

# Consent for Treatment/Procedure Laparoscopic Sleeve Gastrectomy

Patient's Name: \_\_\_\_\_

Today's Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

The purpose of this document is to confirm, in the presence of witnesses, your informed request to have *Laparoscopic Sleeve Gastrectomy Surgery* for obesity.

You are asked to read the following document very carefully. As you read each paragraph, you are encouraged to discuss any questions you have with your surgeon. If you agree with everything in each paragraph as you read it, you are asked to initial each paragraph after reading.

You have been given information about your condition of obesity, the risks of obesity, and the risks and possible benefits of the *Laparoscopic Sleeve Gastrectomy Surgery* procedure. This consent form is designed to provide a written confirmation of these discussions by repeating and recording some of the more significant medical information given to you. It is intended to make you think again about your decision and to make you better informed so that you may be better able to decide whether you wish to give your consent to go forward with the proposed *Laparoscopic Sleeve Gastrectomy* procedure.

**Condition/Diagnosis:** I recognize that I am severely overweight, with a weight of \_\_\_\_\_ pounds at \_\_\_\_ feet, \_\_\_\_ inches tall. My surgeon has clearly explained to me that this level of obesity has been shown to be unhealthy, and that many scientific studies show that persons at this level of obesity are at increased risk of respiratory disease, high blood pressure, heart disease, high cholesterol, stroke, diabetes, arthritis, clotting problems, cancer, and death, as well as other serious medical illnesses.

If you agree that everything in the above paragraph is correct, please check **Yes** \_\_\_\_ and initial here \_\_\_\_\_.

**Comments:** \_\_\_\_\_

# Consent for Treatment/Procedure Laparoscopic Sleeve Gastrectomy

**Proposed Procedure: Laparoscopic Sleeve Gastrectomy:** I understand that the procedure my surgeon has recommended for the treatment of my obesity is *Laparoscopic Sleeve Gastrectomy*. My surgeon has provided a detailed explanation of the history of the development of the surgical treatment of obesity, the Laparoscopic Sleeve Gastrectomy as a treatment of obesity, and the Laparoscopic Sleeve Gastrectomy procedure itself. I understand that the procedure involves removal of a major portion of the stomach. After general anesthesia (unconsciousness caused by drugs) is administered, the surgeon enters the abdominal cavity. This procedure is done using a laparoscope (thin, tubular, lighted instrument for viewing the abdominal and pelvic organs), as well as other slender surgical instruments. The instruments are inserted through very small incisions (surgical cuts) in the abdomen. The surgeon will then remove a major portion of the stomach from the abdominal cavity after disconnecting its blood supply. This is performed with surgical staplers and other instruments. The abdominal wall is then closed with stitches.

I have been provided with drawings, and with both written and verbal descriptions of the operation. I have been permitted to speak with patients who have undergone the surgery. I have been strongly encouraged to make every effort to investigate and understand the details of the operation.

If you agree that everything in the above paragraphs is correct, please check **Yes** \_\_\_\_\_ and initial here \_\_\_\_\_.

**Comments:** \_\_\_\_\_

**Expected Benefits of the Proposed Procedure:** I understand that the proposed procedure will most often result in weight loss and improvement of obesity related conditions. I understand that with these benefits, I may be able to discontinue or decrease the use of medications that I am currently taking. I fully understand that none of the benefits is guaranteed. I also understand that in order to derive these benefits, I am required to be fully compliant with recommended treatments after surgery including the use of medications, nutritional supplements, specific diets, exercise and behavior modifications. I understand that the benefits derived from surgery may alter or be reversed over time.

If you agree that everything in the above paragraphs is correct, please check **Yes** \_\_\_\_\_ and initial here \_\_\_\_\_.

