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?

- 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).

| Risk factors | • Smoking, or having a history of smoking, increases your general risk of surgery.  
• 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. |

Learn more about common risk factors, signs and symptoms, and how to prevent deep vein thrombosis (DVT) and pulmonary embolism (PE).

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 proportionate with my body
- [ ] Deflated after pregnancy or breastfeeding
- [ ] Uneven
- [ ] Not as firm as when I was younger
- [ ] Not as full as when I was younger
- [ ] Other cosmetic breast concern or concerns (please specify): _____________________

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

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?

- Minimal fullness
- Moderate fullness
- Maximum fullness

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:

<table>
<thead>
<tr>
<th>Not important</th>
<th>Very important</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Potential consequences</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleeding, hematoma (a collection of blood), and infection</td>
<td></td>
</tr>
<tr>
<td>● May require additional surgery (reoperation)</td>
<td></td>
</tr>
<tr>
<td>● Reoperations have additional risks. There are certain situations that require implants to be removed but not replaced.</td>
<td></td>
</tr>
<tr>
<td>● Complications following surgery may not be covered by your health insurance.</td>
<td></td>
</tr>
</tbody>
</table>

How to reduce your risk

- Follow your plastic surgeon’s pre- and postoperative instructions and activity restrictions.
- Identify and address with your plastic surgery care team any risk factors specific to your medical history and lifestyle.

Change in nipple sensation including increased, decreased, or complete loss of sensation

<table>
<thead>
<tr>
<th>Potential consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td>● Nipple sensation changes may be temporary or permanent.</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Options:</th>
<th>FDA-approved for:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Key risk of implant rupture or deflation

- 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.

#### Why is this important?

- 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.

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

#### 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.

#### 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.

#### Implant style options vary by manufacturer.

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

- **Mentor**
- **Allergan**

- **Ideal Implant**

#### Why is this important?

- 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](https://www.fda.gov) 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

<table>
<thead>
<tr>
<th>Options:</th>
<th>Key risk of implant rotation or displacement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Key benefit

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

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

- **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:**

- **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.
  - Macrotextured devices carried the highest risk and are now no longer available.

- **Smooth**
  - No known risk of BIA-ALCL with smooth implants

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

- 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.

**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:**
### Surgical approach decisions

**For each option, check ☑ if you have a preference.**

#### 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).

<table>
<thead>
<tr>
<th>Key risk of capsular contracture</th>
<th><em>Decreased risk</em> of capsular contracture with inframammary fold incision</th>
<th><em>Increased risk</em> of capsular contracture with periareolar incision</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Capsular contracture can lead to hardening of the affected breast, pain, and an unnatural appearance; may require additional surgery depending on severity.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>

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

**Options:**

<table>
<thead>
<tr>
<th>Key risk of capsular contracture</th>
<th><em>Decreased risk</em> of capsular contracture</th>
<th><em>Increased risk</em> of capsular contracture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant texturing may reduce this risk</td>
<td>There is no difference in risk of capsular contracture with textured or smooth implants when placed subpectoral</td>
<td>May have increased risk of capsular contracture</td>
</tr>
</tbody>
</table>

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

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

**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.

- 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.

*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.**
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.

1. The risk of breast implant associated anaplastic large cell lymphoma (BIA-ALCL) is associated with:
   - Textured implants
   - Smooth implants
   - I am not sure

2. 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

3. 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

4. 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

5. 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

6. 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

7. Capsular contracture is a risk of breast augmentation that can lead to what?
   - I am not sure

8. 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

9. 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:
<table>
<thead>
<tr>
<th>What questions should I ask my plastic surgeon?</th>
<th>Key risks and considerations</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Am I a good candidate for plastic surgery?</strong></td>
<td>Check ✓ what risks matter most to you</td>
<td></td>
</tr>
<tr>
<td><strong>Is breast augmentation the right decision to address my cosmetic concerns?</strong></td>
<td>General risks of surgery:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓ Anesthesia risks  ✓ DVT/PE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>General risks of breast augmentation surgery:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓ Bleeding  ✓ Hematoma</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓ Infection  ✓ Reoperation for complication</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓ Reoperation requiring removal without replacement  ✓ Nipple sensation changes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Should I consider any alternative or combination procedures to best address my cosmetic breast concerns?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• If so, what different or additional risks do I need to know?</td>
<td></td>
</tr>
<tr>
<td><strong>Which implants will best help me to achieve my goals?</strong></td>
<td>How will my specific breast and chest wall anatomy and tissue characteristics impact my cosmetic result?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient-dependent risks and tradeoffs:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓ Asymmetry (preexisting [persistent] or new)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓ Ability to see or feel the implant in a way that is not cosmetically desirable</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓ Implant wrinkling or rippling</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Implant styles vary by manufacturer, and different implants have different risks &amp; benefits</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Implant-dependent risks and tradeoffs:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓ Implant rupture or deflation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓ BIA-ALCL</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓ Capsular contracture</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓ Implant rotation or displacement</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is my activity level a concern? (such as body-building)</td>
<td></td>
</tr>
<tr>
<td><strong>What size is right for me?</strong></td>
<td>Decision-dependent risks and tradeoffs:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓ Reoperation for cosmetic size exchange</td>
<td></td>
</tr>
<tr>
<td><strong>Are my goals realistic?</strong></td>
<td>What results can I reasonably expect?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Decision-dependent risks and tradeoffs:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓ Cosmetic dissatisfaction</td>
<td></td>
</tr>
<tr>
<td></td>
<td>✓ Reoperation for cosmetic style exchange</td>
<td></td>
</tr>
<tr>
<td><strong>How likely are complications?</strong></td>
<td>Complications are surgeon-specific. This icon array tool can help you and your plastic surgeon talk about risks that matter most to you.</td>
<td></td>
</tr>
</tbody>
</table>
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?

