

# BRIMP- BREAST IMPLANT REGISTER ANNUAL REPORT 2017



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## ANNUAL REPORT 2017

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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.se](http://www.brimp.se) 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 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 having breast implants.

The availability of statistics collected in the register enables the profession to have access to increased knowledge about different implants and their performance, 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 be 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 will 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 which 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.

## THE REGISTRAR'S

### Action plan 2018



*Birgit Stark Registrar for the BRIMP Associate Professor, Specialist in Plastic Surgery*

The work of the BRIMP started on a national level in May 2014. Currently all the Plastic Surgery Clinics at University Hospitals in Sweden have joined the BRIMP. The level of coverage is > 85% for all plastic surgeons working in private practice in Sweden. We manage data from 19,143 primary implants and 5718 revised implants, in co-operation with the Register Centre (RC) for the County of Västra Götaland. Only one clinic in Stockholm has actively chosen not to participate in the BRIMP. During 2018, the work of the register will focus on three main project areas.

**1 Work with the Data Function as a Support for Healthcare** Giving feedback to participating clinics is an important function of the register. In a co-operative effort, together with the RC for County of Västra Götaland, two on-line web modules have been created for use by participating clinics. All clinics that are registering information can access and evaluate the quality of care against aggregated data in the BRIMP. To facilitate the possibility for participating clinics to analyse their own data and to give the opportunity for critical thinking, a module has been created to enabling the specific clinic to access a summary of their six-monthly data.

The module was launched in 2018. The plan is for the first summaries to be available during 2018. The participating clinics can therefore more easily follow their own outcome data over time and undertake quality improvement initiatives.

Necessary development initiatives: To ensure the implementation of (1) a co-operation with the IT department at RC of County of Västra Götaland is required. Time and resources need to be allocated for work with the preparation, analysis and construction of the modules for specific data sets which are presented in a summary to each of the participating clinics. The work of a co-ordinator is required for sending out questionnaires and for communication with participating clinics. Time and resources for the Registrar and the project management team to engage in planning, analysis and implementation of the work of the register..

**2 Improved Register Content:** The BRIMP register is a relatively new register and is still under development. It needs to be established if the data registered in the register is relevant for the questions posed to the register. We also need to assemble information about the response frequency and the response quality. Improving the content of the register regarding the quality of the variables involves continually evaluating the significance of the parameters which are registered. The result of this work will mean that the registration forms will be more user-friendly as the expectation is the possibility to collect statistically valuable data prospectively. It will require several years of work to achieve this new and improved breast implant register. Improvement in the register content will also be achieved by analysis of the level of coverage the register demonstrates. During the period 2015 – 2017 we have noted an 11% increase in the reporting of primary hospital admissions and a 25% increase in the reporting of re-operations. Since the initiation of the BRIMP register, there has been a continual increase in the number of clinics reporting data to the register as the understanding grows within the profession as to the benefits and importance of this quality register. On a national scale, more and more clinics are requesting information about BRIMP from the registrar. On an international scale, much interest in the register's data, has been shown in the register and this is reflected in the increase in requests for presentations at international conferences and through co-operation with ICOBRA. In the autumn of 2017 the registrar held 8 presentations about BRIMP.

The current total level of coverage of the BRIMP is approximately 65%. Reliable sales-data from the industry has been personally conveyed to the registrar and these report that the register has information about an estimated 65% of all implants sold in Sweden. It is worth remembering, that this is a relatively new register and therefore the level of coverage is not more comprehensive. Breast implants are used by various surgical specialities and thus far we have not succeeded in convincing breast surgeons to participate in the BRIMP. We are hoping for a closer co-operation between the breast cancer register and the BRIMP which should help to increase the level of coverage

considerably. To help continually increase the “compliance” and “completeness” in the BRIMP, regular person to person meetings, as well as electronic meetings are required. 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 society. Colleagues are becoming more and more aware of the benefits of the BRIMP for their own clinics and participation in the BRIMP will be an integral part in the workplace. Hopefully more reticent colleagues will also see its benefits and join 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. Many of these units are waiting for a merging of the BRIMP and the Breast Cancer Register, which is why an intensified dialogue with the Breast Cancer Register is needed. Since 2014, the BRIMP has been in contact with the Breast Cancer Register with the goal of sharing data between both registers.

The current discussions will continue during 2018 and an interim solution is needed as the Breast Cancer Register is under renovation. The quality of the data will be tested and evaluated in 2018. Sample controls of three different clinics are planned. These will be conducted at the university clinics and two private clinics with high volumes of surgery. Improving the level of coverage and checking the level of completeness will help to increase the BRIMP's statistical relevance and standing among both the profession and patients.

Necessary developments: The work carried out by the register will require resources for a co-ordinator, the registrar and for project management. The co-ordinator and the registrar will require resources to be able to visit clinics and attend professional clinical meetings and scientific meetings to present information about the work of the BRIMP register for colleagues in the profession.

Co-operation with implant manufacturers will also be required to foster a climate of trust, confidence and understanding for the work of the BRIMP register. The plan is to build up an industry database in the future and this will require resources for both IT-support and project management.

**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 a definite decision is made as to which PROM parameters will be included. A proposal for PROM has been suggested, discussed and a decision has been made by the management group as to which PROM is to be used. In consultation with the project management of the Register Centrum, discussions have taken place regarding as to what is the most suitable form of the PROM to be sent out to breast surgery patients to best capture the required data. The first questionnaires have been sent out to three pilot clinics. An analysis of the instrument will be conducted comparing it against an internationally established tool “BREAST Q”. 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 2018. This work will be summarized in a scientific publication. Ethical approval has been received for a project which will examine the use of anti-biotics in breast-implant surgery in Sweden.

Necessary development efforts: The Register Centre for the County of Västra Götaland will be engaged in this work. Together with the project management, suitable methods for validation and analysis will be agreed upon. Processing of data, critical analysis and summarising results will demand resources for the co-ordinator, statistician, project management and the registrar of the register.

## Summary

The BRIMP is a well-respected register generating increasing interest on both a national and international level, particularly as this quality register is independent and not financed by industry. 16,000 implants, for varying

