

INFORMED SURGICAL CONSENT

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

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Patient's Name: _____

Patient's Age: _____ Today's Date: _____

The purpose of this 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. 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 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* surgical 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 but less serious medical illnesses.

If you agree that everything in the above paragraph is correct, check YES, _____ and initial the paragraph above.

Comments: _____

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Proposed Procedure, *Laparoscopic Roux-en-Y Gastric Bypass*: I understand that the procedure my surgeon has recommended for the treatment of my obesity is the *Laparoscopic Roux-en-Y Gastric Bypass*. My surgeon has provided a detailed explanation of the history of the development of the surgical treatment of obesity, the gastric bypass as a treatment of obesity, and the gastric bypass procedure itself. 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 paragraph is correct, check **YES** _____ and initial the paragraph above.

Comments: _____

Risks/Benefits of Proposed Procedure:

- 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.

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These risks include, but are not limited to, the following:

	<u>Complication</u>	<u>Description</u>
1.	Allergic Reactions	From minor reactions to sudden overwhelming reactions that can cause death.
2.	Anesthetic Complications	Anesthesia used to put you to sleep for the operation can be associated with a variety of complications, up to and including death.
3.	Bleeding	From minor to massive bleeding that can lead to the need for emergency surgery, transfusion, or death.
4.	Blood Clots	Also called deep vein thrombosis, and pulmonary embolus, that can some times cause death.
5.	Infection	Including wound infections, bladder infections, pneumonia, skin and deep abdominal infections that can sometimes lead to death.
6.	Leak	After an 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 lead to death.
7.	Narrowing (stricture)	Narrowing (stricture) of the connection between the stomach and the small bowel can occur after the operation.
8.	Ulceration	Ulcerations may form in the connection of the stomach and the small bowel. Ulcer may also form in the excluded stomach. They make cause pain, and bleeding.
9.	Dumping Syndrome	Dumping syndrome can occur in some patients after gastric bypass. (Symptoms include cardiovascular problems, with weakness, sweating, nausea, diarrhea, and dizziness.)
10.	Bowel Obstruction	Any operation in the abdomen can leave behind scar tissue that can put the patient at risk for later bowel blockage. Internal hernia may also develop.
11.	Need for Drugs and	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, arrhythmia, heart failure, kidney failure, limb loss, and other problems related to operation and anesthesia.
13.	Transfusion Risks	Including hepatitis and acquired immune deficiency syndrome (AIDS) from the administration of blood or blood components.
14.	Hernia	Cuts in the abdominal wall can lead to hernias after surgery.
15.	Hair Loss	Many patients develop hair loss for a short period after the 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 <u>forever</u> 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 the operation, and patients must be certain not to miss any of their vitamins if they decide to go ahead with pregnancy later.
18.	Skin problems	Loose skin may develop after weight loss necessitating plastic surgery. Infections may occur in areas of skin folds.
19.	Other Risks	Major abdominal surgery, including the open gastric bypass, is associated with a large variety of other risks and complications, both recognized and unrecognized, that may occur both soon after and long after the operation.
20.	Depression	Depression is a common medical illness, and has been found to be particularly common in the first weeks after the operation.
21.	Kidney Stones	Usually associated with dehydration, but can occur in any event
22.	Gallbladder disease	Gallstones may form or motility problems of the gallbladder can occur after weight is lost.

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|-----|---------------------------|---|
| 23. | Laparoscopic Risks | Laparoscopic surgery uses punctures to enter the abdomen and can lead to injury, bleeding, and death |
| 24. | Pancreatitis | Inflammation in the pancreas |
| 25. | Death | 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 have had regarding this information, check **YES**____ and initial the paragraph above.

Comments: _____

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- 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, serious intraabdominal 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 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 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 have had regarding this information, check **YES** _____ and initial the paragraph above.

Comments: _____

Complications; Unforeseen Conditions; 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. I further acknowledge that no guarantees or promises have been made to me concerning the results of any procedure or treatment.

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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 may have had regarding this information, check **YES** _____ and initial the paragraph above.

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Acknowledgments: The available alternatives to the *Laparoscopic Roux-en-Y Gastric bypass*, some of which include *open gastric bypass, vertical banded gastroplasty, biliopancreatic diversion with/without duodenal switch, laparoscopic gastric banding, 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 I 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** _____ and initial the paragraph above.

Comments: _____

Consent to Procedure(s) and Treatment: Having read this form, and having discussed its content with my surgeon, 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, his associates, hospital personnel, and other trained persons.

Patient's
Signature: _____

Date: _____

Witness: _____

Date: _____

Surgeon: _____

Date: _____