

INFORMED CONSENT FOR LAPAROSCOPIC ROUX-EN-Y GASTRIC BYPASS SURGICAL PROCEDURE

It is very important to Venice Metabolic and Bariatric Surgery that you understand and consent to the treatment your doctor is providing for you and any procedure your doctor may perform. You should be involved in any and all decisions concerning surgical procedures your doctor has recommended. Sign this form only after you understand the procedure, the anticipated benefits, the risks, the alternatives, the risks associated with the alternatives and all of your questions have been answered. Please initial and date directly below this paragraph indicating your understanding of this paragraph.

Patient's Initials or Authorized Representative

Date

I, _____, hereby authorize Dr. _____ and any associates or assistants the doctor deems appropriate, to perform Laparoscopic Roux-en-Y Gastric Bypass surgery.

The doctor has explained to me the risks of obesity and the benefits of a Laparoscopic Roux-en-Y Gastric Bypass; however, I understand there is no certainty that I will achieve these benefits and no guarantee has been made to me regarding the outcome of the procedure. I also authorize the administration of sedation and/or anesthesia as may be deemed advisable or necessary for my comfort, wellbeing and safety.

Condition. I recognize that I am severely overweight with a weight of _____ lbs. at _____ ft. _____ inches tall, and a BMI of _____. 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 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.

Commitment. I am committed to long-term follow-up with my surgeon or surgeons and to make every effort to follow his/her directions to protect myself from these and other problems associated with Gastric Bypass. I understand that to be effective, I need to make a life-long commitment to lifestyle changes, which may include, but are not limited to, dietary changes, an exercise program, and counseling. I understand that I will need to maintain proper nutrition, eat a balanced diet, and take vitamin and mineral supplements for the rest of my life. I will also be required to maintain follow-up medical care for my lifetime. Laboratory work will be required at least annually and perhaps more often, as directed by a physician.

Pre-operative Requirements. I have completed the Physician-Supervised Multidisciplinary Program, which included Dietary Therapy - a discussion of dietary history and a nutritional visit by either (a physician, dietitian or nutritional counselor) as well as a physician-supervised dietary therapy which included low calorie intake for 3 months or very low calorie intake within 6 months of the scheduled surgery, Physical Activity, and Behavior Therapy/Support. Since the time of my initial evaluation to the date of surgery, I have either maintained my weight or have not gained greater than 5 pounds.

Post-operative Requirements. I agree to participate in a post-surgical multidisciplinary program that includes diet, physical activity, and behavior modification.

Proposed Procedure. 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 strongly encouraged to make every effort to investigate and understand the details of the operation.

I understand the nature of the Roux-en-Y Gastric Bypass will be done laparoscopically and entails the use of a fiberoptic endoscope along with special endoscopic instruments and staplers to facilitate completing the procedure with smaller incisions than in an open approach. It has been further explained to me that the laparoscopic approach to Gastric Bypass surgery to treat morbid obesity is effective in achieving weight loss and in improving comorbidities and quality of life while reducing recovery time and perioperative complications.

The laparoscopic Roux-en-Y gastric bypass procedure involves making several small incisions through which the surgeon(s) insert laparoscopic instruments to perform the surgery. The procedure is designed to make a small reservoir ("pouch") for food at the upper end of the stomach with a capacity of about 2 oz. This pouch is connected to the upper small intestine by a new small anastomosis (outlet) of about ½ inch (1.2 cm) in diameter. The ingested food thereby bypasses the majority of the stomach, which remains alive and undisturbed, but functional otherwise. In other words, the majority of the stomach does not have food passing through. The nature and purpose of this operation is to functionally limit the amount of food or liquid intake at any given time. There may be a small component of malabsorption, at least initially. This procedure is often associated with fairly rapid weight loss initially, which stabilizes over time. With this limited intake, if you eat too much at one meal, you may feel discomfort and may even vomit until you learn the capacity of your "new" stomach.

Risks/Possible Complications. The doctor has explained to me that there are risks and possible undesirable consequences associated with a Laparoscopic Roux-en-Y Gastric Bypass including, ***but not limited to:***

1. **Abscess**
2. **Adult Respiratory Distress Syndrome (ARDS)**
3. **Allergic reactions**
4. **Anesthetic complications**
5. **Atelectasis**
6. **Bleeding, blood transfusion, and associated risks**
7. **Blood clots, including pulmonary embolus (blood clots migrating to the heart and lungs) and deep vein thrombosis (blood clots in the legs and/or arms)**
8. **Bile leak**
9. **Bowel obstruction**
10. **Cardiac rhythm disturbances**
11. **Complications in subsequent pregnancy (no pregnancy should occur within the first year after surgery)**
12. **Congestive heart failure**
13. **Dehiscence or evisceration**
14. **Depression**
15. **Dumping syndrome**

