Informed Consent

Breast Reconstruction with Tissue Expander

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INSTRUCTIONS

This document is about informed consent. It will tell you about Breast Reconstruction with Tissue Expander. It will outline its risks and other treatment options.

It is important that you read this 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

Surgeons have many ways to do breast reconstruction. Breast cancer patients who can have breast reconstruction may choose to have tissue expander breast reconstruction. They can have it right after the mastectomy or later. It is common for women whose breast cancer seems to have been removed by mastectomy and other treatments.

Breast reconstruction does not change the natural history of breast cancer. It does not meddle with breast cancer treatment, like chemotherapy or radiation.

Breast reconstruction with tissue expansion has **two stages**. First, the surgeon will insert a silicone rubber balloon-like tissue expander. It goes under the skin and often under the chest muscles. The surgeon slowly injects saline or air into the tissue expander to fill it over weeks or months. This allows the skin on the chest to stretch over the expander. This creates a breast mound. In most cases, your surgeon will remove the expander and replace it with a permanent breast implant after the skin is stretched enough. Some tissue expanders are to be left in place as the breast implant.

There are good reasons to avoid breast reconstruction. Some surgeons may advise patients to wait until cancer treatment is done or the disease staging has finished. Other patients may need to have more complex breast reconstruction procedures. Surgeons may advise women who smoke or who have other health issues, like obesity, to avoid surgery. There is a greater risk for issues and poor results after surgery for some patients. There is more risk for women with a weak immune system (if they are getting chemotherapy or taking drugs to suppress the immune system). You may have more risk if you have trouble with blood clotting or wound healing. You may have more risk if less blood is going to the breast. This happens of you have had surgery or radiation. Learning about your options for breast reconstruction can help you prepare for a mastectomy and have a more positive outlook.

The shape and size of your breasts before surgery will affect where the tissue expander goes. They will affect the final shape of your reconstructed breast. This surgery does not ensure an exact copy of the breast that was removed. You may need breast symmetry surgery on the opposite breast to make it similar. The nipple and darker skin surrounding it (called the areola) may be reconstructed in a later surgery.

Since May 2000, the United States Food and Drug Administration (FDA) has approved saline-filled breast implants and tissue expander devices for breast augmentation and reconstruction. The FDA approved silicone gel implants for breast augmentation and reconstruction in November 2006.

Patients having breast surgery with tissue expanders and implants should know that:

- Breast augmentation or reconstruction with implants may not be a one-time surgery. More surgeries may be needed.
- The chance of developing breast-implant complications increases over time.
- Breast implants and tissue expanders are not lifetime devices. They do not last forever. You may need to have more surgeries to replace or remove the implant.
- Changes in your breasts after augmentation or reconstruction cannot be undone. You may not like the way the breast looks if you have the breast implant or tissue expander removed later.

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Note: You will need a separate consent form for the use of breast implants in addition to breast reconstruction by tissue expansion. Also, review the Breast Implant Surgery Checklist.

ALTERNATIVE TREATMENTS

Breast reconstruction with tissue expander is not needed medically. Other treatments include external breast prostheses or padding. You could have breast reconstruction without tissue expansion. Or you could use other body tissue for breast reconstruction. Risks and issues come with these other options.

RISKS OF BREAST RECONSTRUCTION WITH TISSUE EXPANDER

All surgeries have risks. 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 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 reconstruction with tissue expander.

The problems that come with breast implants and tissue expanders are from the implanted medical device or issues of the surgery. Patients thinking about getting breast implants and tissue expanders should read about them. You can get more details on breast implants and tissue expanders from the FDA, package inserts that come with the device, or pamphlets required by state laws.

Every patient has their own risks and benefits to having this surgery. Doctors find that most women are happy with the result of this surgery despite the problems that come with it.

SPECIFIC RISKS OF BREAST RECONSTRUCTION WITH TISSUE EXPANDER

Tissue Expanders:

Tissue expanders can stop working, like all medical devices. They can break or leak. When a saline-filled tissue expander breaks, the body will absorb the saline material, but the shell will stay. The expander can break from an injury, for no obvious reason (silent rupture), or during a mammography. It can get damaged during surgery or after when the surgeon is injecting saline into the device to inflate it. Damaged, leaking, or broken tissue expanders cannot be repaired. They must be replaced or removed. After surgery, your breast shape depends on many factors. These are your skin thickness, breast position, where the implants or expanders are put in, and how the surgeon does it. Discuss the chance of the breast having a different or unwanted shape or feel with your surgeon.

