INFORMED CONSENT FOR LAPAROSCOPIC ADJUSTABLE GASTRIC BAND

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 have reviewed drawings of each of the available bariatric operations that diagrammatically show the main characteristics of each type of weight reduction operations, differences among operations, advantages, and disadvantages, of each procedure. I have had a chance to express to the surgeon my eating habits and behavior and my medical history and the surgeon has helped me to personally come to a conclusion as to the most appropriate operation for me, factoring in my eating, dietary, and medical background, and my future weight loss goals, pregnancy plans, and personal limits regarding acceptable meal size, bowel habits, and risk tolerance. The surgeon has counseled me regarding my decision, has made professional recommendations, and together we have agreed on the planned procedure as acceptable and appropriate.

____ _________________________

Patient's Initials or Authorized Representative Date

I, _______________________________, hereby authorize Dr. ______________________and any associates or assistants the doctor deems appropriate, to perform gastric lap band surgery.

The doctor has explained to me the risks of obesity and the benefits of a gastric lap band procedure; 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, well being 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 Lap Band. 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 a physician, dietitian or nutritional counselor), Activity, and Behavior Therapy and 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 gastric lap band procedure. My surgeon or surgeons have provided a detailed explanation of the proposed procedure. I have been strongly encouraged to make every effort to investigate and understand the details of the operation.

I understand the nature of a gastric lap band procedure will be done laparoscopically and entails the use of a fiberoptic endoscope along with special endoscopic instruments and staplers to facilitate in completing the procedure with smaller incisions than in an open approach.

I understand that it may be necessary to convert the procedure to an open technique if it is felt to be the best medical/surgical decision in the judgment of my surgeon (s). This conversion will result in a larger incision, which has been described to me by my surgeon.

I understand that my surgeon will initially attempt to perform this procedure laparoscopically. If the procedure cannot be done laparoscopically, I DO _________, DO NOT __________ wish for my surgeon to proceed with an open procedure.

Contraindications. I understand that if my BMI is less than 40, the Lap Band procedure may not be right for me; however, if my BMI is less than 40 and I have other co-morbidities, I may be a candidate for this surgery, as explained by my physician.

Other Contraindications, ***include, but are not limited to***: current inflammatory disease or condition of the gastrointestinal tract such as ulcers, severe esophagitis, or Crohn's disease; current severe heart or lung disease which may make me a poor candidate for surgery; other diseases that make me a poor candidate for surgery; current health condition which cause bleeding in the esophagus or stomach, which might include esophageal or gastric varices (a dilated vein) or a congenital or acquired intestinal telangiectasia (dilation of a small blood vessel); current portal hypertension; an abnormal esophagus, stomach, or intestine whether congenital or acquired), such as a narrowed opening; prior intra-operative gastric injury such as a gastric perforation at or near the location of the intended band placement, current cirrhosis, chronic pancreatitis, pregnancy, addiction to alcohol or drugs; under the age of 18; an infection anywhere in my body or one that could contaminate the surgical area; chronic, long-term steroid treatment; inability to follow the dietary rules inherent with this procedure; allergy to materials in the device; autoimmune connective tissue disease of my own or family member, such as systemic lupus erythematosus or scleroderma, or symptoms of one of these types of disease. In addition, patients with a "sweet tooth" will not do well with the gastric lap band procedure or those that often drink milk shakes or other high-calorie liquids.

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

1. **Abscess**

2. **Adult Respiratory Distress Syndrome (ARDS)**

3. **Allergic reactions; band allergy**

4. **Anesthetic complications**

5. **Atelectasis**

6. Band slippage, erosion, or deflation

7. Band removal

8. Bleeding, blood loss, blood transfusion and associated risks

9. 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)

10. Bile leak

11. Bowel obstruction

12. Cardiac rhythm disturbances

13. Cardiospasm (an obstruction of passage of food through the bottom of esophagus)

14. Cholecystitis (gall stones)

15. Complications in subsequent pregnancy (no pregnancy should occur within the first year after surgery)

16. Congestive heart failure

17. Constipation or abnormal stools

18. Dehydration

19. Dehiscence or evisceration

20. Depression

21. Diarrhea

22. Dumping syndrome

23. Death

24. Dislocation/displacement of injection port

25. Dysphagia

26. Encephalopathy

27. Esophageal dilatation, pouch or small bowel motility disorders

28. Esophagitis

29. Flatulence (gas)

30. Gastritis

31. Gout

32. Hematemesis (vomiting of blood)

33. Hernias, incisional and internal (including the port sites for laparoscopic access)

34. Inadequate or excessive weight loss

35. Infections at the surgical site, either superficial or deep including port sites for laparoscopic access. These could lead to wound breakdowns and hernia formation.