16. **Death.**
17. **Encephalopathy**
18. **Esophageal, pouch or small bowel motility disorders**
19. **Gout**
20. **Hernias, incisional (including the port sites for laparoscopic access) and internal**
21. **Inadequate or excessive weight loss**
22. **Infections at the surgical site, either superficial or deep including port sites for laparoscopic access. These could lead to wound breakdowns and hernia formation.**
23. **Injury to the bowels, blood vessels, bile duct, and other organs**
24. **Injury to adjacent structures, including the spleen, liver, diaphragm, pancreas and colon**
25. **Intestinal leak**
26. **Kidney failure**
27. **Kidney stones**
28. **Loss of bodily function (including from stroke, heart attack, or limb loss)**
29. **Myocardial infarction (heart attack)**
30. **Narrowing of the connection between the stomach and small bowel**
31. **Need for and side effects of drugs**
32. **Organ failure**
33. **Perforations (leaks) of the stomach or intestine causing peritonitis, subphrenic abscess or enteroenteric or enterocutaneous fistulas**
34. **Pleural effusions (fluid around the lungs)**
35. **Pneumonia**
36. **Possible removal of the spleen**
37. **Pressure sores**
38. **Pulmonary edema (fluid in the lungs)**
39. **Serious intra-abdominal infection such as sepsis or peritonitis**
40. **Skin breakdown**
41. **Small bowel obstructions**
42. **Staple line disruption**

43. **Stoma stenosis**
44. **Stroke**
45. **Systemic Inflammatory Response Syndrome (SIRS)**
46. **Ulcer formation (marginal ulcer or in the distal stomach)**
47. **Urinary tract infections**
48. **Wound infection**

a. Nutritional complications **include but are not limited to:**

1. **Protein malnutrition**
2. **Vitamin deficiencies, including B12, B1, B6, folate and fat soluble vitamins A,D,E,K**
3. **Mineral deficiencies, including calcium, magnesium, iron, zinc, copper, and other**
4. **Uncorrected deficiencies can lead to anemia, neuro-psychiatric disorders and nerve damage, that is, neuropathy**

b. Psychiatric complications **include but are not limited to:**

1. **Depression**
2. **Bulimia**
3. **Anorexia**
4. **Dysfunctional social problem**

c. Other complications **include but are not limited to:**

1. **Adverse outcomes may be precipitated by smoking**
2. **Constipation**
3. **Diarrhea**
4. **Bloating**
5. **Cramping**
6. **Development of gallstones**
7. **Intolerance of refined or simple sugars, dumping with nausea, sweating and weakness**
8. **Low blood sugar, especially with improper eating habits**

9. **Vomiting, inability to eat certain foods, especially with improper eating habits or poor dentition**
10. **Loose skin**
11. **Intertriginous dermatitis due to loose skin**
12. **Malodorous gas, especially with improper food habits**
13. **Hair loss (alopecia)**
14. **Anemia**
15. **Bone disease**
16. **Stretching of the pouch or stoma**
17. **Low blood pressure**
18. **Cold intolerance**
19. **Fatty liver disease or non-alcoholic liver disease (NALF)**
20. **Progression of pre-existing NALF or cirrhosis**
21. **Vitamin deficiencies some of which may already exist before surgery**
22. **Diminished alcohol tolerance**

d. Pregnancy complications were explained as follows:

1. **Pregnancy should be deferred for 12 to 18 months after surgery or until the weight loss is stabilized**
2. **Vitamin supplementation during the pregnancy should be continued**
3. **Extra folic acid should be taken for planned pregnancies**
4. **Obese mothers have children with a higher incidence of neural tube defects and congenital heart defects**
5. **Pregnancy should be discussed with an obstetrician**
6. **Special nutritional needs may be indicated or necessary**
7. **Secure forms of birth control should be used in the first year after surgery**
8. **Fertility may improve with weight loss**

Further, any of these risks or complications may require further surgical intervention during or after the procedure, which I expressly authorize.

I also understand that some or all of the complications listed on this form and also explained to me may exist whether the surgery is performed or not, in that gastric bypass surgery is not the only cause of these complications.

_____ Foreign language (specify)

_____ Sign language

_____ Patient is blind, form read to patient

_____ Other (specify) _____

Interpretation provided by _____

(Fill in name of Interpreter and Title or Relationship to Patient)

Signature (Individual Providing Assistance)

Date

Time