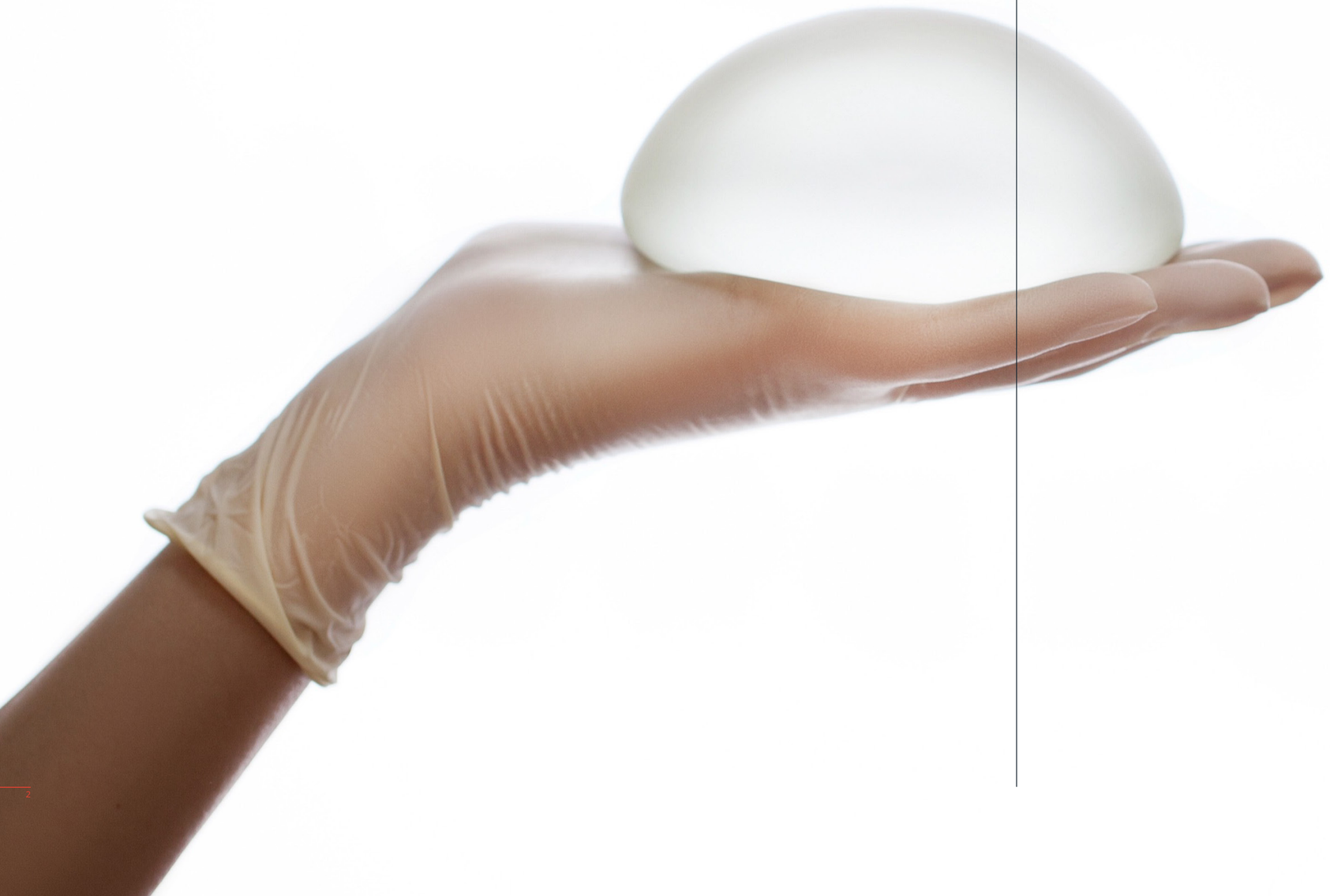
BREAST IMPLANT REGISTER
ANNUAL REPORT

2020

Swedish National Quality Register for Breast Implants



ANNUAL REPORT **2020**

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BRIMP – BREAST IMPLANT REGISTER

INTRODUCTION
A WORD FROM THE FROM THE REGISTRAR

Birgit Stark – Associate Professor, Consultant in Plastic Surgery

The general aim of the BRIMP is to inform patients, members of the caring professions, government authorities and the media about safety regarding the use of various, different breast implants. The specific aim is the objective evaluation of both short- and long-term results in relation to implant operations for both cancer and benign conditions of the breast.

The patients' perceptions of the results of their operation are collected 6-months after surgery using PROM-instruments (Patient-Reported Outcome Measures). The PROM instrument has been developed with support/input from patients; the board of management of BRIMP and the Centre of Registers Västra Götaland. All participating units are invited to use PROM instrument. The response rate, however, has been under 10% and therefore we have chosen to refrain from presenting an analysis in this report. It is up to the individual units to use the PROM instrument for their own use.

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During the years 2018-2020, there has mainly been a consolidation of the data collected in the BRIMP. The work to improve data quality is continually in progress, as well as, adjustment of the BRIMP's variables to be better able to provide answers to relevant questions regarding breast implants.

Since the start of the BRIMP in 2014, implant operations have undergone considerable changes with, for example, the use of hybrid techniques where fat tissue from the patient's body is used together with the implant.

The use of net insertion in conjunction with breast implant surgery is another hybrid technique requiring further evaluation. Implant-related problems have recently come under intense scrutiny in social media, both nationally and internationally. In this context, the symptom complex "Breast-Implant Illness, BII" also known as ASIA-disease requires a mention. The lymphoma condition BIA-ALCL is also an issue raised for consideration at most national and international conferences within the profession. The content of the BRIMP therefore requires continual evaluation and sometimes adjustment to be best able to provide answers to new questions relating to breast implants. Thus, the BRIMP fulfils an important function by providing objective research data which can act as a counterbalance to the subjective information patients can obtain via social media.

BRIMP fulfils an important function by providing objective research data which can act as a counterbalance to the subjective information patients can obtain via social media.

The Swedish and English version of BRIMP's annual report is published each year on the BRIMP's homepage, www.brimp.se and is distributed free of charge to all members of the professional associations. All units and clinics that report in to BRIMP receive a special summary of their clinics results, which is sent out by mail twice a year. The clinics own data in relation to the aggregated data available in the BRIMP can be followed on-line using the clinics individual access code

In order to provide statistically safe answers, a large amount of data is required. This is why the registrar has had a close co-operation with other international breast implant registers within ICOBRA (International Collaboration of Breast Registry Activities). The advantage of working together with other registers to compare large amounts of data is that it is possible to receive answers to various problems relating to breast implants in a much shorter time. This co-operation has resulted in five published works.

BIRGIT STARK

Registrar of BRIMP
06-10-2021

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GOVERNANCE AND MANAGEMENT

2020

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All Annual Reports for the BRIMP are available on the website www.brimp.se.

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AB Victoriakliniken - Saltsjöbaden
Akademikliniken - Göteborg
Akademikliniken - Stockholm
Akademikliniken - Öresund, Malmö
Akademiska Sjukhuset - Uppsala
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
Bröst- och Melanomteamet SUS – Lund
Bröstcentrum SÖS - Stockholm
Conturkliniken - Stockholm
Dalakliniken - Falun
De VitaNova AB - Stockholm
Elite Clinic - Göteborg
Eriksbergskliniken – Stockholm
Estetisk Plastikkirurgi Eya Le Wartie AB – Ockelbo
Gerlee Plastikkirurgi - Helsingborg
Gävledalakliniken - Gävle
Hand- och Plastikkirurgisk klinik - Umeå
Improva Plastikkirurgi AB - Stockholm
Kirurgiska kliniken, bröstenheten - Linköping
Kirurgkliniken - Växjö
Kirurgkliniken - Västervik
Kirurgkliniken - Falun
Kirurgkliniken – Kalmar
Kirurgkliniken Länssjukhuset Ryhov - Jönköping
Klinik 34 – Göteborg
Kliniken för rekonstruktiv plastikkirurgi, Karolinska Universitetssjukhuset - Stockholm
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Linköpings Universitetssjukhus - Linköping
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IMPROVED QUALITY OF CARE
FOR SURGERY WITH BREAST IMPLANTS

Summary of Annual Report 2020

BRIMP aims to improve the quality of care for women in Sweden who have undergone or will undergo a breast operation using a breast implant. The Register is available to both surgeons and patients.

The Breast Implant Register (BRIMP) was started in 2014 and is a national quality register for breast implants which are used in benign breast conditions or after removal of the breast as a result of breast cancer or breast reduction. The general aim of the register is to help contribute to patient safety by studying how implants behave in the human body over time. Data in the BRIMP gives both patients and surgeons reliable information about the breast implants used in Sweden.

Data from 45 000 implants

As all plastic surgery clinics at the university hospitals and 85% of plastic surgeons in private practice in the country have joined and are now contributing to the BRIMP, we are currently monitoring data from more than 45,000 implants.

Every time an implant is used in an operation, the surgeon completes a form with questions about the reason for the operation, the choice of the specific implant used in the operation, the characteristics of the implant with regard to the shape, the type of surface, type of filling material, and the surgical positioning of the implant. The same procedure is carried out for re-operations, where the reason for surgery is described, as well as, any other measures taken.

Contributing clinics receive a report prepared by the BRIMP's registrar twice a year, which describes the clinics outcome data in relation to the data for the rest of the country.

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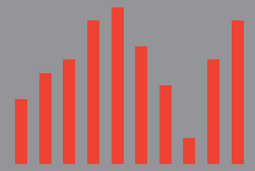
Every year, an annual report is compiled in which the data from the BRIMP is reported. The annual report for 2020 shows the results concerning the use of breast implants in benign conditions of the breast and in breast cancer. These are presented separately.

85% of all private clinics report in to the BRIMP.



Tables can be found in the appendix.

BREAST IMPLANTS
IN BENIGN CONDITIONS OF THE BREAST

In Sweden, Mentor and Motiva's implants are mainly used for these benign conditions. The majority (88.6%) of breast implants are placed partially under the muscle and the most common surgical approach has been to make the incision under the breast in the sub-mammary fold.

- Only 7.4% of implants are inserted via the armhole (axilla).
- With regard to shape, round implants were the most common (65.7%) and the most common type of implant surface coating was the textured implant (48.0%).
- Women in Sweden, chose, for the most part, implants with a volume between 200-399 cc/gr. Larger volumes over 400 cc/gr occurred in 26.8 % and over 600 cc in 3.6 % av patients.
- The risk of having to undergo a re-operation within six years was 7%. The commonest reason for re-operation was that patients wished to alter the size of their implant (55.4%) or the shape of the breast. (48.1%).
- The risk of having to undergo re-operation within six years due to a ruptured implant was very low, 0.13 % for Mentor, 0.06%, for Motiva och 0.35% for other implant brands.
- No statistically significant difference could be seen between the different implant brands in the annual report for 2020.

Benign conditions are for example:

- Congenital conditions such as aplasia /hypoplasia and tuberous breast.

- Secondary hypoplasias, for example, after breast feeding, massive weight loss, undergoing reduction plastic with undesired hypoplasia of the breast, status after surgical removal of cystic mastopathy or benign breast tumour.

- Breast augmentation in trans-gender surgery.

- Aesthetic indications.

IMPLANT-BASED BREAST RECONSTRUCTION
AFTER BREAST CANCER OR RISK-REDUCING MASTECTOMIES

For the most part drop/tear-shaped textured implants (84%) from the manufacturer Mentor are used in breast reconstructions after mastectomy or for risk-reducing mastectomies.

- Data in the BRIMP showed that in 93.6% of reconstructions med textured implants were used. The proportion of smooth implants was 4.1 % during the period 2014–2019 och 17 % for 2020.
- Mentor's products were used in 97.5% of cases and for the remaining 2.5% Motiva's products were used.
- The risk of requiring to undergo a re-operation within six years was significantly higher for patients who had undergone reconstruction for cancer (24.9 %) compared breast augmentation for benign conditions (7 %).
- An analysis of the importance of radiation showed that patients who had undergone radiation and reconstruction ran a 55.6% risk for the first six years of requiring a revision compared to 4.15 % for non-radiated patients.
- The most common argument among patients for undergoing a re-operation has been dissatisfaction with the shape or volume of the reconstructed breast.
- A hard and painful breast with capsule formation was seen in about 30% of the patients requiring re-operation.

BRIMP 2020
ACTIVITIES

FOUR MAIN PROJECTS 2020

1. Work with Data Function as a Support for Healthcare
Feedback to the participating units is an important function of a quality register. In co-operation with the project management at Centre of Registers Västra Götaland, two on-line web modules for the participating units have been completed. All clinics registered in the BRIMP can access and evaluate the quality of the health care delivered at their clinic in comparison to the aggregated data in the BRIMP. To facilitate the individual clinic's possibility for analysis and critical thinking, a module has been constructed which generates a report summarising that clinic's half-yearly data. The module was launched in 2018 and two reports have been sent out during 2020. In this way, the participating clinics can more easily follow their own results over time and initiate quality measures as required.

2. Improved Register Content
A critical analysis of the meaning of the variables for care has occurred continually and has resulted in an update of relevant data. The response rate and quality of data are other factors which have been evaluated during the past year. During the autumn of 2020, the registrar has conducted a new critical analysis of the data quality with a view to new or especially notable implant-related problems. An update of the BRIMP content will be carried out in 2021. A suggestion to changes in the content of the register has been passed by the board. Improvements during 2020 have resulted in an updated registration form with relevant variables, with the aim of collecting statistically valuable data. It will probably require several more years to create a fully complete breast implant register.

An improved register content is created also through analysis of the amount of coverage. During the period 2015-2017 we have noted an increase of 11% in the reporting of primary admissions and a 25% increase with re-operations, but between 2018-2019 unfortunately there has been a stagnation in reporting. There has even been a slight increase in the registration of implant removal in the BRIMP. During the past year, even the COVID pandemic has had an effect on reporting

Since the commencement of the BRIMP, there has been a continual increase in the number of clinics reporting to the BRIMP. We have experienced an increased understanding of the usefulness of this quality register. More and more clinics are requesting information about the BRIMP and the current level of coverage is about 65%.

Reliable sales data from the industry which the registrar has been privy to has shown that we register about 65% of all implants sold in Sweden. One must remember that the BRIMP is a relatively new register which can explain why the level of coverage is not higher.

We have experienced an increased understanding of the usefulness of this quality register. More and more clinics are requesting information about the BRIMP and the current level of coverage is around 65%.

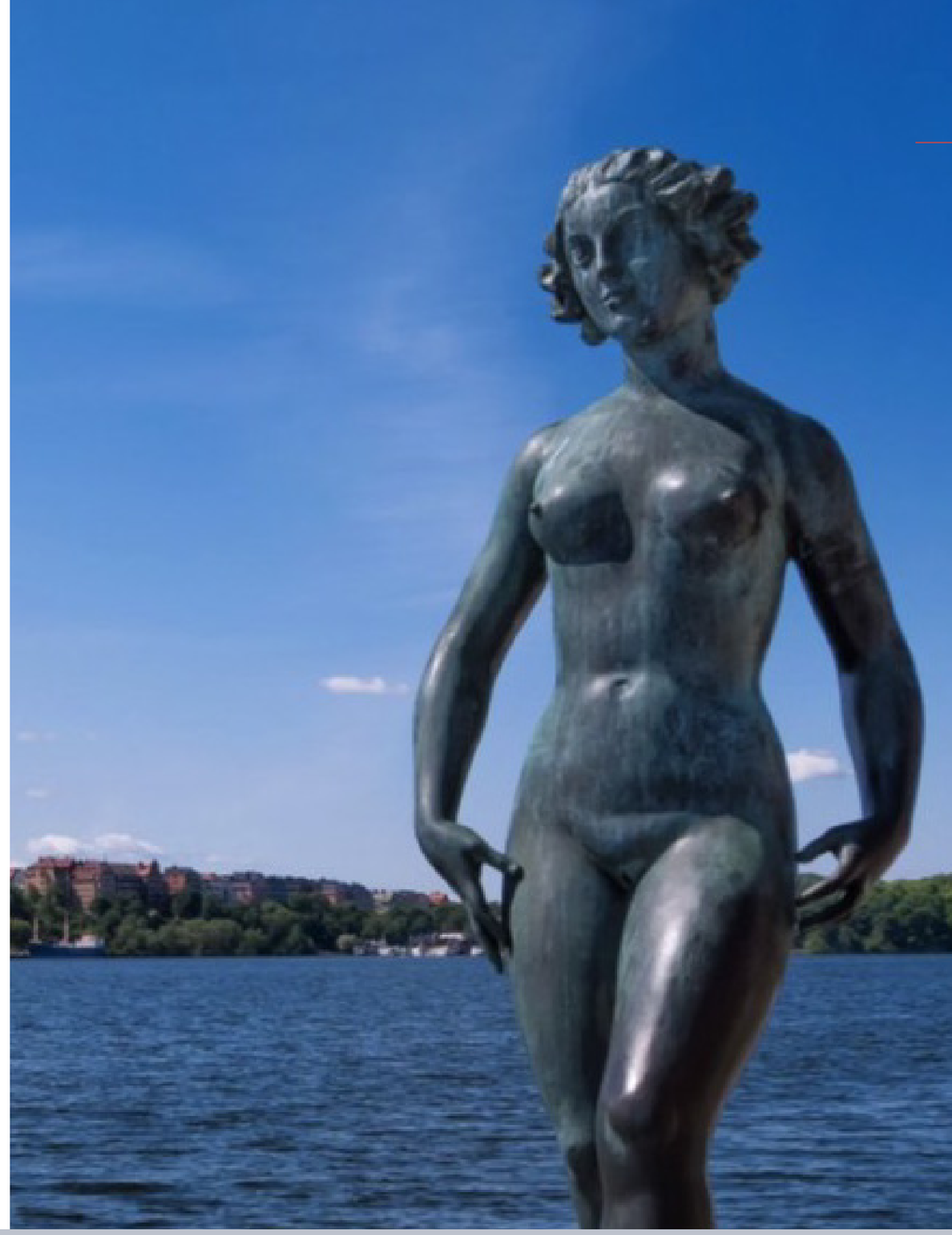
A critical analysis of outcome data in the BRIMP for the years 2015-2020 shows stable statistical results. In co-operation with our statisticians at Centre of Registers Västra Götaland we concluded in the annual reports for 2019 and 2020 that the results presented constitute the Swedish standard.

