

Appendix 2. Final Survey Instrument

Part 1: Breast Implant History

Q1 Have you received breast implants in the past? Please select all that apply:

- Yes, Cosmetic
- Yes, Reconstructive
- No

-----If “Yes-Reconstructive” or “Yes-Cosmetic” was selected in Q1, display Q2-Q6:-----

Q2 Do you know what type of breast implant you received?

- Yes, Silicone
- Yes, Saline
- Unsure

Q3 Did you receive a breast implant device card when you received your implants?

- Yes
- Unsure
- No

Q4 How easy is it to interpret/understand the information on your breast implant device card?

- Very easy
- Easy
- Moderate
- Difficult
- Very Difficult

Q5 How confident are you that you could easily locate information on the style of your implants (i.e. texturing, shape)?

- Very confident
- Confident
- Somewhat Confident
- Not Confident

Q6 How confident are you that you could easily locate information on manufacturing information about your implants (i.e. serial number)?

- Very confident
- Confident
- Somewhat Confident
- Not Confident

Q7 Do you personally know anyone who has breast implants? Please select all that apply:

- Yes, cosmetic
- Yes, reconstructive
- No

Q8 Do you know of any celebrities or social media personalities who received breast implants?

Please select all that apply:

- Yes, cosmetic
- Yes, reconstructive
- No

Part 2: Willingness to Receive Implants vs. Alternatives

-----If “No” was selected in Q1, display Q9-----

Q9 Would you consider receiving breast implants in the future?

- Yes, reconstructive implants only
- Yes, cosmetic implants only
- Yes, either cosmetic or reconstructive implants
- Unsure
- No

-----If “Yes-Reconstructive” was selected in Q1, display Q10-----

Q10 If you had to make the decision again, would you choose to receive breast implants?

- Yes, reconstructive implants only
- Yes, either cosmetic or reconstructive implants
- Unsure
- No

-----If “Yes-Cosmetic” was selected in Q1, display Q11-----

Q11 If you had to make the decision again, would you choose to receive breast implants?

- Yes, cosmetic implants only
- Yes, either cosmetic or reconstructive implants
- Unsure
- No

Q12 For breast reconstruction, as an alternative to implants, it is possible to use your own fat/tissue (either from the belly, thighs, back, or buttocks) for breast reconstruction. These

surgeries are more extensive and require longer hospital stay/recovery times. However, patient satisfaction with these procedures is the same - if not higher - long-term compared to implant-based reconstruction. If receiving fat from the belly, a “tummy tuck” is part of the procedure. You can also choose to forgo breast reconstruction and use external prostheses in your bra to give the appearance of breasts. Would you undergo alternative methods for breast reconstruction?

- Yes
- Unsure – would consider alternative methods
- No

Q13 For cosmetic breast augmentation, you can transfer fat from another part of your body into your breasts using liposuction, either with or without an external breast tissue expander device. This technique is safe but not always successful, and it cannot drastically increase cup sizes. Would you undergo alternative methods for cosmetic breast augmentation?

- Yes
- Unsure – would consider alternative methods
- No

Part 3: Baseline Opinions/Knowledge

Q14 Are breast implants dangerous, from a medical standpoint?

- Yes
- No
- Unsure

Q15 How safe do you consider breast implants to be, from a medical standpoint?

- Very Safe
- Somewhat Safe
- Somewhat Unsafe
- Very Unsafe
- Unsure

Q16 Which of the following would you consider to be a medical device (choose all that apply)?

- Artificial (prosthetic) knee
- Breast Implant
- Bedpan
- Pacemaker

Q17 How do you think that breast implants, when used for cosmetic purposes, impact a woman's quality of life and self-esteem:

- Significant positive impact
- Moderate positive impact
- No impact
- Moderate negative impact
- Significant negative impact

Q18 How do you think that breast implants, when used for reconstructive purposes, impact a woman's quality of life and self-esteem:

- Significant positive impact
- Moderate positive impact
- No impact
- Moderate negative impact
- Significant negative impact

Q19 Where have you received information about breast implants from? (select all that apply)

- Media/News Outlet
- Healthcare Professional
- FDA website
- American Society of Plastic Surgery (ASPS) website
- Healthcare Blog
- Friends and/or Family
- Magazines
- Social Media
- Plastic Surgeon/Physician
- Other (please specify)

Q20 To the best of your knowledge, what are medical risks known to be associated with breast implants? Please select all that apply:

- Implant rupture
- Risky surgery
- Cancer (anaplastic large cell lymphoma, or ALCL)
- Autoimmune disease (i.e. disease body attacks itself, like lupus)
- Chronic fatigue
- Infection
- Muscle and/or joint pain
- Depression
- Other (please specify)
- None of the above

Part 4: Patient Decision Checklist

The FDA has proposed that surgeons and patients sign a decision checklist similar to the one below prior to surgery. Please read the checklist below and answer the following question.

