



# BREAST-Q® | BREAST CANCER

## A User's Guide for Researchers and Clinicians

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## **1. What is the BREAST-Q?**

The BREAST-Q is a rigorously developed patient-reported outcome measure (PROM) designed to evaluate outcomes among women undergoing different types of breast surgery from the patient perspective. BREAST-Q Version 1.0 was published in 2009 and Version 2.0 was published in 2017. Version 2.0 was tested in a much larger sample and the scores derived for the two versions are comparable. Appendix 1 shows the minor modifications made for Version 2.0.

## **2. How was the BREAST-Q Developed and Validated?**

The BREAST-Q represents a new generation of PROMs developed using a modern psychometric approach called Rasch Measurement Theory (RMT). In RMT, scales that compose a PROM are designed to measure and score a unidimensional construct. In scale development, data that meet the requirement of the Rasch model provide interval-level measurement. When a scale has high content validity and is targeted to measure a concept as experienced by a sample, accurate tracking of clinical change can be achieved. In addition to their use in research studies, BREAST-Q scales can be used with individual patients to inform clinical care.

We followed internationally recommended guidelines for PROM development to ensure that the BREAST-Q meets requirements for regulatory bodies. The BREAST-Q was developed using an iterative multiphase mixed methods approach. In Phase 1, a systematic literature review was conducted to identify PROMs developed and validated for use in cosmetic and reconstructive breast surgery patients [1]. This study concluded that a valid, reliable, and responsive instrument PROM for breast surgery was lacking.

To develop the BREAST-Q, in 2004, in-depth qualitative interviews were conducted with 48 women who were seeking or had undergone breast surgery [2]. Data were analyzed and used to develop a conceptual framework and preliminary BREAST-Q scales. These scales were shown to clinician experts who were invited to suggest any missing items. The conceptual framework and BREAST-Q scales were refined and shown to 58 women who took part in two separate focus groups. These sessions were used to examine relevance and comprehensiveness of the conceptual framework and draft scales. Further feedback was obtained from clinical experts. Final refinements were made to the BREAST-Q based on cognitive debriefing interviews with 30 women who provided feedback on the relevance, comprehensiveness and comprehensibility of BREAST-Q items. The content validity of the BREAST-Q was thus well supported by extensive evidence from qualitative studies.

In phase 2, the BREAST-Q was field-tested in a sample of 1950 participants, 491 of whom also completed a test-retest survey [3]. The sample included participants who were seeking or had breast augmentation (pre=222, post=179), reduction (pre=148, post=316),

and reconstruction (pre=295, post=790). Items that did not function well were removed from BREAST-Q scales. RMT analysis of the item-reduced scales supported the summing of the items to form a total score for each scale in each module. Classical test theory and RMT analyses provided evidence to support the validity and reliability of BREAST-Q scales.

In phase 3, the psychometric performance of the BREAST-Q was reexamined in a separate independent sample of 817 women who were seeking or had breast augmentation (n=158), reduction (n=301), or reconstruction (n=358) [4]. BREAST-Q scales exceeded criteria for validity and reliability. Overall, the findings provided support for the use of the BREAST-Q as a tool to study the impact and effectiveness of breast surgery from the patients' perspective.

### **3. How has the BREAST-Q Evolved Over Time?**

The modular structure of the BREAST-Q means it is possible to add new scales and modules to address gaps that are identified. Patient expectations play a crucial role in cancer reconstruction where the primary motivation for surgery is improved health-related quality of life. Given the importance of expectations in breast reconstruction, we interviewed 44 women who had or were waiting to have breast reconstruction after mastectomy. We developed an Expectations Module covering key concerns [5]. The scales were tested in a large sample of women.

We also developed two scales to evaluate outcomes for breast reconstruction in women who have latissimus dorsi reconstruction after a mastectomy. These scales, which measure aesthetic and functional morbidity at the donor site, were field-tested in a sample of 1096 women in the United Kingdom as part of the National Mastectomy and Breast Reconstruction Audit that took place between Jan 2008-March 2009 [6].

An important gap in the BREAST-Q was the lack of a module for breast-conserving therapy (BCT). We conducted qualitative interviews with 24 women who had BCT and developed new items and scales for the BCT module. The BCT module was refined from feedback from 15 women and 5 clinical experts and was field-tested in the Love Army with 3497 women. The validity and reliability of this module was further supported in an independent clinical sample of 3125 women [7].

Reconstructive techniques for restoring sensation to the breast after mastectomy continue to evolve. To provide a means to measure restoration of breast sensation, our team created 3 new sensation scales for the BREAST-Q Reconstruction module. The qualitative phase involved interviews with 36 women, and the field-test sample included 1204 women from the Love Army [8].

Animation deformity is a consequence of subpectoral implant placement that results when the shape of the breast changes or distorts at contraction of the pectoralis muscle and movement of the implant. To provide a better understanding of the impact of

animation deformity on women, we developed the BREAST-Q Animation Deformity scale from patient interviews. This scale was field-tested in a Love Army sample of 651 women who had implant-based reconstruction [9].

Another potential limitation of the BREAST-Q was the lack of scales measuring the frequently reported symptoms of fatigue and cancer worry, as well as the impact of surgery and cancer treatments on work. We developed three scales to measure these concepts and field-tested the scales in a Love Army sample of 1680 women [10]. As part of this study, we also developed 6 new scales that form the LYMPH-Q | Upper Extremity Module [11]. This module is for women with breast-cancer related arm lymphedema. The field-test study for LYMPH-Q involved 3222 women recruited from the United States and Denmark. More information about the LYMPH-Q is available on our website in the LYMPH-Q User's Guide.

Another new BREAST-Q scale developed measures Return to Activity after breast cancer surgery. This scale was field tested in both of the Army of Women studies used to test new BREAST-Q scales as described above [8, 10]. A sample of 203 participants provided 281 assessments. The sample were no more than 6 months from their most recent breast cancer surgery (e.g., lumpectomy, mastectomy, reconstruction, revision surgery). These data were used in the Rasch analysis. One item was dropped from the scale. All 11 items had ordered thresholds, and good fit to the Rasch model with nonsignificant p-values after Bonferroni adjustment. Ten items had item fit residual less than +2.5 and person-item residual correlations for all items were <0.30. The scale mapped out a good clinical hierarchy; 158 assessments scored on the range of measurement provided by the scale. Data for the 11 items had marginal misfit to the Rasch model (Chi-square = 36.44, df=22, p=0.03). Reliability was high with the person separation index values of 0.73 and 0.84 with and without extremes, and Cronbach alpha values of 0.95 and 0.93 with and without extremes.