A SHORT NOTE ABOUT LEVEL OF COVERAGE

Currently the level of coverage for the BRIMP is unchanged and 85% of plastic surgeons colleagues in private practice in the country contribute their data to the register.

Participation in the BRIMP is not obligatory for either the state-funded or privately-funded healthcare, which is in contrast to the situation in The Netherlands, England and Australia. Our level of coverage is therefore totally dependant on the "goodwill "of our colleagues in the whole country.

In co-operation with Centre of Registers Västra Götaland we manage data from more than 46 000 implants. Presently, only one of the clinics in Stockholm has actively chosen not to participate in the work of the BRIMP. During 2020, the work of the BRIMP has focused on four main project areas.



However, breast implants are not only used by specialist in plastic surgery but even used by breast surgeons, many of whom are not members of the BRIMP. We are hoping for closer co-operation between NKBC (National Quality Register for Breast Cancer) and the BRIMP, which will potentially lead to an increase in the level of coverage. In order to continually increase the conformity and completeness of the register in the coming years, regular meetings (both face-to-face and digital) and continued communication are needed with those clinics that are not as yet contributing to the BRIMP.

Through this work and with the help of presentations at scientific conferences there will be an increased knowledge about the role of BRIMP. Hopefully, more colleagues will become increasingly aware of the benefits of the BRIMP for their own clinics and see participation in the register as a necessity. Efforts are being made to encourage breast surgery clinics that have not joined the register to become participating members. Many of these clinics are waiting for the merger of the BRIMP and the NKBC.

Since 2014, the BRIMP has been in close contact with the NKBC with a view to combining the data between these two registers. The discussion is ongoing and will continue in 2021. Transfer of data from the NKBC to the BRIMP requires discussions at a managerial level and we are expecting the first transfer of data to occur during 2021. This data will appear in next year's annual report in 2021.

3. The management of PROM in the BRIMP

The board decided that the PROM form should be introduced in autumn 2019 and thus be available to be sent out to all patients. Evaluation of patient-reported data should occur six months after the primary operation. Six months after the index operation, all clinics are sent a reminder to send out the PROM forms to the patients concerned. Prior to this, information about PROM management and how to deal with it has been sent out to all participating clinics.

The reporting of PROM data from the clinics has thus far been very low (10%) and therefore no evaluation has been done for this report. The registrar will be discussing the introduction of new electronic ways of direct data reporting during 2021.

4. Industry database

In co-operation with the project group from Centre of Registers Västra Götaland the BRIMP has created various different types of reporting models for an industry database for 2019 and 2020. Data concerning complications and reasons for re-operation of a manufacturer's products are compared with the aggregated data in the BRIMP.

For the 2020 industry report, the Centre of Registers Västra Götaland has prepared a contract for co-operation with the companies Motiva and Mentor that manufacture implants. The fee from the Register Centre Västra Götaland covers the actual cost for the establishment of a report to the industry.

THE WORK OF THE BOARD & THE REGISTRAR 2020

Development and Co-operation

The board has convened at three video-telephone meetings during the year. The registrar has participated in about 60 digital meetings, as well as, has had continuing contact via telephone and mail. Contact with the project management and statisticians has been very intensive during the first six months of 2020, as the work with the completion of the annual report for 2019 was underway.

Furthermore, the registrar has been involved in several meetings during the past year with the register coordinator, to plan for the continual work of the register with the participating clinics. The coordinator has had ongoing contact with clinics in the country to provide help and support with the work of the register.

The registrar has had the principal responsibility for the work relating to the annual report and the compilation of relevant data, as well as writing the manuscript and arranging for an English version of the text. The registrar has also participated in national and international working committees with about 10 digital meetings with the BIA-ALCL task force in Europe and ICOBRA.

Co-operation with Industry

During the past year, work with the creation of the industry report has demanded a number of meetings and the work of the registrar has involved arranging and be participating in meetings with representatives from the manufacturing industry as well as, the project management from the Centre of Registers Västra Götaland.

NATIONAL AND INTERNATIONAL **PARTNERS**

INTERNATIONAL COLLABORATION

The BRIMP has experienced a rise in interest both nationally and internationally. English versions of the annual report from 2017 – 2019 have been published on the EASAPS (European Association of Aesthetic Plastic Surgery Societies) homepage and have been given to the members of ICOBRA.

The Swedish and the English versions of the BRIMPS'S report has been published annually on on the BRIMP's home page www.brimp.se and has been distributed to all members of the SFEP (Swedish Society for Aesthetic Plastic Surgery) och SPKF (Swedish Plastic Surgery Society), as well as, the Society of Breast Surgeons.

All clinics that report in to the BRIMP receive both the annual report and a special summary of results for their own clinic which is sent via mail twice a year.

A clinic's own data in relation to aggregated data in the BRIMP can even be followed on-line using the clinic's own specific access code. An international meeting of ICOBRA's partners was planned to be held in June 2020. The registrar was given the task of arranging the meeting in Stockholm. Unfortunately, the meeting had to be cancelled due to the COVID pandemic and will be replaced by a webinar seminar
in 2021.

Co-operation with ICOBRA has resulted in one accepted publication this year. Discussions regarding the aetiology och pathogenic relationship between textured implants och lymphoma illness BIA-ALCL is on-going nationally and internationally.

In order to be able to provide a statistically assured explanation, a large amount of data is required, which is why the registrar has started an intensive collaboration with other international breast implant register within ICOBRA. Collectively we have currently data regarding 200,000 implants. This co-operation will give an explanation as to why this occurs in a much shorter period of time as we are able to compare outcome data from such a large cohort.

The SCHEER report from 2020 has pointed out the importance of having quality registers which are independent of the implant manufacturing industry in order to conduct systematic analyses of the short- and long- term impact of implants on the local and general health of women bearing these implants. SCHEER (Scientific Committee on Health, Environmental and Emerging Risks).

Reference: Scientific opinion on the safety of breast implants in relation to anaplastic large cell lymphoma, 8 October 2020.

FINANCIAL REPORT **2020**

BUDGET IN BALANCE DUE TO MORE STRINGENT WORK PLANNING

Running a quality register is expensive and until now the upkeep of the register has chiefly been financed through funding from SKR. Funding has been applied for in competition with approximately 100 other quality registers in the country. No private clinic or professional association has contributed financially to the running of the PRIMP.

No fee has been taken for the annual report or individual unit reports which are sent out twice a year to the relevant healthcare professionals. The registrar has controlled BRIMP's budget with the Register Centre's management and has regularly participated in meetings regarding BRIMP's finances. In summary, it can be said that BRIMP's budget for 2020 is in balance. This is due to a very tight work schedule.

BRIMP

DATA QUALITY **& SAMPLE CONTROL**

Annual report 2020

AIM

The overall aim is to show data from the BRIMP for primary operations and re-operations in implant-based surgery and also to present a risk analysis for specific parameters against the background of the data reported into the register.

After the extraction of data for the annual report, further registrations have been recorded for 2020. These are therefore not shown in the analyses.

In preparation for the commencement of the actual work, a control of the data quality was carried out in the actual BRIMP register. This is done automatically when generating from the R-data storage. Patients who have had more than one primary operation per side are identified and their recordings are removed from both data sets (primary operation and re-operation). Patients who have had re-operations before their primary surgery are also identified and removed from the re-operation data set. Their primary surgery remains in the data set for primary operation. For the risk analysis we have included all patients with a registered primary operation in the BRIMP.

The extraction of data for the annual report was done in March 2021. After the extraction had been carried out further reporting for data from 2020 occurred, and consequently these are not included in the analysis. The time between operation and registration of the relevant data in the BRIMP differs between clinics and time-periods. In some cases the registration occurs several months after the actual date of operation. After the extraction of data for analysis was completed, further registration of data has occurred for operations performed in 2020 and these, therefore, are not included in the analyses.

ABOUT THE ANNUAL REPORT

In this year's annual report the data from patients who have undergone breast reconstruction and risk-reducing mastectomies has been evaluated separately from the data for implant-based operations for benign conditions.

We have chosen to focus on the patient cohort having their primary operation in the time period 2014-2019 and 2020 separately- Patient-reported reasons for revision, intra-operative finds and measures required have been reported. Furthermore, any re-operations in the BRIMP database are evaluated at 60 days, 1-year and 6 years after operation.

We have chosen to focus on the patient cohort having their primary operation in the time period 2014-2019 and 2020 separately.

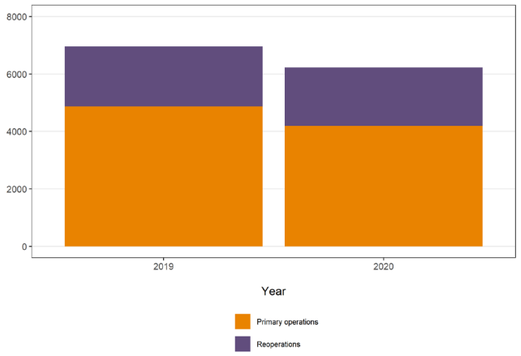
A popular scientific summary of the most important outcome data has been complied and presented in conjunction with the annual report.

The register coordinator, Heléne Fägerblad, has compiled a summary of data from 2020, which shows that the total number of operations registered during 2020 was 6225, divided between 4196 primary operations and 2029 re-operations. The total number was a decline of 11% from 2019.

The on-going pandemic is one explanation for this decline, but even the trend toward fewer choosing to have breast implant operations also contributes. The same trend could be seen in the 2019 figures compared to those of 2018. The number of re-operations (yellow-marked field) at private clinics has risen by 7%.

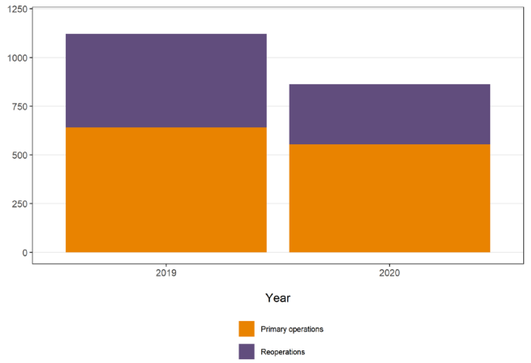
If one looks more closely at how the pandemic has influenced the public-funded healthcare sector, we see a decline of 23%. An analysis at the regional level has shown that the drop in the number of registered primary operations is greatest in Stockholm and Skåne. The figures reported from Västra Götaland are largely unchanged.

The total number of operations registered in 2020 was 6225, divided between 4196 primary operations and 2029 re-operations. Tin all there has been a drop of 11% from the 2019 figures.



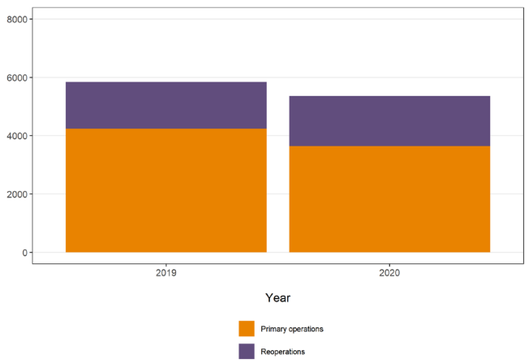
REGISTERED OPERATIONS – IRRESPECTIVE OF DIAGNOSIS

Primary operations and re-operations



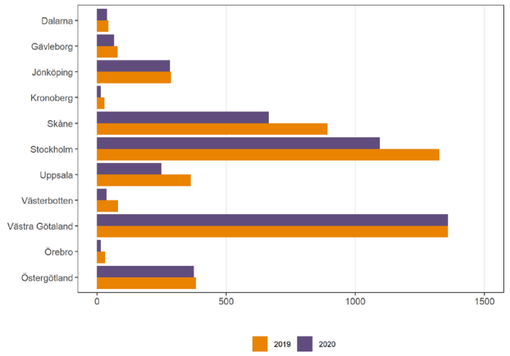
REGISTERED OPERATIONS – PUBLIC HEALTHCARE

Primary operations and re-operations



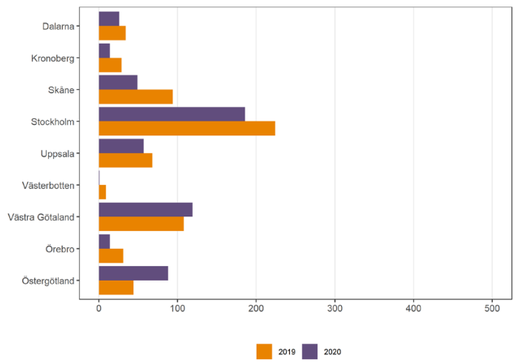
REGISTERED OPERATIONS – PRIVATE CLINICS

Primary operations och re-operations



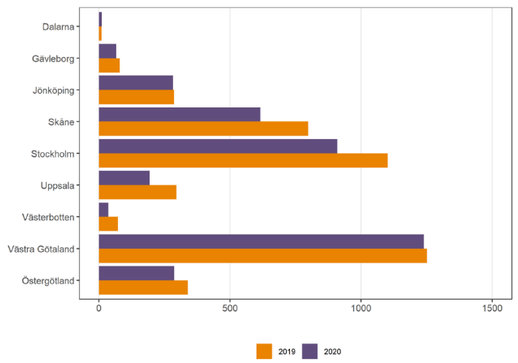
PRIMARY OPERATIONS – ALL CLINICS

2019 och 2020



PRIMARY OPERATIONS – PUBLIC HEALTHCARE

2019 och 2020



PRIMARY OPERATIONS – PRIVATE CLINICS

2019 och 2020

IMPLANT-BASED RECONSTRUCTION **FOR BREAST CANCER OR FOR RISK-REDUCING MASTECTOMIES**

Summary

The COVID-19 pandemic 2020 has influenced all areas of Swedish healthcare. Therefore, in this annual report we have chosen to report the number of implant-based primary operations for breast cancer or for risk-reducing mastectomies from 2014-2019. The data from 2020 is shown (see table 1 in the appendix). All patients underwent surgery in the publicly-financed healthcare sector in Sweden.

A total of 1802 patients who underwent a breast reconstruction with an implant were reported to the BRIMP, and 273 patients underwent surgery in 2020. These patients received 2568 breast implants.

In the Stockholm region and in Västra Götaland, most reconstructions were performed last year according to the data reported to the BRIMP.

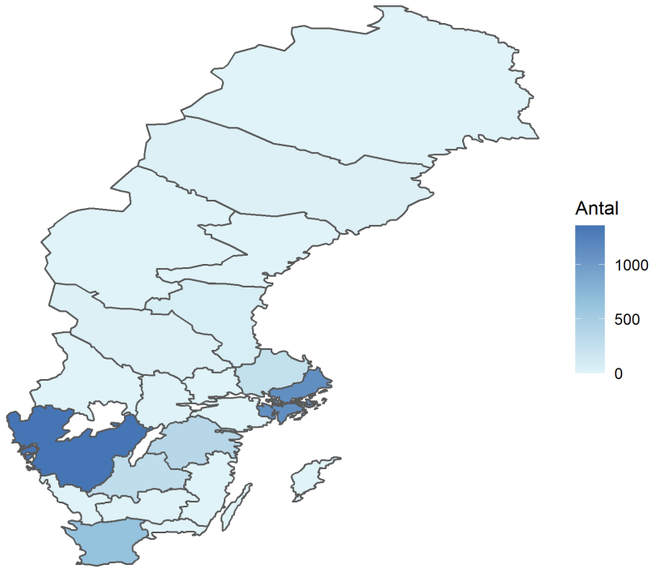


Figure 1.

