Breast Implants - Certain Labeling Recommendations to Improve Patient Communication

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

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You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document, contact the Center for Devices and Radiological Health's (CDRH) Division of Infection Control and Plastic Surgery Devices at 301-796-6970.

When final, the recommendations in this guidance will supplement or in some cases replace recommendations in FDA's Guidance *Saline, Silicone Gel, and Alternative Breast Implants* guidance, issued November 17, 2006.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Product Evaluation and Quality

Preface

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This draft guidance contains recommendations concerning the content and format for certain labeling information for saline and silicone gel-filled breast implants. FDA is issuing this draft guidance to help ensure that a patient receives and understands the benefits and risks of these devices. The recommendations are being made based on concerns that some patients are not receiving and/or understanding information regarding the benefits and risks of these devices.

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

Breast implants are medical devices implanted under the breast tissue or chest muscle to increase breast size (augmentation) or to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality (reconstruction). They are also used in revision surgeries, which correct or improve the result of an original surgery. The use of breast implants in reconstructive and augmentation procedures is elective, and alternatives to the use of breast implants exist (such as an external breast prosthesis).

There are two types of breast implants approved for sale in the United States: saline-filled and silicone gel-filled. Saline-filled breast implants are inflated to the desired size with sterile isotonic saline. Silicone gel-filled breast implants contain a fixed volume of silicone gel. Silicone gel viscosity differs among implants and manufacturers.

Breast implants are manufactured with smooth and textured surfaces. The outer surface, or "shell" for both types of breast implants is manufactured from polysiloxane silicone rubber and may vary in shell surface, shape, profile, volume, and thickness. For breast implants with a textured shell surface, each breast implant manufacturer utilizes a proprietary manufacturing process to create the textured surface, which means that each manufacturer's textured shell is different.

Over the past few years, FDA has received new information pertaining to risks associated with breast implants, including breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) and systemic symptoms commonly referred to as breast implant illness (BII) that some patients attribute to their implants. BIA-ALCL is a type of non-Hodgkin's lymphoma (cancer of the immune system). In most cases, BIA-ALCL is found in the scar tissue and fluid near the implant, but in some cases, it can spread throughout the body. An individual's risk of developing BIA-ALCL is considered to be low; however, this cancer is serious and can lead to death, especially if not treated promptly. In most patients, it is treated successfully with surgery to remove the implant and surrounding scar tissue, but some patients may require chemotherapy and radiation therapy. The most common symptoms of BIA-ALCL are persistent swelling, presence of a mass or pain in the area of the breast implant that may occur years after implant placement. Systemic symptoms such as fatigue, memory loss, rash, "brain fog," and joint pain have been reported by some patients with breast implants. The term "breast implant illness" has been used to describe these symptoms. Researchers are investigating these symptoms to better understand their origins. The exact relationship of these symptoms with breast implants is unclear at this time.

FDA has taken a number of steps to better understand and address risks associated with breast implants,[1] including convening the General and Plastic Surgery Devices Advisory Panel ("Panel") on March 25-26, 2019 to discuss the long-term benefits and risks of breast implants for achieving breast augmentation and reconstruction.[2] The meeting covered a range of important topics on breast implant safety, including characterization of BIA-ALCL incidence and risk factors, and methods for assessing systemic symptoms. The Panel gave recommendations on these topics, including recommending that FDA require a boxed warning in breast implant labeling and a standardized checklist as part of the informed consent process, revise the MRI screening recommendations for silent ruptures of silicone gel-filled breast implants, and provide greater transparency regarding materials present in breast implants; the Panel also discussed the role of the patient device card in providing important information about the patient's breast

[1] For more information, see https://www.fda.gov/medical-devices/implants-and-prosthetics/breast-implants.
[2] For more information and meeting materials, see https://www.fda.gov/advisory-committees/advisory-committee-calendar/march-25-26-2019-general-and-plastic-surgery-devices-panel-medical-devices-advisory-committee.

implant.[3] In addition, FDA learned from presentations at the March 2019 Panel meeting and through comments submitted to the associated public docket,[4] that some patients may not be receiving or understanding important information regarding the benefits and risks of breast implants in a format that allows them to make a well-informed decision about whether or not to have a breast implantation. Notably, approved labeling for currently marketed breast implants is lengthy, often in excess of fifty pages.[5]

For these reasons, FDA is now providing recommendations concerning the content and format of certain labeling information for these devices. Specifically, FDA is recommending that manufacturers incorporate a boxed warning and a patient decision checklist into the labeling for these devices to better ensure certain information is received and understood by patients. This guidance also recommends updated and additional labeling information, including updates to the silicone gel-filled breast implant rupture screening recommendations, inclusion of an easy-to-find description of materials, and provision of patient device cards that were recommended at the March 2019 Panel meeting.

