BRIMP - Breast Implant Register
Annual Report 2018

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OBJECTIVE INFORMATION FOR PATIENTS AND THE PROFESSION

The Breast Implant Register was started in May 2014. This was the beginning of the first systematic registration of breast implants in Sweden. At the same time, the web page www.brimp was also commenced.

The aim of the BRIMP is to offer patients who, for whatever reason, are to undergo breast implant surgery, adequate and objective information about the types of implants available on the market today.

For those surgeons who perform implant operations, it is also important to have access to objective and impartial information about the different breast implants available.

Registration of information in BRIMP facilitates, not only the prompt detection of possible abnormalities, as in the case of the PIP-implant, but also allows for long-term follow-up of the effects of having breast implants.

The statistics collected in the register enables the profession to have access to ever increasing knowledge about different implants and their performance. This allows surgeons to be better able, to more readily adapt the choice of implant to the specific needs of the patient.

Healthcare organizations are expected to experience a gigantic paradigm shift in the coming years. The BRIMP will become an important tool in the evaluation of outcome measures in patient-centred, evidence-based care.

It is of the utmost importance that as many clinics as possible participate in the BRIMP. Those clinics that take part are be shown on the register's home page and some statistical analyses will also be available on the home page.

The home page will show statistics that will be available to the general public, as well as statistics which can only be accessed by the specific clinics that participate in the register.

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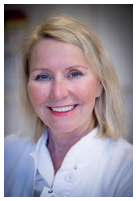
INFORMATION FROM THE REGISTRAR



Birgit Stark, Associate Professor, Consultant in Plastic Surgery and Registrar for the BRIMP

History

The BRIMP was started in 2012 on behalf of the professional associations, the Swedish Plastic Surgeons Association (SPKF) and the Swedish Association for Aesthetic Plastic Surgery (SFEP). The possibility to register on-line was launched nationally in 2014. Initially, the current registrar worked with Ulf Samuelsson, Pelle Sahlin, Marie Wickman and Jonas Lekander. We discussed and evaluated the validity of the different variables for a breast implant register, within the framework of a pilot project, there evidenced-based data was used. We received invaluable help from Göran Garellick who has widespread experience from the Swedish Hip Arthroplasty Register. The other colleagues on the board joined in 2014, when the Breast Implant Register became a candidate to become a national register. The current board consists of colleagues from different parts of the country and there is support from within the private healthcare sector, as well as the publicly financed healthcare system for both breast- and plastic surgery. The patient representative is Heléne Fägerblad. Today, there are no set guidelines as to how registers for quality within healthcare are assigned, for example, the very successful Swedish Hip Arthroplasty Register has no existing rules regarding the election of board members or the length of election terms. This was discussed for the first time within the Swedish Hip Arthroplasty Register in 2018, and it is now planned that board members will be nominated at the yearly meeting for contact doctors. The board members will be elected on a 3 + 3-year basis. This model could also be adopted by the BRIMP.

The BRIMP enjoys an increasing level of interest, both nationally and internationally. English versions of the BRIMP's yearly reports for 2016 and 2017 are published on the EASAP's homepage and have received attention among colleagues in ICOBRA. In the Dutch yearly report for 2017, the BRIMP is mentioned as a role model for other European implant registers. The Swedish and English versions of the yearly report are published on the BRIMP homepage www.brimp.se and are distributed to all members of the SFEP and SPKF. All units that report to the BRIMP receive a special report summary of their own results, which is sent by mail twice a year. The contributing units' own data in relation to aggregated data in the BRIMP can also be followed on-line using the specific unit's password.

The BRIMP's Current Status and Certification

The BRIMP is to be currently seen as a product register, in which breast implants from all manufacturers are monitored prospectively in vivo. Some Patient-Reported Outcome Measures (PROM) data is available since the BRIMP was founded. PROM measures the patients' view of their illness and their perceived health after treatment.

A clinical quality register is defined by, among other things, the clearly defined PROM's evaluated post-operatively after an agreed time. For the BRIMP to live up to the definition of a clinical quality register, apart from variables based on evidence-based data, it requires the commitment of all registered clinics to introduce the PROM instruments into their day to day clinical practice. Only then will we have created a tool which can provide information about "best practice".

During 2018, the BRIMP has developed from candidate level to Certificate level 3, which mirrors the health authorities positive view of the BRIMP's development in the last few years. The BRIMP can soon achieve certification level, which will strengthen the BRIMP's position, both nationally and internationally.

Do we need a Breast Implant Register?

The quality of a register is influenced by its level of "compliance" and "completeness", i.e. that the data is current, consistent and complete, to be able to draw conclusions. The goal is, for all Swedish clinics that use breast implants, to register all relevant events, thus enabling the BRIMP to mirror daily healthcare. The evaluation of data is not

influenced by economic profit or sales strategies, but rather will provide an objective, informative tool for patients, practicing colleagues and health authorities, regarding risks and complications associated with breast implants.

Understanding the importance of a quality register for breast implants is increasing globally. In USA, Germany, Italy, Austria and Switzerland, breast implant registers are to be introduced or optimised. In Holland, UK and Australia, the development has reached a higher level. Through an international independent co-operation, we can gain valuable knowledge about how breast implants affect women's bodies.

Economy

To run and maintain a quality register is costly and up until now this has been financed mainly through grants from SKL. Here, the BRIMP competes with the other approximately 100 quality registers in the country. The SFEP and SPKF have contributed economically since 2014. The BRIMP has received a small income from the sale of an industry report to the implant manufacturer Allergan. Other companies manufacturing implants have been asked about purchasing this report and the question will be raised again during 2019.

As the BRIMP is principally financed through state grants gained in competition with other applicants, the BRIMP's service to the public and clinics is totally free. This, in contrast to other countries, where both the industry, registered units and health insurance are remunerated per registered implant. During 2018, the BRIMP had an income of about 680,000 SEK. This sum meant that certain development projects could not be initiated during 2018 and had to be postponed until 2019. The BRIMP's economy is today in balance, thanks to considerable saving. The registrar has held conferences on economy several times a year with the Register Centrum's (RC) management.

The work of the BRIMP's in 2018

At present, in Sweden, all university clinics performing plastic surgery and 85% of plastic surgeons in private practice have joined the BRIMP. In co-operation with the Registercentrum Västra Götaland (RC-VGR), data from 30,000 breast implants is managed, as of the end of December 2018. There is only one clinic in Stockholm which has actively declined to participate in the work of the BRIMP

During 2018, the continuing work of the register has focused mainly on four projects:

1). Work with Data Function as a Support for Healthcare

Feedback to the participating units is an important function of the register. On the BRIMP's home page, affiliated clinics can see statistics regarding the development of their own clinics level of healthcare quality and compare these with other clinics in the register. The statistics shown are based on data retrieved from the register each night, and this guarantees that the statistics are current. To facilitate participating units, the opportunity for analysis and critical thinking, a model has been constructed which generates a report summarizing the clinics half-yearly data. This model was launched in 2018 and two reports have been sent out during the year. In this way, those units participating can more easily follow their own results over time and initiate quality measures as required.

2). Improved Register Content

The BRIMP is still a relatively new register and is under development. Generally, we must evaluate if the data registered is relevant for our questions, as well as, monitor the response frequency and response quality. The significance of the parameters registered is evaluated continuously. Improvements during 2018 have resulted in an updated data registration form for the collection of statistically valuable data. To create a complete and comprehensive breast implant register, will probably require several more years. Improved register content is also created by analysis of the level of coverage. Over the period from 2015 – 2017, we have noted an increase of 11% for the reporting of primary operations and 25% for re-operations. These figures have remained stable for 2018. Since the BRIMP's initiation, there has been a continual increase in the number of clinics reporting to the register. We have also experienced an increased understanding regarding the benefit and importance of the BRIMP quality register. More clinics and units nationally are requesting information about the BRIMP. During the autumn of 2018, the registrar was invited as guest speaker for presentations at meetings in all the Nordic countries, as well as, at the ISAPS meeting in Miami, USA.

The current total level of coverage of the BRIMP is approximately 65%. Reliable sales-data from the industry which the registrar has received, report that the register has information about an estimated 65% of all implants sold in Sweden. It must be remembered that the BRIMP is a relatively new register, which explains why the level of coverage

is not higher. Also, breast implants are used in special cases where we have not been able to persuade the breast surgeons to participate in the BRIMP. We are hoping for a closer co-operation between the national breast cancer register and the BRIMP, which would facilitate an increase in the level of coverage considerably.

To help increase the level of "compliance" and "completeness" in the BRIMP, regular face to face meetings, as well as electronic meetings are needed during the coming year. It is also important to maintain contact, with those clinics that, up until now, have not joined the register.

This continued work, together with presentations at conferences will help to improve the position of the BRIMP register in the scientific community. Colleagues are becoming, more and more aware of the benefits of the BRIMP, for their own clinics and participation in the BRIMP will become an integral part of the workplace. Hopefully, more reticent colleagues will also see its benefits and contribute to the register. Specific efforts will be made to increase participation within the breast surgery clinics which have thus far not joined the register and among plastic surgeon colleagues in private practice who have not already joined.

It is primarily the breast surgery units that have not participated in reporting to the register, as well as other doctors conducting implant-based work who are neither breast surgeons nor plastic surgeons. Many of these units are waiting for the merging of the BRIMP and the Breast Cancer Register. Therefore, in co-operation with Jonas Lekander (RC-VGR), we have intensified our dialogue with the Breast Cancer Register. Since 2014, the BRIMP has been in contact with the Breast Cancer Register with the goal of sharing data between the two registers and these on-going discussions will even continue during 2019. We see the need for an interim solution as the Breast Cancer Register is under reconstruction.

During 2018, the data quality has been evaluated and tested: Two samples have been taken from the units the Karolinska Hospital and Aleris Plastikkirurgi. Our goal is to further improve the BRIMP's coverage and to check the completeness of data, in order to ensure the relevance of the BRIMP's statistics and increase its credibility among the profession and patients

3). Validation of PROM

Contact has already been established with the Breast Cancer Society and the Breast Cancer Register. It is important to take into consideration what the patients themselves consider to be relevant PROM data, before decisions are made as to how PROM-data is designed. A proposal for PROM has been suggested, discussed and taking into consideration the data received from the Breast Cancer Register, a decision was made by the management group about which PROM was to be used during 2018. In consultation with the project management of the Register Centrum-VGR, discussions have taken place regarding what the most suitable form of the PROM to be sent out to breast surgery patients should be, to best capture the data required. The first questionnaires have been sent out to three pilot clinics. An analysis of the data received will be conducted during 2019. Furthermore, a validation of PROM instruments against certain domains of an internationally established instrument "BREAST Q" is planned. This means that only certain parts of BREAST Q will be compared with the responses received on the PROM questionnaires. Breast Q comprises of more than 100 questions and was considered too detailed to be used in combination with the PROM analysis, which includes 10 relevant questions during follow-up. The degree of agreement of the responses will be studied and analysed.

Prior to the use of the BRIMP's PROM instrument on a national level, a validation of the PROM instrument is planned, and this will take place during 2019. This work will be summarized in a scientific publication. Ethical approval has been received for a project which will examine the use of antibiotic treatment in conjunction with breast-implant surgery in Sweden. This project was planned but not carried out during 2018, due to economic constraints.

4). Report to Industry

During the previous year, the BRIMP, in co-operation with RC-VGR, has created different report models intended for the implant-manufacturing industry. Data regarding complications and reasons for re-operation of specific company products are compared to the aggregated data in the BRIMP. The company Allergan has purchased the report from the BRIMP and it has been delivered twice during 2018. Two companies, Mentor and Motiva have expressed interest in a cooperation for 2019. Both companies were informed, on repeated occasions, about the possibility of acquiring the industry report for 2018.

The Work of the Board and Registrar in 2018

The work of the register in Sweden

The board has met for a face-to-face meeting and several video-telephone meetings during 2018. The registrar had a further two face-to-face meetings with the project group at the RC-VGC, ten Skype-meetings, as well as continual contact via telephone and email. The registrar has also held several separate meetings each term with the register co-ordinator to plan the on-going register work for the units. The co-ordinator has had continual contact with the participating units nationally to provide support with the work of the register.