In the Stockholm region and in Västra Götaland, most reconstructions were performed last year according to the data reported to the BRIMP.

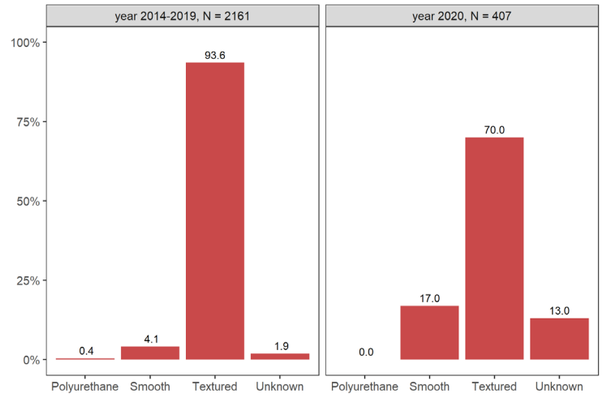


Figure 2.

Implants surface at primary operation for reconstructed patients 2014-2019 and 2020.

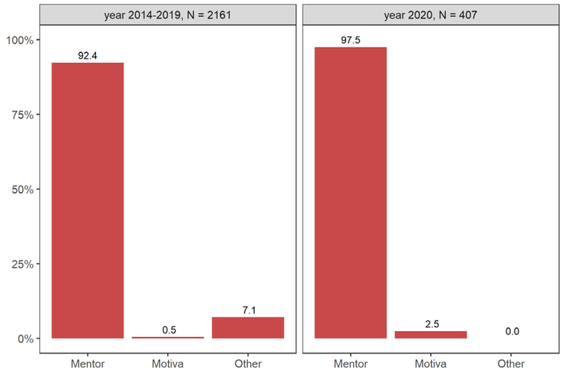


Figure 3.

Implant make at primary operation in patients undergoing reconstruction 2014-2019 and 2020.

IMPLANT CHOICE

A general national recommendation or consensus regarding the choice of implant make or type has not been established during the past year. Some healthcare facilities advocate the choice of smooth implants for this patient group considering the prevalence of BIA-ALCL in conjunction with the use of textured implants.

Data in the BRIMP from 2014 – 2019 show that 93.6% av reconstructions textured implants, principally from the manufacturer Mentor were used. However, there has been an increase in smooth implant usage, from 4.1 % in 2014–2019 to 17% in 2020. Mentor's products were in the majority here. Reconstructions performed using Motiva's products made up only art 2.5 % of the total 407 documented. (Figure 2 and 3).

During 2020, the proportion of textured implants used in breast reconstructions was decreased compared to earlier years.

If we look at the choice of expander-prosthesis compared to permanent implant, there has been a reduction in the number of registrations of expander-prostheses compared to permanent implants in 2020 compared with 2014–2019.

Colleagues choose mainly anatomic forms, but the proportion of round implants had increased in 2020 compared to 2014-2019. Production data regarding filler, shape, manufacturer and implant surface in the different regions of the country is shown in table 10 and 11 (see appendix).

INFECTION PROPHYLAXIS IN CONJUNCTION WITH OPERATION

Per-operative prophylactic antibiotic treatment is routine in reconstructive implant-based breast reconstruction. Data in BRIMP shows that 88,9% of patients in 2020 received prophylactic treatment.

We have chosen to show ”pre- and per-operative” treatment in a column as definitions can be unclear. Generally we can say that patients seem to have good antibiotic cover prior to insertion of an implant. (figure 4).

Intra-operative antibiotic irrigation of the prosthesis cavity or of a prosthesis itself before insertion ***is not in keeping with the accepted national routine for reconstructive surgery.***

Antiseptic irrigation are currently not acceptable within public sector healthcare. Interestingly, a relatively large proportion of patients also receive post-operative treatment. The ordination of antibiotics and the length of treatment should be controlled against The Swedish Prescribed Drug Register.

It can be noted that the use of antibiotics differs between the various regions of Sweden. A more detailed documentation of infection prophylaxis in the country for 2014–2019 och specifically during the past year is shown in table 8 and 9 (see appendix).

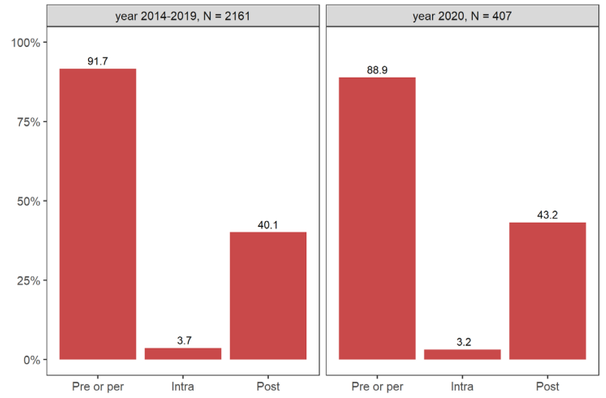


Figure 4.

Infection prophylaxis 2014-2019 and 2020.

BMI IN DIFFERENT AGE GROUPS

BMI in the different age groups is shown in figure 5. It is important that clinics improve their reporting of length and height to the BRIMP as BMI is an important variable that can influence the risk for re-operation.

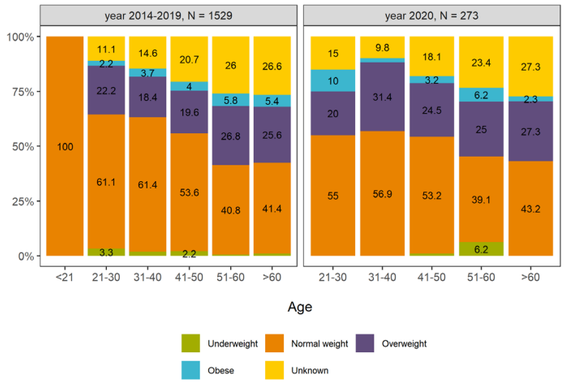


Figure 5.

BMI-distribution in the different age groups 2014-2019 and 2020.

OPERATION INCISION AND IMPLANT POSITION

26.5% of the reconstructions performed in bi-dual implant positioning. This has caused a number of questions about the definition of the variable “bi-dual position”. Information about how the variable is to be registered must be more clearly communicated to colleagues. In conjunction with mastectomy or risk-reducing mastectomies no breast cancer tissue is left remaining in the lower pole of the breast.

Implant i bi-dual position is categorised as a proximal covering of the implant with the pectoral muscle and a distal coverage with breast tissue. It is therefore, surprising that such a high proportion has been reported in to the BRIMP. (see table 6 och 7 in appendix). Targeted efforts about this issue will be taken up with those clinics concerned.

Similarly, a 12.3% ”sub-glandular” positioning of an implant in conjunction with breast reconstruction shows this was not a well answered variable in 2020. In an effort to improve BRIMP”s quality we have conducted a region by region search of the data in order to better communicate the definitions and improve the understanding of the definitions of the variables in the BRIMP. A follow-up is planned for the next annual report..

The most common incision choice in 2020 has been, as expected, via the previous mastectomy scar or in the sub-mammary fold.

Compared with 2014–2019, 10,8% of all implants have been placed via a pre-areolar incision, a figure which also needs to be checked via direct contact with the reporting units. If we look at the use of net in 2020 compared with the years 2014–2019, there has been an increase in usage from 4.9% in 2014-2019 to 20.1% in 2020 in the BRIMP, which indicates an increased tendency for hybrid operations in connection with breast reconstructions in the country.

Use of fat-transplantation in conjunction with the primary insertion of an implant in this patient group does not seem to be the first indication choice (see table 6 och 7).

Even the choice of the volume of the implant at primary insertion of the implant has in the main remained unchanged over the years. Hybrid techniques with an increased volume of transplanted fat in combination with a reduced volume of implant does not seem to performed on a large scale in Sweden.

SUMMARY

- Data from a total of 273 patients who had undergone reconstruction due to a cancer illness or after a risk-reducing mastectomy in 2020.
- In patients undergoing a primary reconstruction the Mentor implant is the main one used.
- A small increase in smooth implants has been registered.
- In Sweden, textured and anatomic implants are inserted mainly via a previous mastectomy incision or alternatively via the sub-mammary fold.
- Outcome data in the BRIMP regarding implant position gives rise to criticism about the understanding of different implant positions.
- The proportion of hybrid operations with net has increased by 15% in 2020 compared with the previous report.
- Fat transplant in conjunction with primary operation does not appear to be a routine intervention.
- Infection prophylaxis is standard in Sweden.

The recording of height and weight has not been adequate for those patients who have had an implant-based reconstruction with a diagnosis of breast cancer or a risk-reducing mastectomy.

BMI is a factor which has importance for re-operation and therefore an increase in the registration of height and weight would be very desirable. We are looking forward to seeing fewer “missing data” in 2021

PRIMARY OPERATION
IN BENIGN BREAST CONDITIONS

Summary

In table 1, 2 och 3 in the appendix shows production data in the BRIMP for 2014–2019 and 2020 for the indication group with benign conditions of the breast including:

- Congenital conditions such as aplasia/hypoplasia and tuberous breast.
- Secondary hypoplasia, for example, after breast feeding, massive weight loss, undergoing reduction plastic surgery with unwanted hypoplasia of the breast, status after surgical removal of cystic mastopathy or benign breast tumours.
- Breast augmentation with transgender surgery.
- Aesthetic indications.

In Sweden 12 884 patients have had 25 554 implants inserted 2014–2019. During the past year 1908 patients received 3373 implants.

Compared with 2019 there has been a slight fall in the number of patients reported the number dropping from 2224 to 1908 in the BRIMP. Table 1, 2 och 3 even show the distribution in the various regions of Sweden.

IMPLANT CHOICE

Parallel with the increasing use of Motiva's implant in Sweden in 2020 compared to the period 2014–2019, there has also been an increase in the reporting of the use of smooth implant surfaces. To be noted is the fact that Motiva's products are registered as smooth implants until a new agreement regarding implant surfaces and the EU standard is available.

Polyurethane and B-lite implants are underrepresented in the BRIMP but will be followed up (see table 10). Silicon-filled round implants dominate in Sweden and a geographical analysis can be seen in table 10.

INFECTION PROPHYLAXIS

Per-operative prophylactic antibiotic treatment is routine for reconstructive implant-based breast reconstruction. Data i the BRIMP shows that 97 % of the patients 2020 received prophylactic treatment.

Antibiotic use is standard in conjunction with the primary insertion of implants in benign breast conditions. However, irrigation of the implant cavity and implant irrigation do not meet the national standards but occurred in 23% of the reported primary operations. (Figure 6).

The use of antibiotic prophylaxis in Sweden can be seen in tables 8 and 9 in the appendix. Intra-operative irrigation with antibiotics in conjunction with primary operations has been reported principally from clinics in the Stockholm region.

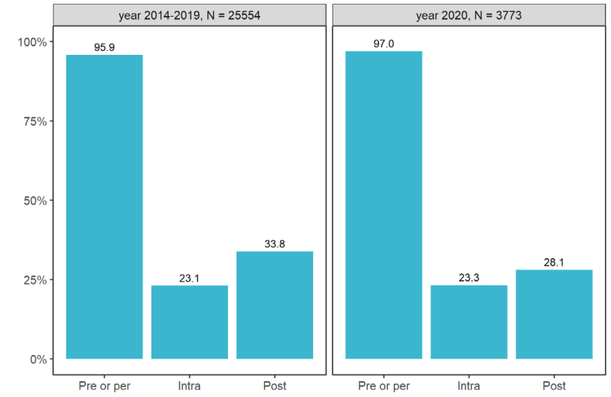


Figure 6.

Infection prophylaxis 2014-2019 and 2020.

BMI IN DIFFERENT AGE GROUPS

The majority of women who underwent primary operations due to benign conditions of the breast were of normal weight.

Figure 8 shows that the proportion of overweight patients in the two older age groups is higher when compared to the younger age groups. This result has remained constant since the commencement of the BRIMP.

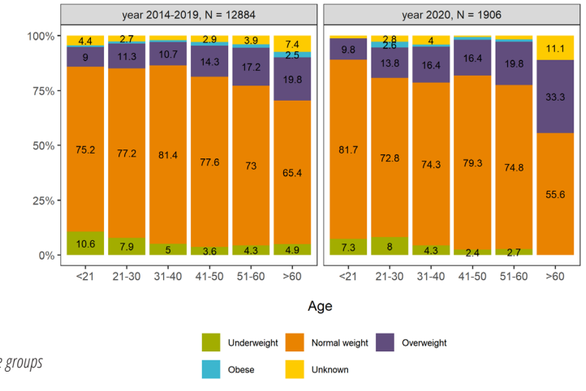


Figure 8.

Distribution of BMI in the various age groups 2014-2019 compared to 2020.

OPERATION INCISION, IMPLANT PLACEMENT AND SIZE

Placement of the implant has been largely unchanged since the introduction of the BRIMP. The majority of colleagues place breast implants in a bi-dual or sub-muscular position.

Sub-glandular- (8.5%) or sub-fascial (1.1%) placement was chosen consistently by a minority of surgeons. See tables 6 and 7 in the appendix.

Use of net/mesh or fat transplants in conjunction primary operations occurred in a minority of patients. Most commonly the incision chosen was the incision in the sub-mammary fold. Only 7.4% of implants were placed in the axilla.

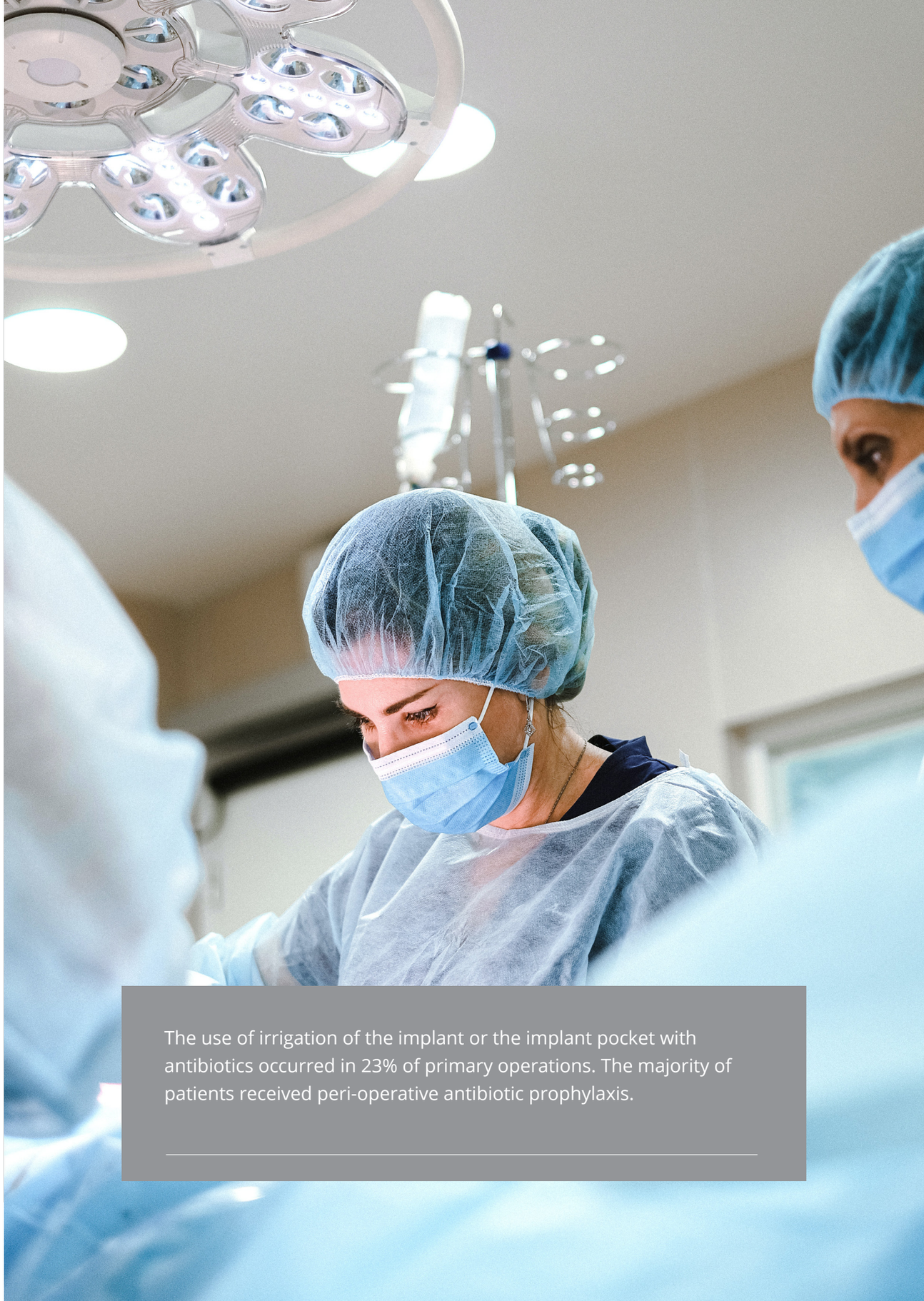
The chosen implant volume was predominately between 200 and 399 cc in 2020. Larger volumes of over 400 cc were chosen by 26. 8 % and over 600 cc by 3.6 % of patients. A discreet tendency toward choice of a smaller implant volume in 2020 compared to 2014–2019 could be discerned in the registrations in the BRIMP. Whether this trend continues in the future, only future annual reports will provide us with the answer.

