

PATIENT CONSENT TO MEDICAL TREATMENT AND / OR SURGICAL PROCEDURE AND ACKNOWLEDGMENT OF RECEIPT OF MEDICAL INFORMATION

READ CAREFULLY BEFORE SIGNING

TO THE PATIENT: As you consider medical treatment / surgery, Louisiana law requires us to tell you (1) the nature of your condition, (2) the general nature of the medical treatment / surgery, (3) the risks of the proposed treatment / surgery, (4) reasonable therapeutic alternatives and material risks associated with such alternatives, and (5) risks of no treatment. You should not sign this document until you feel that all five matters have been addressed to your full satisfaction. You have the right, as a patient to be informed of your condition and the recommended surgical, medical or diagnostic procedure to be used so that you may make the decision whether or not to undergo the procedure after knowing the risks and hazards involved with such procedure.

In keeping with Louisiana law of informed consent, you are being asked to sign a confirmation that we have discussed all these matters. We wish to inform you as completely as possible. Please read this form carefully. Ask about anything you do not understand and we will be pleased to explain.

1. Patient Name: _____

2. Procedures: 1. LAPAROSCOPIC GASTRIC BYPASS (Roux-En-Y)

2. _____

3. _____

**YOU ARE ASKED TO PLEASE READ THIS DOCUMENT VERY CAREFULLY!
AS YOU READ EACH PARAGRAPH, YOU ARE ENCOURAGED TO DISCUSS ANY QUESTIONS ABOUT IT WITH YOUR SURGEON. YOU WILL BE REQUIRED TO INITIAL NEXT TO EACH PARAGRAPH TO INDICATE YOUR UNDERSTANDING OF ALL MATERIAL CONTAINED IN THE PARAGRAPH.**

(1) PREOPERATIVE INFORMATION AND EDUCATION:

My initials in this form are meant to demonstrate that I agree that I have been given extensive preoperative education and information about my condition of obesity, the risks of obesity and the risks and possible benefits of the Gastric Bypass. I understand that this consent form is designed to provide a written confirmation of my discussions with the surgeons of the Obesity Surgery Center and the extensive educational process that I have participated in with regards to this procedure.

I understand that this effort is intended to make me think over my decision to have surgery once again. I confirm that my family, my surgeon and I have extensively reviewed the decision to proceed with this weight loss surgery. This document is written record of my efforts to be well informed about my decision to proceed with the operation. I can confirm that I wish to consent to go forward with the proposed Gastric Bypass procedure.

- If you agree that everything in the above paragraph is correct, initial here

(2) MY CONDITION / DIAGNOSIS:

I recognize that I am severely overweight. The National Institute of Health has concluded that a BMI of 40 or higher indicates morbid obesity. I understand that this level of obesity has been shown to be dangerous, unhealthy and increase my risk of death from a variety of medical illnesses. I affirm that I understand that many scientific studies conclude that persons of this level of obesity are at increased risk of disability, respiratory disease, 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 and should be considered for surgery to help them to lose weight.

❖ My preoperative weight is _____ lbs.

❖ My height is _____ foot _____ inches

❖ Thus, according to the Body Mass Index Table, my BMI is _____

• If you agree that everything in the above paragraph is correct, initial here

(3) CONTROVERSY IN MEDICINE / DISAGREEMENTS OVER THE SURGICAL TREATMENT OF OBESITY

I understand that there are many different types and variations of surgical procedures being performed for weight loss in American at this time. I also know that although many studies document the value of surgery for obesity, there remain many physicians and surgeons who are opposed to the idea of the surgical treatment of obesity. I understand that there are also many NONSURGICAL alternatives to this procedure. I could have chosen medication, diet changes or exercise to attempt weight loss.

Table 1. Different Types of Weight Loss Surgery

TYPES OF WEIGHT LOSS SURGERY	
❖	Laparoscopic Gastric Bypass (Roux-en-Y)
❖	Silastic Ring Vertical Gastric Bypass
❖	Micro pouch Gastric Bypass
❖	Long Limb Gastric Bypass
❖	Biliopancreatic Diversion
❖	Biliopancreatic Diversion with Duodenal Switch
❖	Gastric Band
❖	Laparoscopic Gastric Band
❖	Laparoscopic Adjustable Gastric Band
❖	Vertical Banded Gastroplasty
❖	Laparoscopic Vertical Banded Gastroplasty
❖	Others

I know that because of the numerous problems and complications that can occur with weight loss surgery many physicians and surgeons prefer to avoid all types of weight loss surgery entirely. I realize that there are a variety of different types of weight loss surgery, some of which are shown in the table here and I have been encouraged to research each of these procedures.

