Informed Consent

Breast Reconstruction with DIEP Flap

INSTRUCTIONS

This document is about informed consent. It will tell you about Breast Reconstruction with DIEP Flap. It will outline the 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 a breast reconstruction surgery. Most mastectomy patients can have breast reconstruction. This can be done right after having the breast removed or later. This is common for women whose breast cancer seems to have been removed by mastectomy. There are good reasons to put off having breast reconstruction Some surgeons may advise their 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 or high blood pressure, to avoid surgery. Learning about your options for breast reconstruction can help you prepare for a mastectomy and have a more positive outlook. Some thin people may not be suitable for the DIEP flap surgery. People with obesity have greater risk of surgical issues.

Breast reconstruction does not change the natural history of breast cancer. It does not meddle with other forms of breast cancer treatment like chemotherapy or radiation. However, breast cancer treatment can affect how breast reconstruction is done and its results.

The DIEP flap technique of breast reconstruction involves the use of lower abdominal skin and fat with very little abdominal muscle. This muscle is moved to the chest to rebuild a breast mound. The muscle flap maintains its own blood supply. That helps nurture the tissue that has been moved to the chest. After the breast mound is rebuilt, the lower abdominal cuts are closed. This is a change to the TRAM (transverse rectus abdominis myocutaneous) abdominal muscle flap breast reconstruction. It still tries to preserve the “six-pack” rectus abdominis muscle function. In some cases, your plastic surgeon may insert a breast implant under the muscle flap. This helps the breast mound stick out.

Muscle flap breast reconstruction can be used if:

- There is not enough chest tissue for breast reconstruction with implants or expanders
- The patient has had radiation on the chest after a mastectomy
- The patient is worried about breast implants, even though she may need implants to have the breasts look the same
- An earlier breast reconstruction did not work

Contraindications to DIEP flap breast reconstruction include:

- A patient who is not medically or psychologically suitable for breast reconstruction
- A patient who has had abdominal surgery that stops the DIEP flap blood supply

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

OTHER TREATMENTS

DIEP flap breast reconstruction is not medically needed. Other treatment options include external breast prostheses or padding, breast reconstruction with tissue expansion, or using other body tissue for breast reconstruction. These options come with their own risks and issues.

RISKS OF BREAST RECONSTRUCTION WITH DIEP FLAP SURGERY

All surgeries have some risk. It is important that you know these risks. If a DIEP flap is used without breast implants, risks that come with breast implants will not apply. There is a higher chance of risk and problems from the use of a DIEP flap for breast reconstruction than with other breast reconstruction methods. You must also understand other issues that might come up during or after surgery. Every procedure has its limits. Choosing to have a surgery means comparing the risks and benefits. Most people 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 a DIEP flap.

SPECIFIC RISKS OF BREAST RECONSTRUCTION WITH DIEP FLAP SURGERY

Slow Healing and Loss of Flap:

The wound may open. It could heal very slowly. Some parts of the chest or the DIEP flap tissue may die. You may need to change the bandage often. You may need more surgery to remove the dead tissue. Some areas of the chest or DIEP flap skin may heal abnormally or slowly. That can happen when there is less blood flow to the tissue before the surgery or if you have had radiation. Your belly button cells could die (called necrosis). Smokers are more at risk of losing skin and having problems with wounds healing. Passive smoke can also cause issues with wound healing.

Microvascular Surgery:

The flap may not be usable if there is not enough blood supply to the flap. You may need emergent reoperation to try to save the flap. In some cases, there may be partial or total loss of the flap. This means you may need more surgery. This may affect the way your chest or torso looks. At times, blood clotting disorders can affect the blood supply to the DIEP flap. Tell your plastic surgeon if you have had any abnormal clotting. An artery or vein may get blocked where the surgeon is attaching the DIEP flap. That may make the flap unusable. If there are no contraindications, you may be on aspirin for at least one month after the surgery. Your blood flow through the vessels is watched carefully after the surgery. If it looks like you have a blockage, you may need urgent surgery to remove it and reestablish blood flow in the tissue flap. In rare cases, it may not work. That means the flap tissue may die and would need to be removed completely. You can talk with your surgeon about other reconstructive options at that point.

