Informed Consent

Placement of Breast Implant Following Breast Reconstruction by Tissue Expansion

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INSTRUCTIONS

This is an informed consent document to help you learn about placement of a breast implant following breast reconstruction with tissue expansion. You'll learn about the surgery, its risks, and other treatment(s).

It is important that you read the whole document carefully. Please initial each page. Doing so means 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

Tissue expanders are used for breast reconstruction. This is a two-step process. A tissue expander is first put in either at the time of the mastectomy (immediate breast reconstruction) or later (delayed reconstruction). The expander fills out over time to increase the size of the breast. After that, a second operation is done to put in the breast implant. Procedures such as a "capsulotomy" or "capsulectomy" may be needed to change the space where the breast implant will be placed. These procedures may be done at the same time the breast implant is put in. Nipple and areola reconstruction can also be done during this procedure or later. Breast implants come in a variety of shapes, sizes, and materials. They have either smooth or textured surfaces. Choosing the implant, its size, and how it is placed into your breast will depend on what you want. It also depends on how your body is shaped and your surgeon's recommendation.

What your surgeon recommends, and the final results of surgery will depend on the shape and size of your breasts before surgery. Your breast after this procedure will not look the same as your removed breast. A procedure to make the other breast look similar is possible. This can be done at the same time or later.

In May 2000, the United States Food and Drug Administration (FDA) approved saline-filled breast implant and tissue expanders for use in breast enlargement and reconstruction. The FDA approved silicone gel implants for the same uses in November 2006.

Breast implant surgery is not recommended for women who:

- Have untreated breast cancer
- Have pre-malignant breast disorders
- Have an infection anywhere in the body
- Are currently pregnant or nursing

Women may be at greater risk for complications and poor surgical results if they have:

- A weak immune system (currently getting chemotherapy or using drugs that affect the immune system),
- Medical conditions that interfere with blood clotting or wound healing
- Reduced blood supply to the breast tissue (from prior surgery or radiation)

Please note these important points:

- Breast enlargement or reconstruction with implants may not be a one-time surgery. More surgeries may be needed.
- Breast implants of any type cannot last forever. You may need additional surgery for implant replacement or removal.
- The chance of breast implant-related complications increases over time.
- Some complications will require more surgery.
- Breast implants may be associated with systemic symptoms.
- Changes made to your breasts after this procedure are not reversible. The breast may not look acceptable to you if you have implants removed.

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OTHER TREATMENTS

It is your choice to have a breast implant put in after a tissue expansion procedure. You can opt to not have an implant. You can use an artificial, removable breast or padding. You can also go in for surgery where tissue from another part of your body is used to reconstruct the breast. All treatments have their risks and possible problems.

RISKS OF BREAST IMPLANT AFTER TISSUE EXPANSION SURGERY

Every surgery has risks. It is important that you understand the risks of getting a breast implant after a breast tissue expansion. You can get more information about breast implants from the FDA, inserts in the implant package, or other information from your state laws.

In making the choice to have this surgery, you should compare the risks to the potential benefits. Most women do not face the problems listed below, but you should discuss them with your surgeon. Make sure you understand the potential risks of your surgery. Problems with breast implants can be due to the type of implant or the specific procedure. You should read more on this topic if you are considering surgery.

Every person is different. Your benefits and issues after breast implant surgery may vary. Most women are happy with the results of the surgery even if they experience some problems.

SPECIFIC RISKS OF BREAST IMPLANT SURGERY

Saline-filled Breast Implants:

Like other medical devices, breast implants can fail. When a saline-filled implant ruptures, the saline is taken in by the body, but the shell remains. Ruptures can occur from an injury, a mammogram, or other activity. A "silent rupture" can have no real cause. An implant can be damaged during surgery. Damaged or broken implants cannot be repaired. Ruptured or damaged implants need to be replaced or removed. Breast implants can wear out and you may need surgery to replace one or both implants. Saline-filled breast implants may not have the same shape or feel as silicone implants. Your breast shape after surgery depends on how thick your skin is, your breasts before surgery, the position of the implants, and how the surgeon puts them in. You should talk to your surgeon about your possible results.

Silicone Gel-filled Breast Implants:

When a silicone gel-filled implant ruptures, the gel usually stays in the scar tissue around the implant (called an "intracapsular rupture"). Sometimes, the gel may move into the breast tissue itself (called "extracapsular rupture and gel migration"). The gel may move to other parts of the body. Silicone gel may be very difficult to completely remove. Rupture of a breast implant may or may not make the breast firm. You should read the information from the implant maker about possible ruptures.

