

**Informed Consent Breast Reconstruction**

This information is given to you so that you can make an informed decision about having **Breast Reconstruction**.

**Reason and Purpose of the Procedure**

Breast reconstruction is a surgical procedure to recreate the appearance and shape of a breast after surgical removal (breast mastectomy). Breast reconstruction is done by inserting tissue expanders or implants either above or below the chest muscle. Occasionally, a skin substitute called Acellular Dermal Matrix (ADM) is required to provide additional coverage over the implant. Incisions are made to keep scars as discreet as possible. The method of insertion is based on your body and your surgeon's recommendation. Multiple procedures are usually required for successful completion of breast reconstruction.

**Benefits of this Surgery or Procedure**

You might receive the following benefits. Your doctor cannot promise you will receive any of these benefits. Only you can decide if the possible benefits are worth the risk.

- To correct a loss in breast tissue after mastectomy.
- To balance breast size when there is a difference between breasts.
- To enhance self-concept for personal reasons.

**Risks of Procedure**

No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor cannot expect.

**General Risks of Surgery or Procedure**

- **Small areas of the lungs may collapse.** This would increase the risk of infection. This may need antibiotics and breathing treatments.
- **Clots may form in the legs, with pain and swelling.** These are called DVTs or deep vein thrombosis. Rarely, part of the clot may break off and go to the lungs. This can be fatal.
- **A strain on the heart or a stroke may occur.**
- **Bleeding may occur.** If bleeding is excessive, you may need to have the blood drained or a blood transfusion.
- **Reaction to the anesthetic may occur.** The most common reactions are nausea and vomiting. In rare cases, death may occur.
- **Infection.** That may require antibiotics or additional surgery.

Patient Name: \_\_\_\_\_

DOB: \_\_\_\_\_

**Risks of this Surgery or Procedure**

- **Change in nipple and skin sensation.** Loss of nipple sensation may occur in one or both nipples. This may be permanent.
- **Change in breast shape with change in weight after surgery.** This may require additional surgery.
- **Implants may rupture or deflate.** Replacement or removal may be needed.
- **Follow up mammography may require specialized ultrasound or MRI.** Tell your provider you have implants.
- **Scar tissue can form around the implant.** Treatment may require surgery, implant removal or replacement.
- **Allergic reactions to medication given, tape, suture or topical preparation may occur.** Treatment could be required.
- **Unusual activity or occupation may cause injury or rupture to the tissue expander or implant.** Additional surgery or removal may be needed.
- **Tissue expanders, Gel-filled implants and saline-filled implants have a silicone outer wrap.** An increased risk of autoimmune disease and Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) are possible.\* Treatment may be needed.

\* Information concerning BIA-ALCL has been provided and explained by your provider.

**Risks Associated with Smoking**

Smoking is linked to an increased risk of infections. It can also lead to heart and lung complications, clot formation, skin loss, implant loss or wound healing delays.

I do not use nicotine products: \_\_\_ Yes or \_\_\_ No; Last used nicotine on: \_\_\_\_\_

Patient Signature \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

**Risks Associated with Obesity**

Obesity is linked to an increased risk of infections. It can also lead to heart and lung complications, clot formation, skin loss, implant loss or wound healing delays .

**Alternative Treatments****Other choices:**

- Use external breast prostheses or padding.
- Transfer other body tissue to create a breast.
- Do nothing. You can decide not to have the procedure.

**General Information**

- During this procedure, the doctor may need to perform more or necessary procedures than I agreed to.
- During the procedure the doctor may need to do more tests or treatment.
- Tissues or organs taken from the body may be tested. They may be kept for research or teaching. I agree the hospital may discard these in a proper way.
- Students, technical sales people and other staff may be present during the procedure. My doctor will supervise them.
- Pictures and videos may be done during the procedure. These may be added to my medical record. These may be published for teaching purposes. My identity will be protected.

Patient Name: \_\_\_\_\_

DOB: \_\_\_\_\_

**By signing this form I agree**

- I have read this form or had it explained to me in words I can understand.
  - I understand its contents.
  - I have had time to speak with the doctor. My questions have been answered.
  - I want to have this procedure: **Breast Reconstruction**
- \_\_\_\_\_.
- I understand that other doctors, including medical residents or other staff may help with surgery or procedure. The tasks will be based on their skill level. My doctor will supervise them.

**Provider:** This patient may require a type and screen or type and cross prior to surgery. If so, please obtain consent for blood/products.

Patient Signature \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

Relationship:  Patient       Closest relative (relationship) \_\_\_\_\_       Guardian

**Interpreter's Statement:** I have translated this consent form and the doctor's explanation to the patient, a parent, closest relative or legal guardian.

Interpreter: \_\_\_\_\_ Date \_\_\_\_\_ Time \_\_\_\_\_

Interpreter (if applicable)

**For Provider Use ONLY:**

I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options, and possibility of complications and side effects of the intended intervention, I have answered questions, and patient has agreed to procedure.

Provider signature: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

**Teach Back**

I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options, and possibility of complications and side effects of the intended intervention, I have answered questions, and patient has agreed to procedure.

Patient shows understanding by stating in his or her own words:

\_\_\_\_ Reason(s) for the treatment/procedure: Breast reconstruction.

\_\_\_\_ Area(s) of the body that will be affected: Breast.

\_\_\_\_ Benefit(s) of the procedure: Reconstructed breast.

\_\_\_\_ Risk(s) of the procedure: Bleeding, scarring, infection and death.

\_\_\_\_ Alternative(s) to the procedure: No surgery or non implant based surgery.

**OR**

\_\_\_\_ Patient elects not to proceed: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_

*(patient signature)*

Validated/Witness: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_