

# Making quality decisions about primary breast augmentation surgery

A decision aid to support informed choices that reflect best evidence and what matters most to you

## What is the purpose of this decision aid?

This decision aid is designed to **prepare you for decision-making** and to **facilitate shared decision-making with your plastic surgeon**, by helping to:

- *introduce* the **decisions necessary to consider** before primary breast augmentation surgery,
- *educate* you on the **essential information you need to know** to make each decision, and
- *identify your goals, values, and preferences* relevant to each decision and clearly communicate them to your plastic surgery care team.

## Who should use this decision aid?

### This decision aid is for you if:

- You are a woman age 18 or older, and
- You are considering primary breast augmentation (enlargement) surgery with saline or silicone implants, for cosmetic reasons.
- *Primary* breast augmentation means you have not previously had a breast augmentation surgery.

### This decision aid is not for you if:

- You are under the age of 18, or
- You are considering breast implant surgery for:
  - reconstructive purposes after breast cancer surgery,
  - revision of a previous breast augmentation surgery, or
  - gender affirming male-to-female surgery.

Breast implant surgery for reconstructive, revision, or gender affirming reasons have different or additional information essential for decision-making but not covered in this decision aid, including options, risks, benefits, expectations or limitations.

## What content is and is not covered in this decision aid?

- This decision aid includes only the information considered essential for all patients to understand before surgery when considering primary breast augmentation surgery.
- This decision aid may not include information important to your individual decision-making process or relevant to your specific situation, such as information about certain treatment options, risks, or tradeoffs. **This decision aid is not a replacement for consultation with a plastic surgeon.**

## How should I use this decision aid?

Use this decision aid before and throughout the consultation and informed consent process with your board-certified plastic surgeon. It is structured to help you answer the following questions:

How should I prepare for decision-making?

Is plastic surgery right for me?

Should I have breast augmentation surgery?

What questions should I ask my plastic surgeon?

What are my next steps?

## How should I prepare for decision-making?

- Know what is expected of me in decision-making
- Know what information to trust about plastic surgery
- Verify my surgeon is board-certified or eligible by the American Board of Plastic Surgery

## Why is it important for me to actively participate in decision-making?

**My plastic surgeon cannot read my mind to know what I do and do not want.** Actively participating in decision-making means I need to know and clearly communicate with my plastic surgery care team:

- my specific concerns and goals for the result I want to achieve
- my values based on what risks and benefits matter most to me

Making sure my plastic surgeon and I have a clear understanding of my goals, values, and preferences can **reduce my risk of being unhappy with my surgical results.**

## How do I know what information to trust when reading about plastic surgery?



### 5 key quality checks for appraising health information:

1. **Author and qualifications.** Who wrote the information? Are qualifications listed describing why they are credible to speak on the topic?
2. **Up-to-date.** Is a “date last reviewed” provided? Is the date within the past year?
3. **Evidence-based.** Is a reference list included to the sources of evidence used to support the information? Are the sources credible?
4. **Unbiased.** Are both pros and cons discussed equally? Does the author or publisher have a financial, or other, conflict of interest in how you use the information or your ultimate decisions? If so, is the conflict(s) disclosed?
5. **Useful.** Does the information answer your question? Does it make sense? Can you easily apply what you have learned to your decision-making?

Consider using the HONcode eGuide for Health Consumers [website evaluation tool](#).



- Use the American Board of Plastic Surgery (ABPS) website [surgeon search tool](#) to verify board certification status
- Review [FAQs](#) about board certification

A **board-eligible** plastic surgeon has successfully completed the required training in plastic surgery (residency) and has an approved application by the ABPS to enter the board-certification process.

## How should this inform your decision-making?

- Surgeon technique and judgement can increase or decrease your risk of complications.
- If your surgeon is not board-certified or board-eligible by the American Board of Plastic Surgery, he or she may not have completed the pre-requisite training needed to safely perform plastic surgery.


## Is plastic surgery right for me?

- Understand the general risks of surgery
- Consider factors that increase my risk of surgery and how I can reduce my risks

**All surgery has important risks to consider.** Some risks are general to surgery and others are specific to the type of surgery. The information presented in this patient decision aid does not include all possible risks, but rather the risks considered essential for all patients to understand before undergoing primary breast augmentation surgery.

