Informed Consent

Breast Augmentation with Silicone Gel-Filled Implants

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INSTRUCTIONS

This is an informed consent document to help you understand your breast implant surgery better. This procedure is also called augmentation mammaplasty surgery with silicone gel-filled implants. You will learn more about the risks of this surgery and other options for treatment.

It is important that you read this information carefully and thoroughly. Please add your initial to each page to show that you have read the page. Then, sign the consent for surgery as proposed by your plastic surgeon and agreed by you.

GENERAL INFORMATION

In November 2006, silicone gel-filled breast implant devices were approved by the United States Food and Drug Administration (FDA) for use in breast augmentation and reconstruction.

Breast augmentation is a type of surgery performed to make breasts larger for various reasons:

- To improve the body contour of a woman who, for personal reasons, feels that her breast size is too small.
- To fix a loss in breast size after pregnancy.
- To balance breast size when the breasts are of significantly different sizes.
- To restore breast shape after the breasts may have been totally or partially lost for some reason.
- To fix an issue where the breasts have not developed correctly for some reason.
- To correct or improve the results of existing breast implants, whether for cosmetic or reconstructive reasons.

Breast implant surgery should not be performed for women with untreated breast cancer or a "pre-malignant breast disorder." Surgery should not be performed for women with active infection anywhere in the body, or for women who are currently pregnant or nursing.

Some people may have a greater risk of difficulty with surgery. If you have a weak immune system (for example, from chemotherapy or if you are taking drugs to suppress your immune system), you may have more risks from surgery. You may also have higher risks if you have a condition that causes problems with blood clotting or wound healing. Certain surgeries or radiation therapy treatments that you may have had in the past can also lead to issues with surgery or its results.

According to the United States FDA, a woman must be at least 22 years old to have cosmetic breast augmentation surgery with silicone-filled breast implants.
If you are 22 years and above, you can choose to get silicone implants to change your breast shape and size. You can also get silicone implants to fix or improve the results of a breast implant surgery in the past. **There is NO age limit on having surgery to restore your breast shape after cancer, after an accident or injury, or to fix severe breast abnormalities.**

In this surgery, a surgeon will place a breast implant behind your natural breast tissue or under the muscles of your chest to increase the size of the breast. The surgeon will make careful cuts

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so that the scars are small or nearly invisible. These cuts will usually be under the breast, around part of your nipple, or in your armpit. The FDA does not recommend inserting gel-filled implants through a cut made around the belly button.

There are many types of breast implants that come in various shapes, sizes, and textures. Choosing the right implant for you depends on many factors. You will want to talk with your doctor about picking the right implant. Your surgeon can also recommend the best way to insert the implants based on your preference and body structure. The shape and size of your breasts before surgery will affect your doctor's recommendations and the results of your surgery. If your breasts are not the same size or shape before surgery, they probably won't be completely same afterward.

If your breasts sag or if you have issues with skin tone like stretch marks, you may need additional help to get the results you want. For example, you might choose a breast lift surgery to move your nipple and areola upward or remove loose skin.

Before you decide to have breast implant surgery, you must think about the following:

- No breast implants last a lifetime. You may require surgery in future to replace or remove your implants.
- The chance of developing implant-related complications increases over time.
- Some complications will require more surgery.
- Breast Implants may be associated with systemic symptoms.
- Changes that occur to the breasts after an implant surgery cannot be reversed. If you decide to remove the breast implants later, you may not like how your breasts look.
- Choosing very large implants may cause some problems and may need more surgeries to fix the problems. For example, the implants may bulge out or your skin may look wrinkled. It is also likely that you will see or feel folds in the implant. Other serious issues with very large implants may include infection or significant bruising.

NOTE: Review the Breast Implant Surgery Checklist.

ALTERNATIVE TREATMENTS

Getting silicone breast implants is a personal choice or elective surgery. There are several other choices you can make. These include not having surgery at all or using an external fake breast or padding. You can also use saline-filled breast implants. Another option is a surgery that uses tissue from another part of your body to make your breasts bigger or change their shape. These options have their own risks and potential issues that you should discuss with your doctor.