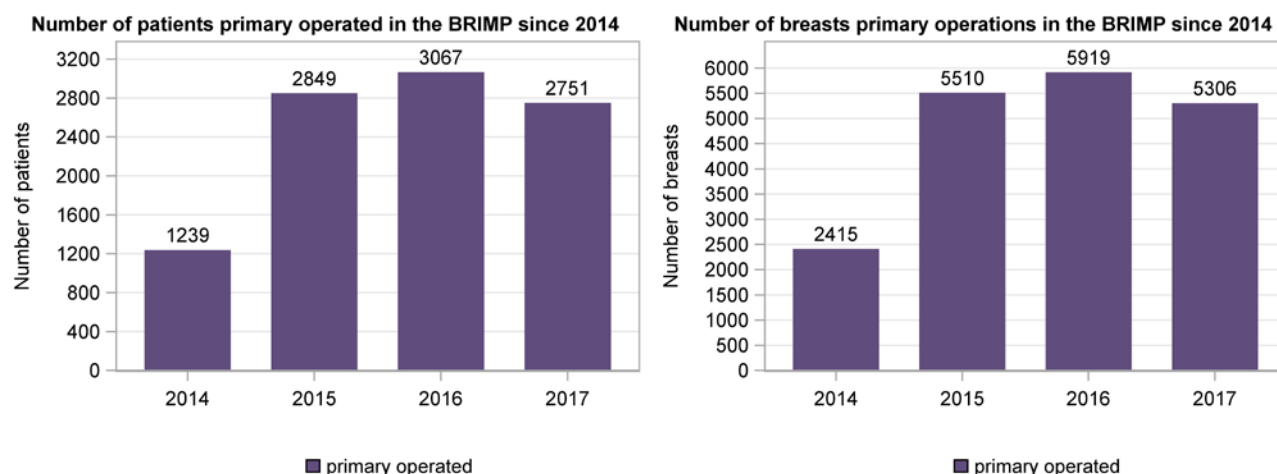
reasons, are expected to be used for surgery on women in Sweden. New implants are being marketed on “patient forums” where no scientific analysis has been carried out. New brands are being introduced and used in a non-critical and non-scientific way in Sweden. We do not know how these implants will perform in the human body in the long term. In the BRIMP we monitor around 7,500 new implants annually and through continually processing and analysing data, we hope to contribute to avoiding similar catastrophes as that with the PIP implant. The BRIMP is an important tool for patients, as we will be able to provide information about the performance of implants regarding, complications in the short and long-term perspective. Through the three projects described above, as well through the continual registration work, we will be able to contribute to raising the reliability of our data, improve the statistical relevance of our analyses and help decision makers in choosing the most suitable implant for the patient. Our international co-operation with Australia, Holland, Germany, Great Britain, Switzerland and Italy through ICOBRA aims to define quality indicators for the care of these patients on an international level. The work mentioned above requires time and resources for the registrar, the project management and the co-ordinator. I consider that the BRIMP should be able to apply for a higher level of certification under the condition that the developmental work of the register is made possible by the provision of economic resources being made available.

Birgit Stark

Stockholm 16th May 2018

## PRIMARY OPERATIONS

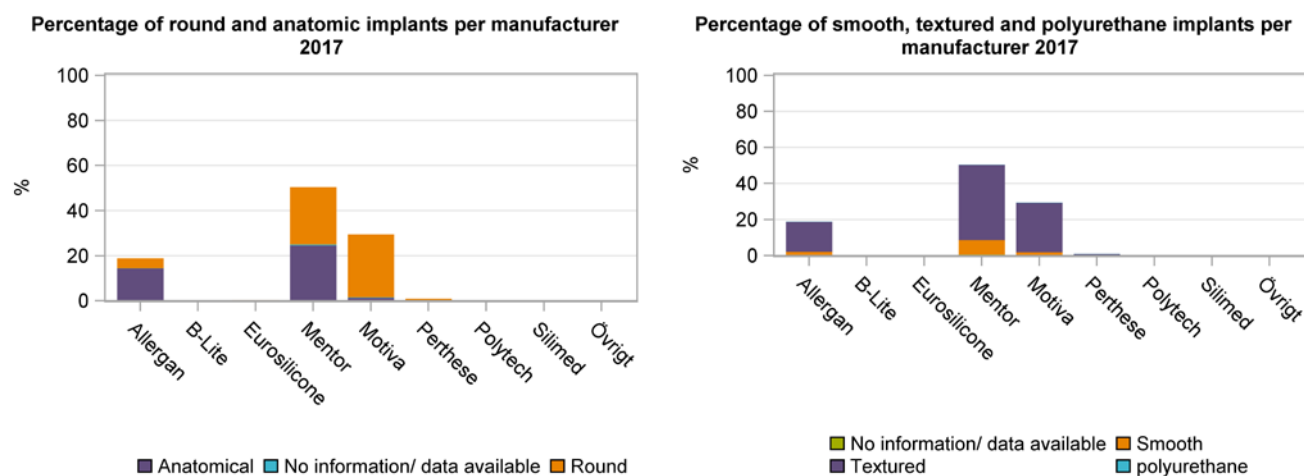
The number of patients registered, and the number of breast implants have risen continually since 2014. During 2017, 2,751 new patients have been registered. The total number of patients registered for their primary operation is 9,906 (Fig. 1a) The number of patients undergoing surgery for primary breast implants during the past year is 5,306 (Fig 1b). Therefore, the profession has the possibility to evaluate and follow-up 19,150 primary breast implants, as well as, study what effect these implants have on the woman's body over time.



**Figure 1a, b** Number of primary operations and breast operations in the BRIMP since 2014.

In the BRIMP, we see that textured implants from three manufacturers, Allergan, Mentor and Motiva were the most common implants used in Sweden during 2017. In 12% (639 of 5303) of cases, smooth implants were reported. Reporting of Motivax products has increased with 37% since 2016 (from 1,138 breasts/implants in 2016 to 1,557 breast/implants 2017). Mentor implants constitute about 50% (2,671 implants) of the implants reported to the register for 2017, while Motiva implants represent 29% (1,557 implants) and Allergan implants make up about 19% (997 implants).

Only two polyurethane implants have been reported and the number has continually decreased since 2014. In comparison to the annual report for 2016, changes in market shares has occurred. Increased awareness among both patients and surgeons about the condition BIA-ALCL has not been reflected in a discernible change in the choice of implant surface, i.e. the percentage of smooth implants versus textured implants. The use of smooth implants has increased by only 27% (502 in 2016 to 639 in 2017) since 2016 in the BRIMP database (Fig 2a, b)