### General risks of surgery

include **anesthesia risks, deep vein thrombosis (DVT) and pulmonary embolism (PE).**

<b>Risk factors</b>	<ul style="list-style-type: none"><li>• Smoking, or having a history of smoking, increases your general risk of surgery.</li><li>• Carefully review your medical and social history with your plastic surgery care team to identify and address any potential risk factors that may impact the safety of your surgery and your ultimate cosmetic result.</li></ul>
	Learn more about common risk factors, signs and symptoms, and how to prevent <b>deep vein thrombosis (DVT) and pulmonary embolism (PE).</b>

## Should I have breast augmentation surgery?

- Clarify my cosmetic concerns, goals, and preferences
- Set realistic expectations for breast augmentation surgery and implants
- Identify the decisions, options, and what matters most to me when weighing the pros & cons

### Why am I considering breast augmentation surgery?

Work through the following questions to clarify your cosmetic breast concerns, goals, and preferences.

**What are my cosmetic breast concerns?** Check  all that apply to you.

My breasts are:

- Too small
- Not as **firm** as when I was younger
- Not proportionate with my body
- Not as **full** as when I was younger
- Deflated after pregnancy or breastfeeding
- Other cosmetic breast concern or concerns
- Uneven
- (please specify): \_\_\_\_\_

**What goals do I hope to achieve with primary breast augmentation?** Check  all that apply to you.

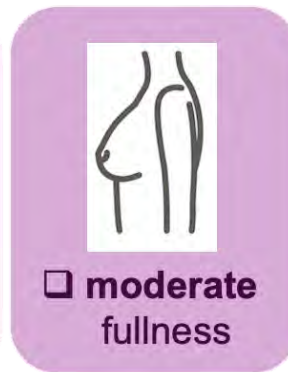
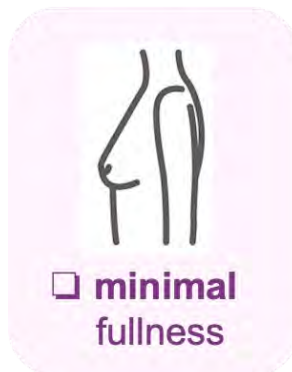
- Have a more balanced figure
- Increase the size of my breasts
- Make my breasts more symmetrical
- Restore volume:
  - Lost with aging
  - After weight loss
  - After pregnancy or breastfeeding
- Feel more:
  - Attractive
  - Confident naked
  - Feminine
  - Confident in how clothes fit
  - Other (please specify): \_\_\_\_\_

Continued on the next page.

## What are my preferences for how I want my breasts to look & feel after surgery?

How **full** do I want my breasts to **look** after breast augmentation?

Check  your **preference**:



Source: Adapted from William P. Adams Jr. MD 2019 "Breast Education Guide & Preferences"

How **natural** do I want my breasts to **feel**?

Check  how much it matters to you that your implants **feel natural**:

**Not important**

**Very important**

① ② ③ ④ ⑤ ⑥ ⑦



It may be helpful to review **before-and-after photos** to get a general idea of what you do and do not like. Look for a before-and-after gallery on your plastic surgeon's website or ask their office. Choose photos of results with a similar body type to you.

I have a photo example of what I want my breasts to look like after surgery:  Yes  No

## What do I need to know when deciding if breast augmentation surgery is right for me?

Check  items that you feel are most important to your decision-making process.

**General risks of breast augmentation surgery** include:

<b>Bleeding, hematoma</b> (a collection of blood), and <b>infection</b>	
<b>Potential consequences</b>	<ul style="list-style-type: none"> <li>• <b>May require additional surgery (reoperation)</b></li> <li>• <b>Reoperations have additional risks.</b> There are certain situations that require implants to be removed but not replaced.</li> <li>• <b>Complications following surgery may not be covered by your health insurance.</b></li> </ul>
<b>How to reduce your risk</b>	<ul style="list-style-type: none"> <li>• Follow your plastic surgeon's pre- and postoperative instructions and activity restrictions.</li> <li>• Identify and address with your plastic surgery care team any risk factors specific to your medical history and lifestyle.</li> </ul>
<b>Change in nipple sensation</b> including increased, decreased, or complete loss of sensation	
<b>Potential consequences</b>	<ul style="list-style-type: none"> <li>• Nipple sensation changes may be temporary or permanent.</li> </ul>

## ❑ There are known and unknown risks of breast implants.

A **known, or true, risk** is defined and supported by scientific evidence of causation. A key example is *breast-implant associated anaplastic large cell lymphoma (BIA-ALCL)* with textured implants.

