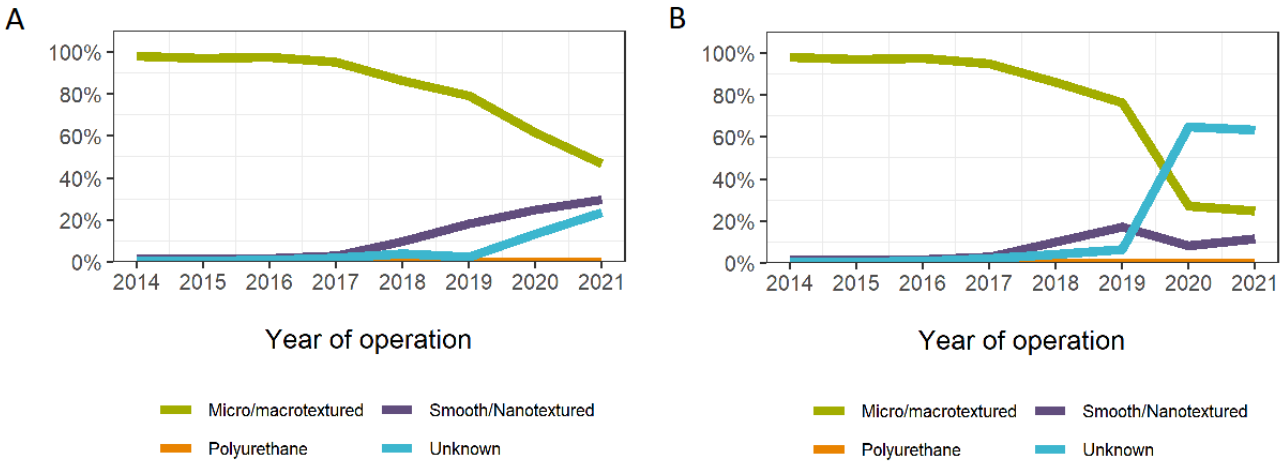



Figure 8. When integrating NKBC-data the proportion unknown grows significantly higher when analysing the surface of the implant (B), which makes it harder to note the clear time trend that can be seen when only BRIMP-data is analysed (A).

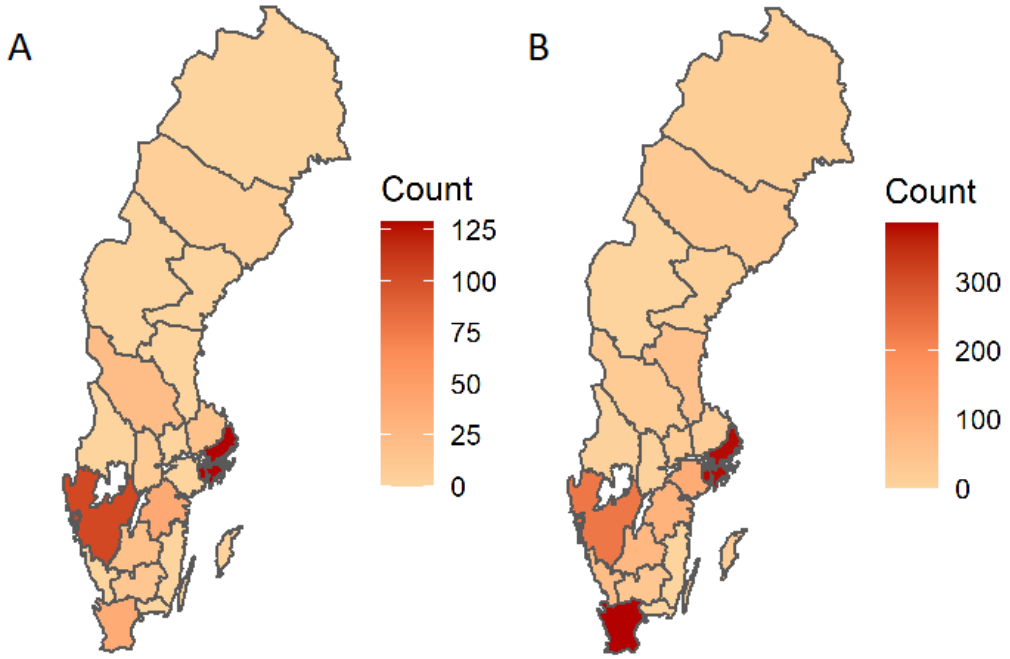



Figure 9. When integrating NKBC-data and BRIMP-data (B) a larger number of cases in above all Skåne is noted, compared with when only BRIMP-data is presented (A). Note the changed colour scale.

**In summary**, data from 435 patients who underwent reconstruction due to a cancer disease or after a risk-reducing mastectomy was reported in 2021, which is an increase with 60% since 2020 when only 273 patients were registered. The reason is probably the increased proportion of implant-based direct reconstructions that are performed after mastectomy due to breast cancer, but also a huge work effort that has been put in by BRIMPs registry coordinator who has aided new units helping them to start registering. After a linkage analysis with data from the National Quality registry for Breast Cancer (NKBC) it became apparent that BRIMP has a very important role to play as NKBC lacks data on the nature of the implant and implant-related operation techniques, symptoms and complications. The patients were primary reconstructed with mainly Mentor's textured implants, but a slight increase of smooth implants has been registered. In the country mainly textured and anatomical implants are used via the mastectomy approach alternatively via the sub mammary fold. Outcome data in BRIMP regarding implant position has given rise to a certain criticism of the comprehensibleness of the different implant positionings in the questionnaires. This has however been updated where prepectoral position, which has grown ever more common, has been added to the questionnaire. Accounting of length and weight has been lacking in this patient category. BMI is a factor that is of importance for reoperation, why we look forward to a decrease of missing data. The proportion of hybrid operations with net has increased by 15% in 2021 compared with earlier report. Fat transplantation in connection with primary operation does not seem to be a routine procedure. Infection prophylaxis is standard in Sweden, but the proportion of patients that are operated with intraoperative antibiotics irrigation of the prosthesis cavity or of the prosthesis before insertion was 4.1% as opposed to more than five times as often for benign conditions. The number is however yet unexpectedly high as it does not correspond to accepted national care routines in connection with reconstructive operations.

## Primary operation for benign breast conditions

Indications for operation with breast implants for benign breast conditions is the larger part and includes:

- Congenital conditions such as aplasia/hypoplasia and tuberous breasts
- Secondary hypoplasias for example after breast feeding, massive weight loss, after having undergone reductionplasty with unwanted hypoplasia of the breasts, status after surgical removal of cystic mastopathy or benign breast tumours
- Breast augmentation during gender dysphoria
- Aesthetic indications

In table 3 production data in BRIMP is accounted for during the years 2014-2020 and in 2021 for benign conditions. In Sweden in total 14 795 patients have been operated with 29 340 implants in 2014-2020. In 2021 1862 patients were given 3699 implants. Compared with the year 2020 there has been a small decrease of the number of reported implants from 3773 to 3699. Table 4 also shows the distribution in different Swedish regions.

*Infection prophylaxis*

The use of antibiotics is standard in connection with primary insertion of implants for benign conditions. Irrigation of the implant cavity or of the implant before insertion is on the contrary not the national standard but existed in 25.7% of the accounted primary operations (figure 10), which is an increase by more than 10% from 23% previous year. Intraoperative irrigation with antibiotics in connection with the primary operation is above all reported from units in region Stockholm, which has become the subject of discussions within doctors' associations.

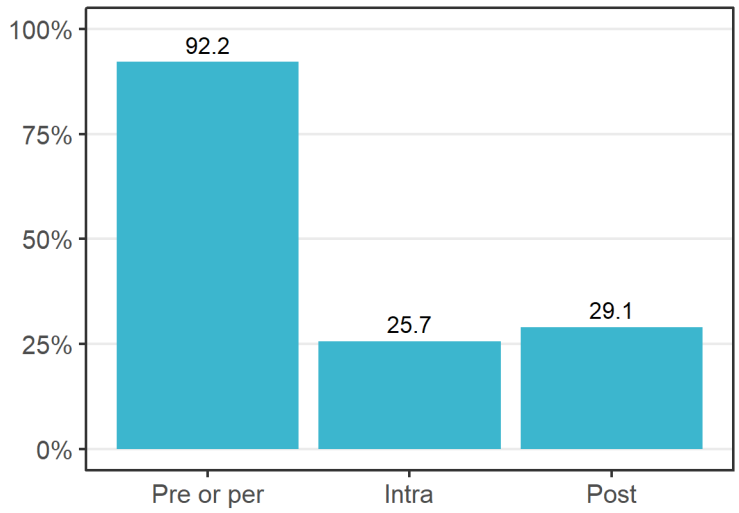



Figure 10. Infection prophylaxis for primary operation of benign conditions.

*BMI in different age groups*

Primary operated patients that are operated due to benign breast conditions are mostly of normal weight (77.7%). Only 1.2% had a BMI of 30 or more, compared with four times as many (5%) in the group with breast cancer or risk-reducing mastectomies. This likely bears witness of the possibility to select harder for benign conditions, since it is well-known that complications increase with heavy overweight. The group with breast cancer or risk-reducing mastectomies had far more cases (19.7%) with unknown BMI, compared with 2.7% for benign conditions.

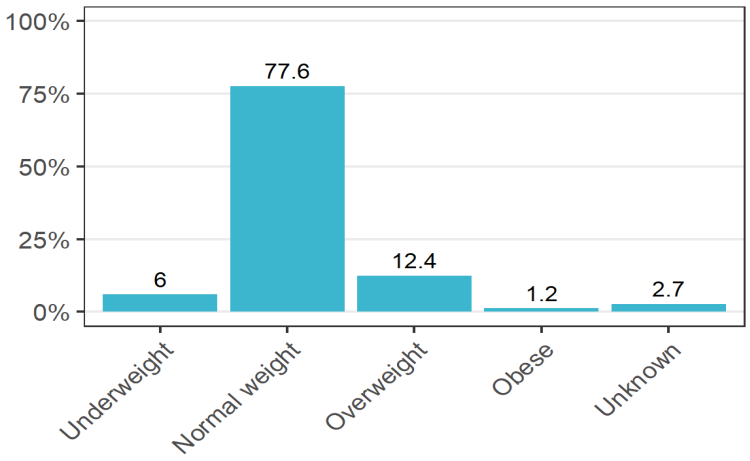



Figure 11. BMI for primary operation of benign conditions.

*Surgical approach, implant positioning and size*
The placement of implants has been more or less unchanged since the start of BRIMP. Most of the colleagues place the breast implant in a bi-dual plane or in a submuscular position. Sub glandular (8.1%) or subfascial (0.6%) placement was chosen consistently by a minority. (Table 6.) The use of net or fat transplantation in connection with primary operation existed in a minority of patients. The most common has been to choose the surgical approach in the sub mammary fold. Only 6.9% of the implants were placed via the axilla. The chosen implant volume was mainly (72%) between 200 and 399 ml in 2021. Volumes over 400 ml was only chosen for 21.2% and over 600 ml for 3.1% of the patients. A discrete tendency to choosing a smaller implant volume in 2021 compared with 2014-2020 was registered in BRIMP. In the future we plan to register exact volumes in order to be able to see mean volume over time and relate it to BMI, outcome etc.

*In summary*, data from 3595 implants, in mainly normal weight patients, having undergone a primary operation for benign breast conditions have been registered in 2021. The products of Mentor and Motiva are clearly dominating the market today. Irrigation of the implant cavity or of the implant before insertion existed in 25.7% of the accounted primary operations, which is an increase of more than 10% compared with the previous year. Most of the patients received perioperative antibiotics prophylaxis. The implant position is mostly bi-dual/dual plane or submuscular. An implant size of up to 399 ml were used in most cases. Only 3.1% of the patients chose a volume larger than 600 ml. Hybrid operations with net or fat are in a minority in BRIMPs database.