INHERENT RISKS OF BREAST AUGMENTATION SURGERY

Every type of surgery has risks. It is important for you to understand these risks and how they may affect you. Every medical procedure also has some limitations of what to expect after surgery. You can get more information about breast implants from the FDA, the sheets found in the implant package from the manufacturer, or other informational material from individual state laws.

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You should make your choice of wanting to have surgery after comparing its risks and benefits. Although most people don't face risks, you should still talk about them with your plastic surgeon. It is important to understand all the possible results of getting breast implants, including the possible problems. These problems may be linked to the type of implant or could be from issues with the surgery itself. You should talk to your doctor and read more on this topic if you are considering surgery.

Every person is different, so you may experience your own unique benefits and issues after breast implant surgery. Research suggests that most women are satisfied with the results of the surgery even if they experience some problems.

SPECIFIC RISKS OF SILICONE GEL-FILLED BREAST IMPLANTS

Implants:

Breast implants, like any other technology, can fail. When a silicone gel-filled implant breaks, the gel usually stays inside the scar tissue around the implant. This is also known as "intracapsular rupture." In some cases, the gel may not stay in this area—it moves into the breast tissue itself ("extracapsular rupture and gel migration") or to other parts of the body. Silicone that moves to another part of the body may be difficult or impossible to remove. If a breast implant breaks, it may or may not make part of your breast feel firm. The companies that make breast implants conduct research on how and why implants may break. You can get this information from the manufacturer. Read this information carefully to understand the possibility of your implant breaking.

Your breast implant might break for several reasons. These can include an injury, during a mammogram, or for no obvious reason. It is possible to damage an implant during surgery. Damaged or broken implants cannot be repaired. According to the FDA, broken or damaged implants must be replaced or removed. Breast implants are not guaranteed to last a lifetime and can wear out. You may need another surgery to replace one or both implants.

Often, a small break will be hard to notice ("silent rupture"). An ultrasound or MRI exam is used to find possible implant ruptures. The FDA recommends for ***asymptomatic patients***, the first ultrasound or MRI should be performed at 5-6 years postoperatively, then every 2-3 years thereafter. For ***symptomatic patients*** or ***patients who have equivocal ultrasound results*** for rupture at any time postoperatively, an MRI is recommended. MRIs are not 100% accurate, though. It is important to understand that you may need to pay for these scans.

Capsular Contracture:

After surgery, as a part of the normal healing process, your body makes scar tissue. Much of this scarring will be inside your breast. Sometimes this scar tissue may become tight. If it does, it can make the breast round, firm, and even painful. This may happen soon after surgery or years later. This kind of scar tightening is called "symptomatic capsular contracture." It's not possible to predict whether your scars will tighten, though the risk of having tight scars increases over time. Scar tightening can happen on one side, both sides, or not at all. It is more common when implants are placed on top of the chest muscles instead of below. Treating tightened scars may need more surgery, replacing your implants, or removing your implants. You may have more scar issues even after having additional surgery to treat the problem. Keep in mind that problems with scar tightening are more common with surgeries to change earlier implants than after your first breast surgery.

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Some surgeons believe that taking preventative antibiotics when you have dental work done or when you have a sinus or urinary tract infection may help prevent breast implant scars from tightening. Talk about this with your surgeon.

Calcification:

Calcium deposits can form in the scar tissue around the implant. These may be seen in a mammogram. They can cause pain and firmness. It is important to find out if calcium deposits that appear are from your breast implant surgery or a sign of breast cancer. If you have calcium deposits, you may need more surgery to examine or remove them.

Implant Extrusion/Tissue Death:

Several things may cause serious problems with your breast implants. If you don't have enough tissue over the implant, have problems healing, or get an infection, the implant may be visible through your skin ("exposure"). It is also possible for some or all the implant to come out of your body ("extrusion"). It's possible for your breast tissue to break down ("necrosis"). This is more likely if you've taken steroids or had chemotherapy or radiation treatment. Smoking, microwave diathermy, and excessive use of heat or cold therapy can also cause problems. In some cases, the cuts your surgeon made may not heal normally. The breast tissue may weaken ("atrophy"). If the implant pushes through layers of skin, it might become visible at the surface of your breast. If your skin breaks down and the implant is exposed, you may need to have the implant removed. There's a chance that you'll have permanent scars or other visible changes. It's impossible to predict how your body will react to surgery or how you will heal.