An **unknown, or poorly understood, risk** is **not** supported by scientific evidence of causation, but may still be a consideration for some patients. These risks **may or may not** be defined. For example, a wide spectrum of *systemic symptoms* have been reported by some women with both saline and silicone, smooth and textured surfaced breast implants. The true relationship between breast implants and these systemic symptoms has yet to be scientifically defined.

Current research shows that silicone gel breast implants **do not** increase your risk of *autoimmune illnesses* nor *connective tissue diseases*. However, breast implant manufacturers are required to list them as possible risks in the directions for use of breast implants.

## ❑ Breast implants are not lifetime devices

It is likely you will need additional surgery related to your implants at some point in your lifetime.

Continue to follow-up with your plastic surgeon as recommended for **implant monitoring and maintenance** and if you experience any implant-related issues or concerns.

### Expect future out-of-pocket expenses

- Health insurance plans likely will not cover any expenses related to your breast implants, including for any complications.
- Available financial assistance programs include implant manufacturer warranties and surgeon-specific cosmetic complication insurance.

### Long-term considerations

- Breast implants may impact breast cancer surveillance.
- Continue routine screening as recommended by your doctor.

**Reoperations for implant maintenance is expected and is not a complication.**

## ❑ What implants can and cannot do.

Implants increase breast size and expand the breast envelope. Minimal breast ptosis (drooping or sagging) can often be corrected with implants, but implants will **not** correct significant skin laxity or severe ptosis. There may be alternative or combination procedures for you to consider.

- A **breast lift (mastopexy)** may be appropriate to consider to reshape or lift the breasts.
- While not interchangeable with breast implants because the results are less predictable, **fat grafting** may be a reasonable alternative or addition to implants to add breast volume.
- **Not having surgery is an option.** Padded bras and inserts can be used to give the appearance of larger breasts without surgery.

**Alternative or combination procedures have different or additional risks to consider beyond what is presented in this decision aid.**

## ❑ Your cosmetic result is directly related to your anatomy.

Understanding the limitations of your specific breast and chest wall characteristics is a key component of good preoperative planning and can help you to set realistic expectations.

### Asymmetry

- 100% of women have differences between their breasts (such as in size, nipple position, inframammary fold position, or chest wall anatomy).
- These differences will **not** be corrected, and breasts will never match.

### Cosmetic dissatisfaction

- You can **expect** that your results will change over time as your body changes, for example with pregnancy, weight change, and normal aging.
- Satisfaction with your implants may change over time and is not a complication.

## Implant style decisions

For each option, check  if you have a preference.

### Decision #1: Implant fill

Options:

FDA-approved for:

Key risk of implant rupture or deflation

Why is this important?

There is more than one type of silicone and saline implants.

Implant style options vary by manufacturer.

Why is this important?

Key benefit

**Silicone**

Women ages 22 and older

Risk of “silent” rupture, meaning you and your surgeon will likely not be able to tell the implant is ruptured just by looking at or feeling the implant.

- Additional monitoring is needed with imaging tests, such as MRI or ultrasound, periodically over the lifetime of the implant.
- The cost of imaging tests will most likely be out-of-pocket.

#### Silicone options

There are a range of silicone gel types and styles that range in cohesivity, or consistency, of the implant that vary by manufacturer.

- Less cohesive** silicone gel implants feel more natural; the implant volume is positional, similar to the behavior of a natural breast.
- Highly cohesive**, form-stable, implants maintain their shape.

**Sientra**    **Mentor**    **Allergan**

**Saline**

Women ages 18 and older

Saline implants will deflate partially or completely if ruptured, so you will know by looking at or feeling implants.

- No additional monitoring is needed beyond following up with your board-certified plastic surgeon.

#### Saline options

**Traditional**

Implant is placed deflated and then filled with sterile saline solution, allowing for a smaller incision and minor volume adjustment

**Structured**

An inner and outer shell structures how the sterile saline solution fills the implant for a different feel compared to traditional saline

**Mentor**  
 **Allergan**

**Ideal Implant**

**Different implants have different risks.** Implant manufacturers use different terms to describe their portfolio of implant styles and different methods for collection and reporting of risk data. Specific risk probabilities are not listed in this decision aid because available data does not allow for direct comparison of different implants and their risks across manufacturers.

**Review current [FDA: Labeling for Approved Breast Implants](#) to learn more.**

Discuss with your plastic surgeon which implant fill option will best meet your desired preference for how you want your breasts to **feel**.

### Decision #2: Implant shape

Options:

Key risk of implant rotation or displacement

Why is this important?

Key benefit

**Anatomic**

- Risk of implant rotation or displacement
- Anatomic implants are textured to reduce this risk.