I understand that it is my surgeon's feeling that no one of these surgical choices is necessarily bad, but I recognize that each type of surgery has its own associated risks and complications that keep any one of them from becoming universally adopted. It demonstrates that surgery for obesity has not yet reached a "perfect" surgical solution. The number and the great variety of the different types of surgery offered for the treatment of obesity suggests that the development of the surgical treatment of obesity is not complete, that there are opportunities for enhancement of the presently available surgical options and that continued assessment of new innovations in surgical procedures is appropriate.

I know that I could have chosen any one of these other types of surgical procedures but after a slow, careful and detailed investigation, I have decided to have the Laparoscopic Gastric Bypass. I know that the Laparoscopic Gastric Bypass is not perfect, (see risks and complications) but after reviewing all of the information I feel comfortable that my family, my surgeon and I agree that this procedure is the best choice for me.

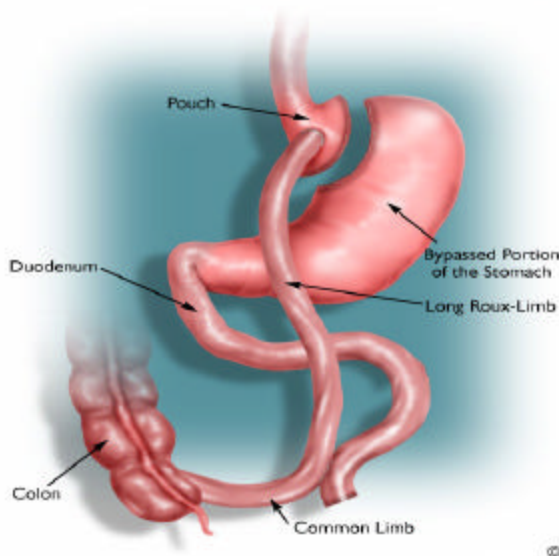
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(4) LAPAROSCOPIC GASTRIC BYPASS (ROUX-EN-Y):

The Laparoscopic Gastric Bypass: I understand that the procedure that my surgeon has recommended for the treatment of my obesity is the Gastric Bypass. My surgeon has provided me with a preoperative handbook which includes drawings and information about the procedure. He has also given a verbal description of the operation. He has encouraged me to talk with patients who have previously undergone the surgery and has strongly encouraged me to make every effort to investigate and understand the details of the operation as well as the changes that must be in my life following the operation.

Procedure in detail: Roux-en-Y is a combination of restrictive and malabsorptive procedure. Please refer to the following diagram to visualize the steps of the procedure:

- The upper portion of the stomach is freed and a row of staples is placed horizontally (from side to side) a few centimeters (1-2 inches) below the esophagus-stomach junction. The gastric pouch measures about 1-2 ounces and is totally separated from the rest of the stomach.
- The small bowel is divided approximately 60 cm (24 inches) beyond the stomach. The lower portion is brought up and attached to the stomach pouch. This forms the food channel.
- The portion extending from the stomach contains secretions of bile and the pancreas and is called the biliopancreatic channel. This channel is attached to the side of the food channel approximately 60 cm distal to the attachment of the stomach and small bowel forming a Y shaped arrangement of the bowel.



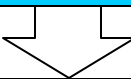
Roux-en-Y Gastric Bypass

- If you agree that everything in the above paragraph is correct, initial here

(5) RISKS / BENEFITS OF PROPOSED PROCEDURE:

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

IF YOU UNDERSTAND AND AGREE INITIAL HERE



LIKELIHOOD:

C = Common

U = Uncommon

V = Very uncommon

COMPLICATION

DESCRIPTION

C **U** **V**

Allergic reactions

All kinds of allergic reactions are possible, from minor reactions such as a rash to a sudden overwhelming reaction that can cause death.

Anesthetic complications

Anesthesia used to put you to sleep for the operation can be associated with a variety of different complications up to and including death.

Bleeding

Surgery involves incisions and cutting that can result in bleeding complications, from minor to massive, that can lead to the need for emergency surgery, transfusion or death.

Blood Clots

Also called Deep Vein Thrombosis (DVT) and Pulmonary Embolus can sometimes cause death. I understand that I need to get out of bed the evening after surgery and move and flex my feet and legs to help prevent clots from forming in my legs.