**Comments:** \_\_\_\_\_

# Consent for Treatment/Procedure

## Laparoscopic Sleeve Gastrectomy

### Known Risks of the Proposed Procedure:

I understand that all medical and surgical procedures involve potential risks and complications, and that my obesity increases the risks of these problems and complications. I understand that complications associated with *Laparoscopic Sleeve Gastrectomy* include, but are not limited to, the following:

- |                            |  |
|----------------------------|--|
| 1. Death                   | Death can occur after Laparoscopic Sleeve Gastrectomy from a number of causes, some of which are listed below.   |
| 2. Leak                    | After surgery, the new staple lines can leak stomach acid, bacteria, and digestive enzymes, causing severe infection and abscess formation. This may require repeated surgery, prolonged stay in Intensive Care Unit, and may lead to death. |
| 3. Blood Clots             | Blood clots, formed after surgery within the deep veins in the body (Deep Vein Thrombosis) and the veins in the lungs (Pulmonary Embolus), may lead to death.  |
| 4. Infection               | Wound infections, bladder infections, pneumonia, skin and deep abdominal infections, and other infections can sometimes lead to widespread infection and death.  |
| 5. Bleeding                | Minor to massive bleeding can occur after surgery, and may require emergency surgery, transfusion, or lead to death.   |
| 6. Need for Drugs          | All drugs have inherent risks and, in some cases, can cause a wide variety of side effects, including death.   |
| 7. Ulceration              | Peptic ulcerations may form along the staple lines in the stomach. They make cause pain, and bleeding, and sometime require additional procedures, re-operation, or even death.  |
| 8. Narrowing (stenosis)    | Narrowing (stenosis) can occur within the remaining stomach, requiring additional procedures including repeat surgery.   |
| 9. Bowel Obstruction       | Any operation in the abdomen can leave behind scar tissue that can put the patient at risk for later bowel blockage.   |
| 10. Disruption of Incision | Cuts in the abdominal wall, most of which are closed after surgery, may get disrupted early on after surgery (dehiscence), or at a later time (incisional hernia), requiring second operation.   |
| 11. Injury                 | Inadvertent injury to stomach, intestines, or other abdominal organs may occur during surgery, requiring repair, or resection of the involved bowel or organ.  |
| 12. Anemia                 | Deficiency of iron, and vitamins may lead to anemia (low red blood cell count in the blood).   |

If you agree that everything in the above paragraphs is correct, please check **Yes** \_\_\_\_\_ and initial here \_\_\_\_\_.

