
BRIMP
Breast implant register
2022
Annual report

Innehåll

Thoughts from the Registry Manager

Martin Halle, docent, chief physician in plastic surgery and registry manager for BRIMP

At the time of writing, I am in my second year as Registry Manager for BRIMP. It has become evident to me that BRIMP is a source of knowledge that we can utilise in many ways and in different contexts. Its overall purpose is to inform patients, health care professionals, authorities and the media about the safety surrounding the use of various breast implants. More specifically, it allows us to objectively evaluate short- and long-term results and complications associated with implant-based operations after breast cancer and in benign breast conditions to continuously evaluate and develop the care we provide.

Personally, the start of 2022 focused on immersing myself into the various tasks including regular meetings, budget follow-ups, applications, and the completion of the annual report for 2021. In addition, our current Development Manager Ulrika Front was new to the position when she took office in March 2022. During this time, the support from our Registry Coordinator Heléne Fägerblad was invaluable, as was the support from colleagues in the steering group and at Registercentrum Västra Götaland. There has been intense collaboration between the project management team and our statistician during the first six months of 2022 to enable the completion of the annual report. In the autumn of 2022, extensive analysis of the existing IT platform was conducted alongside an impact analysis of the possible migration of data as SKR plans to reduce the number of parties involved.

During the year I have, amongst other things, had the opportunity to present our data at the annual Surgeons Week for both breast surgeons and plastic surgeons, at the annual meeting for SFEP, and also been hired as a lecturer internationally. During the fall, I had the honour of being invited as a speaker at the Spanish National Plastic Surgery Annual Meeting in Madrid and to The 4th World Consensus Conference on Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) at MD Anderson Cancer Centre, Houston, USA.
This rare type of T-cell lymphoma continues to gain attention in the media and in the scientific community. The same can be said for the symptom complex Breast Implant Illness (BII), also known as ASIA Syndrome (Autoimmune/Inflammatory Syndrome Induced by Adjuvants). Whether these conditions are related to different types of breast implants is not yet clear. However, what we could determine from the BRIMP annual report in 2021 was that the concern for this has increased and thus has led to increased incidence of permanent removal of implants.

On September 8, 2022, the U.S. Food and Drug Administration (FDA) released an announcement informing the public of reports of cancer, including squamous cell carcinoma (BIA-SCC) and various lymphomas, in the capsule that forms around breast implants. These lymphomas are not the same entity as the lymphomas previously described for BIA-ALCL. The diagnosis of BIA-SCC has only been confirmed in a few cases, but at the time of writing, the reported cases have first been diagnosed between 7 and 42 years after initiated implant surgery. This shows the importance of good quality registries with solid long-term data. In recent years, several important aspects have emerged regarding medical safety as well as the characteristics of various breast implants when used in both public and private health care.
The Swedish and English version of BRIMP's annual report is published annually on BRIMP's website, www.brimp.se, and distributed free of charge to all members of the professional associations. All units that report to BRIMP receive individual summaries of their results. The clinics' own data in relation to aggregated data in BRIMP can be tracked online using the clinic login.

MARTIN HALLE
Registerhållare BRIMP
2022-08-01

Development team

Registerhållare
Martin Halle
Docent, specialist i plastikkirurgi
Rekonstruktiv Plastikkirurgi Karolinska Universitetssjukhuset.
martin.halle@regionstockholm.se

Registerkoordinator
Heléne Fägerblad
helene@hfconsulting.se

Statistiker
Rebecka Bertilsson
Registercentrum Västra Götaland
rebecka.bertilsson@vgregion.se

Utvecklingsledare
Ulrika Front
Registercentrum Västra Götaland
ulrika.front@vgregion.se

Centralt personuppgiftsansvarig myndighet
Regionstyrelsen, Västra Götalandsregionen
För ytterligare information kontakta utvecklingsledare
Ulrika Front
ulrika.front@vgregion.se
www.brimp.se

BRIMP:s årsrapporter finns på www.brimp.se

Steering group

Martin Halle
Registerhållare
Docent, specialist i plastikkirurgi Karolinska Universitetssjukhuset, Solna

Johann Zdolsek
Docent, specialist i plastikkirurgi
Universitetssjukhuset, Örebro

Kerstin Sandelin
Professor, överläkare bröst- och endokrinikirurgiska kliniken
Karolinska Universitetssjukhuset, Solna

Tor Svensjö
Överläkare, specialist i plastikkirurgi
Centralsjukhuset, Kristianstad

Åsa Edsander-Nord
Med. dr. specialist i plastikkirurgi Karolinska Universitetssjukhuset, Solna

Marie Wickman-Chantereau
Professor, specialist i plastikkirurgi Sophiahemmet, Stockholm

Ulf Samuelson
Docent, specialist i plastikkirurgi Akademikliniken, Stockholm

Aili Low
Docent, specialist i plastikkirurgi Läkarhuset, Uppsala

Fredrik Gewalli
Docent, specialist i plastikkirurgi APS kliniken, Göteborg

Alexander Kamali
Leg. läk. specialist i plastikkirurgi
Akademiskt Centrum Plastikkirurgi, Stockholm

Filip Farnebo
Docent, specialist i plastikkirurgi Karolinska Universitetssjukhuset, Solna

Johan Thorfinn
Docent, specialist i plastikkirurgi Plastikakademin, Linköping

Emma Hansson
Adj. professor, överläkare i plastikkirurgi
Sahlgrenska Universitetssjukhuset, Göteborg

Hélene Fägerblad
Patientrepresentant, Göteborg

Participating clinics

AB Victoriakliniken - Saltsjöbaden
Akademikliniken - Göteborg
Akademikliniken - Stockholm
Akademikliniken - Öresund, Malmö
Akademiska Sjukhuset - Uppsala
Akademiskt Centrum Plastikkirurgi - Stockholm
Alberiuskliniken - Helsingborg
Aleris Plastikkirurgi - Umeå
Aleris Plastikkirurgi - Malmö
aps Plastikkirurgi - Göteborg
Art Clinic - Göteborg
Art Clinic - Jönköping
Art Clinic - Stockholm
Art Clinic - Uppsala
Bellakliniken AB - Helsingborg
Bröstenheten, Kirurgiska Kliniken, US - Linköping
Bröst- och Melanomteamet SUS - Lund
Bröstcentrum Kirurgi, Capio St. Göran - Stockholm
Bröstcentrum SÖS - Stockholm
Conturkliniken - Stockholm
Dalakliniken - Falun
De VitaNova AB – Stockholm
Diamond Plastikkirurgi - Örebro
Elite Clinic, Göteborg
Eriksbergskliniken, Stockholm
Estetisk Plastikkirurgi Eya Le Wartie AB, Ockelbo
Gerlee Plastikkirurgi - Helsingborg
Gävledalakliniken – Gävle
Hand- och Plastikkirurgisk klinik, US - Linköping
Hand- och Plastikkirurgisk klinik, US - Umeå
Improva Plastikkirurgi AB - Stockholm
Kirurgkliniken - Halmstad
Kirurgkliniken - Växjö
Kirurgkliniken - Västervik
Kirurgkliniken - Falun
Kirurgkliniken – Kalmar
Kirurgkliniken Länssjukhuset Ryhov - Jönköping
Klinik 34 – Göteborg
Kliniken för rekonstruktiv plastikkirurgi, Karolinska US
Lidingökliniken AB Plastikkirurg - Lidingö
Läkarhuset i Uppsala - Uppsala
Malmö Hyllie Arena Specialistvård, Malmö
Nordiska Kliniken, Stockholm
Nordiskt Centrum för Plastikkirurgi - Linköping
Novokliniken – Värnamo
Olle Löfgren Plastikkirurgi - Stockholm
Plastikakademin – Linköping
Plastikhuset – Linköping
Plastikkirurgen i Stockholm AB - Stockholm
Plastikkirurgen Leif Gylbert AB - Stockholm
Plastikkirurgen Sahlgrenska US, Göteborg
Plastikkirurgi i Hässleholm AB - Hässleholm
Plastikkirurgiska kliniken, US Örebro
Stockholm Plastikkirurgi – Stockholm
PO Bröst, Endokrina, Tumörer, Sarkom, Karolinska US
Stockholms Plastikkirurgiska AB – Stockholm
Strandkliniken Danderyd Läkarhus – Danderyd
Visby lasarett – Visby
VO Kirurgi - Bröst och plastikenheten - Kristianstad
VO spec. kir, Sektion för plastikkirurgi - Malmö

Summary

In 2022, the incidence of reoperations both in the public and private sector continued to increase. Parallel to the number of primary operations increasing in the public health care setting, fewer primary operations have been registered privately. In the oncological setting, mainly Mentors implants have been used and in benign breast disease Mentor and Motivas products dominated in Sweden. A continued increase in permanent explantation of implants alongside a higher frequency of extensive 'en-bloc' capsulectomy has been noted. This may be explained, but not medically motivated, by a simultaneous increase in concern for breast implants as an indication for reoperation. This is a trend that has also been noted globally by the international organization ISAPS who have, at the time of writing, issued information concerning this: https://www.isaps.org/articles/statements-guidelines/breast-imovale-moval-and-capsulectomy/. A tendency for the increased use of smooth implants has been noted in the public sector, although textured implants still constituted the majority. This trend of an increased proportion of smooth implants has been noted in the private sector for many years, but now appears to have turned with an increased use of textured implants. For 2022, a histogram is presented showing the distribution of different implant sizes and the size distribution for the most common implant varieties. When it comes to the risk of reoperation within 60 days and after 5.5 years, we continue to note that it is very low. Patients treated with radiotherapy, however, had a significantly higher risk of reoperation as compared to non-radiated oncological patients. Reoperation due to implant rupture within 5.5 years remains very rare. No differences could be seen between the implant manufacturers. Comparisons have also been made with the Breast Cancer Register NKBC, however this records only primary implant reconstructions and no reoperations. BRIMP is the only quality registry that takes into account implant-specific data and can set these in relation to the symptom complex Breast Implant Illness (BII) and Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). As implant reconstruction after breast cancer is performed in many smaller hospitals, we are now conducting a survey to increase coverage.

During 2022, we have updated several points in the variable list with the aim to improve registry data. We also process and analyse our data continuously to improve the content of the registry. BRIMP is an extremely important tool for our patients allowing them to self-educate about specific implants and complications. We can improve the statistical relevance of our analyses and help decision makers choose the right implant for the right patient. Our international cooperation with Australia, the Netherlands, Germany, the United Kingdom, Switzerland, and Italy in ICOBRA aims to define quality parameters for health care on an international level.

Activities and Main Projects 2022

Data output Functions as Support for Clinical Care
In January 2022, Martin Halle took over as Registry Holder after Birgit Stark, who has been in the role since BRIMP's inception in 2014. Participation in BRIMP remains unchanged with 85% of colleagues practicing plastic surgery in the private sector in the country contributing with their data. In collaboration with Registercentrum (Centre of Registers Västra Götaland), we manage data from close to 60,000 implants. Through proactive spreading of information on BRIMP, the largest clinic in Stockholm, which so far remains unregistered in BRIMP, has now actively reached out to Registry Holder Martin Halle for information about how they can start the registration process. Through a newly designed certificate, which several clinics now use to inform patients and customers about their active participation with BRIMP, we hope for even greater participation going forward. The participation in BRIMP is currently not compulsory, neither for the public or private sector, in contrast to the Netherlands, the United Kingdom and Australia. Participation is therefore completely dependent on the 'goodwill' of colleagues throughout the country. The work in 2022 focused mainly on the following projects:

Improved Registry Content
During 2022, the steering group made several updates to variables. An important aspect of this quality improvement process is to ensure that new additions should not, as far as possible, impair retrospective analysis of an earlier variable. We continuously carry out critical analysis of the significance of the BRIMP-variables for clinical care. Improved registry content is also created through analysis of the degree of coverage. We experience an increased understanding of the benefits and significance of using BRIMP. An increasing number of national clinics request information about BRIMP. The current affiliation with BRIMP amounts to approximately 85%. Regarding degree of coverage, credible sales data from the industry indicates that we register 65% of all implants sold in Sweden. Registry holders have discussed with representatives from the industry as to how we together can improve coverage. A collaboration has been initiated with Mentor, who sell approximately 50% of the implants in Sweden, where Mentor actively supports BRIMP when selling its products to various clinics. Through access to Mentor's customers, which is public information on their website, the coordinator can identify which clinics that conduct implant-based surgery are not affiliated with BRIMP. As a result, active effort can be made to initiate participation in BRIMP. Critical analysis of outcome data from BRIMP from year 2015 to 2021 shows stable statistical results. In consultation with our statisticians at Registercentrum, we have concluded that reported results meet Swedish standard. Breast implants are used across other specialties and so far, we have failed to persuade all general surgeons and breast cancer surgeons to participate in BRIMP. Here, we hope for a closer collaboration between the Breast Cancer Registry and BRIMP. This will increase coverage through transmission of data from NKBC to BRIMP, which commenced in fall of 2021. However, when compiling the annual report 2021, there were deficiencies in data from NKBC with regards to certain implant characteristics, resulting in registration currently having to be made also in BRIMP.

Facilitate Everyday Routines for Reporting Units
To ensure increased participation, it is of utmost importance that the data registration process is simple without significantly affecting workload or production. In a first initiative, the possibility of connecting BRIMP to an industrial database, involving digital transfer of data based on the implant specification, was investigated. The advantage of this would be that data in BRIMP is transferred correctly and "missing data" would decrease in the long term. However, impact analysis demonstrated that BRIMP currently does not possess the necessary financial conditions to run such a project. Furthermore, a survey was performed to evaluate how registering units perceived the daily work with BRIMP and investigate possible associated problems. The overall aim was to improve communication between BRIMP and the clinical environment. The survey responses have been followed up with additional information and opportunities for questions via webinar. The initiative was much appreciated and future digital exchanges between registry management and registering units will continue as a tool to promote interactivity and communication. We have also initiated work to investigate the possibility of scanning barcodes on the implants' packaging. However, after a comprehensive review of all quality registers' IT systems in 2022, we have postponed proceeding with this. Overall, these efforts aim to increase BRIMP's degree of coverage in the long term.

Industry Database
With the large amount of data that BRIMP has now generated, it has become clear that industry places great value in the data output to evaluate and develop new and old health care products. In collaboration with Registercentrum's project management, BRIMP has created various report models for an industry database. Data on complications and reasons for reoperation for a company's products can be compared with aggregated data in BRIMP. The implant companies Motiva and Mentor have purchased these industry reports from BRIMP 2022. Registercentrum has drawn up suitable agreements with the implant manufacturing companies Motiva and Mentor regarding the industry report 2021. The fee to Registercentrum includes the de facto cost of preparing the industry report at cost price, which is of great importance for maintaining independence from industry. Discussions regarding the design of a generic industry database are being had, but in light of the possibility of changes of IT platform, a temporary solution is being considered where companies request data extraction in the same way as all other external parties.

The Work of the Steering Group and Registry Manager in 2022

Registry Work 2022

In 2022, for the first time since the pandemic, the steering group gathered for physical meetings, both during Surgeons' Week and in connection with the annual meeting of SFEP. In addition, four meetings via Zoom have been organised during the year. The Registry Manager has had more than 20 digital meetings as well as ongoing contact via phone and email. Contact with project management and statisticians has been intense during the first 6 months of 2022 whilst the 2021 annual report was completed. During the autumn of 2022, an extensive analysis of the existing IT platform was conducted alongside an impact analysis of the possible migration of data as SKR plans to reduce the number of involved parties. Furthermore, the Registry Manager has had several meetings per semester with the Registry Coordinator to plan the continuous registry work. The coordinator has had ongoing contact with units across the country for support and help with the registry work. The Registry Manager has had the main responsibility for the work pertaining to the annual report, compiling relevant data as well as writing manuscripts and arranging an English version. The Registry Manager has participated in digital meetings with the national and international working group for Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) within e.g. EURAPS and was invited as faculty for "The 4th World Consensus Conference on BIA-ALCL" at MD Andersson Cancer Center, Houston, USA. The Registry Manager has presented BRIMP at national and international meetings and has ensured that finances for 2023 are secured through written applications to SKR during the past year.

Collaboration with Industry

As previous years, the creation of an industry report has required several meetings and hours of work where the Registry Manager has had contact with representatives from industry and project management from Registercentrum. In the future, the plan is instead for industry to request data extraction in the same way that other external parties do.