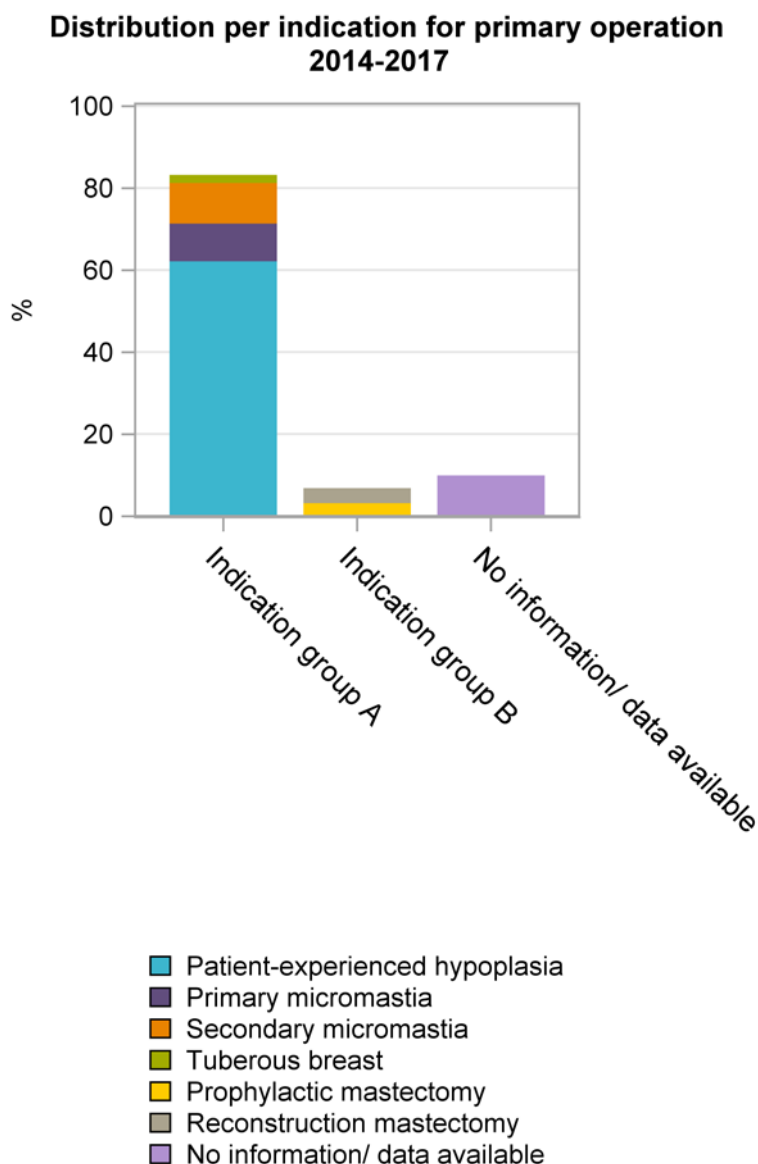


**Fig 2a.** Percentage of round and anatomic implants per manufacturer 2017.

**Fig 2b.** Percentage of smooth, textured and polyurethane implants per manufacturer 2017.

The indication for an implant-based breast operation has been divided up into benign conditions under indication group A and malignant and genetic conditions (primary, secondary breast reconstructions with cancer and risk-reducing surgery for those with increased risk for hereditary breast cancer) under indication group B. In group A, patient-experienced hypoplasia, breast aplasia, primary and secondary hypoplasia as well as trans-sexual breast reconstruction. The accumulated data in the BRIMP shows that the percentage of breast implants in group A make up the majority. 6.8% of all the primary breast operations registered in the BRIMP are performed as a result of a breast cancer diagnosis or for prophylactic mastectomies (1301 patients) (Figure 3)

The quality of the data in the register is continually improving, which is reflected in the fact that the amount of missing data has decreased from 20% in 2016 to 10% in 2017.



**Figure 3.** Distribution per indication for primary operation 2014-2017.

The aggregated data in the BRIMP (n=9906 patients) has shown robust data over the years regarding BMI (Fig 4a) and age distribution (Fig 4b). No significant differences were found compared to the data from 2016. In all age groups, a normal weight distribution was seen in 80% of patients. The graphs below show that 80% of the BRIMP patients undergo their primary operation before the age of 40 years.

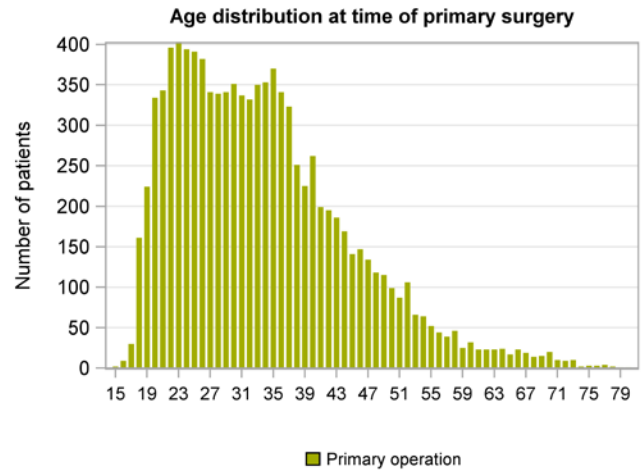
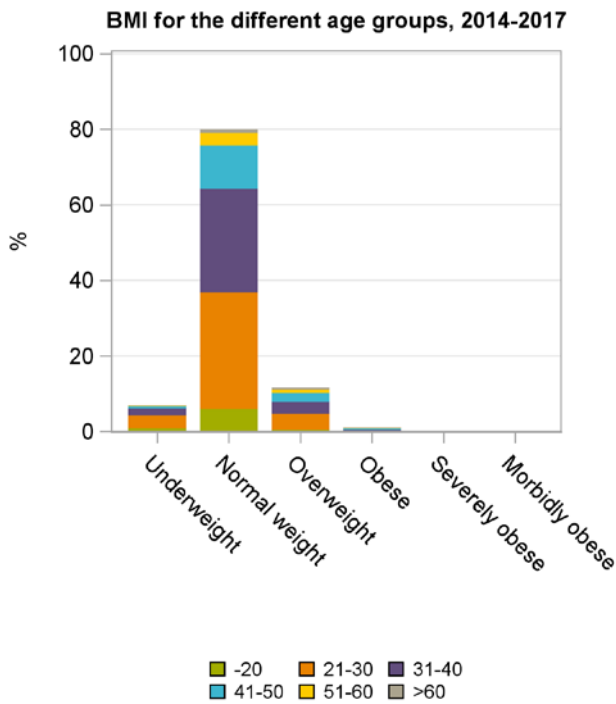


Figure 4b: Age distribution at time of primary surgery

Fig 4a. BMI for the different age groups, 2014-2017

Data in the BRIMP indicates that the majority of patients (68%) in group A chose an implant-based operation due to a combination of dissatisfaction with the shape and volume of their breasts (Fig 5)

154 patients reported pain before surgery and 31 of these belonged to group B. 223 patients underwent radiation treatment before breast reconstruction (this data is not presented graphically).

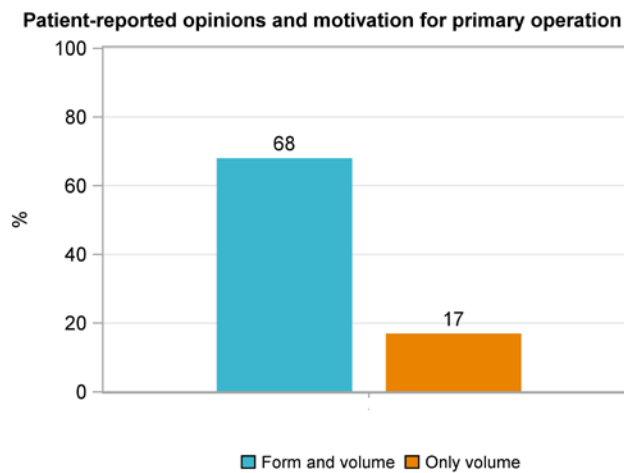


Figure 5. Patient-reported opinions and motivation for primary operation.



## RE-OPERATIONS

The number of re-operations during 2017 has been in parity with the number in 2016 (Fig 6a, b). These results must be interpreted in relation to the level of coverage which has improved from 2016 to the current 65% for 2017. It will be interesting to see, if and how these results, change in the coming years, as the level of coverage increases

