



AMERICAN SOCIETY OF
PLASTIC SURGEONS®

Informed Consent

Breast Implant Exchange

INSTRUCTIONS

This is an informed consent document. It will help you learn more about breast implant exchange. You will learn about the treatment and its potential risks. You will also learn about other treatments you might choose.

It is important that you read the whole document carefully. Please initial each page. Doing so means you have read the page. Then, if you agree with your plastic surgeon's plan, please sign the consent form at the end. Signing the consent agreement means that you agree to the treatment that you have talked about with your plastic surgeon.

GENERAL INFORMATION

Breast implant exchange is a surgical procedure. The goal of this procedure is to remove damaged, unwanted, or "problematic" implants and place new implants into the breast. These new implants may be placed in the same location as the previous implants or in a new location. For example, if the old implants were below the muscle, the new implants may be placed on top of the muscle, and vice versa. If the existing implant pocket is used, the surgeon may need to adjust the pocket. They may make the pocket smaller by stitching it or bigger by releasing the pocket in certain areas. This is to make the implant stay fixed in the correct position. To maintain this position and to support the implant, your surgeon may add a piece of material (e.g., mesh). The surgeon may operate on the existing scars from previous surgery. However, in some cases, the cuts need to be extended. Sometimes, new cuts need to be made. In a few cases, the older implant may not be the issue; the tissue surrounding the implant may cause a problem (e.g. a "capsular contracture"). In such cases, a portion or all of the tissue may be removed.

ALTERNATIVE TREATMENTS

Other treatment options include not removing the implants, removing the implants but not replacing them with new implants, or removing the implants and adding more volume with fat grafting. All treatments have risks.

INHERENT RISKS OF BREAST IMPLANT EXCHANGE SURGERY

Every surgery has risks. It is important that you understand these risks. You must also understand the possible problems that can result from them. All procedures have limits. You must decide whether the possible benefits of having this surgery are better than the possible risks. Most patients do not have problems, but you should talk about each of these risks with your surgeon. Make sure you understand everything that might happen during and after a breast implant exchange surgery.

Specific Risks of Breast Implant Exchange Surgery

Asymmetry

No paired organs (eyes, ears, arms, etc.) are identical. This is also the case for the breasts. Your surgeon will try to make your breasts look equal, but there will be differences. Sometimes, this difference is minimal. Sometimes, the difference may be obvious based on your healing and body structure. More surgery may be needed if the difference is very obvious.

Malposition

Your surgeon will place the implants in the proper position. However, over time, the implants may shift depending on your healing and activity. The implants may turn, flip, or slide to a different location upwards, downwards, or toward your armpit or other breast. More surgery may be needed to correct the malposition.

Changes in Nipple Sensation

It is common to have changes in nipple sensation. There may be a decrease in sensation, but some patients feel an increase in sensation following a breast lift or breast reduction surgery. The sensation usually goes back to normal, but it may take some time. In rare cases, the changes in sensation may be permanent.

No “Size Guarantee”

It is impossible to say what your breast size will be after surgery. While people usually use “cup size” to describe their breast size, bra manufacturers use different measurements. Some bra companies are known for “glamor sizing” in which the tag shows a larger cup size than the recognized standard. This is done to make people think that they have larger breasts. While your surgeon will try to give you the results you desire, exact size and shape are not guaranteed.

Capsular Contracture

The body forms a layer of scar tissue (called “capsule”) around any foreign object inserted into the body. The same happens with breast implants. Usually, this capsule is soft and fragile. This is completely normal. In some cases, the scar tissue may thicken and tighten around the implant (called a “capsular contracture”). This may lead to abnormal appearance, change in the implant position, and pain. In the early stages of capsular contracture, your surgeon may prescribe medications to stop or even reverse its progression. If the medications do not work or the capsular contracture is severe, then surgery may be needed to remove a portion or the entire capsule.

Rupture

Breast implants are man-made. They can break or rupture from age or a specific injury to the breast area. It is difficult to predict how long a breast implant may last. It differs from person to person. Breast implants are not meant to last a “lifetime.” Sometimes, a rupture may not cause any symptoms or changes to how the breast looks. This is known as a “silent rupture.” Other times, the rupture may cause a change in breast appearance (e.g., a smaller breast in the case of ruptured saline implants, or a capsular contracture). There may be symptoms such as chronic breast pain. When you sign this consent form, you agree to have your breast implants checked at regular periods after surgery based on your surgeon’s advice. The implants may be checked using MRI, ultrasound, and routine breast examinations. If your surgeon suspects that there is an implant rupture, you may need surgery to remove or replace the implant.