The registrar has the principal responsibility for the work relating to the design of the yearly report, as well as, compiled relevant data and arranged an English version of the report. The registrar has completed all the applications for economic grants, participated in the national working group for BIA-ALCL and introduced the registration of data relating to ALCL into the BRIMP database. This co-operation resulted in a publication about this illness in the Swedish Medical Associaton's journal Läkartidningen 2018. In conjunction with the working group, the registrar participated in six meetings, as well as, an international conference in Amsterdam in November 2018.

International Collaboration

Since the beginning of 2017, the registrar has been involved in a collaboration with

the Dutch and Australian Breast Implant Registers, which are part of a larger association of several European breast implant registers, the International Collaboration of Breast Registry Activities (ICOBRA). During 2018, the registrar participated in six video meetings, with the goal of designing a common, shared data set of relevant variables. Part of this process involved several rounds of evaluating questionnaires, as a basis for achieving consensus about the importance of specific variables. The BRIMP's experiences as a register at the cutting edge were very much appreciated This collaborative effort resulted in a scientific publication, as well as, several manuscripts which are to be submitted for publication in 2019.

CO-ORDINATORS REPORT

By Heléne Fägerblad

During 2018, the BRIMP has developed as a register and we would like to thank all the participating clinics and units who have been so diligent in the registration of their data. In the past year, the co-ordinator has visited and supported several clinics. The response has been good and an understanding for the importance of questions regarding breast implants is increasing.

One of the challenges for us this year, has been to engage the manufacturing industry in the BRIMP and for them to partake of information offered by the register in the form of the industry reports. Currently, only Allergan is subscribing, and are very satisfied with these reports. They can follow their implants and study if there is continued use of their implants after re-operation.

In 2019, the co-ordinator will continue with the administration of the register, working with the governing board and attending the important meetings held for development of the BRIMP. The role of the co-ordinator is to provide the board with information on the level of reporting, to describe unforeseen incidents and suggest solutions as well as act as secretary at meetings. The co-ordinator's goal is to see that all clinics performing breast implant surgery are registering the relevant information in the BRIMP and to encourage industry to understand the importance of the breast implant register. The co-ordinator will also be responsible for schooling in new personnel who will be registering data, for sending out information to all register users, as well as, helping to launch the PROM project.

DEVELOPMENT MANAGERS REPORT

The Year of the Law (2018) Jonas Lekander

In 2018, we were reminded of the law in the world of quality registers. The 25th May 2018, the EU's data protection legislation, better known as GDPR became law. In general, this new legislation did not have much bearing on the already existing rules governing quality registers, but in one respect there was a substantial change. If a person, whose data is registered, experiences that their rights have been violated by incorrect management of the data, the person has the right to sue for and receive damages. As the maximum amount for damages is 20,000,000 SEK for the public

system and 20,000,000 Euro for the private system, much time was spent on the implications of these legal matters and a great deal of effort was spent clarifying what was regulated in law.

From a legal perspective, a register is regulated by law. The patient data law, chapter 7, allows for patient data from, for example, a patient's medical journal to be provided to a central personal data authority (CPUA) without the requirement of an individual scrutiny of privacy. Only one authority within the healthcare system can act as CPUA and for the BRIMP, this authority is the Regional Authority for the Västra Götalands Region. The only legitimate purpose of the collection of personal data in quality registers is for the generation of statistics to be used in improving the quality of healthcare. This encompasses the use data in the analysis of healthcare and for use in hypothesis-generating research.

For the BRIMP, the introduction of GDPR has not brought with it any large practical changes as CPUA was regulated previously. The management of data in the register is secure and access to the register is strictly limited to the registrar and specific personnel at the Registercentrum Västra Götalands Region.

The patient information that has been used earlier was basically correct but was less than adequate in its description. This has now been rectified and the information gives clear descriptions of what a quality register is and what rights a patient has. These are:

- You have the right to say no to the registration of data about you in the quality register
- You have the right at any time to have information about you struck from the quality register
- You have the right to know what information about you is in the register and to receive a copy of these at no cost to you i.e. a register withdrawal. You have the right to receive this in electronic form
- You have the right to have incorrect about you rectified. You have the right to have incomplete information amended.
- Under certain circumstances, you have the right to request the treatment of information about you be limited. This applies during the period that other objections are being adjudicated on. This limitation means that the quality register may not use information about you in any way other than continuing to collect it.
- You have the right to know which care units have had access to information about you and when i.e. log excerpts
- You have the right to remunerative damages if information about you is managed in contravention of the data protection regulations and the patient data law.
- You have the right to make a complaint to the Integrity Protection Authority, which is the governing authority for this area.

PRIMARY OPERATIONS

We have chosen, in the annual report for 2018, to present the data for benign conditions separately from breast reconstruction. Under the heading "breast reconstructions" there is a summary of all implant-based operations for primary and secondary breast reconstructions after cancer and prophylactic mastectomies performed on the basis of heredity for breast cancer (BRCA + patient group). Congenital breast asymmetry is covered under the heading "benign breast conditions"

The BRIMP's definitions of smooth, micro-textured and macro-textured implants, concur with the definitions used by the ICOBRA and refer to those described in Jones et al. BRS 2018 Vol. 142(4):837-49. The BRIMP database contains data to show that most textured implants used in Sweden in 2018 were from the manufacturers; Allergan, Mentor, and Motiva. Other companies are marginally represented; Eurosilicone implants (2), B-Lite implants (74) and 1 polyurethane implant. Reporting of Motiva's products has increased from 1557 implants in 2017 to 2050 implants in 2018. Mentor's implant makes up about 55% (3018 implants) of reported implants during 2018, Motiva has 37% (2050 implants), while Allergan has 8% (424 implants). As in the 2017 report, we see a continued trend toward changes in market share between manufacturers.

The number of smooth implants has increased from 639 to 948 in 2018. An increased awareness of the condition BLA-ALCL has been mirrored in a change in the choice of the type of implant surface. The number of smooth implants has almost doubled since 2016 (502 in 2016 to 948 in 2018) in the BRIMP database. The panorama of indications for operation has not changed noticeably from the observations in the annual report of 2017. Purely

aesthetic implant-based operations have been performed in 63.5% of all cases, and primary and secondary indications made up 20% of cases. In total, 6.8% of entries in the register corresponded to either a cancer diagnosis or prophylactic mastectomies. The percentage of unclear indications has decreased from 10% in 2017 to 7.7% in 2018. Further improvement is needed to better clarify the definition of variables with respect to indication for primary operation in the BRIMP database. A table of definitions for variables is contained in the 2018 annual report.

The BRIMP has displayed robust data through the years regarding BMI and the age distribution. No significant changes could be seen compared to the 2017 data. In all age categories, a normal weight distribution was seen in 80% of patients. The figure below, presents age distribution against primary operation, shows that 80% of patients in the BRIMP have their primary operation before the age of 40. In regard to patients reporting dissatisfaction with the breast shape and size, 70% of patients were dissatisfied with both the shape and volume of the breast, while 16% of patients were not satisfied with the size of the breast.

The number of patients with breast implants in the register has steadily increased since 2014. In this report, patients were divided into two groups, those with benign conditions shown in group A and those requiring breast reconstruction, as a result of cancer or a genetic pre-disposition for breast cancer in group B (figure 1). The total number of breast implants in group A is 21,163 and in group B 1,699. In group A, the implants were used in more than 70% of patients for patient-experienced hypoplasia. The percentage of breast implants used for prophylactic mastectomies was about 45% in the group B.

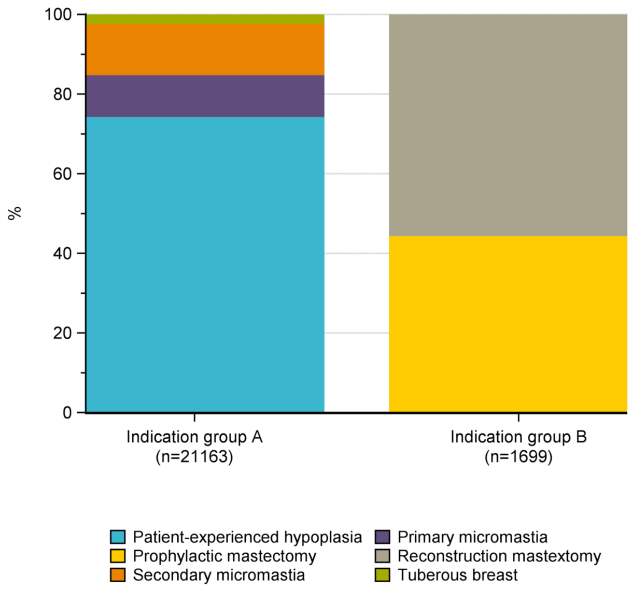


Figure 1 Indication for primary operation of breast implant

Breast Reconstruction, primary operations in group B

Since the BRIMP was founded in 2014, the total number of patients with breast implants, due to a cancer diagnosis or genetic predisposition for breast cancer is 1267. This patient group has received in total 1781 breast implants and will be followed up prospectively, particularly when considering eventual revision operations (figures 2a,2b)

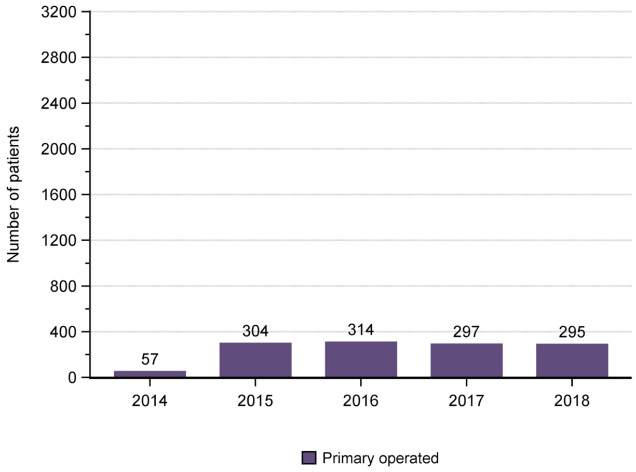


Figure 2a. The number of patients undergoing primary operations due to cancer or BRCA 2014 - 2018

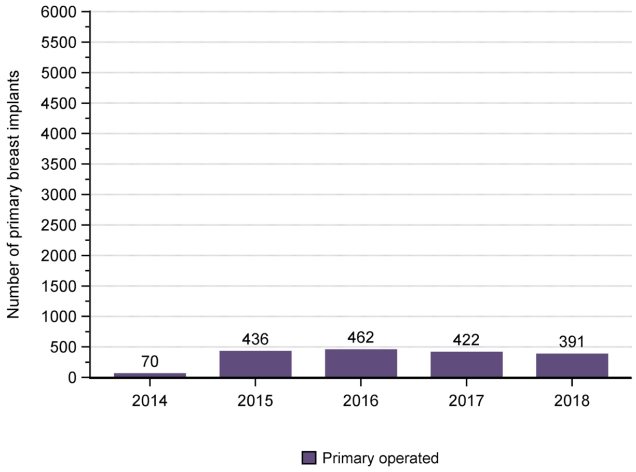


Figure 2b. The number of primary breast operations due to cancer or BRCA 2014 - 2018

The age distribution is shown in Figure 3. As expected, breast reconstructive surgery was most common in the older patients (>50 years) and prophylactic mastectomies surgery and surgery for congenital breast conditions were more common in younger patients (<44 years). In the 51 – 60-year age group, there was a larger proportion of patients who were overweight or obese compared to those with normal weight or underweight (figure 4)