## Production data regarding reoperation regardless of date for primary operation and indication

To note is that we only look at reasons for the first reoperation, it is thus only reasons that were registered for the first reoperation that are accounted for. In Sweden in total 14 063 implants have been revised since the start of BRIMP in 2014. Data is presented regardless of date for primary operation and indication.
In 2021 in total 2309 revisions were registered, which corresponds to an increase of 15% from 2029 revisions in 2020. As in previous years reoperations with other makes than Mentor and Motiva dominated. In some of these cases it may have been hard to assess the implant's make which can be seen in figure 12. There it can also be seen that round implants were the most common. As in earlier annual reports patient-reported factors dominated, like desired change of volume (47%) and form (44%) during reoperation. New in 2021 was however an increase of 50% of worry for the implant (from 19.8 to 29.2%) together with an even greater increase (from 20.1 to 34.8%) of desired permanent removal of implant. Implant rupture was observed in 12.0% of 11 754 revised implants 2014-2020 and in 11.6% in 2021. (Figure 13.) Rotation of implant was noted in 3.6% of the cases in 2021 compared with 4.6% 2014-2020. Implant dislocation was confirmed in 8.1% of the cases in 2014-2020 and in 4.9% of the revisions in 2021. This variable has not been clear for all, why a newly performed update of the parameter dislocation has been done in questionnaires, but it is not accounted for in the annual report of 2021. Data concerning dislocation of implants in connection with smooth implants will become important to highlight in coming annual reports. The registration of the surface character of Motiva's implants leaves some uncertainty in the interpretation.

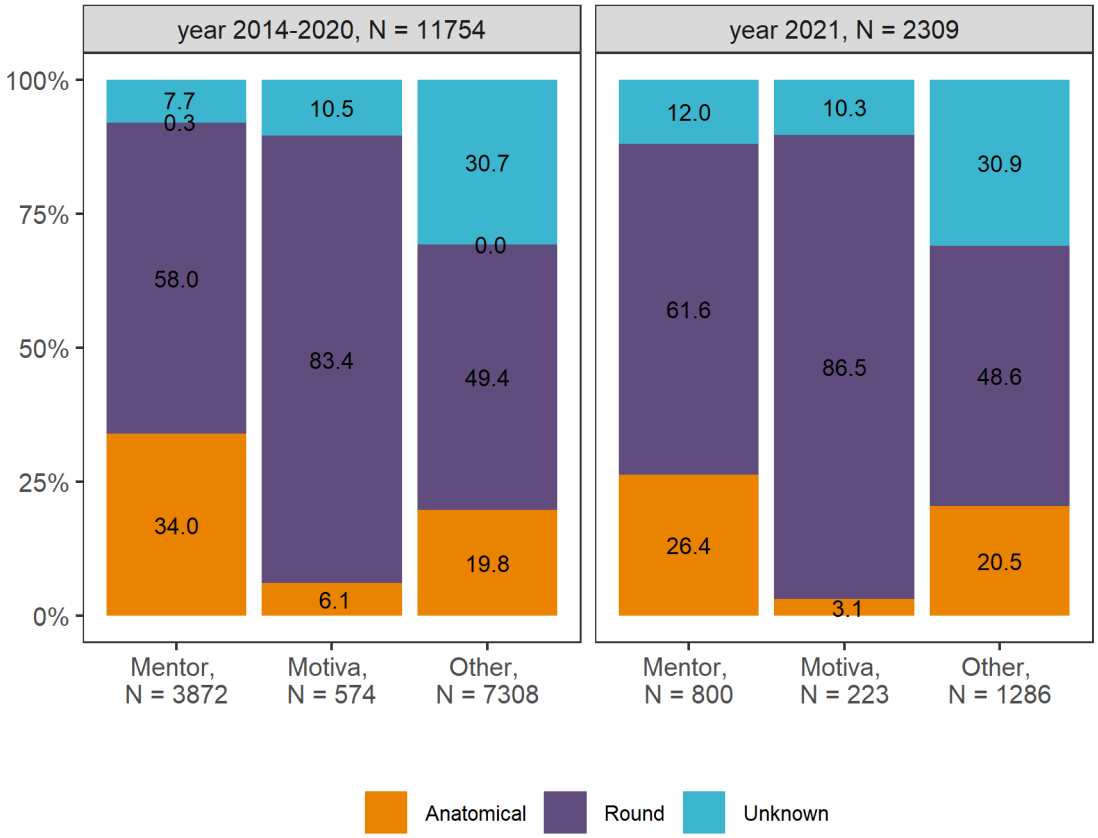



Figure 12. Distribution of form for different implant producers for reoperation of implants in 2014-2020 and in 2021.

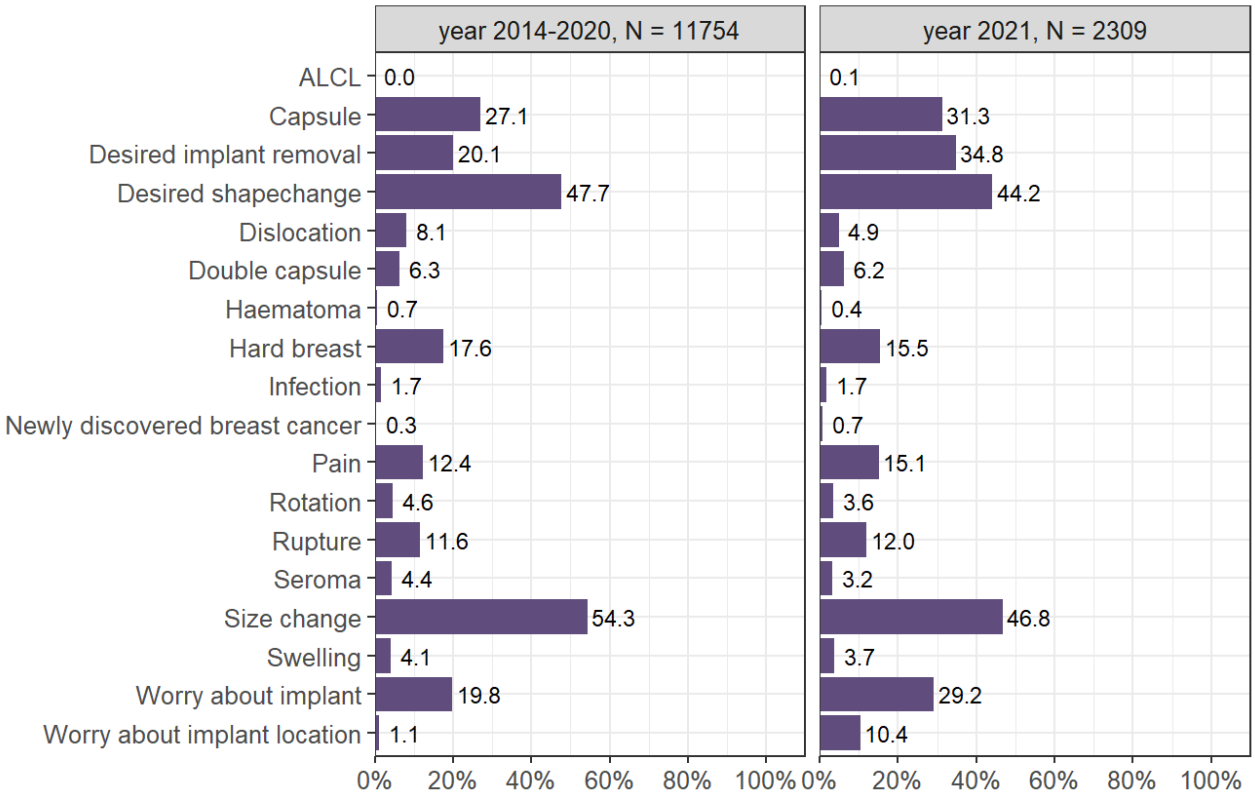



Figure 13. Reported complications for reoperation of implants in 2014-2020 and in 2021.

*Permanent removal of implants*

Permanent removal of implants has increased successively over the years but reached a new record level in 2021 with an almost doubling from previous year. (Figure 14.) The reasons for permanent removal are shown in figure 15. In total 1680 patients underwent reoperation for explantation/permanent removal of implants in 2014-2020. In 2021, this number was 755 patients. The main reason has been the worry for the implant's impact on the body. Many patients stated worry for negative effects due to the information on Breast Implant Illness and the breast implant-related lymphoma disease in the breast capsule, BIA-ALCL, in social media and therefore sought after removal of their implants. Painful capsule formations have long been a dominant reason for permanent removal of implants but worry for long-term effects in the body has now become dominating. It can also be noted that 17.9% of the patients in 2014-2020 and 15.8% of the patients in 2021 had a ruptured implant at the time of the reoperation. If implant rupture was diagnosed preoperatively cannot be seen from the information in BRIMP.

It is clear that worry for both the implant and its positioning has increased in the group that has undergone a permanent removal of implant, so called explantation. (Figure 16.) In the group worry for the implant textured implants were most common (figure 17), but neither Mentor nor Motiva dominated in the group (figure 18).

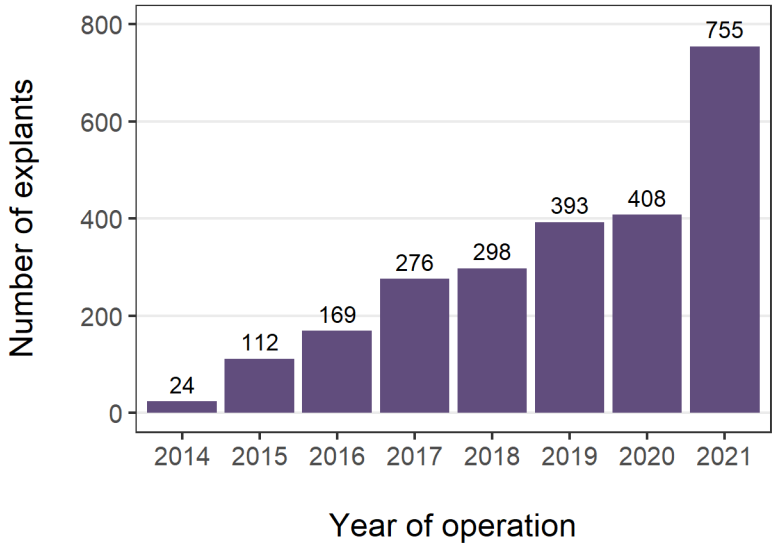



Figure 14. Permanent removals per year.

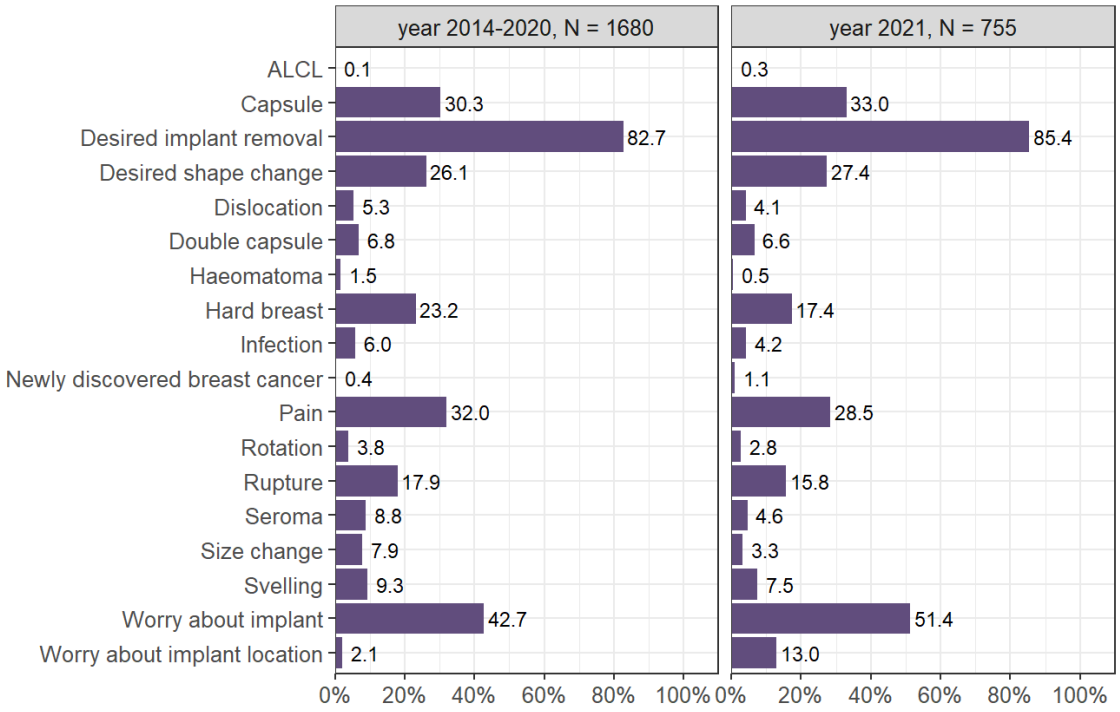



Figure 15. Reported reasons for permanent removal of implants in 2014-2020 and in 2021.

