

Consent for Surgery/procedure or Treatment

1. I hereby authorize Dr. John P. Stratis and such assistants as may be selected to perform the following procedure or treatment:

INFORMED-CONSENT FOR NIPPLE RECONSTRUCTION SURGERY

2. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgement necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.

3. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involves risk and the possibility of complications, injury, and sometimes death.

4. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.

5. I consent to the photographing or televising of the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.

6. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.

7. I consent to the disposal of any tissue, medical devices or body parts which may be removed.

8. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.

9. THE FOLLOWING HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND

- a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
- b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
- c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you about nipple reconstruction surgery, its risks, and alternative treatments.

It is important that you read this information carefully and completely.

GENERAL INFORMATION

Nipple reconstruction involves the restoration of the nipple-areolar complex lost due to injury, breast cancer or other conditions. A variety of different techniques exist for reconstruction of the nipple and

its surrounding areolar tissue. These include the use of skin grafts taken from other regions of the body, local flaps of breast skin that are shaped into a nipple, or the sharing of tissue from the opposite nipple-areolar region. Additional techniques such as tattooing may be used to add color to the tissue if needed.

ALTERNATIVE TREATMENT

Nipple reconstruction surgery is an elective surgical operation. Alternative treatment would consist of not undergoing the surgical procedure or the use of external nipple-areolar prostheses.

RISKS of NIPPLE RECONSTRUCTION SURGERY

Every surgical procedure involves a certain amount of risk and it is important that you understand the risks involved with nipple reconstruction surgery. An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. Although the majority of woman do not experience the following complications, you should discuss each of them with your plastic surgeon to make sure you understand the risks, potential complications, and consequences of nipple reconstruction surgery.

Bleeding- It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain accumulated blood (hematoma). Do not take and aspirin or anti-inflammatory medications for ten days before surgery, as this may increase the risk of bleeding. Non-prescription "herbs" and dietary supplements can increase the risk of surgical bleeding.

Infection- Infection is unusual after this type of surgery. Should an infection occur, treatment including antibiotics or additional surgery may be necessary. It is possible that skin graft loss or nipple loss may occur from an infection following nipple reconstruction surgery.

Skin scarring- Excessive scarring is uncommon. In rare cases, abnormal scars may result. Scars may be unattractive and of different color than surrounding skin. Scars may occur in both the nipple reconstruction site and the donor site for tissues used in the nipple reconstruction. Additional surgery may be needed to treat abnormal scarring after surgery.

Skin grafts- Skin grafts are used in some nipple reconstruction techniques. The location of where the graft is taken may have residual scarring, poor healing, or abnormal color. Chronic itching sensations have been reported. Skin graft loss can occur due to infection or other causes. Additional skin grafts may be needed.

Hair growth- Skin grafts used in nipple reconstruction may contain hair follicles. Unattractive hair growth may occur in the reconstructed nipple. Additional treatment may be required to remove the hair follicles.

Long term effects- Subsequent alterations in nipple contour and appearance may occur. Loss of nipple projection may occur.

Tattoos- If tattooing is required as an additional procedure, it may be impossible to precisely match the color and texture of the opposite nipple-areolar complex.

Nipple sensation- Nipple reconstruction cannot restore normal sensation to the breast or nipple.

Breast implant damage- breast implant damage can occur during a nipple reconstruction surgery. A damaged or broken implant will require surgery for replacement or removal.

Pregnancy and breast feeding- If a woman has undergone a mastectomy, it is unlikely that she would be able to breast feed a baby on the affected side. Reconstructed nipples cannot be used for breast feeding.

Allergic reactions- In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions which are more serious may result from drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.

Delayed healing- Wound disruption or delayed wound healing is possible in either the site of nipple-areolar reconstruction or donor location(s) for tissue. Some areas of the nipple reconstruction or tissue donor sites may heal abnormally or slowly. Some areas of skin may die, requiring frequent dressing changes or further surgery.

Smokers have a greater risk of skin loss and wound healing complications

Surgical anesthesia- Both local and general anesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anesthesia or sedation.

Damage to opposite nipple- Some nipple reconstruction procedures use a tissue-borrowing technique from the opposite nipple region. It is possible that the donor nipple region may be damaged or lose normal sensation.

Unsatisfactory result- You may be disappointed with the results of surgery. Asymmetry in nipple placement, shape, projection, and appearance may occur after surgery. Unsatisfactory nipple placement may occur. It may not be possible to precisely match the opposite nipple areolar complex. It may be necessary to perform additional surgery to improve your results.

HEALTH INSURANCE

Most insurance carriers consider nipple reconstruction surgery a covered benefit. There may be additional requirements. Please review your health insurance subscriber-information pamphlet, call your insurance company, and discuss this further with your plastic surgeon. Most insurance plans exclude coverage for secondary or revisionary surgery.

ADDITIONAL SURGERY NECESSARY

Should complications occur, additional surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are particularly associated with nipple reconstruction surgery; other complications and risks can occur but are even more uncommon. The practice of medicine is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied on the results that may be obtained.

FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges provided. The total includes fees charged by your doctor, the cost of implants and surgical supplies, anesthesia, laboratory tests, and possible outpatient hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is

covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered. Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day-surgery involved with revisionary surgery would also be your responsibility.

DISCLAIMER

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s). The informed consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

However, informed-consent documents should not be considered all inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information which is based on all the facts in your particular case and the state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

It is important that you read the above information carefully and have all of your questions answered before signing the consent.