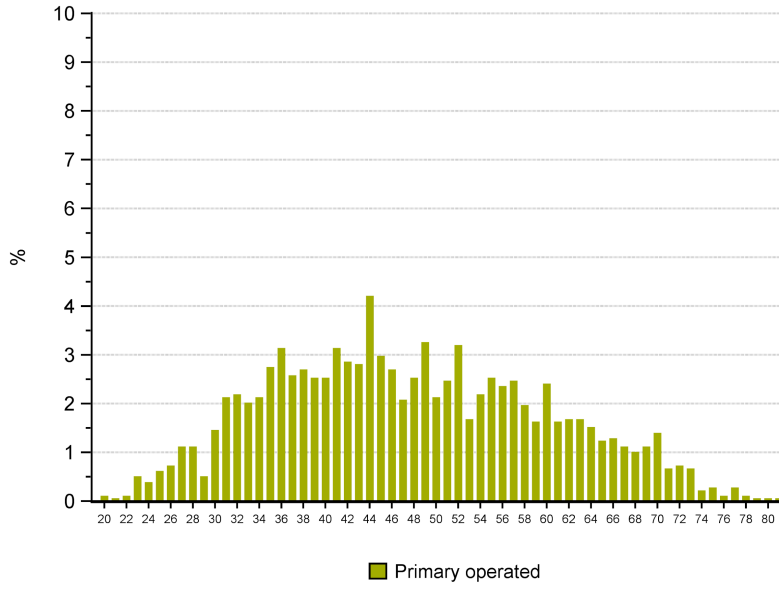


Figure 3. Age distribution in group B for primary breast operations 2014–2018
Grupp B för bröst vid primäroperation 2014 – 2018

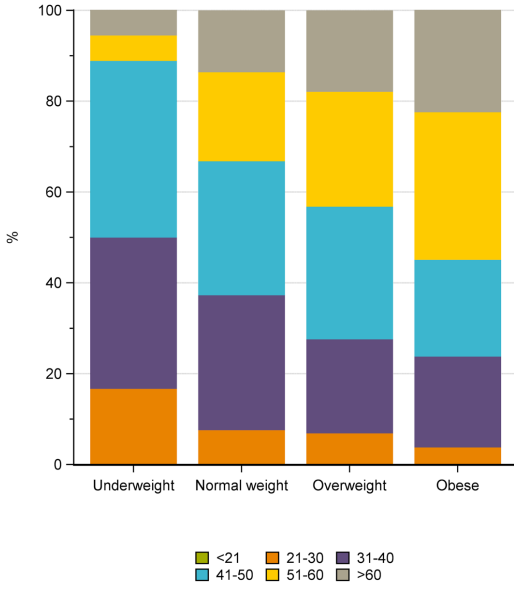


Figure 4 BMI versus age distribution in group B at primary operation 2014-2018

During 2018, the proportion of permanent expanders protheses and implants registered in the BRIMP remained similar (figure 5). In the reconstructive context, more implants from the manufacturer Mentor were used during 2018. Anatomical, textured implants dominated the scene (figure 6). The use of Allergan's implant has markedly declined in reconstructive conditions during 2018. The BIA-ALCL discussion has with all probability contributed to this decrease.

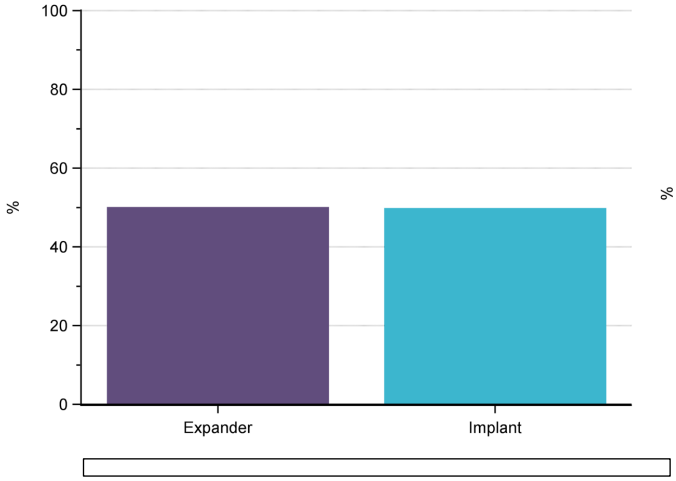


Figure 5. Proportions of expander prostheses and implants registered for primary operations in group B

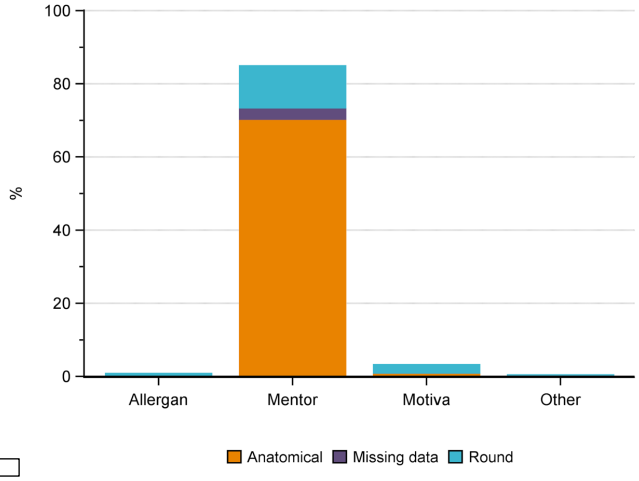


Figure 6. The distribution of implant brands and shape in 2018

If we consider the implant surface which reconstructive surgeons have used, the data shows that textured implants were chosen before smooth implants in the majority of cases (figure 7). Smooth implants have, up until now, not played a crucial role in breast reconstruction according to the register data.

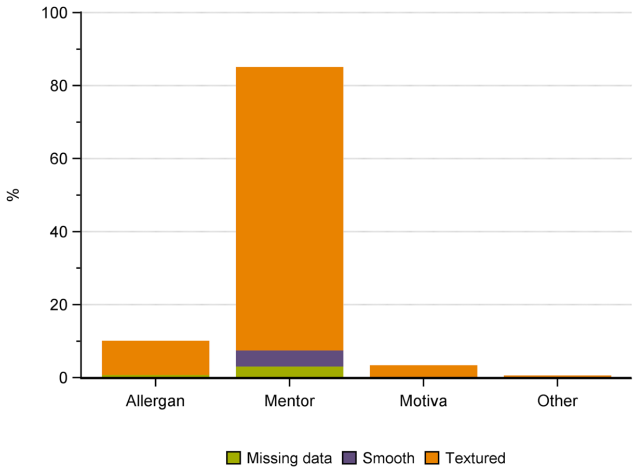


Figure 7. The distribution of implant surface and implant manufacturer for breast reconstruction cases in 2018

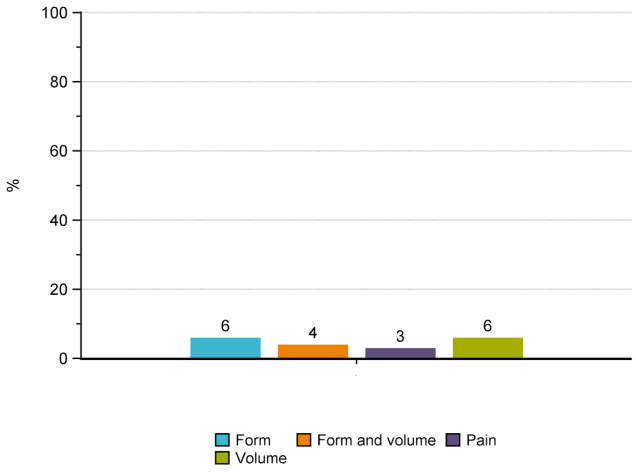


Figure 8. The reasons given by patients before surgery 2014-2018

Primary-operation patients were asked to evaluate their satisfaction with the shape and volume of their breasts. They were also asked if they experienced tenderness or pain in the breast tissue. A young woman who, because of a genetic pre-disposition to develop cancer, chooses to undergo a bilateral breast reconstruction, will have differing expectations about the end result compared to, older women undergoing reconstructive breast surgery after treatment for breast cancer. Therefore, it is extremely important to ask patients about their expectations of their pre-operative condition. In group B, 6% of women were dissatisfied with their breast shape and 8% with breast volume. 4% were dissatisfied with both the shape and volume of their breasts. 3%of women experienced discomfort and pain in their breast tissue (figure 8). The data from these patients form the basis for further follow-up in this group. The follow-up will be done 6 months, 5 and 10 year after operation (PROM).

In primary operations, 8.3% of patients receive a net and 3% of reconstructions are supplemented with a fat transplant.

Implant-based primary operations in group A

Since the register was started in 2014, the BRIMP manages data from 11,567 patients who have received 22,976 implants for benign conditions (figure 9a, 9b).

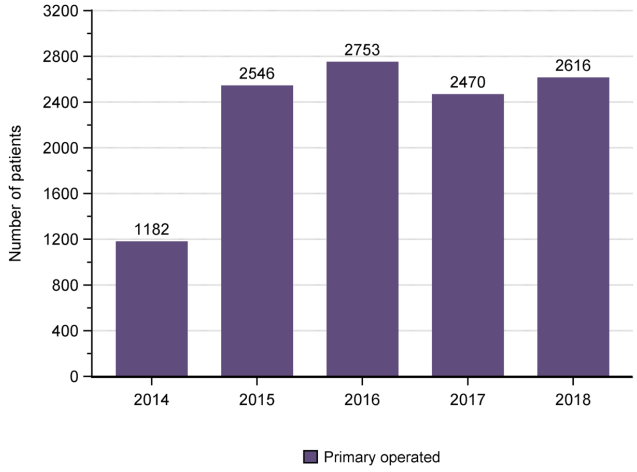


Figure 9a. The number patients having primary operations for benign conditions 2014-2018

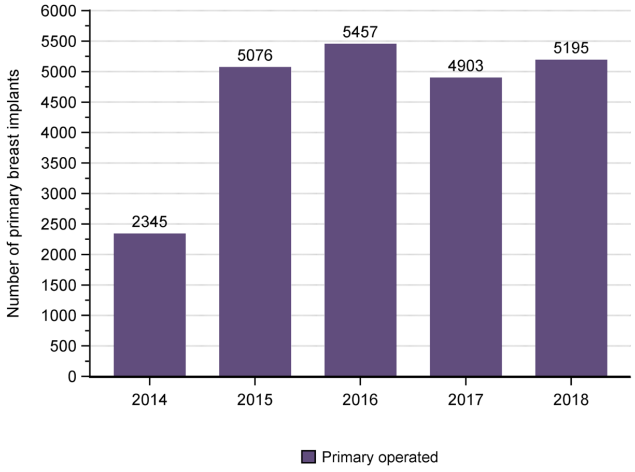


Figure 9b. The number breasts having primary operations for benign conditions 2014-2018

The age distribution in group A shows, that the majority of patients undergoing surgery are primarily between 20-40 years (figure 10). Although, the desire for breast enlargement is even present in older patients.

The proportion overweight or obese patients, who have undergone primary insertion of breast implants is shown in figure 11. Primary breast implant operations are performed even in overweight and obese patients. The 21-30-year age group dominate here.