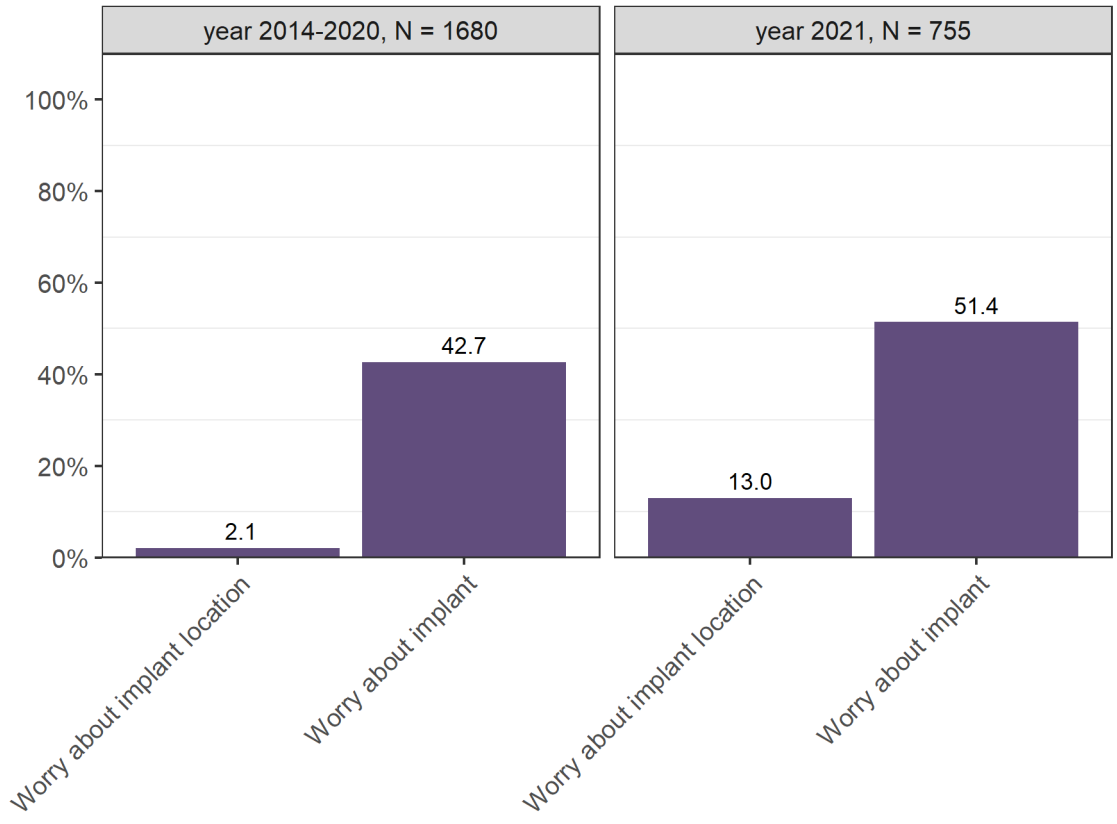



Figure 16. Number of patients with worry for permanent removal of implant.

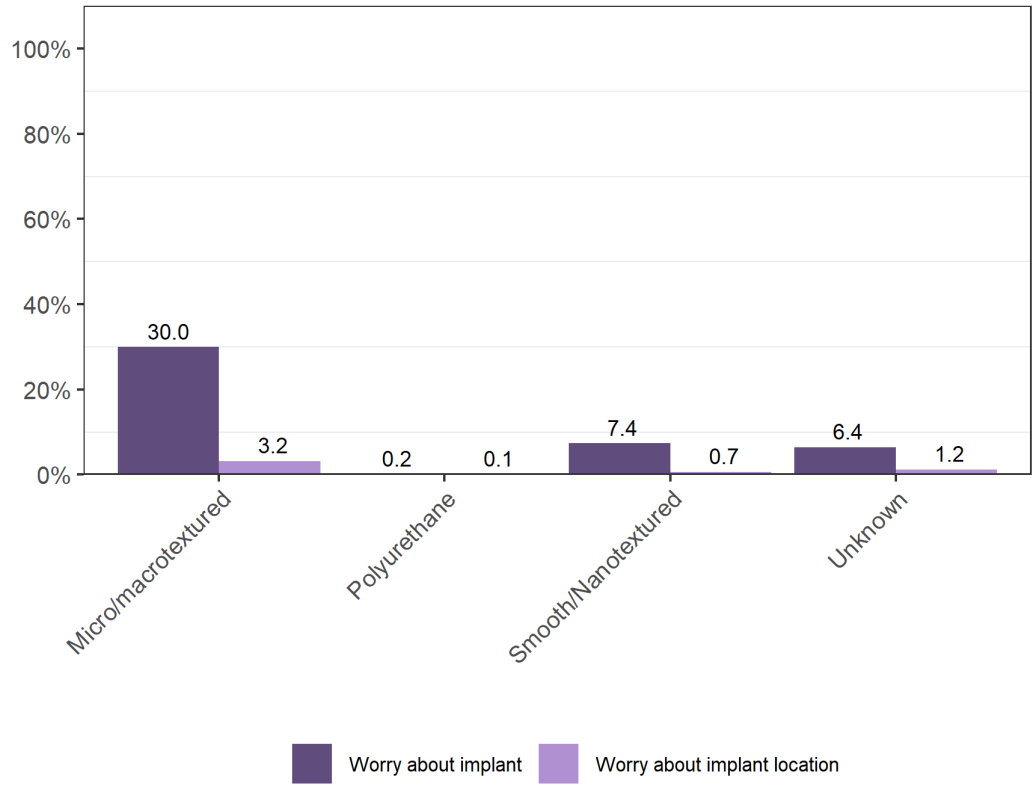



Figure 17. The implant surface for permanent removal of implant.

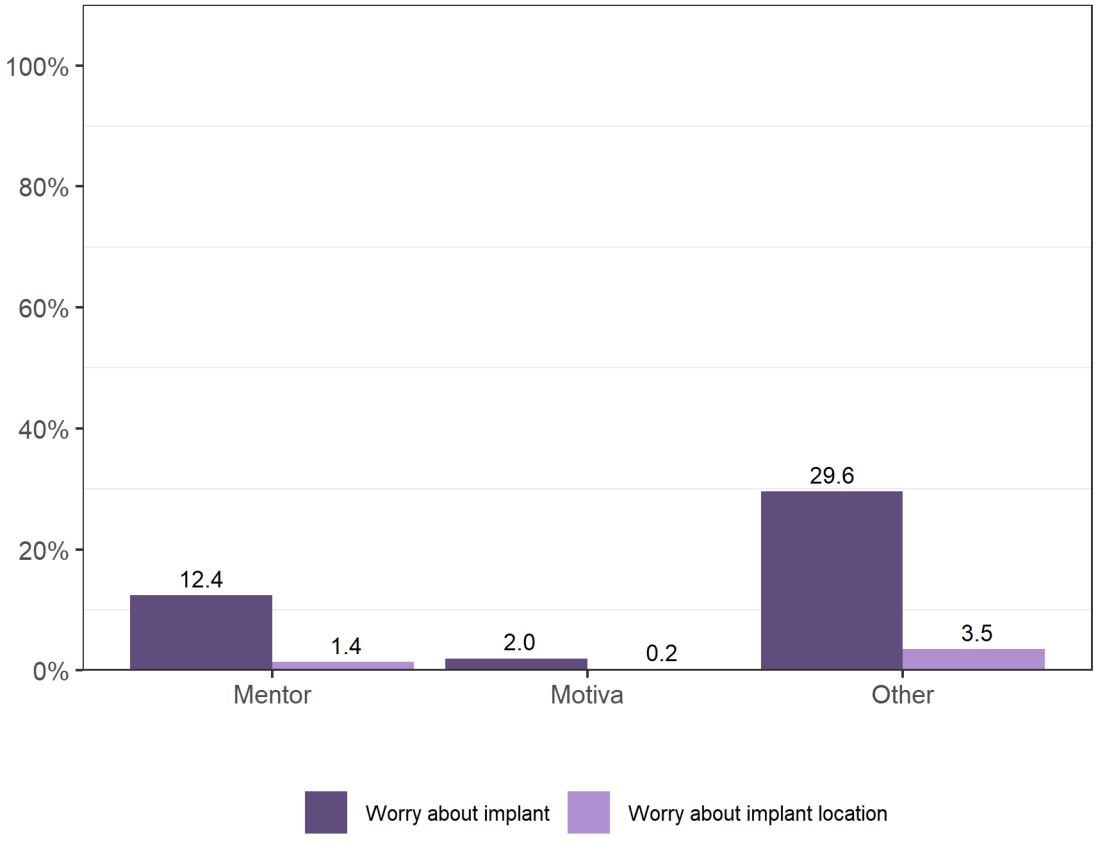



Figure 18. The implant make for permanent removal of implant.

*Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)*

Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) is a rare T-cell lymphoma that can arise a long time after the insertion of breast implants. There are only eight known cases of BIA-ALCL in Sweden, of which three are registered in BRIMP. The discrepancy highlights the importance of a high completeness rate in BRIMP in the future. In the first registry extraction in 2021 there was however nine cases of BIA-ALCL, which is most conspicuous. Care providers for the current registrations were contacted immediately to confirm the cases, but it could be shown that all registrations of BIA-ALCL in 2021 were faulty. Each registrator was called upon to correct the registration whereupon only two faulty cases remained in the summer of 2022. Both care providers for these cases have confirmed in writing that these are faulty registrations but have not yet corrected them. We have once again asked them to carry out a correct registration. Faulty registrations thus explain the outcome regarding BIA-ALCL in figures 13 and 15.

*Breast Implant Illness*

Breast Implant Illness is a complex of symptoms where muscular and joint pain, headache and fatigue are some of the symptoms some women have related to silicon implants. According to FDA, the American counterpart to the Swedish Medical Products Agency, there are at present no scientific evidence that breast implants cause connective tissue diseases and there are today no studies that safely prove an association between breast implants and these symptoms. The research in the area is however intense and within BRIMP we have added the variable Symptom complex Breast Implant Illness as selectable indication of operation on the questionnaire for reoperation. In 2021, 88 cases of the symptom complex BII were registered preoperatively. Whether the symptoms have been affected by the operation is at present not possible to answer with the help of BRIMP.