Skin Wrinkling and Rippling:

It's possible for both implants and breast skin to wrinkle. These wrinkles may be visible, or you may feel them, or both. Some amount of wrinkling is normal and expected with silicone gel-filled breast implants. You may have more wrinkling if you choose a textured implant or if you have thin breast tissue. It's important to know your body and what it feels like. If you feel wrinkles or folds in your breast after surgery, tell your doctor. These changes in your breast should be checked to find out what's causing them, because they can feel like a tumor.

Chest Wall Irregularities:

You may experience changes to your chest wall after the breast implant surgery. This can cause problems to your ribs.

Implant Displacement and Tissue Stretching:

It's possible for a breast implant to move, rotate, or shift after surgery. This may be uncomfortable. It can also cause your breast to look different, change shape, or have wrinkles or ripples in the skin. Some ways of placing your implant can increase the risk of it moving. You may need more surgery to correct this problem. It may not be possible to resolve this problem if it happens.

Surface Contamination of Implants:

It's possible for skin oil, lint from surgical drapes, or talc to get on the surface of the implant when it's inserted. The consequences of this are unknown.

Unusual Activities and Occupations:

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Activities and occupations that may involve things hitting or injuring your chest ("potential for trauma") could potentially break or damage your breast implants. They may also cause bleeding or fluid leakage ("seroma").

Silicone Gel Bleed:
It's possible for the silicone gel in your implant to leak from the implant itself ("silicone gel bleed"). At present, there's mixed evidence about how this could affect you. Over time, extremely small amounts of silicone gel can pass through the implant's outer layer and coat the outside of it. Studies show that silicone gel contains small amounts of platinum. This platinum can interact with your body ("zero oxidation state"). This may contribute to scar tightening ("capsular contracture") and may make your lymph nodes swell. However, most studies suggest that the extremely low levels of gel bleed do not pose a serious risk to your health.

Change in Nipple and Skin Sensation:
Your nipples and the skin of your breast may be less sensitive after getting breast implants. After many months, most people get normal feeling back. In some cases, it's possible you might partially or permanently lose feeling in your nipples and skin. Such changes may affect your sex life or your ability to breastfeed a baby.

Anaplastic Large Cell Lymphoma (ALCL):
"Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL)" is an uncommon form of cancer. It may occur after breast implant surgery. This type of lymphoma can occur in the scar formed around saline or silicone breast implants. Scientists are studying this risk and how this disease might be linked to breast implants. Lymphoma is a rare cancer of the immune system and can occur anywhere in the body.

The FDA estimates that there have been at least 733 unique confirmed cases of BIA-ALCL in the world. Most BIA-ALCL patients had textured or rough surface silicone gel-filled breast implants or temporary expanders. Researchers do not have exact numbers of disease risk. Current estimates for lifetime risk of BIA-ALCL range from 1 in 1,2207 to 1 in 86,029 in women. This depends on type of textured breast implant. BIA-ALCL usually involves the breast swelling about 8 to 10 years after the first breast implant operation. Most cases were successfully treated by removing the implant and the scar surrounding it. Some rare cases need chemotherapy and/or radiation therapy.

Stay in touch with your surgeon after your breast implant operation. See your doctor in case of symptoms such as pain, lumps, swelling, or unevenness. It is important to do regular breast self-exams. It is also important to follow your doctor's advice for care, like taking a mammogram, ultrasound, or MRI. If you have unusual test results or implant-related symptoms, you may need to pay for tests and/or methods to assess and treat your problem. These tests and methods could include getting breast fluid or tissue to run various tests, having surgery to remove the scar around the breast implant, and removing or replacing implants.