International and International Collaboration

There has been continued interest in BRIMP both nationally and internationally. The English versions of BRIMP's annual report 2017 – 2021 are published on the EASAPS (European Association of Aesthetic Plastic Surgery Societies) website and have been provided to international members of ICOBRA (International Collaboration of Breast Registry Activities). The annual reports are available on BRIMP's website www.brimp.se and are distributed to all members of the two plastic surgery associations SFEP and SPKF. In addition to the annual report, all units that report to BRIMP receive an annual individual summary of their results sent via email. The units' own data in relation to aggregated data in BRIMP can be tracked online using the clinic login.

Former Registry Manager Birgit Stark planned to attend a meeting with ICOBRA representatives and partners in LIMA, Peru at the meeting with ICOPLAST in May 2022, but due to the pandemic, the meeting was postponed to May 2023 in conjunction with the meeting with ICOPLAST in Dubai. Birgit Stark has now attended this meeting, which will be reported in the next annual report.

Economy

It is of utmost importance that BRIMP continues to be publicly funded and independent of industry. Running a quality registry is costly and, so far, SKR (formerly SKL) has financed BRIMP following annual applications in competition with the other more than 100 quality registries in Sweden. No private sector clinic or professional association has contributed to BRIMP's expenses. No fee has been paid for annual reports or specific clinic reports sent bi-annually to healthcare professionals concerned. BRIMP has received a nominal income through the sale of industry reports to the implant manufacturing companies Motiva and Mentor. The Registry Manager has set the budget for BRIMP through collaboration with management from Registercentrum and has regularly participated in follow-up meetings held at least once per quarter. In summary, BRIMP's finances are in line with the budget for 2022.

Data quality and Sample Controls for the Annual Report of 2022

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 2022. Registrations made after this date were therefore not part of any analyses. The time passed before 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 have been more registrations for 2022 which therefore have not been part of the analyses. These registrations will be registered on the current date for the next annual report, so the number of implants for a given year may differ between annual reports. The goal is thus that all registrations end up in BRIMP long-term, regardless of when they are received.

Improvement Proposals

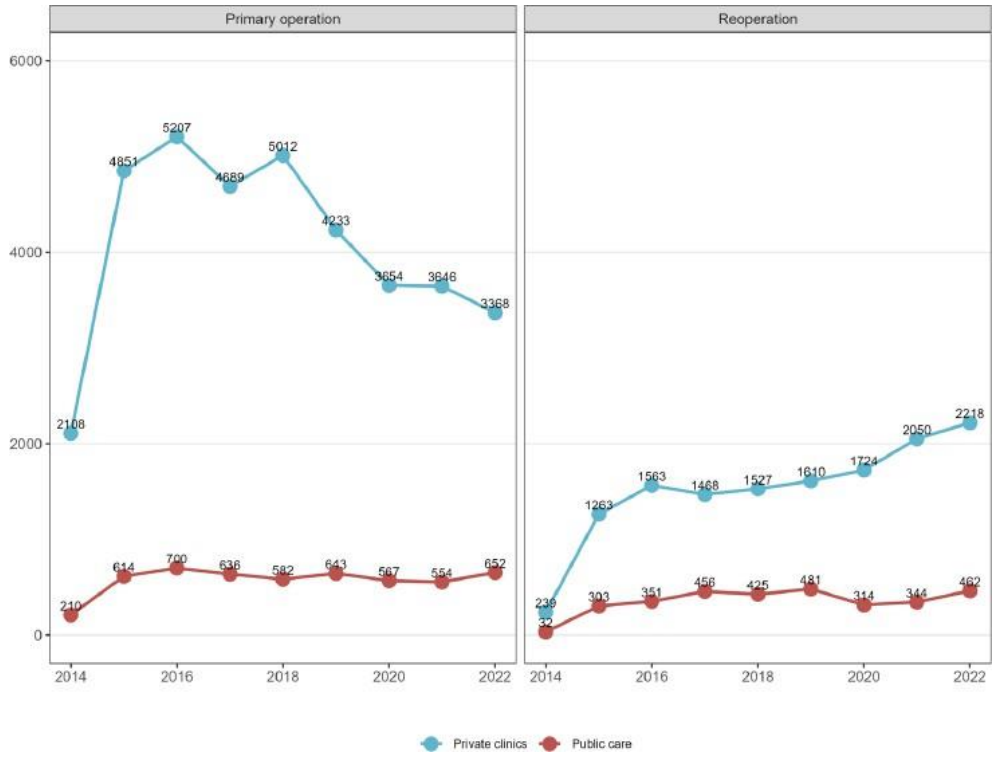
The main future aim is that most units should register intraoperatively without delay. This, however, demands that staff with the right to register is available in the operating room. Going forward, one could add a warning that appears when a user tries to input a new primary operation for a patient that has already been operated. It could suffice if the system prints only the date for the registration of the primary operation, in order not to infringe on patient confidentiality. The same applies if a reoperation is registered with an earlier date than the primary operation. However, this change has not been a priority as SKR is currently reviewing which IT platforms to prioritise in the future.

The Annual Report 2022

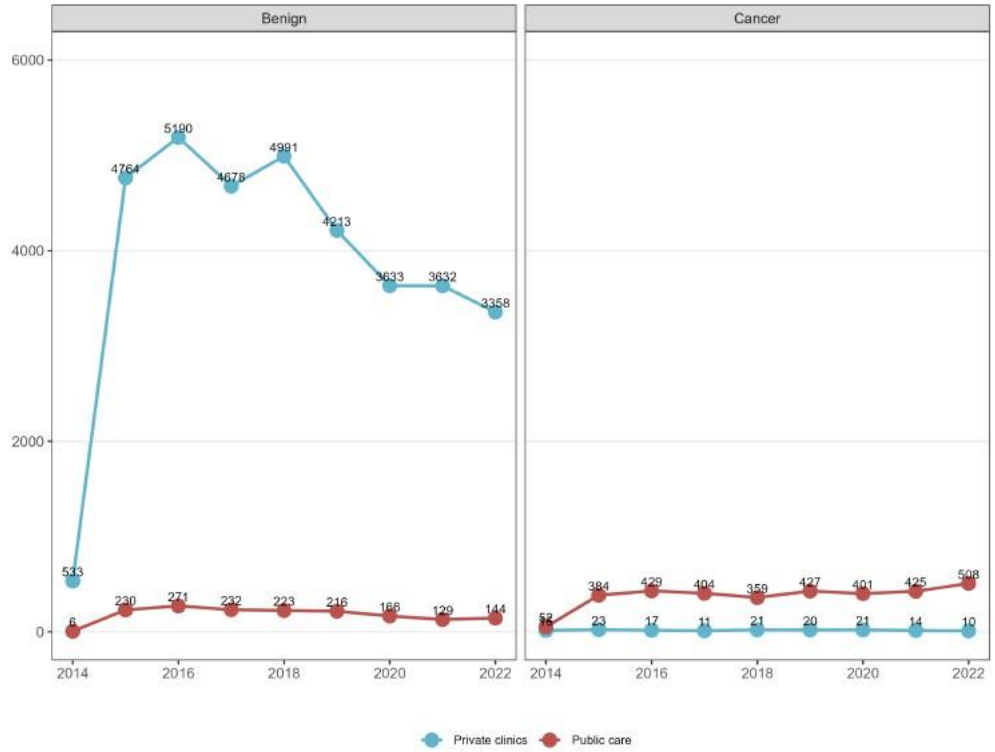
As in previous years, this annual report evaluates data from patients undergoing breast reconstruction for oncological reasons and risk-reducing mastectomies separately to implant-based operations for benign conditions. We have chosen to present data for 2022 both in relation to all previous years and, in some cases, in relation to the aggregated patient cohort with primary operations in 2014-2021. It is worth mentioning that some variables have been added between 2014-2022. 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 intervention are accounted for. Furthermore, the reoperations in BRIMPs database are evaluated at 60 days, one and six years post-operatively. The total number of registered operations in 2022 was 6700; 4020 primary operations and 2680 reoperations. In total, this is an increase by 5%, as shown in Figure 1. An analysis of all primary operations shows that the majority of operations for cancer/cancer risk and for benign conditions were registered within the Västra Götaland region, closely followed by Stockholm. Following Stockholm, the gap was large to Skåne causing suspicion of some under-reporting. It also seems likely that there is certain under-reporting of the number of primary operations in Stockholm as several large private clinics are not yet reporting to BRIMP. However, since January 2023, the largest of these clinics has started registering in BRIMP after an information meeting with the Registry Manager.

Statistics

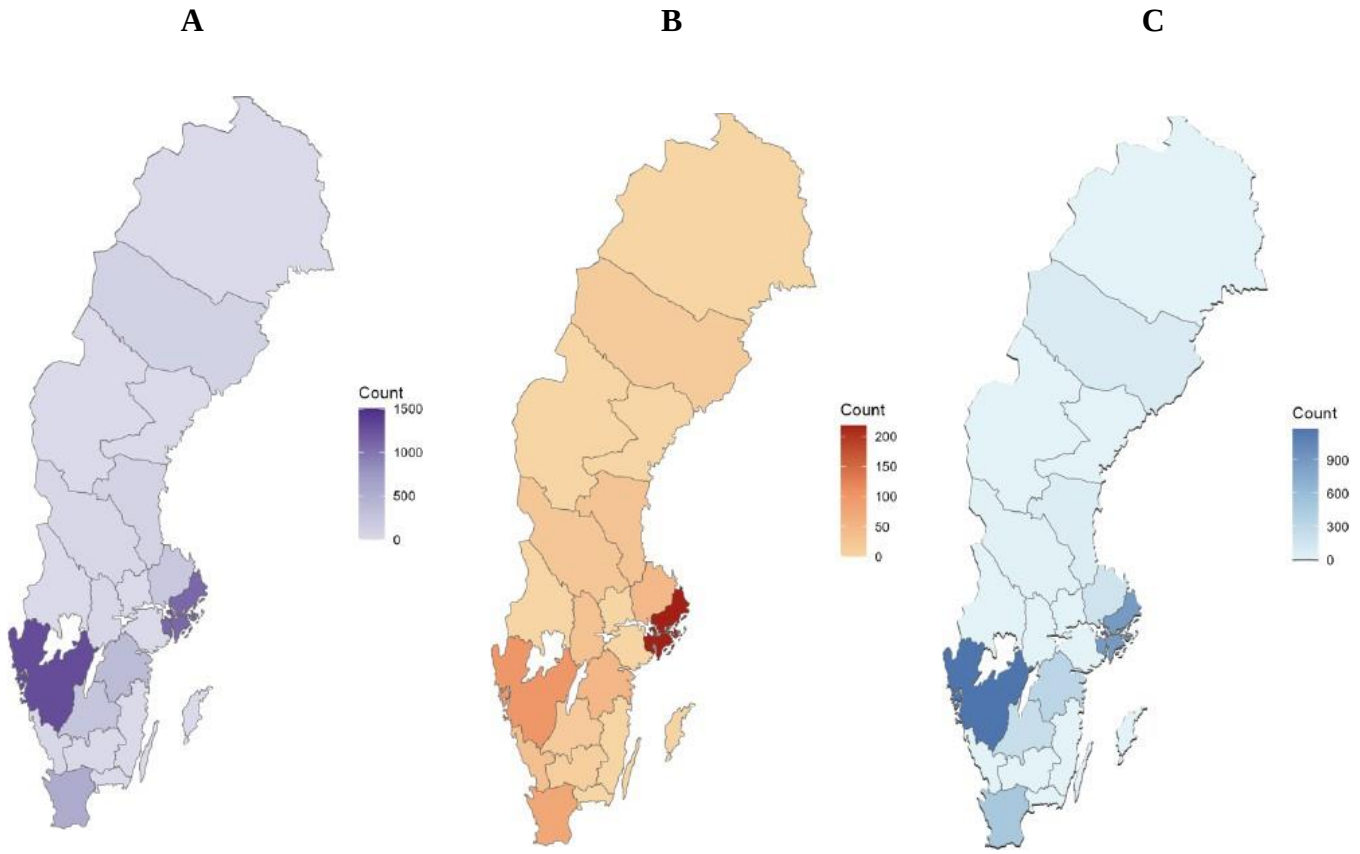
This is the first time we show a trend over time regarding the number of registered operations in BRIMP since its inception in 2014. It is evident that the number of primary operations has decreased in two stages alongside a steady increase in the number of reoperations in the private setting (Fig. 1). In addition, a proportion of reoperations consist of permanent implant removal, where the stated cause was patient-perceived anxiety (Fig. 11). A clear decrease was seen in 2020, which could possibly be attributed to the pandemic, but the trend seems to persist. The downward trend was however already evident in 2019 when Allergan withdrew the macrotextured implants from the market after several reports showing a connection between these implants and the lymphoma Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). Presented in figures is the total number of operations in the private and public sector regardless of diagnosis (Fig. 1a), and primary operations based on indication (red: cancer or risk reduction and blue: benign conditions) (Fig. 1b),



Figur 1a. All registered operations 2014-2022 distributed in the private and public sector



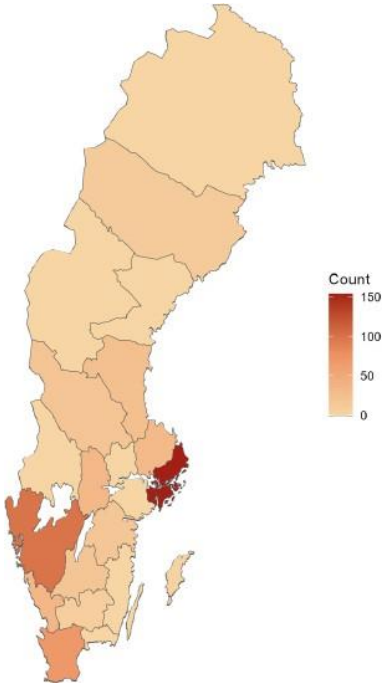
Figur 1b. All registered operations 2014–2022 divided into indications for benign conditions and cancer/cancer risk



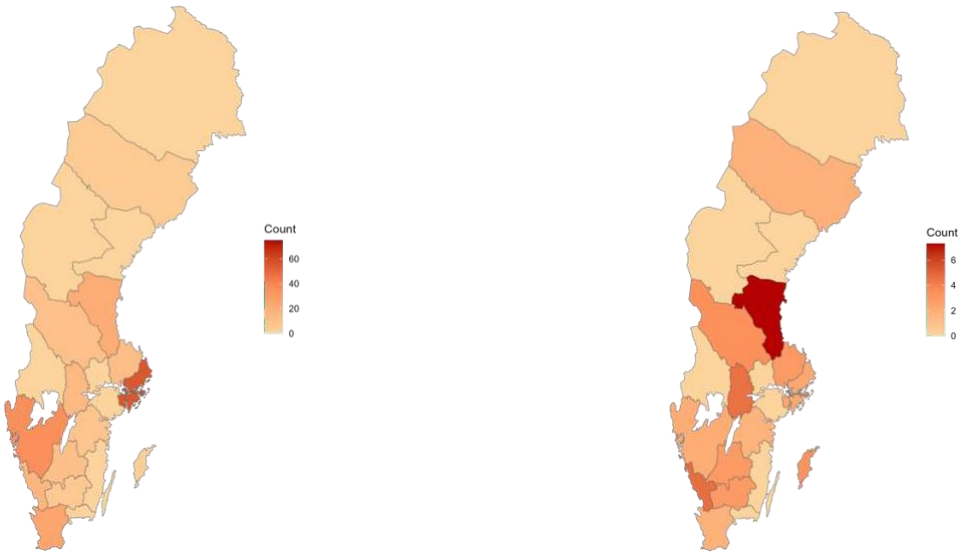
Figur 2. A) Registered primary operations in 2022, all clinics. B) Registered primary operations in 2022, public sector. C) Registered primary operations in 2022, private sector

Implant-based Reconstruction for Breast Cancer or Risk Reducing Mastectomies

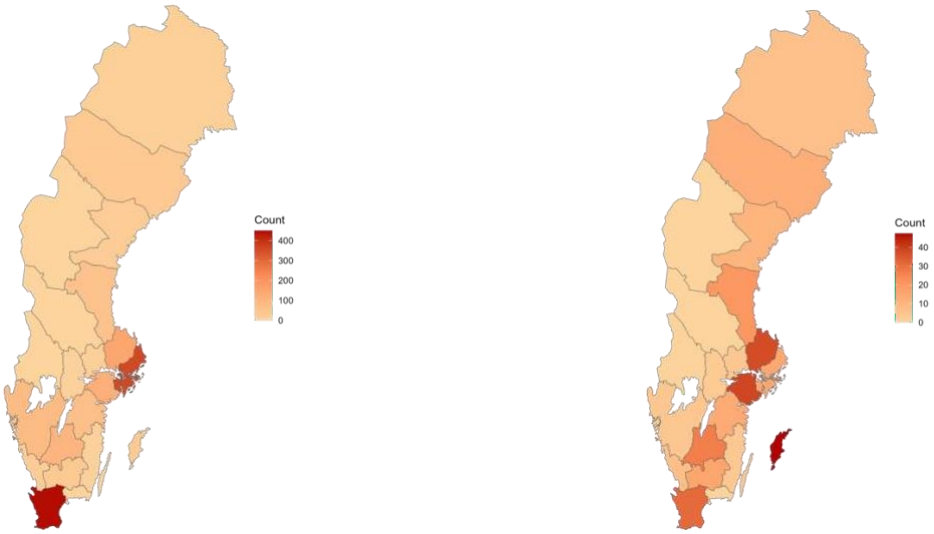
In 2022, we noted the second highest number of implants (n=518) in primary operations for reconstruction in cancer or risk-reducing mastectomy in 363 patients since the start. This is an 18% increase in the number of implants compared to 2021 (n=439). For reoperations, the corresponding increase was 45%, from 229 implants in 2021 to 331 in 2022. The increase can either be explained by more registering clinics or a backlog after the Covid-19 pandemic, or a combination of both. A total of 2453 patients who underwent primary breast reconstruction with implants have been reported to BRIMP. According to the reported data in BRIMP, the largest proportion of reconstructions last year were performed in Region Stockholm and in the Västra Götaland region (Table 2) (Figure 3a,b). As a comparison, we have also chosen to report data from NKBC which highlights the number of mastectomies performed in the country.