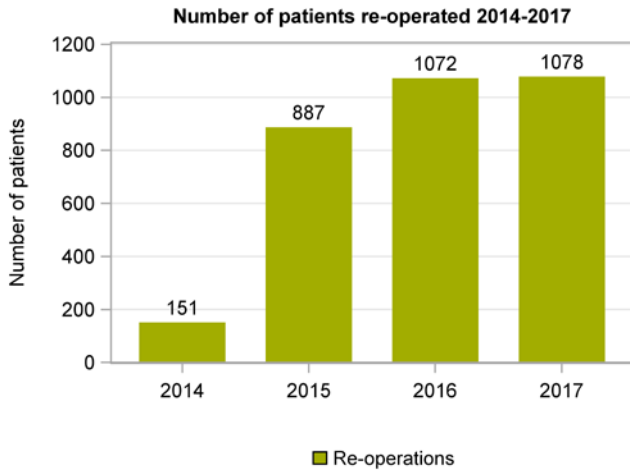


Figure 6a. Number of patients re-operated 2014-2017

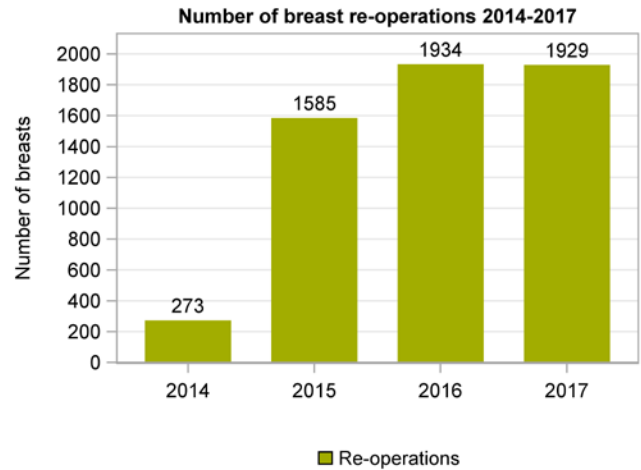


Figure 6b. Number of breast re-operations 2014-2017

Figure 7 shows the percentage of re-operations in relationship to time after the index operation. 34% of these implants required re-operation within 2 years, 34% between 3-10 years and 32% after 10 years. There was no difference regarding BMI at operation compared to 2016 data. 17% of patients were overweight and 3% were obese (Fig 8). In this report, we will examine the patient cohort specifically relating to both the patients' primary surgery as well as re-operations

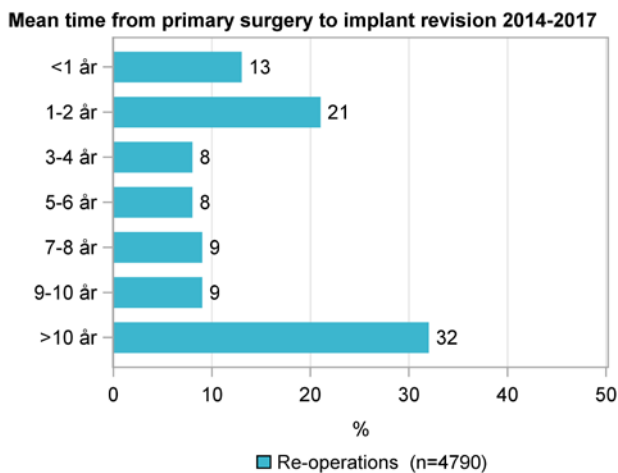


Figure 7. Mean time from primary surgery to implant revision 2014-2017.

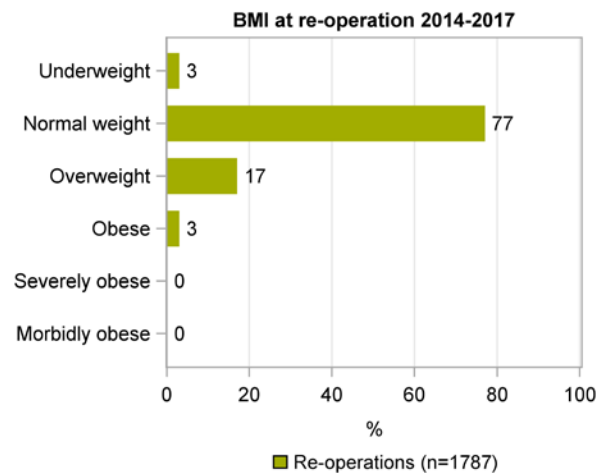
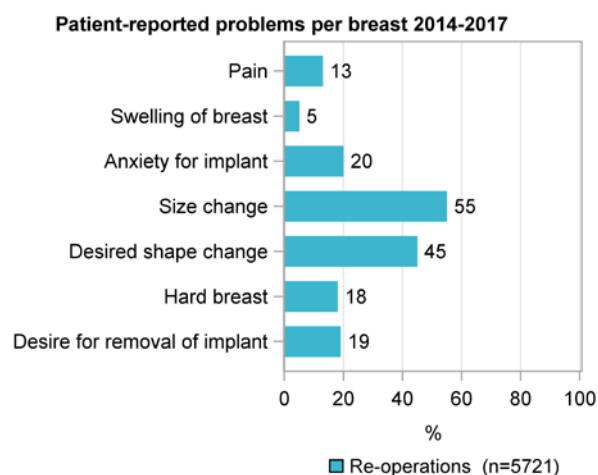


Figure 8. BMI at re-operation 2014-2017

## Patient-reported symptoms

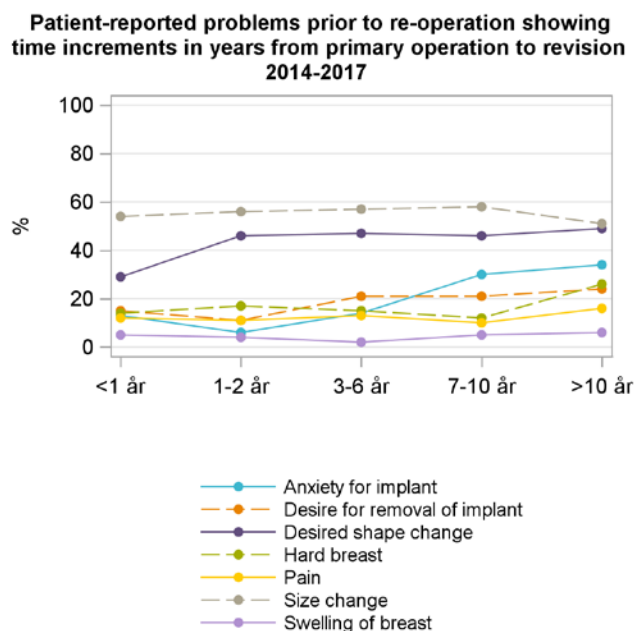
Our aggregated data in the BRIMP concerning motivation for re-operation is robust over time, as the 2017 analysis has shown. The desire for change of size and change of shape are the most common patient-reported reasons for a re-operation. This next most common reasons are anxiety about the implant, desire for removal of the implant and hardness of the breast. (Fig.9a, b).



**Figure 9a** Patient-reported problems per breast 2014-2017

Pain, Swelling of breast, Anxiety for implant, Size change, Desired shape change, Hard breast, Desire for removal of implant.

Patient-reported problems prior to revision operation 2014-2017



**Figure 9b** Patient-reported problems prior to re-operation showing time increments in years from primary operation to revision 2014-2017

Figure 9b shows the time aspect when patients request a revision operation for the various reported problems.

The outcome measure, change in size is reported by 55% of patients as the reason for reoperation. Unfortunately, 55% were not satisfied with the breast volume up to two years after their index surgery. The profession should be aware of this data and critically analyse the reason for this dissatisfaction. In this context, it should be noted that both the subjective experience and the objective result in cancer patients can be influenced by adjuvant treatment and the development of the disease.

The outcome measure, change of shape is mainly seen an extended time after the primary operation. Changes in weight, pregnancy and cancer treatment can also be contributing factors.

Pain, anxiety for implant and hardness of the breast as motivation for re-operation increase substantially over time. In the BRIMP database, 1% of all the revised breasts (n=5,721) developed a combination of seroma in the implant cavity, hardness and swelling of the breast. These patients require special vigilance particularly considering the risk for BIA-ALCL. All late onset seromas (>1 year after primary surgery) can be an indicator for the illness BIA-ALCL. The BRIMP has included registration of confirmed ALCL, which enables documentation of the specific implant in relation to the appearance of BIA-ALCL.

