



# Informed Consent

## Surgical Treatment of Breast Capsule via Capsulectomy



## **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.

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.

## **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.

## **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, but 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 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.

### **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.

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.



**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.**



### CONSENT FOR PROCEDURE OR TREATMENT

1. I permit Dr. Matthew C Camp and the doctor’s assistants to do the procedure **Breast Capsulectomy**.
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 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 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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## Informed Consent – Breast Implant Capsules

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\_\_\_\_\_ Patient Initials

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