AirXpanders

Are you considering breast reconstruction after a mastectomy?

Would you be interested in participating in a clinical research study using an investigational device for breast reconstruction?

Breast reconstruction is a procedure in which the surgeon rebuilds the breast(s), to recover the feminine shape after mastectomy.

If you are considering breast reconstruction, you should weigh your options carefully and discuss them with your family and doctors. There are many options to choose from, and it can be a long process that may require multiple surgical procedures.

Tissue Expansion And Implantation

Most women choose to have tissue expansion followed by breast implants. It is the most common reconstruction option, accounting for over 60% of all breast reconstructions in the United States[1].

Current techniques for tissue expansion involve a surgeon placing a temporary saline tissue expander under the skin and chest muscle. During weekly office visits, the surgeon inserts a syringe through the breast skin, into a valve on the tissue expander and injects saline to fill the expander. As the device expands, the skin and tissue covering the expander stretches until there is enough tissue to cover a permanent implant. The expansion process can take up to several months to complete. Most surgeons will then wait up to two months before performing the second operation to exchange the expander for a permanent implant.[2]

Investigational Expander

Doctors at this hospital and others are continuing to evaluate an investigational device for patients undergoing breast reconstruction after a mastectomy. Instead of requiring weekly saline injections to fill an expander, this investigational expander, known as the AeroForm®

Tissue Expander, is filled with carbon dioxide (CO_2) that is contained within the device.

The expander comes with a small, hand-held wireless “remote control” that you can use to gradually release small amounts of carbon dioxide into the expander, as prescribed by your surgeon. As the expander gradually fills with carbon dioxide, the skin and tissue covering the expander will stretch. Once your tissue is expanded, you will return to your surgeon to have the expander exchanged for a permanent implant.

The study will continue to evaluate this investigational expander, while AirXpanders, the company who makes the product, requests marketing authorization from the US FDA.

If you decide to enter this clinical study, what will you be required to do?

If you decide to participate in this study, you will need to sign a HIPAA authorization and Informed Consent prior to any study procedures being performed. You will need to complete a screening visit to determine your eligibility to participate in the study. You will be shown a presentation and taught how to use the expander controller, and will also be required to demonstrate that you understand how to use the controller to fill your expander. Photographs will be taken throughout the study, but the photographs will be taken of your chest only, and your privacy and identity will be protected.

Following surgery to place the expander, you will require follow up office visits with your doctor, until the expander is removed and exchanged for a permanent implant. You will be compensated for your time to complete these follow up visits.

How long will the study last?

You will be in the study until your surgeon determines that the tissue expansion is complete and ready for exchange to a permanent implant. This will vary depending on the surgeon, and your needs. Total length of study participation may be up to six months.

What is the cost?

There is no cost to you to participate in this study. Federal law[3] mandates that any woman who has had a mastectomy is guaranteed the right to have breast reconstruction covered by your insurance company. The reconstruction procedure should be reimbursed by insurance but you should check with your insurance provider to ensure coverage. The investigational expander will be provided by the sponsor of the study (AirXpanders).

What are some of the risks or side effects of the device?

Any surgical procedure involves the risk of complications from anesthesia or the procedure itself. You should speak to your doctors about common side effects of tissue expansion. Some additional risks with this investigational device may include failure to expand, deflation, over-expansion and/or rupture of the device. As with any investigational device, there may be risks associated with the use of the investigational device that are unknown.

What are the benefits of participating?

This is an opportunity to participate in a clinical study of an investigational device for breast reconstruction after mastectomy. This expander eliminates the need for weekly doctor visits for saline injections, while empowering you to play an active role in your expansion process. However, we cannot guarantee that you will receive any benefit from participation. This device has been studied at this facility and at other centers in the USA, and has received approval in Europe and Australia. Once marketing authorization is granted in the USA, this technology will provide an additional means of expanding tissue for breast reconstruction after mastectomy.

Who is eligible?

To be eligible for the study, you must:

- Be between the ages 18-70;
- Require tissue expansion as part of breast reconstruction;
- Be able to provide informed written consent;
- Be able and willing to comply with all the study requirements;
- Be able to understand and manage the dosing regimen at home.

How do I enroll in the study?

If you think you might be a good candidate for this study, contact:

Who is not eligible?

You are not eligible for the study if:

- Your skin is not suitable for tissue expansion
- You have remaining tumor cells following your mastectomy
- You have a current or prior infection at the intended expansion site
- You previously had a failed breast reconstruction in the breast to be expanded
- You have any existing medical condition that your doctor thinks puts you at an increased risk of complications (e.g., severe collagen vascular disease, poorly managed diabetes)
- You are taking any medications that your doctor thinks puts you at an increased risk of complications (e.g., prednisone, Coumadin)
- You are currently participating in another investigational drug or device study
- You are a current tobacco smoker
- You are overweight (BMI > 33)
- You are unwilling to comply with instructions to notify the study doctor and discontinue dosing prior to air travel and during the travel period
- You have a currently implanted electronic device such as a pacemaker, defibrillator, neurostimulator device, or drug infusion device
- You are pregnant or planning on becoming pregnant during the study period
- You have a history of a psychological condition, drug or alcohol misuse which may interfere with your ability to use the device safely

1 http://www.plasticsurgery.org/News-and-Resources/Breast-Reconstruction/Fact-Sheet.html

2 Pusic, A., Breast Reconstruction with Tissue Expanders and Implants: A Practical Guide to Immediate and Delayed Reconstruction Semin Plast Surg. 2004 May; 18(2): 71–77

3 Women's Health and Cancer Rights Act of 1998