SUMMARY

- Patients over 50 years had a significantly higher BMI.
- Predominately Mentor och Motiva's products are used in Sweden today.
- In 23 % av primary operations irrigation with antibiotics of the implant or the prosthesis cavity was carried out.
- Majority of patients received peri-operative antibiotic prophylaxis.
- Implant position is mostly bi-dual or sub muscular.
- Implant size up to 399 cc was used in priority.
- 3.6 % av patients chose a larger volume than 600 cc.
- Hybrid operations with net or fat are in the minority in the BRIMP database.

The recording of height and weight has not been adequate for those patients who have had an implant-based reconstruction with a diagnosis of breast cancer or a risk-reducing mastectomy

BMI is a factor which has importance for re-operation and therefore an increase in the registration of height and weight would be very desirable. We are looking forward to seeing fewer "missing data" in 2021



The use of irrigation of the implant or the implant pocket with antibiotics occurred in 23% of primary operations. The majority of patients received peri-operative antibiotic prophylaxis.

PRODUCTION DATA FOR RE-OPERATIONS **IRRESPECTIVE OF INDICATION OR DATE OF PRIMARY OPERATION**

Summary

The register collects only data concerning the reason for the patient's first re-operation. In Sweden a total of 11 750 implants in 6221 patients were revised since the introduction of the BRIMP in 2014 (see table 12 in the appendix).

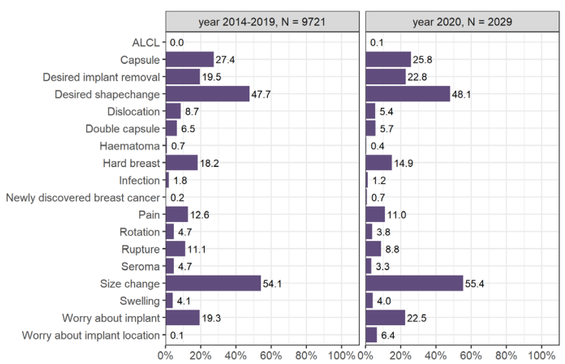
Data is collected irrespective of the date of the primary operation and the indication for surgery. In keeping with previous annual reports, patient-reported factors, such as volume and shape changes, dominate the lists of reasons for revision surgery.

The experience of hard breast due to capsule formation made up >25% of the revisions performed because of symptoms.

Implant rupture was found in 11.1% of 9721 revised implants 2014–2019 and in 8.8 % of 2029 revised implants in 2020 (Figure 9).

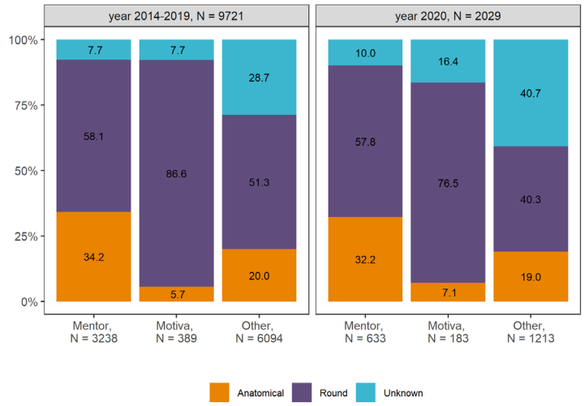
Dislocation of the implant was found intra-operatively in 8.7 % (2014–2019) and in 5.7 % (2020) of the revisions.

Data concerning incorrect implant placement with accompanying shape change in connection with smooth implants from Mentor and Motiva will become an important information to highlight in coming annual reports. Proportionally, there were more re-operations in round implants than anatomical implants from Mentor (Figure 10). Registration of surface characteristics of Motiva's implant has left some uncertainty in the interpretation.



Figur 9.

Reported complications in re-operation of implants in 2014-2019 and 2020.



Figur 10.

Distribution of the form for the various implant manufacturers in re-operation of implants in 2014-2019 and2020.

PERMANENT REMOVAL OF IMPLANT

Permanent removal of the implant has steadily risen (figure 11A). Despite the COVID-19 pandemic, 404 implants have been taken out in 2020, which is the highest figure since the register was started.

The reasons for permanent removal is shown in figure 11B. In total, 713 patients underwent a re-operation in the time span 2014–2019. In 2020 the figure was 214 patients.

The main reason for removal has been anxiety for the implants effect on the body. Many patients cited "anxiety for negative effects" due to the information about" breast implant illness" that has been shown on social media and have therefore sought care for the removal of their implants.

The variable" Anxiety for the implant" in the BRIMP's database will be clarified in 2021 in order to be better able to evaluate if the patient's desire for removal of the implant is related to the patient's experience of "breast implant illness".

Painful capsule formation and anxiety for long-term effects in the body have been shown to the be the most common reasons for removal.

It was noted that even 21.6 % (2014–2019) respective 13.6% (2020) of patients had a ruptured implant at the time of re-operation. The BRIMP does not contain any information about implant rupture even if the rupture was diagnosed pre-operatively.

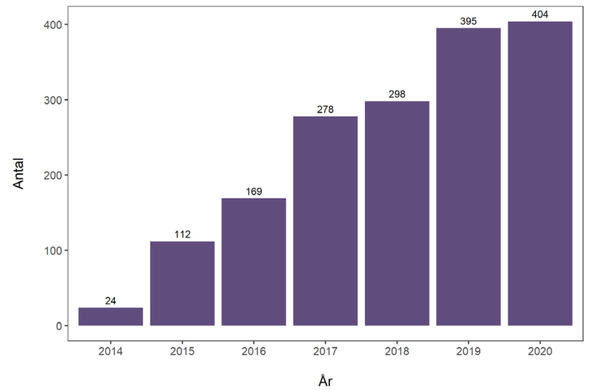


Figure 11 A.

The number of permanent removals per year.

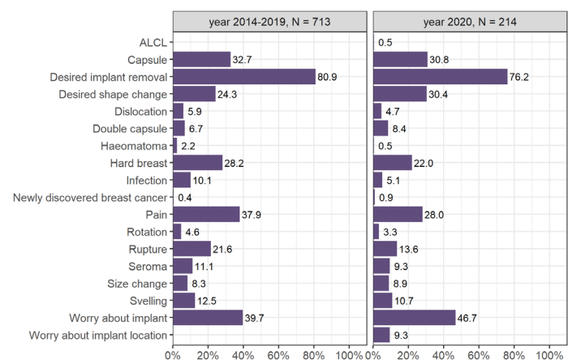


Figure 11 B.

Rapporterade orsaker till permanent uttag av implantat år 2014-2019 samt år 2020.

WHAT IS DONE WITH THE CAPSULE WHEN THE IMPLANT IS REMOVED?

In 2020 we have provided detailed information about the treatment of the capsule at re-operation. ”En bloc” resection av capsule round the implant was performed in 21.3 % of permanent removals of implants. This occurs despite the fact that only eight known cases of BIA- ALCL in Sweden, three of which are registered in the BRIMP (Figure 12).

Lege artis for the curative treatment of BIA-ALCL is an ”en bloc resection”. There is, however, no international or Swedish standard for this type of treatment in benign conditions of the breast.

Therefore 21.3 % ”en bloc” resections is a relatively high percentage and must be interpreted as self-selected from the patient’s perspective.

Of those who have had permanent removal of the implant for capsule formation, 42.6% have been treated with a total capsule removal and 28.7% with a partial resection.

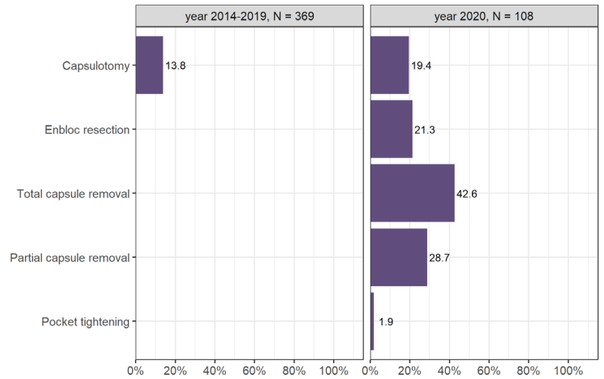


Figure 12.

Treatment of capsule in permanent removal of implant, 2014-2019 and 2020.

TREATMENT OF THE CAPSULE IN RE-OPERATIONS WITH NEW INSERTION OF IMPLANT

Generally we have seen a tendency toward more extensive treatment of the capsule over the years. In some cases the patient needs to undergo several operations if she contracts an infection in conjunction with the primary surgery. In many cases, removal of the implant is required to heal an infection in the prosthesis cavity. A new implant can be inserted after several months.

Figure 13 shows the capsular work done during re-operations for secondary augmentations i.e. after infection and removal of the primary implant. The concept ”en bloc resection” shown here in the diagram demonstrates that at registration there has been a clear misunderstanding of its meaning. The variable’s definition needs to be clarified during the year to reduce the occurrence of incorrect data in the BRIMP.

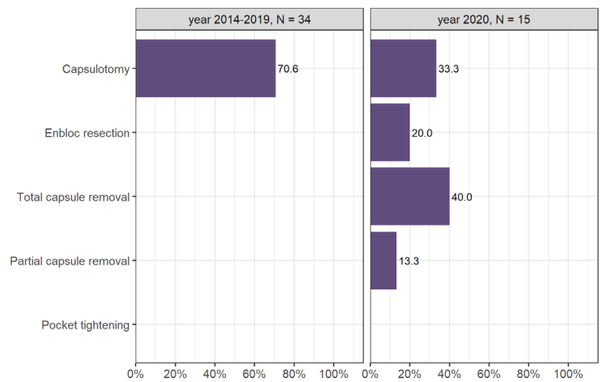


Figure 13.

Treatment of the capsule with new insertion of implant, 2014-2019 and 2020.

SUMMARY

- Data has been registered in the BRIMP from 6221 patients and 11 750 implants for a documented re-operation, irrespective of diagnosis or time of primary operation.
- Patient-reported data shows that the reason for re-operation is a desire for a change in shape or volume of the breast.
- Hard and painful capsule formation was reported in 25% of cases.
- A ruptured implant was found in 11.1% of 9721 revised implants 2014–2019 and in 8.8 % of 2029 revised implants in 2020.
- Incorrect placement of the implant was found intra-operatively in 8.7% (2014–2019) and 5.7 % (2020) of cases.

Whether the tendency for removal of implants as desired by the patient is increasing in the country cannot be determined based on the data as implant removal is also becoming more common among those patients who undergo re-operation for other reasons.

Future data will give a clearer picture about this. Reporting clinics require more information about the definition of variables concerning treatment of the capsule.

RE-OPERATION **23,3%**

BREAST RECONSTRUCTION

There is evidence in the BRIMP that 23.3% of patients who underwent primary reconstruction 2014–2020 with implant have undergone a re-operation.

A hard and painful breast is seen in 30 % of those who undergo re-operation.

apsule tissue at re-operation is treated differently in different parts of the country. Data in the BRIMP shows that only a minority perform a total or partial removal of the capsule.

RE-OPERATION **5%**

BENIGN BREAST CONDITIONS

There is evidence in the BRIMP that 5 % of patients who underwent primary surgery for benign conditions 2014–2020 with an implant have undergone a re-operation.

Reasons of appearance were the dominating motivation for re-operation, 15.5% of patients developed a hard capsule.

RISK FOR RE-OPERATION AFTER BREAST RECONSTRUCTION
FOR CANCER AND IN BENIGN BREAST CONDITIONS

Summary

The reports encompasses all patients in the BRIMP who underwent their primary operation from 2014–2020 and the outcome which has been examined if time to first re-operation for each respective breast.

The risk for a first re-operation is calculated at breast and not patient level and is graphically illustrated using a Kaplan-Meier diagram. Significance tests for the differences between groups have been done using the log rank-test where p <0.05 considered significant. Further re-operations on the same breast are not included in the analysis.

SHORT-TERM RISK FOR RE-OPERATION WITHIN 60 DAYS AND 1 YEAR

The short-term overall risk irrespective of cause of re-operation within 60 days is very low even if the groups differ significantly (p <0.05) (Figure 14).

Figure 15 shows the risk increases over time and reaches 4.6% at six months and 13.1% for the observation time of one year in breast the reconstruction cohort which includes breast reconstructions after cancer and risk-reducing mastectomies. The difference between the patient groups is statistically significant (figure 15).

Infection och haematoma are the main reasons for early revision within 60 days in both groups an and the figure for these lies below 1%. The reconstruction cohort has, however, a higher risk than for patients undergoing surgery for benign conditions of the breast. (p <0.05). See figure 16.

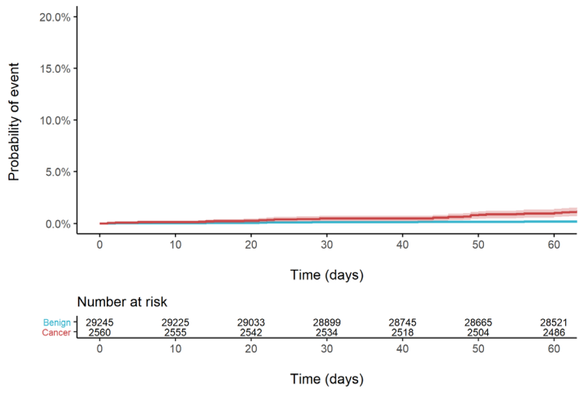


Figure 14.

Risk for re-operation within 60 days.

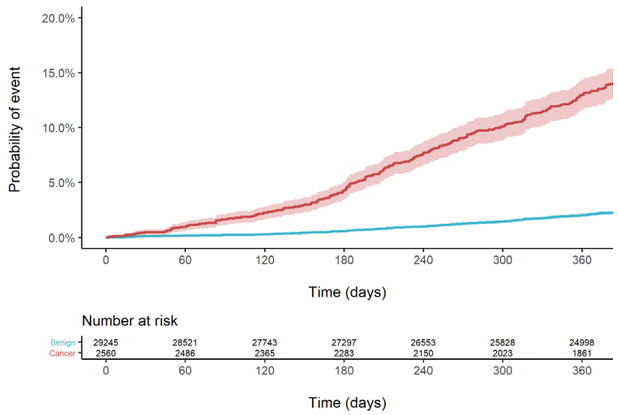


Figure 15.

Risk for re-operation within one year

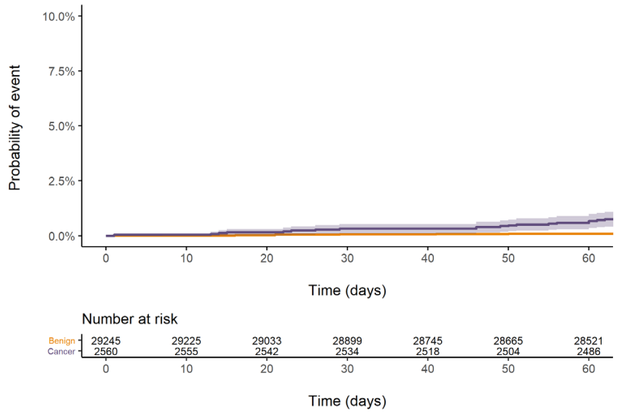


Figure 16.

Risk for haematoma or infection within 60 days.

LONG-TERM RISK FOR RE-OPERATION WITHIN 6 YEARS

In the reconstruction cohort after breast cancer and risk-reducing mastectomies, the general risk for a revision surgery is significantly higher (24.9%) than with breast augmentations for benign conditions (6.92 %).

Breast reconstructed patients show a relatively constant risk profile for re-operation during the first two to six years after their primary operation. One known ”confounding factor” is radiation therapy which significantly increases the risk re-operation in the cancer group during the observation period. the BRIMP’s early data confirms the clinical experience.

Risk for re-operation (%)	*Benign conditions*	*Reconstructions*
6 months	0,61	4,62
1 year	2,11	13,18
6 years	6,92	24,97

RISK ANALYSIS WITH RESPECT TO **IMPLANT-RELATED FACTORS**

Summary

Different variables have been analysed regarding potential effect on the risk for re-operation.

RISK ANALYSIS REGARDING NEED FOR THE CORRECTION OF IMPLANT POSITION.

