Informed Consent

Surgical Treatment of Breast Capsule Including Capsulotomy, Capsulorrhaphy, and Capsulectomy

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INSTRUCTIONS

This document is about informed consent. It will tell you about breast implant capsule surgery. You will learn about the risks of this surgery 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

Your body forms a layer of scar tissue (capsule) around each breast implant after surgery. This is like an envelope around a letter. This capsule may shrink (capsular contracture) in some patients. This can change the implant's position. The implant can get abnormally round, firm, and sometimes painful if the capsule shrinks more. The capsule can also stretch too much and change the implant's position.

The risk of this condition increases the longer you have implants. Capsular contracture may affect one breast or both. If untreated for a long time, the tight capsule can calcify. This makes the implants even firmer.

Surgery is needed to treat capsular contracture or an implant that has moved. See the types of capsular surgery below. Your surgeon may advise getting new ones if you want to keep getting breast implants. You may decide to change the size of your implants. Your surgeon may suggest placing the implants in a new location. This could be shifting them from behind the breast tissue to behind the muscle, or *vice versa*. Your surgeon may suggest changing the type of implant. Your surgeon may suggest the use of other treatments (medication, laser, using biologic or synthetic meshes) to reduce the risk of recurrence after surgery.

Surgery is needed to remove the silicone if your silicone implants fail. This is the case even if they are soft. Surgery may be needed if the saline implants fail and the capsules have shrunk more.

You may need more surgery in the future if you are having this surgery and are getting new implants. All implants are at risk of failure or other issues. Surgery may be needed to remove or replace them.

Incisions for capsular surgery may differ from those in the first surgery. If your breasts are not the same size or shape before surgery, they will likely not be the same afterward. If your breasts sag or 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.

Types of Capsular Surgery:

Capsulotomy makes the capsule larger. The surgeon will cut the capsule in one or more places. The cut(s) will be spread open to enlarge the implant pocket and replace the implant correctly.

Capsulorrhaphy makes the capsule smaller. If the capsule is too big, the implant may be too low or off to the side. Making the capsule smaller will let the implant be held correctly. Other biological material may also be used to strengthen the repair.

Capsulectomy partially or completely removes the capsule. Your body will form a new capsule once new implants are placed. Hopefully that will be more successful.

Your surgeon will recommend a surgery based on your symptoms, the position of your implants, and whether your implants have failed.

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ALTERNATIVE TREATMENTS

Capsular surgery with implant replacement is your choice. There are many other choices you can make. These include not having surgery or using external fake breasts 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 risks and issues. You should discuss these with your doctor.

RISKS OF CAPSULAR SURGERY

All surgeries have some risk. It is important that you 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 the risks and benefits. Most patients do not face problems, buy you should talk about them with your plastic surgeon. Make sure to know all possible risks of breast implant surgery.

SPECIFIC RISKS OF CAPSULAR SURGERY

Capsular Contracture:

Your body makes scar tissue after surgery as a part of normal healing. Much of this scarring 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. More surgery may be needed to replace or remove the breast implants in that case.

Implants:

Breast implants can fail. They can break because of injury, for no obvious cause (silent rupture), or during a mammogram. An implant may get damaged during surgery. Damaged implants cannot be repaired. Ruptured or damaged implants need to be replaced or removed. When a saline implant breaks, the saline is absorbed into your body. When a gel implant breaks, ultrasound or magnetic resonance imaging (MRI) may be needed to know if your implant broke. 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. These tests may not be 100% accurate.

The shape of your breasts after surgery depends on many factors. These could be skin thickness and the position of the implants. The surgeon's method may also affect results. You should talk with your surgeon about the possible outcomes that may not be what you wanted.

Skin Wrinkling:

It is possible for the implants and breast skin to wrinkle. These may be visible, felt, or both. You may have more wrinkling with saline implants, textured implants, or if you have thin breast tissue. You may have more wrinkling with implants placed over the chest muscles. You may feel the implant valve.

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 if calcium deposits are from your breast implant surgery or a sign of breast cancer. You may need more surgery to assess or remove calcium deposits.

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 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.

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Use of Non-living Biological Tissue:

Your surgeon may use other biological tissue to secure the implant in place. Usually, this tissue comes from a human cadaver, pig or cow tissue. You should ask your surgeon about these materials. They help form the pocket around the implant and provide more cover for it. Your cells will move into the tissue and make it your own. These products may produce fluid. They need to be drained for a long period. They may increase your risk of infection.

Implant Exposure & Tissue Death:

Various 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"). This may happen if your breast tissue breaks down ("necrosis"). This is more likely if you have taken steroids, chemotherapy, or radiation treatment. Smoking and excess heat or cold therapy can also cause issues. In some cases, the cuts your surgeon made may not heal normally. You may have to remove the implant if your skin breaks down and the implant is exposed.

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 develop 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. It can occur anywhere in the body.

The FDA estimates that there have been at least 733 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 the type of textured breast implant. BIA-ALCL usually involves the breast swelling about 8 to 10 years after the first breast implant. Most cases were 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 surgery. See your doctor if you have 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 mammography, ultrasound, or MRI. If you have unusual test results or implant-related symptoms, you may need to pay for more tests and/or procedures. These tests and procedures 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 increases 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 notice a lump. If your surgeon notices anything before or during your breast surgery, you may need more tests or treatment. These may cost extra.

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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 Implant Capsules.**
2. I got the information sheet on Breast Implant Capsules.
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

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