**Comments:** \_\_\_\_\_

# Consent for Treatment/Procedure

## Laparoscopic Sleeve Gastrectomy

- |                                |  |
|--------------------------------|--|
| 13. Removal of Spleen          | During surgery, spleen may get injured and if injury is severe, spleen needs to be removed completely.   |
| 14. Heart Attack               | Heart attack may range from minor to very severe, and may require procedures, medications, and may lead to death.  |
| 15. Stroke                     | Blood flow to part of the brain may get cut off as a result of blood clots or bleeding. This may result in permanent and irreversible loss of function of a part of body, or if very severe it may lead to death.  |
| 16. Protein Deficiency         | After Sleeve Gastrectomy, patients may experience protein deficiency due to inadequate intake or absorption, leading to generalized weakness, leg swelling, hair loss, and malnutrition.   |
| 17. Allergic Reactions         | These range from minor reactions to sudden overwhelming reactions and can cause death.   |
| 18. Anesthetic Complications   | Anesthesia used to put you to sleep for surgery can be associated with a variety of complications, including death.  |
| 19. Loss of Bodily Function    | Including stroke, heart attack, heart failure, kidney failure, limb loss, and other problems related to surgery or anesthesia.   |
| 20. Transfusion Risks          | Although the blood and blood components that are administered are tested, there is still a small risk of acquiring infections including hepatitis and Acquired Immune Deficiency Syndrome (AIDS).  |
| 21. Hair Loss                  | Many patients develop hair loss for a short period after the operation. This usually responds to increased intake of protein and vitamins.   |
| 22. Vitamin and Mineral        | After Sleeve Gastrectomy, there may be decreased intake and absorption of many vitamins and minerals. Patients must take vitamin and mineral supplements forever, to protect themselves from these problems.   |
| 23. Complications of Pregnancy | Vitamin and mineral deficiencies can put the newborn babies of mothers at risk of permanent and irreversible damage. No pregnancy should occur for the first two years after the operation, and patients must be certain not to miss any of their vitamins if they decide to go ahead with pregnancy after that. |
| 24. Skin problems              | Loose skin may develop after weight loss, necessitating plastic surgery. Infections may occur in areas of skin folds.  |
| 25. Depression                 | Depression is a common medical illness, and has been found to be particularly common in the first weeks after the operation.   |
| 26. Kidney Stones              | Usually associated with dehydration, but can occur in any event.   |
| 27. Gallbladder disease        | Gallstones may form or motility problems of the gallbladder can occur after weight is lost. Specific medication that is given to you after surgery to decrease the risk of gall stone formation has to be taken for six months.  |
| 28. Laparoscopic Risks         | Laparoscopic surgery uses punctures to enter the abdomen, and can lead to injury to abdominal contents, bleeding, & death.   |
| 29. Pancreatitis               | Inflammation in the pancreas may occur after surgery.  |
| 30. Other Complications        | Major abdominal surgery may be associated with a variety of other complications, both recognized and unrecognized. These may occur both soon or long after the operation.  |

If you agree that everything in the above paragraphs is correct, please check **Yes** \_\_\_\_\_ and initial here \_\_\_\_\_.

**Comments:** \_\_\_\_\_

## Consent for Treatment/Procedure Laparoscopic Sleeve Gastrectomy

**Unforeseen Complications, Conditions, or Results:** I know that the practice of medicine and surgery is not an exact science, and I acknowledge that no guarantee has been made about the results that may be obtained from this procedure. I am aware that, in the practice of medicine, other unexpected problems, risks, or complications may occur. I also understand that, during the course of the proposed procedure, unforeseen conditions may be revealed, requiring the performance of additional procedures, and I authorize such procedures to be performed if deemed necessary by my surgeon. I further acknowledge that no guarantees or promises have been made to me concerning the results of any procedure or treatment. I understand that my sleeve gastrectomy may have to be converted to a gastric bypass if there is an unforeseen stapling problem or stenosis (narrowing of the sleeve).

If you agree that everything in the above paragraphs is correct, please check **Yes** \_\_\_\_\_ and initial here \_\_\_\_\_.

**Comments:** \_\_\_\_\_

**Possibility of Conversion to Open Procedure:** I realize that my surgeon plans to perform the operation **laparoscopically**, and that this approach has special risks, including injury to the abdominal contents such as blood vessels, the bowel, and other organs. Also, I realize that, in the event that the procedure cannot be completed laparoscopically, it will be completed if possible by way of the conventional open surgical approach.

If you agree that everything in the above paragraphs is correct, please check **Yes** \_\_\_\_\_ and initial here \_\_\_\_\_.

**Comments:** \_\_\_\_\_

**Alternatives to the Proposed Procedure:** The available alternatives to *Laparoscopic Sleeve Gastrectomy*, some of which include *open sleeve gastrectomy, laparoscopic or open gastric bypass, vertical banded gastroplasty, biliopancreatic diversion with/without duodenal switch, laparoscopic gastric banding, various diets, exercise, and drug treatments* have been explained and discussed in detail with me. The potential benefits and risks of the proposed *Laparoscopic Sleeve Gastrectomy* procedure, and the likely results with other treatments, have been discussed with me in detail. I understand what has been discussed with me, as well as the contents of this consent form, and I have been given the opportunity to ask questions, and have received satisfactory answers.

If you agree that everything in the above paragraphs is correct, please check **Yes** \_\_\_\_\_ and initial here \_\_\_\_\_.