*What is done with the surrounding capsule upon removal of implant?*

Prior to 2020 it was registered only if capsulotomy had been performed or not. Since 2020 more detailed information on the way the capsule is taken care of for reoperation is registered with the following variables: pocket tightening, partial capsule removal, total capsule removal and en bloc. En bloc-resection of the capsule around the implant means a resection of implant and intact surrounding connective tissue capsule in one piece and was registered in 21.3% of the cases of permanently removed implants in 2020. It increased to 34.2% in 2021. Lege artis for the curative treatment of BIA-ALCL is an en bloc-resection, but as has been described above there are historically eight known cases of BIA-ALCL in Sweden. There is however no international or Swedish standard for this type of treatment for benign conditions why 34.2% en bloc-resections is a relatively large proportion and must be interpreted as self-selected from the patient's perspective. There is today no evidence-based medical indication for en bloc-resection for only worry or symptoms corresponding to Breast Implant Illness (BII). It is also connected to risks like for example pneumothorax. When removing the implant permanently during capsule formation 59.1% have been taken care of with a total capsulotomy and 13.9% with a partial resection. (Figure 19.)

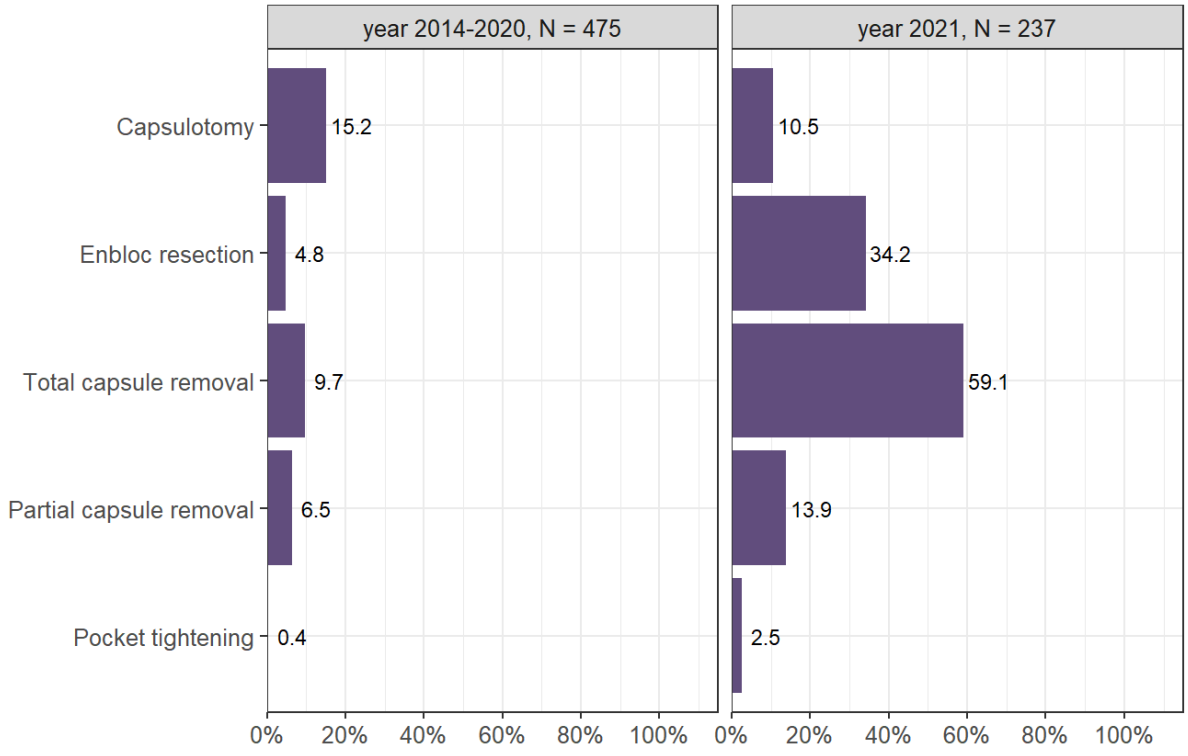



Figure 19. Measures of capsule for permanent removal of implants in 2014-2020 and in 2021.

*Capsule handling during reoperation and new insertion of implant*

An ever more increasing capsule handling has been noted over the years. In some cases, the patient needs to undergo several operations if the patient is hit by an infection in connection with the primary operation. In order to heal an infection in the prosthesis cavity, an implant removal is needed. A new implant can be inserted after a couple of months. In figure 20 it is shown how the rest of the capsule is handled during the reoperation and new insertion of an implant. In 2021, only one case of en bloc-resection was registered in this group (N = 17), which must be deemed acceptable. This bears witness of a faulty understanding when registering. The definition of the variable has been clarified in 2021 for registering units and we will continue to clarify this in newsletters and webinars to decrease faulty data in BRIMP.

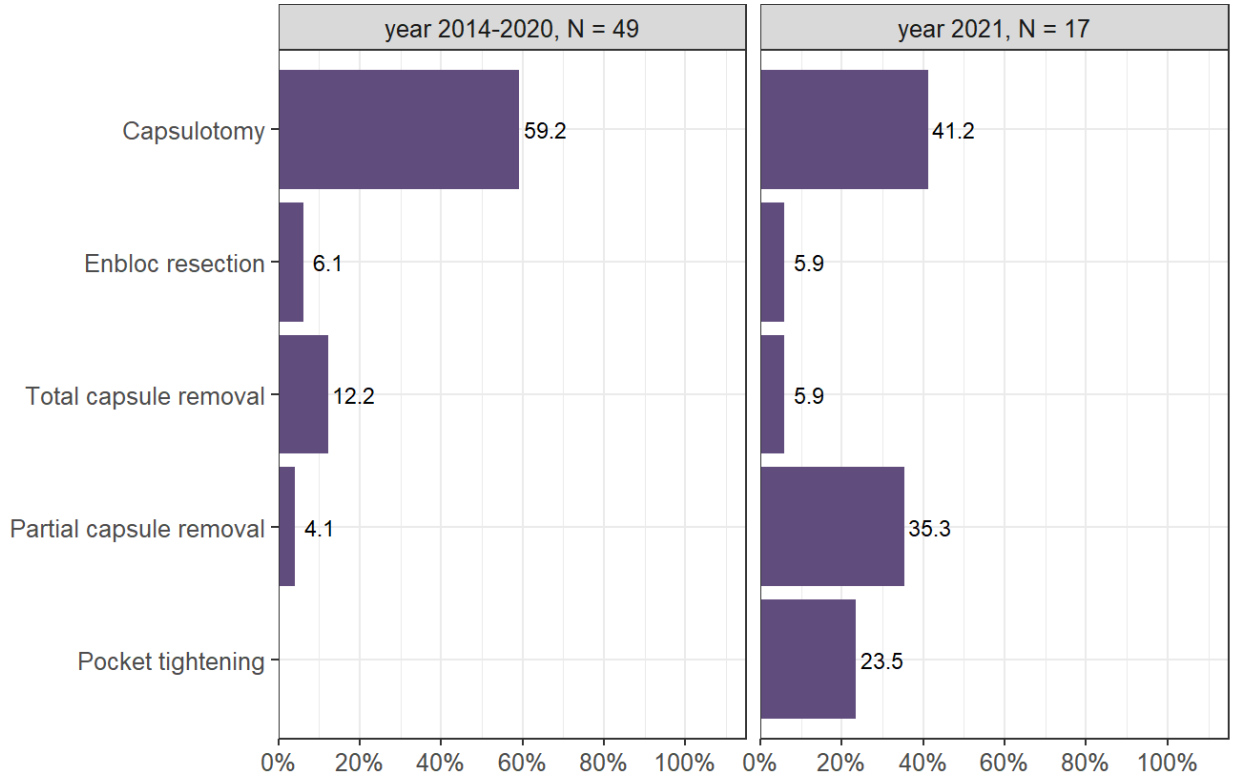



Figure 20. Measures for capsule for permanent removal of implants and new insertion, in 2014-2020 and in 2021.

***In summary***, data in BRIMP shows that a documented reoperation is associated to 14 063 implants regardless of diagnosis and time for primary operation. Patients reported that what motivated the reoperation was desires of form and volume change. Capsule formation was reported in 31.3% of the cases where 15.5% reported a hard chest and 15.1% pain. A ruptured implant was confirmed for 11.6% of the 11 754 revised implants in 2014-2020 and for 12.0% of 2309 revised implants in 2021, which must be deemed a constant frequency. A faulty positioning of implants was confirmed in 8.1% of the cases 2014-2020 with a possible tendency towards decrease from 5.7% in 2020 to 4.9% in 2021. Permanent implant removal has increased steadily over these current eight years. In total, 1680 patients underwent reoperation for permanent removal of implants 2014-2020. In 2020 this number was 408 and in 2021 755 cases were registered. The main reason has been worry for the implant's impact on the body. Many patients stated worry for negative effects due to the information in social media on Breast Implant Illness and the breast implant-related lymphoma disease in the breast capsule, BIA-ALCL. A few faulty registrations of BIA-ALCL are noticeable and reporting units need clearer information about the variable. The questionnaire has also been made clearer for the registration of BIA-ALCL as a separate entity.

# Risk of a new operation regardless of indication

The accounting pertains to all patients in BRIMP with a primary operation in 2014-2020 and the outcome studied is time to first reoperation for each breast respectively. The risk of a first reoperation is calculated on breast level and not on patient level and is graphically illustrated according to Kaplan-Meier. Tests of significance of the difference between groups are made with the log rank-test where $p < 0.05$ means significance. Further reoperations of the same breast are not part of the computations below.

### Short-term risk of reoperation within 60 days and 1 year

The short-term general risk regardless of reason of having to undergo a reoperation within 60 days is very low even if the groups differ with a higher risk for the group with cancer and risk-reducing mastectomies ($p < 0.001$). (Figure 21.) The figure shows that the risk increases over time and is 4.1% at six months and increases to 12.3% at observational time one year in the breast reconstruction cohort, encompassing breast reconstructions after cancer and risk-reducing mastectomies. The difference between the patient groups is statistically significant ($p < 0.001$). (Figure 23.)

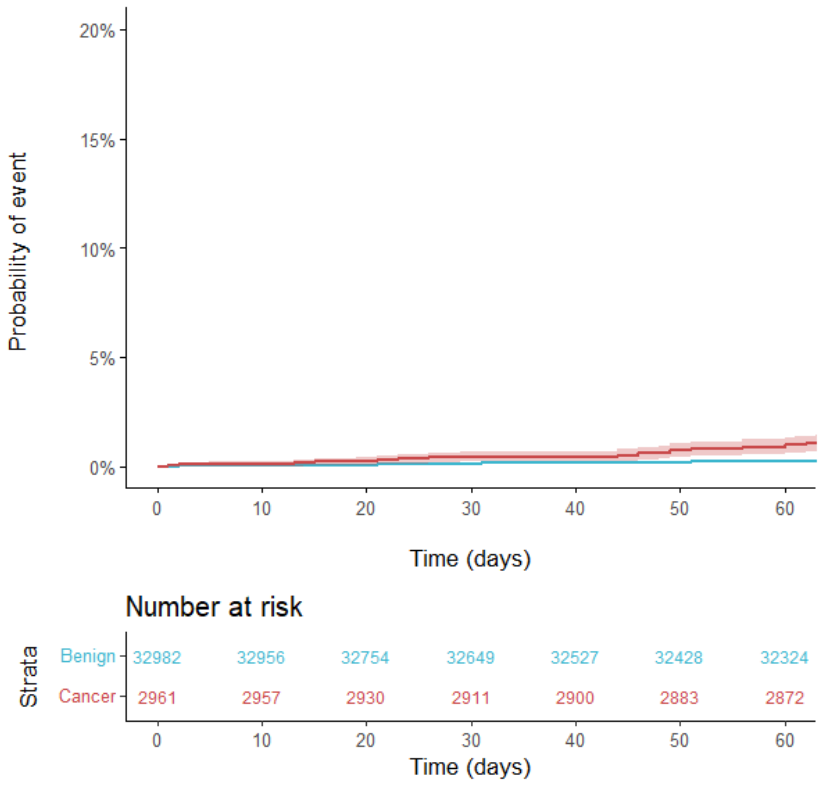



Figure 21. Risk for Reoperation within 60 Days.