Figur 3a. Number of registered primary reconstructions in BRIMP



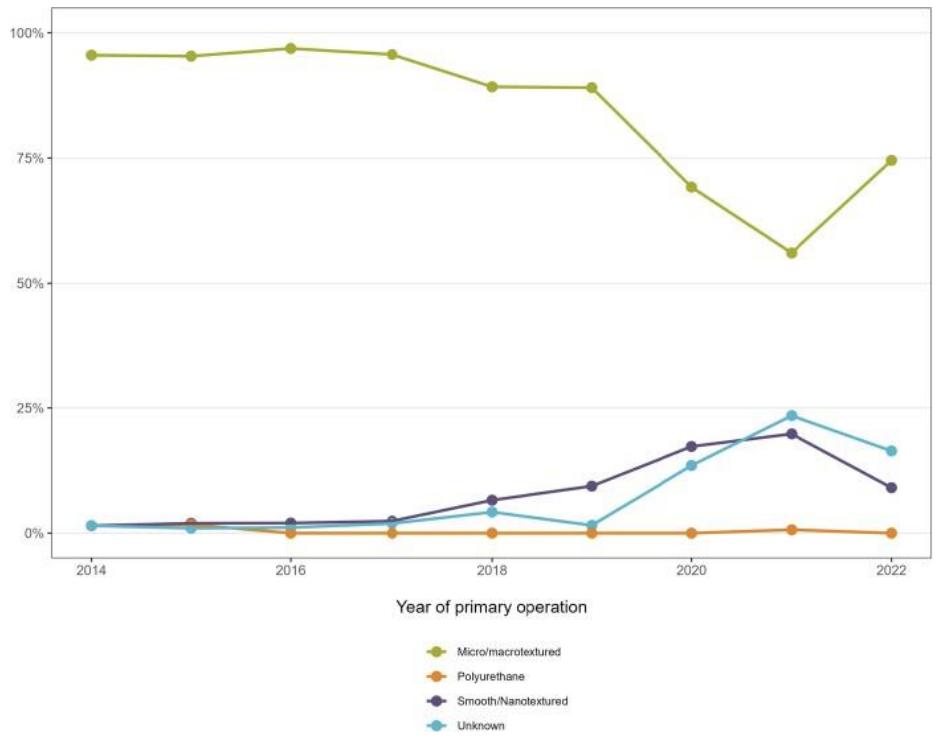
Figur 3b. Number of registered primary reconstructions in BRIMP without prophylactic mastectomies in total (left) and per capita (right)



Figur 3c. Antal registrerade mastektomier i NKBC totalt (till vänster) samt per capita (till höger).

Choice of Implant

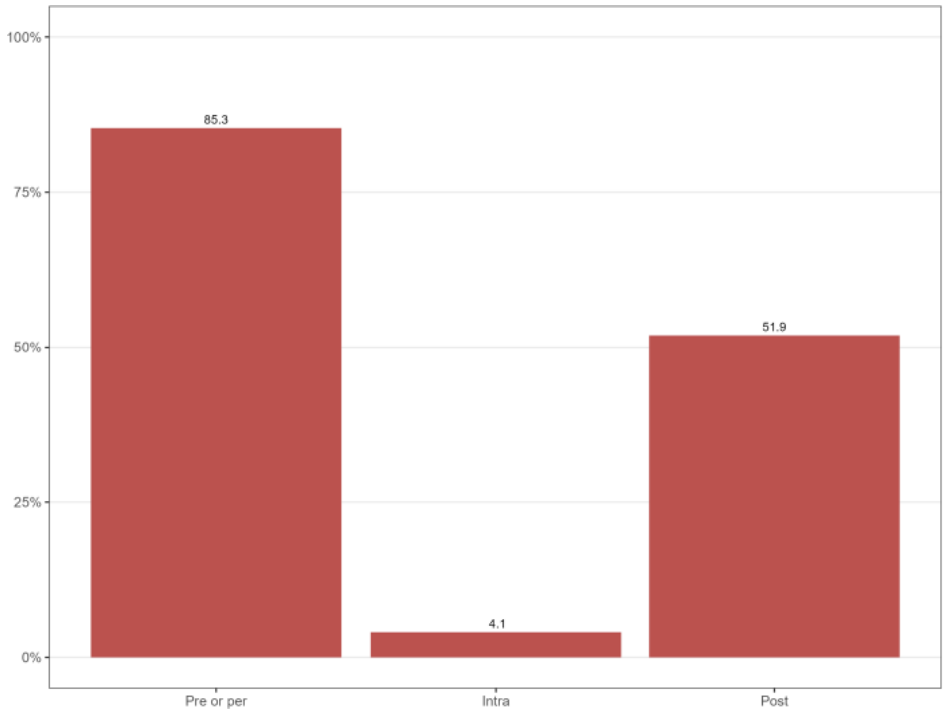
When it comes to choosing the brand or type of implant, there are no national recommendations or consensus in Sweden. Some health care providers advocate the choice of smooth implants for this patient group given the increased relative risk of BIA-ALCL with use of textured implants. However, that risk is primarily related to macrotextured implants, which were therefore removed from the market in 2019. Data in BRIMP from 2014-2020 showed that 89% of reconstructions were performed with textured implants, mainly from the company Mentor. There was, however, a decrease in textured implants in breast reconstructions from 89% to 55% along with an increase in smooth implants from 6.5% in 2014-2020, to 22% in 2021. In 2022 we could see an increase in textured implants from 55 % to 75% as smooth implants decreased (Fig. 4). It is worth mentioning that the unregistered surface "unknown" decreased in the corresponding comparison. Mentor's products were used in the majority of cases.



Figur 4. Implant surface for primary operations for cancer/cancer risk

Infection Prophylaxis

Perioperative prophylactic antibiotic treatment is routine in implant-based breast reconstruction. Data in BRIMP shows that 85.3% of patients received prophylactic treatment pre- or perioperatively, which is in line with 2021 (81.3%). We have chosen to show pre- and perioperative treatments combined as the definitions can be unclear. In general, it can be concluded that patients appear to be well covered with antibiotics before insertion of implants. Intraoperative antibiotic irrigation of the prosthesis cavity or the prosthesis before insertion was 4.1% and does not correspond to current national recommended care in reconstructive surgery. Antiseptic irrigation is, to date, not permitted in public healthcare. Somewhat surprising, however, is the increased use of postoperative antibiotics, which increased from 38.5% in 2021 to 51.9% in 2022 (Figure 5). Prescriptions of antibiotics and the duration of treatment can be investigated through the drug register.



Figur 5. Infection prophylaxis for reconstructive primary operations

Surgical Approach and Implant Positioning

Thirty two percent of reconstructions were performed with dual plane implant position. In previous years, there have been some questions regarding the definition of the variable dual plane position', which corresponds to the English term 'dual plane', a term many are more familiar with. Information on how the variable should be registered has been communicated via letter and webinar. During mastectomy or risk-reducing mastectomy, no breast tissue is left in the lower pole of the breast. Implants in dual plane position' characterise proximal coverage of the implant with the pectoralis muscle and distal coverage with breast tissue. It is surprising that such a large proportion of 'bi-dual' implant position were reported to BRIMP, but this could be explained by the combination with synthetic or biological meshes that are increasingly used where total muscle coverage is not sought. The use of mesh was 31% in 2022 compared to 11% in 2014–21 (Table 4). This corresponds well with 32% for dual plane implant placement. Similarly, sub-glandular implant placement during breast reconstructions has been an unclear variable as no breast tissue remains. As pre-pectoral breast reconstructions have increased, the decision was made to use the term sub-glandular placement, which is logical, but not strictly the correct terminology. The form has therefore been updated for 2022 with a clarifying addition "sub-glandular/pre-pectoral" for the same registration. This is reported for the first time in this annual report.

The most common incision in 2022 has, as expected, been via the old mastectomy scar or in the infra-mammary fold. Regarding so-called hybrid surgeries, we are seeing an increased use of the aforementioned mesh during breast reconstructions throughout the country. Also, regarding the use of fat grafts during primary insertion of implants in this patient group, an increase from 1.3% in 2014–21 to 3.1% in 2022 has been seen. It should be noted that for hybrid procedures answers are missing for a significant proportion of patients (Table 4) and only primary operations are presented.

Integration with Data from National Quality Registry for Breast Cancer

Since 2021 we fetch data from National Quality registry for Breast Cancer (NKBC) and integrate it with BRIMPs data. NKBC started in 2008 and contains data on lead times, diagnostics, tumour characteristics, preoperative oncological treatment, breast- and axillary 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 as the data sets are aggregated. Our hope was that NKBCs data would be more similar to what we have in BRIMP thereby complementing BRIMPs data, but when many parameters are missing in NKBC there will be a high proportion of missing/unknown/other for those patients only registered in NKBC. This leads to outcomes that are unclear and difficult to interpret and illustrates that both registries are needed in their own right. NKBCs data should therefore be accounted for separately in the future on a yearly basis. Furthermore, a larger number of cases in several regions are noted when integrating NKBC and BRIMP data, compared with when only BRIMP-data is presented. This illustrates that there are several regions that could increase their registration in BRIMP when it comes to mastectomies after cancer and possibly also risk-reducing mastectomies. Worth mentioning is that no reoperations are registered in the NKBC.

After meeting with the steering group, we have therefore determined that it is of utmost importance that we have good coverage regarding both primary- and reoperation of cancer reconstructions in BRIMP. As these are to some extent done outside the regional hospitals, albeit on a small scale, we have now tried to reach out to more breast cancer surgeons and, among other things, recruited new members to the steering group.

Conclusion

In summary, data from 652 implants for reconstruction due to cancer or after a risk-reducing mastectomy in 2022 was reported. This is an 18% increase from 2021 when only 554 implants were registered. The reason is likely the increased proportion of implant-based direct reconstructions performed after mastectomy due to breast cancer, but also the considerable work done by BRIMP's Registry Coordinator who assisted new units to start registering. After joint analysis with data from the NKBC, it became clear that BRIMP has an important role, as NKBC lacks data on reoperations as well as the nature of the implant and implant-related surgical techniques, symptoms and complications. Patients were primarily reconstructed with Mentor's textured implants where the previous increase in smooth implants has decreased somewhat. Throughout the country, mainly textured and anatomical implants are used via the mastectomy incision, alternatively the infra-mammary fold. Outcome data from BRIMP regarding implant position has given rise to a clarification on the forms where pre-pectoral position, which has become increasingly common, has been added to the form. Previously, pre-pectorally placed implants have been registered under sub-glandular, which is not semantically correct. Reporting of height and weight in this patient category has been deficient. BMI is a contributing factor for reoperation, which is why we look forward to increased registration in this regard. The proportion of hybrid operations with mesh has increased from 25% to 31% in 2022 compared to the previous report. Fat grafting during primary surgery is still uncommon (3%), but likely higher in reoperation, which we plan to study next year. Infection prophylaxis is common practice in Sweden, but the percentage of patients undergoing intraoperative antibiotic irrigation of the prosthesis cavity or of the prosthesis before insertion was 4.1%, in contrast to more than five times as often in benign conditions. This figure is still unexpectedly high as it does not correspond to current national recommended care in reconstructive surgery. For 2022, we have, for the first time, analysed the number of reconstructions with implants after cancer, after filtering out prophylactic mastectomy reconstructions. We have chosen to report this data geographically in absolute numbers as well as in relation to numbers per capita for BRIMP with comparative data from NKBC. For the first time, this shows clear geographical differences.

Primary Operation for Benign Breast Conditions

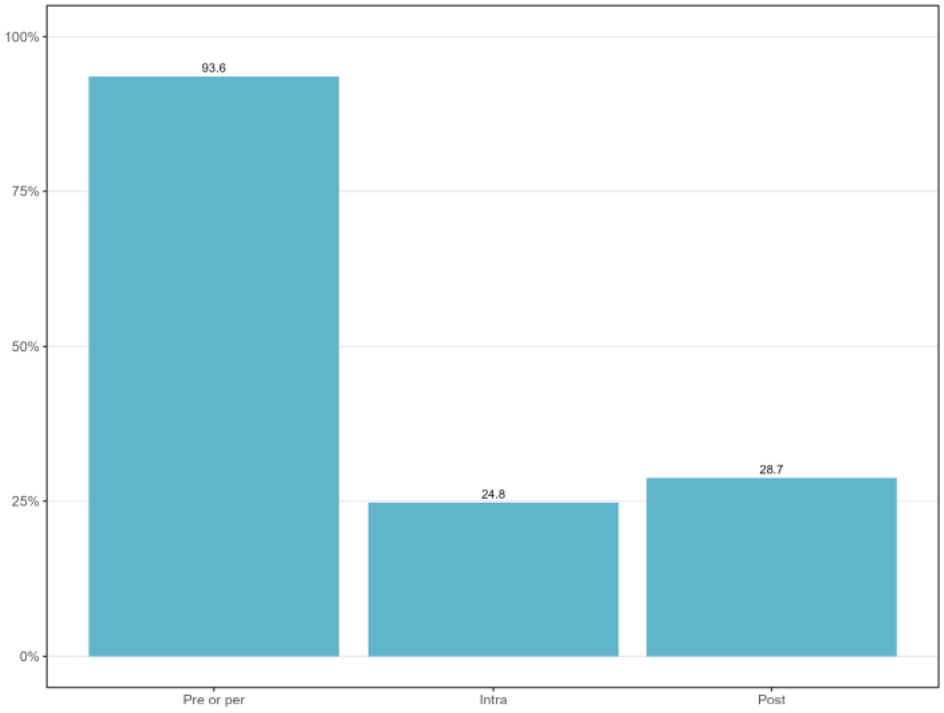
Indications for an operation with breast implants for benign breast conditions constitutes the larger group and include:

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

In table 3, the production data in BRIMP for benign conditions for years 2014-2021 and 2022 is reported. In Sweden a total of 16 691 patients have been operated with 33 107 implants in 2014-2021. In 2022 1758 patients received 3502 implants. Compared with the year 2021 there has been a small decrease in the number of reported implants from 3699 to 3502. Table 3 also shows the distribution in different Swedish regions.