The Agency will continue to monitor information about potential safety risks and take steps to ensure they are being adequately conveyed to and understood by physicians and patients.

III. Scope

This draft guidance provides recommendations concerning the content and format of certain labeling information for breast implants filled with saline or silicone gel indicated for breast augmentation or breast reconstruction.

FDA believes it is important for patients considering breast implants to have the information they need for a balanced discussion with their physicians regarding the benefits and risks of breast implants. To help ensure that patients have this information, a boxed warning, a patient decision checklist, and a patient information booklet/brochure specific to the breast implant should be provided by manufacturers and given to patients prior to implantation. For those patients who decide to have breast implants, a patient device card should also be provided to patients after surgery. FDA intends to work with manufacturers of new breast implants through the premarket approval application (PMA) process, and manufacturers of currently marketed breast implants through the PMA supplement process, to integrate these important labeling recommendations.

This draft guidance is not intended to include a complete listing of all labeling components for breast implants. When finalized, this draft guidance should be used as a complement to FDA's "Guidance on Medical Device Patient Labeling"[6] (which describes FDA's current thinking on

[3] Ibid.
[4] FDA-2019-N-0426.
[5] In some cases, the labeling exceeds 100 pages. Links to patient labeling at the time FDA approved the implant are available here: https://www.fda.gov/medical-devices/breast-implants/labeling-approved-breast-implants.
[6] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-medical-device-patient-labeling.

making medical device patient labeling understandable to and usable by patients), existing regulations, and other relevant guidance documents containing additional labeling recommendations.

This draft guidance, when finalized, also supplements FDA's Guidance "Saline, Silicone Gel, and Alternative Breast Implants"[7] (hereafter referred to as the "2006 Breast Implant Guidance") and should not be construed as a replacement for that prior guidance. Manufacturers should consider both the recommendations in this draft guidance, when finalized, as well as the recommendations in the 2006 Breast Implant Guidance, unless it is specifically noted that the recommendations in this guidance supersede the 2006 Breast Implant Guidance (see Section V. A Rupture Screening Recommendations Update and Section V. C Patient Device Card below).

We note that accurate product labeling and effective communication of that labeling are important to help ensure that patients are aware of the risks associated with breast implants prior to undergoing implantation. Moreover, a device shall be deemed misbranded if, among other things: its labeling is false or misleading; its labeling does not contain adequate warnings; or any information required to be in the labeling is not prominently placed with such conspicuousness and in such terms to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use (see sections 502(a), 201(n), 502(c), and 502(f)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)).[8]

IV. Labeling Components

FDA recommends that the patient labeling for breast implants include a patient information booklet/brochure, patient decision checklist, boxed warning, and patient device card. Specifically, FDA believes manufacturers should include a boxed warning and patient decision checklist to help ensure patients receive and understand information about the benefits and risks of breast implants. This section contains FDA's format and content recommendations for these components, and to help illustrate, FDA has provided examples of each in the appendices.

A. Boxed Warning

FDA believes that a boxed warning should be part of physician and patient labeling materials for breast implants. In general, boxed warnings are noticeable and easy to read and understand, and FDA believes a boxed warning here would be particularly useful in communicating risks that have been identified in new information and for which patients may be unaware. To achieve the goals described above, FDA recommends that a boxed warning generally inform patients that:

- Breast implants are not considered lifetime devices;

[7] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/saline-silicone-gel-and-alternative-breast-implants.

[8] Under section 301(a) of the FD&C Act, it is a prohibited act to introduce or deliver for introduction into interstate commerce any device that is misbranded.

- The chance of developing complications increases over time;
- Some complications will require more surgery; and
- Breast implants have been associated with the risk of developing BIA-ALCL and may be associated with systemic symptoms.

FDA believes that this form and content of boxed warning will help to ensure that patients receive and understand information regarding the benefits and risks of these devices. An example of a boxed warning that follows these recommendations is provided in **Appendix A**.