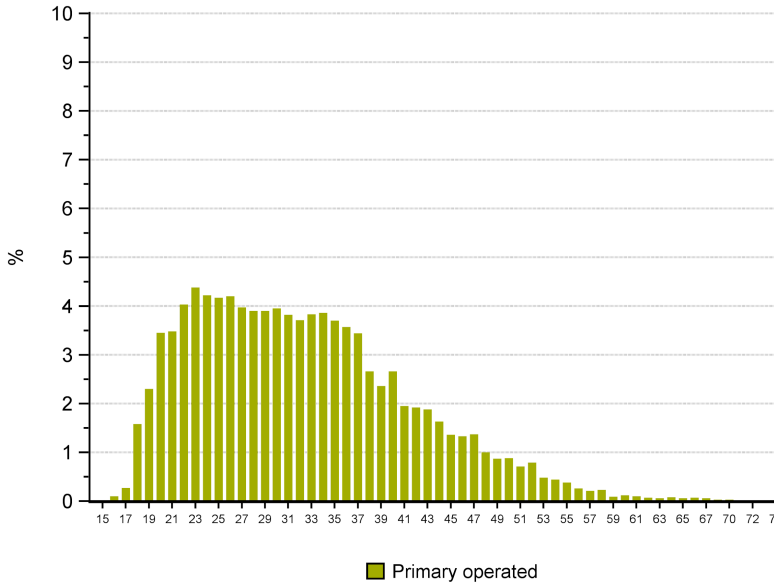


Figure 10. The age distribution for benign indications group A 2014-2018

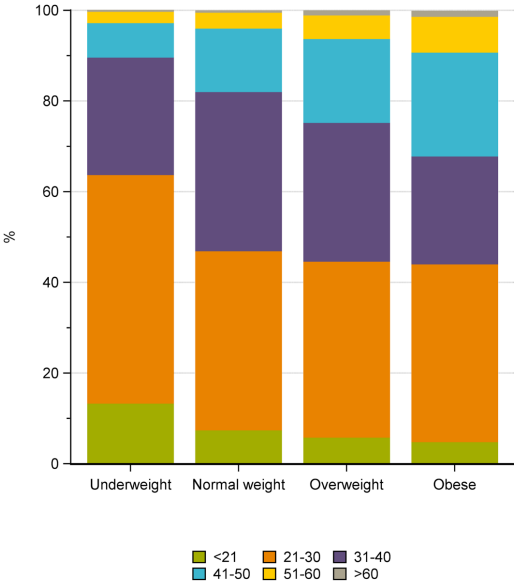


Figure 11. BMI versus age distribution in group A at primary operation 2014-2018

In the past year, the data shows that the manufacturer Motiva has attained about 37% of implants registered in the BRIMP. This marked change in market share reflects both professional and patient concern over macro-textured implants. The distribution of anatomical versus round implants is shown in figure 12. Texturing of implants is probably correctly reported for Mentors and Allergans implants. Data in the BRIMP concerning Motivas implant report a certain proportion of smooth implants. Motivas products are sold as "nanotextured" and now smooth. According to Jones' publication, the Motiva Silk Smooth corresponds to a nanotextured surface and Motiva Velvet to a microtextured surface.

Data in the 2018 annual report is shown as reported. The governing body will improve the definition of texturing in accordance with current literature and international scientific consensus to avoid any misunderstanding in future reports

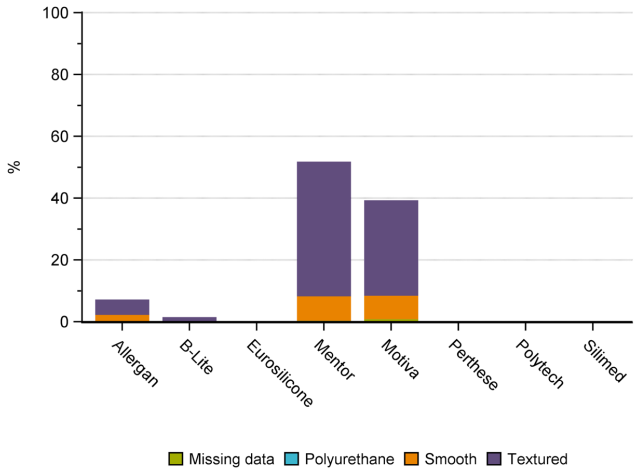


Figure 12. Proportion smooth, textured and polyurethane implants per manufacturer in 2018

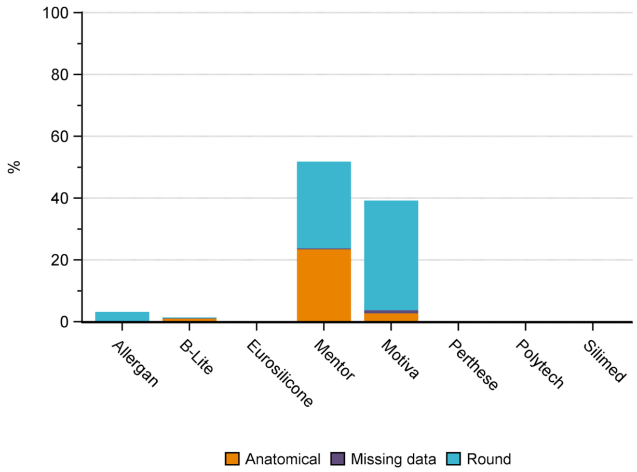


Figure 13. Proportion round and anatomical implants per manufacturer in 2018

Patients who request a breast enlargement, experience seldom pain in breast tissue (1%) prior to operation. In this patient group, 93% experienced dissatisfaction with the breast volume, 77% with the shape and 76% with both breast shape and volume (figure 14). These results differ significantly from the patient group who underwent reconstructive breast surgery, although this was to be expected.

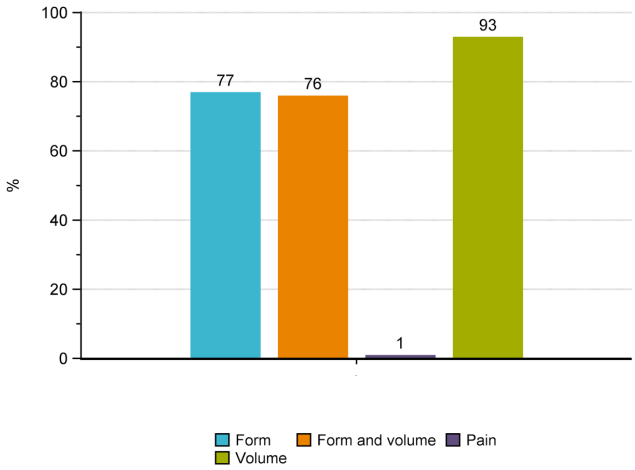


Figure 14. Patient-reported data regarding dissatisfaction with breast volume, form and pain prior to operation 2014-2018

The use of net (0.3%) and supplementary fat transplantation in conjunction with breast enlargement due to benign conditions, was performed to a lesser extent compared to group B.

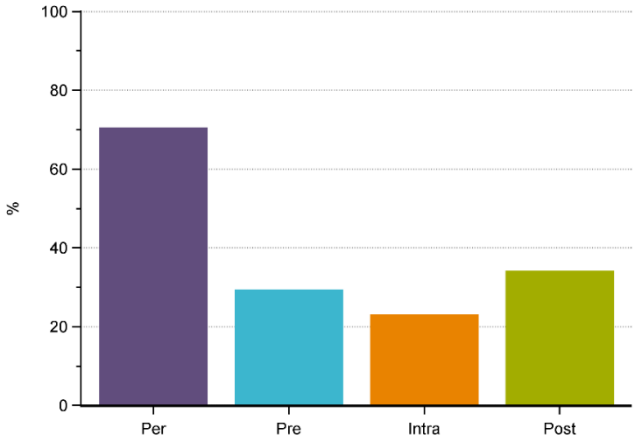


Figure 15a. Proportion of patients who received antibiotics in conjunction with primary operation in group A in 2018

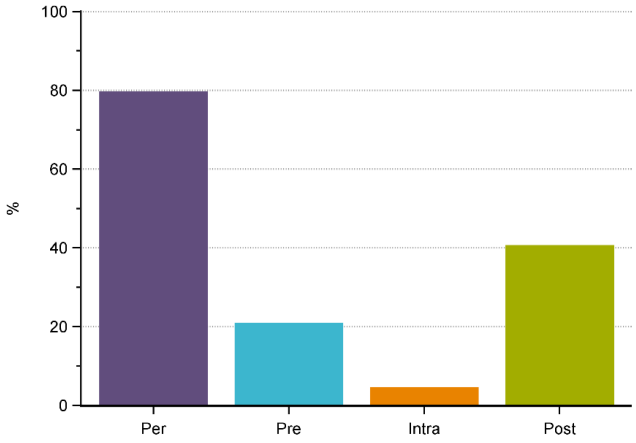


Figure 15b. Proportion of patients who received antibiotics in conjunction with primary operation in group B in 2018

Figure 15 illustrates the use of antibiotics in conjunction with the index operation. Irrigation of implants and the surgical cavity with antibiotics occurs in about 20% of breast enlargements performed for benign conditions (figure 15a). This is not standard procedure in reconstructive surgery (figure 15b). It will be interesting to follow these patient cohorts prospectively.

RE-OPERATIONS

The BRIMP holds data from a total of 4,292 admissions where patients have had re-operations during the period 2014 – 2018, irrespective of the date and reason for the primary operation. Some of these patients underwent their primary operation many years ago, before the BRIMP was founded (figure 16a). The sample used in the statistical analysis, which is shown, means that one and the same patient can be represented in each column, if she has undergone re-operation every year. Figure 16b, shows the number of breasts undergoing re-operations between 2014-2018.The total number during this period was 7,694. Even here, it should be recognised that a breast may have had re-operations several times. If we examine the proportion of breasts having re-operations within one year of the index operation, there is no substantial difference between the groups. In group B, 4% (figure16c) and in group A, 2% (figure16d). If we follow the proportion of re-operations in patients with benign conditions, the BRIMP data shows that 8% of patients with benign conditions underwent re-operation within 5 years from their index operation. The re-operations were done for varying reasons (data is not illustrated graphically).

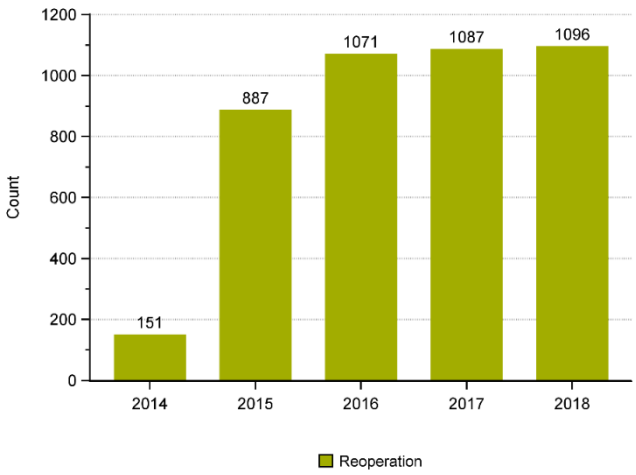


Figure 16a. The number of admissions registered as re-operations irrespective of patient group, 2014-2018

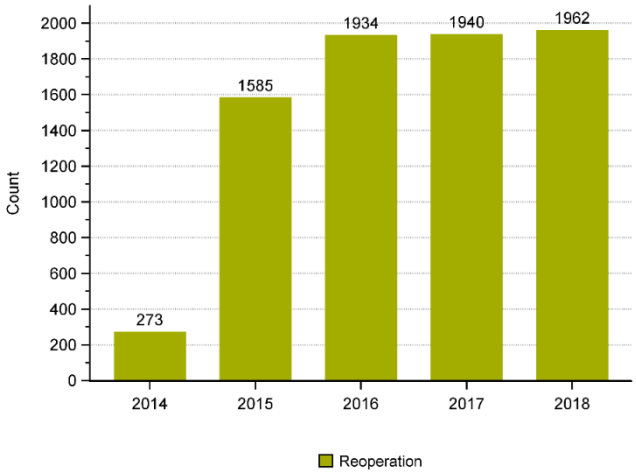


Figure 16b. The number of breasts registered as re-operations irrespective of patient group, 2014-2018

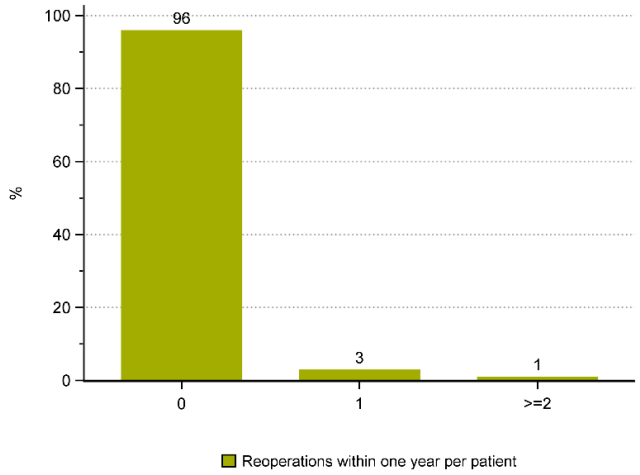


Figure 16c. The proportion of patients registered as re-operations in group B, up to one year after index surgery

