

## Informed Surgical Consent (addendum to OF-522)

(Informed Consent for Laparoscopic Roux-en-Y Gastric Bypass Surgical Procedure)

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

Time: \_\_\_\_\_

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

Patient Age: \_\_\_\_\_

The purpose of this legal document is to confirm in the presence of witnesses your informed request to have Laparoscopic Roux-en-Y Gastric Bypass for obesity.

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

You have been given information about your condition of obesity, the risks of obesity and the risks and possible benefits of the Laparoscopic Roux-en-Y Gastric Bypass surgical 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 Roux-en-Y Gastric Bypass procedure.

**Condition/Diagnosis:** I recognize that I am severely overweight with a weight of \_\_\_\_\_ lbs. with a BMI of \_\_\_\_\_ at \_\_\_\_\_ ft. \_\_\_\_\_ in. tall. My surgeon or surgeons have clearly explained to me that this level of obesity has been shown to be unhealthy and that many scientific studies show that persons of this level of obesity are at increased risks of respiratory diseases, high blood pressure, heart disease, high cholesterol, stroke, diabetes, arthritis, clotting problems, cancer and death as well as other serious and less serious medical illnesses. If you agree that everything in the above paragraph is correct, check YES here by initialing the paragraph above: \_\_\_\_\_.

Comments: \_\_\_\_\_.

**Proposed Procedure, The Laparoscopic Roux-en-Y Gastric Bypass:** I understand that the procedure that my surgeon or surgeons have recommended for the treatment of my obesity is the Laparoscopic Roux-en-Y Gastric Bypass. My surgeon or surgeons have provided a detailed explanation of the medical history of the development of the surgical treatment of obesity, the gastric bypass as a treatment of obesity, the development of laparoscopic (minimally invasive) surgery and the Gastric Bypass. I have been provided with drawings, written and verbal descriptions of the operation. I have been permitted to talk with patients that have previously 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 paragraph is correct, check YES here by initialing the paragraph above: \_\_\_\_\_.

Comments: \_\_\_\_\_.

**Risks/Benefits of Proposed Procedure(s):**

A. Just as there may be some expected benefits from the Laparoscopic Roux-en-Y Gastric Bypass procedure proposed in my case, I also understand that all medical and surgical procedures, including the Laparoscopic Roux-en-Y Gastric Bypass involve risks. I have been told and I understand that my obesity increases my risks of these problems and complications.

These risks include but are not limited to the following:

<u>Complication</u>	<u>Description</u>
1. <b>Allergic Reactions</b>	From minor reactions such as a rash to sudden overwhelming reactions that can cause DEATH.
2. <b>Anesthetic Complications</b>	Anesthesia used to put you to sleep for the operation can be associated with a variety of complications up to and including DEATH.
3. <b>Bleeding</b>	From minor to massive bleeding that can lead to the need for emergency surgery, transfusion, or DEATH.
4. <b>Blood Clots</b>	Also called deep vein thrombosis and Pulmonary Embolus that can sometimes cause DEATH.
5. <b>Infection</b>	Including wound infections, bladder infections, pneumonia, skin infections and deep abdominal infections that can sometimes lead to DEATH.
6. <b>Leak</b>	After operation to bypass the stomach the new connections can leak stomach acid, bacteria and digestive enzymes causing a severe abscess and infection. This can require repeated surgery, intensive care and even DEATH.
7. <b>Narrowing (stricture)</b>	Narrowing (stricture) or ulceration of the connection between the stomach and the small bowel can occur after the operation and require repeated surgery.
8. <b>Dumping Syndrome</b>	Dumping syndrome (Symptoms of dumping syndrome include cardiovascular problems with weakness, sweating, nausea, diarrhea and dizziness) can occur in some patients after gastric bypass.