BRIMP's variable "incorrect position" of the implant denotes the position of the implant in relation to the breast's shape assuming that about 40% of the natural breast is located proximal and 50–60% distal to the breast areola. Shape changes thus involve incorrect positions proximally and distally in relation to the nipple

Proximal incorrect placement is seen mainly in patients with breast reconstructions who develop a constrictive capsule around the implant. In benign conditions the natural breast can become ptotic and glide down while the textured implant remains in place.

Distal/lateral incorrect positioning of implants which glide down have been clinically observed chiefly in smooth implants. BRIMP's database collects all the above mentioned clinical states under the variable "incorrect position".

With the use of Mentor's implant for reconstruction the risk for re-operation increases due to incorrect positioning (including the variable incorrect position, rotation and double capsule) to 5.1% during the 6-year observation period.

In the graphic showing the risk for re-operation due to incorrect position. The variable include "incorrect position", "rotation" and "double capsule" (figure 17). Evaluation of the variable implant "incorrect position" with respect to re-operation shows a low risk of under 2.8% in benign conditions within the 6-year observation period for the other implants (Arion, Allergan, B-lite, Eurosilicone, Perthese Polytech and Silimed).

During the six-year observation Motiva's (0.46%) and Mentor's (0.84%) products showed a low risk but Mentor's implant had a significantly higher risk for re-operation (p <0.05).

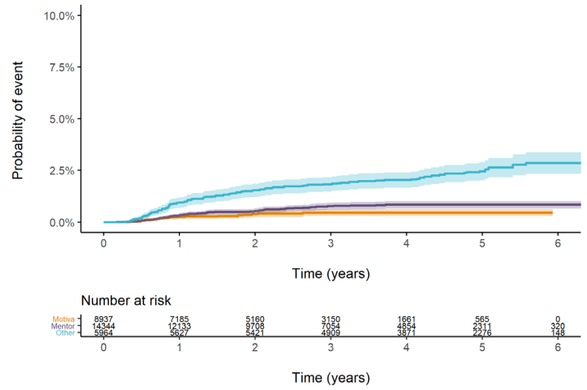


Figure 17.

Risk for re-operation due to incorrect position in benign conditions of the breast divided into implant make.

- In figure 17 "Risk for re-operation due to incorrect position, rotation och double capsule".
- Evaluation of the variable "incorrect position" in re-operations shows a low risk of less than 2.8% in benign breast conditions within a 6-year observation period for other implants (Arion, Allergan, B-lite, Eurosilicone, Perthese Polytech and Silimed).
- During the six-year observation period it was shown that Motiva's (0.46%) and Mentor's (0.84%) products had a low risk, but Mentor's implant had a significantly higher risk of re-operation (p <0,05).

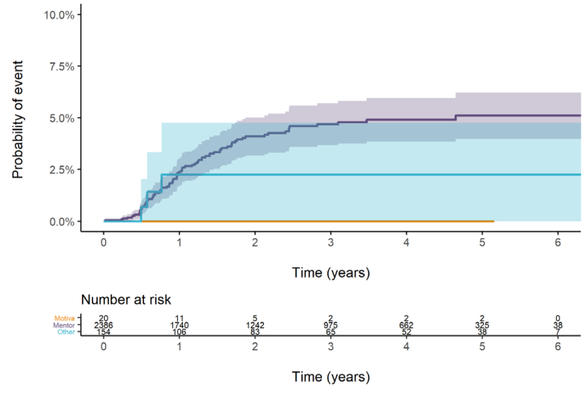


Figure 18.

With the use of Mentor's make in reconstruction, the risk for re-operation increases due to incorrect positioning (including variables incorrect position, rotation and double capsule) to 5.1 % over a 6- year observation period.

RISK ANALYSIS CONCERNING DEFLATION/RUPTURE OF IMPLANT

During the past few years we have not seen any great differences between implant manufacturers; Allergan, Arion, B-lite Eurosilicone, Perthese Polytech and Silimed which have been grouped together under the heading “Other” and the manufacturers Mentor and Motiva in regard to the risk for implant rupture. Please note that Motiva’s products are not used to any great extent in reconstructive surgery in Sweden.

In the reconstruction group there is a risk of 1.58% of undergoing revision due to a ruptured gel or en an empty saline portion of the implant from the manufacturer Mentor within six years. The other manufacturers have a 2% risk within six years. (figure 19). One important aspect which must be taken into consideration is the relationship between a defective implant and radiation treatment.

Figure 20 shows clearly that patients who have undergone radiation have almost a 100% risk of re-operation due to a ruptured implant within 4 years. Den overall assessment is that the risk for requiring a re-operation due to a ruptured implant within six years after the primary operation is very low in benign breast conditions. The risk amounted to 0.35% for other implant manufacturers, 0.06% for Motiva and 0.13 % for Mentor (figure 21).

No significant differences between manufacturers could be seen with breast augmentation due to benign conditions.

SUMMARY

- Patient has after a breast reconstruction a significantly higher risk of undergoing a re-operation within 60 days, 1 and 6 years after the primary operation compared to patients who underwent operation for benign conditions.
- The risk of undergoing a re-operation is very low within 60 days but thereafter increases within 6 years to 25% for reconstruction and to 7% for benign conditions.
- Having gone through radiation treatment is of great significance for re-operation.
- Other factors are incorrect positioning of implant, capsule and implant rupture, deflation, for example, with the use of expanded prostheses.
- The risk of having to undergo re-operation due to a ruptured implant within 6 years is generally very low. It is <1% in benign conditions. Although having undergone radiation prior to operation appears to be a risk factor.
- No significant differences between implant manufacturers have been seen.

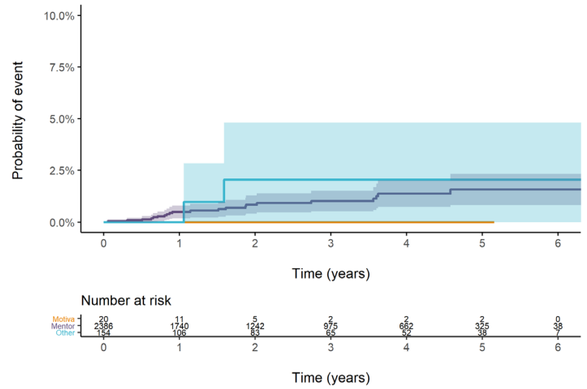


Figure 19.

Risk for re-operation within 6 years due to deflation of implant in reconstructed patients as opposed to implant manufacturer.

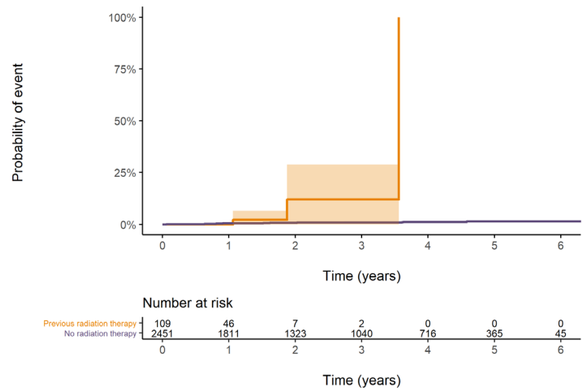


Figure 20.

Risk for re-operation due to deflation in patients with reconstructions, divided into groups as to whether they have been treated with radiation or not.

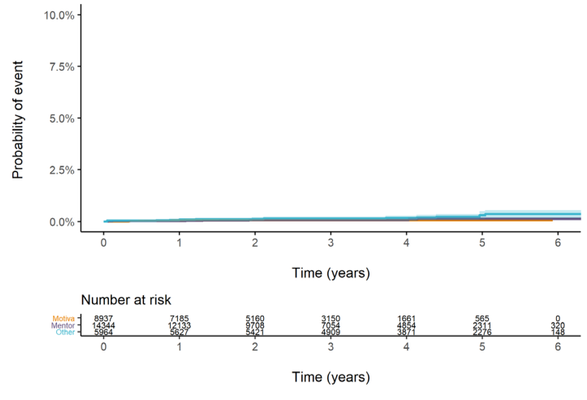


Figure 21.

Risk for re-operation due to deflation in benign conditions shown against implant manufacturer.

APPENDIX
TABLES

See references to tables in the annual report.

TABLE 1.
Production data irrespective of indication.

Region	Number of implants, year 2014-2019	Number of implants, year 2020	Number of patients, year 2014-2019	Number of patients, year 2020
Dalarna	254	38	168	168
Gävleborg	711	66	356	356
Jönköping	1168	283	596	596
Kalmar	542	0	300	300
Kronoberg	43	14	38	38
Skåne	5774	643	3008	3008
Stockholm	9985	1115	5157	5157
Uppsala	1909	250	999	999
Västerbotten	631	37	327	327
Västmanland	11	0	9	9
Västra Götaland	7256	1359	3678	3678
Örebro	175	14	123	123
Östergötland	1032	361	558	558
Riket	29 491	4180	15 317	15 317

TABLE 2.
Production data for benign indications.

Region	Number of implants, year 2014-2019	Number of implants, year 2020	Number of patients, year 2014-2019	Number of patients, year 2020
Dalarna	116	17	62	9
Gävleborg	711	66	356	33
Jönköping	1162	281	591	141
Kalmar	371	0	188	0
Kronoberg	1	0	1	0
Skåne	5293	596	2663	302
Stockholm	8384	998	4227	505
Uppsala	1743	214	883	111
Västerbotten	594	36	298	18
Västmanland	1	0	1	0
Västra Götaland	6349	1262	3189	633
Örebro	52	3	32	2
Östergötland	777	300	393	152
Riket	25 554	3773	12 884	1906

TABLE 3.
Production data for reconstruction.

Region	Number of implants, year 2014-2019	Number of implants, year 2020	Number of patients, year 2014-2019	Number of patients, year 2020
Dalarna	136	21	104	15
Gävleborg	0	0	0	0
Jönköping	6	2	5	1
Kalmar	79	0	66	0
Kronoberg	42	14	37	14
Skåne	429	47	319	33
Stockholm	777	117	511	79
Uppsala	166	36	116	19
Västerbotten	37	1	29	1
Västmanland	10	0	8	0
Västra Götaland	121	97	90	69
Örebro	123	11	91	9
Östergötland	235	61	153	33
Riket	2161	407	1529	273

TABLE 4.
Inoperative techniques for benign indications.

Variable	*Outcome*	*Proportion year 2014-2019 (%)*	*Proportion year 2020 (%)*
Fat graft	Yes	0.4	0.2
Fat graft	No	48.4	91.8
Fat graft	Unknown	51.2	8.0
Incision	Axillary	12.3	7.4
Incision	Mastectomy scar	0.6	0.4
Incision	Mastopexy with augmentation	2.8	8.1
Incision	Periareolar	0.6	0.1
Incision	Submammary	79.8	82.8
Incision	Unknown	4.0	1.2
Mesh	Yes	0.1	0.1
Mesh	No	31.4	92.2
Mesh	Unknown	68.5	7.8
Position	Dual plane	57.4	53.9
Position	Subfascial	0.6	1.1
Position	Subglandular	5.0	8.5
Position	Submuscular	35.3	34.7
Position	Unknown	1.8	1.8
Previously operated due to infection	Yes	0.3	0.1
Previously operated due to infection	No	88.8	91.7
Previously operated due to infection	Unknown	10.9	8.2
Previously operated due to mastopexy/reduction	Yes	2.9	4.5
Previously operated due to mastopexy/reduction	No	86.3	87.2
Previously operated due to mastopexy/reduction	Unknown	10.8	8.3
Previously operated due to tumor	Yes	0.5	0.2
Previously operated due to tumor	No	88.8	91.5
Previously operated due to tumor	Unknown	10.7	8.2
Volume ml/cc/g	<199	2.5	3.0
Volume ml/cc/g	200-399	66.8	69.4
Volume ml/cc/g	400-599	25.4	23.2
Volume ml/cc/g	>=600	4.0	3.6
Volume ml/cc/g	Unknown	1.4	0.7

TABLE 5.
Inoperative techniques for reconstruction.

Variable	*Outcome*	*Proportion year 2014-2019 (%)*	*Proportion year 2020 (%)*
Fat graft	Yes	1.3	0.5
Fat graft	No	52.9	85.3
Fat graft	Unknown	45.8	14.3
Incision	Axillary	0.3	0
Incision	Mastectomy scar	55.2	44.2
Incision	Mastopexy with augmentation	1.6	4.4
Incision	Periareolar	5.8	10.8
Incision	Submammary	24.4	33.9
Incision	Unknown	12.8	6.6
Mesh	Yes	4.9	20.1
Mesh	No	31.0	74.2
Mesh	Unknown	64.1	5.7
Position	Dual plane	12.9	26.5
Position	Subfascial	0.3	1.5
Position	Subglandular	1.6	12.3
Position	Submuscular	83.1	51.1
Position	Unknown	2.1	8.6
Previously operated due to infection	Yes	1.9	0.5
Previously operated due to infection	No	93.0	91.4
Previously operated due to infection	Unknown	5.1	8.1
Previously operated due to mastopexy/reduction	Yes	5.0	11.8
Previously operated due to mastopexy/reduction	No	90.1	80.6
Previously operated due to mastopexy/reduction	Unknown	4.8	7.6
Previously operated due to tumor	Yes	46.4	35.6
Previously operated due to tumor	No	50.9	58.2
Previously operated due to tumor	Unknown	2.7	6.1
Volume ml/cc/g	<199	10.2	8.4
Volume ml/cc/g	200-399	53.4	57.5
Volume ml/cc/g	400-599	25.5	23.8
Volume ml/cc/g	>=600	1.6	2.2
Volume ml/cc/g	Unknown	9.2	8.1

TABLE 6A. INCISION FOR BENIGN INDICATIONS

Region	*Outcome*	*Proportion year 2014-2019 (%)*	*Proportion year 2020 (%)*
Dalarna	Axillary	0	0
	Mastectomy scar	0	0
	Mastopexy with augmentation	1.7	23.5
	Periareolar	6.9	23.5
	Submammary	73.3	35.3
	Unknown	18.1	17.6
Gävleborg	Axillary	0	0
	Mastectomy scar	0	0
	Mastopexy with augmentation	7.3	21.2
	Periareolar	0	0
	Submammary	72.7	78.8
	Unknown	20.0	0
Jönköping	Axillary	0	0
	Mastectomy scar	0.9	0
	Mastopexy with augmentation	3.4	8.5
	Periareolar	0	0
	Submammary	94.4	91.5
	Unknown	1.4	0
Kalmar	Axillary	0	0
	Mastectomy scar	0	0
	Mastopexy with augmentation	0	0
	Periareolar	0	0
	Submammary	99.7	0
	Unknown	0.3	0
Kronoberg	Axillary	0	0
	Mastectomy scar	0	0
	Mastopexy with augmentation	0	0
	Periareolar	0	0
	Submammary	100.0	0
Skåne	Axillary	57.5	46.6
	Mastectomy scar	1.4	0.8
	Mastopexy with augmentation	2.1	11.1
	Periareolar	0.7	0
	Submammary	36.9	37.2
	Unknown	1.3	4.2
Stockholm	Axillary	0.2	0.1
	Mastectomy scar	0.1	0
	Mastopexy with augmentation	1.1	4.1
	Periareolar	0.3	0
	Submammary	93.9	94.7
	Unknown	4.4	1.1
Uppsala	Axillary	3.2	0
	Mastectomy scar	0.2	0.5
	Mastopexy with augmentation	2.5	9.8
	Periareolar	0.9	0.5
	Submammary	90.6	88.8
	Unknown	2.6	0.5
Västerbotten	Mastectomy scar	0	0
	Mastopexy with augmentation	2.4	33.3
	Periareolar	0.3	0
	Submammary	96.8	66.7
	Unknown	0.5	0
	Unknown	0.5	0
Västmanland	Axillary	0	0
	Mastectomy scar	0	0
	Mastopexy with augmentation	0	0
	Periareolar	0	0
	Submammary	100.0	0
Västra Götaland	Axillary	0.2	0
	Mastectomy scar	0.8	0.5
	Mastopexy with augmentation	3.2	4.8
	Periareolar	1.1	0
	Submammary	89.6	94.2
	Unknown	5.1	0.5
Örebro	Axillary	0	0
	Mastectomy scar	5.8	0
	Mastopexy with augmentation	13.5	66.7
	Periareolar	0	0
	Submammary	73.1	33.3
	Unknown	7.7	0
Östergötland	Axillary	0	0
	Mastectomy scar	0.8	1.3
	Mastopexy with augmentation	18.8	19.7
	Periareolar	0.3	0
	Submammary	78.4	79.0
	Unknown	1.8	0