Our team has collaborated with researchers in Australia to develop and test the BREAST-Q Implant Surveillance module (BREAST-Q IS). This module, which includes a small number of questions, can be used in implant recipients in a registry setting to monitor the performance of breast devices in augmentation and breast reconstruction [12-13].

The various scales and modules described here expand the BREAST-Q measurement system and provide a means to evaluate additional important outcomes. Figure 1 shows the BREAST-Q | Cancer conceptual framework.

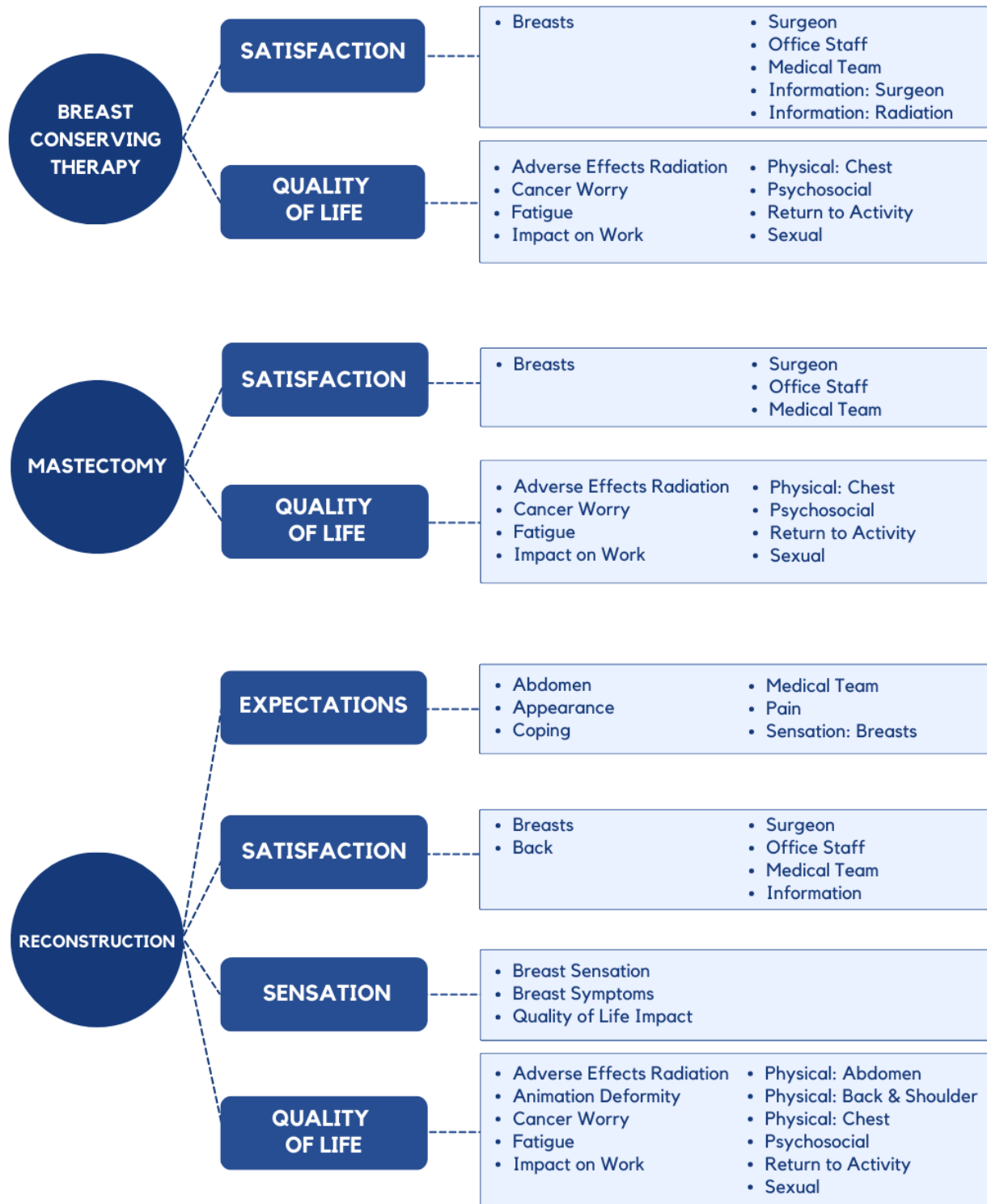
#### **4. Are There Other BREAST-Q Cancer Scales Being Developed?**

We conducted an international mixed methods study to develop a new preference-based measure for women with breast cancer, i.e., BREAST-Q Utility Module [14-15]. We

developed a health state classification system and field-tested it in the Love Army sample. This module is forthcoming.

The safety of breast implants has been questioned over the years with substantial media attention focused on the topic of “breast implant illness” (BII). This condition is poorly understood but has a substantial impact on patient quality of life and wellbeing. Our team is currently developing a BII module of the BREAST-Q.

Figure 1: BREAST-Q | Breast Cancer conceptual framework



## 5. How Many BREAST-Q Modules Are There?

The BREAST-Q has separate modules for different types of breast surgery including Augmentation, Reduction/Mastopexy, and Breast Cancer. This User's Guide describes the BREAST-Q Breast Cancer modules. Separate User's Guides are available for BREAST-Q modules for augmentation and reduction/mastopexy.

## 6. Is There Normative Data for the BREAST-Q | Breast Cancer?

Normative data for the BREAST-Q Breast Cancer modules were collected from 1201 women aged 18 years and older without a prior history of breast cancer. The sample were recruited using the Love Army sample, an online community of women with and without breast cancer [16]. Participants completed the four pre-operative versions of BREAST-Q scales, which are the same in the Mastectomy, BCT and Reconstruction Pre-Operative BREAST-Q modules. Mean scores for these 4 BREAST-Q scales ( $\pm$ standard deviation) were as follows: Satisfaction with Breasts (58  $\pm$ 18), Psychosocial Well-being (71  $\pm$ 18), Sexual Well-being (56  $\pm$ 18), Physical Well-being Chest (93  $\pm$ 11). In addition, the mean score for the Physical Well-being Abdomen scale in the Reconstruction Module was (78  $\pm$ 20). Women with BMI  $\geq$ 30, cup size  $\geq$ D, age <40, and income <\$40,000/year reported lower scores. These data may be used for normative comparison values for those seeking and undergoing surgery. For more information, see our publication [16].