Breast Disease:
Current research doesn't prove that breast implant surgery increases your risk of breast cancer. If you have a personal or family history of breast cancer, you may have a higher risk of developing

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breast cancer than a woman with no family history of this disease. You should regularly do a self-exam of your breasts. You should also get routine mammograms as recommended by the American Cancer Society. If you notice a lump, talk to your doctor. If your surgeon notices anything unusual before or during your breast surgery, you may need additional tests or treatment, which may cost extra.

Interference with Sentinel Lymph Node Mapping Procedures:

Breast surgery procedures that involve cutting through breast tissue, like a breast biopsy, may make it harder to check how your lymph nodes drain. This is important when diagnosing or treating breast cancer.

Future Pregnancy and Breastfeeding:

Getting breast implants should not interfere with getting pregnant in the future. If you're planning to get pregnant, remember that your breast skin may stretch as your body changes. This can change the look of your breasts and may make you less satisfied with the results of your surgery. You may have difficulty breastfeeding after this operation.

DISCLAIMER

Informed consent documents give you information about a surgery you are considering. These documents explain the risks of that surgery. They also discuss other treatment options, including not having surgery. The informed consent process tries to explain your risks in a way that most patients will understand in most circumstances.

However, informed consent documents can't cover everything. Your plastic surgeon may give you more or different information. This may be based on the facts of your case and the current state of medical knowledge.

Informed consent documents are not meant to define or serve as the standard of medical care. Standards of medical care are determined based on the facts involved in an individual case. They may change with advances in science and technology. They can also change with the ways doctors practice medicine and evolve.

It is important that you read the above information carefully and get all your questions answered before signing the consent agreement on the next page.

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CONSENT FOR PROCEDURE OR TREATMENT

1. I hereby authorize Dr. Thomas Jeneby MD and such assistants as may be selected by the physician to perform the following procedure or treatment**: Breast Augmentation with Silicone Gel-Filled Implants.**

2. I have received the following information sheet: Breast Augmentation with Silicone Gel-Filled Implants.

3. I understand that, during the procedure or treatment, unforeseen conditions may require the use of different procedures or treatments than those above. Therefore, I authorize the above physician, assistants and/or designees to perform such procedures or treatments that are necessary or advisable, as determined by the above physician's professional judgment. The authority granted under this paragraph includes all additional procedures or treatments that are not known to my physician at the beginning of the above procedure or treatment.

4. I understand what my surgeon can and cannot do, and understand that there are no warranties or guarantees, implied or specific, about the outcome of the procedure(s) or treatment(s). I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not realistic. All my questions have been answered, and I understand the inherent (specific) risks to the procedure(s) or treatment(s), as well as the additional risks and complications, benefits, and alternatives. Understanding all of this, I choose to proceed with the procedure or treatment.

5. I consent to the use of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.

6. I am aware that there are potential significant risks to my health with the use of blood products, and I consent to their use should they be deemed necessary or advisable by my physician, assistants and/or designees.

7. I consent to the disposal of any tissue, medical devices, or body parts that may be removed during or after this procedure or treatment, or any additional procedures or treatments that are necessary or advisable.

8. I consent to be photographed or televised before, during, and after the procedure(s) or treatment(s), including appropriate portions of my body, for medical, scientific, or educational purposes, provided my identity is not revealed by the pictures.

9. For purposes of advancing medical education, I agree that observers may be admitted into the operating room.

10. I authorize the release of my Social Security Number to appropriate agencies for legal reporting and medical device registration, as applicable.

11. I agree to the charges associated with this procedure or treatment. I understand that the physician's charges are separate from those associated with the hospital and the administration of anesthesia. I also understand that there may be additional charges if additional procedures or treatments are necessary or advisable, and I agree to those charges, if any.

12. I realize that not having the procedure or treatment is an option, and that I can opt out of having this procedure or treatment.

13. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:

    a. THE ABOVE PROCEDURE OR TREATMENT TO BE UNDERTAKEN

    b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT

    c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

I CONSENT TO THE SURGERY AND THE ITEMS THAT ARE LISTED ABOVE (1-13).
I UNDERSTAND THE EXPLANATION AND HAVE NO MORE QUESTIONS.

_____

Patient or Person Authorized to Sign for Patient Date/Time

_____

Witness Date/Time

_____ Patient Initials

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