We cannot predict how everyone will respond to the breast implants or how you will heal following surgery. Ruptures can occur from an injury, a mammogram, or other activity. A "silent rupture" can have no apparent cause. An implant can be damaged during surgery. Damaged or broken implants cannot be repaired. Ruptured or damaged implants need to be replaced or removed. Breast implants can wear out and surgery may be required to replace one or both implants.

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.

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Silicone Gel Bleed:

We don't know for sure whether leaking silicone causes any problems. Over time, very small amounts of silicone gel can pass through the shell of the implant. Studies show that silicone contains small amounts of platinum. Tiny amounts of platinum may move outside of the breast implants. This may contribute to "capsular contracture" or tightening of scars and swelling in the lymph node. Most evidence shows that the very low levels of gel that may leak do not cause problems.

Capsular Contracture:

Scar tissue, which forms inside the breast around the implant, can tighten and make the breast round, firm, and even painful. Such firmness can occur soon after surgery or years later. We cannot predict when this will occur, but it is more likely to occur over time. It may occur on one side, both sides, or not at all. It is more common if the implant is placed in front of the chest muscle. Radiation therapy for cancer before or after the implant is placed increases the risk. The condition may already be present while the tissue expander is in place. You may require surgery to replace or remove the implant. Capsular contracture may come back even after it is fixed. It occurs more often in breast implant surgeries after the first one. Another method of reconstruction may be required if the condition recurs with a new implant.

Implant Exposure/Tissue Death:

The implant may be exposed if there is not enough tissue covering the implant. This can happen even if you have an infection. There are several causes for tissue breakdown or tissue death (necrosis):

- The use of steroids
- After chemotherapy and/or radiation to breast tissue
- Smoking
- Certain microwave therapy (diathermy)
- Too much heat or cold therapy

In some cases, cuts fail to heal normally. Breast tissue may die. An implant may push through layers of skin and become visible. If tissue breaks down and the implant is exposed, the implant may need to be removed. You may have permanent scars.

Skin Wrinkling:

Wrinkling or folds can be seen and felt in the implants or breast skin. Some wrinkling is normal and expected. Wrinkling may increase with textured implants or thin breast tissue. You may feel the implant fill valve. Visible wrinkles may not look nice. These conditions may be confused with tumors. You should talk to your doctor if you are unsure.

Calcification:

Calcium deposits can form in the scar tissue around the implant. This can cause pain and firmness. They could be visible on a mammogram. Some calcium deposits are a sign of breast cancer. These deposits may need to be removed through surgery.

Chest Wall Changes:

Changes in your chest wall may occur with tissue expanders and breast implants.

Implant Shift and Tissue Stretching:

The breast implant may move from its initial place. This could cause discomfort and change your breast shape (visible folds in the skin). Certain techniques of putting implants may increase the risk of shifting. More surgery may be required to correct this problem. It may not be possible to fix this problem once it happens.

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Contamination of Implants:

Skin oil, lint from surgical drapes, or talc may get on the implant's surface during surgery. Effects of this are not known.

Unusual Activities and Occupations:

Certain activities and occupations may impact the breast implant. Trauma can break or damage the implants. It can also lead to bleeding, fluid buildup, or other problems.

Change in Nipple and Skin Sensation:

If your nipples are not removed in your breast surgery, you may not have any feeling after the surgery. Other areas of your breast skin may also be numb or have less sensation.

Use of Non-living Biological Tissue:

Your surgeon may use other biological tissue to put the implant in place. Usually, this tissue comes from a human cadaver or pig or cow skin. 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. This tissue material may produce fluid and need drains for a long time.

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 occur 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 and 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 type of textured breast implant. BIA-ALCL usually involves the breast swelling about 8 to 10 years after the first breast implant operation. Most cases were successfully treated by removing the implant and the scar surrounding it. Some rare cases need chemotherapy and/or radiation therapy.

Stay in touch with your surgeon after your breast implant operation. See your doctor in case of 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 mammography, ultrasound, or MRI. If you have unusual test results or implant-related symptoms, you may need to pay for tests and/or methods to assess and treat your problem. These tests and methods could include getting breast fluid or tissue to run various tests, having surgery to remove the scar around the breast implant, removing implants, or replacing implants.

Breast Disease:

Current research does not prove that breast implant surgery can increase 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 suspect before or during 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 **Placement of Breast Implant Following Breast Reconstruction by Tissue Expansion.**
2. I got the information sheet on Placement of Breast Implant Following Breast Reconstruction by Tissue Expansion.
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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