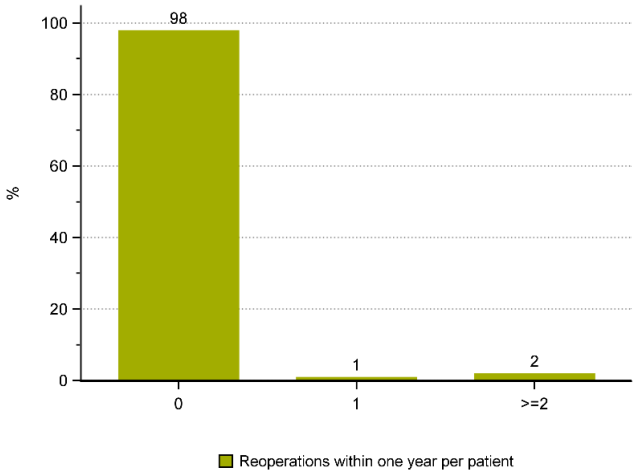


Figure 16d. The proportion of patients registered as re-operations in group A, up to one year after index surgery

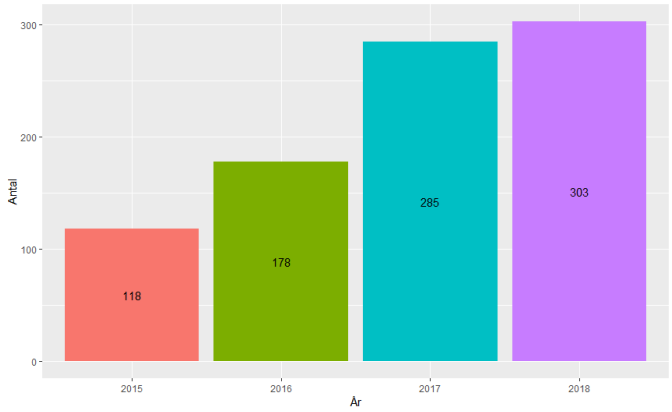


Figure 17a. The number of implants removed permanently

Reason	
Pain	34.16 %
Hard breast	25.57 %
Swollen	11.2 %
Anxiety	40.05 %
New cancer	0.23 %
Infection	6.56 %

Figure 17b. The reasons for permanent removal

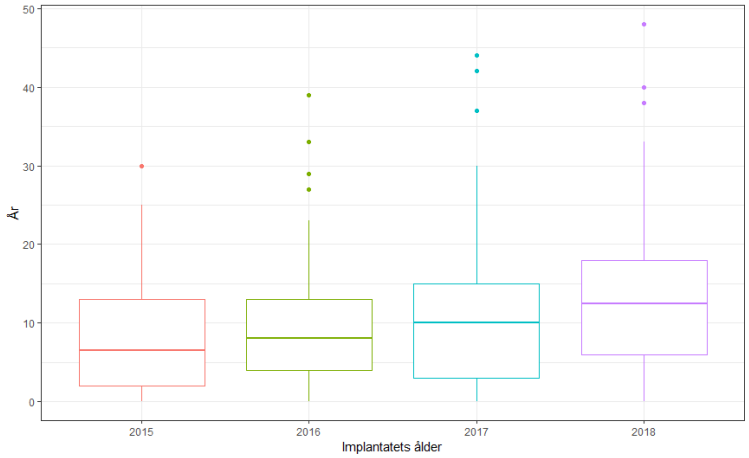


Figure 17c. Implant age at time permanent removal

Figure 17 illustrates the number of permanently removed implants, irrespective of whether in group A or B in the BRIMP database. The motivation for patients wanting permanent removal is mainly because of anxiety about the implant's effect on the body (40%), pain in the enlarged breast accounts for 34% of patients requesting permanent

removal. The median time to removal after the index operation varies between about 6-13 years. This is illustrated in the box plot (figure 17c).
In keeping with previous annual reports, the BRIMP data shows that 33% of breasts underwent re-operation within two years of the index operation, irrespective of the group indication (figure 18a). In conjunction with the re-operation, the weight of the patient is registered. Data from 2018 shows that 24% of patients are overweight or obese at the time of re-operation (figure 18b). The correlation between weight and re-operation can be studied in the further.

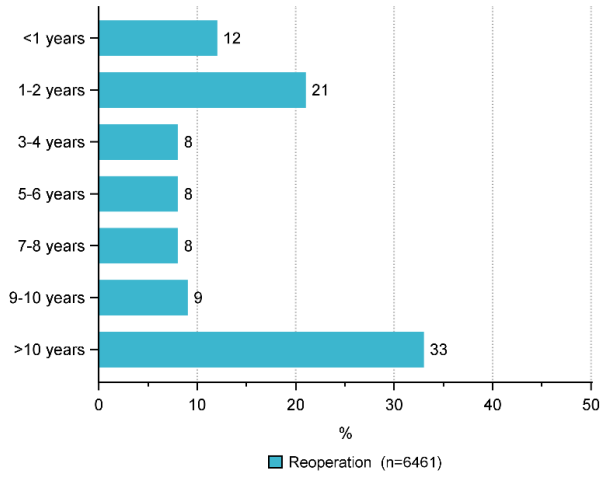


Figure 18a. The average age for re-operation

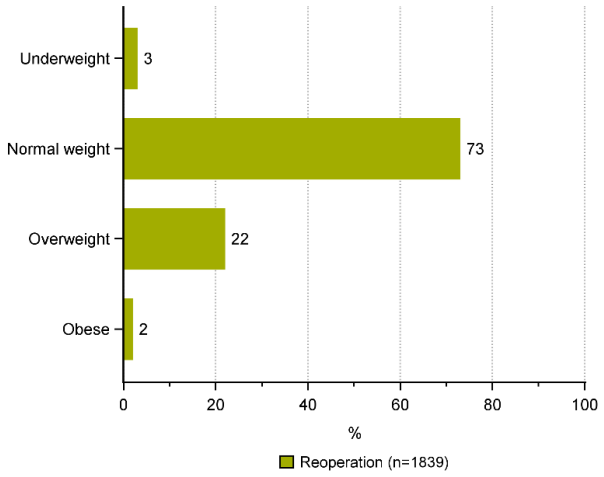


Figure 18b. The distribution of BMI at re-operation during 2018

The patient's motivation for re-operation focused predominately on dissatisfaction with the shape and volume of the breast. This data has been described in earlier annual reports and there has been no change. Anxiety for the implant and the desire for permanent removal accounted for a significant proportion of removals. Pain was experienced in 13% and swollen breasts in 5% of these (figure 19). No new cases of ALCL were reported to the BRIMP, which cannot be considered as realistic in the circumstances. The registrar has knowledge of cases of ALCL occurring at clinics that are not providing data to the register.

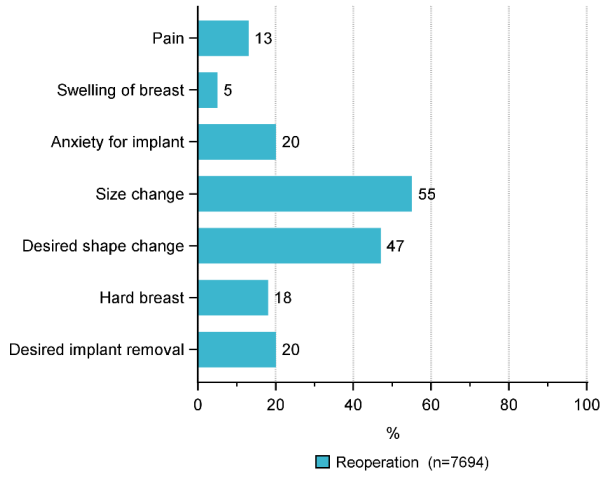


Figure 19. Patient-reported reasons for re-operation, 2014-2018

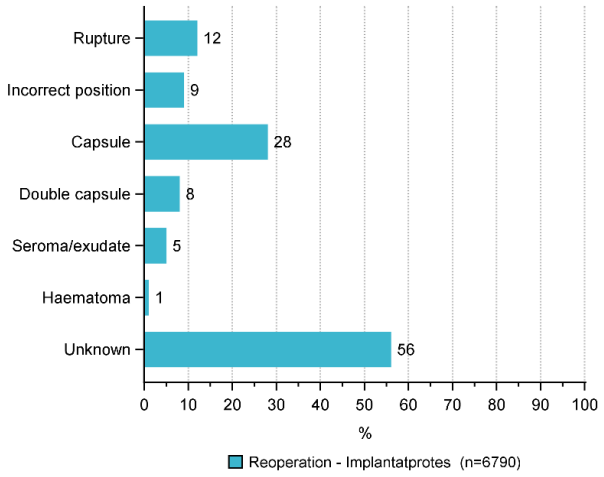


Figure 20. Intra-operative findings regarding implant status at re-operation, 2014-2018

In this annual report, an analysis of intra-operative findings related to implant manufacturer has been done (figures 21a, 21 b). The sample from the database was an analysis of breasts that underwent re-operation 2014-2018, due to capsule formation, rupture or implant rotation in relation to the geometric form of the implant. It should be noted, that the same breast can have undergone several re-operations and have more than one type of problem. Motiva's

implant is presently under-represented in the BRIMP database. Results in the coming years will be able to provide answers regarding re-operation in Motiva implants in a statistically more conclusive way. Trends have shown that more re-operations due to rupture occur in round implants compared to those with a more anatomical shape, regardless of manufacturer. In the register, the Motiva and Allergan implants differed regarding rotation problems. A higher percentage was present in those patients who received Mentor's anatomical implant. The proportion suffering capsule formation did not differ in the groups, regarding the shape of the implant, but Mentors products have been shown to require a lower proportion of re-operations compared to other brands, when examining the sample criteria shape. Future data analysis will monitor and follow-up these observations.

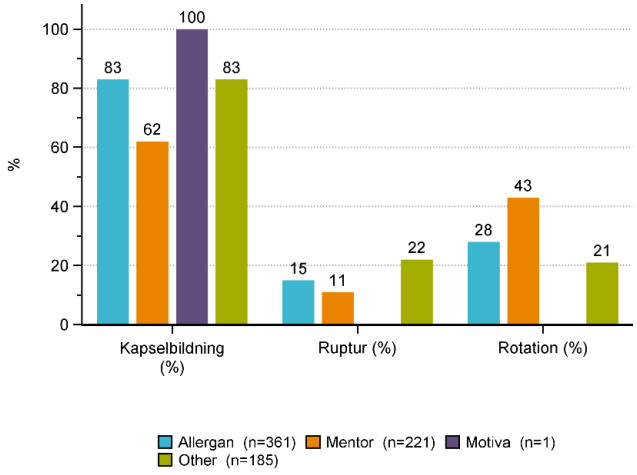


Figure 21a. Re-operation due to capsule, implant rupture, rotation in anatomical implants

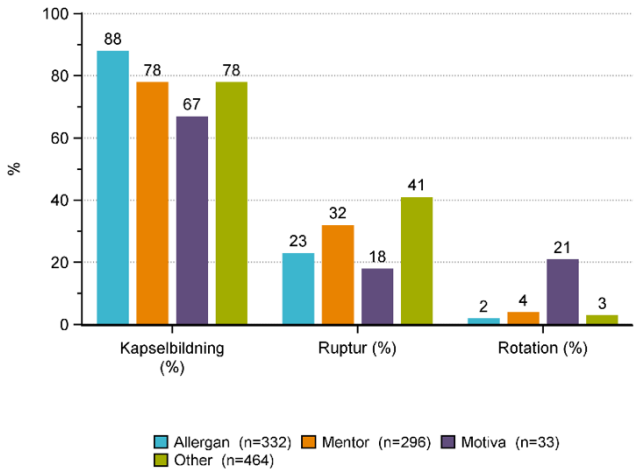


Figure 21b. Re-operation due to capsule, implant rupture, rotation in round implants

RISK FOR RE-OPERATION

In conjunction with the analysis av BRIMP data for re-operation, we have deliberated over the possibility of providing a valid risk assessment, taking into consideration certain specific questions for patients in groups A and B within the specific time interval of 5.5 years