Pain was seen in 728 of the 5,721 of the revised breasts. The majority of these symptoms developed in the period 10 years after the primary operation.

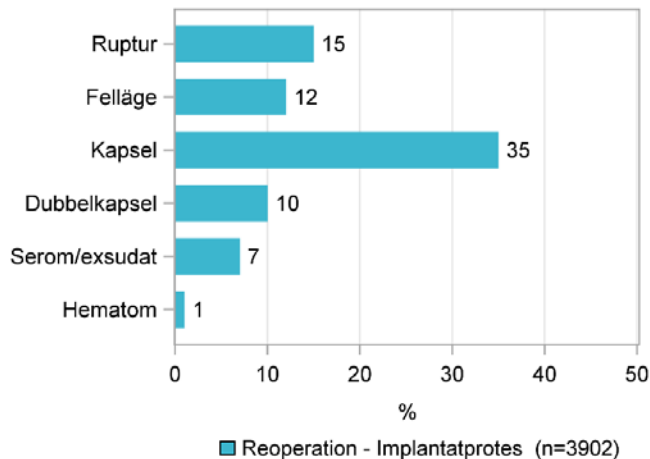
Hardness of the breast and patient anxiety has been shown to increase substantially 10 years after the initial operation. Often patients experience more than one symptom which can lead to a visit to the doctor several years after their primary operation.

## Intra-operative findings

Aggregated data regarding implant rupture, incorrect positioning, capsule formation and rotation have been evaluated irrespective of the indication. Aggregated data showing implant-related complications have been documented since May 2014. Information regarding implant rupture, incorrect implant positioning, capsule and double capsule formation and implant rotation irrespective indication as well as treatment with radiation is available from the register.

Fig 10 shows data on the aggregated level (n=3,902). Irrespective of indication, 15% of implants were defective; in 12% of cases correction of implant position was required and 35% of cases had suffered capsule formation requiring treatment. 10% of patients showed double capsule formation. Acute re-operations on the day of operation or later due to haemorrhage occurred in only 1% of cases.

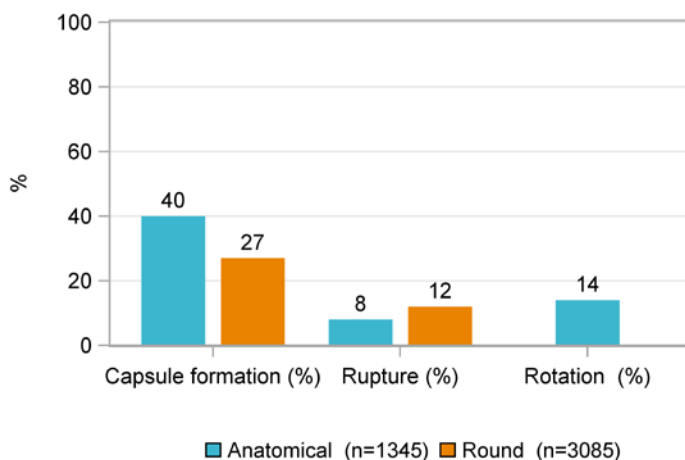
**Intraoperativa fynd, aggregerade data om implantatprotesstatus, 2014-2017.**



**Figure 10** intra-operative findings, complications related to implant 2014-2017

On closer analysis of the relationship between capsule formation, rupture, rotation and implant geometry for 3085 revised implants, the figures were unchanged compared to the figures for 2016. Intra-operatively, 14% of the anatomical implants were rotated and a substantial number of capsule formation were associated with this type of implant. As many as 20% of these implants were found to be defective.

**Capsule formation, rupture, rotation in relation to implant shape. 2014-2017**



**Figure 11.** Intra-operative findings in relation to implant geometry.

## PRIMARY AND REVISED PATIENTS IN BRIMP; 3.5 YEARS FOLLOW-UP

There is a total of 458 patients who have a both an index operation and a re-operation registered in the BRIMP since the register was launched nationally in May 2014. This is equivalent to 807 breasts. Of these 45 required acute revision i.e. on the day of the index operation.

Of the 807 reported breasts reoperations, 660 had an implant and 147 had an expander prosthesis. For breast reconstructions performed on the indication of cancer or prophylactic mastectomies, 65 implants and 133 expander prostheses required revision within 3.5 years. The corresponding figures for benign breast conditions (breast abnormalities, benign tumours, primary and secondary breast hypoplasias and aplasias) 485 with implants were revised and 2 with expander prostheses. Data in unavailable for the indication for the initial operation in 110 implant cases and 12 expander cases.

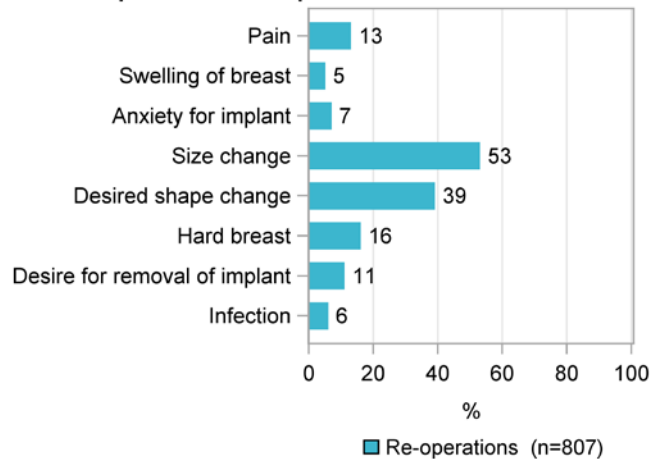
### A Patient-reported problems and motivation for re-operation

It is mainly size correlation (53%) and increased shape change (39%) which is responsible for the early re-operation in the cohort. (Fig 12) (This is consistent with what we see in the register for the aggregated data where the corresponding figure is 55% and 45% (See re-operations fig 9a, 9b.)

Pain and hardness of the breast and desired removal of the implant accounted for more than 10% of revision cases. Infection was the cause of 5% of revisions while swelling also accounted for 5% of revisions.

**It is worth pointing out that combinations of various symptoms also occurred**

**Patient-reported problems per breast for patients with both index operation and re-operation. 2014-2017**



**Figure 12** Patient-reported problems per breast for patients with both index operation and re-operation

BMI has no influence on revision rate regarding those patients choosing altered breast volume within the 3.5-year time-period after operation.

There is a significantly larger percentage of patients who desired a larger breast compared with the index operation. (Figure 13)

| Change of volume at the desire of size change against BMI |              |              |            |
|---|--------------|--------------|------------|
|   | Mindre volym | Större volym | Total      |
| <b>Obese</b>  | <b>4</b>     | <b>6</b>     | <b>10</b>  |
| <b>Normal weight</b>                                      | <b>45</b>    | <b>254</b>   | <b>299</b> |
| <b>Underweight</b>  | <b>6</b>     | <b>16</b>    | <b>22</b>  |
| <b>No data available</b>                                  | <b>10</b>    | <b>14</b>    | <b>24</b>  |
| <b>Overweight</b>   | <b>16</b>    | <b>26</b>    | <b>42</b>  |
| <b>Total</b>  | <b>81</b>    | <b>316</b>   | <b>397</b> |

**FIGUR 13** Change of volume at the desire of size change against BMI

### Breast reconstruction patients

Since the start of the BRIMP in 2014, 572 expander prostheses have been index registered in the BRIMP; of these 147 have required re-operation. Of these 14 are round, 531 anatomical shapes and there is no information available for 27 expander prostheses. In 26% (147 of 572) of expander prosthesis cases, the goal of offering the patient a one-stage reconstruction has not been met.