## 7. BREAST-Q | Breast Cancer Scales

The tables below show the core scales as well as the scales included in each BREAST-Q Breast Cancer module, and provide information on the number of items, response options, recall period, scoring, and the Flesch-Kincaid (FK) grade reading level.

Table 1 shows the Breast Cancer Core scales. What is unique about this set of scales is that their content is exactly the same for all breast cancer patients. More specifically, the scales in Table 1 can be used with any breast cancer patient regardless of the type of surgery and/or cancer treatment they have. As such, these scales, which can be used before and after treatment, are included in the Mastectomy, Breast Conserving Therapy (BCT), and Reconstruction modules.

## 8. BREAST-Q Scales Qualified as Medical Device Development Tools

In August 2020, the US Food and Drug Administration qualified the BREAST-Q Reconstruction Module as a medical device development tool (MDDT) to aid in the assessment of certain medical devices (eg, breast implants). More specifically, 4 scales from the BREAST-Q Reconstruction Module were qualified: Satisfaction with Breasts, Physical Well-being (Chest), Psychosocial Well-being, Sexual Well-being. For more information, see: <https://www.fda.gov/media/141349/download>



**Table 1: BREAST-Q | Breast Cancer Core Scales**

Scales	Items	Response Options	Recall	Scoring	FK
Psychosocial Well-Being	10	none → all of the time	past week	0 to 100	7.0
Sexual Well-Being	6	none → all of the time	past week	0 to 100	10.0
Cancer Worry	10	disagree / agree	n/a	0 to 100	4.6
Fatigue	10	very much/not at all	past week	0 to 100	4.7
Impact on Work	8	disagree / agree	last working	0 to 100	5.3
Return to Activity	11	not at all / extremely difficult	past week	0 to 100	2.5

**Table 2: BREAST-Q | Mastectomy Scales**

Scales	Items (Pre/Post)	Response Options	Recall	Scoring	FK (Pre/Post)
Psychosocial Well-Being*	10	none → all of the time	past week	0 to 100	7.0
Sexual Well-Being*	6	none → all of the time	past week	0 to 100	10.0
Cancer Worry*	10	disagree / agree	n/a	0 to 100	4.6
Fatigue*	10	very much/not at all	past week	0 to 100	4.7
Impact on Work*	8	disagree / agree	last working	0 to 100	5.3
Physical Well-Being: Chest	10/11	none → all of the time	past week	0 to 100	4.5/4.6
Satisfaction with Breasts	4	dissatisfied → satisfied	past week	0 to 100	2.7
Adverse Effects Radiation	6	not at all / a lot	past week	checklist	7.9
Return to Activity*	11	not at all / extremely difficult	past week	0 to 100	2.5
Surgeon	12	disagree / agree	n/a	0 to 100	5.5
Medical Team	7	disagree / agree	n/a	0 to 100	5.1
Office Staff	7	disagree / agree	n/a	0 to 100	5.1

\*Core scales

**Table 3: BREAST-Q | Breast Conserving Therapy Scales**

Scales	Items (Pre/Post)	Response Options	Recall	Scoring	FK (Pre/Post)
Psychosocial Well-Being *	10	none → all of the time	past week	0 to 100	7.0
Sexual Well-Being *	6	none → all of the time	past week	0 to 100	10.0
Cancer Worry*	10	disagree / agree	n/a	0 to 100	4.6
Fatigue*	10	very much/not at all	past week	0 to 100	4.7
Impact on Work*	8	disagree / agree	last working	0 to 100	5.3
Physical Well-Being: Chest	10/9	none → all of the time	past week	0 to 100	4.5/5.7
Satisfaction with Breasts	4/11	dissatisfied → satisfied	past week	0 to 100	2.7/5.0
Adverse Effects Radiation	6	not at all / a lot	past week	checklist	7.9
Return to Activity*	11	not at all / extremely difficult	past week	0 to 100	2.5
Info: Breast Surgeon	12	dissatisfied → satisfied	n/a	0 to 100	8.4
Info: Radiation Oncologist	11	dissatisfied → satisfied	n/a	0 to 100	6.9
Surgeon	12	disagree / agree	n/a	0 to 100	5.4
Medical Team	7	disagree / agree	n/a	0 to 100	5.1
Office Staff	7	disagree / agree	n/a	0 to 100	5.1

\*Core scales

**Table 4: BREAST-Q | Reconstruction Scales**

RECONSTRUCTION MODULE	Items (Pre/Post)	Response Options	Recall	Scoring	FK (Pre/Post)
Psychosocial Well-Being *	10	none → all of the time	past week	0 to 100	7.0
Sexual Well-Being *	6	none → all of the time	past week	0 to 100	10.0
Cancer Worry*	10	disagree / agree	n/a	0 to 100	4.6
Fatigue*	10	very much/not at all	past week	0 to 100	4.7
Impact on Work*	8	disagree / agree	last working	0 to 100	5.3
Physical Well-Being: Chest	10/11	none → all of the time	past week	0 to 100	4.5/4.6
Satisfaction with Breasts	4/15	dissatisfied → satisfied	past week	0 to 100	2.7/4.6
Satisfaction with Abdomen	1/3	dissatisfied → satisfied	past week	single item	4.4/8.6
Physical Well-Being: Abdomen	4/7	none → all of the time	past week	0 to 100	13.2/11.0
Implants	2	dissatisfied → satisfied	past week	single item	4.8
Animation Deformity	12	extreme → not bothered	past week	0 to 100	5.2
Nipple Reconstruction	1	dissatisfied → satisfied	past week	single item	10.3
Back Appearance†	8	none → all of the time	past week	0 to 100	1.2
Physical Well-Being: Back & Shoulder†	11	none → all of the time	past week	0 to 100	7.2
Sensation‡	9	no → complete feeling	past week	0 to 100	4.3
Breast Symptoms‡	15	a lot → not at all	past week	0 to 100	4.3
Sensation: Quality of Life Impact‡	8	very much/not at all	past week	0 to 100	7.4
Adverse Effects Radiation	6	not at all → a lot	past week	checklist	7.9
Return to Activity*	11	not at all / extremely difficult	past week	0 to 100	2.5
Information	15	dissatisfied → satisfied	n/a	0 to 100	7.7
Surgeon	12	disagree / agree	n/a	0 to 100	5.6
Medical Team	7	disagree / agree	n/a	0 to 100	5.1
Office Staff	7	disagree / agree	n/a	0 to 100	5.1