Infection Prophylaxis

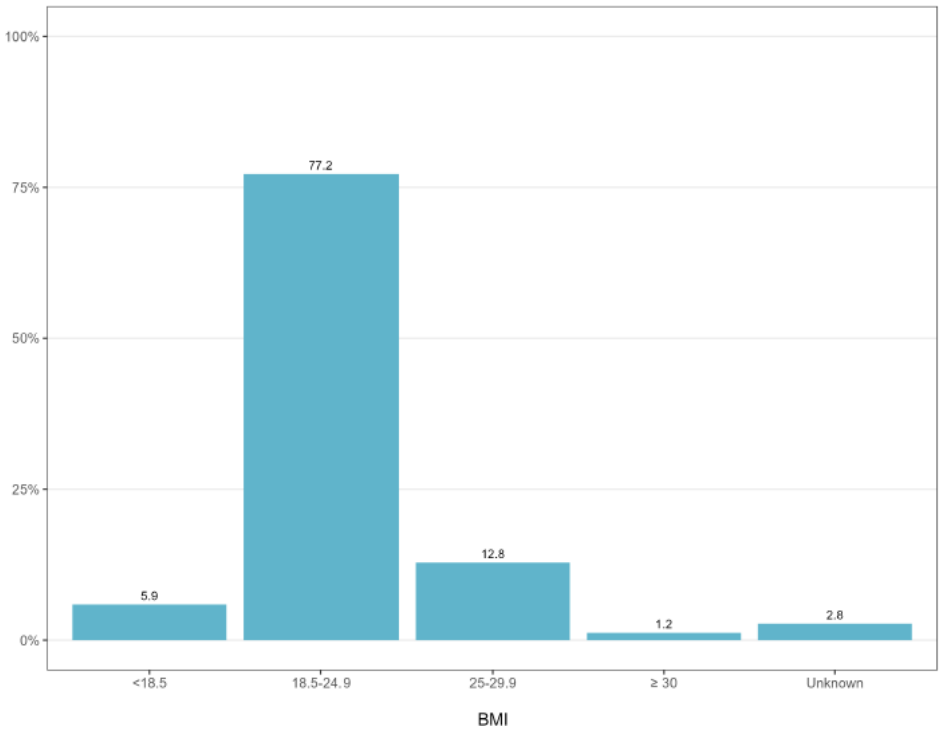
The use of antibiotics is standard during primary insertion of implants for benign conditions. On the contrary, irrigation of the implant cavity or of the implant before insertion is not the national standard but occured in 24.8% of the reported primary operations (Figure 10). This is an increase by more than 10% from 23% in the previous year. Intraoperative irrigation with antibiotics during the primary operation is primarily reported from units in Region Stockholm, which has become the subject of discussions within doctors' associations.



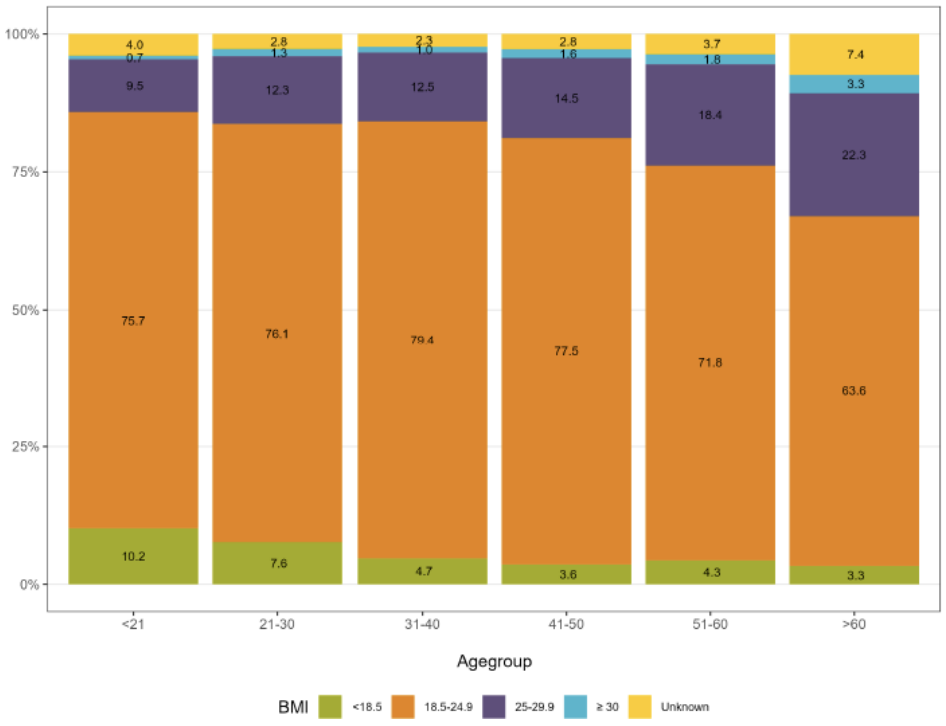
Figur 6. Infection prophylaxis during primary surgery for benign conditions

BMI in Different Age Groups

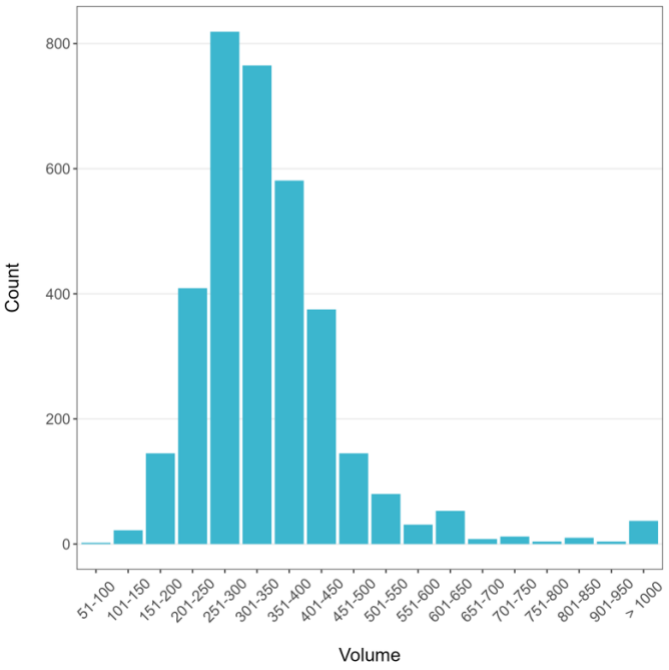
Patients undergoing primary operations due to benign breast conditions are mostly of normal weight (77.2%). Only 1.2% had a BMI of 30 or more. This, compared to four times as many in the group with breast cancer or risk-reducing mastectomies, as per the 2021 annual report. This is likely due to the possibility to select harder for benign conditions, since it is well-known that complications increase with obesity. The group with breast cancer or risk-reducing mastectomies had far more cases with unknown BMI (19.7%), compared with 2.7% for benign conditions.



Figur 7a. BMI at time of primary surgery for benign conditions



Figur 7b. BMI at time of primary surgery for benign conditions in relation to age



Figur 7c. Distribution of implant volumes in primary surgery for benign conditions

Surgical Approach, Implant Positioning and Size

The placement of implants has been more or less unchanged since the start of BRIMP. Most colleagues place the breast implant in a dual plane or a sub-muscular position. Sub glandular (7.7%) or subfascial (0.7%) placement was chosen consistently by a minority (Table 5). The use of mesh or fat transplantation during the primary operation occured in a minority of patients. The most common incision is through the infra-mammary fold. Only 5.1% of implants were placed via the axilla. The chosen implant volume was primarily (72%) between 200 and 399 ml in 2022. Volumes greater than 400 ml were chosen for 23.9% whereas volumes greater than 600 ml were used in 2.8% of the patients. For the first time, we present a histogram stratified into steps of 50 ml to illustrate the most common implant sizes more clearly.

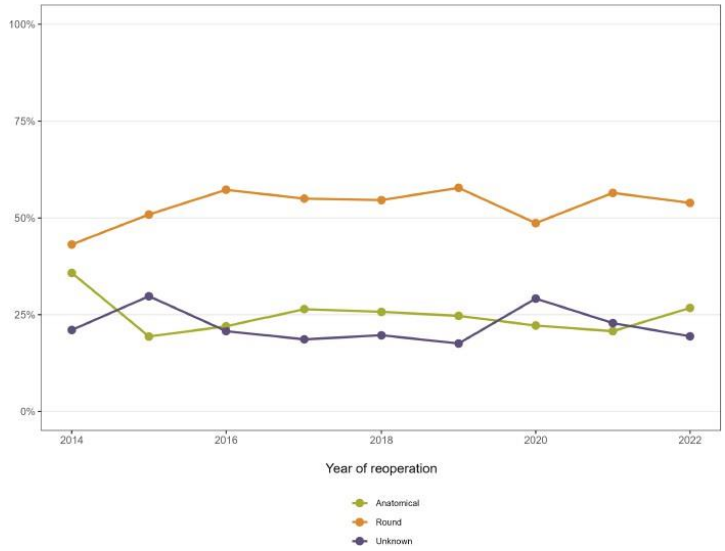
Summary

In 2022, data for primary operations in patients with benign breast disease has registered 3502 implants in 1758, mainly normal-weight, patients. Mentor and Motiva's products clearly dominate the market today. Irrigation of the implant cavity or the implant before insertion occurred in 24.8% of the reported primary operations, which is a reduction of 3.5% from the year previously. Possibly, this is related to the previous increase being highlighted and discussed at the national meetings for the Swedish Plastic Surgery Association, and the Swedish Association for Aesthetic Plastic Surgery, where BRIMP data was presented. Implant position is primarily dual plane or submuscular. Implant size up to 399 ml was used in the majority of cases, where size 251-300 ml was most common. Hybrid operations with mesh or fat form a minority of procedures among the primary operations for benign disease in the BRIMP database.

Reoperations - Production Data Regarding Reoperation Regardless of Indication and Date for Primary Operation

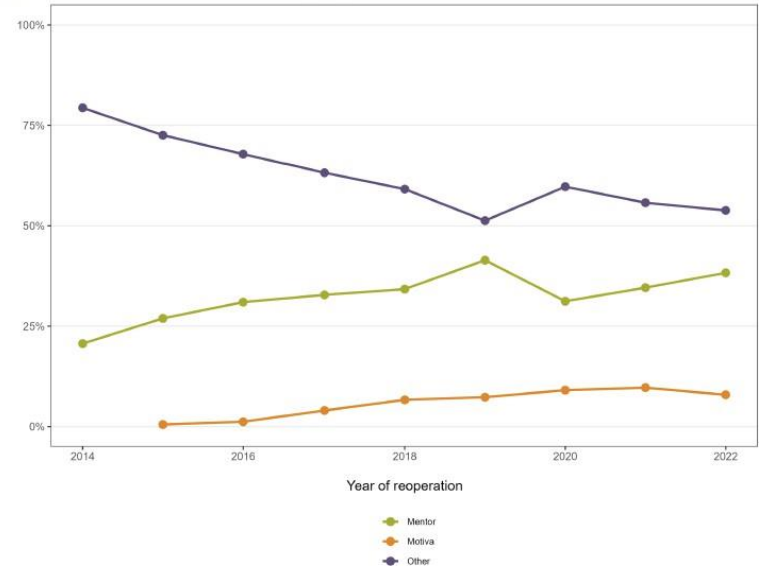
Of note, we only look at reasons for the first reoperation. Thus, only the indications registered at the first reoperation are reported. Data is presented regardless of the date of the primary operation and indication.

In 2022, a total of 2680 revisions were registered. This corresponds to an increase of 16 % from 2309 revisions in 2021. The increase the year before was 15 %. As in previous years, the use of brands other than Mentor and Motiva dominated the reoperations. In some of these cases, it may have been difficult to determine the implant's make, as shown in Figure 9. Figure 8 demonstrates that round implants were most commonly associated with reoperation. As in previous annual reports, patient reported factors, such as a desired change in volume (48%) and shape (43%), dominated reasons for reoperation. Of particular interest, we noted a continued high proportion of reoperations due to concern for the implant (27%) as well as a continued increase of desired permanent implant removal (37%) (Figure 10). Implant rupture was identified in 11.6% of 14,150 revised implants 2014–2021 and in 12.2% in 2022 (Figure 10). Rotation of implants was noted in 3.7% of cases in 2022, compared with 4.4% in 2014-2021.
Implant displacement was found in 7.6% of cases 2014–2021 and 6.3% of revisions in 2022. Data regarding displacement of implants associated with smooth implants will be important to examine in future annual reports.

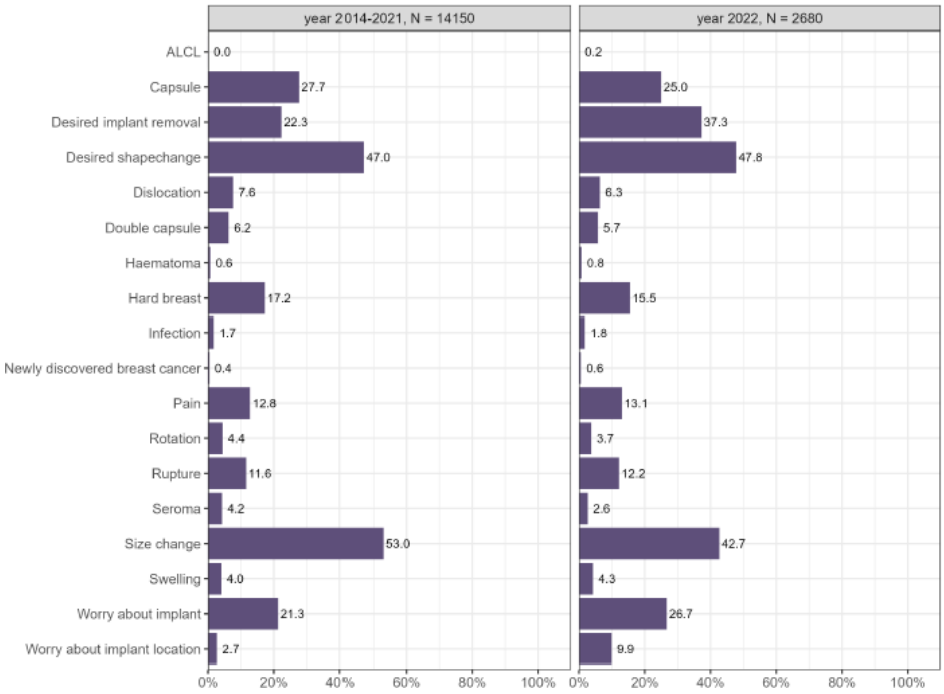


Figur 8a. Implant surface in reoperation regardless of indication

[1] “Figur8b_Fabrikat_över_tid.png”



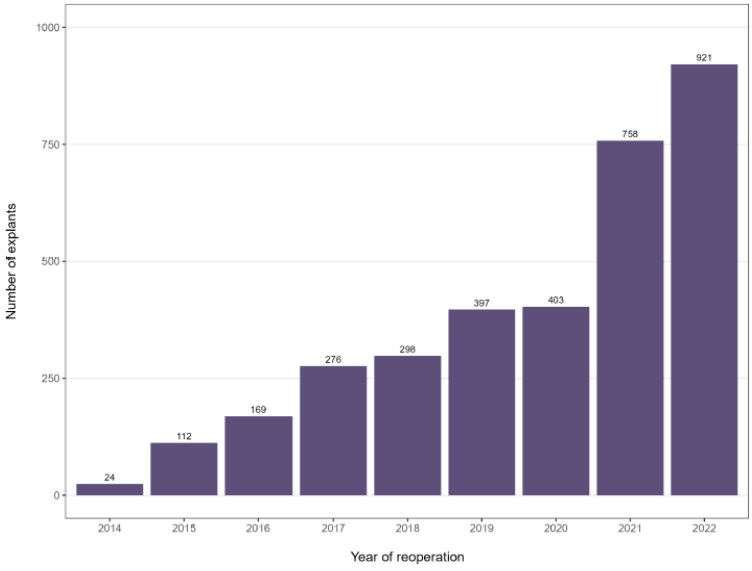
Figur 8b. Implant manufacturer in reoperation regardless of indication