If a breast implant rotates or becomes displaced your breasts will change shape or become noticeably asymmetric and may require surgical correction.

Discuss with your plastic surgeon which implant shape option will best meet your desired preference for how **full** you want your breasts to **look**.

**Round**

- No concern of implant rotation, you will not be able to tell any difference.
- There **is** a possibility for round implants to become displaced or flipped in relation to the pocket.

### Decision #3: Implant shell

#### Options:

**Key risk of breast implant associated anaplastic large cell lymphoma (BIA-ALCL)**

#### Textured

- All textured implants have an association with ALCL.
- There is an increased risk with high degree of texturing and lower risk with lower degree of texturing.
- Macrot textured devices carried the highest risk and are now no longer available.

#### Smooth

- No known risk of BIA-ALCL with smooth implants

#### Why is this important?

- 80% of BIA-ALCL cases present with an enlargement of one or both breasts, called a seroma. Other (less common) symptoms are breast lumps, hardness of the breast, pain, and skin rash on the breast.
- All patients diagnosed promptly have been cured; however, more advanced cases and patient deaths have occurred.
- Treatment typically involves removing the implant and surrounding scar capsule, but may include other therapies such as chemotherapy or radiation.
- Continue to follow-up with your plastic surgeon for the lifetime of the implant.
- Review the [FDA: Questions and Answers about Breast Implant-Associated Anaplastic Large Cell Lymphoma \(BIA-ALCL\)](#) for more information.

#### Key benefit

This decision is related to Decision #2: Implant shape. Discuss with your plastic surgeon your desired preference for how **full** you want your breasts to **look** and whether textured or smooth implants are right for you.

### How do I choose the right size?

#### Sizing methods

During your consultation, the plastic surgeon will take measurements of your breasts and chest. Using a variety of methods, the plastic surgeon can help guide you to select the right size implant for you.

#### Key risk of reoperation for cosmetic reasons

- Reoperations for cosmetic reasons include implant style or size change.
- **Reoperations carry additional risks.**
- Reduce this risk by carefully selecting with your plastic surgeon an implant size, projection, and style that fits with your body and your goals.

**Advisory of increased risks with oversized implants.** Risk of cervical spine changes, back/neck pain.



Learn more about the [risks and complications of breast implants](#). This resource from the FDA includes a glossary of risks and photo examples of capsular contracture and saline implant deflation as well as links to additional information and resources about breast implants.

#### Notes and additional quality information resources:

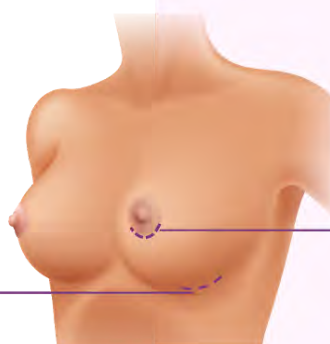
## Decision #1: Incision location\*

### Options:

\*Your plastic surgeon may discuss other incision locations than the 2 options described here if appropriate for you, such as transaxillary (through the armpit).

### Key risk of capsular contracture

Why is this important?



**Inframammary fold**  
(under the breast)

**Periareolar**  
(around the areola)

### Decreased risk of capsular contracture with inframammary fold incision

- Capsular contracture can lead to hardening of the affected breast, pain, and an unnatural appearance; may require additional surgery depending on severity.
- Signs and symptoms of capsular contracture may mimic other issues, such as implant displacement, BIA-ALCL, or ptosis. Reducing the risk of capsular contracture can help to avoid confusion or unnecessary alarm about other risks.

### Increased risk of capsular contracture with periareolar incision

## Decision #2: Placement plane (pocket selection)

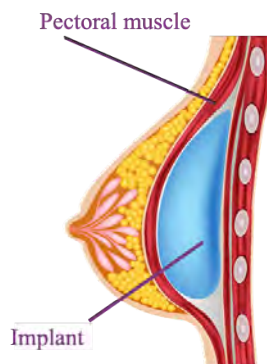
### Options:

### Key risk of capsular contracture

Implant texturing may reduce this risk

### Key risks of seeing or feeling the implant in a way that is not cosmetically desirable and implant wrinkling or rippling

Why is this important?