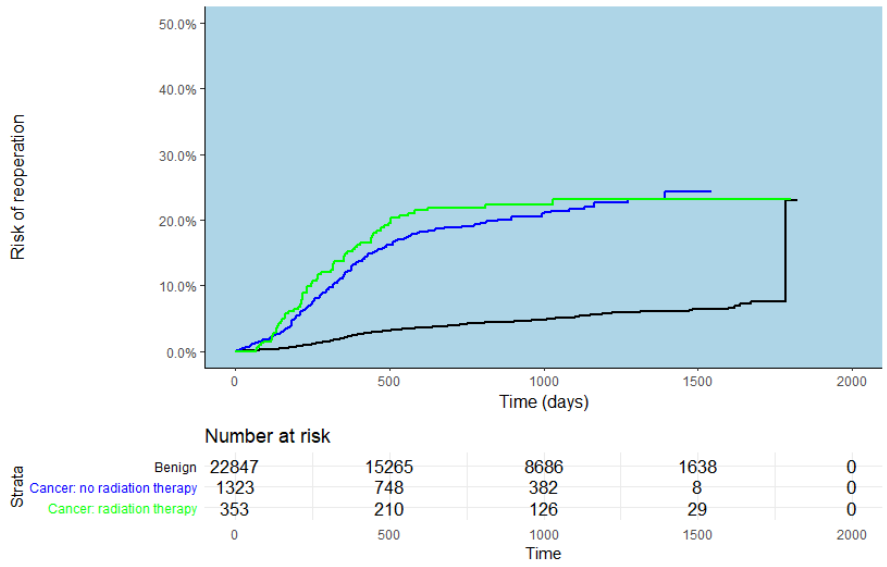


Figure 22. Risk for re-operation in groups A and B, as well as, the risk due to radiation

The Kaplan-Meier figure shows that patients in group B had a higher risk for re-operation within 2 years after their index operation than patients in group A. The further increase, approximately 5 years after the index operation, for patients in group A is probably dependant on the small number of re-operations (figure 22). The patients in group A had a lower and constant increased risk. This data correlates well with the numeric values shown in figures 16 and 17. If log rank test is used, a significant difference in risk for re-operation in group A between patients not receiving radiation ($p<0.001$) and those receiving radiation ($p<0.001$). No significant difference was found between radiated and radiated patients in group B ($p=0.541$).

On a group level, it has been shown that patients who received expander prostheses had a considerably higher risk for change to another type of reconstruction compared to the cohort that had received a permanent implant initially. This difference is significant within 1.5 years post-operatively (figure 23). In benign conditions, few expander prostheses were registered, but the documented risk for re-operation followed the same trend described in reconstructive conditions. The expected results for the expander prostheses has not transpired, when the relatively high frequency of re-operation within the short observation period is taken into consideration.

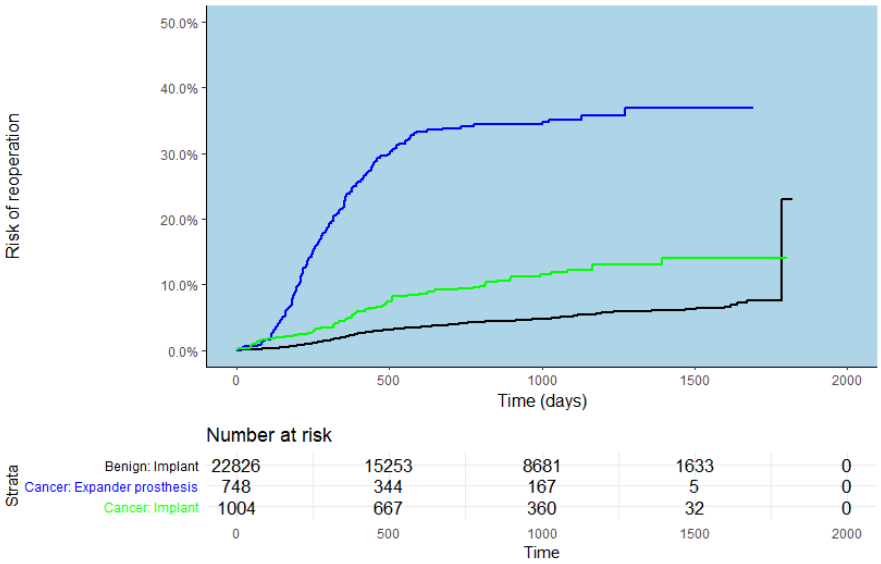


Figure 23. Risk for re-operation in group B, in choice of expander prosthesis or permanent implant compared to group A

A comparison of the results in group B and A regarding dissatisfaction with the shape of the breast achieved with anatomical implants, showed a significantly higher risk ($p<0.001$) for re-operation with the choice of anatomical implants compared to round shapes for reconstructed patients (figure 24a). There is a significant difference in risk for re-operation when considering implant shape in patients with benign breast conditions ($p<0.001$). With a longer follow-up, at 5.5 years no great difference was seen between the groups (figures 24a, 24b)

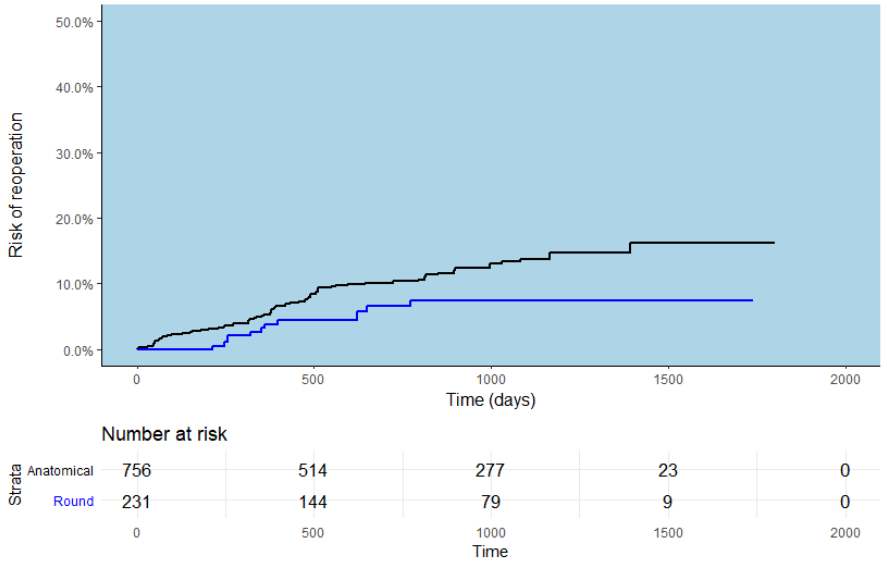


Figure 24a. Risk for re-operation in choice of anatomical and round implant in group B

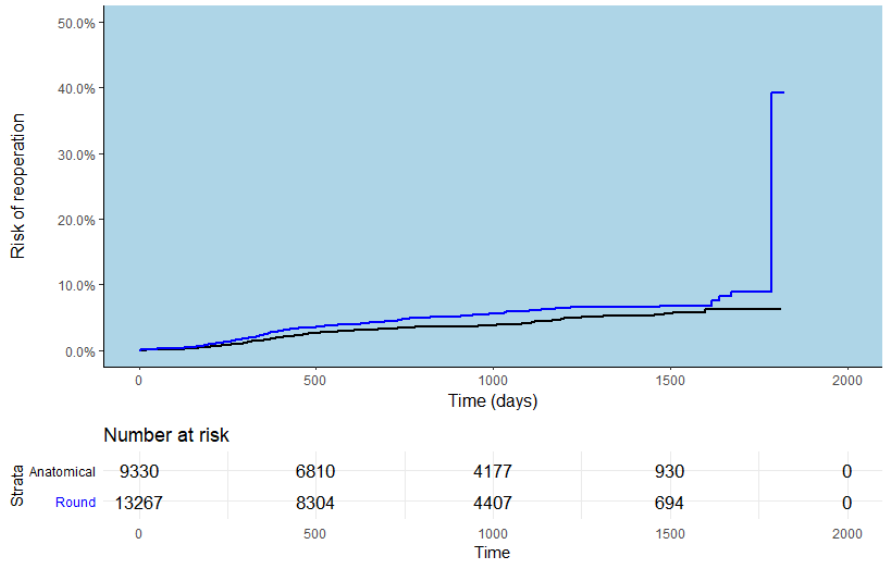


Figure 24b. Risk for re-operation in choice of anatomical and round implant in group A

The risk of re-operation in relation to the implant surface is shown in figure 25b. Data in the BRIMP speaks for a parallel low risk development for textured and smooth implants over time in group A. Reconstructive patients do not display the same low risk. Textured surface on implants seem to have a greater bearing on risk for re-operation than smooth shapes (figures 25a, 25b). This data needs to be consolidated in future annual analyses.

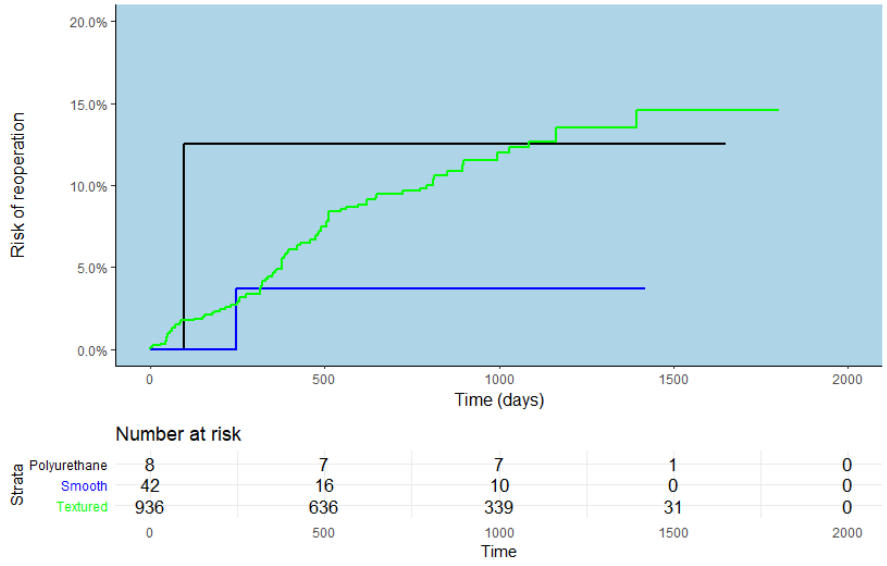


Figure 25a. Risk for re-operation related to implant surface in group B

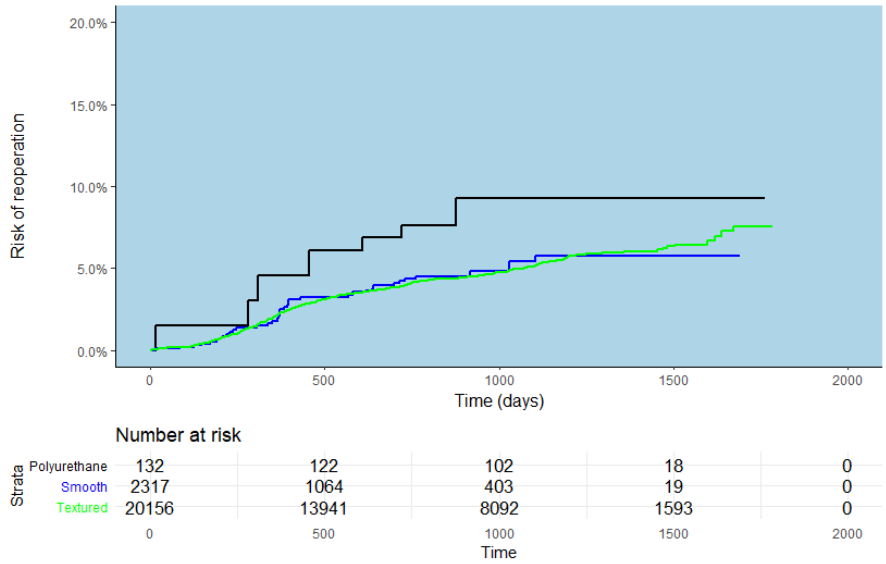


Figure 25b. Risk for re-operation related to implant surface in group A

At re-operation the occurrence of a ruptured implant and the manufacturer is recorded in relation to the index operation. Data in the BRIMP has facilitated a risk analysis for the three manufacturers, Allergan, Mentor and Motiva. The products from all manufacturers showed a very low risk for re-operation, on the basis of rupture within 5 years, in both groups (figures 26a, 26b). The Kaplan Meier analysis could not show any relevant differences between the products. Seroma development lay within the same reference values for the different products within 5 years (data is not graphically represented)