A closer analysis of the reconstruction cohort undergoing reoperation within 3.5 years, showed that 87 of the expander prostheses had been replaced by an implant (Fig 15). Of these 87 expander prostheses, 55 were revised due to request by the patients for an alteration of shape (Fig 14).

### Benign breast conditions

466 augmentation implants of a total of 19,150 primary implants registered in the BRIMP were revised within 3.5 years (Fig 14). The proportion of anatomical implants revised to round implants is higher than the change of round implants to anatomical implants. 272 round implants were revised where a round implant was used again (Fig 15) .

| Of those who indicated a change of shape as a patient-reported inconvenience, the change has been made according to the table |                          |                     |                     |                |            |
|---|--------------------------|---------------------|---------------------|----------------|------------|
|   | Anatomical to Anatomical | Anatomical to Round | Round to Anatomical | Round to Round | Total      |
| <b>Expander prostheses to Implant</b>   | <b>54</b>                | <b>1</b>            | <b>0</b>            | <b>0</b>       | <b>55</b>  |
| <b>Implant to Implant</b>   | <b>53</b>                | <b>21</b>           | <b>14</b>           | <b>107</b>     | <b>195</b> |
| <b>Total</b>  | <b>107</b>               | <b>22</b>           | <b>14</b>           | <b>107</b>     | <b>250</b> |

**Figure 14** Of those who indicated a change of shape as a patient-reported inconvenience, the change has been made according to the table

| Shape change throughout the cohort                |                          |                     |                     |                |            |
|---|--------------------------|---------------------|---------------------|----------------|------------|
|   | Anatomical to Anatomical | Anatomical to Round | Round to Anatomical | Round to Round | Total      |
| <b>Expander prostheses to Expander prostheses</b> | <b>2</b>                 | <b>0</b>            | <b>0</b>            | <b>0</b>       | <b>2</b>   |
| <b>Expander prostheses to Implant</b>             | <b>79</b>                | <b>8</b>            | <b>0</b>            | <b>0</b>       | <b>87</b>  |
| <b>Implant to Expander prostheses</b>             | <b>2</b>                 | <b>0</b>            | <b>0</b>            | <b>0</b>       | <b>2</b>   |
| <b>Implant to Implant</b>                         | <b>123</b>               | <b>49</b>           | <b>22</b>           | <b>272</b>     | <b>466</b> |
| <b>Total</b>                                      | <b>206</b>               | <b>57</b>           | <b>22</b>           | <b>272</b>     | <b>557</b> |

**Figure 15** Shape change throughout the cohort

## B. Patient-reported symptoms; hardness of the breast as motivation for re-operation

A total of 129 patients experienced hardness of the breast within 3.5 years of their index surgery which led to re-operation (Fig 16). Data in the BRIMP show that removal of the capsule (defined as removal of the capsule, excluding the thoracic capsule section) is seldom performed in reconstruction patients, despite that these patients often undergo radiation therapy. Patients having surgery for benign breast conditions undergo capsule removal to a greater extent.

*A prospective follow-up of these patients with relevant variables concerning capsule formation will hopefully give interesting information/ data for calculating the potential risk for capsule formation.*

### Patients with hard breast operated with capsule exstirpation shown per the operation indication

| Operation indication              | Capsule extirpation            |    |     | Total |
|-----------------------------------|--------------------------------|----|-----|-------|
|                                   | No information/ data available | No | Yes |       |
| <b>Benign breast conditions</b>   | 12                             | 20 | 35  | 67    |
| <b>No information/ data avail</b> | 2                              | 7  | 13  | 22    |
| <b>Reconstruction</b>             | 6                              | 30 | 4   | 40    |
| <b>Total</b>                      | 20                             | 57 | 52  | 129   |

**Figure 16** Patients with hard breast operated with capsule exstirpation shown per the operation indication

Antibiotic treatment in combination with implant-based operation is also of interest to be examined. In the actual study cohort of 807 revised breasts, a total of 195 have received antibiotic treatment during the index operation. Pre-operative antibiotics are defined as antibiotic treatment which is given the day before the day of operation. The majority of the patients in the register, who received pre-operative antibiotics, appear to be those patients requiring surgery for benign conditions (161 breasts) (Fig 17)

### Has the patient received antibiotics pre-operatively for the primary and re-operation groups distributed over operative indication

| Operation indication                  | Antibiotics pre-operatively    |     |     | Total |
|---------------------------------------|--------------------------------|-----|-----|-------|
|                                       | No information/ data available | No  | Yes |       |
| <b>No information/ data available</b> | 7                              | 59  | 56  | 122   |
| <b>Benign breast conditions</b>       | 62                             | 264 | 161 | 487   |
| <b>Reconstruction</b>                 | 12                             | 152 | 34  | 198   |
| <b>Total</b>                          | 81                             | 475 | 251 | 807   |

**Figure 17** Pre-operative antibiotic

It is worth noting, that 178 patients did not receive per-operative antibiotics for their index operation (data is missing for 12 patients). The percentage of reconstruction cases and those with benign conditions are shown in figure 18. By per-operative antibiotics is meant the giving of antibiotics 20-30 minutes before surgical incision, in accordance with the current WHO recommendation

In the BRIMPs special cohort, 59% of breast patients had received per-operative antibiotics at the index operation.

**Has the patient received antibiotics per-operatively for the primary and re-operation groups distributed over operative indication**

|                                       | Antibiotics per-operatively       |     |     | Total |
|---------------------------------------|-----------------------------------|-----|-----|-------|
|                                       | No information/<br>data available | No  | Yes |       |
| <b>Operation indication</b>           |                                   |     |     |       |
| <b>No information/ data available</b> | 47                                | 12  | 63  | 122   |
| <b>Benign breast conditions</b>       | 23                                | 143 | 321 | 487   |
| <b>Reconstruction</b>                 | 12                                | 23  | 163 | 198   |
| <b>Total</b>                          | 82                                | 178 | 547 | 807   |

Figure 18 per-operative antibiotics

There is no consensus, in Sweden and internationally, as to how the implant cavity should be treated prior to insertion of the implant. This is true for both primary implant surgery as well as revision surgery. Data from international publications advocate the irrigation of the implant cavity with an antiseptic solution, antibiotics or with a saline solution. Currently no standard or strict recommendations exist. Patients treated within the public healthcare system receive no systematic irrigation of the prosthesis cavity with antiseptic solution or with antibiotics as evidence-based support in the literature is considered weak.

In the BRIMP's special cohort, a total of 134 breasts (17 reconstructions and 117 benign enlargement) have received intra-operative irrigation with antibiotics during the index operation.

Thus, 16.6% patients undergoing primary breast operations have been treated with intra-operative antibiotic irrigation. This data is interesting to prospectively compare a control group who have not received antibiotic irrigation to study how this influences the incidence of capsule formation

**Has the patient received antibiotics intra-operatively (irrigation of implant or cavity) for the primary and re-operation groups distributed over operative indication**

|                                       | Antibiotics intra-operatively     |     |     | Total |
|---------------------------------------|-----------------------------------|-----|-----|-------|
|                                       | No information/<br>data available | No  | Yes |       |
| <b>Operation indication</b>           |                                   |     |     |       |
| <b>No information/ data available</b> | 55                                | 56  | 11  | 122   |
| <b>Benign breast conditions</b>       | 68                                | 302 | 117 | 487   |
| <b>Reconstruction</b>                 | 13                                | 168 | 17  | 198   |
| <b>Total</b>                          | 136                               | 526 | 145 | 807   |

Figure 19 per-operative antibiotics

Post-operative antibiotic treatment means that patients receive antibiotics the day after operation.