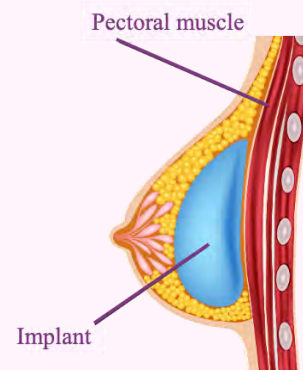
### **Subpectoral** (under the chest muscle)

#### Decreased risk of capsular contracture

There is no difference in risk of capsular contracture with textured or smooth implants when placed subpectoral

**Breast animation deformity** may occur with subpectoral placement. The degree of implant distortion depends on the thickness and position of your chest muscle and the amount of muscle coverage of the implant.

- Subpectoral placement may not be possible if you are a bodybuilder.
- Discuss your lifestyle and activity level with your plastic surgeon.



### **Subglandular** (over the chest muscle)

#### May have increased risk of capsular contracture

Using textured implants may help reduce the risk of capsular contracture when placing implants subglandular

**Your skin and breast tissue characteristics** impact the likelihood of seeing or feeling the implant in a way that is not cosmetically desirable, including implant wrinkling or rippling.

- This risk may be increased if you have thin skin or breast tissue.
- Discuss how your skin, breast and chest anatomy will impact your ultimate result with your surgeon.



## What else do I need to prepare for decision-making?

Find out how well this decision aid helped you learn the key facts. Check  the best answer.

- The risk of breast implant associated anaplastic large cell lymphoma (BIA-ALCL) is associated with:  
 Textured implants       Smooth implants       I am not sure
- Unless I experience a complication, it is unlikely that I will need to have another surgery related to my breast implants during my lifetime.  
 True       False       I am not sure
- My plastic surgeon and I may not be able to tell if \_\_ implants rupture just by looking at or feeling my breasts.  
 Saline       Silicone       Both saline and silicone       I am not sure
- After undergoing primary breast augmentation surgery, additional **out-of-pocket** costs may include: (Check  all that apply)  
 Image screening tests for implant monitoring, such as MRI or ultrasound  
 Reoperation(s), one or more repeat surgery related to my breast implants  
 There are no further expenses beyond my initial breast augmentation surgery, everything else is covered by insurance and the breast implant warranty  
 I am not sure
- The true relationship between breast implants and a wide spectrum of systemic symptoms reported by some women with breast implants has yet to be scientifically defined.  
 True       False       I am not sure
- My board-certified plastic surgeon can correct any asymmetry I have with implants so that my breasts are symmetric after surgery.  
 True       False       I am not sure
- Capsular contracture is a risk of breast augmentation that can lead to what?  

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 I am not sure
- If \_\_ implants rupture, my plastic surgeon and I will be able to tell by looking at or feeling my breasts.  
 Saline       Silicone       Both saline and silicone       I am not sure
- How will implants change your breasts? (Check  all that apply.)  
 Make them larger       Lift them       Make them a different shape       I am not sure

Check your answers for the key facts:

- Textured implants, 2. False, 3. Silicone, 4. Image screening tests and reoperations, 5. True, 6. False, 7. Hardening of the affected breast, pain, and an unnatural appearance; commonly requires surgery, 8. Saline, 9. Make them larger.

# What questions should I ask my plastic surgeon?

- Consultation guide

	Key risks and considerations Check <input checked="" type="checkbox"/> what risks matter most to you	Notes
<b>Am I a good candidate for plastic surgery?</b>	General risks of surgery: <input type="checkbox"/> Anesthesia risks <input type="checkbox"/> DVT/PE	
	Do I have any specific risk factors in my medical or social history?	
<b>Is breast augmentation the right decision to address my cosmetic concerns?</b>	General risks of breast augmentation surgery: <input type="checkbox"/> Bleeding <input type="checkbox"/> Hematoma <input type="checkbox"/> Infection <input type="checkbox"/> Reoperation for complication <input type="checkbox"/> Reoperation requiring removal without replacement <input type="checkbox"/> Nipple sensation changes	
	<ul style="list-style-type: none"> <li>• Should I consider any alternative or combination procedures to best address my cosmetic breast concerns?</li> <li>• If so, what different or additional risks do I need to know?</li> </ul>	
<b>Which implants will best help me to achieve my goals?</b>	How will my specific breast and chest wall anatomy and tissue characteristics impact my cosmetic result? Patient-dependent risks and tradeoffs: <input type="checkbox"/> Asymmetry (preexisting [persistent] or new) <input type="checkbox"/> Ability to see or feel the implant in a way that is not cosmetically desirable <input type="checkbox"/> Implant wrinkling or rippling	
	Implant styles vary by manufacturer, and different implants have different risks & benefits Implant-dependent risks and tradeoffs: <input type="checkbox"/> Implant rupture or deflation <input type="checkbox"/> BIA-ALCL <input type="checkbox"/> Capsular contracture <input type="checkbox"/> Implant rotation or displacement Is my activity level a concern? (such as body-building)	
<b>What size is right for me?</b>	Decision-dependent risks and tradeoffs: <input type="checkbox"/> Reoperation for cosmetic size exchange	
<b>Are my goals realistic?</b>	What results can I reasonably expect? Decision-dependent risks and tradeoffs: <input type="checkbox"/> Cosmetic dissatisfaction <input type="checkbox"/> Reoperation for cosmetic style exchange	
<b>How likely are complications?</b>	Complications are surgeon-specific. This <a href="#">icon array tool</a> can help you and your plastic surgeon talk about risks that matter most to you.	