B. Patient Decision Checklist

FDA also believes that a patient decision checklist highlighting key information regarding risks should be included at the end of the patient information booklet/brochure.

To help ensure the checklist is read and understood by patients, FDA recommends the following elements and organization tips. First, FDA recommends that the introduction for the checklist include a description of the purpose and importance of the checklist, as well as instructions to patients on how to review and complete the document prior to deciding whether to undergo the implant procedure. Next, to achieve the goals described above, FDA recommends that the body of the checklist include the following:

- Situations in which the device should not be used or implanted;
- Considerations for a successful breast implant candidate;
- Risks of undergoing breast implant surgery;
- Importance of appropriate physician education, training and experience;
- Risk of BIA-ALCL and systemic symptoms; and
- Discussion of options other than breast implants.

Additionally, to help ensure the material is reviewed, FDA recommends the checklist allow for patients and physicians to affirmatively acknowledge (e.g., via initials and/or signatures) that specific information was read and discussed.

FDA recommends that a copy of the patient decision checklist be provided to the patient so that the patient can refer back to this important information. The FDA also encourages device manufacturers to develop a plan to ensure that patients are adequately informed of the risks of breast implants and breast implant surgery, to update the checklist as additional data is collected with post-market experience, and to provide a dedicated website link for each device that allows providers involved in the care of breast implant patients and patients with that specific breast implant to regularly monitor changes to the patient decision checklist, boxed warning, and product label. FDA specifically recommends that the rates of BIA-ALCL included in the patient decision checklist reflect current information based on estimated incidence rates. These rates include overall incidence rates of BIA-ALCL, as well as rates for the manufacturer's specific breast implant based on published literature, registries, and medical device reports.

An example of a checklist that follows these recommendations is provided in **Appendix B**. Please note the rates for risks provided in this example checklist are derived from percentages of reported complications for approved breast implants in publicly available summaries of safety and effectiveness data (SSEDs) at the time of issuance of this guidance document. These numbers are provided for illustrative purposes only. FDA recommends that manufacturers' patient decision checklists identify the percentages of reported complications for their specific implants based on current information.

V. Additional Labeling Recommendations

This section contains additional labeling recommendations for the physician and patient labeling of breast implants. Specifically, this section includes recommendations on rupture screening for silicone gel-filled breast implants, materials/device description in the product labeling of breast implants filled with saline or silicone gel indicated for breast augmentation or breast reconstruction, and a patient device card.

The updated rupture screening recommendations follow the consensus recommendation of the Panel to remove the current FDA MRI screening recommendations, and to adopt screening recommendations that begin between years 5 and 6 post surgery, and occur every 2-3 years after that.[9] Additionally, FDA is also recommending ultrasound as an acceptable alternative for screening asymptomatic patients pursuant to the Panel's recommendation. These additional labeling recommendations were discussed at the March 2019 Panel Meeting.[10]

As noted above, manufacturers should consider both the recommendations in this draft guidance, when final, as well as the recommendations in the 2006 Breast Implant Guidance, unless it is specifically noted that the recommendations in this guidance supersede the 2006 Breast Implant Guidance (see Section V. A Rupture Screening Recommendations Update and Section V. C Patient Device Card below).

A. Rupture Screening Recommendations Update

When final, the recommendations below supersede the labeling recommendations with respect to rupture screening in Sections 10.2 and 10.3 of the 2006 Breast Implant Guidance. The magnetic resonance (MR) screening recommendations in Section 8.5 of the 2006 Breast Implant Guidance related to premarket studies are consistent with current recommendations. We recommend the physician and patient labeling for silicone gel-filled breast implants[11] include the specific, updated rupture screening recommendation as shown below:

[9] 24-hour Panel meeting summary available at, https://www.fda.gov/media/122960/download.

[10] For more information and meeting materials, see https://www.fda.gov/advisory-committees/advisory-committee-calendar/march-25-26-2019-general-and-plastic-surgery-devices-panel-medical-devices-advisory-committee.

[11] Saline filled breast implants do not have screening recommendations as rupture is detectable without screening.

Physician Labeling:

For asymptomatic patients, the first ultrasound or magnetic resonance imaging (MRI) should be performed at 5-6 years postoperatively, then every 2 years thereafter.

For symptomatic patients or patients with equivocal ultrasound results for rupture at any time postoperatively, an MRI is recommended.