Checklist Items: Patients considering implants must initial to acknowledge the following risks associated with breast implants.

- Some of the most common risks of breast implant surgery and the frequency at which they occur include breast pain (36.5%), loss of sensation (35%), asymmetry (28%), infection (9%), scarring (7%), tissue death (2%), inability to breast feed (1.6%).
- Certain symptoms have been reported in association with breast implants, including joint pain, fatigue, rash, memory loss, and “brain fog.” Systemic symptoms in relation to breast implants have been referred to as breast implant illness. In some cases, patients have reported relief of symptoms after removal of breast implants. However, medical research does not currently support these associations.
- There is an association between breast implants and a rare cancer of the immune system called anaplastic large cell lymphoma (ALCL), which has been supported by medical research. Estimated risk ranges from 1 in 3817 to 1 in 30,000 cases of breast implants. It is more frequently associated with textured implants. While ALCL responds well to

therapy, some patients have died. Diagnosis and treatment of this cancer may not be covered by insurance.

- The FDA is now recommending new breast implant rupture screening recommendations - instead of screening for rupture at 3 years after inserting implants, they now recommend screening at 5 years because there is virtually no risk of rupture before 5 years.
- Breast implants are not lifelong devices. The longer you have implants, the greater your risk of experiencing a complication. One fifth of women have implants removed within 8-10 years.

Q21 Given the patient decision checklist, has your opinion of breast implants for cosmetic or reconstructive purposes changed?

- I am more likely to receive implants
- I am less likely to receive implants
- No, my opinion is unchanged

Part 5: Information on Breast Implant Utility

In women who underwent cosmetic breast augmentation, research has demonstrated that breast implants improved quality of life, with sustained long-term improvements in satisfaction and psychosocial well-being.

Similarly, breast reconstruction surgery has been demonstrated to improve quality of life in women after mastectomy (removal of the breast) for breast cancer.

Q22 Given the research on breast implant utility, has your opinion of breast implants for cosmetic or reconstructive purposes changed?

- I am less likely to receive implants
- I am more likely to receive implants
- My opinion is unchanged

Part 6: Chemical Composition of Breast Implants

The FDA is now recommending that patients know about the composition of breast implants.

The following ingredients are in breast implants: Dimethyl Silicone Elastomer Dispersion, Diphenyl Silicone Elastomer Dispersion, MED 4750 Silicone Elastomer, Silicone Gel, Platinum Catalyst.

The following chemicals are released by breast implants: Siloxane, Methoxytrimethylsilane, Dimethoxydimethylsilane, Methoxytriethoxysilane, Tetramethyldiethyldisiloxane, Acetone, Isopropanol, 2-Pentanone, Methyl Butanoate, Ethylbenzene, m- & p-xylene, 4-Methyl-3-penten-2-one, o-xylene, Alpha-Pinene, Cyclohexanone, 1-Ethyl-2-methylbenzene, Xylene, Benzaldehyde, Decane, Acetophenone, Dodecane, Limonene, Undecane, 1,3,5-Trimethylbenzene. (Total Volatiles = 3.67)

Q23 Given the chemical composition of implants, has your opinion of breast implants for cosmetic or reconstructive purposes changed?

- I am more likely to receive implants
- I am less likely to receive implants
- No, my opinion is unchanged

Part 7: Boxed Warning

The FDA is proposing to apply the following boxed warning (known as a "black box warning") to breast implants.

WARNING:

- **Breast implants are not considered lifetime devices. The longer people have them, the greater the chances are that they will develop complications, some of which will require more surgery.**
- **Breast implants have been associated with the development of a cancer of the immune system called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). This cancer occurs more commonly in patients with textured breast implants than smooth implants, although rates are not well defined. Some patients have died from BIA-ALCL.**
- **Patients receiving breast implants have reported a variety of systemic symptoms such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases and others. Individual patient risk for developing these symptoms has not been well established. Some patients report complete resolution of symptoms when the implants are removed without replacement.**

Such "black box warnings" are also used for other medications/medical devices - there is a warning on antidepressants for increased risk of suicidal tendencies in adolescents.