\*Core scales; †Latissimus Dorsi module; ‡Sensation module

**Table 5: BREAST-Q | Reconstruction Expectations Scales**

EXPECTATIONS MODULE	Items	Response Options	Scenario	Scoring	FK
Support from Medical Staff	5	unlikely → very likely	during process	0 to 100	5.4
Pain: Postop	6	unlikely → very likely	first week post	0 to 100	1.4
Coping	5	unlikely → very likely	first year	0 to 100	4.0
Appearance: Clothed	5	unlikely → very likely	1 year post	0 to 100	3.0
Sensation: Breasts	5	unlikely → very likely	1 year post	0 to 100	3.8
Function: Abdomen	4	unlikely → very likely	1 year post	checklist	7.8

Note: The Expectations Module includes 21 stand-alone items on topics that are described in section 8

## 9. BREAST-Q | Breast Cancer Scales Descriptions of Content

### QUALITY OF LIFE

**Adverse Effects of Radiation:** This 6-item checklist measures physical changes such as sore or dry skin due to radiation.

**Animation Deformity:** This 12-item scale measures how much someone is bothered by the appearance of their breast after breast reconstruction using an implant. Items ask about how the upper breast area looks when the arm is in different positions (e.g., relaxed, raised, during activities), when lifting something heavy or flexing the chest muscles, as well as the impact of upper breast area appearance on choice of clothes.

**Cancer Worry:** This 10-item scale measures worry someone may be experiencing about their breast cancer. The scale asks how much a woman agrees or disagrees with statements such as worry about cancer spreading to other parts of the body, getting another type of cancer, late effects that might happen to them, and cancer treatment damaging their body.

**Fatigue:** This 10-item scale measures how much fatigue (feeling tired) from breast cancer or its treatment affects quality of life. Items ask about how much fatigue has interfered with walking or moving around, doing chores, staying awake during the day, standing for a long time, and mood.

**Impact on Work:** This 8-item scale measures the effect of breast cancer or its treatment on work life. The scale asks how much a woman agrees or disagrees with statements such as needing help with her job, trouble performing their job, reducing the number of hours worked, and needing more breaks than before cancer.

**Return to Activity:** This 11-item scale measures return to activity after breast surgery. The scale asks women to indicate how difficult (not at all to extremely) it is for them to do a range of activities on their own. Items include getting up from a chair, walking or moving around, walking up or down stairs, putting on or taking off clothes, and moderate exercise.

### Physical Well-Being:

a. **Chest:** This 11-item scale measures physical problems such as chest muscle pain and problems in the breast area (e.g., tightness, pulling, tenderness). Other items ask about activity limitations and sleep problems due to discomfort.

b. **Abdomen:** This 7-item scale measures negative physical sequelae of the abdomen following autologous tissue reconstruction (TRAM or DIEP flap). Items cover abdominal discomfort, bloating, bulging and pain, as well as difficulty doing certain activities due to abdominal weakness.

c. **Back and Shoulder (Latissimus Dorsi module):** This 11-item scale measures negative

physical sequelae such as pain and scarring following latissimus dorsi flap reconstruction (LD flap). Items cover arm and shoulder limitations that lead to difficulty performing certain activities due to arm stiffness and weakness.

**Psychosocial Well-Being:** This 10-item scale measures psychosocial well-being with items that ask about body image (e.g., accepting of body, feeling attractive) and a woman's confidence in social settings. Other items cover emotional health and self-confidence.

### **Sensation**

- a. **Breast Symptoms:** This 15-item scale measures the experience of breast symptoms. Items ask a range of symptoms such as pain, tingling, swelling, heaviness, pulling, pressure, and tightness.
- b. **Sensation:** This 9-item scale measures how much (none to complete feeling) breast sensation someone can feel. Items ask about feeling in the breast area when it is massaged deeply, pressed firmly, touched through clothing, and touched sexually.
- c. **Sensation: Quality of Life Impact:** This 8-item scale measures how much (not at all to very much) the loss of sensation in the breast area affects quality of life. Items ask about the impact of sensation on the ability to enjoy life, self-confidence, body image, and sexual life.

**Sexual Well-Being:** This 6-item scale measures sexual well-being with items that ask about feelings of sexual attractiveness (clothed and unclothed), sexual confidence as it relates to one's breasts and feeling comfortable or at ease during sexual activity.

### **SATISFACTION**

**Satisfaction with Abdomen:** These items are about patient satisfaction with abdominal appearance following autologous tissue breast reconstruction (TRAM or DIEP flap). Items ask about overall appearance as well as the position of navel (belly button) and scars.

**Satisfaction with Back (Latissimus Dorsi module):** This 8-item scale measures patient satisfaction with back and back scar appearance following latissimus dorsi flap reconstruction (LD flap). Items ask about overall back and scar appearance, as well as location of scar.

**Satisfaction with Breasts:** This scale measures body image in terms of a woman's satisfaction with her breasts and asks questions regarding how comfortably bras fit and how satisfied a woman is with her breast area both clothed and unclothed. Postoperative items ask about breast appearance (e.g., BCT: shape, size, contour; Recon: size, symmetry, softness) and being able to wear fitted clothes.

### **Satisfaction with Care:**

- a. **Information: Breast Surgeon (BCT):** This 12-item scale measures satisfaction with information provided about breast surgery from the surgeon. Items cover types of

breast surgery, complications and risks, healing and recovery time, how the breast(s) would look, implications for future breast cancer screening, how the surgery would be done, and breast appearance (e.g., breast size, scars).