In this cohort 807 of revised breasts, 32.2% received post-operative treatment at the primary insertion of the implant (Fig 20). Whether these patients received pre- or per-operative antibiotic prophylaxis will be investigated.

### Has the patient received antibiotics post-operatively for the primary and re-operation groups distributed over operative indication

| Operation indication           | Antibiotics post-operatively      |            |            | Total      |
|--------------------------------|-----------------------------------|------------|------------|------------|
|                                | No information/<br>data available | No         | Yes        |            |
| No information/ data available | 11                                | 92         | 19         | 122        |
| Benign breast conditions       | 67                                | 256        | 164        | 487        |
| Reconstruction                 | 10                                | 92         | 96         | 198        |
| <b>Total</b>                   | <b>88</b>                         | <b>440</b> | <b>279</b> | <b>807</b> |

Figure 20 Post-operative antibiotics

## C. Patient-reported desire for removal of implant as the motivation for re-operation

In this special cohort, we identified a total of 89 breasts (11%) of patients who desired removal of an implant without insertion of a replacement implant. The reasons for this decision for removal of the implant is multifactorial (Fig 21, 22).

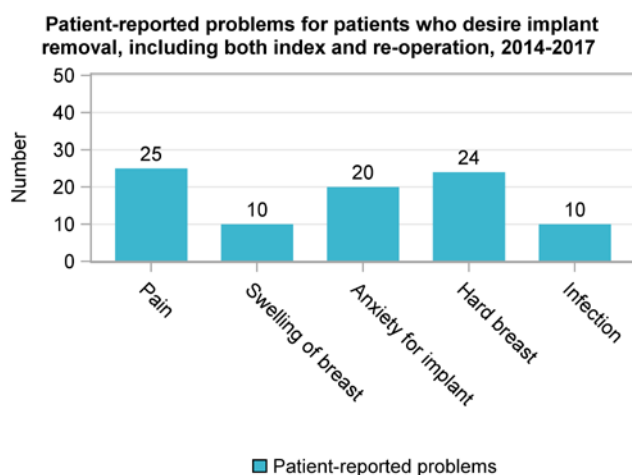


Figure 21 Patient-reported problems for the group who desire implant removal

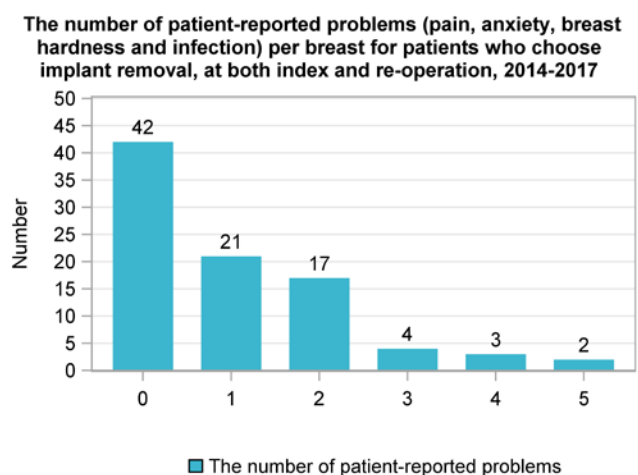


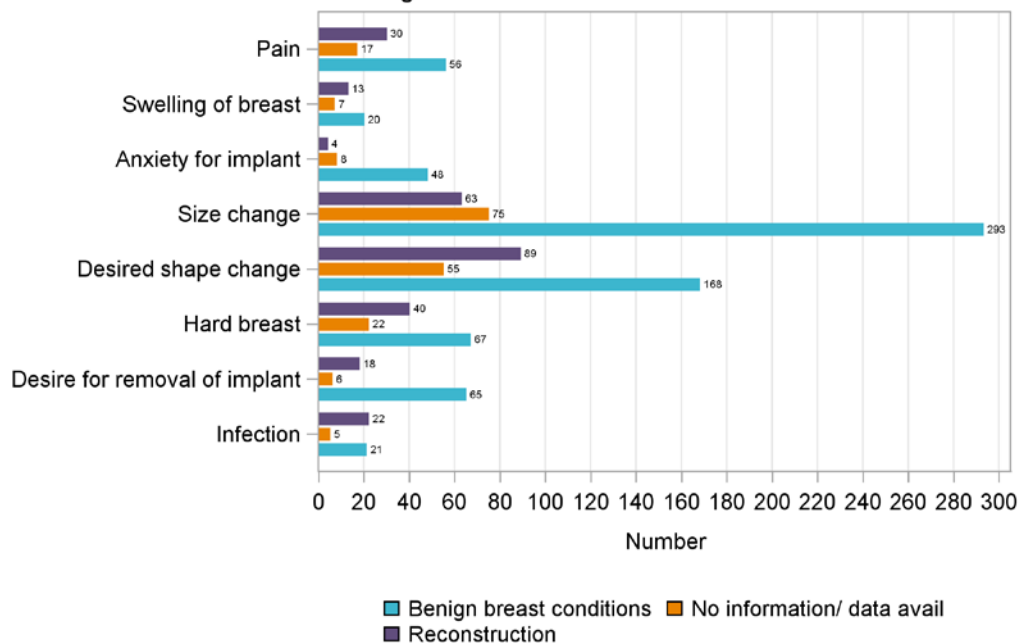
Figure 22 The number of patient-reported problems/discomfort for the group who choose implant removal



A comparison between patients undergoing surgery for benign breast conditions and those requiring breast reconstruction showed that the number of infections is similar in both groups. However, the number of reconstructions is fewer, which means that rate of infection is higher in the reconstruction group. (11% for reconstructions and 4% for benign conditions). The other parameters presented show mainly data for the benign breast condition group (Fig 23). Hardness of the breast was present in 14% of those having revision surgery for benign breast conditions compared to 20% for revised reconstructions. Unfortunately, there is some missing data for these parameters, but as the coverage and quality of the data in the register increases, it is expected that these figures will decrease.

Change in volume as a reason for re-operation is about 60% for patients having surgery for benign conditions compared to 32% for reconstructions. In 34.5% of re-operations in patients with benign conditions, the patients were dissatisfied with the breast shape compared to 45% for those having reconstructions.

