Informed Consent

Breast Augmentation with Saline-Filled Implants

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INSTRUCTIONS

This document is about informed consent. It will help you learn about your breast implant surgery. This procedure is also called augmentation mammaplasty with saline-filled implants. You will learn about its risks and treatment options.

It is important that you read the whole document carefully. Please initial each page. Doing so means that you have read the page. Signing the consent agreement means that you agree to the surgery that you have talked about with your plastic surgeon.

GENERAL INFORMATION

Breast augmentation is done to enlarge the breasts for the following reasons.

- To improve the body shape of a woman who 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 different sizes
- To restore breast shape after partial or total breast loss for some reason
- To address breast growth failure
- To correct or improve existing breast implants

Women with untreated breast cancer or a pre-malignant breast disorder should not get breast implant surgery. Surgery should not be performed on those with active infection in the body, or on women who are pregnant or nursing. People with a weak immune system (for example, from chemotherapy or drugs to suppress the immune system) may have more risks from surgery. Anyone with conditions that affect blood clotting or wound healing, or reduced blood supply to the breast tissue from prior surgery or radiation treatments may face greater risks and poor results.

According to the United States Food and Drug Administration (FDA), a woman must be at least 18 years old to get saline-filled breast implants for cosmetic reasons. There is no age limit for surgery to restore breast shape after cancer, trauma, or for abnormal breasts.

To enlarge breasts, the surgeon will place a breast implant either behind the breast tissue, or partially or completely under the chest muscles. Careful cuts are made to keep scars small or invisible. These cuts are usually under the breast, around the lower part of the areola, in the armpit, or around the belly button. Breast implants differ in shape, size, and texture. Implant selection and size, and the method your surgeon uses for placing the breast implants depends on your liking, body structure, and your surgeon's advice. The shape and size of the breasts before surgery will affect your surgeon's advice and results. If the breasts are not the same size or shape before surgery, they likely will not be the same after.

If your beasts sag of if you have other issues like stretch marks, you may need more surgery to get the results you want. For example, you may choose a breast lift surgery to move your nipple and areola upward or remove loose skin.

Before you decide to have breast augmentation 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.

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- 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 saline-filled implants is a personal choice. There are many other choices you can make. These include not having surgery at all or using external fake breasts or padding. You can also use silicone gel-filled 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 issues that you should discuss with your doctor.

RISKS OF BREAST AUGMENTATION SURGERY

All surgeries have some risk. It is important to know these risks. You must also understand other issues that might come up during or after surgery. Every procedure has its limits.

Choosing to have a surgery means comparing both risks and benefits. Most patients do not face problems, but you should talk about them with your plastic surgeon. Make sure you know all possible risks of breast augmentation.

SPECIFIC RISKS OF SALINE-FILLED BREAST IMPLANTS

Implants:

Breast implants, like any medical device, can fail. When a saline-filled implant breaks, the saline is absorbed by the body, but the shell remains. If this happens, it may or may not make part of your breast feel firm. The makers of breast implants study how and why implants may break. Please read these details carefully to understand the chance of your implant breaking.

Your breast implant might break for many reasons. These can be 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 assured to last a lifetime and can wear out. You may need another surgery to replace one or both implants. An ultrasound or other test (such as MRI, or magnetic resonance imagery) may be needed to find out why your implant broke. These tests may not be 100% correct. Your insurance may not cover these tests.

Saline-filled breast implants may not have the same shape or feel as silicone-filled implants. The shape of your breasts after surgery depends on many factors. These could be your skin thickness and the position of the implants. The surgeon's method and placement of the implants may also affect results. You should talk with your surgeon about possible outcomes that may not be what you wanted.

Capsular Contracture:

Your body makes scar tissue after surgery as a part of the normal healing process. Much of this will be inside your breast. Sometimes this scar tissue may become tight. This 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." We cannot predict if scars will tighten. The risk of having tight scars increases over time. It 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 and not below.

Treating tightened scars may need more surgery. You may need to replace or remove your implants. You may have more scar issues even after having more surgery to treat the problem. Scar tightening is more common with surgeries to change earlier implants than after first breast surgery. Some surgeons think that

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taking antibiotics when you have dental work, a sinus, or urinary tract infection may help prevent scars 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 know if calcium deposits are from breast implant surgery or a sign of breast cancer. You may need more surgery to assess or remove them.

Implant Exposure/Tissue Death:
Many things may cause serious problems with your breast implants. If you do not have enough tissue over the implant, have problem healing, or get an infection, the implant may be visible through your skin (exposure). Some or all the implant may come out of your body (extrusion). These things may happen if your breast tissue breaks down (necrosis). This is more likely if you have taken steroids, chemotherapy, or radiation treatment. Smoking, microwave therapy, and excess 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 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 is a chance of permanent scars or other visible changes. It is not possible to predict how your body will react to surgery or how you will heal.