Breast Disease

Research does not show that breast implant surgery increases your chances of developing breast cancer in the future. However, if you have a personal or family history of breast cancer, you may have a higher chance of developing breast cancer than others with no such family history. You should regularly self-examine your breasts. You should also get mammograms regularly, following the advice of the American Cancer Society. If you notice a lump in the breast, talk to your doctor. If your surgeon notices anything unusual before or during your breast surgery, you may need more tests or treatment, which may have extra costs.

Anaplastic Large Cell Lymphoma (ALCL)

Lymphoma is a rare type of cancer that affects the immune system. It can occur anywhere in the body. A breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is an uncommon form of lymphoma that may occur after breast implant surgery in rare cases. BIA-ALCL can occur in the scar formed around saline or silicone breast implants.

According to the FDA, there have been at least 733 confirmed cases of BIA-ALCL in the world. Most BIA-ALCL patients had rough breast implants or temporary expanders. Researchers do not have exact numbers for disease risks. The risk of developing BIA-ALCL in one’s lifetime can range from 1 in 2,207 to 1 in 86,029 in women. This depends on the type of textured breast implant. An early symptom of BIA-ALCL is breast swelling about 8–10 years after the first breast implant operation. Most cases are successfully treated by removing the implant and the scar around it. Some rare cases need chemotherapy and/or radiation therapy.

Stay in touch with your surgeon after your breast implant operation. See your doctor if you feel pain, lumps, swelling, firmness, or unevenness. It is important to do regular breast self-exams. It is also important to follow your doctor's advice for care, like getting mammograms, ultrasounds, or MRIs. If you have unusual test results or implant-related symptoms, you may need to pay for more tests and/or procedures to diagnose and treat your problem. These procedures may include extracting breast fluid or tissue for various tests, surgery to remove the scar around the breast implant, and removing or replacing implants.

Systemic Symptoms

"Systemic symptoms" are symptoms, sensations, and diseases that may occur away from the breast implant. Some patients may attribute these symptoms to the implant. Some people refer to this as "breast implant illness." Despite vast scientific research, we do not know if breast implants cause these symptoms. As different medical problems can cause similar symptoms, a detailed evaluation may be required for patients who have symptoms. Patients with these symptoms may choose to have their implants removed. However, if the implants are not causing the symptoms, then these symptoms may not go away even after removal.

Palpability

You may be able to feel the new implants through your tissue.

Wrinkling

There may be wrinkles or ripples that you can see or feel. This is more likely for saline-filled implants.

Tissue-Stretch

With time, the breast skin may stretch. This may result in sagging of the breast. You may need more surgery, such as a breast lift. Tissue stretch may be more likely with larger, heavier implants.

Motion of the Breast

In cases where the implant is placed behind the pectoral muscle, you may see temporary motion of the breast. This motion may be seen when performing physical activities that use these muscles.

Difficulties with Mammography

It may be difficult to get a clear image of the breast tissue when an implant is present. Additional imaging using ultrasound or MRI testing may be useful.

Additional Costs

Extra tests, imaging, and future surgeries may have additional costs. You may also need to take time off from work or other routine activities. You will need to bear these costs.

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. This information should meet most people's needs.

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 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 of each 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. Make sure to have all of your questions answered before signing the consent on the next page.

CONSENT for SURGERY/PROCEDURE or TREATMENT

1. I permit Dr. _____ and the doctor's assistants to perform any or all of the following operations for Breast Implant Exchange.
2. I have received the information sheet on Breast Implant Exchange.
3. I understand that, during the procedure, an unexpected situation may require a different medical procedure than the procedure listed above. I permit the doctor listed above, the assistants, and/or designees to provide any treatment(s) that my doctor thinks are needed or helpful. My permission includes all treatments that my doctor does not plan to do at the start of the procedure.
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 procedure. I have explained my goals. I understand which outcomes are realistic and which are not. All my questions have been answered. I understand the procedure's risks. I am aware of other risks and possible issues, benefits, and options. I understand and choose to have the procedure.
5. I agree to the anesthetics and medications 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 this procedure. I also agree to any additional surgeries or treatments that are needed or helpful.
8. I agree to have parts of my body photographed or televised appropriately before, during, and after the procedure 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 procedure. 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 procedure is an option and that I can opt out of having the procedure.
13. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
 - a. THE ABOVE PROCEDURE OR TREATMENT TO BE PERFORMED
 - b. THERE MAY BE OTHER PROCEDURES OR TREATMENTS
 - c. THERE ARE RISKS TO THIS PROCEDURE OR TREATMENT

I CONSENT TO THE PROCEDURE OR TREATMENT AND THE ABOVE LISTED ITEMS (1-13).
I AM SATISFIED WITH THE EXPLANATION AND HAVE NO ADDITIONAL QUESTIONS.

Patient or Person Authorized to Sign for Patient

Date/Time

Witness

Date/Time