- b. Information: Radiation Oncologist (BCT):** This 11-item scale measures satisfaction with information provided about radiation treatment from the radiation oncologist. Items cover why you need radiation, how the beam will feel, how the radiation might change breast skin over time, and potential problems.
- c. Information (Recon):** This 15-item scale measures satisfaction with information provided about reconstruction surgery from the surgeon. Items cover types of reconstruction, complications and risks, healing and recovery time, how the breast(s) would look, implications for future breast cancer screening, how the surgery would be done, and how the breast(s) would look (e.g., breast size, scars).
- d. Medical Team:** This 7-item scale measures satisfaction with members of the medical team (other than the surgeon). Items ask whether the staff were professional, knowledgeable, friendly and kind, and made time for the patient's concerns.
- e. Office Staff:** This 7-item scale measures satisfaction with interactions with members of the office staff. Items ask whether staff were professional, knowledgeable, friendly and kind, and thorough.
- f. Surgeon:** This 12-item scale measures satisfaction with the surgeon. Items ask about whether the surgeon was professional, reassuring and sensitive, their ability to communicate (e.g., easy to talk to, answered questions), and whether the patient was involved in the decision-making process.

**Satisfaction with Implants:** Two implant-specific items ask about rippling that can be seen or felt.

**Satisfaction with Nipple Reconstruction:** This item asks about satisfaction with the appearance of the reconstructed nipple(s).

## **RECONSTRUCTION EXPECTATIONS**

This module was designed to be administered preoperatively to assess patient expectations for the process and outcome of surgery. Multi-item and categorical scale structures are used. The five scales provide a 0-100 score. In addition to the scales, the long-form version of this module includes 25 stand-alone items measure expectations for a range of concepts important to women.

**Support from Medical Staff:** This 5-item scale measures how much time and emotional support a patient expects to receive from the medical team and surgeon during the breast reconstruction process.

**Pain: Postop:** This 6-item scale measures patient expectations about pain (e.g., sore, uncomfortable, intense) in the first week after reconstruction surgery.

**Coping:** This 5-item scale measures how a patient expects to cope with the process of breast reconstruction during the first year (e.g., will think positively).

**Appearance: Clothed:** This 5-item scale measures how a patient expects her breasts to look one year after breast reconstruction when clothed (e.g., look good in a bra, clothes will hang well).

**Sensation: Breasts:** This 5-item scale measures how a patient expects her breast(s) to feel to the touch one year after breast reconstruction (e.g., firm, hard, rippling).

**Single items:** There are 25 single items that measure a range of concepts. Each item has 3 or 4 response options. The 25 items measure expectations about the following concepts: (1) information needs before surgery, (2) involvement in the decision-making before surgery, (3) how likely a complication would be after surgery, (4), chest appearance after a tissue expander is placed, (5) how much pain a tissue expander would cause, (6), how each tissue expansion would feel, (7) how breast looks unclothed at 1 year, (8), breast symmetry at 1 year, (9) breast scar at 1 year, (10) breast sensation at 1 year, (11) breast size at 1 year, (12) breast shape at 1 year, (13) natural appearance at 1 year, (14) breast movement at 1 year, (15) sides of the chest at 1 year, (16) sensation in sides of chest at 1 year, (17) nipple appearance at 1 year, (18) nipple sensation at 1 year, (19) awareness of implants at 1 year, (20) abdomen – do everyday activities at 1 year, (21) abdomen – sit up at 1 year, (22) abdomen – discomfort at 1 year, (23) abdomen – feel tight at 1 year, (24) breast symmetry at 10 years, and (25) need for revision at 10 years.

## 10. Administration of the BREAST-Q

Each BREAST-Q scale is designed to function independently. The BREAST-Q's modular approach makes it possible to administer only the most relevant scales for your patient population or research study. The BREAST-Q scales are designed for patients to complete on their own (self-report). Each scale takes only a few minutes to complete. Patients are given instructions at the beginning of each scale. The preoperative scales can be completed at any time prior to surgery (baseline assessment) and the postoperative scales at any time point after surgery (follow-up data). The BREAST-Q may also be administered at a single time point, such as in a cross-sectional survey. Each researcher or clinician may decide the time points at which they would like to administer the scales.

The BREAST-Q has been tested using two modes of data collection, i.e., online data collection using Research Electronic Data Capture System (REDCap) and paper-and-pencil [3,17]. You may use the paper-and-pencil format or create an online version for ease of administration in non-profit academic research (e.g., REDCap) and in clinical care (e.g., hospital EMR such as Epic). If you have or plan to have an ePRO company convert BREAST-

Q scales into an electronic format, e-conversion review and certification is required, please email [qportfolioteam@gmail.com](mailto:qportfolioteam@gmail.com).

## **11. Scoring the BREAST-Q Version 1.0**

QScore software is no longer supported. If you need to score BREAST-Q Version 1.0 data, we can provide scoring tables. Please email [qportfolioteam@gmail.com](mailto:qportfolioteam@gmail.com), indicating when you obtained a license to use BREAST-Q.

## **12. Scoring the BREAST-Q Version 2.0**

There is no overall or total BREAST-Q score, only scores for each independently functioning scale. Table 1 shows BREAST-Q scales that can be used before and after surgery to measure change. Some scales include the preoperative items in addition to items that address unique postoperative issues (e.g., scars). The preoperative and postoperative scales are linked psychometrically so that they can be used to measure change. The BREAST-Q modules are composed of scales, checklists, and stand-alone items (identified in Table 1).

To score a scale, the raw scores for the set of items in a scale are added together to produce a total raw score. The choice of how to handle missing data, such as whether or not to impute the mean when there is missing data, is ultimately up to the end user of BREAST-Q. Our suggestion follows the most popular method for scoring when there is missing data, which is to impute a missing value by the mean response to completed items if more than 50% of items are answered. This method is recommended in the scoring manuals of numerous widely used PROMs, such as the SF-36 generic questionnaire used extensively in research for decades [19-20]. As such, BREAST-Q scores can be computed if missing data is less than 50% of the scale's items. In this approach, the within person mean for the completed items can be imputed for the missing items prior to computing a total raw score. For example, if there is a 10-item scale and someone has not responded to all the items, but has responded to  $\geq 5$  items, all other items for that person can be imputed with a within-person mean (rounded to the nearest integer), and a summed score can be calculated. Alternatively, for a 10-item scale, if someone has responded to  $\leq 4$  items, the summed score for this person cannot be computed and is classified as missing data.

Once a total raw score for the scale is computed, the Conversion Table can be used to convert the raw score into a score that ranges from 0 (worst) to 100 (best). The conversion, which linearizes the scores, is based on the findings from the Rasch analysis. Higher scores for all BREAST-Q scales, with the exception of one, reflect a better outcome. The exception is the Cancer Worry scale where a higher score indicates more cancer worry.

