

Consent to Breast Reconstruction Surgery (Template)

Patient's Name: _____ Patient's Date of Birth: _____
Medical Record No. : _____ Name of Responsible
Physician: _____

I. Surgery to be implemented (please add a brief explanation for any complicated medical term)

1. Recommended Surgery (Site):

2. Recommended Reason for the Surgery:

(please note the specific side for the part with difference of left and right)

II. Statement of the Physician (please mark "V" for an item that has been notified to the patient and "X" for an item that hasn't been notified to the patient)

1. I have tried my best to explain the information relevant to the surgery in a way that the patient can understand, particularly involving the following items:

- Reason for the surgery, steps, range, risk and success rate of the surgery and possibility of blood transfusion
- Surgical complications and possible treatments
- Possible consequence of not implementing the surgery and other alternative treatments
- Any temporary or permanent symptom that may occur after the surgery
- I have delivered the additional surgery-related descriptive information the patient if any

2. I have left sufficient time to allow the patient to ask questions related to the surgery and have answered the questions too:

- (1)
- (2)
- (3)

Signature of the Physician Responsible for the Surgery:

Date: _____

Time: ____ (h) ____ (m)

III. Statement of Patient

1. The physician has explained to me and made me fully understand the information relevant to necessity, steps, risk and success rate of the surgery.
2. The physician has explained to me and made me fully understand the risks of other alternative treatments.
3. The physician has explained to me and made me fully understand the possible prognosis of the surgery and the risk of not implementing the surgery.
4. I've understood blood transfusion may be necessary during the surgery; **I** **agree** **disagree with blood transfusion.**
(Except for an emergent case as specified in Article 63 of the Medical Care Act.)
5. I have put up my questions and doubts regarding my condition, the surgery and treatment etc. and received replies.
6. I understand in case it is necessary to incise an organ or tissue during the surgery, the organ or tissue may be kept for a period of time in the hospital for the purpose of pathological analysis and report and the organ or tissue will be disposed discreetly as per relevant laws and regulations by the hospital.
7. I understand the surgery may be the most appropriate option at present but it cannot be ensured that the surgery would improve my condition definitely.

I agree with implementation of the surgery based on the statement above.

Signature of the Consenter:

Relation with the Patient: _____

Tel: (0) _____

Address: _____

Date: _____

Time: ____ (h) ____ (m)

Signature of the Witness:

Witness is unnecessary, Signature:

Date: _____

Time: ____ (h) ____ (m)

Remarks: _____

I. General Surgical Risks

1. Except for surgeries with local anesthesia, a small part of lungs may collapse and lose function during a surgery, resulting in an increase of the possibility of chest infection, which may require antibiotics and respiratory therapy.
2. Surgeries except for those with local anesthesia may cause vascular embolization accompanied by pain and swelling in legs. And coagulated blood clots may disperse and enter into lungs, causing a deadly danger; but such situation is not common.
3. Since the heart is under stress during a surgery, a heart disease or stroke may be induced.
4. Medical institutions and medical staff will try their best to provide a treatment and surgery to a patient; but the operation will not be necessarily successful and an accident that may even cause death still might happen.

II. The patient shall sign the field of "Signature of the Consenter" personally; but if the patient is a minor or unable to sign in the field personally, the person provided in Item 2, Article 13 of the Medical Care Act shall sign in the field <The Civil Law provides: an adult is a person whose age is 20 or above.>.

III. In case the consenter is not the patient, the relation between the consenter and the patient shall be filled in the field of "Relation with the Patient".

IV. As for the witness, the field may be left blank when there isn't any witness; but the box in front of "Witness is unnecessary" should be ticked and the person who ticks the box should leave a signature.

V. **Any medical activity relevant to a plastic or cosmetic surgery that is not necessary medically must not be executed for minors under the age of eighteen in accordance with Item 4.1 of Article 28, Physicians Act of Republic of China, Taiwan.** ◦

Description of Breast Reconstruction Surgery (Template)

The description is used to explain conditions of concerned patients and the purpose, method, benefit, complications, success rate and alternatives of breast reconstruction surgery, possible problems during recovery and consequences without implementing the surgery. Please discuss with your physician if you still have any doubt after the physician gives his/her explanation before you sign on the consent.

I、 Patient's Conditions:

Immediate and delayed breast reconstruction may be adopted for a female who has accepted a mastectomy and lost her breasts due to a disease, trauma or congenital factor so that the female may regain her breasts and confidence for life.

II、 Purpose & Benefit:

1. An immediate breast reconstruction may reduce the sense of loss or adaptive phase due to mastectomy.
2. A delayed breast reconstruction may improve the condition of breast skin that is tight originally.