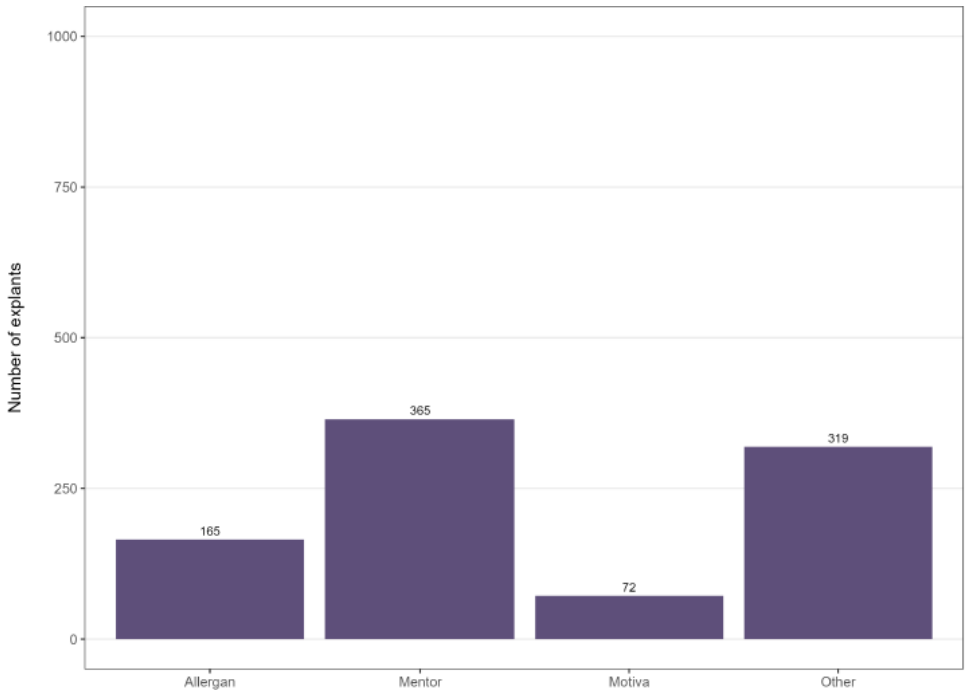
Figur 9. Reported indications and perioperative status in the reoperation of implants in 2014–2021 and in 2022

Permanent Removal of Implants

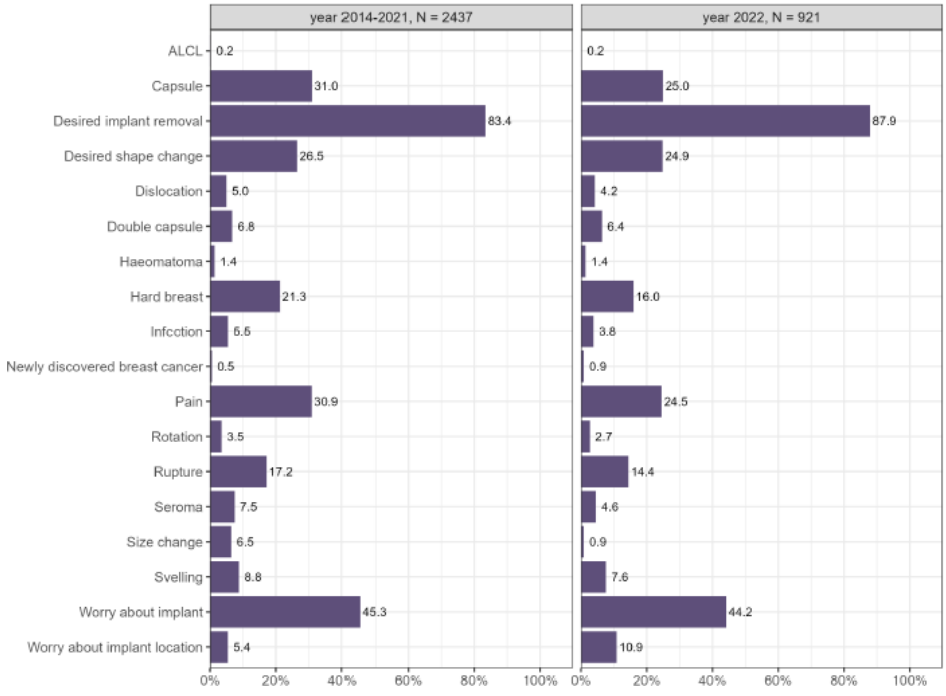
Permanent removal of implants has gradually increased over the years and reached a new record level in 2022. This represents an increase in number from 758 in 2021 to 921 in 2022 (Figure 11). Mentor was the most common manufacturer for the implants that were permanently removed (Figure 12). Investigating the causes of permanent removals, we identified the main reason being patient concern about the implants. This is true for all, regardless of diagnosis (Figure 13), or benign indications alone (Figure 14). The most frequently used implant surface was micro/ macrotextured implants (Figure 15).Painful capsular contracture has long been a dominating cause for permanent removal of implants but patient concerns about long-term systemic effects have now come to dominate. It is also noted that 17.2 % of patients 2014–2021 and 14.4 % in 2022 had a ruptured implant at the time of reoperation. Whether the implant rupture was diagnosed preoperatively was not evident from the information in BRIMP.



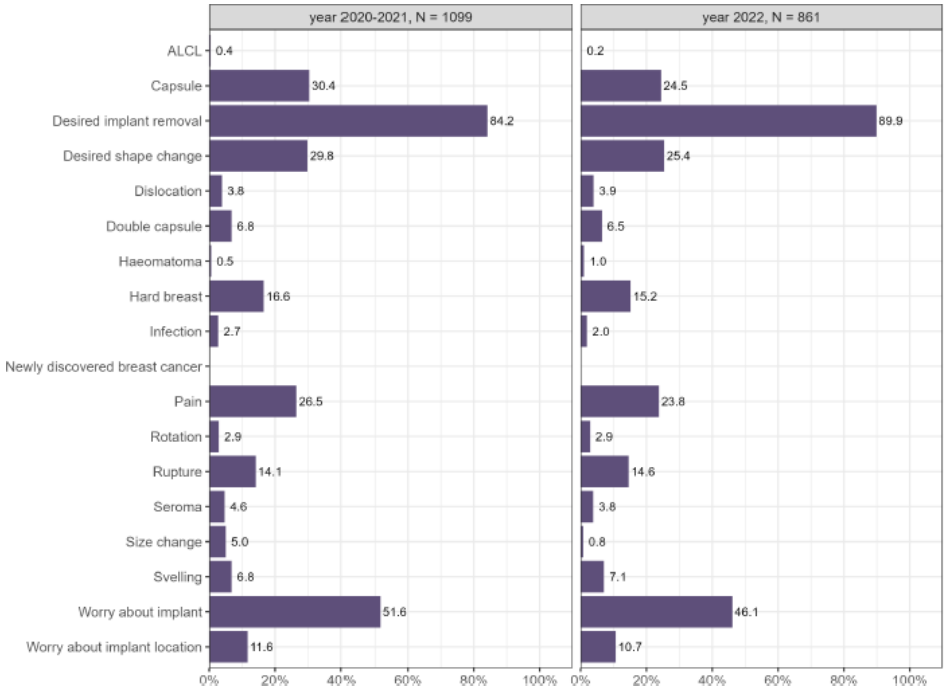
Figur 10a. Number of permanent removals of implants per year



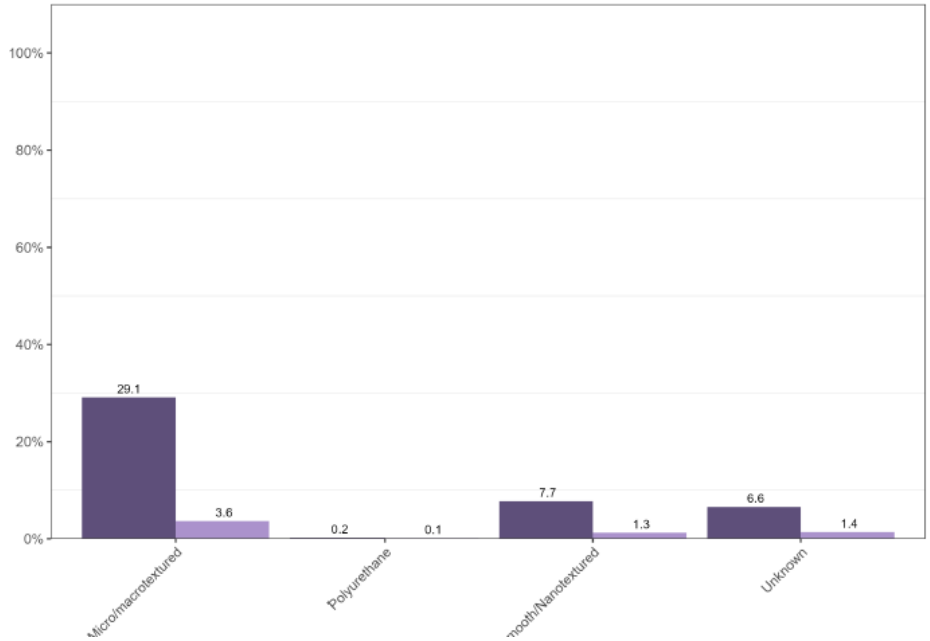
Figur 10b. Manufacturer for the implants that were permanently removed



Figur 11a. Reported indications for permanent implant removal of all implants in 2014-2021 and in 2022



Figur 11b. Reported causes of permanent removal of implants, benign indications in 2014-2021 and in 2022



Figur 12. Reported implant surface for permanent removal of implants in 2014–2021 and in 2022

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

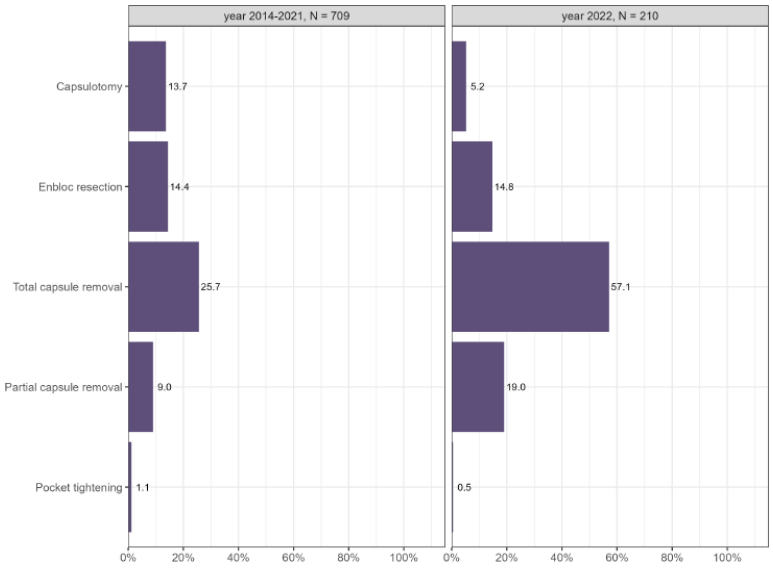
Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) is a rare T-cell lymphoma that can develop long after insertion of breast implants. There are about ten known cases of BIA-ALCL in Sweden, where not all are registered in BRIMP. This is partly explained by the fact that some were operated before the inception of BRIMP, but the discrepancy also highlights the importance of ensuring high future coverage in BRIMP. In the first registry withdrawal in 2022, there were eight cases of BIA-ALCL, which is remarkable. The same occurred last year when health care providers were contacted immediately to confirm the cases, however it turned out that all registrations of BIA-ALCL were incorrect in 2022. The health care professionals responsible for these cases have confirmed in writing that an error in registration has occurred but have not yet corrected them. We have repeated our request for corrections in the registrations. These errors therefore explain the outcome regarding BIA-ALCL shown in Figures 13 and 14. We have revised the form for registration where we have separated BIA-ALCL, and where you must now also register diagnosis preoperatively and postoperatively. This will first be evaluated in the next annual report.

Breast Implant Illness (BII)

Breast Implant Illness is a complex of symptoms where muscle and joint pain, headache and fatigue are some of the symptom's women experience related to silicone implants. According to the FDA, the American counterpart to the Swedish Medical Products Agency, there is currently no scientific evidence that breast implants cause connective tissue diseases, and, to date, there are no studies that clearly prove an association between breast implants and these symptoms. Research on the topic is intense and within BRIMP we have added the variable Symptom Complex Breast Implant Illness as a selectable indication for operation on the questionnaire for reoperation. In 2021, 88 cases of the symptom complex BII were registered preoperatively. Whether the symptoms are affected by the operation is currently not possible to determine with the help of BRIMP. Going forward, we predict BRIMP being an important cohort to study BII.

What is done with the capsule upon removal of implant?

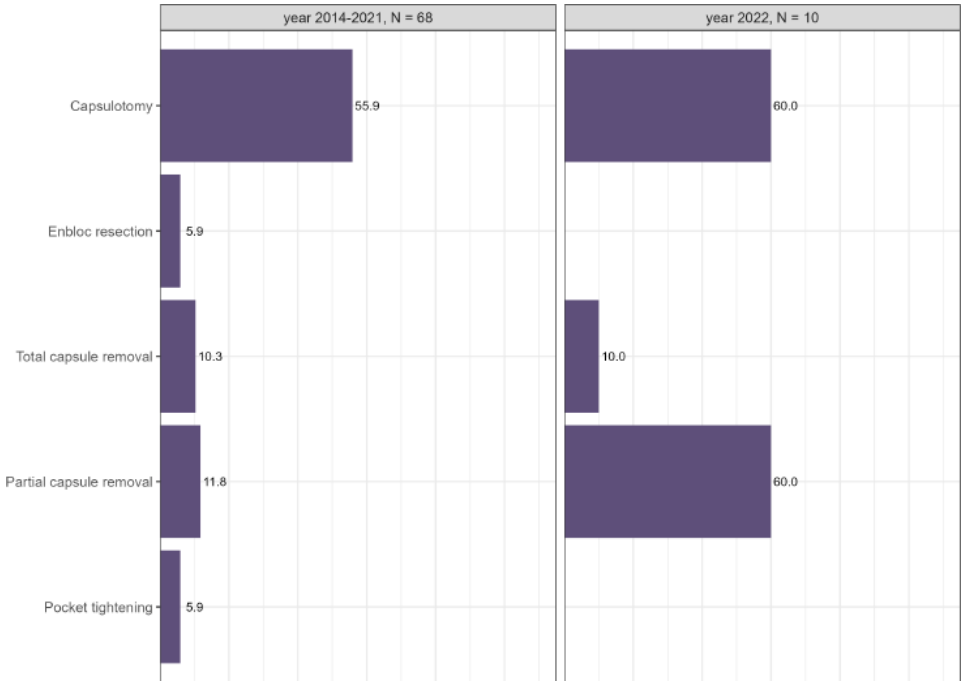
Prior to 2020, only whether capsulectomy had been performed or not, was registered. Since 2020, more detailed information on the handling of the capsule during reoperation has been registered with the following variables: capsulorrhaphy, partial capsulectomy, total capsulectomy and 'en bloc' resection. En bloc resection means resection of the implant and the intact capsule in one piece and was registered in 15% of cases of permanently removed implants in 2022. Recommended practice for the curative treatment of BIA-ALCL is en bloc resection but, as described above, there are to date only ten known cases of BIA-ALCL in Sweden. Of note, there is no international or Swedish standard for this treatment in benign conditions, thus 15% en bloc resections is a relatively high proportion and must be interpreted as self-selected by the patient. There is currently no evidence-based medical indication for en bloc resection in cases of patient concern or symptoms of BII. It is also associated with risks such as pneumothorax. Where permanent removal of implant was performed, 57% have undergone total capsulectomy and 19% a partial capsulectomy (Figure 16).