### Long-term risk for reoperation within 6 years

In the "reconstruction after breast cancer" and "risk-reducing mastectomies" cohort the general risk for a revision operation is significantly higher (26%) compared with breast augmentations for benign conditions (6.8%). Patients with breast reconstructions show a relatively constant risk profile for reoperation during the time two to six years after the primary operation. One known confounding factor is radiative treatment that increases the risk for reoperation substantially in the cancer group during the observational time. BRIMP's data confirm the clinical experience. (Figure 23.) When analysing the importance of radiative treatment, it became clear that radiation-treated reconstruction patients have a risk of 100% to undergo a revision within six years compared with 22.2% for non-radiated patients. The difference is significant ($p < 0.001$). (Figure 22.)

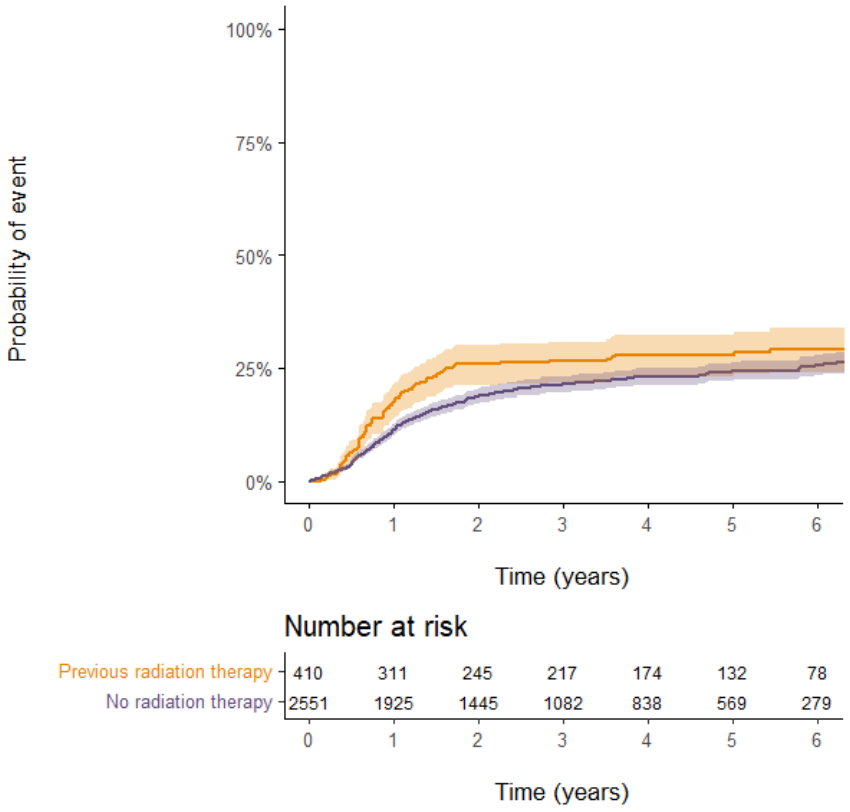



Figure 22. Risk for Reoperation within Six Years for Reconstructive Patients, Divided into Radiation-treated and Non-radiation-treated Patients.

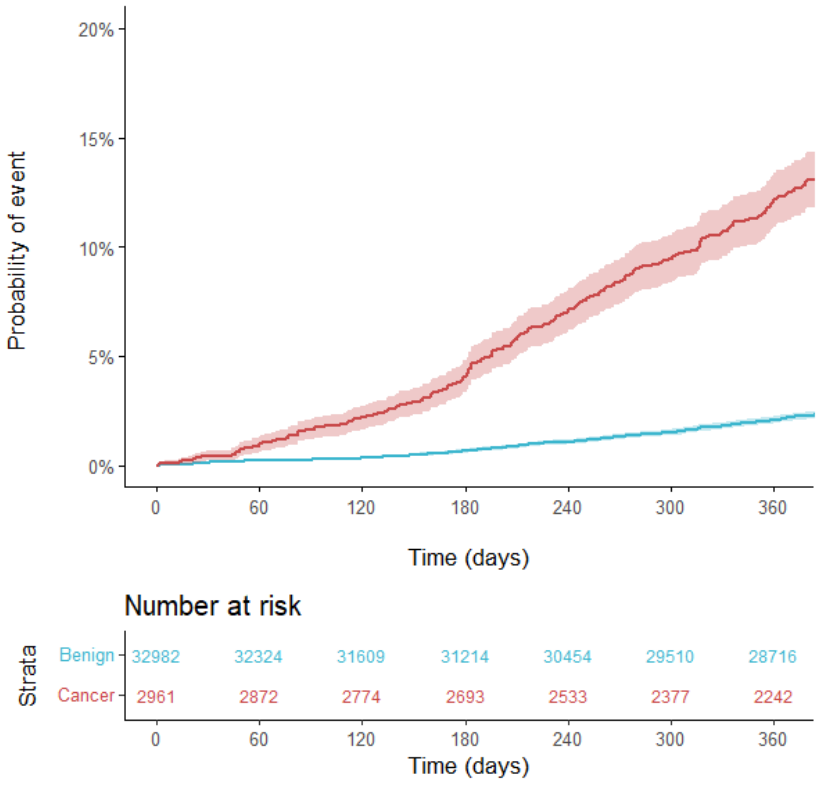



Figure 23. Risk for Reoperation within 365 Days.

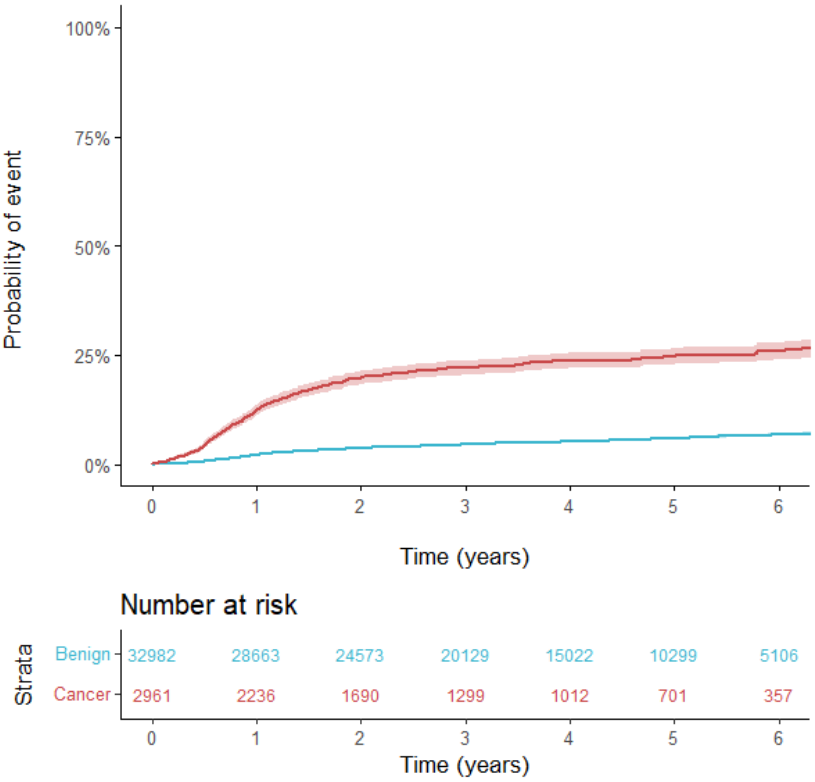



Figure 24. Risk for Reoperation within Six Years.

Table 1. Risk for Reoperation.

| Risk för reoperation i % | Benigna tillstånd | Rekonstruktioner |
|---|---|---|
| 6månader | 0,7% | 4,5% |
| 1 år | 2,2% | 12,3% |
| 6 år | 6,8% | 26% |

## Trends for implant choice regardless of indication 2014-2021

A gradual increase of smooth implants has been noted after the WHO in 2016 defined BIA-ALCL to be an own disease entity. The diagnosis has mainly been related to macro-textured implants from Allergan, which are no longer available on the Swedish market. Polyurethane implants comprise only a small part of the Swedish market. For newly inserted implants the group micro/macro-textured implants thus mainly comprise micro-textured implants nowadays. To be noted is also that Motiva's products, that are called nano-textured, are registered in BRIMP as smooth implants until a new agreement on different implant surfaces as EU-standard is available. At the same time there has been a debate around a potentially increased risk for reoperation of smooth implants due to malpositioning, which has led some surgeons to revert to textured implants. We have therefore chosen to illustrate the use of implants with different surfaces over time in private care (figure 25a) and public care (figure 25b) respectively and for all primary operations (figure 25c) and reoperations (figure 25d) in 2014-2020. The combined picture shows that there is a successive increase of smooth implants in public care together with a relative decrease of textured implants. This trend has been noted during several years in the private care but seems to have been broken in 2021 according to BRIMP-data when the lines once again cross each other.

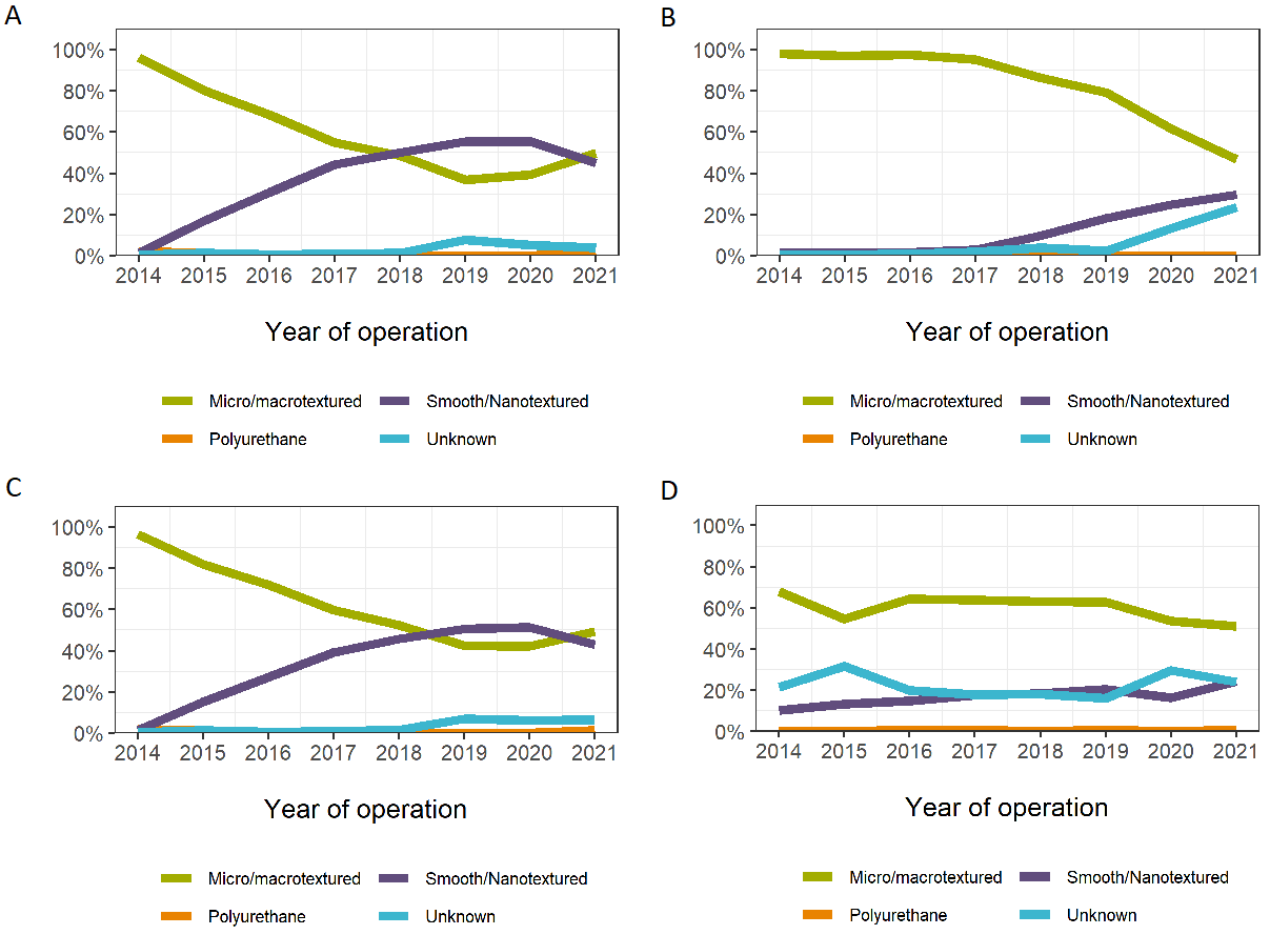
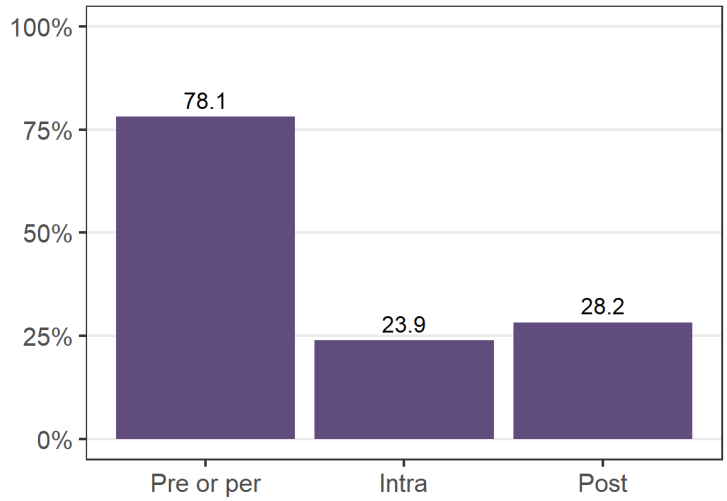