# What are my next steps?

- Am I clear about what is expected of me and about what matters most to me?

## Before scheduling surgery

### 1. Am I clear about what to expect before, the day of, and immediately after surgery?

- Postoperative expectations (e.g., pain) and restrictions (e.g., exercise)
  - After surgery, you will be given a **Device Identification Card** that contains your implants unique identifier number. It is important to keep this card for your records because if you experience any issues with your implants this information should be shared with your health care provider and the implant manufacturer.
- I have received pre- and postoperative instructions from my plastic surgeon

### 2. What are my financial responsibilities, both now and in the future?

What am I responsible for <u>now</u> ?	<input type="checkbox"/> Quote for cost of surgery
What will I, or could I, be responsible for in the <u>future</u> ?	<ul style="list-style-type: none"><li>■ <b>Expected out-of-pocket costs</b> associated with implant surveillance (silicone) and maintenance (all implants)</li><li>■ <b>Possible out-of-pocket costs</b> if I experience a complication following surgery</li></ul>
What <u>financial assistance</u> is available?	<input type="checkbox"/> Implant manufacturer warranty <input type="checkbox"/> Cosmetic complication insurance

### 3. Find out how comfortable you feel about deciding.

	Yes	No
1. Do you know the benefits and risks of each option?	<input type="checkbox"/>	<input type="checkbox"/>
2. Are you clear about which benefits and risks matter most to you?	<input type="checkbox"/>	<input type="checkbox"/>
3. Do you have enough support and advice to make a choice?	<input type="checkbox"/>	<input type="checkbox"/>
4. Do you feel sure about the best choice for you?	<input type="checkbox"/>	<input type="checkbox"/>

(The SURE Test © O'Connor & Légaré, 2008)

- If you answered 'No' to any of these, you are not ready to make a decision. Consider the following suggested activities to try based on your specific decision-making needs and discuss with your plastic surgery care team.

**Need more information?** Review the additional quality information resources linked throughout this decision aid, and ask your plastic surgery care team for additional resources specific to your informational needs:

**Unsure what matters most to you?** Work through this decision aid again with your plastic surgery care team, a trusted friend, family member, or significant other.

**Need more support?** List your support concerns and discuss with your plastic surgery care team:

- If you answered 'Yes' to all of these, you are ready to make a decision.

## Confirm your decision

I have decided to **proceed** with primary breast augmentation surgery with the following specifications:

**Fill:**

- Silicone
- Traditional saline
- Structured saline

**Shape:**

- Round
- Anatomic

**Shell:**

- Smooth
- Textured

**Manufacturer:**

- Sientra
- Ideal Implant
- Allergan
- Mentor

**Style #:**

**Placement:**

- Subpectoral
- Subglandular

**Incision location:**

- IMF
- Periareolar

**Size:**

Left: \_\_\_\_\_ cc  
Right: \_\_\_\_\_ cc

**Other specification (if applicable):**

\_\_\_\_\_  
\_\_\_\_\_

I have decided to **decline** primary breast augmentation surgery.

Considering your decisions selected above, please answer the following questions:

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
1. I feel I have made an informed choice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. My decision shows what is important to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I expect to stick with my decision.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I am satisfied with my decision.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

(Effective Decision Subscale of the Decisional Conflict Scale © AM O'Connor, 1993, revised 2005)

## Patient Acknowledgement of Informed Consent

- I confirm my decision and voluntarily give my consent to undergo **primary breast augmentation surgery** with the specifications detailed on this form.
- I authorize \_\_\_\_\_ and assistants to perform the procedure.
- I understand and accept the possibility of unforeseen circumstances that require other procedures not described on this form. I voluntarily give my consent and authorize my surgeon and assistants to perform such procedures as deemed necessary based on the professional medical judgement of my surgeon to save my life or to prevent serious harm to my health.
- I confirm my acceptance and voluntarily consent to be photographed or recorded before, during, and after surgery for the purposes of medical documentation.
- I authorize the release of my protected health information for the purposes of medical device registration and registry reporting.
- I actively participated in a shared decision-making informed consent process with my plastic surgeon and plastic surgery care team as demonstrated in this decision aid and informed consent workbook.