Patient Labeling:

It is recommended that you have periodic imaging of your silicone gel-filled breast implants to screen for implant rupture regardless of whether your implants are for cosmetic augmentation or reconstruction. These recommendations do not replace other additional imaging that may be required depending on your medical history or circumstances (i.e., screening mammography for breast cancer).

Even if you have no symptoms, you should have your first ultrasound or MRI at 5-6 years after your initial implant surgery and then every 2 years thereafter. If you have symptoms at any time or uncertain ultrasound results for breast implant rupture, an MRI is recommended.

B. Materials/Device Descriptions

At the March 2019 Panel meeting,[12] patients and panel members expressed concern about not knowing the materials used in breast implants and the possible deleterious health effects of these materials. They emphasized the importance of greater communication and transparency regarding the materials present in breast implants to help patients to make an informed decision about implantation in light of potential adverse effects due to these materials, including in the event of rupture, leakage or diffusion. Therefore, in addition to the recommendations provided in Section 10.3 of the 2006 Breast Implant Guidance, FDA recommends the patient information booklet/brochure also include a detailed device description of the materials of construction of the breast implant shell and filling in a format that is understandable to the patient. **Appendix C** provides an example of a format that follows these recommendations. Please note the concentrations included in the Materials Device Description Example in **Appendix C** are provided for illustrative purposes only.

Although this information is currently publicly available in the FDA Summary of Safety and Effectiveness Data (SSED) for each of the approved breast implants,[13] FDA recommends this detailed device description information be available and easily accessible to the patients to help ensure transparency and patient safety. This device description information is intended to help inform the patients of the types and quantities of chemicals and heavy metals that are detected in breast implants. The patient should also be informed that most of these chemicals stay inside the

[12] For more information and meeting materials, see https://www.fda.gov/advisory-committees/advisory-committee-calendar/march-25-26-2019-general-and-plastic-surgery-devices-panel-medical-devices-advisory-committee.
[13] See https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm.

shell of the implant but small quantities have been found to diffuse (gel bleed) through the implant shell, even if the implant is intact and not ruptured or leaking.

C. Patient Device Card

Breast implants are subject to medical device tracking requirements under section 519(e) of the FD&C Act; tracking is intended to facilitate notification and recall in the event a device presents a serious risk to health that requires prompt attention. As such, we believe it is important to include specific information related to the device in the patient device card. When final, the recommendations below supersede the labeling recommendations with respect to the patient device card in Section 10.4 of the 2006 Breast Implant Guidance.

This piece of labeling has been referred to in different ways by manufacturers, such as manufacturer device card, patient identification card, or patient information card. Regardless of the name used, the purpose of the patient device card is to provide patients with specific information about their device(s). As such, FDA recommends that the card clearly be labeled so that the physician can easily find it and provide it to the patient immediately following surgery.

Additionally, we recommend that the device card include, but need not be limited to, the following information:

- A statement that "This card belongs to the patient. Please give it to the patient."
- Device's serial or lot number;
- Device's style and size;
- Unique Device Identifier (UDI);[14]
- Boxed Warning; and
- Web link to access most current patient decision checklist, boxed warning, and labeling for the specific implant that the patient received.

[14] For additional details on the requirements for the unique device identifier, see FDA's Unique Device Identification System final rule (78 FR 58785 (Sep. 2013)).

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Appendix A: Boxed Warning Example

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 paint, 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.**

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Appendix B: Patient Decision Checklist Example

To the patient considering breast implants filled with saline or silicone gel intended for breast augmentation or breast reconstruction:

The review and understanding of this document is a critical step in making the decision whether you should choose breast implant surgery. You should learn about breast implants and then carefully consider the benefits and risks associated with breast implants and breast implant surgery before you make that decision. This form lists important risks, including those known or reported to be associated with the use of the device based on information from clinical trials, scientific literature, and reports from patients who have undergone device placement.

The patient labeling should include the patient information booklet/brochure, patient device card, boxed warning and patient decision checklist. This patient decision checklist is intended to supplement the additional patient labeling that should be provided to you by your physician. After reviewing the information in the patient information booklet/brochure for the specific implant that will be used, please read and discuss the items in this checklist carefully in consultation with your physician. You should place your initials in the location provided next to each item to indicate that you have read and understood the item. Your full signature at the end of this document means that you have read the materials and that your physician has answered all questions to your satisfaction.