The Conversion Tables for changing raw scores into 0 to 100 scores are provided with each scale and are available after a licensing agreement is signed. Please read the instructions carefully in the Conversion Tables to know if you need to re-score the data prior to computing a total score. There are some scales in the distribution versions of the Mastectomy, BCT, and Reconstruction Modules where the raw scores indicate a worse outcome. For these scales, the raw scores need to be rescored prior to using the Conversion Tables to ensure that higher scores for the scale reflect a better outcome. For an example about rescoring, see the Box below.

To score a checklist, the raw scores for the items in a checklist can be used to identify problems experienced by a patient or a sample. Checklists do not have Rasch Conversion Tables because the set of items did not work together statistically (i.e., the item set did not map out a clinical hierarchy for the concept of interest). Even though there are no Conversion Tables based on Rasch analysis for checklists, they can provide clinically important information, such as monitoring for post-operative complications.

To score stand-alone items, the raw score can be used to provide descriptive information about the patient or sample. There is no Conversion Table for the stand-alone items.

### EXAMPLE FOR HOW TO SCORE A BREAST-Q SCALE

For most scales, higher answers to each item reflect a better outcome. For example, Satisfaction with Breasts is scored as follows: “Very Dissatisfied” = 1, “Somewhat Dissatisfied” = 2, “Somewhat Satisfied” = 3, “Very Satisfied” = 4.

There are some exceptions, so it is important to carefully read the scoring instructions that are included when you obtain the BREAST-Q after signing a license. For example, the 8-item Satisfaction with Back scale includes 5 response options that are scored as follows: “None of the time” = 1, “A little of the time” = 2, “Some of the time” = 3, “Most of the time” = 4, “All of the time” = 5. Prior to computing a total raw score for this scale, the 8 items need to be rescored to ensure that higher scores reflect a better outcome. The items should be rescored as follows: “None of the time” = 5; “A little of the time” = 4; “Some of the time” = 3; “Most of the time” = 2; “All of the time” = 1.

## 13. What is a Minimal Importance Difference in BREAST-Q Scores?

The ability of the BREAST-Q to measure clinical change was examined by our team in a study of prospectively collected data from 3052 Mastectomy Reconstruction Outcomes Consortium patients [18]. Distribution based methods were used to investigate the minimal important difference (MID) for the entire patient sample and three clinically relevant groups. We used both 0.2 SD units (effect size) and standardized response mean



values of 0.2 as distribution-based criteria. The MID estimates for each domain were 4 (Satisfaction with Breasts), 4 (Psychosocial Well-being), 3 (Physical Well-being), and 4 (Sexual Well-being). The MID estimates for each domain were similar when compared within the three clinically relevant groups. The authors propose that a MID score of 4 points on the transformed 0 to 100 scale is clinically useful when assessing an individual patient's outcome using the reconstruction module of the BREAST-Q. When designing research studies, investigators should use the MID estimate for their domain of interest when calculating sample size. The authors acknowledge that distribution-based MID are estimates and may vary based on patient population and context.

## 14. Conditions of Use

Memorial Sloan-Kettering Cancer Center, Memorial Hospital for Cancer and Allied Diseases, Sloan-Kettering Institute for Cancer Research, The University of British Columbia, McMaster University, and Brigham and Women's Hospital hold the copyright of the BREAST-Q and all of its translations (past, on-going, and future). To avoid any copyright infringement, please ensure that the copyright notice of the BREAST-Q is included in the questionnaire. If you're unsure of the copyright notice for the BREAST-Q, our website lists the copyright and trademark notice: <https://qportfolio.org/copyright-information/>

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## PLEASE NOTE

When you sign a BREAST-Q license, you agree to the following terms:

- You will not modify, adapt, or create another derivative work from the BREAST-Q
- You will not sell, sublicense, rent, loan, or transfer the BREAST-Q to anyone
- You will not reproduce any BREAST-Q scales in publications or other materials
- You will not translate the BREAST-Q without permission from our team

For questions regarding study design and optimal use of BREAST-Q scales, contact [qportfolioteam@gmail.com](mailto:qportfolioteam@gmail.com) or:

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## 15. Frequently Asked Questions

### *Which BREAST-Q scales are in the ICHOM standard set?*

BREAST-Q scales are included in the ICHOM standard set for breast cancer. To use the BREAST-Q as part of the ICHOM initiative, you must sign a licensing agreement (see above). More information is available on the ICHOM website:

<https://connect.ichom.org/standard-sets/breast-cancer/>

### *What is the difference between BREAST-Q Version 1.0 and 2.0?*

BREAST-Q Version 1.0 was published in 2009 and Version 2.0 was published in 2017. **Appendix 1** shows the minor modifications made. Version 2.0 was tested in a much larger sample and the scores derived for the two versions are comparable.

### *Do I have to use all of the BREAST-Q scales?*

Each scale functions independently, therefore patients can be asked to complete some or all of a module's BREAST-Q scales. It is not necessary for a patient to complete all of the scales within a module as there is no overall or total BREAST-Q score. A researcher or clinician may therefore select a subset of scales depending on the particular purpose of the study or use.

### ***Can I delete or add or change any items or response options of the BREAST-Q?***

You cannot delete or add or change the wording of any items or response options of the BREAST-Q. Any modification to the content of the BREAST-Q is prohibited under copyright laws. Also, making any changes to BREAST-Q scales would invalidate their psychometric properties.

### ***Can I reproduce BREAST-Q scales in a publication or other public document (e.g., PhD thesis)?***

According to the licensing agreement, you cannot reproduce the content of BREAST-Q scales verbatim in a publication. However, it is possible to show shortened versions of items. The short forms of items that can be used in a publication are shown in Table 6 below.

### ***Which module do I use for oncoplastic procedures?***

For oncoplastic surgery procedures, the BREAST-Q Reduction/Mastopexy module and the BCT module are recommended, depending on the exact nature of the procedure (i.e., for oncoplastic breast reduction, use Reduction module; for oncoplastic lumpectomy/glandular remodeling, use BCT module).

### ***Which module do I use for fat grafting procedures?***

For patients undergoing fat grafting procedures, either the BREAST-Q Reconstruction or Augmentation modules may be used depending on the indications for the procedure (i.e., correction of defect following oncologic resection or cosmetic augmentation).