Q24 Given the boxed warning, has your opinion of breast implants for cosmetic or reconstructive purposes changed?

- I am more likely to receive implants
- I am less likely to receive implants
- No, my opinion is unchanged

Part 8: Post-Survey Assessment

Q25 After taking this survey, would you consider receiving breast implants in the future?

- Yes, reconstructive implants only
- Yes, cosmetic implants only
- Yes, either cosmetic or reconstructive implants
- Unsure
- No

Q26 After taking this survey, would you consider alternative options for breast reconstruction (i.e. reconstruction with your own tissue)?

- Yes
- Unsure
- No

Q27 After taking this survey, would you consider alternative options for cosmetic breast augmentation (i.e. fat grafting/liposuction)?

- Yes
- Unsure
- No

Q28 Has the information provided in this survey changed your likelihood of receiving a breast implant?

- Yes, I am more likely to receive a breast implant
- Yes, I am less likely to receive a breast implant
- No, my likelihood is unchanged

Q29 After taking this survey, how safe do you consider breast implants to be, from a medical standpoint?

- Very Safe
- Somewhat Safe
- Somewhat Unsafe
- Very Unsafe
- Unsure

Q30 After taking the survey, which of the following would you consider to be a medical device (choose all that apply)?

- Artificial (prosthetic) knee
- Breast Implant
- Bedpan
- Pacemaker

Q31 After taking this survey, how do you think that breast implants, when used for cosmetic purposes, impact a woman's quality of life and self-esteem:

- Significant positive impact
- Moderate positive impact
- No impact
- Moderate negative impact
- Significant negative impact

Q32 After taking this survey, how do you think that breast implants, when used for reconstructive purposes, impact a woman's quality of life and self-esteem:

- Significant positive impact
- Moderate positive impact
- No impact
- Moderate negative impact
- Significant negative impact

Q33 After taking this survey, what do you believe are medical risks known to be associated with breast implants? Please select all that apply:

- Unnatural feel
- Implant rupture
- Risky surgery
- Unnatural appearance
- Risk of foreign object in your body
- Cancer (anaplastic large cell lymphoma, or ALCL)
- Autoimmune disease (i.e. disease body attacks itself, like lupus)
- Chronic fatigue
- Infection
- Muscle and/or joint pain
- Depression
- Other (please specify)
- None of the above

Q34 Prior to this survey, have you heard of breast implant illness (BII)?

- Yes
- No

Q35 Prior to this survey, have you heard of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL)?

- Yes
- No

Q36 After taking this survey, how important do you think a boxed warning would be in making sure women considering breast implants are adequately informed about breast implant safety?

- Very Important
- Important
- Neutral
- Unimportant

Q37 After taking this survey, how helpful do you think a patient decision checklist would be in making sure women considering breast implants are adequately informed about breast implant safety?

- Very Helpful
- Helpful
- Neutral
- Unhelpful
- Very Unhelpful

Q38 In your opinion, do you think it is important for women to know the chemical composition of breast implants?

- Very Important
- Important
- Neutral
- Unimportant

Q39 After taking this survey, do you think it is important for women considering implants to know data from studies on the benefits of breast implants?

- Very Important
- Important
- Neutral
- Unimportant

-----If “Yes-Reconstructive” or “Yes-Cosmetic” was selected in Q1, display Q40-Q41-----

Q40 After taking this survey, how comprehensively do you feel that your plastic surgeon covered breast implants’ benefits and risks when you received your implants?

- A lot
- Quite a bit
- Somewhat
- A little
- Not at all


Q41 Given your implants, how worried are you about breast implant safety?

- Very worried
- Moderately worried
- Slightly worried
- Not at all worried

Part 9: Demographics

Q42 What is your age?

18 26 34 43 51 59 67 75 84 92 100

Age (in years) ()	
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Q43 Choose one or more races you identify as:

- White
- Black or African American
- American Indian or Alaska Native
- Asian
- Native Hawaiian or Pacific Islander
- Other (please specify)

Q44 Do you identify as Hispanic or Latino?

- Yes
- No

Q45 What is the highest level of school you have completed or the highest degree you have received?

- Less than high school
- High school graduate
- Some college
- 2-year degree
- 4-year degree
- Master's degree
- Professional degree
- Doctorate

Q46 What is your approximate household income?

- Less than \$10,000
- \$10,000 - \$24,99
- \$25,000 - \$49,999
- \$50,000 - \$74,999
- \$75,000- \$99,999
- \$100,000+