Figure 25. Surface for Reoperation A) Private Units B) Public Units C) Primary Operations D) Reoperations.

# The prospective cohort

*The cohort*

Ever since the start of BRIMP in 2014 a unique cohort has been generated consisting of patients with both a registered primary operation and a reoperation. At present this cohort comprises 2425 breasts in 1498 patients regardless of indication and year of operation. This cohort will grow successively and will in the future be an important material for several questions where data has been gathered prospectively.




. Figure 26. Use of Antibiotics for Reoperation.

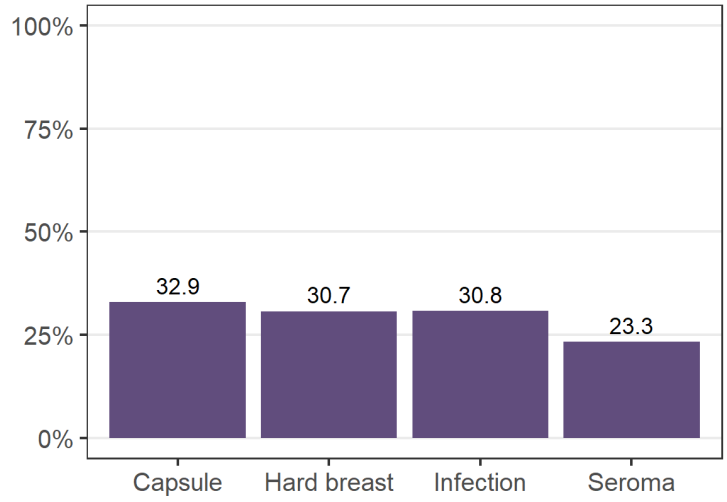



Figure 27. Use of Intraoperative Antibiotics for Complications.

*Intraoperative antibiotics use – an initial analysis*

On the basis that the use of intraoperative antibiotics varies heavily we have chosen to study the prevalence of intraoperative antibiotics use (irrigation of implants in sterile package or implant pocket with antibiotics) in the cohort of prospectively gathered data. It could be noted that intraoperative antibiotics was used in 23.9% of the reoperation cases. (Figure 26.) The use was however more than 30% for the indications Confirmed Capsule, Infection and Hard Breast. (Figure 27.) On the other hand, when one analyses antibiotic use in primary operations in patients that have been reoperated the antibiotics use is only 14.8% (Figure 28.): For those reoperated for Infection the use of intraoperative antibiotics for the primary operation was only 5.9%, while the corresponding number for

reoperation for Capsule (23.8%) and Hard Breast (21.3%) (figure 29) was closer to the mean use for reoperation. (Figure 26.) Since this cohort is a mix of indications and of limited size the results must be interpreted with caution. We foresee that this cohort will be of great importance in the future, as patients with both a registered primary operation and reoperation will provide prospectively gathered data for valuable analyses.

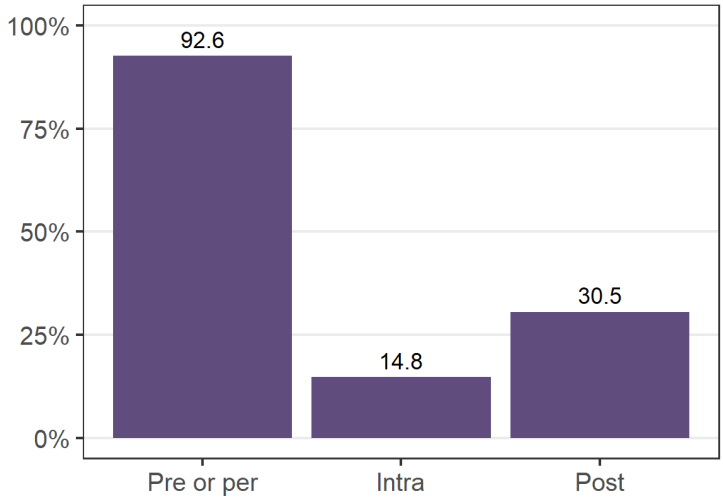



Figure 28. Use of Antibiotics for Primary Operation in Patients Who have been Reoperated.

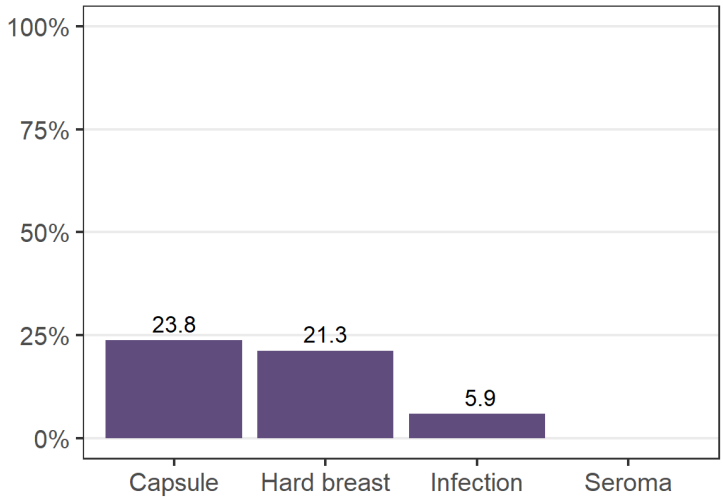



Figure 29. Use of Intraoperative Antibiotics for Primary Operations in Patients Who have been Reoperated with Complications.

# TABLES

**Table 2. Registered Primary Operations.**

| Region | Number of implants, year 2014-2020 | Number of implants, year 2021 | Number of patients, year 2014-2020 | Number of patients, year 2021 |
|---|---|---|---|---|
| **Dalarna** | 292 | 39 | 192 | 25 |
| **Gotland** | 0 | 3 | 0 | 3 |
| **Gävleborg** | 777 | 66 | 389 | 33 |
| **Jönköping** | 1455 | 267 | 742 | 140 |
| **Kalmar** | 542 | 0 | 300 | 0 |
| **Kronoberg** | 57 | 15 | 51 | 14 |
| **Skåne** | 6419 | 669 | 3342 | 340 |
| **Stockholm** | 11108 | 1049 | 5740 | 547 |
| **Uppsala** | 2159 | 256 | 1125 | 130 |
| **Västerbotten** | 668 | 62 | 346 | 32 |
| **Västmanland** | 11 | 0 | 9 | 0 |
| **Västra Götaland** | 8619 | 1317 | 4381 | 680 |
| **Örebro** | 190 | 10 | 135 | 7 |
| **Östergötland** | 1393 | 341 | 742 | 176 |
| **Total Sweden** | 33690 | 4094 | 17494 | 2127 |

**Table 3. Registered Primary Operations, Benign Indication.**

| Region | Number of implants, year 2014–2020 | Number of implants, year 2021 | Number of patients, year 2014–2020 | Number of patients, year 2021 |
|---|---|---|---|---|
| **Dalarna** | 133 | 18 | 71 | 10 |
| **Gotland** | 0 | 1 | 0 | 1 |
| **Gävleborg** | 777 | 66 | 389 | 33 |
| **Jönköping** | 1443 | 249 | 732 | 125 |
| **Kalmar** | 371 | 0 | 188 | 0 |
| **Kronoberg** | 1 | 2 | 1 | 2 |
| **Skåne** | 5891 | 631 | 2966 | 316 |
| **Stockholm** | 9390 | 920 | 4736 | 466 |
| **Uppsala** | 1957 | 239 | 994 | 120 |
| **Västerbotten** | 630 | 57 | 316 | 29 |
| **Västmanland** | 1 | 0 | 1 | 0 |
| **Västra Götaland** | 7614 | 1213 | 3822 | 608 |
| **Örebro** | 55 | 2 | 34 | 1 |
| **Östergötland** | 1077 | 301 | 545 | 151 |
| **Total Sweden** | 29340 | 3699 | 14795 | 1862 |

**Table 4. Registered Primary Operations, Indication Cancer.**

| Region | Number of implants, year 2014–2020 | Number of implants, year 2021 | Number of patients, year 2014–2020 | Number of patients, year 2021 |
|---|---|---|---|---|
| **Dalarna** | 157 | 21 | 119 | 15 |
| **Gotland** | 0 | 2 | 0 | 2 |
| **Gävleborg** | 0 | 0 | 0 | 0 |
| **Jönköping** | 12 | 18 | 10 | 15 |
| **Kalmar** | 79 | 0 | 66 | 0 |
| **Kronoberg** | 56 | 13 | 50 | 12 |
| **Skåne** | 476 | 38 | 350 | 24 |
| **Stockholm** | 894 | 129 | 585 | 81 |
| **Uppsala** | 202 | 17 | 131 | 10 |
| **Västerbotten** | 38 | 5 | 30 | 3 |
| **Västmanland** | 10 | 0 | 8 | 0 |
| **Västra Götaland** | 219 | 104 | 160 | 72 |
| **Örebro** | 135 | 8 | 101 | 6 |
| **Östergötland** | 296 | 40 | 185 | 25 |
| **Total Sweden** | 2574 | 395 | 1795 | 265 |

Table 5. Intraoperative Techniques, Primary Operations, Benign Indication.