TABLE 6B. IMPLANT PLACEMENT FOR BENIGN INDICATIONS

Position

Region	*Outcome*	*Proportion year 2014-2019 (%)*	*Proportion year 2020 (%)*
Dalarna	Dual plane	1.7	0
	Subfascial	0	0
	Subglandular	80.2	47.1
	Submuscular	16.4	35.3
	Unknown	1.7	17.6
Gävleborg	Dual plane	87.5	97.0
	Subfascial	0	3.0
	Subglandular	0	0
	Submuscular	12.5	0
Jönköping	Dual plane	71.6	82.2
	Subfascial	0.5	0
	Subglandular	2.6	3.6
	Submuscular	25.3	14.2
Kalmar	Dual plane	52.0	0
	Subfascial	0	0
	Subglandular	2.4	0
	Submuscular	45.3	0
	Unknown	0.3	0
Kronoberg	Dual plane	100.0	0
	Subfascial	0	0
	Subglandular	0	0
	Submuscular	0	0
Skåne	Dual plane	69.4	84.9
	Subfascial	0.1	0
	Subglandular	3.6	2.3
	Submuscular	24.7	7.4
	Unknown	2.4	5.4
Stockholm	Dual plane	61.0	37.9
	Subfascial	0.6	1.0
	Subglandular	3.8	11.3
	Submuscular	32.4	48.2
	Unknown	2.2	1.6
Uppsala	Dual plane	41.3	77.6
	Subfascial	0.8	2.8
	Subglandular	5.0	6.5
	Submuscular	52.4	13.1
	Unknown	0.4	0
Västerbotten	Dual plane	51.5	88.9
	Subfascial	0	0
	Subglandular	2.9	0
	Submuscular	45.6	11.1
Västmanland	Subfascial	0	0
	Subglandular	100.0	0
	Submuscular	0	0
Västra Götaland	Dual plane	45.1	43.3
	Subfascial	1.3	1.7
	Subglandular	4.2	4.6
	Submuscular	47.6	49.0
	Unknown	1.9	1.3
Örebro	Dual plane	75.0	66.7
	Subfascial	1.9	0
	Subglandular	0	33.3
	Submuscular	21.2	0
	Unknown	1.9	0
Östergötland	Dual plane	39.4	36.0
	Subfascial	0	0
	Subglandular	32.7	34.3
	Submuscular	25.9	29.7
	Unknown	2.1	0

TABLE 7A. INCISION FOR RECONSTRUCTION

Incision

Region	*Outcome*	*Proportion year 2014-2019 (%)*	*Proportion year 2020 (%)*
Dalarna	Axillary	0	0
	Mastectomy scar	2.9	0
	Mastopexy with augmentation	0	4.8
	Periareolar	3.7	0
	Submammary	34.6	0
	Unknown	58.8	95.2
Gävleborg	Axillary	0	0
	Mastectomy scar	0	0
	Mastopexy with augmentation	0	0
	Periareolar	0	0
	Submammary	0	0
Jönköping	Axillary	0	0
	Mastectomy scar	100.0	0
	Mastopexy with augmentation	0	0
	Periareolar	0	0
	Submammary	0	100.0
Kalmar	Axillary	1.3	0
	Mastectomy scar	78.5	0
	Mastopexy with augmentation	0	0
	Periareolar	5.1	0
	Submammary	13.9	0
	Unknown	1.3	0
Kronoberg	Axillary	0	0
	Mastectomy scar	71.4	64.3
	Mastopexy with augmentation	4.8	0
	Periareolar	11.9	0
	Submammary	11.9	35.7
Skåne	Axillary	0.2	0
	Mastectomy scar	88.3	78.7
	Mastopexy with augmentation	0.7	0
	Periareolar	0.9	4.3
	Submammary	7.7	17.0
	Unknown	2.1	0
Stockholm	Axillary	0	0
	Mastectomy scar	31.4	12.8
	Mastopexy with augmentation	2.1	0.9
	Periareolar	8.0	25.6
	Submammary	41.7	54.7
	Unknown	16.9	6.0
Uppsala	Axillary	0	0
	Mastectomy scar	42.2	27.8
	Mastopexy with augmentation	5.4	36.1
	Periareolar	21.1	16.7
	Submammary	18.7	19.4
	Unknown	12.7	0
Västerbotten	Axillary	2.7	0
	Mastectomy scar	51.4	100.0
	Mastopexy with augmentation	0	0
	Periareolar	5.4	0
	Submammary	21.6	0
	Unknown	18.9	0
Västmanland	Axillary	0	0
	Mastectomy scar	80.0	0
	Mastopexy with augmentation	0	0
	Periareolar	20.0	0
	Submammary	0	0
Västra Götaland	Axillary	2.5	0
	Mastectomy scar	66.9	71.1
	Mastopexy with augmentation	2.5	3.1
	Periareolar	1.7	0
	Submammary	26.4	25.8
Örebro	Axillary	0	0
	Mastectomy scar	80.5	54.5
	Mastopexy with augmentation	0	0
	Periareolar	4.1	18.2
	Submammary	11.4	27.3
	Unknown	4.1	0
Östergötland	Axillary	0	0
	Mastectomy scar	80.9	54.1
	Mastopexy with augmentation	0.4	0
	Periareolar	0	6.6
	Submammary	9.4	39.3
	Unknown	9.4	0

TABLE 7B. IMPLANT PLACEMENT FOR RECONSTRUCTION

Position

Region	*Outcome*	*Proportion year 2014-2019 (%)*	*Proportion year 2020 (%)*
Dalarna	Subfascial	0	0
	Subglandular	1.5	0
	Submuscular	96.3	0
	Unknown	2.2	100.0
Gävleborg	Subfascial	0	0
	Subglandular	0	0
	Submuscular	0	0
Jönköping	Dual plane	0	100.0
	Subfascial	0	0
	Subglandular	0	0
	Submuscular	100.0	0
Kalmar	Dual plane	19.0	0
	Subfascial	0	0
	Subglandular	0	0
	Submuscular	81.0	0
Kronoberg	Dual plane	71.4	92.9
	Subfascial	0	7.1
	Subglandular	0	0
	Submuscular	26.2	0
	Unknown	2.4	0
Skåne	Dual plane	19.8	12.8
	Subfascial	0.5	2.1
	Subglandular	0.5	2.1
	Submuscular	79.0	83.0
	Unknown	0.2	0

Region	*Outcome*	*Proportion year 2014-2019 (%)*	*Proportion year 2020 (%)*
Stockholm	Dual plane	5.0	4.3
	Subfascial	0	0.9
	Subglandular	1.5	0.9
	Submuscular	90.9	84.6
	Unknown	2.6	9.4
Uppsala	Dual plane	6.6	5.6
	Subfascial	2.4	8.3
	Subglandular	3.0	25.0
	Submuscular	78.3	55.6
	Unknown	9.6	5.6
Västerbotten	Dual plane	8.1	0
	Subfascial	0	0
	Subglandular	2.7	0
	Submuscular	86.5	100.0
	Unknown	2.7	0
Västmanland	Dual plane	20.0	0
	Subfascial	0	0
	Subglandular	0	0
	Submuscular	80.0	0
Västra Götaland	Dual plane	51.2	78.4
	Subfascial	0	0
	Subglandular	5.8	9.3
	Submuscular	42.1	11.3
	Unknown	0.8	1.0
Örebro	Dual plane	19.5	36.4
	Subfascial	0	0
	Subglandular	2.4	0
	Submuscular	78.0	63.6
Östergötland	Dual plane	3.0	0
	Subfascial	0	0
	Subglandular	1.3	49.2
	Submuscular	94.5	50.8
	Unknown	1.3	0

TABLE 8. INFECTION PROPHYLAXIS FOR BENIGN INDICATIONS

Region	*Year*	*Antibiotics*	*Proportion (%)*
Dalarna	2014-2019	Pre or per	98.3
	2014-2019	Intra	0.0
	2014-2019	Post	84.5
	2020	Pre or per	88.2
	2020	Intra	0.0
	2020	Post	88.2
Gävleborg	2014-2019	Pre or per	98.9
	2014-2019	Intra	2.0
	2014-2019	Post	98.0
	2020	Pre or per	100.0
	2020	Intra	0.0
	2020	Post	100.0
Jönköping	2014-2019	Pre or per	98.8
	2014-2019	Intra	8.4
	2014-2019	Post	2.6
	2020	Pre or per	100.0
	2020	Intra	0.0
	2020	Post	0.7
Kalmar	2014-2019	Pre or per	99.5
	2014-2019	Intra	0.5
	2014-2019	Post	4.3
	2020	Intra	0.0
	2020	Post	0.0
	2020	Pre or per	0.0
Kronoberg	2014-2019	Pre or per	100.0
	2014-2019	Intra	0.0
	2014-2019	Post	0.0
	2020	Intra	0.0
	2020	Post	0.0
	2020	Pre or per	0.0
Skåne	2014-2019	Pre or per	95.3
	2014-2019	Intra	19.8
	2014-2019	Post	68.8
	2020	Pre or per	92.4
	2020	Intra	23.5
	2020	Post	58.7
Stockholm	2014-2019	Pre or per	95.6
	2014-2019	Intra	53.2
	2014-2019	Post	30.2
	2020	Pre or per	97.2
	2020	Intra	66.6
	2020	Post	17.4
Uppsala	2014-2019	Pre or per	99.8
	2014-2019	Intra	0.3
	2014-2019	Post	19.8
	2020	Pre or per	99.5
	2020	Intra	1.4
	2020	Post	36.9
Västerbotten	2014-2019	Pre or per	83.8
	2014-2019	Intra	0.3
	2014-2019	Post	20.2
	2020	Pre or per	100.0
	2020	Intra	0.0
	2020	Post	11.1
Västmanland	2014-2019	Pre or per	100.0
	2014-2019	Intra	0.0
	2014-2019	Post	0.0
	2020	Intra	0.0
	2020	Post	0.0
	2020	Pre or per	0.0
Västra Götaland	2014-2019	Pre or per	95.5
	2014-2019	Intra	4.3
	2014-2019	Post	6.7
	2020	Pre or per	97.7
	2020	Intra	5.5
	2020	Post	6.5

TABLE 8. INFECTION PROPHYLAXIS FOR BENIGN INDICATIONS (CONTINUED)

Region	*Year*	*Antibiotics*	*Proportion (%)*
Örebro	2014-2019	Pre or per	67.3
		Intra	15.4
		Post	40.4
	2020	Pre or per	33.3
		Intra	0.0
		Post	0.0
Östergötland	2014-2019	Pre or per	99.6
	2014-2019	Intra	0.0
	2014-2019	Post	93.3
	2020	Pre or per	98.0
	2020	Intra	0.0
	2020	Post	96.3
Riket	2014-2019	Pre or per	95.9
	2014-2019	Intra	23.1
	2014-2019	Post	33.8
	2020	Pre or per	97.0
	2020	Intra	23.3
	2020	Post	28.1

TABLE 9. INFECTION PROPHYLAXIS FOR RECONSTRUCTION

Region	*Year*	*Antibiotics*	*Proportion (%)*
Dalarna	2014-2019	Pre or per	97.8
	2014-2019	Intra	0.7
	2014-2019	Post	58.8
	2020	Pre or per	100.0
	2020	Intra	0.0
	2020	Post	85.7
Gävleborg	2014-2019	Intra	0.0
	2014-2019	Post	0.0
	2014-2019	Pre or per	0.0
	2020	Intra	0.0
	2020	Post	0.0
	2020	Pre or per	0.0
Jönköping	2014-2019	Pre or per	83.3
	2014-2019	Intra	0.0
	2014-2019	Post	83.3
	2020	Pre or per	100.0
	2020	Intra	0.0
	2020	Post	0.0
Kalmar	2014-2019	Pre or per	96.2
	2014-2019	Intra	2.5
	2014-2019	Post	58.2
	2020	Intra	0.0
	2020	Post	0.0
	2020	Pre or per	0.0
Kronoberg	2014-2019	Pre or per	100.0
	2014-2019	Intra	0.0
	2014-2019	Post	78.6
	2020	Pre or per	100.0
	2020	Intra	0.0
	2020	Post	78.6
Skåne	2014-2019	Pre or per	81.4
	2014-2019	Intra	7.5
	2014-2019	Post	53.6
	2020	Pre or per	72.3
	2020	Intra	2.1
	2020	Post	48.9
Stockholm	2014-2019	Pre or per	97.3
	2014-2019	Intra	3.0
	2014-2019	Post	22.0
	2020	Pre or per	86.3
	2020	Intra	5.1
	2020	Post	18.8
Uppsala	2014-2019	Pre or per	87.3
	2014-2019	Intra	8.4
	2014-2019	Post	50.6
	2020	Pre or per	83.3
	2020	Intra	16.7
	2020	Post	88.9
Västerbotten	2014-2019	Pre or per	81.1
	2014-2019	Intra	0.0
	2014-2019	Post	21.6
	2020	Pre or per	100.0
	2020	Intra	0.0
	2020	Post	0.0
Västmanland	2014-2019	Pre or per	100.0
	2014-2019	Intra	0.0
	2014-2019	Post	0.0
	2020	Intra	0.0
	2020	Post	0.0
	2020	Pre or per	0.0

TABLE 9. (CONTINUED) INFECTION PROPHYLAXIS FOR RECONSTRUCTION

Region	*Year*	*Antibiotics*	*Proportion (%)*
Västra Götaland	2014-2019	Pre or per	93.4
	2014-2019	Intra	2.5
	2014-2019	Post	20.7
	2020	Pre or per	93.8
	2020	Intra	0.0
	2020	Post	14.4
Örebro	2014-2019	Pre or per	82.9
	2014-2019	Intra	0.0
	2014-2019	Post	84.6
	2020	Pre or per	90.9
	2020	Intra	0.0
	2020	Post	72.7
Östergötland	2014-2019	Pre or per	94.0
	2014-2019	Intra	1.7
	2014-2019	Post	34.5
	2020	Pre or per	95.1
	2020	Intra	0.0
	2020	Post	78.7
Riket	2014-2019	Pre or per	91.7
	2014-2019	Intra	3.7
	2014-2019	Post	40.1
	2020	Pre or per	88.9
	2020	Intra	3.2
	2020	Post	43.2

TABLE 10. IMPLANT CHOICE FOR BENIGN INDICATIONS

Divided by region.

Region	*Variable*	*Outcome*	*Proportion year 2014-2019 (%)*	*Proportion year 2020 (%)*
Dalarna	Fill	Saline	0.0	11.8
	Fill	Saline and silicone	0.0	0.0
	Fill	Silicone	100.0	70.6
	Fill	Unknown	0.0	17.6
	Manufacturer	Mentor	100.0	100.0
	Manufacturer	Motiva	0.0	0.0
	Manufacturer	Other	0.0	0.0
	Shape	Anatomical	6.9	23.5
	Shape	Round	92.2	64.7
	Shape	Unknown	0.9	11.8
	Surface	Polyurethane	0.0	0.0
	Surface	Smooth	0.0	11.8
	Surface	Textured	97.4	70.6
	Surface	Unknown	2.6	17.6
Gävleborg	Fill	Saline	0.3	0.0
	Fill	Saline and silicone	0.0	0.0
	Fill	Silicone	99.7	100.0
	Fill	Unknown	0.0	0.0
	Manufacturer	Mentor	99.2	100.0
	Manufacturer	Motiva	0.8	0.0
	Manufacturer	Other	0.0	0.0
	Shape	Anatomical	0.0	0.0
	Shape	Round	100.0	100.0
	Shape	Unknown	0.0	0.0
	Surface	Polyurethane	0.0	0.0
	Surface	Smooth	72.4	100.0
	Surface	Textured	27.6	0.0
	Surface	Unknown	0.0	0.0
Jönköping	Fill	Saline	0.2	0.0
	Fill	Saline and silicone	0.2	0.0
	Fill	Silicone	99.4	98.9
	Fill	Unknown	0.3	1.1
	Manufacturer	Mentor	62.8	66.5
	Manufacturer	Motiva	21.0	33.5
	Manufacturer	Other	16.2	0.0
Jönköping - forts	Shape	Anatomical	60.4	26.3
	Shape	Round	39.5	73.7
	Shape	Unknown	0.1	0.0
	Surface	Polyurethane	0.3	0.0
	Surface	Smooth	4.9	50.2
	Surface	Textured	94.5	49.8
	Surface	Unknown	0.3	0.0
Kalmar	Fill	Saline	0.5	0.0
	Fill	Saline and silicone	2.2	0.0
	Fill	Silicone	96.8	0.0
	Fill	Unknown	0.5	0.0
	Manufacturer	Mentor	100.0	0.0
	Manufacturer	Motiva	0.0	0.0
	Manufacturer	Other	0.0	0.0
	Shape	Anatomical	24.0	0.0
	Shape	Round	74.9	0.0
	Shape	Unknown	1.1	0.0
	Surface	Polyurethane	0.0	0.0
	Surface	Smooth	0.5	0.0
	Surface	Textured	98.7	0.0
	Surface	Unknown	0.8	0.0
Kronoberg	Fill	Saline	0.0	0.0
	Fill	Saline and silicone	0.0	0.0
	Fill	Silicone	100.0	0.0
	Fill	Unknown	0.0	0.0
	Manufacturer	Mentor	100.0	0.0
	Manufacturer	Motiva	0.0	0.0
	Manufacturer	Other	0.0	0.0
	Shape	Anatomical	0.0	0.0
	Shape	Round	100.0	0.0
	Shape	Unknown	0.0	0.0
	Surface	Polyurethane	0.0	0.0
	Surface	Smooth	0.0	0.0
	Surface	Textured	100.0	0.0
	Surface	Unknown	0.0	0.0
Skåne	Fill	Saline	0.0	0.3
	Fill	Saline and silicone	0.0	0.2
	Fill	Silicone	97.9	99.5
	Fill	Unknown	2.0	0.0

TABLE 10. IMPLANT CHOICE FOR BENIGN INDICATIONS (CONTINUED)

Division by region.