### ***Can I translate BREAST-Q scales into a new language?***

Yes, with permission, you can translate the BREAST-Q into different languages. Before starting a translation, check our translation list on [www.qportfolio.org](http://www.qportfolio.org) to see if there is a translation in the language you need. If there is not a translation in the language you need, you will need to obtain permission from our team, sign a translation licensing agreement, and receive information on the method you need to follow. Email us at [qportfolioteam@gmail.com](mailto:qportfolioteam@gmail.com) for more information. Please note that the developers of the BREAST-Q own the copyright of all translations of BREAST-Q.

### ***Are there specific time points when patients complete the scales?***

A researcher or clinician can decide the time points they would like to administer the scales.

### ***Does it cost money to use the BREAST-Q?***

Use of BREAST-Q is free to non-profit users, including use by hospitals in patient care. For-profit users should contact [qportfolioteam@gmail.com](mailto:qportfolioteam@gmail.com) or Memorial Sloan Kettering Cancer Center for information about fees ([gotdtrm@mskcc.org](mailto:gotdtrm@mskcc.org)).

**Table 6a: Shortened items for BREAST-Q Core Scales to use in a publication**

<b>PSYCHOSOCIAL WELL-BEING</b>	<b>SEXUAL WELL-BEING</b>	<b>CANCER WORRY</b>	<b>FATIGUE</b>	<b>IMPACT ON WORK</b>	<b>RETURN TO ACTIVITY</b>
confident	attractive in clothes	might spread	move around	needed help	up from chair
emotionally able	comfortable	other cancer	do chores	performing	move around
emotionally healthy	confident	back of mind	stay awake	changed	make food
equal worth	satisfied	late effects	social life	reduced hours	stairs
self-confident	confident unclothed	damage body	exercise	needed breaks	bath or shower
feminine	attractive unclothed	might die	stand	keep up	personal grooming
accepting		not working	get out of bed	reduced amount	stand
normal		worry daily	participate in life	symptoms	up from bed
like others		daily activities	mood		clothes
attractive		enjoying life	pay attention		moderate exercise

**Table 6b: Shortened items for the Mastectomy module to use in a publication**

<b>CHEST</b>	<b>BREASTS</b>	<b>RADIATION</b>	<b>SURGEON</b>	<b>MEDICAL TEAM</b>	<b>OFFICE STAFF</b>
<b>PRE-OP</b>	mirror clothed	different	professional	professional	professional
pain	bras fit	marks	gave confidence	respect	respect
lift arms	fitted clothes	dry	involved you	knowledgeable	knowledgeable
sleep	mirror unclothed	sore	reassuring	friendly	friendly
tightness		thick	answered questions	comfortable	comfortable
pulling		irritated	comfortable	thorough	thorough
nagging			thorough	made time	made time
tenderness			easy to talk		
sharp pains			understood		
aching			sensitive		
throbbing			made time		
<b>POST-OP</b>			available		
swelling					

**Table 6c: Shortened items for BCT module to use in a publication**

CHEST	BREASTS	RADIATION	INFO: BREAST SURGEON	INFO: RADIATION ONCOLOGIST	SURGEON	MEDICAL TEAM	OFFICE STAFF
<b>PRE-OP</b>	<b>PRE-OP</b>	different	radiation need	radiation time	professional	professional	professional
pain	mirror clothed	marks	surgery options	position in radiation	gave confidence	respect	respect
lift arms	bras fit	dry	same survival	why radiation	involved you	knowledgeable	knowledgeable
sleep	fitted clothing	sore	healing time	how much	reassuring	friendly	friendly
tightness	mirror unclothed	thick	treatment plan	feel	answered questions	comfortable	comfortable
pulling	<b>POST-OP</b>	irritated	pain expect	care for skin	comfortable	thorough	thorough
nagging	mirror clothed		complications	skin markings	thorough	made time	made time
tenderness	shape		cancer come back	how tired	easy to talk		
sharp pain	feel normal		look after surgery	skin change	understood		
aching	fitted clothing		scars look	change look	sensitive		
throbbing	breast hangs		size expect	potential problems	made time		
<b>POST-OP</b>	smoothly shaped		shape		available		
lift arms	contour						
sleep	equal in size						
tightness	normal look						
pulling	same						
tenderness	mirror unclothed						
sharp pain							
aching							
lay on side							
swelling							

**Table 6d: Shortened items for the scales in the Reconstruction and Expectations Modules to use in a publication**

CHEST	BREASTS	ANIMATION DEFORMITY	BREAST SENSATION	ABDOMEN: APPEARANCE	BACK: APPEARANCE	RADIATION	SURGEON	EXPECTATIONS
<b>PRE-OP</b>	<b>PRE-OP</b>	arm relaxed	massage deeply	<b>PRE-OP</b>	scar location	different	professional	<b>MEDICAL STAFF</b>
pain	mirror clothed	everyday activity	press firmly	unclothed	scar length	marks	gave confidence	attention quickly
lift arms	bras fit	people noticing	lay on stomach	<b>POST-OP</b>	noticeable	dry	involved you	available
sleep	fitted clothing	physical activity	bump breasts	unclothed	not matching	sore	reassuring	hold my hand
tightness	mirror unclothed	raise arm	hug someone	belly button position	back looks	thick	answered questions	only patient
pulling	<b>POST-OP</b>	move arm	touch lightly	scars look	shape	irritated	comfortable	lot of time
nagging	mirror clothed	dress to hide	take a shower	<b>ABDOMEN: WELL-BEING</b>	scar looks	<b>INFORMATION</b>	thorough	<b>PAIN: POSTOP</b>
tenderness	shape	abnormal	through clothing	<b>PRE-OP</b>	clothes hide	surgery done	easy to talk	sore
sharp pains	normal	certain clothes	touch sexually	sit up	<b>BACK: WELL-BEING</b>	healing time	understood	uncomfortable
aching	size	skin dimpling	<b>BREAST SYMPTOMS</b>	activities	stiffness	complications	sensitive	pressure
throbbing	fitted clothing	heavy object	stinging	discomfort	shoulder pain	option types	made time	pain intense
<b>POST-OP</b>	lined up	flex chest	throbbing	bloating	back pain	options timing	available	pain medication
swelling	bras fit		tingling	<b>POST-OP</b>	arms above head	timing pros cons	<b>MEDICAL TEAM</b>	great deal pain
	softness		burning	sit up	activities	how long	professional	<b>COPING</b>
	equal size		swollen	activities	weakness	size expect	respect	better
	natural look		sharp pain	discomfort	use muscles	pain expect	knowledgeable	think positively
	natural hang		spasms	bloating	tightness	look expect	friendly	better place
	feels to touch		tender	bulging	pulling	feel self	comfortable	normal life
	feels natural		pressure	tightness	reaching objects	future screen	thorough	come to terms
	matched		fullness	pulling	carrying objects	sensation	made time	<b>APPEARANCE: CLOTHED</b>
	mirror unclothed		aching			others	<b>OFFICE STAFF</b>	clothes hang
	<b>IMPLANTS</b>		heavy			scars look	professional	shape
	rippling see		pulling				respect	normal in bra
	rippling feel		tightness				knowledgeable	mirror
	<b>NIPPLE RECON</b>		unnatural				friendly	look good
	natural		<b>QOL IMPACT</b>				comfortable	<b>SENSATION: BREASTS</b>
			enjoy life				thorough	firm
			self-confidence				made time	harder than natural
			move on					hard
			physical activity					edges implant
			feel about body					rippling
			choice clothes					<b>FUNCTION: ABDOMEN</b>
			bras feel					difficulty activities
			sexual life					difficulty sitting up
								discomfort
								tight