| Variable | Outcome | Proportion year 2014-2020 (%) | Proportion year 2021 (%) |
|---|---|---|---|
| **Fat graft** | Yes | 0.4 | 0.1 |
| **Fat graft** | No | 54.0 | 89.1 |
| **Fat graft** | Unknown | 45.6 | 10.8 |
| **Incision** | Axillary | 11.6 | 6.9 |
| **Incision** | Mastectomy scar | 0.6 | 0.1 |
| **Incision** | Mastopexy with augmentation | 3.5 | 8.6 |
| **Incision** | Periareolar | 0.5 | 0.2 |
| **Incision** | Submammary | 80.2 | 81.0 |
| **Incision** | Unknown | 3.6 | 3.1 |
| **Mesh** | Yes | 0.1 | 0.5 |
| **Mesh** | No | 39.3 | 84.3 |
| **Mesh** | Unknown | 60.7 | 15.2 |
| **Position** | Dual plane | 56.9 | 58.5 |
| **Position** | Subfascial | 0.7 | 0.6 |
| **Position** | Subglandular | 5.4 | 8.1 |
| **Position** | Submuscular | 35.2 | 29.7 |
| **Position** | Unknown | 1.8 | 3.2 |
| **Previously operated due to infection** | Yes | 0.2 | 0.2 |
| **Previously operated due to infection** | No | 89.2 | 90.3 |
| **Previously operated due to infection** | Unknown | 10.6 | 9.6 |
| **Previously operated due to mastopexy/reduction** | Yes | 3.1 | 3.4 |
| **Previously operated due to mastopexy/reduction** | No | 86.4 | 87.0 |
| **Previously operated due to mastopexy/reduction** | Unknown | 10.5 | 9.6 |
| **Previously operated due to tumor** | Yes | 0.4 | 0.1 |
| **Previously operated due to tumor** | No | 89.2 | 90.4 |
| **Previously operated due to tumor** | Unknown | 10.4 | 9.5 |
| **Volume ml/cc/g** | <199 | 2.5 | 3.1 |
| **Volume ml/cc/g** | 200–399 | 67.1 | 72.2 |
| **Volume ml/cc/g** | 400–599 | 25.1 | 21.2 |
| **Volume ml/cc/g** | >=600 | 4.0 | 3.1 |
| **Volume ml/cc/g** | Unknown | 1.3 | 0.4 |

Table 6. Intraoperative Techniques, Primary Operations Indication Malignant Disease

| Variable | Outcome | Proportion year 2014–2020 (%) | Proportion year 2021 (%) |
|---|---|---|---|
| **Fat graft** | Yes | 1.2 | 1.8 |
| **Fat graft** | No | 58.1 | 84.6 |
| **Fat graft** | Unknown | 40.7 | 13.7 |
| **Incision** | Axillary | 0.2 | 0 |
| **Incision** | Mastectomy scar | 53.4 | 40.0 |
| **Incision** | Mastopexy with augmentation | 2.0 | 6.1 |
| **Incision** | Periareolar | 6.6 | 4.3 |
| **Incision** | Submammary | 26.0 | 40.0 |
| **Incision** | Unknown | 11.8 | 9.6 |
| **Mesh** | Yes | 7.5 | 25.1 |
| **Mesh** | No | 37.8 | 50.1 |
| **Mesh** | Unknown | 54.8 | 24.8 |
| **Position** | Dual plane | 15.0 | 33.9 |
| **Position** | Subfascial | 0.5 | 4.6 |
| **Position** | Subglandular | 3.3 | 8.6 |
| **Position** | Submuscular | 77.9 | 39.7 |
| **Position** | Unknown | 3.2 | 13.2 |
| **Previously operated due to infection** | Yes | 1.7 | 0.8 |
| **Previously operated due to infection** | No | 92.7 | 89.9 |
| **Previously operated due to infection** | Unknown | 5.6 | 9.4 |
| **Previously operated due to mastopexy/reduction** | Yes | 6.1 | 4.1 |
| **Previously operated due to mastopexy/reduction** | No | 88.6 | 85.8 |
| **Previously operated due to mastopexy/reduction** | Unknown | 5.2 | 10.1 |
| **Previously operated due to tumor** | Yes | 44.6 | 26.1 |
| **Previously operated due to tumor** | No | 52.1 | 66.3 |
| **Previously operated due to tumor** | Unknown | 3.2 | 7.6 |
| **Volume ml/cc/g** | <199 | 9.9 | 8.4 |
| **Volume ml/cc/g** | 200–399 | 54.2 | 59.7 |
| **Volume ml/cc/g** | 400–599 | 25.2 | 21.5 |
| **Volume ml/cc/g** | >=600 | 1.7 | 0.8 |
| **Volume ml/cc/g** | Unknown | 9.0 | 9.6 |

FORMS 2021

Primary Operation

# PRIMÄROPERATION

Personnummer:_____

Operationsdatum (åååå-mm-dd): _____

Längd (cm): _____

Vikt (kg): _____

| **Antibiotika** | Ja | Nej |
|---|---|---|
| Profylaktiskt behandling i samband med operation | ☐ | ☐ |
| Intraoperativt (sköljning implantat/håla) | ☐ | ☐ |
| Postoperativt | ☐ | ☐ |

## VÄNSTER bröst

**Operationsindikation**

- ◯ Godartade brösttillstånd
- ◯ Medfödda bröstsjukdomar
- ◯ Rekonstruktion efter riskreducerande mastektomier
- ◯ Rekonstruktion efter cancer

**Genomgången strålbehandling innan primäroperation**

◯ Nej ◯ Ja ◯ Okänd

**Fettransplantation** ◯ Nej ◯ Ja Volym fett _____ml

**Typ av permanent implantat**

◯ Implantat ◯ Expanderprotes

Tillverkare _____

**Innehåll implantat**

◯ Koksaltlösning ◯ Silikon ◯ Koksaltlösning och silikon

Serienummer _____

Volym _____ml / cc / g

Stämplad volym (expanderprotes)_____

**Typ av yta**

◯ Slät/Nanotexturerad ◯ Mikro/Makrotexturerad ◯ Polyuretan

**Form**

◯ Rund* ◯ Anatomisk

**Motiva Ergonomix registreras som rund form.*

**Implantat- eller expanderläge**

◯ Submuskulärt ◯ Subglandulärt
◯ Subfasciellt ◯ Dual plane

**Operationssnitt**

◯ Submammart ◯ Axillärt ◯ Periareolärt
◯ Mastektomi ärr ◯ Mastopexi med augmentation

**Nät/ADM in** ◯ Ja ◯ Nej

**Tidigare bröstopererad**

| | | |
|---|---|---|
| Tumör | ◯ Ja | ◯ Nej |
| Infektion | ◯ Ja | ◯ Nej |
| Mastopexi / Reduktion | ◯ Ja | ◯ Nej |

**Patientens upplevelse innan operation**

| | | |
|---|---|---|
| Missnöjd med form | ◯ Ja | ◯ Nej |
| Missnöjd med volym | ◯ Ja | ◯ Nej |
| Kände smärta i sitt bröst | ◯ Ja | ◯ Nej |

## HÖGER bröst

**Operationsindikation**

- ◯ Godartade brösttillstånd
- ◯ Medfödda bröstsjukdomar
- ◯ Rekonstruktion efter riskreducerande mastektomier
- ◯ Rekonstruktion efter cancer

**Genomgången strålbehandling innan primäroperation**

◯ Nej ◯ Ja ◯ Okänd

**Fettransplantation** ◯ Nej ◯ Ja Volym fett _____ml

**Typ av permanent implantat**

◯ Implantat ◯ Expanderprotes

Tillverkare _____

**Innehåll implantat**

◯ Koksaltlösning ◯ Silikon ◯ Koksaltlösning och silikon

Serienummer _____

Volym _____ml / cc / g

Stämplad volym (expanderprotes)_____

**Typ av yta**

◯ Slät/Nanotexturerad ◯ Mikro/Makrotexturerad ◯ Polyuretan

**Form**

◯ Rund* ◯ Anatomisk

**Motiva Ergonomix registreras som rund form.*

**Implantat- eller expanderläge**

◯ Submuskulärt ◯ Subglandulärt
◯ Subfasciellt ◯ Dual plane

**Operationssnitt**

◯ Submammart ◯ Axillärt ◯ Periareolärt
◯ Mastektomi ärr ◯ Mastopexi med augmentation

**Nät/ADM in** ◯ Ja ◯ Nej

**Tidigare bröstopererad**

| | | |
|---|---|---|
| Tumör | ◯ Ja | ◯ Nej |
| Infektion | ◯ Ja | ◯ Nej |
| Mastopexi / Reduktion | ◯ Ja | ◯ Nej |

**Patientens upplevelse innan operation**

| | | |
|---|---|---|
| Missnöjd med form | ◯ Ja | ◯ Nej |
| Missnöjd med volym | ◯ Ja | ◯ Nej |
| Kände smärta i sitt bröst | ◯ Ja | ◯ Nej |

*BRIMP – Primäroperationsformulär 2021-03-11*

**Bröstimplantatregistret**
Nationellt Kvalitetsregister • www.brimp.se

# REOPERATION

Personnummer: _____

Operationsdatum (åååå-mm-dd): _____

Längd (cm): _____

Vikt (kg): _____

| **Antibiotika** | Ja | Nej |
|---|---|---|
| Profylaktiskt behandling i samband med operation | ☐ | ☐ |
| Intraoperativt (sköljning implantat/håla) | ☐ | ☐ |
| Postoperativt | ☐ | ☐ |

**Mammografi**

| | | |
|---|---|---|
| Genomgången under de senaste 6 månaderna | ☐ | ☐ |

## Registrering

| **Patientrapporterade besvär/ Operationsindikationer** | **VÄNSTER** | | **HÖGER** | |
|---|---|---|---|---|
| Smärta | Ja | Nej | Ja | Nej |
| Svullnad av bröst | Ja | Nej | Ja | Nej |
| Oro för implantat | Ja | Nej | Ja | Nej |
| Oro för implantatläge | Ja | Nej | Ja | Nej |
| Storleksbyte | Ja | Nej | Ja | Nej |
| Önskad formförändring | Ja | Nej | Ja | Nej |
| Hårt bröst | Ja | Nej | Ja | Nej |
| Önskat implantatuttag | Ja | Nej | Ja | Nej |
| Infektion (T81.4) | Ja | Nej | Ja | Nej |
| Nyupptäckt bröstcancer | Ja | Nej | Ja | Nej |
| Symptomkomplex Breast Implant Illness | Ja | Nej | Ja | Nej |

| **Peroperativ status** | | | | |
|---|---|---|---|---|
| Ruptur/deflation | Ja | Nej | Ja | Nej |
| Rotation | Ja | Nej | Ja | Nej |
| Bekräftad ALCL | Ja | Nej | Ja | Nej |
| Felläge | Ja | Nej | Ja | Nej |
| Kapsel (T85.4) | Ja | Nej | Ja | Nej |
| Dubbelkapsel | Ja | Nej | Ja | Nej |
| Serom/exsudat (T81.8) | Ja | Nej | Ja | Nej |
| Hematom | Ja | Nej | Ja | Nej |

| **Åtgärd** | **VÄNSTER** | | **HÖGER** | |
|---|---|---|---|---|
| Permanent uttag av implantat | Ja | Nej | Ja | Nej |
| Återinsättning av befintligt implantat | Ja | Nej | Ja | Nej |
| Nyinsättning av implantat efter tidigare protesuttag | Ja | Nej | Ja | Nej |
| Implantatbyte | Ja | Nej | Ja | Nej |
| Kapselklyvning | Ja | Nej | Ja | Nej |
| Enbloc resektion | Ja | Nej | Ja | Nej |
| Total kapselborttagning | Ja | Nej | Ja | Nej |
| Partiell kapselborttagning | Ja | Nej | Ja | Nej |
| Kapselförsnävning | Ja | Nej | Ja | Nej |
| Nät/ADM in | Ja | Nej | Ja | Nej |
| Fettransplantation | Ja | Nej | Ja | Nej |

Volym fett i ml _____

| | | | | |
|---|---|---|---|---|
| Har patient haft bröstcancer på aktuell sida | Ja | Nej | Ja | Nej |
| Genomgången strålbehandling innan operation | Ja | Nej | Ja | Nej |