Region	Variable	Outcome	Proportion year 2014-2019 (%)	Proportion year 2020 (%)
Skåne	Manufacturer	Mentor	22.7	8.6
	Manufacturer	Motiva	66.6	91.4
	Manufacturer	Other	10.8	0.0
	Shape	Anatomical	7.6	2.0
	Shape	Round	91.1	91.9
	Shape	Unknown	1.3	6.0
	Surface	Polyurethane	0.7	0.3
	Surface	Smooth	20.6	63.3
	Surface	Textured	78.0	30.2
	Surface	Unknown	0.7	6.2
Stockholm	Fill	Saline	0.0	0.0
	Fill	Saline and silicone	0.0	0.0
	Fill	Silicone	93.3	89.1
	Fill	Unknown	6.7	10.9
	Manufacturer	Mentor	35.2	39.2
	Manufacturer	Motiva	26.3	40.0
	Manufacturer	Other	38.6	20.8
	Shape	Anatomical	44.5	27.6
	Shape	Round	52.2	58.4
	Shape	Unknown	3.3	14.0
	Surface	Polyurethane	1.0	0.0
	Surface	Smooth	13.2	43.5
	Surface	Textured	80.7	41.7
	Surface	Unknown	5.1	14.8
Uppsala	Fill	Saline	0.1	1.4
	Fill	Saline and silicone	0.0	0.0
	Fill	Silicone	97.9	98.6
	Fill	Unknown	2.0	0.0
	Manufacturer	Mentor	50.8	16.8
	Manufacturer	Motiva	43.9	83.2
	Manufacturer	Other	5.3	0.0
	Shape	Anatomical	27.7	28.0
	Shape	Round	71.5	70.1
	Shape	Unknown	0.9	1.9
	Surface	Polyurethane	0.0	0.0
Uppsala - forts	Surface	Smooth	31.7	83.2
	Surface	Textured	67.2	16.8
	Surface	Unknown	1.1	0.0
Västerbotten	Fill	Saline	0.0	0.0
	Fill	Saline and silicone	0.0	0.0
	Fill	Silicone	100.0	100.0
	Fill	Unknown	0.0	0.0
	Manufacturer	Mentor	100.0	100.0
	Manufacturer	Motiva	0.0	0.0
	Manufacturer	Other	0.0	0.0
	Shape	Anatomical	14.8	11.1
	Shape	Round	85.2	88.9
	Shape	Unknown	0.0	0.0
	Surface	Polyurethane	0.0	0.0
	Surface	Smooth	18.5	0.0
	Surface	Textured	81.5	100.0
	Surface	Unknown	0.0	0.0
Västmanland	Fill	Saline	0.0	0.0
	Fill	Saline and silicone	0.0	0.0
	Fill	Silicone	100.0	0.0
	Fill	Unknown	0.0	0.0
	Manufacturer	Mentor	100.0	0.0
	Manufacturer	Motiva	0.0	0.0
	Manufacturer	Other	0.0	0.0
	Shape	Anatomical	0.0	0.0
	Shape	Round	100.0	0.0
	Shape	Unknown	0.0	0.0
	Surface	Polyurethane	0.0	0.0
	Surface	Smooth	0.0	0.0
	Surface	Textured	100.0	0.0
	Surface	Unknown	0.0	0.0
Västra Götaland	Fill	Saline	0.1	0.0
	Fill	Saline and silicone	0.0	0.0
	Fill	Silicone	99.4	99.1
	Fill	Unknown	0.5	0.9
	Manufacturer	Mentor	67.2	74.2
	Manufacturer	Motiva	6.8	25.6
	Manufacturer	Other	26.1	0.2
	Shape	Anatomical	64.8	52.6

TABLE 10. IMPLANT CHOICE FOR BENIGN INDICATIONS (CONTINUED)

Division by region.

Region	*Variable*	*Outcome*	*Proportion year 2014-2019 (%)*	*Proportion year 2020 (%)*
Västra Götaland - forts.	Shape	Round	34.7	45.8
	Shape	Unknown	0.4	1.6
	Surface	Polyurethane	0.0	0.0
	Surface	Smooth	3.5	22.6
	Surface	Textured	95.9	75.8
	Surface	Unknown	0.6	1.7
Örebro	Fill	Saline	1.9	0.0
	Fill	Saline and silicone	3.8	0.0
	Fill	Silicone	65.4	100.0
	Fill	Unknown	28.8	0.0
	Manufacturer	Mentor	32.7	0.0
	Manufacturer	Motiva	1.9	0.0
	Manufacturer	Other	65.4	100.0
	Shape	Anatomical	38.5	0.0
	Shape	Round	59.6	100.0
	Shape	Unknown	1.9	0.0
	Surface	Polyurethane	0.0	0.0
	Surface	Smooth	21.2	100.0
	Surface	Textured	75.0	0.0
	Surface	Unknown	3.8	0.0
Östergötland	Fill	Saline	0.0	0.0
	Fill	Saline and silicone	0.0	0.0
	Fill	Silicone	99.4	100.0
	Fill	Unknown	0.6	0.0
	Manufacturer	Mentor	76.4	77.3
	Manufacturer	Motiva	23.6	22.7
	Manufacturer	Other	0.0	0.0
	Shape	Anatomical	0.3	0.0
	Shape	Round	99.5	100.0
	Shape	Unknown	0.3	0.0
	Surface	Polyurethane	0.0	0.0
	Surface	Smooth	58.0	88.7
	Surface	Textured	41.7	11.3
	Surface	Unknown	0.3	0.0
Riket	Fill	Saline	0.1	0.2
	Fill	Saline and silicone	0.1	0.0
	Fill	Silicone	96.9	96.4
	Fill	Unknown	3.0	3.3
	Manufacturer	Mentor	48.6	51.7
	Manufacturer	Motiva	28.8	42.6
	Manufacturer	Other	22.6	5.7
	Shape	Anatomical	37.7	29.0
	Shape	Round	60.7	65.7
	Shape	Unknown	1.6	5.4
	Surface	Polyurethane	0.5	0.1
	Surface	Smooth	16.1	46.4
	Surface	Textured	81.3	48.0
	Surface	Unknown	2.1	5.5

TABLE 11. IMPLANT CHOICE FOR RECONSTRUCTION

Division by region.

Region	*Variable*	*Outcome*	*Proportion year 2014-2019 (%)*	*Proportion year 2020 (%)*
Dalarna	Fill	Saline	1.5	0.0
	Fill	Saline and silicone	2.2	0.0
	Fill	Silicone	91.9	0.0
	Fill	Unknown	4.4	100.0
	Manufacturer	Mentor	99.3	100.0
	Manufacturer	Motiva	0.0	0.0
	Manufacturer	Other	0.7	0.0
	Shape	Anatomical	84.6	4.8
	Shape	Round	9.6	23.8
	Shape	Unknown	5.9	71.4
	Surface	Polyurethane	0.0	0.0
	Surface	Smooth	0.0	0.0
	Surface	Textured	94.9	0.0
	Surface	Unknown	5.1	100.0
Gävleborg	Fill	Saline and silicone	0.0	0.0
	Fill	Silicone	0.0	0.0
	Fill	Unknown	0.0	0.0
	Manufacturer	Mentor	0.0	0.0
	Manufacturer	Motiva	0.0	0.0
	Manufacturer	Other	0.0	0.0
	Shape	Anatomical	0.0	0.0
	Shape	Round	0.0	0.0
	Shape	Unknown	0.0	0.0
	Surface	Polyurethane	0.0	0.0
	Surface	Smooth	0.0	0.0
	Surface	Textured	0.0	0.0
	Surface	Unknown	0.0	0.0
	Surface	Unknown	0.0	0.0
Jönköping	Fill	Saline	0.0	0.0
	Fill	Saline and silicone	0.0	0.0
	Fill	Silicone	100.0	100.0
	Fill	Unknown	0.0	0.0
	Manufacturer	Mentor	0.0	100.0
	Manufacturer	Motiva	0.0	0.0
	Manufacturer	Other	100.0	0.0
Jönköping - forts	Shape	Anatomical	100.0	100.0
	Shape	Round	0.0	0.0
	Shape	Unknown	0.0	0.0
	Surface	Polyurethane	100.0	0.0
	Surface	Smooth	0.0	0.0
	Surface	Textured	0.0	100.0
	Surface	Unknown	0.0	0.0
Kalmar	Fill	Saline	2.5	0.0
	Fill	Saline and silicone	12.7	0.0
	Fill	Silicone	84.8	0.0
	Fill	Unknown	0.0	0.0
	Manufacturer	Mentor	100.0	0.0
	Manufacturer	Motiva	0.0	0.0
	Manufacturer	Other	0.0	0.0
	Shape	Anatomical	91.1	0.0
	Shape	Round	7.6	0.0
	Shape	Unknown	1.3	0.0
	Surface	Polyurethane	0.0	0.0
	Surface	Smooth	0.0	0.0
	Surface	Textured	98.7	0.0
	Surface	Unknown	1.3	0.0
Kronoberg	Fill	Saline	0.0	0.0
	Fill	Saline and silicone	2.4	0.0
	Fill	Silicone	97.6	100.0
	Fill	Unknown	0.0	0.0
	Manufacturer	Mentor	100.0	100.0
	Manufacturer	Motiva	0.0	0.0
	Manufacturer	Other	0.0	0.0
	Shape	Anatomical	95.2	92.9
	Shape	Round	0.0	0.0
	Shape	Unknown	4.8	7.1
	Surface	Polyurethane	0.0	0.0
	Surface	Smooth	0.0	0.0
	Surface	Textured	97.6	92.9
	Surface	Unknown	2.4	7.1
Skåne	Fill	Saline	2.3	0.0
	Fill	Saline and silicone	58.7	53.2
	Fill	Silicone	38.2	44.7
	Fill	Unknown	0.7	2.1

IMPLANT CHOICE FOR RECONSTRUCTION (CONTINUED)

Division by region.

Region	Variable	Outcome	Proportion year 2014-2019 (%)	Proportion year 2020 (%)
Skåne	Manufacturer	Mentor	99.3	91.5
	Manufacturer	Motiva	0.7	8.5
	Manufacturer	Other	0.0	0.0
	Shape	Anatomical	93.0	76.6
	Shape	Round	7.0	23.4
	Shape	Unknown	0.0	0.0
	Surface	Polyurethane	0.0	0.0
	Surface	Smooth	0.2	6.4
	Surface	Textured	99.8	91.5
	Surface	Unknown	0.0	2.1
Stockholm	Fill	Saline	3.9	0.0
	Fill	Saline and silicone	49.3	23.1
	Fill	Silicone	45.6	23.9
	Fill	Unknown	1.3	53.0
	Manufacturer	Mentor	97.0	100.0
	Manufacturer	Motiva	0.5	0.0
	Manufacturer	Other	2.4	0.0
	Shape	Anatomical	93.1	79.5
	Shape	Round	5.4	4.3
	Shape	Unknown	1.5	16.2
	Surface	Polyurethane	0.3	0.0
	Surface	Smooth	1.5	5.1
	Surface	Textured	97.0	75.2
	Surface	Unknown	1.2	19.7
Uppsala	Fill	Saline	28.9	44.4
	Fill	Saline and silicone	15.7	25.0
	Fill	Silicone	27.1	27.8
	Fill	Unknown	28.3	2.8
	Manufacturer	Mentor	86.7	88.9
	Manufacturer	Motiva	2.4	11.1
	Manufacturer	Other	10.8	0.0
	Shape	Anatomical	71.7	77.8
	Shape	Round	17.5	5.6
	Shape	Unknown	10.8	16.7
	Surface	Polyurethane	0.0	0.0
Uppsala - forts	Surface	Smooth	6.0	2.8
	Surface	Textured	84.9	97.2
	Surface	Unknown	9.0	0.0
Västerbotten	Fill	Saline	10.8	0.0
	Fill	Saline and silicone	0.0	0.0
	Fill	Silicone	83.8	100.0
	Fill	Unknown	5.4	0.0
	Manufacturer	Mentor	89.2	100.0
	Manufacturer	Motiva	0.0	0.0
	Manufacturer	Other	10.8	0.0
	Shape	Anatomical	94.6	100.0
	Shape	Round	0.0	0.0
	Shape	Unknown	5.4	0.0
	Surface	Polyurethane	0.0	0.0
	Surface	Smooth	0.0	0.0
	Surface	Textured	97.3	100.0
	Surface	Unknown	2.7	0.0
Västmanland	Fill	Saline	0.0	0.0
	Fill	Saline and silicone	50.0	0.0
	Fill	Silicone	50.0	0.0
	Fill	Unknown	0.0	0.0
	Manufacturer	Mentor	100.0	0.0
	Manufacturer	Motiva	0.0	0.0
	Manufacturer	Other	0.0	0.0
	Shape	Anatomical	70.0	0.0
	Shape	Round	30.0	0.0
	Shape	Unknown	0.0	0.0
	Surface	Polyurethane	0.0	0.0
	Surface	Smooth	0.0	0.0
	Surface	Textured	100.0	0.0
	Surface	Unknown	0.0	0.0
Västra Götaland	Fill	Saline	14.0	0.0
	Fill	Saline and silicone	8.3	1.0
	Fill	Silicone	70.2	99.0
	Fill	Unknown	7.4	0.0
	Manufacturer	Mentor	94.2	97.9
	Manufacturer	Motiva	0.0	2.1
	Manufacturer	Other	5.8	0.0
	Shape	Anatomical	87.6	94.8

IMPLANT CHOICE FOR RECONSTRUCTION (CONTINUED)

Division by region.

Region	Variable	Outcome	Proportion year 2014-2019 (%)	Proportion year 2020 (%)
Västra Götaland - forts.	Shape	Round	7.4	1.0
	Shape	Unknown	5.0	4.1
	Surface	Polyurethane	0.0	0.0
	Surface	Smooth	2.5	3.1
	Surface	Textured	97.5	91.8
	Surface	Unknown	0.0	5.2
Örebro	Fill	Saline	50.4	72.7
	Fill	Saline and silicone	4.9	0.0
	Fill	Silicone	13.8	0.0
	Fill	Unknown	30.9	27.3
	Manufacturer	Mentor	30.9	100.0
	Manufacturer	Motiva	0.0	0.0
	Manufacturer	Other	69.1	0.0
	Shape	Anatomical	79.7	90.9
	Shape	Round	13.0	9.1
	Shape	Unknown	7.3	0.0
	Surface	Polyurethane	0.0	0.0
	Surface	Smooth	4.9	9.1
	Surface	Textured	91.1	90.9
	Surface	Unknown	4.1	0.0
Östergötland	Fill	Saline	3.4	0.0
	Fill	Saline and silicone	0.0	0.0
	Fill	Silicone	96.2	100.0
	Fill	Unknown	0.4	0.0
	Manufacturer	Mentor	94.0	100.0
	Manufacturer	Motiva	0.0	0.0
	Manufacturer	Other	6.0	0.0
	Shape	Anatomical	43.0	9.8
	Shape	Round	56.6	90.2
	Shape	Unknown	0.4	0.0
	Surface	Polyurethane	0.0	0.0
	Surface	Smooth	24.3	90.2
	Surface	Textured	74.9	6.6
	Surface	Unknown	0.9	3.3
Riket	Fill	Saline	8.5	5.9
	Fill	Saline and silicone	32.2	15.2
	Fill	Silicone	54.0	57.2
	Fill	Unknown	5.4	21.6
	Manufacturer	Mentor	92.4	97.5
	Manufacturer	Motiva	0.5	2.5
	Manufacturer	Other	7.1	0.0
	Shape	Anatomical	84.3	69.3
	Shape	Round	13.0	19.7
	Shape	Unknown	2.7	11.1
	Surface	Polyurethane	0.4	0.0
	Surface	Smooth	4.1	17.0
	Surface	Textured	93.6	70.0
	Surface	Unknown	1.9	13.0

TABLE 12. RE-OPERATION PRODUCTION DATA

Division by region.