\_\_\_\_\_  
PATIENT SIGNATURE

\_\_\_\_\_  
PATIENT PRINTED NAME

\_\_\_\_\_  
DATE

## Surgeon Acknowledgement of Informed Consent

I confirm my agreement with the decision detailed above and agree to perform the procedure as authorized.

\_\_\_\_\_  
SURGEON SIGNATURE

\_\_\_\_\_  
SURGEON PRINTED NAME

\_\_\_\_\_  
DATE

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<b>Disclosures:</b>	<sup>a</sup> No disclosures; <sup>b</sup> Sientra Post Approval Study Clinical Investigator Since 2012; <sup>c</sup> Educator Sientra, business advisory board realself, Allergan collaboration; <sup>d</sup> Medical Director Motiva Breast Implant Clinical Trial; <sup>e</sup> Consultant Allergan, Establishment Labs, Hans Biomed Clinical investigator Motiva US FDA Clinical trials
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<b>Developer contact information</b> For any questions or concerns about the content or development of this patient decision aid, please contact the author directly at <a href="mailto:chelsea.hagopian@alumni.emory.edu">chelsea.hagopian@alumni.emory.edu</a> .	

## Development and design <sup>†</sup>

Hagopian CO, Hagopian TM, Wolfswinkel EM, Ades TB, Stevens WG. Development and preliminary evaluation of a patient decision aid to replace traditional informed consent documents for primary breast augmentation surgery [unpublished manuscript; not yet submitted for peer-review].

<sup>†</sup>An overview of the development process and design with recommendations is included as an appendix for convenience of review.

## Content informed by

Hagopian CO, Ades TB, Hagopian TM, Wolfswinkel EM, Stevens WG. Attitudes, beliefs, and practices of aesthetic plastic surgeons regarding informed consent. *Aesthet Surg J*. 2020;40(4):437-447.

Hagopian CO, Hagopian TM, Wolfswinkel EM, Ades TB, Stevens WG. An expert consensus study for informed consent in primary breast augmentation surgery [accepted 2020-08-13 for publication in *Aesthet Surg J*].

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Breast Device Collaborative Community (BDCC) Implant Checklist Submitted FDA 10-2019, 2-1-2020. This checklist was used to cross-check the PDA for content comprehensiveness. Authors include breast implant patient advocates and board-certified plastic surgeons. The BDCC is run by William P. Adams Jr., MD, and functions to bring together interested stakeholders with diverse perspectives to address challenges and concerns surrounding breast implants.

### Additional content contributors

The following contributors are board-certified plastic surgeons who participated in a follow-up survey of active members of the American Society for Aesthetic Plastic Surgery (ASAPS) exploring current practices for confirming patient comprehension before primary implant-based breast augmentation surgery conducted to further inform the content of this decision aid. Additional survey participants chose to remain anonymous.

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## What are my implant options?

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## What are my surgical approach options?

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Hagopian CO, Hagopian TM, Wolfswinkel EM, Ades TB, Stevens WG. Information behavior of women considering primary breast augmentation surgery, a crowdsourcing study [unpublished manuscript; not yet submitted for peer-review].

Presentations and testimony of patients and representatives from patient advocacy groups on information they wish they knew before undergoing breast augmentation surgery with implants and believe all women considering this surgery should know during the March 25-26 2019 Food and Drug Administration (FDA) public advisory committee meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee:

(<https://www.fda.gov/advisory-committees/advisory-committee-calendar/march-25-26-2019-general-and-plastic-surgery-devices-panel-medical-devices-advisory-committee>)

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## What are my next steps?