Skin Wrinkling:
It is possible for both implants and breast skin to wrinkle. These may be visible and can be felt. You may have more wrinkling with saline implants, textured implants, or if you have thin breast tissue. It may be possible to feel the implant valve. You may not like the way this looks and feels. If you feel wrinkles or folds in your breast after surgery, tell your doctor. These changes in your breast may feel like a tumor and should be checked to find their cause.

Chest Wall Irregularities:
You may notice changes to your chest wall after the breast implant surgery. This can cause problems with your ribs.

Implant Movement and Tissue Stretching:
A breast implant can move, rotate, or shift after surgery. This may cause discomfort. It can also cause your breast to look different, change shape, or have wrinkles or folds in the skin. The way your surgeon places your implant can increase the risk of it moving. You may need more surgery to correct this. This problem may not be solved.

Surface Contamination of Implants:
Skin oil, lint from surgical drapes, or talc may get on the surface of the implant during insertion. The effect of this is not known.

Unusual Activities and Occupations:
Work where you may get hit or injure your chest could break or damage breast implants. This may cause bleeding or fluid leakage (“seroma”).

Change in Nipple and Skin Sensation:
Your nipples and the skin of your breast may be less sensitive after getting breast implants. Most people get their normal feeling back after many months. You may partially or permanently lose feeling in your nipples and skin. Such changes may affect your sex life or your ability to breastfeed.

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

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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 2,207 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 does not prove that breast implant surgery can increase the risk of breast cancer. If you have a personal or family history of breast cancer, you may have a higher risk of developing breast cancer. You should do a regular self-exam of your breasts. You should also get routine mammograms as advised by the American Cancer Society. Talk to your doctor if you see a lump. If your surgeon notices anything before or during breast surgery, you may need more tests or treatment. These may cost extra.

Interference with Lymph Node Examination:

"Sentinel Lymph Node Mapping" helps check if cancer has spread beyond the primary tumor. Breast surgeries that involve cutting through breast tissue, like a breast biopsy, may make it harder to check these lymph nodes. This may affect the diagnosis of breast cancer.

Future Pregnancy and Breastfeeding:

Getting breast implants should not affect getting pregnant in the future. If you are planning to get pregnant, keep in mind that your breast skin may stretch as your body changes. This can change the look of your breasts. This 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. 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.

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 way doctors practice medicine.

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 permit Dr. Thomas Jeneby MD and the doctor's assistants to do the procedure Breast **Augmentation with Saline-Filled Implants.**
2. I got the information sheet on Breast Augmentation with Saline-Filled Implants.
3. I understand that, during the surgery, an unexpected situation may require a different medical procedure than the surgery listed above. I permit the doctor listed above, the assistants and/or designees to provide any treatment that my doctor thinks is needed or helpful. My permission includes all treatments that my doctor does not plan to do at the start of the surgery.
4. I understand what my surgeon can and cannot do. I understand that no warranties or guarantees have been hinted at or stated outright about the outcome of the surgery. I have explained my goals. I understand which outcomes are realistic and which are not. All my questions have been answered. I understand the surgery's risks. I am aware of other risks and possible issues, benefits, and options. I understand and choose to have the surgery.
5. I agree to the anesthetics that are needed or helpful. I understand that all types of anesthesia have risks and may result in complications, injury, and even death.
6. I am aware of the serious risks to my health when blood products are used. I agree to my doctor using them if my doctor, assistants, and/or designees think they are needed or helpful.
7. I agree to the disposal of any tissue, medical devices, or body parts taken out during or after surgery. I also agree to any additional surgeries or treatment that is needed or helpful.
8. I agree to have parts of my body photographed or televised appropriately before, during, and after the surgery for medical, scientific, or educational reasons, if the pictures do not reveal my identity.
9. For medical education, I agree that onlookers can be in the operating room.
10. I permit my Social Security Number to be given to the right agencies for legal reasons and medical device registration, when necessary.
11. I agree to the charges for this surgery. I understand that the doctor's charges are separate from the charges for the hospital and the anesthesia. I understand that there may be more charges if more procedures or treatments are needed or helpful. I agree to those charges, if any.
12. I understand that not having the surgery is an option and that I can opt-out of having the surgery.
13. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
    a. THE ABOVE SURGERY TO BE PERFORMED
    b. THERE MAY BE OTHER SURGERIES OR TREATMENT OPTIONS
    c. THERE ARE RISKS TO THE SURGERY

I CONSENT TO THE SURGERY AND THE ITEMS 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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