Considerations for a Candidate for Successful Breast Implantation

I understand that I am not a candidate for breast implants if any of the following situations applies to me:

- I have an active infection anywhere in my body;
- I have an existing cancer or pre-cancer of my breast tissue that has not been adequately treated; or
- I am pregnant or nursing.

I understand that if I have any of the following conditions, I may be at a higher risk for a poor surgical outcome:

- Autoimmune disease (e.g., Hashimoto's, Lupus, Rheumatoid Arthritis) or family history of autoimmune disease;
- Medical condition that affects my body's ability to heal (e.g., diabetes, connective tissue disorder);
- Active smoker or a former smoker;
- Currently taking drugs that weaken the body's natural resistance to disease, such as steroids and chemotherapy drugs (e.g., prednisone, tacrolimus, sirolimus, mycophenolate, azathioprine, cyclosporine, methotrexate, chlorambucil, leflunomide, or cyclophosphamide);

- History of chemotherapy or planned chemotherapy following breast implant placement;
- History of radiation therapy or planned radiation following breast implant placement;
- Conditions that interfere with wound healing or blood clotting (e.g., hemophilia, von Willebrand disease, factor V leiden, hyperhomocysteinemia, protein C deficiency, anti-thrombin III deficiency, or systemic lupus erythematosus); or
- Reduced blood supply to the breast tissue.

I understand the following conditions have not been adequately studied to determine whether the conditions put me at higher risk:

- Clinical diagnosis of depression or other mental health disorder (including body dysmorphic disorder or eating disorder); or
- Have other products permanently implanted in the breast.

Patient Initials: _____

Risks of Breast Implant Surgery

I understand that there are risks of undergoing breast implant surgery. I understand that risks of undergoing breast implant surgery may include:

- bleeding (may occur but specific rates are not publicly available in SSEDs),
- hematoma (reported in up to 2.8% of procedures),
- infection requiring possible removal of implant (reported in up to 9% of procedures),
- scarring (reported in up to 7% of procedures),
- breast pain (reported in up to 36.5% of procedures),
- chronic pain (may occur but specific rates are not publicly available in SSEDs),
- skin or nipple areola sensitivity changes or loss (reported in up to 35% of procedures),
- inability to breast feed (reported in up to 1.6% of procedures),
- asymmetry (reported in up to 28% of procedures),
- fluid collections (seroma) (reported in up to 6.5% of procedures),
- swelling (reported in up to 9% of procedures),
- damage to deeper structures (may occur but specific rates are not publicly available in SSEDs),
- tissue death of my breast skin or nipple (reported in up to 2% of procedures),
- impact of aging or weight change on size and shape of breast (reported in up to 10% of procedures),
- impact on imaging of breast tissue (may occur but specific rates are not publicly available in SSEDs) and
- risks of anesthesia (reported in up to 1% of procedures).

My provider has discussed these risks and has provided me with the patient information booklet/brochure with information on the types of risks that are possible and expected rates of occurrence.

My physician has discussed the potential use of other implanted products during my breast implant surgery. My physician has also discussed the risks and benefits of using these implanted products and their planned surgical approach.

Patient Initials: _____

Risk of Cancer - Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

I understand that breast implants are associated with the development of a type of cancer of the immune system called Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). The current information available suggests that the risk of developing BIA-ALCL varies from 1 in 3,817 to 1 in 30,000 patients with textured breast implants. I understand that this cancer has been reported more frequently for textured breast implants, but that patients with smooth surfaced implants have also been diagnosed.

I understand that patients with breast implants have a higher risk of developing BIA-ALCL within the scar tissue and fluid surrounding the breast implant.

I understand that BIA-ALCL typically takes several years to develop after implantation, but cases have been reported as early as within one year. Typical symptoms to be aware of include: swelling, breast tightness, pain, lumps, or swelling of the breast months or years after I receive my implants.

I understand that treatment for BIA-ALCL involves an operation to remove the implants and the surrounding scar tissue capsule. Based on the stage of the cancer at diagnosis, some patients have required chemotherapy or radiation. While BIA- ALCL typically responds well to therapy, some patients have died from BIA-ALCL. Diagnosis and treatment may be at my own expense and is not always covered by insurance.

Patient Initials: _____

Systemic Symptoms

I understand that some patients who have received breast implants have reported a variety of systemic symptoms including joint pain, fatigue, rash, memory loss, and "brain fog" that some patients have called breast implant illness. While the causes of these symptoms are unclear, some patients have reported relief of these symptoms with removal of their implants and surrounding scar tissue capsule. Researchers are working to better understand the possible link between breast implants and these symptoms.