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## Appendix

**Table.** Overview of PDA development process

<p><b>Preliminary work</b></p>	<p>(1) A needs assessment to define best practice of informed consent in the context of elective aesthetic procedures, explore decisional needs of relevant patients and clinicians, draft a working causal and program theory, and identify a leverage point for improvement; and</p> <p>(2) Design of a 4-phase development process model for creating PDAs that meet certification standards defined by the IPDAS Collaboration and the NQF to replace traditional ICDs for elective aesthetic procedures.</p> <p>Overarching theoretical, conceptual, and operational guidance drew from complexity science, quality improvement, knowledge translation and evidence-based practice. Additional theory and conceptual models inform each phase of the development process model.</p>
<p><b>Prototype development</b></p>	<p>Guided by the development process model:</p> <p><i>Phase 1: <b>Expert consensus</b></i> of active members of The Aesthetic Society, board-certified plastic surgeons who specialize in aesthetic (cosmetic) plastic surgery [relevant clinical experts], using a modified Delphi process, a recognized method of establishing professional consensus, to define a core set of informed consent information considered essential for all patients to understand when considering primary breast augmentation surgery with implants [index decision].</p> <p><i>Phase 2: <b>Consumer crowdsourcing</b></i> survey to learn the information behavior, e-health literacy skills, and knowledge gaps of adult (age 18+) females actively considering the index decision [target audience], and to define the level of detail needed to inform decision-making.</p> <p><i>Phase 3: <b>Drafting of PDA prototype.</b></i> Initial drafting of the PDA was done following the first Delphi round. The PDA was refined with each iterative cycle of the development process. Final drafting of the PDA prototype followed the consumer crowdsourcing survey. Phases (1) and (2) helped to specify a search strategy for selecting evidence to further inform the final content of the PDA.</p> <p><i>Phase 4: <b>Preliminary evaluation (alpha testing)</b></i> for (1) Expert medical review, (2) <b>acceptability</b> of (a) the PDA prototype to relevant medical experts and to relevant patient experts* [Breast implant patient advocates, have previously faced the index decision] and (b) the development process to relevant medical experts, (3) <b>quality</b> of the PDA prototype, and (4) <b>fidelity</b> of the development process.</p>
<p><b>Next steps</b></p>	<p>Beta (field) testing:</p> <p><b>Acceptability</b> to primary end-users (clinicians involved in counseling patients on the index decision and patients actively considering the index decision), both clinicians internal and external to development process</p> <p><b>Effectiveness</b> (decision quality, informed consent process)</p> <p>Comparative effectiveness evaluation: PDA compared to usual care (traditional ICD)</p>

PDA, patient decision aid. IPDAS, International Patient Decision Aid Standards. NQF, National Quality Forum. ICD, informed consent document. \*Proposed.

**Table.** Overview of PDA design with recommendations

Element	Comments	Recommendations
<b>Structure</b>	<p>Each section [content block] is guided by an overarching question contextualized to the decisional timeline and includes:</p> <ul style="list-style-type: none"> <li>the relevant decision or decisions necessary to consider;</li> <li>the essential information needed to make a decision;</li> <li>details about why the information is important or how it should specifically inform the patients' decision-making</li> </ul>	<p>If prototype is acceptable to end-users (plastic surgeons and patients), consider spreading to additional elective aesthetic procedures with the ultimate goal being a database containing procedure-specific content blocks.</p> <p>Apply the strategy of mass customization for building educational informed consent modules tailored to the specific needs of the individual patient, e.g., considering primary breast augmentation and liposuction.</p>
<b>Format</b>	<p>PDF, can be viewed digitally or as a printed document</p> <p>Content blocks are color-coded for easy identification of the relevant decision</p>	<p>Scaling-up to an interactive, web-based platform with:</p> <ul style="list-style-type: none"> <li>Foundational content providing the general structure of the PDA (e.g., How to prepare for decision-making, Is plastic surgery right for me, etc.)</li> <li>Procedure-specific content blocks interactive, defined as allows for user input, (both patient and practice-specific)</li> <li>Modifiable to populate relevant procedure-specific content when the procedure content block is selected, and interactive to allow for patient and practice-specific input.</li> </ul> <p>Consider changing color coding to make all foundational content a single anchor color and procedure-specific content different colors, e.g., primary breast augmentation [purple], liposuction [blue]</p>
<b>Mode of delivery</b>	<p>Designed to integrate into routine clinical practice as a replacement to traditional informed consent documents</p> <p>Pre-encounter (prepare for decision-making) and during consultation and informed consent process (facilitate shared decision-making)</p>	<p>A permanent link for where this PDA can be accessed will be included once known--will submit to Ottawa Inventory; consider housing it on The Aesthetic Society Smart Beauty Guide website.</p> <p>Sustainability considerations: integrate with EHR platforms for real-time documentation of progressive patient learning and informed consent</p>

PDA, patient decision aid. EHR, electronic health record.