Capsular Contracture:

Scar tissue forms around the tissue expander. It can tighten and make the breast round, firm, and painful. The breasts can feel too firm soon after surgery or years later. It is hard to predict symptomatic capsular contracture. It is more likely to happen over time. It may occur on one side, both sides, or not at all. It is more common when the tissue expander is put in front of the chest muscle (in the "prepectoral" position). You may need surgery to fix capsular contracture. You may need to replace or remove the tissue expander. Capsular contracture may happen again after you have had surgery to fix it. Some surgeons believe that taking antibiotics during dental work or for sinus and urinary tract infections can make it less likely to happen. Discuss this with your surgeon.

Implant Extrusion/Tissue Necrosis:

Getting an infection or not having enough tissue to cover the expander or implant may cause it to become visible or push through the skin. Tissue breakdown (necrosis) can happen with steroid drugs after chemotherapy/radiation on breast tissue. The tissue can break down with smoking, microwave diathermy, and too much heat or cold therapy. In some cases, surgical cuts do not heal normally. Atrophy of breast tissue may occur. A tissue expander or implant may become visible in the breast because the device is pushing through the skin. If the tissue breakdowns and you can see the tissue expander or implant, it may need to be removed. You may get a permanent scar or deformity.

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Change in Nipple and Skin Sensation:
You may NOT have normal sensation in your breast or nipple after breast reconstruction. Changes in sensation may affect sexual response. They may affect ability to breastfeed a baby.

Skin Wrinkling:
You may get wrinkles that you can feel and see in the implants, tissue expanders, or breast skin. Some wrinkling is normal. This may be more obvious in patients with saline-filled implants with textured surfaces or thin tissue. You may feel the tissue expander fill valve. Some patients may not like the wrinkles or having a valve that you can feel. A valve that you can feel, wrinkling, and folds may be confused with a tumor. You should talk to your doctor in that case.

Calcification:
Calcium deposits can form in the scar tissue around the tissue expander. They may cause pain or firmness. They may be visible on a mammography. The doctor needs to make sure these deposits are not the calcium deposits that are a sign of breast cancer. If they form, you may need more surgery to remove and assess them.

Chest Wall Irregularities:
Patients find that their chest is uneven after getting expanders and breast implants. Leftover uneven skin at the ends of the cuts (called “dog ears”) can come from having too much skin in an area. It may improve with time. It can also be fixed with surgery.

Implant Displacement and Tissue Stretching:
A breast implant or tissue expander can move or rotate. That can cause discomfort and/or a distorted breast shape (the skin may look rippled). If your surgeon has to place the implant or expander in an unusual way it can increase the risk of it being displaced. You may need more surgery to fix this problem. It may not be fixable.

Surface Contamination:
Skin oil, lint from surgical drapes, or talc may stick to the surface of the tissue expander or implant when it is inserted. The results of this are not known.

Unusual Activities and Work:
Work that may cause trauma to the breast may break or damage the tissue expander or implant. This can cause bleeding or fluid buildup.

Magnetic Resonance Imaging Examination During the Expansion Period:
Most expanders have a magnet at the injection site to make it easy to locate the injection port during the expansion. MRI uses very strong magnets that may move, heat, or dislocate the expander. Patients with a breast tissue expander should not have an MRI until the expander is removed and replaced with an implant.

Use of Acellular Dermal Matrix (ADM):
Your plastic surgeon may use biological materials to place the expander in the right position. Often these materials come from human or pig skin. Usually, these materials are processed and do not have living cells. You should ask your surgeon about these materials. They help shape the pocket around the implant and cover it. Your own cells will grow into the ADM, and the tissue will be like your own. These products may cause fluid to build up. This may need to be drained for a long period.

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

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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 Cancer:

Medical researchers have not found evidence of more risk of breast cancer in women who have had tissue expander surgery. A person who has had breast cancer or has family members with breast cancer may be at more risk. The American Cancer Society guidelines say all women should do regular breast self-exams and a mammogram. Seek medical care if you find a lump. If a lump is found before or during breast surgery, you may need more tests and treatment. These have their own charges.

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 Reconstruction with Tissue Expander.**
2. I got the information sheet on: Breast Reconstruction with Tissue Expander.
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 do any treatment that my doctor thinks it 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 realistic. All my questions have been answered. I understand the surgery's built-in 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 sometimes 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 the planned surgery or any other operation that is needed or helpful.
8. I agree to have the right parts of my body photographed or televised 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 the 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

_____ Patient Initials

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