**Comments:** \_\_\_\_\_

## Consent for Treatment/Procedure Laparoscopic Sleeve Gastrectomy

**Information about General Anesthesia:** A member of the anesthesia care team will visit you before your treatment/procedure to discuss the type of anesthesia you may need and to give you more information about anesthesia. It may become necessary to alter your anesthesia care plan after this discussion. Devices may be applied to your body and placed in your veins and arteries to monitor you during your anesthesia. All forms of anesthesia involve some risk. Minor (not life-threatening) risks include nausea, vomiting, and pain where an injection is given. Although rare, severe complications include injury to blood vessels, drug reactions, bleeding, blood clots, loss of sensation or limb function, infection, paralysis, stroke, brain damage, heart attack, and death.

General Anesthesia involves drug being injected into the bloodstream or breathed into the lungs. A tube or other device may be inserted into your airway to help you breathe. The anticipated benefit is that you will be totally unconscious and you will not feel pain during the procedure. Additional risks include injury to the teeth, throat, eyes, or lungs. In less than 1 case in 1000, patients may be aware of the occurrences during their surgery.

If you agree that everything in the above paragraph is correct, please check **Yes** \_\_\_\_ and initial here \_\_\_\_\_.

**Comments:** \_\_\_\_\_

**Long term results:** I understand that the sleeve gastrectomy is a relatively new procedure. I understand that there is a lack of long term data with regard to outcomes, risks, and resolution of medical problems. I understand that a second stage procedure may be required in the future if I fail to lose adequate weight or if I start to regain weight. I understand there is a chance that my sleeve will stretch (dilate) over time which could lead to weight regain and failure of weight loss.

If you agree that everything in the above paragraph is correct, please check **Yes** \_\_\_\_ and initial here \_\_\_\_\_.

**Comments:** \_\_\_\_\_

# Consent for Treatment/Procedure Laparoscopic Sleeve Gastrectomy

## Signatures:

### I. Practitioner:

By signing below, I attest to the following:

- All relevant aspects of the proposed procedure and its alternatives (including no treatment) have been discussed with the patient (or surrogate) in language that s/he could understand. This discussion included the nature, indications, benefits, risks, and likelihood of success of each option.
- The patient (or surrogate) demonstrated comprehension of the discussion.
- I have given the patient (or surrogate) an opportunity to ask questions.
- I did not use threats, inducements, misleading information, or make any attempt to coerce the patient/surrogate to consent to this treatment/procedure.
- I have offered the patient (or surrogate) the opportunity to review a printed copy of the consent form.

\_\_\_\_\_  
**Practitioner's Signature**

\_\_\_\_\_  
**Practitioner's Name:**

\_\_\_\_\_  
/\_\_\_\_\_/\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Time**

### II. Patient (or Surrogate):

By signing below, I attest to the following

- My surgeon has explained this procedure, what it is intended for, and what would happen if I have no treatment/procedure.
- My surgeon has explained how this treatment/procedure could help me, and what things could go wrong.
- My surgeon has told me about other treatments/procedures.
- My surgeons and his associates have answered all my questions
- I know that I may refuse or change my mind about having this procedure. If I do refuse or change my mind, I will not lose my healthcare.
- I have been offered the opportunity to read the consent form.
- I choose to have this treatment/procedure voluntarily.

\_\_\_\_\_  
**Patient's Signature**

\_\_\_\_\_  
**Patient's Name:**

\_\_\_\_\_  
/\_\_\_\_\_/\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Time**

# Consent for Treatment/Procedure Laparoscopic Sleeve Gastrectomy

## III. Witness:

By signing below, I attest to the fact that I have witnessed the patient (or surrogate) and the practitioner sign this consent form.

\_\_\_\_\_  
**Witness Signature**

\_\_\_\_\_  
**Witness Name:**

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Time**