I also understand that some patients with breast implants have reported health problems in their children after birth or breastfeeding. While a causal link between breast implants and these reported health problems in children has not been demonstrated, more research is needed.

Patient Initials: _____

Breast-Implant Specific Risks

I understand that a breast implant is NOT a lifetime device and the longer I have my implants, the more likely I am to experience a complication and the more likely I am to require a reoperation requiring the replacement or removal of my breast implant. As many as 20 percent of women who receive breast implants for augmentation have to have their implants removed within 8 to 10 years, but my implants may last for a shorter or longer time.

I understand that my breast implant may rupture or leak. I understand that if I have a saline-filled implant, my breast may deflate in appearance if there is a rupture or leakage of the saline.

I understand that if I have a silicone gel-filled breast implant, I or the doctor may not be able to tell on physical exam whether my implant has ruptured or is leaking silicone gel. Because rupture or leakage of silicone gel-filled breast implants is difficult to detect, I understand that periodic imaging evaluation is recommended for screening of silicone gel-filled breast implant rupture. It is recommended that I have periodic imaging of my silicone gel-filled breast implants to screen for implant rupture regardless of whether my implants are for cosmetic augmentation or reconstruction. These recommendations do not replace other additional imaging that may be required depending on my medical history or circumstances (i.e., screening mammography for breast cancer).

Even if I have no symptoms, I should have regular imaging evaluations as described in the "Recommended Follow-Up" section below. These imaging evaluations may not detect all ruptures or leaks, be costly, and the expense may not be covered by my medical insurance.

I understand that silicone can migrate from my implant into nearby tissues (e.g., chest wall, lymph nodes under the arm) and organs (e.g., liver, lungs) where it may not be possible to remove. Ruptured silicone implants should be removed as soon as possible because they may cause health problems.

I understand that all breast implants can interfere with mammography and breast exams, which could delay the diagnosis of breast cancer. Mammography can also cause the breast implant to rupture or leak. I should tell the mammography technician if I have breast implants.

I understand that the long-term risks of breast implants may include:

- painful or tightening of scar tissue around my implant (capsular contracture) (reported in up to 51.7% of patients),
- rupture or leaking of the implant (reported in up to 31.2% of patients),
- wrinkling of the implant (reported in up to 20% of patients),
- visibility of the implant edges (reported in up to 6% of patients),
- shifting of the implant (reported in up to 11.5% of patients), or
- need for reoperation (reported in up to 59.7% of patients).

I understand that I will receive a patient device card after my surgery that has information on each of my specific implants. I understand that it is important for me to keep each card in case I or my doctor need to know what kind of implant I have many years later.

I understand that all breast implants contain chemicals and small amounts of heavy metals. A list of the components, chemicals, and heavy metals is available in the patient information booklet/brochure.

Patient Initials: _____

Recommended Follow-up

Even if I have no symptoms, I should have my first ultrasound or MRI at 5-6 years after my initial implant surgery and then every 2 years thereafter. If I have symptoms or uncertain ultrasound results for breast implant rupture at any time, an MRI is recommended.

I understand that I will need routine and regular follow up with my physician as long as I have a breast implant for examination of my breast implant as well as to discuss any updates regarding breast implant issues.

Patient Initials: _____

Questions for My Physician

I have had the opportunity to ask my physician questions about his or her experience, medical degree, specialty of training, and credentials. I understand that breast implants have associated procedural risks and should only be used by physicians who are appropriately trained.

Patient Initials: _____

Options Following Mastectomy

I understand that breast reconstruction is an elective procedure which I can choose to do or not.

I understand that I may choose not to have breast reconstruction ("going flat") and may choose to use an external prosthesis in my bra to look like I have a breast when wearing clothes.

I understand the surgical options for breast reconstruction, including the use of a breast implant and the use of my own tissue ("autologous reconstruction").

I understand that if my breast implants are ever removed I may be left with dimpling, chest wall concavity, puckering, or sagging of my breasts or skin.

I understand that more surgeries may be necessary in the future due to complications or to remove or replace the breast implants.

I have discussed all of the options for breast reconstruction with my provider, including whether I am a candidate and the benefits and risks of each, and I believe that breast reconstruction with a breast implant is the best option for me.