Region	Number of implants, year 2014-2019	Number of implants, year 2020	Number of patients, year 2014-2019	Number of patients, year 2020
Dalarna	47	15	31	10
Gävleborg	203	40	103	20
Halland	0	1	0	1
Jönköping	213	47	104	23
Kalmar	112	0	63	0
Kronoberg	12	4	10	4
Skåne	1718	297	921	158
Stockholm	4169	850	2202	455
Uppsala	809	128	432	70
Västerbotten	101	10	54	5
Västra Götaland	1966	550	978	290
Örebro	177	19	120	13
Östergötland	194	68	116	38
Riket	9721	2029	5134	1087

FORM
PRIMARY OPERATION

To be completed at primary operation.

Breast Implant Register - Primary Operation 2020

Personal Identity Number_____
Date of operation _____ yyyy-mm-dd
Height _____ cm
Weight _____ kg

Antibiotic therapy

Pre-operative (Excluding day of operation)	No	Yes
Peri-operative	No	Yes
Intra-operative (Irrigation implant/ pocket)	No	Yes
Post-operative	No	Yes

LEFT SIDE

Indication for operation
- ☐ Benign breast condition
- ☐ Reconstruction after cancer
- ☐ Reconstruction after risk-reducing mastectomy
- ☐ Congenital breast disease

Irradiation therapy

Before primary operation	No	Yes
Fat transplantation	No	Yes

Volume fat _____ml

Type of permanent implantat
Implant Expander prosthesis
Manufacturer_____
Content
Saline Silicone Saline and Silicone
Serial number: _____
Volume: _____ml/cc/g
Stamped volume (expander prosthesis):_____

Form
Round Anatomical
Type of surface
Smooth Textured Polyurethane
Pocket of implant or expander prosthesis
Sub-muscular Sub-glandular
Sub-fascial Dual plane

Incision
- ☐ Sub-mammary
- ☐ Axillary
- ☐ Peri-areolar
- ☐ Mastectomy scar
- ☐ Mastopexy with augmentation

Drain after operation	No	Yes
Mesh /ADM	No	Yes

Previous breast surgery

Tumour	No	Yes
Infection	No	Yes
Mastopexy/Reduction	No	Yes

Patient's reported experience before surgery

Dissatisfied with shape	No	Yes
Dissatisfied with volume	No	Yes
Painful breast	No	Yes

RIGHT SIDE

Operationsindikation
- ☐ Benign breast condition
- ☐ Reconstruction after cancer
- ☐ Reconstruction after risk-reducing mastectomy
- ☐ Congenital breast disease

Irradiation therapy

Before primary operation	No	Yes
Fat transplantation	No	Yes

Volume fat _____ml

Type of permanent implant
Implant Expander prosthesis
Manufacturer_____
Content
Saline Silicone Saline and Silicone
Serial number: _____
Volume: _____ml/cc/g
Stamped volume (expander prosthesis):_____

Form
Round Anatomical
Type of surface
Smooth Textured Polyurethane
Pocket of implant or expander prosthesis
Sub-muscular Sub-glandular
Sub-fascial Dual plane

Incision
- ☐ Sub-mammary
- ☐ Axillary
- ☐ Peri-areolar
- ☐ Mastectomy scar
- ☐ Mastopexy with augmentation

Drain after operation	No	Yes
Mesh /ADM	No	Yes

Previous breast surgery

Tumour	No	Yes
Infection	No	Yes
Mastopexy/Reduction	No	Yes

Patient's reported experience before surgery

Dissatisfied with shape	No	Yes
Dissatisfied with volume	No	Yes
Painful breast	No	Yes

FORM
RE-OPERATION

To be completed at re-operation.

Breast Implant Register - Re-operation 2020

Personal Identity Number_____
Date of operation _____ yyyy-mm-dd
Height _____ cm **Weight** _____ kg

Year for start of implant surgery _____ yy
Year for the current implant surgery _____ yy

Surgery for the current implant performed at my clinic	No	Yes

Indication for operation	**LEFT**		**RIGHT**	
Pain	No	Yes	No	Yes
Swelling of the breast	No	Yes	No	Yes
Anxiety for implant	No	Yes	No	Yes
Anxiety for the position of implant	No	Yes	No	Yes
Change of size desired	No	Yes	No	Yes
Change of shape desired	No	Yes	No	Yes
Hardness of the breast	No	Yes	No	Yes
Removal of implant desired	No	Yes	No	Yes
Infection (T81.4)	No	Yes	No	Yes
Newly diagnosed breast cancer	No	Yes	No	Yes
Pre-operative status				
Palpable lymph node in axilla / armpit	No	Yes	No	Yes
Per-operative status				
Implant rupture	No	Yes	No	Yes
Implant rotation	No	Yes	No	Yes
Confirmed BIA-ALCL	No	Yes	No	Yes
Implant deflation	No	Yes	No	Yes
Incorrect implant position	No	Yes	No	Yes
Capsule (T85.4)	No	Yes	No	Yes
Double capsule	No	Yes	No	Yes
Seroma / exudate (T81.8)	No	Yes	No	Yes
Hematoma	No	Yes	No	Yes
	No	Yes	**No**	**Yes**
Measure taken				
Permanent removal of implant	No	Yes	No	Yes
Replantation of existing implant	No	Yes	No	Yes
Secondary augmentation after previous implant removal /i.e. infection	No	Yes	No	Yes
Brand implant change	No	Yes	No	Yes
Partial capsular removal	No	Yes	No	Yes
Total capsular removal	No	Yes	No	Yes
En-bloc resection (Capsule +implant)	No	Yes	No	Yes
Capsulotomy	No	Yes	No	Yes
Pocket reduction	No	Yes	No	Yes
Mesh/ADM	No	Yes	**No**	**Yes**
Fat transplantation	No	Yes	**No**	**Yes**
Volume (ml):	_____		_____	
Has the patient had breast cancer on the actual side?	No	Yes	No	Yes
Undergone radiation therapy before operation?	No	Yes	No	Yes

Recently performed mammography	No	Yes

Antibiotic therapy

Pre-operative (Excluding day of operation)	No	Yes
Peri-operative	No	Yes
Intra-operative (Irrigation implant/ pocket)	No	Yes
Post-operative	No	Yes

Information about implant REMOVED LEFT
Type of implant
Implant Expander prosthesis Manufacturer_____
Content
Saline Silicone Saline and silicone
Serial number_____ Volyme _____
Stamped volyme (expander prosthesis) _____
Form Round Anatomical
Surface Smooth Textured Polyurethane
Pocket Sub-muscular Sub-glandular
Sub-fascial Dual plane

Information about implant INSERTED LEFT
Type of implant
Implant Expander prosthesis Manufacturer_____
Content
Saline Silicone Saline and silicone
Serial number_____ Volyme _____
Stamped volyme (expander prosthesis) _____
Form Round Anatomical
Surface Smooth Textured Polyurethane
Pocket Sub-muscular Sub-glandular
Sub-fascial Dual plane

Information about implant REMOVED RIGHT
Type of implant
Implant Expander prosthesis Manufacturer_____
Content
Saline Silicone Saline and silicone
Serial number_____ Volyme _____
Stamped volyme (expander prosthesis) _____
Form Round Anatomical
Surface Smooth Textured Polyurethane
Pocket Sub-muscular Sub-glandular
Sub-fascial Dual plane

Information about implant INSERTED RIGHT
Type of implant
Implant Expander prosthesis Manufacturer_____
Content
Saline Silicone Saline and silicone
Serial number_____ Volyme _____
Stamped volyme (expander prosthesis) _____
Form Round Anatomical
Surface Smooth Textured Polyurethane
Pocket Sub-muscular Sub-glandular
Sub-fascial Dual plane

APPENDIX
VARIABLE DEFINITIONS PRIMARY OPERATION

2020

Variabel	***Definition***
Personal identity number	Patient's date of birth + last 4 digits. (YYYYMMDD-NNNN).
Date of Operation	The date the index operation was performed (YYYY-MM-DD).
Height	Patient's self-reported height in cm.
Weight	Patient's self-reported weight in kg.
The side or sides on which the breast operation was performed are to be registered separately.	
Left side	Data registration for the left breast.
Right side	Data registration for the right breast.
Indication for surgery	The reason for the implant surgery.
Patient-reported hypoplasia	Patient-reported experience that breast volume is too small.
Asymmetry	A difference in volume or shape between the breasts.
Primary Micromastia	Disproportionately small breasts in relation to height and weight in a nulliparous woman.
Secondary Micromastia	Disproportionately small breast in relation to length and weigh or loss of breast volume after pregnancy and breast feeding, massive weight loss, trans-sexual surgery, status after breast operations such as reductions, ptos- plastic surgery, breast-retaining operations for cancer or other conditions associated with reduction of breast volume.
Tuberous breasts	Abnormality or malformation of the breast.
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 implant or expander prosthesis simultaneously or at a later date after removal of breast tissue.
Completed radiation before primary operation	Radiation of the breast or thorax before the actual implant surgery.
Fat transplantation	Supplement to breast implant surgery using patient's own fat tissue.
Type of permanent implant	Specification of the actual implant.
Implant	EU-certified medical product intended for augmentation or reconstruction of the breast.
Expander prosthesis	EU-certified medical product used for the gradual expansion of the soft tissue of the thorax wall when reconstructing the breast in a "one-stage" operation.
The BRIMP does not register "two-stage" procedures, implant change after intermittent expander use is registered as primary insertion of implant and not as a re-operation.	
Manufacturer	Name of the company which manufactures the actual implant.
Content	Describes the implant's or expander prosthesis' chemical filler material.
Silicone, Normal Saline or combination	Type of filler material.
Serial number	Serial number of the implant or expander prosthesis.
LOT-number	LOT number of the implant or expander prosthesis.
Ref-number	Catalogue reference number of the implant or expander prosthesis.
Volume	Measured in ml, cc or g. Printed on the implant or expander prosthesis by the manufacturer or measured inter-operatively using the Archimedes principle.
Type of surface	Specification of the implant's or expander prosthesis' surface.

Variabel	***Definition***
Smooth, textured, polyurethane	The nature of implant's or expander prosthesis' surface.
Shape	Shape of the implant or expander prosthesis.
Round	Implant's shape is round.
Anatomical	The implant's or expander prosthesis' shape imitates the drop-shaped form of a mature breast.
Implant or expander prosthesis position	Position of the actual of the implant or expander prosthesis.
Sub-muscular	Implant or expander prosthesis is placed under the pectoral muscle.
Sub-glandular	Implant or expander prosthesis is placed superficial to the pectoral muscle.
Sub-fascial	Coverage of the implant with pectoral fascia over the pectoral muscle.
Dual plane	Coverage proximally of the areola with pectoral muscle, distally of the areola with breast tissue.
Operation incision	Type of incision used for insertion of implant or expander prosthesis.
Sub-mammary	Operation incision in the natural fold under the breast or in the scar after a previous mastectomy.
Axillary	Operation incision in the armpit.
Peri-areolar	Operation incision on the edge of the areola.
Mastectomy scar	Operation incision in the scar after a previous mastectomy.
Mastopexy with augmentation	Insertion of the implant through a planned skin resection caudally of the areola.
Drain	Use of drain in the implant pocket and / or subcutaneously during the actual operation.
Net/ADM	Insertion of net or ADM during the actual operation.
Previous breast surgery	Document if patient has had any previous breast surgery due to tumour, infection or breast reduction / breast lift prior to the actual operation.
Patient's experience before surgery	Description of patient's self-reported dissatisfaction with breast volume or shape and any pain in breast tissue.
Antibiotics	Describe if and when patient received antibiotics in connection with the actual operation.
Pre-operatively	Antibiotics given intravenously or orally on the day before surgery.
Per-operatively	Antibiotics given intravenously or orally on the day of surgery.
Intra-operatively	Irrigation of the implant in sterile package or of the implant pocket with antibiotics (antiseptics do not apply).
Post-operatively	Antibiotics given intravenously or orally the day after surgery.

APPENDIX
VARIABLE DEFINITIONS RE-OPERATION

2020

Variabel	***Definition***
Personal identity number	Patient's date of birth + last 4 digits (YYYYMMDD-NNNN).
Date of re-operation	Date when re-operation is performed.
Height	Patient's self-reported height in cm.
Weight	Patient's self-reported weight in kg.
Year for initial implant insertion	The year when the initial breast implant was inserted.
When was the current implant inserted	When was the current implant, that is described in this entry in the register, inserted.
Was the surgery for the current implant performed at this department	Was the operation for the current implant performed at this department.
Indication for operation right and left side	The reasons for re-operation.
Pain	Patient-reported pain in breast.
Swelling of the breast	Patient-reported swelling of breast.
Anxiety about the implant	Patient-reported anxiety for existing implant.
If anxiety exists, is it due to the result of recent mammography	Patient-reported anxiety due to mammography within the last 3 months.
Change of size	Patient experienced that breast volume is too small or too large.
Desired shape change	Patient's desire for a change in breast shape.
Hardness of the breast	Patient's experience that the breast is hard.
Desired implant removal	Patient's desire for removal of the implant.
Infection (T81.4)	Infection after breast surgery.
Recently diagnosed breast cancer	A diagnosis of breast cancer is the reason for the current operation.
Pre-operative status	Patient's medical status prior to operation.
Palpable lymph nodes in axilla	Lymph nodes in the axilla which can be palpated.
Per-operative status	Patient's medical status/condition and implant status during operation.
Rupture	Damage to or defect in the implant's exteriorl casing (from hole in the casing to total degeneration of the implants shape).
Rotation	The implant has rotated in the implant pocket.
Confirmed ALCL	Breast implant-associated Anaplastic Large Cell Lymphoma, confirmed with CD30 and ALK.
Deflation	Volume and/or change in shape of implant / expander prosthesis due to loss of normal saline.
Incorrect position	The implant is positioned incorrectly in the breast.
Kapsel (T85.4)	Hard connective tissue capsule formation around the implant which requires surgical correction (Baker III,IV).
Double Capsule	A capsule in contact with the exterior of the implant and a capsule in contact with breast tissue. Between the capsules, seroma fluid may be present.
Seroma/ Exudate (T81.8)	A collection of wound fluid in the implant pocket.
Haematoma	A collection of blood in or around the implant pocket.
Measure	Treatment

Variabel	***Definition***
Permanent removal of implant	The breast implant is removed and not replaced.
Return of existing implant	The breast implant is removed and after treatment the same implant is re-used in the patient.
Insertion of new implant after removal of existing implant	A new implant is inserted after the removal of an existing implant e.g. after an infection or other conditions where breast tissue requires several months to heal without the presence of an implant insitu.
Change of implant	A new implant is inserted during operation after removal of existing implant.
Capsule dissection	Incision of the capsule in one or more quadrants.
Capsule exstirpation	Removal of capsule tissue except the thoracic section.
Drain	Use of drain in the implant pocket and / or breast tissue.
Net/ADM inserted	Insertion of net/ADM during the actual operation.
Net/ADM removed	Removal of net/ADM during the actual operation.
Fat transplantation	Supplementation of implant-based surgery with the patient's own fat tissue.
Completed radiation before operation	Radiation of the breast or thorax prior to the actual implant surgery.
Information about implant which is removed from the right or left side	Registration of data concerning the right or left side.
Implant	Specifikation av det aktuella implantatet som tas ut.
Implantat	EU-certified medical product intended for augmentation or reconstruction of the breast.
Expander prosthesis	EU-certified medical product used for the gradual expansion of the tissue of the thorax wall when reconstructing the breast in a "one-stage" procedure.
Manufacturer	Name of the company which manufactures the actual implant.
Content	Describes the implant's or expander prosthesis' chemical filler material.
Silicone, Normal Saline or combination	Type of filler material used.
Serial number	Serial number of the implant or expander prosthesis.
LOT-number	LOT number of the implant or expander prosthesis.
Ref-number	Catalogue reference number of the implant or expander prosthesis.
Volume	Measured in ml, cc or g. Printed on the implant or expander prosthesis by the manufacturer or measured inter-operatively using the Archimedes principle.
Type of surface	Specification of the implant's or expander prosthesis' surface.
Smooth, textured, polyurethane	The nature of implant's or expander prosthesis' surface.
Shape	Implantatets- eller expanderprotesens form.
Round	The shape of the implant is round.
Anatomical	The implant's or expander prosthesis' shape imitates the drop-shaped form of a mature breast.
Half-moon /Crescent shaped	The implant is shaped like a half-moon or crescent shape.
Position	The placement of the actual implant or prosthesis expander.
Sub-muscular	Implant or expander prosthesis placed under the pectoral muscle.
Sub-glandular	Implant or expander prosthesis placed superficial to the pectoral muscle.
Sub-fascial	Coverage of the implant with pectoral fascia over the pectoral muscle.
Dual plane	Coverage proximally of the areola with pectoral muscle, distally of the areola with breast tissue implant with pectoral fascia over the pectoral muscle.