III、 Method:

| Operative Method | Operative Duration | Number of Hospital Day | Method | Merit | Demerit |
|--------------------------------|--------------------|---|---|--|---|
| Insertion of Implant (Implant) | About 1 hour 時 | Immediate: 3 - 5 days | Immediate Reconstruction: Insertion of implant is completed instantly | <ol style="list-style-type: none"> 1. Operative duration is short 2. Success rate of the surgery is 98% to 100% and the surgery can achieve a symmetric appearance of both breasts when the patient wears clothes. 3. No additional wound | <ol style="list-style-type: none"> 1. Unnatural 2. Asymmetry of breasts may occur among about 21.5% of patients 3. The possibility of capsule contracture is 30% approximately in year 5 4. Deflation may happen among about 12.9% of patients 5. Deflation may happen among about 15.8% of patients 6. Wound healing may be slow in 8.6% of patients 7. The |
| | | Delayed reconstruction: no need for hospitalization | Delayed Breast Reconstruction: completed in two stages: Stage 1: Implantation of tissue expander Stage 2 (about 3 months later): implantation of saline implant | | |

| | | | | | | |
|--|----------------------|---------------------|---|--|---|--|
| | | | | | | surgery is not recommended for patients who have just accepted a radiation therapy |
| Reconstruction with Pedicle LD Flap | About 3 hours | 3 to 5 days | LD flap will be transferred to the chest | <ol style="list-style-type: none"> Operative duration is short Postoperative recovery is quick Success rate is 99% to 100% | <ol style="list-style-type: none"> Commonly myocutaneous flap is not enough, likely to atrophy and is relatively hard with poor tactility Sometimes the shoulders may feel tight And there will be a scar on the back | |
| Reconstruction with Pedicle TRAM Flap | About 4 hours | 7 to 10 days | Abdominal flap, fat and rectus abdominis of one side will be transferred to the chest through a tunnel in the upper abdomen and there will be no need to connect blood vessels with microsurgery | <ol style="list-style-type: none"> Natural Symmetric Soft Success rate is 99% to 100% | <ol style="list-style-type: none"> Possibility of partial fat necrosis is around 7% to 30% in a relatively wide range Possibility of partial flap necrosis is about 3% to 15% Possibility of abdominal sequelae (e.g. hernia, abdominal weakness) is 3% - 15% approximately Abdominal pain is serious | |
| Reconstruction with DIEP Flap | 6 to 10 hours | 7 to 10 days | Abdominal flap including skin, | 1. Natural, symmetric | 1. The duration of | |

| | | | | | |
|-------------------------------------|--|--|---|--|--|
| Reconstruction with GAP flap | | | <p>fat and artery and vein which can supply nutrition will be transferred to the chest and the artery and vein will be connected blood vessels of the chest with microsurgery. The patient will need to stay in ICU for about 3 to 5 days for monitoring of blood vessels after the surgery. * A surgery similar to that stated above, which uses flap and fat from buttocks for reconstruction</p> | <p>and soft with good tactivity</p> <ol style="list-style-type: none"> 2. Muscles of abdomen will be retained; so no abdominal weakness will appear after the surgery 3. Abdominal wound will not be very painful and will recover quickly 4. Patient's satisfaction is highest 5. Success rate is 98% | <p>surgery and hospitalization is long</p> <ol style="list-style-type: none"> 2. The patient has to rest in bed for 3 to 5 days due to microsurgery 3. Possibility of partial fat necrosis is around 3% to 5% in a relatively small range 4. Possibility of partial flap necrosis is about 1% to 2% 5. Probability of wound inflammation is around 2% to 3% 6. Probability of hernia is no more than 1% |
|-------------------------------------|--|--|---|--|--|

IV 、 Possible Complications, Probability of Sequelae (including but not limited to the following) and Treatment:

The risk depends on physical conditions of the patient and severity of the surgery. Since every patient has specific body constitution and risks; the patient should inform the physician of his/her existing medication, disease history and allergic history prior to the surgery so that the physician may adopt necessary preventions to ensure a smooth surgery.

1. Reconstruction with Insertion of Implant (or Tissue Expander)
 - (1) Possibility of asymmetry is about 21.5%, which may need a reoperation.
 - (2) Capsule Contracture: occurrence rate is about 30% in year 5 and an reoperation may be required to release the capsule for a serious condition
 - (3) Deflation: the possibility is 12.9% and the implant needs to be replaced or removed for deflation together with deformation
 - (4) Infection: the possibility is 15.8%. A mild infection requires antibiotic therapy; but a serious one may need removal of the implant.
 - (5) Slow wound healing: 8.6%; a long-term dressing change is required
2. Reconstruction with Pedicle LD Flap
 - (1) Seroma: 10% - 30%; a long-term drainage is required for such case

(2) Numb or tight back: 50%. Frequent postoperative rehabilitation may improve the condition