Weakness of Abdominal Muscle Function:

Your muscles will feel weak after the abdominal tissue has been relocated. The weakness is less obvious with a DIEP flap than with a TRAM flap. Most patients can return to most activities in two to four months. Patients may notice weakness in their tummy when they do sit-ups or such movements.

Abdominal Wall Hernia:

It is rare, but the part of the abdomen that has been operated on can become weak and result in a hernia. Very rarely, you may need another surgery to fix the bulge. In some cases, the surgeon will insert a mesh or other material that has been made from a biological source (plant, animal, human) where the cut is being closed to help support and strengthen the abdomen.

Implant Extrusion:

If you do not have enough tissue to cover the breast implant, it may become visible or push through the skin. This is possible if it is used with the DIEP flap. If the tissue breaks down and you can see the breast implant, it usually needs to be removed. You may not be able to get a new implant at the same time. The wound may need to heal without an implant before your breast reconstruction can be completed.

Firmness:

Your breasts can get too firm after surgery. That is due to scarring inside the chest or around the breast implant. The doctor cannot tell if this will happen. You may need another treatment or surgery to fix it. Getting

radiation on the chest after breast reconstruction with a DIEP flap may result in too much firmness or other long-term problems.

Other Perforator and Tissue Flaps:

Apart from the lower abdomen, the surgeon can use other parts of the body as a donor site to reconstruct the breasts after mastectomy. One area is the buttocks. An elliptic segment of skin and fat can be removed from the upper buttock (superior gluteal) or lower buttock close to the crease (inferior gluteal). Usually, the surgeon tries to remove the tissue and keep the muscles in that region. The skin and fat are removed with their small blood vessels (perforators). These blood vessels are reconnected to the vessels on the chest later during the surgery to get the blood flowing in the tissue that has been moved. This process needs microsurgical methods. If the tissue is taken from the upper buttock, the flap is called a superior gluteal artery perforator (SGAP) flap. The tissue from the lower part of the buttock is called an inferior gluteal artery perforator (IGAP) flap. Taking tissue from one buttock may cause asymmetry. You may need more surgeries to balance the look of the buttocks. Sometimes, skin and fat can be taken from the thigh or hip. These tissues can be moved to the chest for breast reconstruction. The surgeon can use the microsurgical methods the same way as described above.

The risks involved in SGAP, IGAP, and other microvascular surgeries are like the risks of the DIEP flap reconstruction. Ask your surgeon for more details if you want one of these procedures.

Change in Nipple and Skin Sensation:

Breast reconstruction cannot bring back normal feeling to your breast or nipple. You will not have the same sense of touch in the skin that is moved with the muscle flap. Your skin may feel numb on the abdomen where the skin of the DIEP flap used to be. Such change in sensation may affect sexual response or the ability to breastfeed a baby.

Asymmetry:

Most women's left and right breasts do not look the same. Differences in breast and nipple shape, size, or symmetry may also occur after surgery. You may need more surgery to fix the asymmetry after breast reconstruction with DIEP flap.

Fat Necrosis:

The fat in the flap may die. This may make part of the flap firm. You may need more surgery to remove the fat that has died. The shape of the flap may be uneven because of the fat that has died.

Breast Implants:

The risks that come with breast implants are talked about in another informed consent form.

Unsatisfactory Result:

You may not like the results of the breast reconstruction surgery. Where the muscle flap is placed may be uneven. The shape and size of your breasts can differ. You may not like how the flap is placed or where the scar is. You may need more surgery to improve your results. Any type of breast reconstruction can fail due to issues with the mastectomy or chemotherapy/radiation. These breast cancer treatments are not related to the DIEP flap surgery. The unwanted results may NOT improve with more surgeries.

Breast Disease:

Medical research has not found more risk of breast disease or breast cancer or its return in women who have reconstructive breast surgery. A person who has had breast cancer or has family members with breast cancer may be at more risk of getting breast cancer. 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 costs.

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.

_____ **Patient Initials**

CONSENT FOR PROCEDURE OR TREATMENT

1. I permit Dr. _____ and the doctor's assistants to do the procedure **Breast Reconstruction with DIEP Flap.**
2. I got the information sheet on Breast Reconstruction with DIEP Flap.
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 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 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**