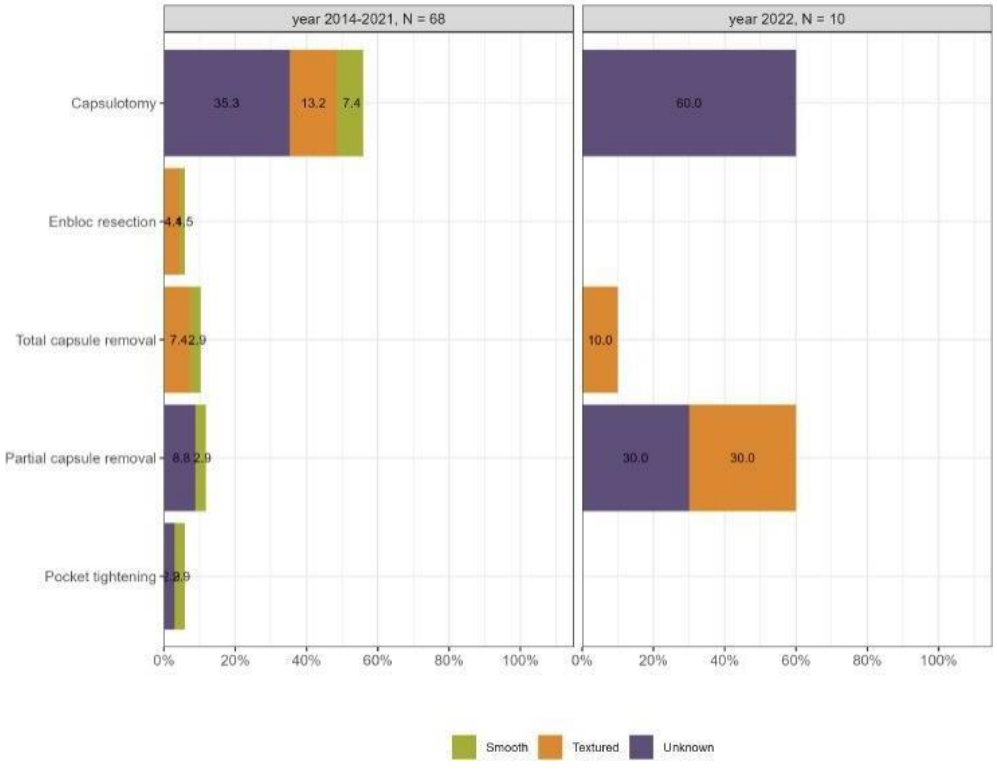
Figur 13. Capsule procedures for permanent removal of implants in 2014–2021 and in 2022

Capsule Handling During Reoperation and Insertion of New Implant

Increasingly extensive handling of the capsule has been noted over the years. In some cases, the patient undergoes several operations if she is affected by an infection associated with the primary operation. To manage an infection in the implant cavity, removal of implant is required. A new implant can be inserted after a few months. Figure 20 shows how the residual capsule is handled during the reoperation and upon insertion of a new implant. In 2022, no cases of en bloc resection were recorded in this group (n = 10), which is encouraging.



Figur 14. Capsule procedures for permanent removal of implants and insertion of a new implant in 2014–2021 and in 2022



Figur 15. Implant surface for permanent removal of implants and insertion of new implants in 2014–2021 and in 2022

Summary

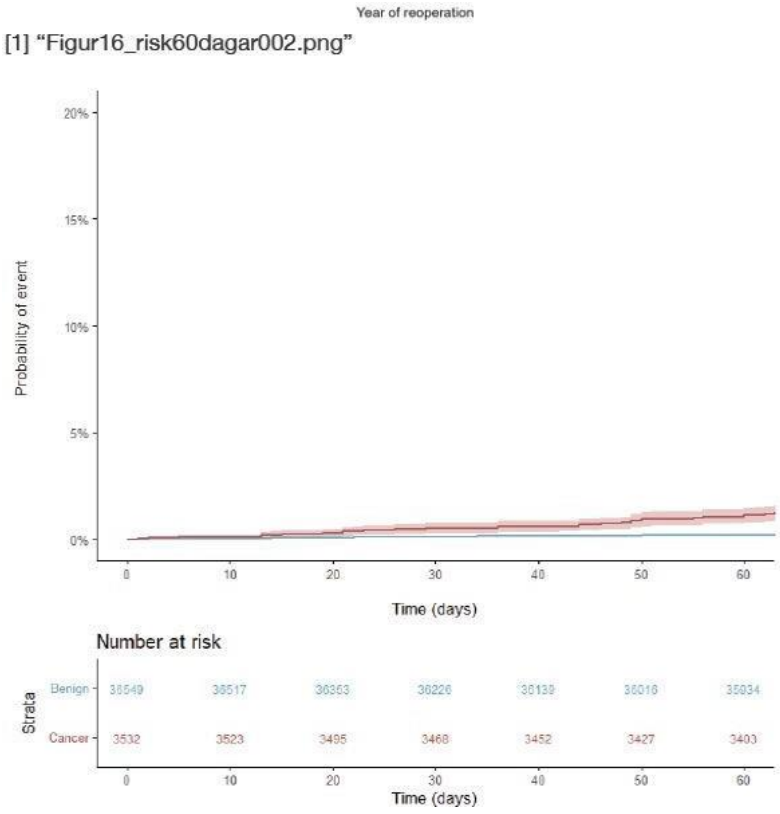
This section shows data in BRIMP from reoperations of 16,830 implants regardless of diagnosis and time of primary surgery. Patients reported that the most common motivation for reoperation was a desire for change in form and volume. In 2022, capsule formation was reported in 25% of cases where 15.5% reported a hard breast and 13.1% reported pain. A ruptured implant was noted in 11.6% of 14,150 revised implants in 2014–2021 and in 12.2% of 2680 revised implants in 2022. This is regarded as a constant frequency. Implant malposition was identified in 7.6% of cases in 2014–2021 with an increase from 4.9% in 2021 to 6.3% in 2022. Permanent removal of implants has increased steadily over these nine years. In 2020, this number was 403, in 2021 758, and in 2022 a total of 921 cases were registered. The main reason for this has been patient concern about the implant's systemic effects on the body. Concerns about the negative effects of implants have increased due to information in social media about Breast Implant Illness and the breast implant-related lymphoma of the breast capsule, BIA-ALCL. A number of errors in registration of BIA-ALCL are noteworthy, and reporting clinics need clearer information about this variable. In 2022, the form for registration of BIA-ALCL has been clarified and has been made a separate entity. Recently, it has been further clarified with separate variables for preoperative and postoperative diagnosis of BIA-ALCL to reduce the risk of errors in registration.

Risk of a New Operation Regardless of Indication

The reporting pertains to all patients in BRIMP with a primary operation in 2014-2021 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 done with log rank-test where $p < 0.05$ are significant. Further reoperations of the same breast are not part of the calculations below.

Short-term Risk of Reoperation Within 60 Days and 1 Year

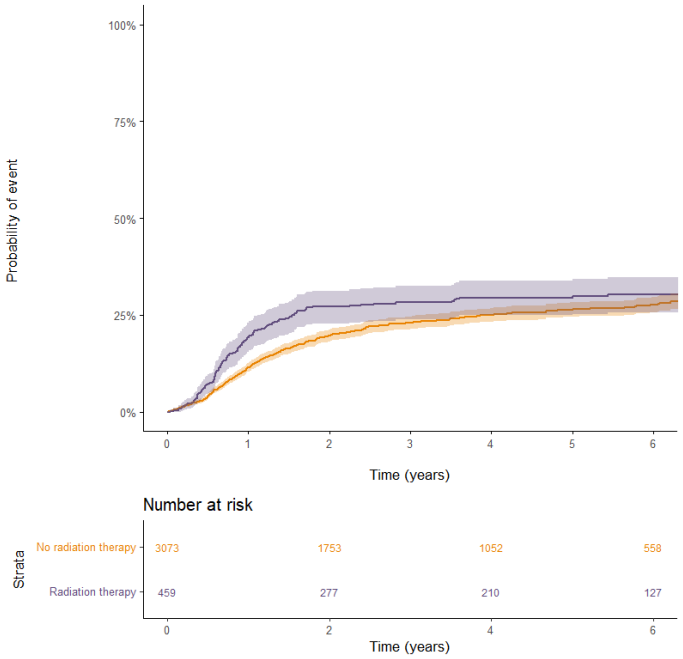
The short-term general risk of reoperation within 60 days, regardless of indication, is very low. Although the groups did differ somewhat, with a higher risk in the breast cancer and risk-reducing mastectomy groups ($p < 0.001$) (Figure 16). The figure shows that the risk increases over time, at observation time one year, in the breast reconstruction cohort (breast reconstruction after cancer and risk-reducing mastectomies). The difference between the patient groups is statistically significant ($p < 0.001$).



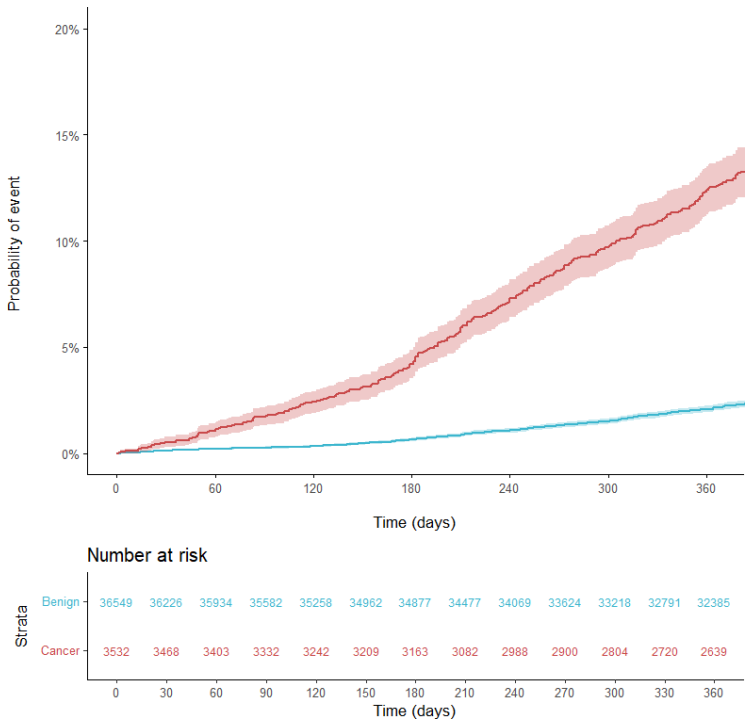
Figur 16. Risk of reoperation within 60 days

Long-term Risk of Reoperation Within 6 Years

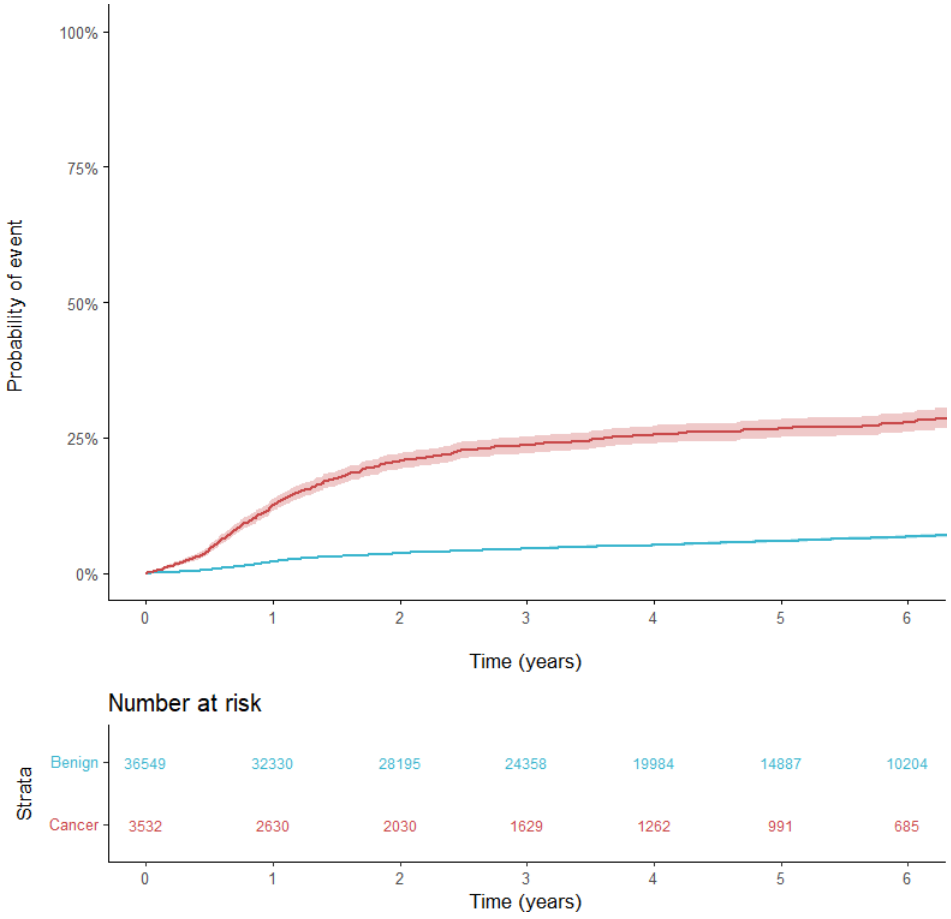
In the cohort receiving reconstruction after breast cancer and risk-reducing mastectomies, the general risk of reoperation is significantly higher (26 %) compared to breast augmentation for benign conditions (6.8 %). Reconstructed patients show a relatively constant risk profile for reoperation two to six years after the primary operation. A known confounding factor is radiotherapy which significantly increases the risk of reoperation in the cancer group during the observation period. BRIMP's data confirms the clinical experience (Figure 23). When analysing the impact of radiotherapy, it was found that reconstructed patients receiving radiotherapy have a 29.1 % risk of reoperation within six years compared to 25.6 % for non-irradiated patients. The difference is significant ($p < 0.001$) (Figure 20).



Figur 17. Risk of reoperation within six years in reconstructed patients, divided into radiated and non-irradiated patients



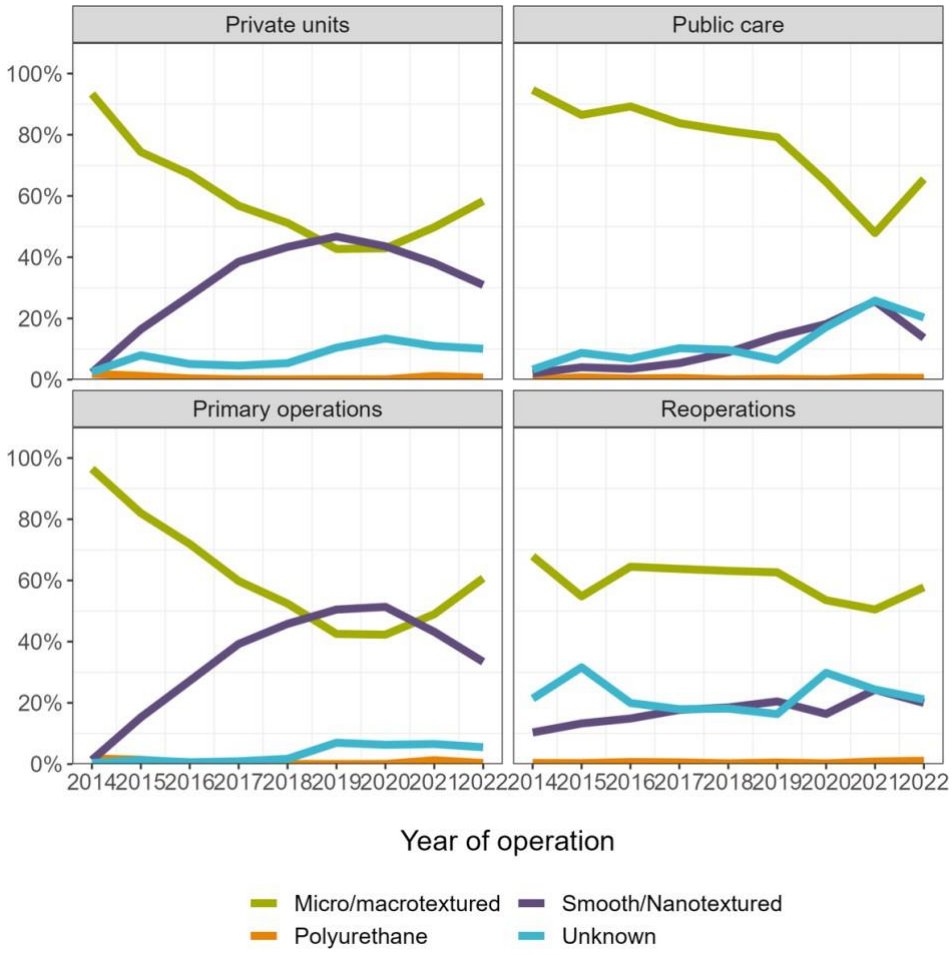
Figur 18. Risk of reoperation within 365 days