(3) Inability to engage in heavy work: 33% - 39%

(4) Partial or whole flap necrosis: <1%; a debridement may be needed

3. Reconstruction with Pedicled TRAM Flap

(1) Partial Fat Necrosis: 7% to 30%; a debridement may be needed

(2) Partial Flap Necrosis: 3% to 15%; a debridement may be needed

(3) Abdominal sequelae (e.g. hernia, abdominal weakness): 3% - 15%; an reoperation may be needed to reconstruct fascia of the abdominal wall

(4) Abdominal pain is serious

4. For patients who have accepted reconstruction with DIEP flap

(1) Partial Fat Necrosis: 2% -3%; a debridement may be needed

(2) Wound Disruption: 2% - 3%; a long-term dressing change is required and debridement may be needed

(3) Partial Flap Necrosis: 1% - 2%; a debridement may be needed

(4) Whole Flap Necrosis: 1% - 2%; a debridement may be needed

(5) Abdominal Hernia: < 1%; an reoperation may be needed to reconstruct fascia of the abdominal wall

5. Any surgery may cause complications including infection and bleeding. A patient who accepts skin flap grafting may be in the danger due to her allergic reaction to the drugs that are used for promoting blood circulation during vascular anastomosis.

6. Other incidental diseases or complications

V - Alternative to Breast Reconstruction: Wearable Breast Implant

1. Merit: the implant size can be chosen by the patient discretionally without surgical risk.

2. Demerit: it requires the patient to change and wear it everyday; it is likely to shift when the patient engages in intensive activities; surface of the implant may cause eczema after friction with skin and deformation or defect of breasts is obvious when the patient is naked.

VI - Risk without Implementation of the Surgery: no risk will appear without implementation of breast reconstruction.

VII - Possible problems during postoperative recovery period:

1. The patient may feel most uncomfortable within 24 - 48 hours after the surgery and better thereafter.

2. The patient may only take some liquid food such as milk, juice or soup within 48 hours after the surgery.

3. Smoking is banned and the patient should avoid second-hand smoke as nicotine can cause vasoconstriction.

4. A reconstructed breast may slightly swell and bruise and the swelling will reduce within one week after the surgery.

5. Generally the drainage tube will be kept for 1 - 2 weeks after the surgery, and even a few more days if liquid volume in the drainage tube exceeds 30 cc per day. The liquid volume drained and poured should be recorded everyday. The drainage tube may be pulled out by the physician in the outpatient department.

6. As a 3M breathable tape will be applied on the wound; so it is no need to change the dressing; but the skin may itch sometimes. For a patient who has accepted a surgery with abdominal flap, her navel needs to be applied with some ointment for twice per day. And stitches on the navel should be

removed in the clinic within 3 weeks after the surgery.

7. The patient may take a shower in 1 week after the surgery. In the event that the patient has accepted a surgery with abdominal flap, it would be better that she walks with back and knees bent within 2 weeks after the surgery till she wouldn't feel so tight at her waist. The patient may pad 2 or 3 pillows under her knees when she sleeps.
7. The patient should avoid intense activity of her shoulder joint on the operated side within 2 weeks after the surgery especially the exercise of stretching outward by 90 degrees and tightening up shoulders.
8. The patient may wear bra when the gauze is taken off after the surgery.

VIII 、 Supplementary Description:

1. The patient should inform her physician if she meets any one of the following conditions:
 - (1) Likely to suffer from blood coagulation dysfunction.
 - (2) Suffering from a chronic disease such as diabetes, hypertension, heart disease and vascular sclerosis
 - (3) Likely to suffer from scar hyperplasia
 - (4) Taking medicines that may affect blood coagulation such as Aspirin, Vitamin E and Warfarin etc.
 - (5) Smoking and drinking
 - (6) Allergic to some drug
 - (7) Having accepted a surgery before
2. As smoking may inhibit bloodstream of skin and affect wound healing accordingly; it would be better for a smoker to quit smoking for one month prior to accepting such surgery.
3. A patient who is taking any anticoagulant drug should discuss with her internist about the feasibility of stopping taking such drug for 1 - 2 weeks since such drug may cause a disturbance of blood coagulation and affect wound healing.
4. Existing surgical expense is limited to existing surgery and for any further surgery or subsequent treatment, the expense will be calculated separately.

IX 、 Questions from the Patient and Her Family:

1. _____
 2. _____
 3. _____
- _____

Patient (or Family/ Legal Representative): _____(Signature & Seal)

- I have understood the description stated above and agree to accept the breast reconstruction surgery (please sign on the Consent to Breast Reconstruction Surgery).
- I have understood the description stated above and disagree to accept the breast reconstruction surgery.

Relation with the Patient: _____(Required)

Physician for Explanation: _____(Signature & Seal)

Date & Time: