

TOM J. POUSTI, MD, F.A.C.S.
PLASTIC AND RECONSTRUCTION SURGERY

INFORMED-CONSENT-BREAST IMPLANT REMOVAL SURGERY

INSTRUCTIONS:

This is an informed-consent document that has been prepared to help your plastic surgeon inform you concerning breast implant removal, its risks, and alternative treatment.

It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page and sign the consent for surgery as proposed by your plastic surgeon.

INTRODUCTION:

The removal of breast implants that have been placed either for cosmetic or reconstructive purposes is a surgical operation. Breast implant removal may be performed as a single procedure or combined with additional procedures such as:

- Removal of scar tissue surrounding the breast implant
- Breast biopsy
- Removal of escaped silicone gel
- Secondary breast augmentation
- Breast lift (mastopexy)

Implants that are found to be damaged or ruptured cannot be repaired; surgical removal or replacement is recommended. There are options concerning general versus local anesthesia for breast implant removal.

There are both risks and complications associated with this operation.

ALTERNATIVE TREATMENT:

Alternative forms of non-surgical management consist of not undergoing breast-implant removal or additional procedures.

RISKS of BREAST-IMPLANT REMOVAL:

Every surgical procedure involved a certain amount of risk and it is important that you understand that risks involved with surgery to remove breast implant (s). An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. Although the majority of women do not have these complications, you should discuss each of them with your plastic surgeon to make sure you understand the risks, potential complications, and consequences of breast implant removal.

BLEEDING:

It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain accumulated blood or blood transfusion. Do not take any aspirin or anti-inflammatory medications for ten days before surgery, as this contributes to a greater risk of bleeding.

INFECTION:

Infection is unusual after this surgery. Should an infection occur, treatment including antibiotics or additional surgery may be necessary.

CHANGE IN NIPPLE AND SKIN SENSATION:

Your breasts will be sore after surgery, and you may experience a change in the sensitivity of the nipples. This usually resolves in 3 to 4 weeks. To have decreased or permanent loss in nipple sensation is more likely to occur if extensive surgical dissection is needed to remove scar tissue or silicone gel from a broken implant.

SKIN SCARRING:

Although good wound healing after a surgical procedure is expected, abnormal scars may occur both within the skin and deeper tissues. Excessive scarring is uncommon. Additional treatments including surgery may be needed to treat abnormal scarring.

FIRMNESS:

Excessive firmness of the breasts can occur after surgery due to internal scarring. The occurrence of this is not predictable.

SEROMA:

Tissue fluid may accumulate in the space where the breast implant was located. Additional treatment or surgery may be necessary to remove this fluid.

IMPLANTS:

As with any man-made object implanted in the human body, device failure can occur. It is possible that an implant can rupture causing silicone gel to be released from the implant. Implants also can rupture during the removal process. If implant rupture has occurred, it may not be possible to completely remove all of the silicone gel that has escaped. Implant shell material of textured breast implants may be possible to completely remove. Calcification around implants can occur and may require removal of the scar tissue surrounding the implant. It may not be possible to completely remove the scar tissue that has formed around a breast implant or silicone gel.

MAMMOGRAPHY:

It is important to continue to have regular mammography examinations and to perform periodic breast self-examination. Should a breast lump be detected with either a mammography or self-examination, please contact your physician.

PSYCHOLOGICAL/APPEARANCE CHANGES:

It is possible that after breast implant removal you may experience a strong negative effect on your physical appearance, including significant loss of breast volume, distortion, and wrinkling of the skin. Your appearance may be worse than prior to your surgery for the placement of the breast implants. There is the possibility of severe psychological disturbances including depression. It is possible that you or your partner will lose interest in sexual relations.

OTHER:

Breast asymmetry may occur after surgery. You may be disappointed with the results of surgery. Additional surgery may be necessary to reshape breasts after implant removal. Scars resulting from breast-implant removal may complicate future breast surgery.

HEALTH DISORDERS ALLEGED TO BE CAUSED BY BREAST IMPLANTS: Currently there is insufficient evidence to state that the removal of breast implant(s) and capsule(s) will alter the course or prevent auto-immune or other disorders alleged to be caused by breast implants. The removal of breasts implants may be of no health benefit to you.

BREAST DISEASE:

Current medical information does not demonstrate an increased risk of breast disease or breast cancer in women who have breast implant surgery for either cosmetic or reconstructive purposes. Breast disease can occur independently of breast implants. It is recommended that all women perform periodic self-examination of their breasts, have mammography per American Cancer Society guidelines, and to seek professional care should they notice a breast lump.

SURGICAL ANESTHESIA:

Both local and general anesthesia involves risk. There is a possibility of complications, injury, and even death from all forms of surgical anesthesia or sedation.

ALLERGIC REACTIONS:

In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions, which are more serious, may occur to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.

HEALTH INSURANCE:

Most health insurance companies exclude coverage for the removal of breast implants or any complications that might occur from breast implants. Some carriers have excluded breast diseases in patients who have breast implants. Please carefully review your health insurance subscriber information pamphlet.

ADDITIONAL SURGERY NECESSARY:

Should complications occur, additional surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with breast implant removal; other complications and risks can occur but are even more uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guaranteed or warranty expressed or implied, on the results that may be obtained.

FINANCIAL RESPONSIBILITIES:

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, anesthesia, laboratory tests, and possible outpatient hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered. Fees charged for the removal of breast implants do not include charges for additional surgical procedures performed at the same time of implant removal. Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day-surgery charges involved with revisionary surgery would also be your responsibility.

DISCLAIMER:

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

However, informed consent documents should not be considered all inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information, which is based on all the facts in your particular case and a state of medical knowledge.

Informed consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

It is important that you read the above information carefully and have all of your questions answered before signing the consent on the next page.

CONSENT FOR SURGERY/PROCEDURE or TREATMENT

I hereby authorize Dr. Tom J. Pousti and such assistant as may be selected to perform the following procedure or treatment:

BREAST IMPLANT REMOVAL SURGERY

I have received the following information sheet:

INFORMED CONSENT FOR BREAST IMPLANT REMOVAL

I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants of designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure has begun.

I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and possibility of complications, injury, and sometimes death.

I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.

I consent to the photographing or televising of the operation or procedure to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.

For purposes of advancing medical education, I consent to the admittance of observers to the operating room.

I consent to the disposal of any tissue, medical devices or body parts, which may be removed.

I authorize the release of my social security number to appropriate agencies for legal reporting and medical device registration if applicable.

IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:

- a) THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
- b) THERE MAY BE ALTERNATIVE PROCEDURE OR METHODS OF TREATMENT
- c) THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

Sign A or B Below

- A. I consent to the treatment or procedure and the above listed items. I have been asked if I want more detailed explanation, but I am satisfied with the explanation and do not want more information.

Patient or person authorized to sign for patient

Date

- B. I consent to the treatment or procedure and above listed items. I requested and received, in substantial detail, further explanation of the procedure or treatment, other alternative procedures or methods or treatment and information about the material risks or the procedure of treatment.

Patient or person authorized to sign for patient

Date