Patient Initials: _____

Breast Augmentation Options

I understand that breast augmentation is an elective procedure to increase the size of my breasts.

I understand that breast augmentation may result in permanent changes to my breast tissue and if my implants are ever removed I may be left with changes to size and shape of my breasts, including but not limited to dimpling, puckering, or sagging.

If I am an augmentation patient, any additional surgeries or medical procedures will likely be at my own expense.

Patient Initials: _____

CONFIRMATION OF DISCUSSION OF RISKS

Patient: I acknowledge that I have received and read the patient information booklet/brochure for the specific implant that will be used during my surgery and that I have had time to discuss the information in it and on this document with my doctor. I have had the opportunity to ask questions and understand the benefits and risks of breast implants for me, given my specific health conditions. I have considered alternatives to breast implants, including reconstruction without breast implants, no reconstruction/augmentation, and their benefits and risks.

_____

Patient Signature and Date

Physician: I acknowledge that I have discussed the benefits and risks of breast implants as described in the patient information booklet/brochure as well as this document. I have also explained the benefits and risks of the alternatives. I have encouraged the patient to ask questions, and I have addressed all questions.

_____

Physician Signature and Date

Appendix C: Materials Device Description Example

FDA recommends that patient labeling include tables listing breast implant materials, chemicals that can be released from breast implants and heavy metals present in breast implants. The following tables provide examples for providing this information.

1. Breast Implant Device Materials

Device Materials
Dimethyl Silicone Elastomer Dispersion
Diphenyl Silicone Elastomer Dispersion
MED 4750 Silicone Elastomer
Silicone Gel
Platinum catalyst

2. Chemicals Released by Breast Implants

Volatiles: Chemicals that are released by breast implants as a gas.

Extractables: Chemicals that are released by breast implants following soaking in water and/or organic solvent (liquid).

Volatiles		Extractables	
Compound	Whole Device (ppm*)	Compound	Whole Device (ppm)
D_3 Siloxane	0.18	D_3 Siloxane	0.5
D_4 Siloxane	0.46	D_4 Siloxane	<2.5
D_5 Siloxane	1.47	D_5 Siloxane	<4.8
Methoxytrimethylsilane	0.43	D_6 Siloxane	<8.4
Dimethoxydimethylsilane	0.03	D_7 Siloxane	<8.4
Methoxytriethoxysilane	ND	D_8 Siloxane	<8.3
Tetramethyldiethyldisiloxane	0.04	D_9 Siloxane	<10.92
Acetone	0.18	D_{10} Siloxane	<21.86

Isopropanol	0.26	D_{11} Siloxane	32.92
2-Pentanone	ND	D_{12} Siloxane	47.85
Methyl Butanoate	0.01	D_{13} Siloxane	113.11
Ethylbenzene	ND	D_{14} Siloxane	172.4
m- & p-xylene	0.08	D_{15} Siloxane	203.8
4-Methyl-3-penten-2-one	0.01	D_{16} Siloxane	584.9
o-xylene	ND	D_{17} Siloxane	533.0
Alpha-Pinene	ND	D_{18} Siloxane	429.4
Cyclohexanone	ND	D_{19} Siloxane	609.9
1-Ethyl-2-methylbenzene	0.01	D_{20} Siloxane	775.5
Decane	ND	o-Xylene	<0.4
Benzaldehyde	0.01	Siloxane	3.9
1,3,5-Trimethylbenzene	0.01	Di(Ethylhexyl) Phthalate	ND
Limonene	0.01	**Total Extractables (µg/g)**	**<4086.7**
Undecane	0.35		
Acetophenone	0.01		
Dodecane	0.07		
Total Volatiles	**3.67**		

Data preceded with a "<" symbol means that the level of the individual component, if present, was below the method detection limit indicated. ND=Not detected.
*ppm = parts per million

3. Heavy Metals Found in Breast Implants

Heavy Metals	
Metal	**Concentration (ppm)**
Antimony	0.014
Arsenic	0.123
Barium	0.001
Beryllium	0.006
Cadmium	0.002
Chromium	0.028
Cobalt	0.052
Copper	0.025

Lead	0.011
Magnesium	0.391
Mercury	0.004
Molybdenum	0.001
Nickel	0.050
Platinum	0.299
Selenium	0.069
Silver	0.001
Tin	0.004
Titanium	0.033
Vanadium	0.310
Zinc	0.034

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