## 16. Acknowledgements

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## APPENDIX 1: Modifications to BREAST-Q to create Version 2.0

**NOTE:** If a scale is not in the list, it is because it has not been changed.

Modifications to pre-operative BREAST-Q scales		
	Version 1.0	Version 2.0
<b>Changed original stem for all modules</b>	in the past two weeks	in the past week
<b>Mastectomy</b>	<b>Version 1.0</b>	<b>Version 2.0</b>
Sexual Well-Being	n/a option	removed
Physical Well-Being: Chest	neck pain, upper back pain, shoulder pain, arm pain, rib pain, shooting pains	removed
	5 response options	3 response options
<b>Reconstruction</b>	<b>Version 1.0</b>	<b>Version 2.0</b>
Satisfaction w Breast	stem - breasts in mind or if you have had a mastectomy with your breast area in mind	change stem to 'breast area in mind'
Satisfaction w abdomen	a. How your abdomen looks?	a. How your abdomen looks when <u>unclothed</u> ?
Sexual Well-Being	n/a option	removed
	Confident sexually about how your breast(s) look when <u>unclothed</u> ?	Confident sexually about how your breast area looks when <u>unclothed</u> ?
Psychosocial Well-being	stem - breasts in mind or if you have had a mastectomy with your breast area in mind	changed stem to 'breast area in mind'
Physical Well-Being: Chest	neck pain, upper back pain, shoulder pain, arm pain, rib pain, shooting pains	removed
	5 response options	3 response options
Physical Well-Being: Abdomen	lower back pain	removed
<b>BCT</b>	<b>Version 1.0</b>	<b>Version 2.0</b>
Physical Well-Being: Chest	5 response options	3 response options
	neck pain, upper back pain, shoulder pain, arm pain, shooting pains	removed
		added 'Pain in the muscles of your chest?'
		added 'Nagging feeling in your breast area?'
		added 'Throbbing feeling in your breast area?'
Sexual Well-Being	n/a option	removed

<b>Modifications to post-operative BREAST-Q scales</b>		
	<b>Version 1.0</b>	<b>Version 2.0</b>
<b>Changed original stem for all modules</b>	in the past two weeks	in the past week
<b>Mastectomy</b>	<b>Version 1.0</b>	<b>Version 2.0</b>
Sexual Well-Being	n/a option	removed
Physical Well-Being: Chest	5 response options	3 response options
	neck pain, upper back pain, shoulder pain, arm pain, rib pain, shooting pains	added k. Swelling of the arm (lymphedema) on the side(s) that you had your breast surgery? removed
Adverse Effects of Radiation		added
<b>Reconstruction</b>	<b>Version 1.0</b>	<b>Version 2.0</b>
Satisfaction with breasts		Instructions added: If you had a mastectomy and reconstruction of both breasts, answer these questions thinking of the breast you are least satisfied with
	n. How closely matched your breasts are to each other?	n. How closely matched (similar) your breasts are to each other?
	o. How your reconstructed breast(s) look now compared to before you had any breast surgery?	removed
Satisfaction with Abdomen	a. How your abdomen looks?	a. How your abdomen (tummy area) looks when <u>unclothed</u> ?
Satisfaction with Implants		Added instructions: If you had implants in both breasts, answer these questions thinking of the breast you are least satisfied with.
Satisfaction with Outcome		removed
Sexual Well-Being	n/a option	removed
Physical Well-Being: Chest	5 response options	3 response options
	neck pain, upper back pain, shoulder pain, arm pain, rib pain, shooting pains	added k. Swelling of the arm (lymphedema) on the side(s) that you had your breast surgery? removed
Physical Well-Being: Abdomen	a. How your abdomen feels now compared to before your surgery?	removed
	b. How your abdomen looks now compared to before your surgery?	removed
	h. Lower back pain?	removed
Adverse Effects of Radiation		added
Nipple Reconstruction	shape, look, color, height questions	removed

Satisfaction with Surgeon	word 'plastic' in the stem	removed
<b>BCT</b>	<b>Version 1.0</b>	<b>Version 2.0</b>
Satisfaction with breasts		added to instructions: If you have had a lumpectomy and radiation of both breasts, answer these questions thinking of the breast you are least satisfied with.
Sexual Well-Being	n/a option	removed
	g. That you enjoy your lumpectomy breast being touched?	removed
	h. That you feel sexual pleasure when your lumpectomy breast is touched?	removed
Physical Well-Being: Chest	neck pain, upper back pain, shoulder pain, arm pain, shooting pains	removed
	Items with wording 'lumpectomy breast'	changed to 'breast area'
Adverse Effects of Radiation	b. Your radiated areola looking different (e.g., too dark or too light)?	removed
		instructions: added 'If you have had radiation on both breasts, answer these questions thinking of the breast you are least satisfied with'. Also changed word 'lumpectomy' to 'radiated'.
	Response option: 'I don't have this problem' & 'I have this problem and it bothers me....'	removed
		word 'skin' added to question b & f
Satisfaction with Surgeon		added c. Involved you in the decision-making process?