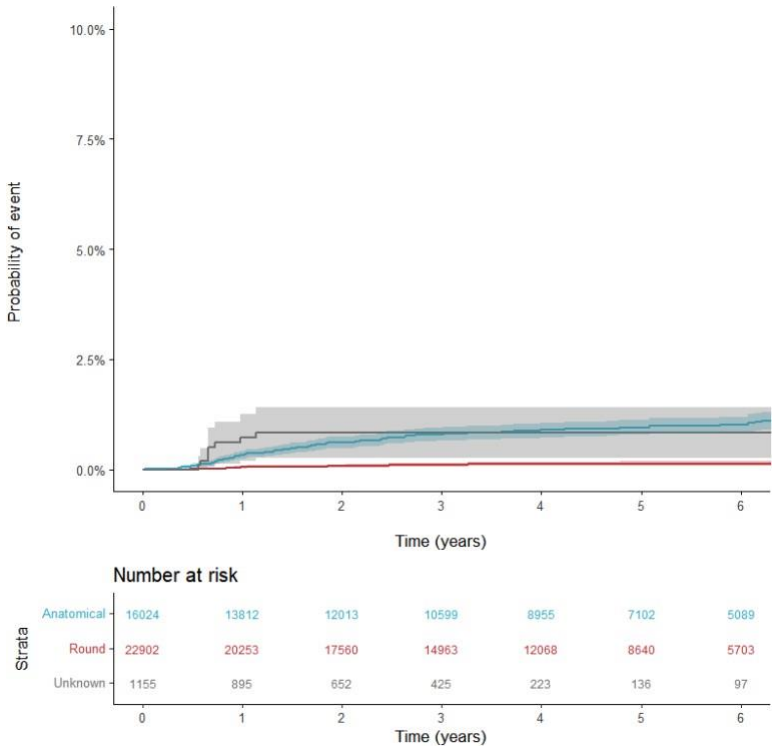
Figur 19. Risk of reoperation within six years; benign vs cancer

Trends for Implant Choice Regardless of Indication 2014-2021

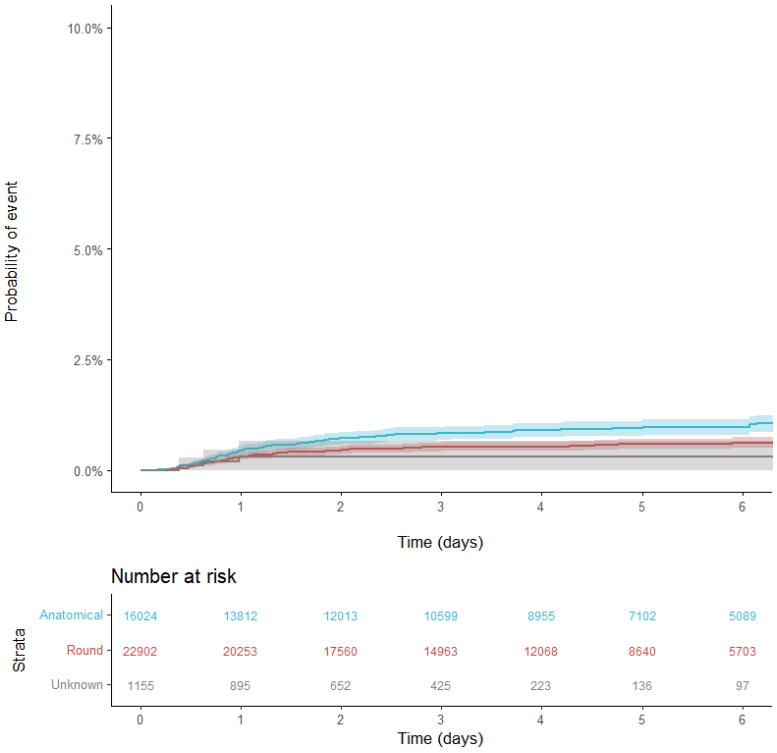
A gradual increase in the use of smooth implants has been noted after WHO defined BIA-ALCL as its own disease entity in 2016. The diagnosis has mainly been related to macrotextured implants from Allergan, which are no longer on the market Sweden. Polyurethane implants make up only a small portion of the Swedish market. Thus, for new implants, the group micro/macrotextured now consists mainly of microtextured implants. Of note, Motiva's nanotextured implants are currently registered as smooth implants until a new agreement for a EU standard on various implant surfaces is available. Simultaneously, there has been a debate regarding the possible increased risk of reoperation with smooth implants due to malposition. This has led to some clinicians returning to textured implants. We have therefore chosen to show the use of implants with different surfaces over time within private (Figure 25a) and public care (Figure 25b), and for all primary operations (Figure 25C) and reoperations (Figure 25D) 2014–2021. Results show that there is a gradual increase in the use of smooth implants in the public setting, and a relative reduction in the use of textured implants. This trend has been noted over the course of several years in the private setting, but according to BRIMP data it looks to have reversed during 2021.



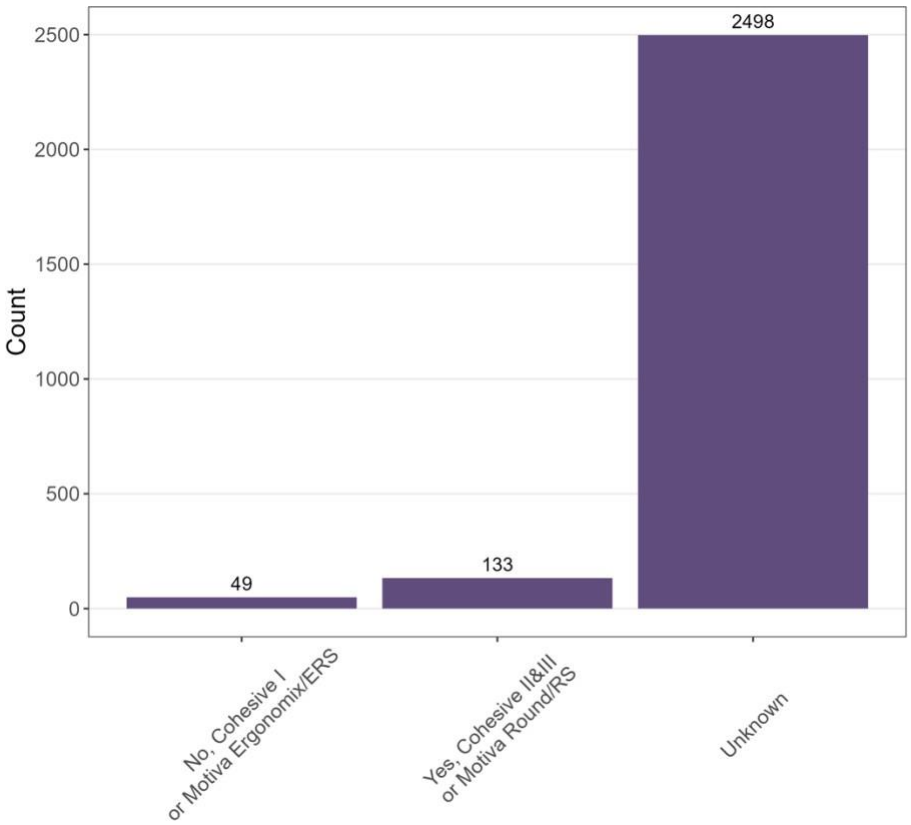
Figur 20. Implant surface for all implants in BRIMP divided into comparison between a) private clinics vs b) public clinics, and divided into c) primary operations vs d) reoperations



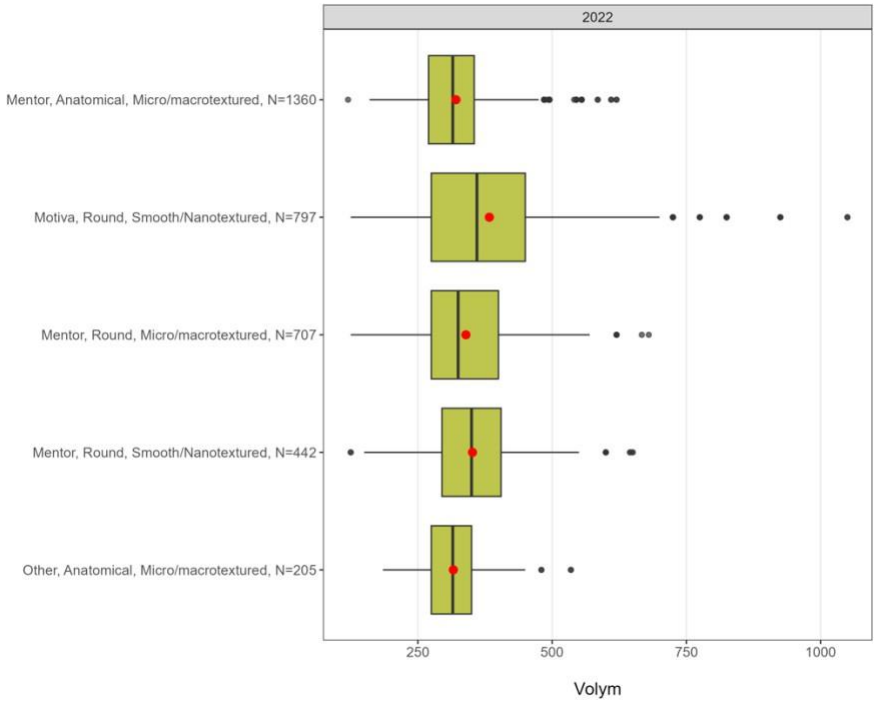
Figur 21. Risk of rotation of anatomical implants (blue) within six years (1.02%)



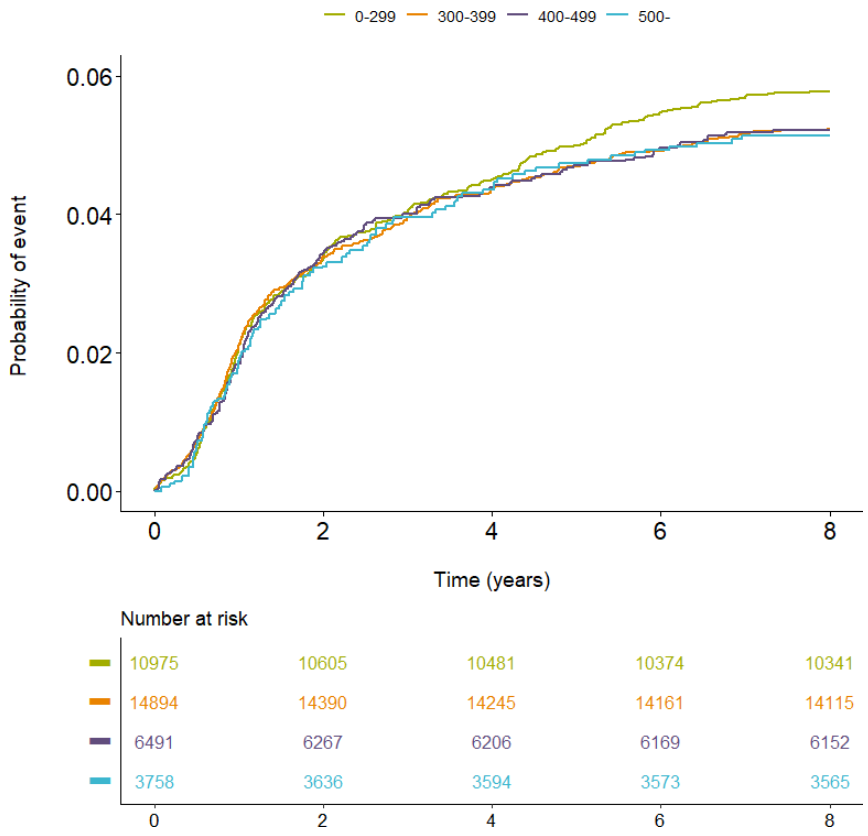
Figur 22. Risk of reoperation within six years due to malposition



Figur 23. Form stability of implants at reoperation



Figur 24 The most common implants based on make and surface, reported in box plots for volume distribution (benign primary operations only)



Figur 25. Risk of reoperation within eight years related to volume (benign primary operations only)

Tables

Tabell 1. Registrerade primäroperationer, samtliga indikationer.

Region	Number of implants, year 2014–2021	Number of implants, year 2022	Number of patients, year 2014–2021	Number of patients, year 2022
Dalarna	336	39	221	25
Gotland	3	2	3	1
Gävleborg	848	80	427	48
Halland	42	34	26	23
Jönköping	1723	238	883	126
Kalmar	542	0	300	0
Kronoberg	72	10	64	8
Skåne	7089	547	3682	285
Stockholm	12168	1093	6288	582
Uppsala	2420	206	1258	109
Västerbotten	730	94	378	48
Västmanland	11	0	9	0
Västra Götaland	9944	1284	5065	658
Örebro	200	32	142	23
Östergötland	1778	361	939	185
Riket	**37906**	**4020**	**19685**	**2121**

Tabell 2. Registrerade primäroperationer, indikation cancer/cancerrisk.

Region	Number of implants, year 2014–2021	Number of implants, year 2022	Number of patients, year 2014–2021	Number of patients, year 2022
Dalarna	183	19	138	15
Gotland	2	2	2	1
Gävleborg	5	24	5	19
Halland	41	34	25	23
Jönköping	31	18	26	16
Kalmar	79	0	66	0
Kronoberg	69	7	61	6
Skåne	513	70	373	46
Stockholm	1023	154	662	110
Uppsala	222	31	143	21
Västerbotten	43	11	33	7
Västmanland	10	0	8	0
Västra Götaland	323	99	232	65
Örebro	143	32	107	23
Östergötland	336	17	209	11
Riket	**3023**	**518**	**2090**	**363**

Tabell 3. Registrerade primäroperationer, benign indikation.

Region	Number of implants, year 2014–2021	Number of implants, year 2022	Number of patients, year 2014–2021	Number of patients, year 2022
Dalarna	151	20	81	10
Gotland	1	0	1	0
Gävleborg	843	56	422	29
Halland	1	0	1	0
Jönköping	1692	220	857	110
Kalmar	371	0	188	0
Kronoberg	3	3	3	2
Skåne	6524	477	3283	239
Stockholm	10 321	939	5207	472
Uppsala	2198	175	1115	88
Västerbotten	687	83	345	41
Västmanland	1	0	1	0
Västra Götaland	8835	1185	4434	593
Örebro	57	0	35	0
Östergötland	1422	344	718	174
Riket	**33 107**	**3502**	**16 691**	**1758**

Tabell 4. Intraoperativa tekniker, primäroperationer indikation cancer/cancerrisk.

Variable	Outcome	Proportion year 2014-2021 (%)	Proportion year 2022 (%)
Fat graft	Yes	1.3	3.1
Fat graft	No	61.6	87.3
Fat graft	Unknown	37.1	9.7
Incision	Axillary	0.2	0.4
Incision	Mastectomy scar	51.3	34.6
Incision	Mastopexy with augmentation	2.6	6.9
Incision	Periareolar	6.2	4.2
Incision	Submammary	28.0	44.4
Incision	Unknown	6.2	9.5
Incision	NA	5.4	0
Mesh	Yes	10.9	30.5
Mesh	No	39.0	49.0
Mesh	Unknown	50.1	20.5
Position	Dual plane	17.2	32.4
Position	Subfascial	1.1	2.1
Position	Submuscular	73.0	45.4
Position	Unknown	4.7	6.8
Position	NA	4.0	13.3
Previously operated due to infection	Yes	1.6	0.8
Previously operated due to infection	No	91.8	89.0
Previously operated due to infection	Unknown	6.7	10.2
Previously operated due to mastopexy/reduction	Yes	5.8	5.6
Previously operated due to mastopexy/reduction	No	87.7	84.2
Previously operated due to mastopexy/reduction	Unknown	6.5	10.2
Previously operated due to tumor	Yes	41.8	29.2
Previously operated due to tumor	No	53.8	63.5
Previously operated due to tumor	Unknown	4.4	7.3
Volume ml/cc/g	<199	9.7	9.3
Volume ml/cc/g	200-399	54.9	56.9
Volume ml/cc/g	400-599	24.6	24.7
Volume ml/cc/g	>=600	1.6	1.2
Volume ml/cc/g	Unknown	9.3	7.9

Tabell 5. Intraoperativa tekniker, primäroperationer, godartad indikation.

