Informed Consent

Breast Implant Removal

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INSTRUCTIONS

This is a document about informed consent. This well tell you more about your breast implant removal surgery. You will learn about the risks and other 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

Surgery is needed to remove breast implants. This may be a simple implant removal without removal of the capsule tissue around the implant. Or the surgery may have more procedures such as:

- Removal of the capsule tissue around your breast implant (capsulectomy)
- Removal of leaked silicone gel in your breast tissue (extracapsular, or outside the capsule layer) from silicone implants (breast biopsy)
- Breast lift (mastopexy following breast implant and/or capsule removal)

Broken or damaged implants cannot be repaired. Surgery is needed to remove or replace the implants. You may be able to choose either general or local anesthesia for breast implant removal.

There are both risks and possible issues with this surgery.

If you choose to have revisions made to your breast implants, you must sign other consent documents also. This document is for the permanent removal of breast implants and/or capsule tissue around the implants, or a breast biopsy to remove leaked silicone gel.

If you choose to have a breast lift at the same time of breast implant removal, you must sign another informed consent document.

OTHER TREATMENTS

There are other treatment options. These include not having surgery at all, or having other procedures to replace, relocate, or revise existing implants. These options have their own risks and issues. You should discuss these with your doctor.

RISKS OF BREAST IMPLANT REMOVAL 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 you know all possible risks of breast implant removal.

SPECIFIC RISKS OF BREAST IMPLANT REMOVAL SURGERY

Skin Wrinkling:

Wrinkling of the breast skin can occur. These may be visible, felt, or both. More surgery may be needed to tighten loose skin after breast implants are removed. Your breasts will have much lesser volume after implants are removed.

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Ruptured Silicone Gel-Filled Breast Implants:

Breast implants can fail. Silicone gel can enter the body when a silicone implant breaks. Implants can break as they are being removed. If an implant breaks, it may not be possible to completely remove all the leaked silicone gel. It may not be impossible to completely remove the shell of textured breast implants. Calcification can occur around implants. The scar tissue around the implant may need to be removed (capsulectomy). It may not be possible to completely remove the scar tissue around a breast implant. More surgery might be needed to remove all of these things.

An ultrasound or MRI exam is used to find possible implant ruptures. 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.

Delayed Healing and Tissue Death:

Some areas of the breast skin or nipple may not heal normally. They may take a long time to heal. Areas of the skin or nipple tissue may die. Tissue death (necrosis) can occur with many breast surgeries. This includes implant removal. Necrosis may be likely if steroid drugs have been used or after chemotherapy/radiation for breast tissue. Necrosis may also be due to smoking, microwave treatments, and excess heat or cold therapy. Dressing changes may be needed often. More surgery may be needed to remove the non-healed tissue. If you have less blood supply to breast tissue from past surgery or radiation therapy, you may be at increased risk for delayed wound healing and poor outcomes. Smokers are at greater risk of skin loss and wound healing issues.

Change in Nipple and Skin Sensation:

Your nipples and breast skin may be less sensitive after surgery. The sensitivity usually comes back in three to four weeks. Partial or permanent loss of the nipple and skin sensation is rare. However, this is more likely if the surgery area is large. This occurs during scar tissue or silicone gel removal from a broken implant.

Skin and Shape Irregularities:

Surgery may cause skin and shape issues. There may be wrinkling. This could be seen or felt. One breast may be smaller than the other. Nipple position and shape will not be the same on each side. Skin issues at the ends of the incisions or “dog ears” are may occur when there is extra skin. This may improve with time, or more surgery may be needed.

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 see 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 Removal.**
2. I got the information sheet on Breast Implant Removal.
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 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

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