



Informed Consent

Saline Breast Implant Deflation

I confirm that I have SALINE (salt water)-filled implants and NOT silicone gel-filled implants or double lumen implants (both saline and silicone gel).
Deflation of implants filled with silicone gel is NOT possible. It may cause problems in the future and may need surgery.

PATIENT SIGNATURE _____

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INSTRUCTIONS

This is an informed consent document. It will help you learn more about saline breast implant deflation. You will learn about the procedure 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

Sometimes, it may be better to deflate saline breast implants before surgery instead of removing the implant. To deflate an implant, a needle is placed through the skin. Then, a small hole is made in the implant to remove the salt water inside. As this permanently damages the implant, the implant's warranty is considered void. The deflated implant cannot be repaired. The results can only be reversed by placing a new implant. The implant shell may be left in place or taken out later.

For patients with SALINE-filled (not silicone gel) breast implants, the implant can be drained intentionally. This is done when a patient does not desire the breast size or shape that the saline implant provides.

___ I confirm that the implants to be deflated are filled with saline water and not silicone gel or any other material.

___ I understand that if the implants are not filled with saline water and an attempt is made to deflate them, the breast implant material will enter my body. I understand that the material can then be removed only with surgery.

___ I understand that deflating an implant will permanently damage it and that it cannot be used again. The procedure is not reversible unless a new implant is placed by surgery.

___ I understand that after deflating an implant, I may not be happy with the result. I also understand that my breast cannot be changed to how it looked before unless a new implant is placed by surgery.

___ I understand that I must bear the costs for any problems resulting from implant deflation. This includes any corrective surgery or other procedures if I am unhappy with the result or if a complication occurs.

ALTERNATIVE TREATMENTS

An alternative treatment is removing the implant completely.

INHERENT RISKS OF SALINE BREAST IMPLANT DEFLATION

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 saline breast implant deflation.

Specific Risks of Saline Breast Implant Deflation

Bleeding

There may be some bleeding during or after surgery, although it is rare. You may need emergency treatment if there is bleeding. Do not take aspirin or anti-inflammatory medications for ten days before surgery. Such medications may increase the chances of bleeding. Nonprescription "herbs" and dietary supplements can also increase the chances of bleeding.

Infection

Infection rarely occurs after this procedure. However, if it occurs, treatment with antibiotics or additional surgery may be needed.

Skin Scarring

In rare cases, there may be a small scar where the needle is inserted.

Seroma

Tissue fluid may collect in the space where the breast implant was located. You may need more treatment or surgery to remove this fluid.

Psychological/Appearance Changes

Breast implant deflation may greatly affect how you look. You may lose your breast volume or shape. The skin may become wrinkled. Your appearance may be worse than before your breast implant surgery. You may have severe psychological problems such as depression. You or your partner may lose interest in sex.

Other

Your breasts may become asymmetrical after deflating the implant. You may not like the results of the procedure. Additional surgery may be necessary to reshape the breasts and to remove the deflated implant shell(s).

You may be able to feel the shell(s) of the deflated implant through your skin. Sometimes, the area over the implant may become tender.

Allergic Reactions

In rare cases, tape, suture materials, or topical substances may cause local allergies. There may be systemic reactions to drugs used during surgery and prescription medicines. These reactions may require additional treatment.

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 particular case and current 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 Saline Breast Implant Deflation.
2. I have received the information sheet on Saline Breast Implant Deflation.
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