Variable	Outcome	Proportion year 2014-2021 (%)	Proportion year 2022 (%)
Fat graft	Yes	0.3	0.4
Fat graft	No	58.0	81.7
Fat graft	Unknown	41.7	17.9
Incision	Axillary	11.1	5.1
Incision	Mastectomy scar	0.5	0.4
Incision	Mastopexy with augmentation	4.1	11.9
Incision	Periareolar	0.5	0.2
Incision	Submammary	80.3	77.6
Incision	Unknown	1.4	4.9
Incision	NA	2.2	0
Mesh	Yes	0.1	0.3
Mesh	No	44.4	77.0
Mesh	Unknown	55.5	22.7
Position	Dual plane	57.1	60.6
Position	Subfascial	0.7	0.7
Position	Submuscular	34.5	28.5
Position	Unknown	1.9	2.4
Position	NA	5.8	7.7
Previously operated due to infection	Yes	0.2	0.1
Previously operated due to infection	No	89.3	85.3
Previously operated due to infection	Unknown	10.5	14.5
Previously operated due to mastopexy/reduction	Yes	3.1	2.9
Previously operated due to mastopexy/reduction	No	86.5	82.4
Previously operated due to mastopexy/reduction	Unknown	10.4	14.8
Previously operated due to tumor	Yes	0.4	0.2
Previously operated due to tumor	No	89.3	85.3
Previously operated due to tumor	Unknown	10.3	14.5
Volume ml/cc/g	<199	2.6	3.4
Volume ml/cc/g	200-399	67.7	71.7
Volume ml/cc/g	400-599	24.6	21.1
Volume ml/cc/g	>=600	3.9	2.8
Volume ml/cc/g	Unknown	1.2	1.0

Operation form

PRIMÄROPERATION

Personnummer:_____

Operationsdatum (åååå-mm-dd): _____

Längd (cm): _____

Vikt (kg): _____

Antibiotika	Ja	Nej
Profylaktisk 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: _____

Serienummer: PLATS FÖR DEKAL

Innehåll

◯ Koksaltlösning ◯ Silikon ◯ Koksaltlösning och silikon

Volym _____ml / cc / g

Stämplad volym (expanderprotes)_____

Yta

◯ Slät/Nanotexturerad ◯ Mikro/Makrotexturerad ◯ Polyuretan

Form före implantation *Motiva Ergonomix registreras som rund form.*

◯ Rund ◯ Anatomisk

Implantat- eller expanderläge

◯ Submuskulärt ◯ Subglandulärt/Prepektoralt
◯ 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: _____

Serienummer: PLATS FÖR DEKAL

Innehåll

◯ Koksaltlösning ◯ Silikon ◯ Koksaltlösning och silikon

Volym _____ml / cc / g

Stämplad volym (expanderprotes)_____

Yta

◯ Slät/Nanotexturerad ◯ Mikro/Makrotexturerad ◯ Polyuretan

Form före implantation *Motiva Ergonomix registreras som rund form.*

◯ Rund ◯ Anatomisk

Implantat- eller expanderläge

◯ Submuskulärt ◯ Subglandulärt/Prepektoralt
◯ 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 2022-05-18

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 st tatus				
Ruptur/Deflaion	Ja	Nej	Ja	Nej
Rotation	Ja	Nej	Ja	Nej
Felläge/Migration	Ja	Nej	Ja	Nej
Double Bubble	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

Bekräftad ALCL preoperativt	**Ja**	**Nej**	**Ja**	**Nej**
Bekräftad ALCL postoperativt	**Ja**	**Nej**	**Ja**	**Nej**

Åtgärd	**VÄNSTER**		**HÖGER**	
Permanent uttag av implantat	Ja	Nej	Ja	Nej
Återint sättning av befinligt 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
Lambå	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 2022-05-18

REOPERATION

Personnummer: _____

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 *Motiva Ergonomix registreras som rund form.*

◯ Rund ◯ Anatomisk

Yta ◯ Slät/Nanotexturerad ◯ Mikro/Makrotexturerad ◯ Polyuretan

Läge ◯ Submuskulärt ◯ Subglandulärt/Prepektoralt ◯ Subfasciellt ◯ Dual plane

Implantat som SÄTTS IN

Typ av permanent implantat

◯ Implantat ◯ Expanderprotes

Tillverkare: _____

Serienummer:

PLATS FÖR DEKAL

Innehåll

◯ Koksaltlösning ◯ Silikon ◯ Koksaltlösning och silikon

Volym: _____

Stämplad volym (expanderprotes): _____

Form före implantation *Motiva Ergonomix registreras som rund form.*

◯ Rund ◯ Anatomisk

Yta ◯ Slät/Nanotexturerad ◯ Mikro/Makrotexturerad ◯ Polyuretan

Läge ◯ Submuskulärt ◯ Subglandulärt/Prepektoralt ◯ Subfasciellt ◯ Dual plane

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 *Motiva Ergonomix registreras som rund form.*

◯ Rund ◯ Anatomisk

Yta ◯ Slät/Nanotexturerad ◯ Mikro/Makrotexturerad ◯ Polyuretan

Läge ◯ Submuskulärt ◯ Subglandulärt/Prepektoralt ◯ Subfasciellt ◯ Dual plane

Implantat som SÄTTS IN

Typ av permanent implantat

◯ Implantat ◯ Expanderprotes

Tillverkare: _____

Serienummer:

PLATS FÖR DEKAL

Innehåll

◯ Koksaltlösning ◯ Silikon ◯ Koksaltlösning och silikon

Volym: _____

Stämplad volym (expanderprotes): _____

Form före implantation *Motiva Ergonomix registreras som rund form.*

◯ Rund ◯ Anatomisk

Yta ◯ Slät/Nanotexturerad ◯ Mikro/Makrotexturerad ◯ Polyuretan

Läge ◯ Submuskulärt ◯ Subglandulärt/Prepektoralt ◯ Subfasciellt ◯ Dual plane

BRIMP – Reoperationsformulär 2022-05-18

Variabel definitions

Primäroperation

Variabel	Definition
Personnummer	Patientens födelsedag och 4 sista siffror
Operationsdatum	Datum när indexoperationen sker
Längd	Patientens självrapporterade kroppslängd i cm
Vikt	Patientens självrapporterade vikt i kg
Sida. Respektive sidas bröstoperation registreras var för sig.	
Vänster sida	Dataregistrering avseende vänster bröst
Höger sida	Dataregistrering avseende höger bröst
Operationsindikation	Anledning till implantatbaserad operation
Godartade brösttillstånd	Aplasier, hypoplasier, patientupplevd hypoplasie, hypoplsier efter graviditet eller massiv viktnedgång, insättning av implantat TS patienter
Medfödda bröstsjukdomar	Tuberösa bröst, bröstassymetrier
Rekonstruktion efter riskreducerande mastektomier	Kirurgisk åtgärd där bröstet rekonstrueras med implantat eller expanderprotes samtidigt eller vid ett senare skede efter borttagning av bröstvävnad
Rekonstruktion efter cancer	Kirurgisk åtgärd där bröstet rekonstrueras med implantat eller expanderprotes samtidigt eller vid ett senare skede efter borttagning av tumör
Genomgången strålbehandling innan primäroperation	Strålbehandling given till bröst eller bröstkorgen innan det aktuella implantatet sätts in
Fettransplantation	Komplettering av implantatbaserad operation med patientens eget fett
Typ av permanent implantat	Specifikation av det aktuella implantatet
Implantat	EU-godkänd medicinsk produkt avsett för förstoring eller rekonstruktion av bröst
Expanderprotes	EU-godkänd medicinsk produkt avsett för stegvis expansion av thoraxväggens mjukdelar i syfte att rekonstruera bröstet i ett ”enstegsförfarande”
BRIMP registrerar inga tvåstegsförfarande. Implantatbyten efter intermittenta expandrar registreras som primärinsättning av implantat och inte som reoperation.	
Implantattillverkare	Namn på industriföretaget som tillverkar det aktuella implantatet
Innehåll	Beskriver implantatets eller expanderprotesens kemiska fyllnadsmaterial
Silikon, koksalt eller kombination	Varianter av fyllnadsmaterial
Serienummer	Serienummer på implantat eller expanderprotes
Volym	Mäts i ml, cc eller g. PRINT på implantat eller expanderprotes via tillverkande industri eller mätt intraoperativt genom Arkimedes princip
Typ av yta	Specifikation av implantatets eller expanderprotesens yta
Slät/Nanotexturerad, Mikro/Makrotexturerad, Polyuretan	Beskaffenhet av implantatets eller expanderprotesens yta
Form före implantation	Form på implantat eller expanderprotes

Rund	Implantatets form är rund. Motiva Ergonomix registreras som rund form
Anatomisk	Implantatets eller expanderprotesens form liknar formen på ett droppformat mer moget bröst
Operation	
Implantat- och expanderläge	Läge på implantatet eller expanderprotesen
Submuskulärt	Implantatet eller expanderprotesen placeras under pektoralismuskeln
Subglandulärt/Prepektoralt	Implantatet eller expanderprotesen placeras ovanpå pektoralismuskeln
Subfaciellt	Täckning av implantatet med pektoralisfascia ovanpå pektoralismuskeln
Dual plane	Täckning proximalt om bröstvårtgården med pektoralismuskeln, distalt om bröstvårtgården med bröstvävnad
Operationssnitt	Tillvägagångssättet vid insättning av implantat eller expanderprotes
Submammart	Operationssnitt i det naturliga vecket under bröstet eller i det tidigare naturliga vecket efter mastektomi
Axillärt	Operationssnitt i armhåla
Periareolärt	Operationssnitt i kanten av bröstvårtan
Mastektomi ärr	Operationssnitt i det tidigare ärret efter mastektomi
Mastopexi med augmentation	Insättning av implantat genom planerad hudresektion kaudalt om bröstvårdgården
Nät/ADM	Insättning av nät eller ADM vid operationen
Tidigare bröstopererad	Dokumenterar om patienten har genomgått en operation på grund av tumör, infektion eller bröstreduktion/bröstlyft innan den aktuella operationen
Patientens upplevelse innan operation	Beskriver patientens självrapporterade missnöje med bröstvolym eller form och eventuella smärtor i bröstens vävnader
Profylastisk antibiotikabehandling	Beskriver om patienten har erhållit antibiotika i samband med den aktuella operationen
Intraoperativt	Sköljning av implantat i steril förpackning eller proteshåla med antibiotika (gäller ej antiseptiska)
Postoperativt	Behandling oralt eller intravenöst dagen efter operationsdagen

Reoperation

Variabel	Definition
Personnummer	Patientens födelsedag och 4 sista siffror
Operationsdatum	Datum när reoperationen sker
Längd	Patientens självrapporterade kroppslängd i cm
Vikt	Patientens självrapporterade vikt i kg
Årtal för start av implantatkirurgi	När implantatbaserad operation påbörjades
När sattes aktuellt implantat in	När det implantat sattes in som denna registrering behandlar
Sattes aktuellt implantat in på min klinik	Har min klinik satt in implantatet som denna registrering behandlar
Har patient haft cancer	Ja eller Nej
Operationsindikationer vänster och höger sida	Anledning till reoperation
Smärta	Patientupplevd smärta i bröstet
Svullnad av bröst	Patientupplevd svullnad av bröstet
Oro för implantat	Patientupplevd oro för sitt insatta implantat
Oro för implantatläge	Patientupplevd oro för sitt insatta implantats läge
Storleksbyte	Patientens upplevelse att bröstens volym är för liten eller för stor
Önskad formförändring	Patientens önskan om ändrad bröstform
Hårt bröst	Patientens upplevelse att bröstet är hårt
Önskat implantatuttag	Patientens önskan om implantatuttag
Infektion (T81.4)	Infektion efter kirurgiskt ingrepp
Nyupptäckt bröstcancer	Diagnos bröstcancer som anledning till den aktuella reoperationen
Symtomkomplex Breast Implant Illness, BII	Diagnos BII som anledning till den aktuella reoperationen
Preoperativ status	Patientens medicinska tillstånd innan operation
Ruptur/Deflation	Skada i implantatets hölje (från hål i hölje till upplösningstillstånd av implantatets form). Volym och/eller formförändring av implantat /expanderprotes på grund av koksaltförlust
Rotation	Implantatet har roterat i proteshålan
Felläge/Migration	Implantatet befinner sig inte på rätt läge i bröstet
Double Bubble	Bröstet har en synlig rest av gamla bröstfåran som påverkar konturen
Kapsel (T85.4)	Hård bindvävskapsel som bildats runt implantatet och kräver kirurgisk åtgärd (Baker III, IV)
Dubbelkapsel	En kapsel i kontakt med implanta och en kapsel i kontakt med Patientens vävnad.
Serom/Exsudat (T81.8)	Ansamling av sårvätska i proteshålan
Hematom	Ansamling av blod i eller utanför proteshålan
Bekräftad ALCL preoperativt	Diagnosen bekräftad innan operation
Bekräftad ALCL postoperativt	Diagnosen bekräftad med PAD
Åtgärd	Behandling
Permanent uttag av implantat	Bröstimplantatet tas ut och inget nytt implantat sätts in
Återinsättning av befintligt implantat	Bröstimplantatet tas ut och efter behandling sätts samma implantat in igen
Nyinsättning av implantat efter tidigare protesuttag	Nytt bröstimplantat sätts in efter tidigare uttag av implantat som till exempel efter en infektion eller andra tillstånd där bröstvävnad behöver läka flera månader utan implantat
Implantatbyte	Nytt bröstimplantat sätts in i under samma operation som befintligt implantat tas ut
Kapselklyvning	Incision av kapseln i en eller flera kvadranter
En-bloc resektion	Implantat och kapsel avlägsnas som en enhet utan incision av kapselvävnadoavsett indikation och diagnos.
Total kapselborttagning	Hela kapseln avlägsnas inklusive kapseln i kontakt med thoraxväggen
Partiell kapselborttagning	Delar av kapseln avlägsnas
Kapselförsnävning	Kapseln minskas med sutur eller diatermi s.k. ”pop-corn”
Nät/ADM in	Insättning av nät eller ADM vid den aktuella operationen
Lambå	Metoden går ut på att hud och vävnad tas från sidan av bröstkorgen och flyttas fram för att fylla ut med vävnad till yttre sidan av bröstet

Fettransplantation	Komplettering av implantatbaserad operation med patientens eget fett
Genomgången strålbehandling innan operation	Strålbehandling av bröst eller bröstkorg innan den aktuella operationen
Uppgifter om implantatet som tas UT på VÄNSTER resp. HÖGER sida	Dataregistrering avseende vänster respektive höger sida
Typ av implantat	Specifikation av det implantat som tas ut
Implantat	EU-godkänd medicinsk produkt avsett för förstoring eller rekonstruktion av bröst
Expanderprotes	EU-godkänd medicinsk produkt avsedd för stegvis expansion av thoraxväggens mjukdelar i syfte att rekonstruera bröstet i ett ”en-stegsförfarande”
Tillverkare	Namn på industriföretaget som tillverkar det aktuella implantatet
Innehåll	Beskriver implantatets eller expanderprotesens fyllnadsmaterial
Silikon, koksalt eller kombination av både och	Varianter av fyllnadsmaterial
Serienummer	Implantatets eller expanderprotesens serienummer
Volym	Mäts i ml, cc eller g. PRINT på implantat eller expanderprotes via tillverkande industri eller mätt intraoperativt genom Arkimedes princip.
Form före implantation	Implantatet eller expanderprotesens form Motiva Ergonomix registreras som rund form
Rund	Implantatets form är rund
Anatomisk	Implantatets eller expanderprotesens form liknar formen på ett droppformat mer moget bröst
Yta	Specifikation av implantatets eller expanderprotesens yta
Slät/Nanotexturerad, Mikro/Makrotexturerad, Polyuretan	Beskaffenhet av implantatet eller expanderprotesens yta
Implantatläge	Placering av det aktuella implantatet eller expanderprotesen
Submuskulärt	Implantatet eller expanderprotesen placeras under pektoralismuskeln
Subglandulärt/Prepektoralt	Implantatet eller expanderprotesen placeras ovanpå pektoralismuskeln
Subfaciellt	Täckning av implantatet med pektoralisfascia ovanpå pektoralismuskeln
Dual plane	Täckning proximalt om bröstvårtgården med pektoralismuskeln, distalt om bröstvårtgården med bröstvävnad