Infection

Including wound infections, bladder infections, pneumonia, skin infections and deep abdominal infections that can sometimes lead to death.

Leak

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 additional surgery and even death.

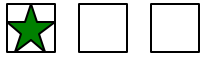
Narrowing (stricture)

Narrowing (stricture) or ulceration of the connection between the stomach and the small bowel can occur after the operation which could require emergency surgery, intensive care and can sometimes lead to death. To protect your new stomach from ulcers, you must never again take aspirin, or aspirin like drugs such as Motrin, Ibuprofen, Naproxen, Relafen or other similar drugs.



Indigestion,
Acid/Bile Reflux

The operation can sometimes lead to severe nausea, vomiting, indigestion, abdominal pain, gastritis or ulcers. This can be severe and can last for days, weeks and possibly even longer. This is especially likely if you have had previous problems with nausea, abdominal pain or ulcers. Nausea is much more common in women than men. Women who have been treated with any type of hormone therapy are much more likely to have nausea and vomiting after surgery.



Dumping Syndrome

Dumping Syndrome can occur in some patients after gastric bypass. Symptoms include cardiovascular problems with weakness, sweating, nausea, diarrhea and dizziness. This can be so severe that the surgery may have to be reversed.



Bowel obstruction

Any operation in the abdomen can leave behind scarring that can put the patient at risk for later bowel blockage or obstruction. The bowel can twist, obstruct and even perforate leading to serious complications, even death.



Laparoscopic
Surgery Risks

Laparoscopic surgery uses punctures to enter the abdomen and this can lead to abdominal injury, bleeding and even death.



Side Effects of Drugs

All drugs have inherent risks and complications and in some cases can cause a wide variety of side effects, reactions and in some cases even death.



Loss of Bodily Function

The performance of surgery and anesthesia can stress the body's systems leading to a variety of complications including stroke, heart attack, limb loss and other problems related to operation and anesthesia.



Risks of Transfusion

Including Hepatitis and AIDS from the administration of blood and/or blood components. These illnesses are serious and can be fatal.



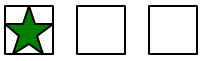
Hernia

Cuts and incisions in the abdominal wall can lead to hernias after surgery. Hernias can lead to pain, bowel blockage, obstruction and even perforation and death in some cases. Treatment of hernias usually requires another operation.



Hair Loss

Many patients develop hair loss for a period after the operation. When this occurs, it usually starts at 3-4 months following the surgery and resolves at 7-9 months. This usually responds to increased oral intake of protein and vitamins but it may be permanent.



Vitamin and Mineral Deficiencies

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. You also need to have yearly blood tests to measure the blood levels of these vitamins and minerals. Common deficiencies following this surgery are iron, calcium, B12 and folate.



Inadequate Weight Loss

WARNING: Remember that you might not lose weight after the operation. There are patients that will fail any type of weight loss surgery. Inadequate weight loss is a risk of all types of weight loss surgery and all types of weight loss treatment.

I recognize that the Gastric Bypass is not by any means a perfect treatment and that one of the risks is a real possibility of inadequate weight loss following my Gastric Bypass surgery.



Excessive Weight Loss

Some patients sustain excessive weight loss after the operation and may require reversal of the bypass to prevent severe malnutrition, nausea, or vitamin and mineral deficiencies or death.



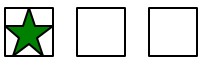
Complications of Pregnancy

Vitamin and mineral deficiencies can put the newborn babies of gastric bypass mothers at risk. No pregnancy should occur for the first one to two years after operation. Gastric Bypass has been shown to cause multiple types of vitamin and mineral deficiencies. Many of these deficiencies have been shown to cause birth defects. We also know that many patients who lose weight feel that they are well after surgery and forget to take their vitamins. Patients must be certain not to miss any of their vitamins if they decide to go ahead with pregnancy later.



Gallstones

Reducing the amount of food intake can reduce the amount of bile secreted by the gallbladder. This can lead to accumulation of bile in the gallbladder, which can cause formation of gallstones. Gallstones can become painful and require surgery to remove the gallbladder. This can also lead to inflammation of the liver and /or pancreas.



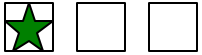
Depression

Depression and anxiety are common medical illnesses and have been found to be particularly common after operation.



Cancer

Cancer can occur in anyone. Many cancers are more common in obese as compared to thin patients. Overweight men have a significantly higher rate of prostate cancer. Obese women have higher risks of developing breast cancer and cancer of the uterus and ovaries. It is expected, but not certain, that with weight loss you will have an overall decrease in your risk of cancer.