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. **Laparoscopic Risks** Laparoscopic Surgery uses punctures to enter the abdomen and can lead to injury, bleeding and DEATH.
11. **Need for and side effects of drugs** All drugs have inherent risks and in some cases can cause a wide variety of side effects including DEATH.
12. **Loss of Bodily function** Including stroke, heart attack, limb loss and other problems related to operation and anesthesia.
13. **Risk of Transfusion** Including Hepatitis and Acquired Immune Deficiency Syndrome (AIDS), from the administration of blood and/or blood components.
14. **Hernia** Cuts in the abdominal wall can lead to hernias after surgery and may require surgery to repair.
15. **Hair Loss** Many patients develop hair loss for a short period after operation. This usually responds to increased levels of vitamins.
16. **Vitamin and Mineral** After gastric bypass there is a malabsorption of many vitamins and minerals. Patients must take vitamin and mineral supplements forever to protect themselves from these problems.
17. **Complications of Pregnancy** Vitamin and mineral deficiencies can put the newborn babies of gastric bypass mothers at risk. No pregnancy should occur for the first year after operation and patients must be certain not to miss any of their vitamins if they decide to go ahead with pregnancy later.
18. **Other** Major abdominal surgery, including Laparoscopic Roux-en-Y Gastric Bypass, is associated with a large variety of other risks and complications, both recognized and unrecognized that occur both soon after and long after the operation.

19. **Depression**

Depression is a common medical illness and has been found to be particularly common in the first weeks after operation.

20. **DEATH**

If you agree that you have been advised regarding all of the items in the above paragraph and have received answers to any questions you had regarding this information. Check Yes by initialing here: \_\_\_\_\_.

Comments: \_\_\_\_\_.

B. I also realize that there are particular risks associated with the Laparoscopic Roux-en-Y Gastric Bypass procedure proposed for me and that these risks include, but are not limited to: Bleeding, Leak, Abscess and serious intra-abdominal infection and Blood clots all of which can lead to repeated operation, admission to the Intensive Care Unit and sometimes DEATH. I realize that my surgeon or surgeons plan 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 by way of the conventional open surgical approach. If you agree that you have been advised regarding all of the items in the above paragraph and have received answers to any questions you had regarding this information, check YES here by placing your initials \_\_\_\_\_.

Comments: \_\_\_\_\_.

C. I recognize that bypassing my stomach and upper digestive tract is a serious undertaking with known long term risks that my surgeon or surgeons have described to me including hair loss, serious vitamin and mineral deficiencies and other known and unknown problems. I am committed to long term follow-up with my surgeon or surgeons and to make every effort to follow his directions to protect myself from these and other problems associated with the bypass. In addition I understand that smoking has a 100% risk of causing ulcerations within my pouch and that carries with it the risks of bleeding and transfusions and could possibly result in my DEATH. If you agree that you have been advised regarding all of the items in the above paragraph and have received answers to any questions you had regarding this information, check YES here by placing your initials \_\_\_\_\_.

Comments: \_\_\_\_\_.

**Complications, Unforeseen Conditions and 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 not discussed 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. I further acknowledge that no guarantees or promises have been made to me concerning the results of any procedure

or treatment. If you agree that you have been advised regarding all of the items in the above paragraph and have received answers to any questions you had regarding this information, check YES here by initialing the paragraph above \_\_\_\_\_.

Comments \_\_\_\_\_.

**Acknowledgments:** The available alternatives to the Laparoscopic Roux-en-Y Gastric Bypass, some of which include: Open gastric bypass, vertical banded gastroplasty, various diet, exercise, and drug treatments have been explained and discussed in detail with me. The potential benefits and risks of the proposed Laparoscopic Roux-en-Y Gastric Bypass 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 have been given the opportunity to ask questions and have received satisfactory answers. If you agree that everything in the above paragraph is correct, check YES here by initialing the above paragraph \_\_\_\_\_.

Comments:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_.

**Consent to Procedure(s) and Treatment:** Having read this form and having discussed its content with my surgeon or surgeons, my signature below acknowledges that: I voluntarily give my authorization and consent to the performance of the Laparoscopic Roux-en-Y Gastric Bypass procedure described above (including the administration of blood and disposal of tissue) by my physician and/or his/her associates assisted by hospital personnel and other trained persons. For the purpose of advancing medical education, I consent to the admittance of observers and discussion of my procedure with others who may not be directly responsible for my care.

***Patient Signature***

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

***Parent or other person authorized to sign for patient***

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

***Witness***

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

***Surgeon or Physician***

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