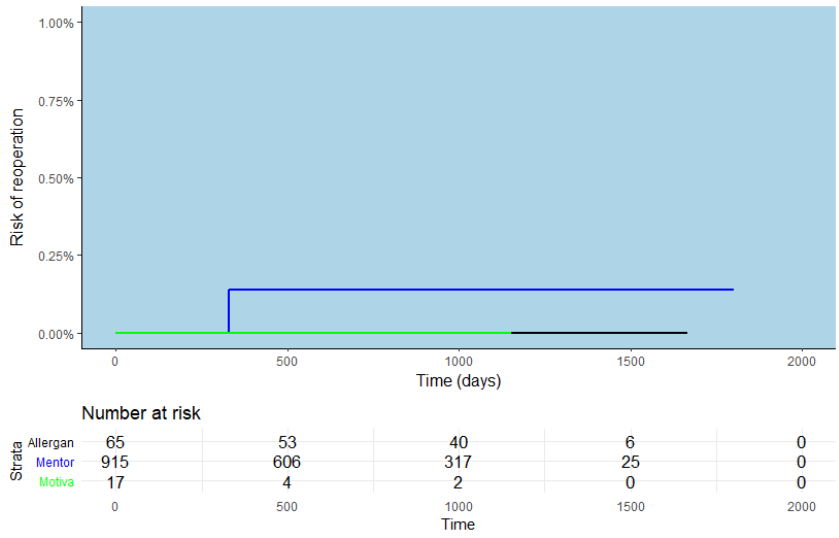


Figure 26a. Risk for re-operation based on rupture, related to implant manufacturer in group B

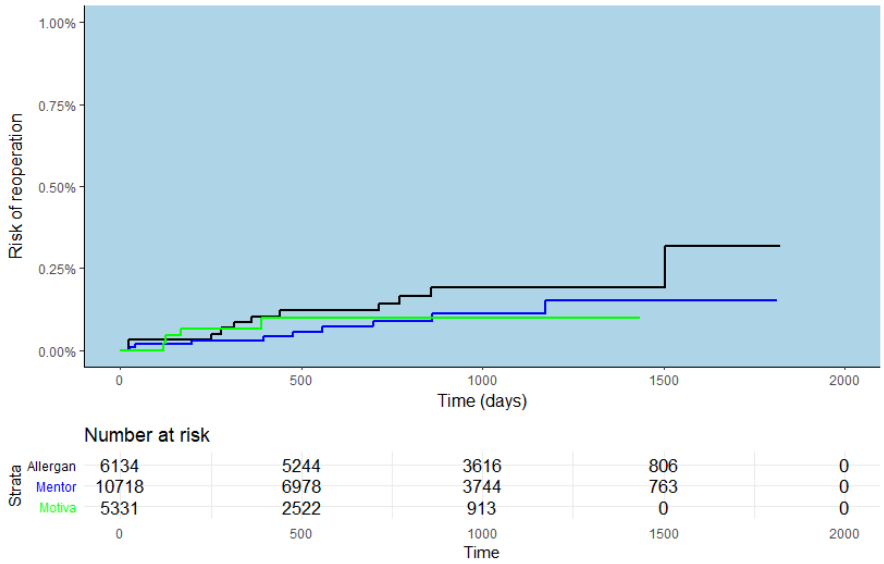


Figure 26b. Risk for re-operation based on rupture, related to implant manufacturer in group A

Interesting data has been shown for the relationship between capsule formation and the risk of re-operation within 5.5 years. In group B, the risk for re-operation increased with Allergan's implant relatively late, about 1.5 years after the index operation (figures 27a, 27b, 27c), Mentors implant had a relatively stable risk within 1.5 years in group B. The general risk for re-operation related to capsule formation after a breast reconstruction within 5 years, is low. As expected, radiated patients had a higher risk compared to non-radiated patients in group B. The Kaplan-Meier figure shows a greater risk for patients with Allergan's implant compared to Mentor's products. The cohorts are not the same size and therefore caution should be used when making comparative interpretations.

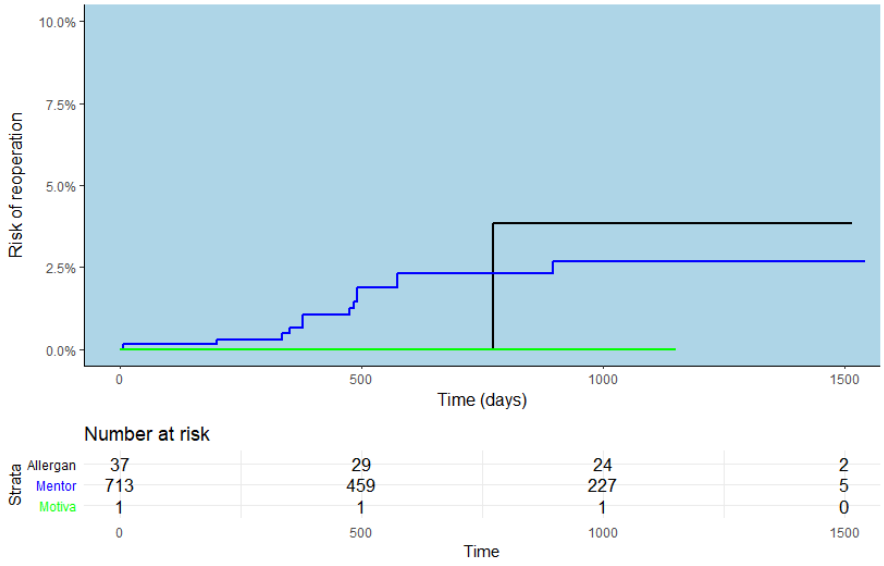


Figure 27a. Risk for re-operation due to capsule formation in non-radiated patients related to product in group B

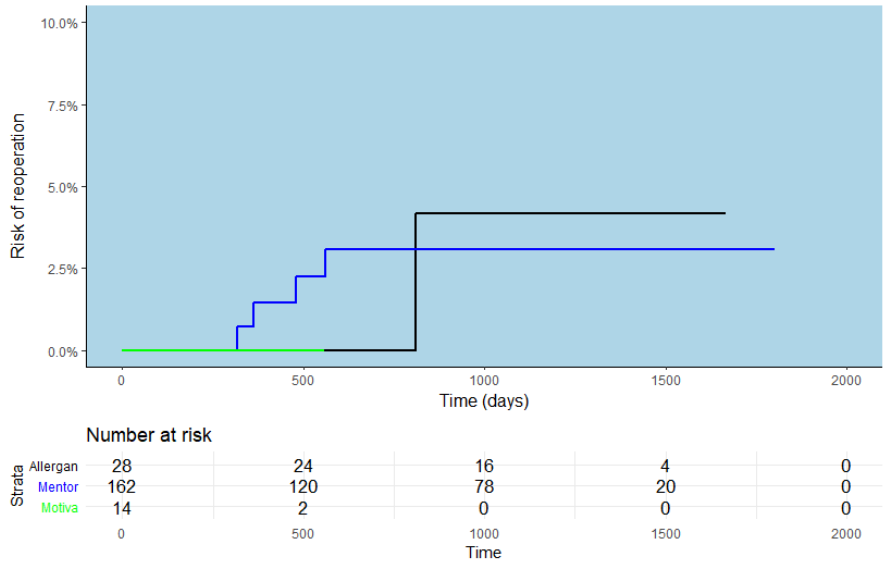


Figure 27b. Risk for re-operation due to capsule formation in radiated patients related to product group B

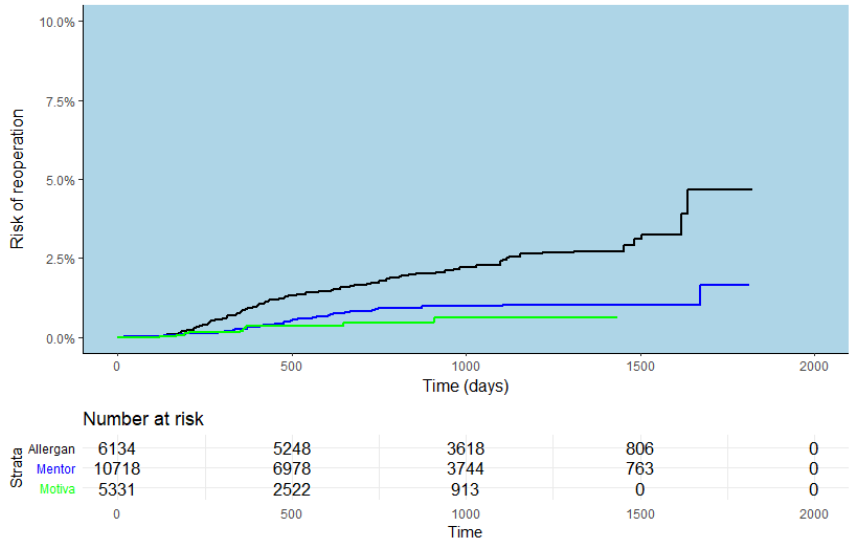


Figure 27c. Risk for re-operation due to capsule formation in group A

Patients who received a breast implant due to a cancer diagnosis showed an increased risk to develop pain ($p<0.001$) in the breast after operation and experienced that the breast had a hard consistency compared to patients who underwent operation in group A (figures 28a, 28b)

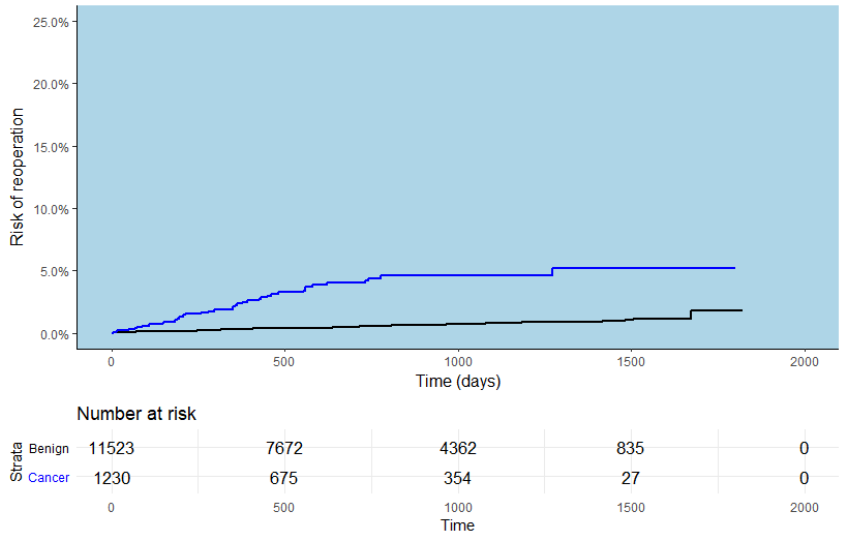


Figure 28a. Risk for re-operation due to pain in group B and A

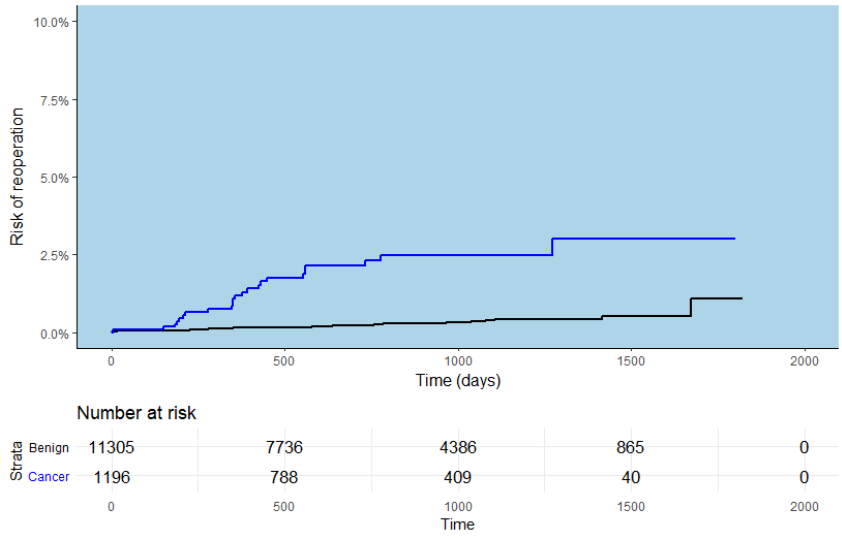


Figure 28c. Risk for re-operation due to hard breast and pain in group B and A

SUMMARY

During 2018, the main focus has been a consolidation of the data collected in the BRIMP. We have worked with making it easier for participating clinics to have access to their own results. Each clinic can follow their own data results compared to the aggregated data in the BRIMP. The aim of this quality work is to decrease complications and increase patient safety. The BRIMP register has a good reputation and is receiving more attention both nationally and internationally. The fact that the BRIMP is an independent register, not financed industry, helps to strengthen its status. An amalgamation of data from the BRIMP with the ICOBRA data is planned. The purpose of this is to give even better information to our patients and professional groups. The work of synchronising the databases is on-going.