Loose skin

It is common for persons who experience extensive weight loss to have loose skin in areas which were previously much larger. For cosmetic reasons, you may desire to have additional procedures to remove the excess skin. This would have to be done by a Plastic Surgeon and your insurance policy may not cover this procedure due to "cosmetic" need.



Breathing difficulty

Occasionally following surgery, patients can develop pneumonia or other breathing problems requiring prolonged need for ventilator. Your pulmonary status will be evaluated prior to surgery, however, breathing complications can effect you. Patients are strongly encouraged to stop smoking at least one month prior to the procedure.



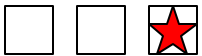
Diarrhea or excessive flatulence

Patients can experience diarrhea or excessive gas due to rapid transit of food to the colon. This condition may simply last during the adjustment period or can be permanent.



Dilation of pouch and/or remnant stomach

Patients can experience dilation of the stomach pouch or remnant if the new intestinal connections become obstructed with food, adhesions or a blood clot caused by excessive bleeding inside the intestines.



Death

This is a major and serious operation. It may lead to death from complications. While uncommon, you must be aware that death can occur following this procedure, just as any procedure.

(6) PATIENT RESPONSIBILITY:

I recognize that an operation upon my stomach and upper digestive tract is a very serious undertaking with known long term risks that my surgeon has described to me. I am committed to fulfilling my surgeon's instructions for long term follow-up. I promise I will make every effort to follow his directions to protect myself from these and other problems associated with the bypass. I will follow the advice of my surgeon as well as the various team members of the Obesity Surgery Center. This is to include lifestyle changes as educated, diet changes as educated, daily vitamins, postoperative follow-up as directed and all testing as ordered.

I will not leave the Lake Charles area following surgery until I have been approved by my surgeon for discharge from the area.

I will return to my follow-up appointments for further evaluation and education. In extraordinary circumstances in which I cannot reach my surgeon or the Obesity Surgery Center for my follow-up, I will make certain that I seek a qualified doctor to resume my care. I understand that it is my sole responsibility to ensure the continued success of this procedure.

- If you agree that everything in the above paragraph is correct, initial here

(7) UNEXPECTED OUTCOMES:

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 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 this or any procedure.

- **If you agree that everything in the above paragraph is correct, initial here**

(8) ACKNOWLEDGMENTS:

The available alternatives to the Gastric Bypass, including Laparoscopic Banding, diet and exercise or drug treatments, have been explained and discussed in detail with me. The potential benefits and risks of the proposed Gastric Bypass 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 received satisfactory answers.

- **If you agree that everything in the above paragraph is correct, initial here**

(9) AUTHORIZATION FOR RELEASE OF MEDICAL INFORMATION:

I hereby confirm that I freely approve of the release of my medical information for the purposes of education and advocacy of the rights of obese patients and I have not in any way been coerced into this authorization. I recognize that I can refuse to approve of the use of my personal medical information with no negative impact upon my care or treatment by my surgeon or his staff. I have had the opportunity to consider whether or not to approve the use of my personal information. I hereby authorize surgeon and his staff to use any portions or parts of my medical records and information pertaining to medical history, physical condition, services rendered or treatment given for the purposes of education of future patients.

_____ My name and photographs may be used for education and clinical data.

_____ I wish for my name and photographs to be withheld from public knowledge.

- **If you agree that everything in the above paragraph is correct, initial here**

(10) CONSENT TO PROCEDURE AND TREATMENT:

Having read this form, talked with my surgeon and feeling confident that I have received adequate preoperative education, my signature below acknowledges that:

I voluntarily give my authorization and consent to the performance of Gastric Bypass as described above, administration of blood and/or blood components if needed and any procedures necessary during the operation.

I understand that at this or any point prior to surgery, I can decide against this or any procedure and I will have my decision fully supported by my surgeon and staff. I understand that my best interest is the priority and I make this decision freely.

PATIENT SIGNATURE **DATE**

WITNESS **DATE**

SURGEON **DATE**

*** THIS CONSENT (TEN PAGES PLUS ADDENDUM FOR ANY ADDITIONAL PROCEDURES INDICATED ON PAGE ONE) WILL BECOME A PERMANENT PART OF THE PATIENT'S MEDICAL RECORD. A COPY HAS ALSO BEEN GIVEN TO THE PATIENT FOR HIS / HER REFERENCE.**