American Society of Plastic Surgeons

▶ **PRACTICE REFERENCE**

Issued January 16, 2026

Communicating the FDA-Mandated Breast Implant Patient Decision Checklist

Summary: The FDA Breast Implant Patient Decision Checklist is a federally mandated tool designed to strengthen risk communication and support informed decision-making for patients considering breast implants. The American Society of Plastic Surgeons (ASPS) has developed this ***practice reference*** to provide guidance on compliant, ethical, and effective use of the Checklist, including recommendations on timing and surgeon-led communication to enhance patient understanding and safety.

▶ BACKGROUND & RATIONALE

The Food and Drug Administration (FDA)-mandated Breast Implant Patient Decision Checklist was developed in response to growing concerns from patients, advocacy groups, and clinicians about the long-term safety and informed consent process surrounding breast implants.

In March 2019, the FDA held a public advisory committee meeting to gather input on breast implant safety, during which numerous patients and advocates testified about adverse outcomes and the need for clearer risk communication before breast implant surgery. As a result, the FDA recommended a "black box warning" and proposed a standardized checklist to ensure patients receive consistent and comprehensive information prior to surgery.

Patient advocates, professional societies, and health organizations pressed the FDA to strengthen its approach to risk communication. Their efforts emphasized plain language, direct explanations of risks, and inclusion of evidence-based data on systemic symptoms and cancers linked to implants. A patient-centered checklist was submitted to the FDA in 2019 and supported by multiple leading organizations, including ASPS, ultimately gaining broad public backing through a petition with more than 77,000 signatures.

The FDA issued final guidance in September 2021, making The Checklist a mandatory part of the implant labeling and restricting the sale of implants to surgeons who use The Checklist. There is ongoing work by a group known as the Breast Surgery Collaborative Community, which is a coalition of stakeholders including plastic surgeons, implant manufacturer representatives and patient advocates, to craft ongoing improvements in patient communication and the checklist.

▶ PRACTICE REFERENCE *for Surgeons*

ASPS believes the FDA-mandated Breast Implant Patient Decision Checklist is a powerful tool for supporting informed consent and promoting patient safety in breast implant procedures. Breast implant manufacturers are required to include a device-specific checklist for their products and require surgeons to review The Checklist with patients prior to surgery, ensuring that the individual fully understands the known risks and limitations of breast implants before proceeding. Breast implant manufacturers are prohibited from selling implants to any surgeon who does not comply with these labeling requirements.

Ethical Responsibilities

Ethically, The Checklist supports a transparent and patient-centered consent process, helping surgeons uphold their professional duty to ensure patients make well-informed decisions with a clear understanding of potential risks.

The Checklist enhances patient safety by standardizing risk disclosure and promoting consistent communication about known complications, including rare but serious conditions and cancers. It also helps identify individuals who may not be good candidates for implants and outlines the importance of long-term monitoring, making it an essential part of both preoperative planning and ongoing care.

Checklist Content Overview

Each checklist is specific to the implant type and manufacturer, but all include the following key elements:

- Criteria for determining whether a patient is a suitable implant candidate
- Alternatives to breast implants, including no surgery or autologous reconstruction
- An explanation of the FDA's black box warning, the strongest label used to highlight serious risks
- Information on Breast Implant Illness (BII) and related symptoms
- Risks of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) and breast implant-associated squamous cell carcinoma (BIA-SCC)
- Potential for other systemic diseases and autoimmune conditions
- Disclosure of chemicals and metals found in implants
- Implant-specific risks such as rupture, leakage, capsular contracture, and asymmetry
- Possible interference with breastfeeding and mammography
- A statement on who should *not* receive implants
- Information on implant longevity and the likelihood of future surgeries
- The need for regular monitoring using high-resolution ultrasound or MRI

By incorporating The Checklist into routine practice, surgeons not only meet regulatory requirements but also strengthen trust with patients and reinforce their commitment to safe, ethical, and evidence-based care.

Timing of the Checklist

The Checklist should be reviewed and signed ***before the day of surgery***. It should be introduced early in the consultation process—ideally during the initial or second preoperative visit—allowing ample time for the patient to read, understand, and consider the information presented. Rushed or last-minute delivery undermines The Checklist's purpose and may compromise the validity of informed consent.