**Patient-reported problems per breast showing both index and re-operations for reconstructions and benign conditions 2014-2017**

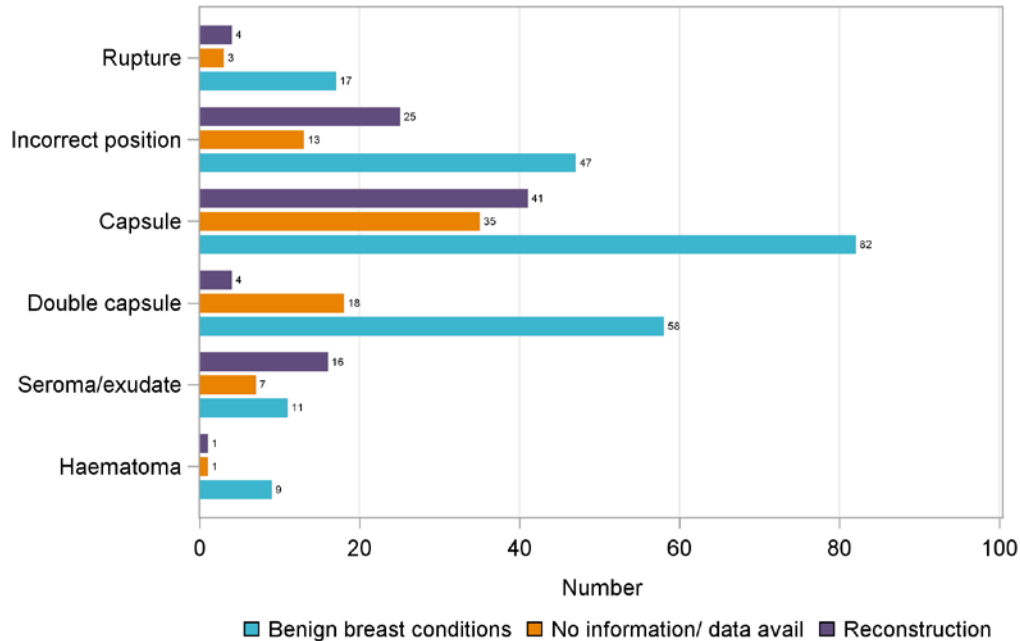


**Figure 23** Patient-reported problems per breast showing both index and re-operations for reconstructions and benign conditions

### Implant-related problems as reason for re-operation 3.5 years after primary surgery

Implant rupture within 3.5 years was seldom found (7 of 807 implants). Incorrect positioning of the implant was found in 12% of reconstructed breasts compared to 10% in benign conditions. Capsule formation was treated in 17% of benign conditions and 21% of reconstructions. Certain implants are used more frequently for benign conditions, which explains why double-capsule formation is more common in this group. This is dependent on type of implant. Seroma formation as an implant-related intra-operative finding occurred in 2% of breast with benign conditions and 8% of reconstructions

**Implant-related problems affecting both those with benign conditions and reconstructions for patients at index surgery and re-operation, 2014-2017**



**Figure 24** Implant-related problems affecting both those with benign conditions and reconstructions for patients at index surgery and re-operation

### Measures for pain, breast hardness and infection

In Figure 25 below, symptoms are correlated to measure taken in the special cohort which required reconstruction within 3.5 years. Re-insertion of the existing implant occurred even capsule formation and swelling, which is debatable in view of the current data in the literature. The use of net in revision surgery is not a common practice according to the data registered in the BRIMP. Similarly, fat-tissue transplant is also not common as a measure to treat the symptoms described below.

| Measure                              | Pain (n=103) | Swelling (n=40) | Hard breast (n=129) | Infection (n=48) |
|--------------------------------------|--------------|-----------------|---------------------|------------------|
| Drain                                | 23% (24)     | 40% (16)        | 24% (31)            | 33% (16)         |
| Fat-tissue transplant                | 4% (4)       | 0               | 2% (2)              | 0                |
| Implant Change                       | 62% (64)     | 48% (19)        | 76% (98)            | 48% (23)         |
| Capsule extirpation                  | 34% (35)     | 33% (13)        | 40% (52)            | 13% (6)          |
| Capsule /dissection                  | 33% (34)     | 20% (8)         | 54% (70)            | 13% (6)          |
| Net/ADM in                           | 3% (3)       | 0               | 1% (1)              | 0                |
| Permanent removal of implant         | 28% (29)     | 38% (15)        | 17% (22)            | 44% (21)         |
| Re-insertion of the existing implant | 8% (8)       | 15% (6)         | 5% (6)              | 2% (1)           |

NOTE: For each operation indication, there may be several measures

**Figure 25** Correlated symptoms to measure taken

## Summary

The BRIMP has followed 9,906 primary surgery patients as of the end of December 2017 with 19,150 breast implants. The level of coverage for BRIMP is 65%, though this must be improved, which is expected when the breast surgery units join the BRIMP register. The Breast Cancer register is going through a re-organization phase, which is why, at present, it is difficult to merge. The BRIMP and INCA have had repeated discussions concerning a co-operation to facilitate care. It is our hope that relevant data from INCA can be imported into the BRIMP, which will help to improve both the level of coverage and the quality of data.

In Sweden, implants from well-established and reputable manufacturers are used. Even new manufacturers have established themselves via the patient forum and through other advertising. The BRIMP is an economically and ethically independent partner which evaluates how implants behave in women's bodies over time. The BRIMP helps to provide patients and the profession with an independent post-market surveillance of products recently introduced to Sweden and follows the quality of well-established products over time. Implant-related problems, intra-operative findings and corrective surgical measures have been continually documented and analysed in the BRIMP. The implant-related observations have been constant over time. We have not been able to see that implants rupture unexpectedly early after primary breast surgery or caused unusual problems in the women's breast. There is, however, the fact remaining that a third of patients choose to have re-operation due dissatisfaction with the shape or volume of the breast. Other implant-related problems increase over time from the primary operation.

Breasts that have been reconstructed due to cancer or because of a hereditary predisposition for malignancy exhibit a higher incidence of complications within 3.5 years after the index surgery than augmented breasts with benign conditions. Volume change was more common in benign conditions but even 45% of the reconstructed breasts led to a re-operation due to dissatisfaction with the shape within 3.5 years of the primary surgery. The patient-reported symptoms, which led to re-operation were multifactorial. Expander prostheses which are designed to be used as a one-step reconstruction did not reach the goal in more than 25% of cases. These expander prostheses are later replaced by implants which entails increased costs for both patients and the society at large. Capsule formation is treated in 21% of reconstructed breasts. Considering the fact, that 40% of reconstructed breasts did not receive per-operative antibiotic prophylaxis, it is debatable as to whether this incidence could not be decreased. Patient expectations were not reached in a large group of patients irrespective of BMI. A long-term prospective evaluation of reasons for re-operations will be able to identify risk factors which limit patient benefit.

Birgit Stark

Registrar BRIMP

Stockholm

18th May 2018

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## 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      No      Yes  
 (Irrigation implant/ cavity)  
 Post-operative      No      Yes \_\_\_ Days

## LEFT SIDE

**Indication for surgery:**

Patient Perceived hypoplasia      Asymmetry  
 Primary Micromasty      Asymmetry  
 Secondary Micromasty      Asymmetry  
 Tuberos 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  
 Tuberos 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****Patient reported symptoms**

|                               | LEFT |     | RIGHT |     |
|-------------------------------|------|-----|-------|-----|
| 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) _____ |                     |              |
| <b>Surface</b> | Smooth                    | Textured            | Polyurethane |
| <b>Shape</b>   | Round                     | Anatomical          | Half moon    |
| <b>Pocket</b>  | 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) _____ |                  |                     |              |
| <b>Type of surface</b>    | Smooth           | Textured            | Polyurethane |
| <b>Shape</b>              | Round            | Anatomical          | Half moon    |
| <b>Pocket</b>             | 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) _____ |                     |              |
| <b>Surface</b> | Smooth                    | Textured            | Polyurethane |
| <b>Shape</b>   | Round                     | Anatomical          | Half moon    |
| <b>Pocket</b>  | 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) _____ |                  |                     |              |
| <b>Type of surface</b>    | Smooth           | Textured            | Polyurethane |
| <b>Shape</b>              | Round            | Anatomical          | Half moon    |
| <b>Pocket</b>             | 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<br>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 |