*BRIMP – Reoperationsformulär 2021-03-16*

# REOPERATION

Personnummer: _____

## VÄNSTER bröst

Årtal för start av implantatkirurgi: _____

När sattes aktuellt implantat in: _____

Sattes aktuellt implantat in på min klinik ◯ Ja ◯ Nej

### Implantat som TAS UT

**Typ av implantat**

◯ Implantat ◯ Expanderprotes

Tillverkare: _____

Serienummer: _____

**Innehåll**

◯ Koksaltlösning ◯ Silikon ◯ Koksaltlösning och silikon

Volym: _____

Stämplad volym (expanderprotes): _____

**Form** ◯ Rund* ◯ Anatomisk

**Yta** ◯ Slät/Nanotexturerad ◯ Mikro/Makrotexturerad ◯ Polyuretan

**Läge** ◯ Submuskulärt ◯ Subglandulärt ◯ Subfasciellt ◯ Dual plane

**Motiva Ergonomix registreras som rund form.*

### Implantat som SÄTTS IN

**Typ av implantat**

◯ Implantat ◯ Expanderprotes

Tillverkare: _____

Serienummer: PLATS FÖR DEKAL/TEXT

**Innehåll**

◯ Koksaltlösning ◯ Silikon ◯ Koksaltlösning och silikon

Volym: _____

Stämplad volym (expanderprotes): _____

**Form** ◯ Rund* ◯ Anatomisk

**Yta** ◯ Slät/Nanotexturerad ◯ Mikro/Makrotexturerad ◯ Polyuretan

**Läge** ◯ Submuskulärt ◯ Subglandulärt ◯ Subfasciellt ◯ Dual plane

**Motiva Ergonomix registreras som rund form.*

## HÖGER bröst

Årtal för start av implantatkirurgi: _____

När sattes aktuellt implantat in: _____

Sattes aktuellt implantat in på min klinik ◯ Ja ◯ Nej

### Implantat som TAS UT

**Typ av implantat**

◯ Implantat ◯ Expanderprotes

Tillverkare: _____

Serienummer: _____

**Innehåll**

◯ Koksaltlösning ◯ Silikon ◯ Koksaltlösning och silikon

Volym: _____

Stämplad volym (expanderprotes): _____

**Form** ◯ Rund* ◯ Anatomisk

**Yta** ◯ Slät/Nanotexturerad ◯ Mikro/Makrotexturerad ◯ Polyuretan

**Läge** ◯ Submuskulärt ◯ Subglandulärt ◯ Subfasciellt ◯ Dual plane

**Motiva Ergonomix registreras som rund form.*

### Implantat som SÄTTS IN

**Typ av implantat**

◯ Implantat ◯ Expanderprotes

Tillverkare: _____

Serienummer: PLATS FÖR DEKAL/TEXT

**Innehåll**

◯ Koksaltlösning ◯ Silikon ◯ Koksaltlösning och silikon

Volym: _____

Stämplad volym (expanderprotes): _____

**Form** ◯ Rund* ◯ Anatomisk

**Yta** ◯ Slät/Nanotexturerad ◯ Mikro/Makrotexturerad ◯ Polyuretan

**Läge** ◯ Submuskulärt ◯ Subglandulärt ◯ Subfasciellt ◯ Dual plane

**Motiva Ergonomix registreras som rund form.*

*BRIMP – Reoperationsformulär 2021-03-16*

# VARIABLE DEFINITIONS

## Primary Operations

| Variable | Definition |
|---|---|
| Personal identity number | The patient's date of birth and four last numbers |
| Date of operation | The date of the index operation |
| Length | The patient's self-reported body length in cm |
| Weight | The patient's self-reported weight in kg |
| Side, each side's breast operation is registered separately | |
| Left side | Data registration regarding the left breast |
| Right side | Data registration regarding the right breast |
| Operational indication | The reason for implant-based operation |
| Patient-experienced hypoplasia | The patient's experience that the volume of the breasts is too small |
| Asymmetry | Volume or form difference between the breasts |
| Primary micromasty | Disproportionally small breasts in relation to length and weight in nulliparous woman |
| Secondary micromasty | Disproportionally small breasts in relation to length and weight or loss of breast volume after pregnancy and breastfeeding, massive weight loss, transsexual surgery, status after breast operations such as reductions, mastopexy, breast-preserving cancer operations or other conditions with reduction of breast volume |
| Tuberous breasts | Malformation of breasts |
| Prophylactic mastectomy | Surgical procedure where one or both breasts are removed to reduce the risk of breast cancer |
| Reconstruction after mastectomy | Surgical procedure where the breast is reconstructed with an implant or tissue expander concurrent with or at a later stage after removal of breast tissue |
| Radiation treatment before primary operation | Radiation treatment given to breast or to chest before the current implant is inserted |
| Fat transplantation | Adjunct to implant-based operation with the patient's own fat |
| Type of permanent implant | Specification of the current implant |
| Implant | EU-approved medical product for enlargement or reconstruction of breast |
| Expander prosthesis | EU-approved medical product for stepwise expansion of the soft tissue of the thoracic wall with the aim of reconstructing the breast in a "one stage procedure" |
| BRIMP does not register any two stage procedures. Implant changes or intermittent expanders are registered as primary insertion of implant and not as reoperation | |
| Manufacturer | The name of the industrial company that manufactures the current implant |
| Content | Describes the implant's or tissue expander's chemical filler |
| Silicone, sodium chloride or combination | Variants of fillers |
| Serial number | Serial number of the implant or tissue expander |
| LOT-number | LOT-number of the implant or tissue expander |
| Ref-number | Catalogue reference number of implant or tissue expander |
| Volume | Measured in ml, cc or g. PRINT on implant or tissue expander according to manufacturing industry or measured intraoperatively by Archimedes' principle |
| Type of surface | Specification of the surface of the implant or tissue expander |

| | |
|---|---|
| Smooth, textured, polyurethane | The nature of the implant's or tissue expander's surface |
| Form | Form of implant or tissue expander |
| Round | The form of the implant is round |
| Anatomical | The form of the implant or tissue expander is similar to the form of a drop-shaped more mature breast |
| Implant and expander position | Position of the implant or tissue expander |
| Sub muscular | The implant or the tissue expander is placed under the pectoralis muscle |
| Sub glandular | The implant or the tissue expander is placed on top of the pectoralis muscle |
| Sub fascial | Covering of the implant with pectoralis fascia on top of the pectoralis muscle |
| Dual plane | Coverage cranially of the breast areola with the pectoralis muscle, caudally of the breast areola with breast tissue |
| Surgical approach | Surgical approach for the insertion of implant or tissue expander |
| Sub mammary | Surgical approach in the natural fold under the breast or in the previous natural fold after mastectomy |
| Axillary | Surgical approach in the armpit |
| Peri areolary | Surgical approach in the edge of the areola |
| Mastectomy scar | Surgical approach in the earlier scar after mastectomy |
| Mastopexy with augmentation | Insertion of implant through planned skin resection caudally of the breast areola |
| Drainage | Insertion of drainage in the implant cavity and/or subcutaneously during the operation |
| Net/ADM | Insertion of net or acellular dermal matrix (ADM) during the operation |
| Earlier breast operated | Documents if the patient has undergone an operation due to tumour, infection or breast reduction/mastopexy before the current operation |
| The patient's experience before operation | Describes the patient's self-reported dissatisfaction with breast volume or form and possible pains in the tissue of the breasts |
| Antibiotics | Describes if and when the patient has received antibiotics in connection with the current operation |
| Preoperatively | Treatment intravenously or orally the day before the operation day |
| Per operatively | Treatment intravenously or orally on the day of the operation |
| Intraoperatively | Irrigation of implant in sterile package or implant pocket with antibiotics (does not apply to antiseptic) |
| Postoperatively | Treatment orally or intravenously the day after the operation day |

## Reoperation

| Variable | Definition |
|---|---|
| Personal identity number | The date of birth of the patient and last four numbers |
| Date of operation | The date of when the reoperation takes place |
| Length | The patient's self-reported body length in cm |
| Weight | The patient's self-reported weight in kg |
| Year of start of implant surgery | When the implant-based operation was started |
| When was the current implant inserted | When the implant was inserted that this registration pertains to |
| Was the current implant inserted at my unit | Has my unit inserted the implant that this registration pertains to |
| Indications of operation left and right side | The reason for reoperation |
| Pain | Patient-experienced pain in the chest |
| Swelling of breast | Patient-experienced swelling of the breast |
| Worry for implant | Patient-experienced worry for the inserted implant |
| If worry, is it due to newly performed mammography | Patient-experienced worry due to mammography the last three months |
| Change of size | The patient's experience that the volume of the breasts is too small or too large |
| Desired form change | The patient's wish for a change of breast form |
| Hard breast | The patient's experience that the breast is hard |
| Desire of implant removal | The patient's wish for implant removal |
| Infection (T81.4) | Infection after surgical procedure |
| Newly discovered breast cancer | Diagnosis breast cancer as reason for the current operation |
| Preoperative status | The patient's medical status before operation |
| Palpable lymph node in armpit | Lymph node that can be felt in the axilla |
| Per operative status | The patient's medical condition and the status of the implant during the operation |
| Rupture | Damage of the implant's outer layer (from hole in outer layer to breaking up of the implant form) |
| Rotation | The implant has rotated in the cavity |
| Confirmed ALCL | Breast implant-associated Anaplastic Large Cell Lymphoma confirmed with CD30 and ALK |
| Deflation | Volume and/or form change of implant/tissue expander due to loss of sodium chloride |
| Malpositioning | The implant is not in the right position on the chest wall |
| Capsule (T85.4) | Hard connective tissue capsule that has formed around the implant and demands a surgical measure (Baker III, IV) |
| Double capsule | One capsule in contact with implant's outer layerand one capsule in contact with breast tissue. Between the capsules there may be serous fluid |
| Seroma/exudate | Accumulation of wound fluid in the implant pocket |
| Hematoma | Accumulation of blood in or outside of the implant pocket |
| Measure | Treatment |
| Permanent removal of implant | The breast implant is removed and no new implant is inserted |
| Reinsertion of existing implant | The breast implant is removed and after treatment the same implant is inserted again |
| New insertion of implant after earlier prosthesis removal | A new breast implant is inserted after earlier removal of implant, for example after an infection or other condition where the breast tissue needs to heal for several months without implant |
| Implant change | A new breast implant is inserted during the same operation as the existing implant is removed |
| Capsule cleavage | Incision of the capsule in one or more quadrants |
| Capsule exstirpation | Removal of capsule tissue apart from the thoracic part |
| Drainage | Insertion of drainage in the implant cavity and/or in the breast tissue |
| Net/ADM in | Insertion of net or ADM during the current operation |
| Net/ADM out | Removal of net or ADM during the current operation |
| Fat transplantation | Adjunct to implant-based operation with the patient's own fat |

| | |
|---|---|
| Radiation treatment before operation | Radiation treatment of breast or chest before the current operation |
| Data on the implant that is removed on the left or the right side | Data registration regarding left and right side respectively |
| Type of implant | Specification of the implant that is removed |
| Implant | EU-approved medical product for the enlargement or reconstruction of breasts |
| Expander prosthesis | EU-approved medical product for the stepwise expansion of the walls of the thoracic soft tissue with the aim of reconstructing the breast in a "one-stage procedure" |
| Manufacturer | The name of the industrial company that manufactures the current implant |
| Content | Describes the implant's or tissue expander's filler |
| Silicon, sodium chloride or a combination of both | Variants of fillers |
| Serial number | The implant's or tissue expander's serial number |
| LOT-number | The implant's or tissue expander's LOT-number |
| Reference number | The implant's or tissue expander's catalogue reference number |
| Volume | Measured in ml, cc or g. PRINT on implant or tissue expander according to manufacturing industry or measured intraoperatively through Archimedes' principle |
| Surface | Specification of the implant's or tissue expander's surface |
| Smoot, textured, polyurethane | The nature of the implant's or tissue expander's surface |
| Form | The implant's or tissue expander's form |
| Round | The implant's form is round |
| Anatomic | The implant's or tissue expander's form resembles the form of a drop-shaped more mature breast |
| Crescent | The implant's form resembles a crescent |
| Position | Positioning of the current implant or tissue expander |
| Sub muscular | The implant or the tissue expander is placed under the pectoralis muscle |
| Sub glandular | The implant or the tissue expander is placed on top of the pectoralis muscle |
| Sub fascial | Covering of the implant with pectoralis fascia on top of the pectoralis muscle |
| Dual plane | Covering cranially of the breast areola with the pectoralis muscle, caudally of the breast areola with breast tissue |