<table>
<thead>
<tr>
<th>What am I responsible for now?</th>
<th>❑ Quote for cost of surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>What will I, or could I, be responsible for in the future?</td>
<td>❑ <strong>Expected out-of-pocket costs</strong> associated with implant surveillance (silicone) and maintenance (all implants)</td>
</tr>
<tr>
<td>What financial assistance is available?</td>
<td>❑ Implant manufacturer warranty</td>
</tr>
</tbody>
</table>

3. Find out how comfortable you feel about deciding.

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

(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

  **Placement:**
  - ❏ Subpectoral
  - ❏ Subglandular

  **Incision location:**
  - ❏ IMF
  - ❏ Periareolar

  **Size:**
  - Left: _______ cc
  - Right: _______ cc

  **Manufacturer:**
  - ❏ Sientra
  - ❏ Ideal Implant
  - ❏ Allergan
  - ❏ Mentor

  **Style #:**

  **Other specification (if applicable):**

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

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

<table>
<thead>
<tr>
<th>1. I feel I have made an informed choice.</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither Agree nor Disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. My decision shows what is important to me.</td>
<td>❏</td>
<td>❏</td>
<td>❏</td>
<td>❏</td>
<td>❏</td>
</tr>
<tr>
<td>3. I expect to stick with my decision.</td>
<td>❏</td>
<td>❏</td>
<td>❏</td>
<td>❏</td>
<td>❏</td>
</tr>
<tr>
<td>4. I am satisfied with my decision.</td>
<td>❏</td>
<td>❏</td>
<td>❏</td>
<td>❏</td>
<td>❏</td>
</tr>
</tbody>
</table>

(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
### Development and design†

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].

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

### Content informed by


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*].

Hagopian CO, Hagopian TM, Wolfswinkel EM, Ades TB, Stevens WG. Behaviors and perspectives of women considering primary breast augmentation surgery relevant to decision-making and informed consent [unpublished manuscript; not yet submitted for peer-review].

Breast Device Collaborative Community (BDCC). Jamee Cook, Raylene Hollrah, Mindy Haws MD, Lisa Schlager, Pat McGuire MD, Andrea Pusic MD, Madris Tomes, Debra Johnson MD, William P. Adams Jr. MD, Rosalyn d’Incelli, Kourtney Cavallio, Raina Dauria, Robert Hamas MD. Implant Checklist Submitted FDA 10-2019, 2-1-2020. This checklist was used to cross-check the PDA for content comprehensiveness. BDCC functions to bring together stakeholders with diverse perspectives to address challenges and concerns surrounding breast implants and related topics for the FDA.

### 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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- Susan MacLennan, MD
- Tracy Pfeifer, MD
- Emily Hartmann, MD
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Additional references and hyperlinked content, by section

How should I prepare for decision-making?


Links
HONcode Health website evaluation tool (https://www.hon.ch/HONcode/Patients/HealthEvaluationTool.html)
American Board of Plastic Surgery (ABPS) FAQs about board certification (https://www.abplasticsurgery.org/public/faqs/)

Is plastic surgery right for me?


Links
Centers for Disease Control and Prevention (CDC) What is Venous Thromboembolism? (https://www.cdc.gov/ncbddd/dvt/facts.html)

Should I have breast augmentation surgery?

Why am I considering breast augmentation surgery?

Links

What should I know when deciding if breast augmentation surgery is right for me?


**What are my implant options?**

**Links**


Saline or silicone implants?


**Round or anatomical implants?**


**Textured or smooth implants?**


How do I choose the right size?


What are my surgical approach options?
Implant placement: Above or below the muscle?


Incision location: Inframammary fold or periareolar?

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

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:

What questions should I ask my plastic surgeon?

What are my next steps?

### Preliminary work

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
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.

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.

### Prototype development

Guided by the development process model:

**Phase 1:** Expert consensus 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].

**Phase 2:** Consumer crowdsourcing 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.

**Phase 3:** Drafting of PDA prototype. 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.

**Phase 4:** Preliminary evaluation (alpha testing) for (1) Expert medical review, (2) acceptability 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) quality of the PDA prototype, and (4) fidelity of the development process.

### Next steps

Beta (field) testing:

**Acceptability** 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

**Effectiveness** (decision quality, informed consent process)

Comparative effectiveness evaluation:

PDA compared to usual care (traditional ICD)

<table>
<thead>
<tr>
<th>Element</th>
<th>Comments</th>
<th>Recommendations</th>
</tr>
</thead>
</table>
| **Structure**    | Each section [content block] is guided by an overarching question contextualized to the decisional timeline and includes:  
  - the relevant decision or decisions necessary to consider;  
  - the essential information needed to make a decision;  
  - details about why the information is important or how it should specifically inform the patients’ decision-making | 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.  
  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. |
| **Format**       | PDF, can be viewed digitally or as a printed document                                                                                                                                                     | Scaling-up to an interactive, web-based platform with:  
  - Foundational content providing the general structure of the PDA (e.g., How to prepare for decision-making, Is plastic surgery right for me, etc.)  
  - Procedure-specific content blocks interactive, defined as allows for user input, (both patient and practice-specific)  
  - Modifiable to populate relevant procedure-specific content when the procedure content block is selected, and interactive to allow for patient and practice-specific input.  
  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] |
| **Mode of delivery** | Designed to integrate into routine clinical practice as a replacement to traditional informed consent documents  
  Pre-encounter (prepare for decision-making) and during consultation and informed consent process (facilitate shared decision-making) | 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.  
  Sustainability considerations: integrate with EHR platforms for real-time documentation of progressive patient learning and informed consent |

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