36. Injury to the bowels, blood vessels, bile duct, and other organs

37. Injury to adjacent structures, including the spleen, liver, diaphragm, pancreas and colon

38. Intestinal leak or port leak

39. Kidney failure

40. Kidney stones

41. Loss of bodily function (including from stroke, heart attack, or limb loss)

42. Myocardial infarction (heart attack)

43. Nausea and/or vomiting

44. Need for and side effects of drugs

45. Organ failure

46. Perforations (leaks) of the stomach or intestine causing peritonitis, subphrenic abscess or enteroenteric or enterocutaneous fistulas

49. Pleural effusions (fluid around the lungs)

50. Pneumonia

51. Possible removal of the spleen

52. Pressure sores

53. Pulmonary edema (fluid in the lungs)

54. Possibility of a reoperation

55. Pouch dilatation or twisting

56. Reflux or regurgitation

57. Serious intra-abdominal infection such as sepsis or peritonitis

58. Skin breakdown

59. Small bowel obstructions

60. Stoma stenosis or obstruction

61. Stomach slippage

62. **Stroke**

63. **Systemic Inflammatory Response Syndrome (SIRS)**

64. **Ulcer formation (marginal ulcer, esophageal, or in distal stomach)**

65. **Urinary tract infections**

66. **Weight regain, slow weight loss, or no weight loss**

67. **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. **Bloating**

3. **Cramping**

4. **Development of gallstones**

5. **Low blood sugar, especially with improper eating habits**

6. **Vomiting, inability to eat certain foods, especially with improper eating habits or poor dentition**

7. **Loose skin**

8. **Intertriginous dermatitis due to loose skin**

9. **Hair loss (alopecia)**

10. **Anemia**

11. **Bone disease**

12. **Low blood pressure**

13. **Cold intolerance**

14. **Fatty liver disease or non-alcoholic liver disease (NALF)**

15. **Progression of pre-existing NALF or cirrhosis**

16. **Vitamin deficiencies some of which may already exist before surgery**

17. **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 lap band surgery is not the only cause of these complications.

Alternative Procedures. In permitting my doctor to perform this procedure, I understand that unforeseen conditions may necessitate change or extension of the original procedure(s), including completing the operation by way of the conventional open surgical approach, or a different procedure from what was explained to me. I therefore authorize and request that the above-named physician, his assistants or designees to perform such procedure(s) as may be necessary and desirable in the exercise of his/her professional judgment.

In the unlikely event that one or more of the above complications may occur, my physician(s) will take appropriate and reasonable steps to help manage the clinical situation and be available to me and my family to address our concerns and questions.

The reasonable alternative(s) to the procedure(s), as well as the risks to the alternatives, have been explained to me. These alternatives include, ***but are not limited to***, open gastric band, gastric bypass, vertical banded gastroplasty, various diet exercise and drug treatments, or no surgery at all.

I understand that my surgeon will initially attempt to perform this procedure laparoscopically. If the procedure cannot be done laparoscopically, I DO _________, DO NOT __________ wish for my surgeon to proceed with an open procedure.

I hereby authorize the disposal of removed tissues resulting from the procedure(s) authorized above.

I consent to any photographing or videotaping of the procedure(s) that may be performed, provided my identity is not revealed by the pictures or by descriptive texts accompanying them. I consent to the admittance of students or authorized equipment representatives to the procedure room for purposes of advancing medical education or obtaining important product information.

By signing below, I certify that I have had an opportunity to ask the doctor all my questions concerning anticipated benefits, material risks, alternative therapies, and risks of those alternatives, and all of my questions have been answered to my satisfaction.

______/______/____________________________________ _________________________

Date Time Signature of Patient or Authorized Rep. Relationship of Authorized Rep.

- ❑ The Patient/Authorized Representative has read this form or had it read to him/her.
- ❑ The Patient/Authorized Representative states that he/she understands this information.
- ❑ The Patient/Authorized Representative has no further questions.

_______________ _______________ ____________________________________

Date Time Signature of Witness

CERTIFICATION OF PHYSICIAN:

I hereby certify that I have discussed with the individual granting consent, anticipated benefits, material risks, alternative therapies and the risks associated with the alternatives of the procedure(s).

________________ _____________ ____

Date Time Signature of Physician

USE OF INTERPRETER OR SPECIAL ASSISTANCE

An interpreter or special assistance was used to assist patient in completing this form as follows:

______ 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