Overall, the data in the BRIMP show that there is a 40% increased risk of re-operation in group B (reconstructive indication) and a 5% increased risk in the group A (benign conditions) within 5.5 years of the index operation. To try and account for this clear difference, various variables have been examined. In group B, it is principally implant shape and surface type, as well as radiation treatment which influence the results. Expander prostheses affected the risk for re-operation negatively, and consequently these patients were less satisfied than patients who received a permanent implant. The development of capsule formation influenced the risk for re-operation in group B. Other factors, such as pain and the development of a hard breast increased the risk in group B compared with group A. Monitoring of the different implants has shown that implant rupture within 5.5 years of the index surgery is not common. An increased risk for re-operation, on the basis of implant-related problems with sustainability, has not been shown. Patients with benign conditions have a low risk for re-operation within 5,5 years of the initial surgery. The predominate reasons for revision surgery were the patient's desire for a change in breast volume or shape. All data presented in this annual report will be followed up prospectively.

Finally, I would like to thank Heléne Fägerblad and Jonas Lekander for excellent co-operation and continual support, since the BRIMP was foundered. We have had many interesting and productive discussions over the years. Our co-operative efforts have contributed to the development of the BRIMP. Through the years, I have even received invaluable help from the statisticians at the register. Without Rebecka, Ludwig and Jan, the statisticians at Registercentrum Västra Götaland, the production of this annual report would not have been possible.

Birgit Stark

Stockholm

June 2019

PRIMARY OPERATION FORM

The Swedish Register for Breast Implants (BRIMP)

Primary Surgery 2018

Personal ID _____

Date of operation _____ yyyy-mm-dd

Length _____ cm **Weight** _____ kg

Use of Antibiotics:

Pre-operative	No	Yes ___Days
Per-operative	No	Yes
Intra-operative (Irrigation implant/ cavity)	No	Yes
Post-operative	No	Yes ___Days

LEFT SIDE

Indication for surgery:

Patient Perceived hypoplasia	Asymmetry
Primary Micromasty	Asymmetry
Secondary Micromasty	Asymmetry
Tuberous breast	Asymmetry
Prophylactic Mastectomy	
Reconstruction after Mastectomy	

Type of permanent implant:

Implant Expander Prosthesis (ep)

Manufacturer .....

Content

Saline Silicone Saline and Silicone

Serial Number.....
LOT-number .....
Ref. number .....
Volyme ..... ml / cc / g
Stamped Volume (ep): .....

Type of surface:

Smooth Textured Polyurethane

Shape

Round Anatomical Half moon

Implant- or Expanderprosthesis

Sub-muscular Sub-glandular
Sub-fascial Dual plane

Surgical incision

Sub-mammary	Axillary
Periareolar	Mastectomy scar
Mastopexy with augmentation	

Drain after surgery No Yes

Breast surgery prior to present operation

Tumor	No	Yes
Infection	No	Yes
Reduction/ mastopexy	No	Yes

Patient's experience before surgery

Dissatisfaction with shape	No	Yes
Dissatisfaction with volume	No	Yes
Pain in breast	No	Yes

Fat transplantation No Yes

Completed radiation therapy before primary operation No Yes

RIGHT SIDE

Indication for surgery:

Patient Perceived hypoplasia	Asymmetry
Primary Micromasty	Asymmetry
Secondary Micromasty	Asymmetry
Tuberous breast	Asymmetry
Prophylactic Mastectomy	
Reconstruction after Mastectomy	

Type of permanent implant:

Implant Expander Prosthesis (ep)

Manufacturer .....

Content

Saline Silicone Saline and Silicone

Serial Number.....
LOT-number .....
Ref. number .....
Volyme ..... ml / cc / g
Stamped Volume (ep): .....

Type of surface:

Smooth Textured Polyurethane

Shape

Round Anatomical Half moon

Implant- or Expanderprosthesis

Sub-muscular Sub-glandular
Sub-fascial Dual plane

Surgical incision

Sub-mammary	Axillary
Periareolar	Mastectomy scar
Mastopexy with augmentation	

Drain after surgery No Yes

Breast surgery prior to present operation

Tumor	No	Yes
Infection	No	Yes
Reduction/ mastopexy	No	Yes

Patient's experience before surgery

Dissatisfaction with shape	No	Yes
Dissatisfaction with volume	No	Yes
Pain in breast	No	Yes

Fat transplantation No Yes

Completed radiation therapy before primary operation No Yes

RE-OPERATION FORM

The Swedish Register for Breast Implants (BRIMP)

Secondary Surgery 2018

Personal ID _____
Date of surgery _____ yyyy-mm-dd
Length _____ cm Weight _____ kg
Date of primary implant surgery _____ Year
Date of actual implant surgery _____ Year
Surgery performed at my clinic

Use of Antibiotics:
Pre-operative - Y/N
Per-operative - Y/N
Intra-operative - Y/N
(Rinsing of implant/pocket) - Y/N
Post-operative - Y/N

Indication for operation	LEFT		RIGHT	
Patient reported symptoms				
Pain	No	Yes	No	Yes
Swelling of breast	No	Yes	No	Yes
Anxiety for implant	No	Yes	No	Yes
If anxiety is it because of recent mammography	No	Yes	No	Yes
Change of size	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 t	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
Implant related				
Rupture	No	Yes	No	Yes
Rotation	No	Yes	No	Yes
Confirmed ALCL	No	Yes	No	Yes
Deflation	No	Yes	No	Yes
Incorrect position	No	Yes	No	Yes
Capsular (T85.4)	No	Yes	No	Yes
Double capsule	No	Yes	No	Yes
Seroma/exsudate (T81.8)	No	Yes	No	Yes
Hematoma	No	Yes	No	Yes
Measure				
Permanent removal of implantat	No	Yes	No	Yes
Replacement with the existing implant	No	Yes	No	Yes
Replacement with new implant after prosthesis removal	No	Yes	No	Yes
Implant change	No	Yes	No	Yes
Capsule/dissection	No	Yes	No	Yes
Capsular extirpation	No	Yes	No	Yes
Neopocket	No	Yes	No	Yes
Drain	No	Yes	No	Yes
Mesh/ADM in	No	Yes	No	Yes
Mesh/ADM out	No	Yes	No	Yes
Fat transport	No	Yes	No	Yes
Completed radiation before operation	No	Yes	No	Yes

Details of removed implant LEFT
Type of implant:
Implant Expander Prosthesis (ep) Manufacturer_____
Content
Saline Silicone Saline and Silicone
Volyme _____ Stamped volume (ep)_____
Surface Smooth Textured Polyurethane
Shape Round Anatomical Half moon
Pocket Submuscular Subglandular
Subfascial Dual plane

Details of inserted implant LEFT
Type of implant:
Implant Expander Prosthesis (ep) Manufacturer_____
Content
Saline Silicone Saline and Silicone
Serial Number _____ LOT-number _____
Ref. number _____ Volyme _____
Stamped volume (ep)_____
Type of surface Smooth Textured Polyurethane
Shape Round Anatomical Half moon
Pocket Submuscular Subglandular
Subfascial Dual plane

Details of removed implant LEFT
Type of implant:
Implant Expander Prosthesis (ep) Manufacturer_____
Content
Saline Silicone Saline and Silicone
Volyme _____ Stamped volume (ep)_____
Surface Smooth Textured Polyurethane
Shape Round Anatomical Half moon
Pocket Submuscular Subglandular
Subfascial Dual plane

Details of inserted implant LEFT
Type of implant:
Implant Expander Prosthesis (ep) Manufacturer_____
Content
Saline Silicone Saline and Silicone
Serial Number _____ LOT-number _____
Ref. number _____ Volyme _____
Stamped volume (ep)_____
Type of surface Smooth Textured Polyurethane
Shape Round Anatomical Half moon
Pocket Submuscular Subglandular
Subfascial Dual plane

VARIABLE DEFINITIONS

Primary operation

Variable	Definition
Civic identity number	Patients date of birth + 4 last digits
Date of Operation	Date of index operation
Height	Patient's self-reported height in cm
Weight	Patient's self-reported weight in kg
Side: Each breast operation per side is registered separately	
Left side	Data registration concerning left breast
Right	Data registration concerning right breast
Indication for surgery	The reason for the implant surgery
Patient-reported hypoplasia	Patient-reported experience that breast volume is too small
Asymmetry	Difference in volume or shape between breasts
Primary Micromastia	Disproportionally small breasts in relation to height and weight in a nulliparous woman
Secondary Micromastia	Disproportionally small breasts in relation to height and weight or loss of breast volume after pregnancy and breast feeding, massive weight loss, trans-sexual surgery, status after breast surgery e.g. reductions, ptosis plastic Breast-saving cancer surgery or other conditions with reduction in breast volume.
Tuberous breasts	Abnormality of breast
Prophylactic mastectomy	Surgical measure where one or both breasts are removed to reduce the risk of breast cancer
Reconstruction after mastectomy	Surgical measure 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 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
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 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
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 cavity 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 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 prosthesis cavity with antibiotics (antiseptics do not apply)
Post-operatively	Antibiotics given intravenously or orally after the day of surgery

Re-operation

Variable	Definition
Civic identity number	Patients date of birth + 4 last digits
Date of Operation	Date of index operation
Height	Patient's self-reported height in cm
Weight	Patient's self-reported weight in kg
Year for initial implant insertion	The year when breast implant was inserted
When was current implant surgery performed at this department	Date for insertion of current implant at this department
Indication for operation right and left side	Reasons for re-operation
Pain	Patient-reported pain in breast
Swelling	Patient-reported swelling of breast
Anxiety for 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's experience of that breast volume is too small or large
Desired shape change	Patient's desire for change in breast shape
Breast hardness	Patient's experience that breast is hard
Desired implant removal	Patient's desire for implant removal
Infection (T81.4)	Infection after breast surgery
Recently diagnosed breast cancer	Diagnosis breast cancer is reason for the actual 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	Defect/injury in the implants exterior casing (from hole in the casing to total degeneration of the implants shape)
Rotation	Implant has rotated in the prosthesis cavity
Confirmed ALCL	Breast implant-associated Anaplastic Large Cell Lymphoma, confirmed with CD30 and ALK
Deflation	Volume and/or shape change of implant / expander prosthesis due to normal saline loss
Incorrect position	Implant is in incorrect position in the breast
Capsule (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)	Collection of wound fluid in implant cavity
Haematoma	Collection of blood in or outside implant cavity
Measure	Treatment
Permanent removal of implant	Breast implant is removed and not replaced
Return of existing implant	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 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
Change of implant	New implant is inserted during operation after removal of existing implant
Capsule dissection	Incision of capsule in one or more quadrants
Capsule extirpation	Removal of capsule tissue except the thoracic section
Drain	Use of drain in the implant cavity 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 before the actual implant surgery
Information about implant which is removed from Right or Left side	Registration of data concerning Right or Left side
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 tissue of the thorax wall when reconstructing the breast in a "one-stage" 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
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
Half-moon	The implant is shaped like a half-moon
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