Ensuring patients have sufficient time to absorb the material and ask questions is essential to The Checklist's effectiveness. A thoughtful, unhurried approach supports true shared decision-making and may reduce future misunderstanding or dissatisfaction.

Delivery of the Checklist

The Checklist should not be treated as a formality or administrative task. It must not be merely handed to the patient or read aloud without explanation. Instead, the surgeon must ***personally review The Checklist*** with the patient, using plain, accessible language to clarify any unfamiliar terms or complex risks.

Importantly, only the implanting surgeon may sign The Checklist—this responsibility cannot be delegated to a non-physician provider, office staff, resident, or any physician not performing the procedure. The Checklist signature is both a legal attestation and a professional affirmation that the surgeon has reviewed the information directly with the patient. According to the FDA, allowing a staff member to review the checklist while the surgeon simply signs it creates a compliance gap: the surgeon would be signing an attestation for a conversation they did not actually witness or lead.

While supportive materials such as videos, online tools, or educational handouts may be useful in reinforcing The Checklist's content, they do not absolve the surgeon from the responsibility of reviewing The Checklist with the patient. The completed and signed checklist should be retained in the patient's medical record and available in the event of an audit or a future liability claim.

By integrating The Checklist early in the consultation timeline and delivering it through a thorough, surgeon-led discussion, practices help ensure compliance, foster informed decision-making, and demonstrate a strong commitment to patient safety and ethical care.

Discussing The Checklist

When communicating the FDA Breast Implant Patient Decision Checklist, it is important that a surgeon approach the conversation as a collaborative part of the informed consent process—not simply as a regulatory requirement. Achieving The Checklist's maximum value depends on how thoughtfully it is explained in the context of a larger informed consent conversation. The Checklist should be framed as a resource designed

to help patients understand their options and make confident, well-informed decisions.

A surgeon should use plain language, avoid medical jargon, and take care to ensure that the patient comprehends each section of The Checklist. Patients vary widely in their health literacy and may be experiencing stress or uncertainty; therefore, a surgeon should pause regularly to check for understanding and explain complex concepts in accessible terms. For example, instead of referencing "capsular contracture" without explanation, it may be more helpful to describe how scar tissue forms around the implant and potentially causes firmness or discomfort.

It is also important that The Checklist be treated as a conversation rather than a scripted review. A surgeon should actively invite questions, particularly when discussing more serious risks such as BII or BIA-ALCL and allow time for reflection. Normalizing the discussion of risks as a standard and responsible part of surgical care can help patients process the information without undue alarm. In addition to obtaining the required signatures, key aspects of the discussion should be documented in the medical record. Providing The Checklist in advance, incorporating visual aids, or encouraging a support person to be present can further enhance patient comprehension. Thoughtful communication of The Checklist strengthens trust, reinforces the principles of informed consent, and helps protect both patients and surgeons.

CONCLUSION

The FDA Breast Implant Patient Decision Checklist represents a critical step forward in strengthening informed consent, improving patient safety, and supporting surgeon-patient communication. As the field of breast implant safety continues to evolve, so does The Checklist.

Ongoing collaboration between patient advocacy organizations and plastic surgeons has led to refinements in checklist content, format, and clarity. Updated versions are currently in development to better reflect current evidence and improve accessibility for patients of all educational backgrounds. It is essential that surgeons remain current with any changes to The Checklist, as continued improvements are anticipated.

Breast implant manufacturers will incorporate the latest version of their device-specific version of The Checklist for surgeons to use with patients as new iterations are approved as part of the implant labeling. Surgeons are advised to pay close attention to manufacturer communications and use the latest version provided once available. Further, the FDA provides updates on its website, and ASPS communicates changes directly to members as it becomes available from the FDA and industry.

This document was approved for distribution by the ASPS Breast Implant Patient Decision Checklist Task Force on October 29, 2025; the ASPS Heath Policy Committee on January 30, 2026; and the ASPS Board of Directors on March 25, 2026.

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