INFORMED CONSENT FOR LAPAROSCOPIC

SLEEVE GASTRECTOMY 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 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 we have together agreed on the planned procedure as acceptable and appropriate.

I, _____, hereby authorize Dr. _____and any associates or assistants the doctor deems appropriate, to perform Laparoscopic Sleeve Gastrectomy surgery. The doctor has explained to me the risks of obesity and the benefits of a Laparoscopic Sleeve Gastrectomy; 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 Sleeve Gastrectomy. I understand in order 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 or dietitian and supervised dietary therapy, as well as Physical Activity, and Behavior Therapy/Support Groups. Since the time of my initial evaluation to the date of surgery, I have either maintained my weight or have lost weight.

Post-operative Requirements. I agree to participate in post-surgical follow-up visits at intervals of one to 3 weeks for the first 3 months after surgery, then at 6 months post-surgery, 9 months post-surgery, and annually for life thereafter with my surgeon or someone designated by my surgeon. I also agree to follow a multi-disciplinary program post-surgery as suggested by my surgeon or other designated physician which may include 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 Sleeve Gastrectomy. My surgeon or surgeons have provided a detailed explanation of the medical history of the development of the surgical treatment of obesity, the sleeve gastrectomy as a treatment for obesity and the development of laparoscopic (minimally invasive) surgery. I have been strongly encouraged to make every effort to investigate and understand the details of the operation.

I understand the nature of the Sleeve Gastrectomy will be done laparoscopically and entails the use of a fiber optic endoscope along with special endoscopic instruments and staplers to facilitate completing the procedure with smaller incisions than in an open approach. I understand that the Laparoscopic Sleeve Gastrectomy is an acceptable option as a primary bariatric procedure and as a first-stage procedure in high risk patients as part of a planned staged approach.

<u>Risks/Possible Complications.</u> The doctor has explained to me that there are risks and possible undesirable consequences associated with a Laparoscopic Sleeve Gastrectomy 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. Need for and side effects of drugs

31. Organ failure

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

33. Pleural effusions (fluid around the lungs)

34. Pneumonia

35. Possible removal of the spleen

36. Pressure sores

37. Pulmonary edema (fluid in the lungs)

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

39. Skin breakdown

40. Small bowel obstructions

41. Staple line disruption

42. Stoma stenosis

43. Stroke

44. Systemic Inflammatory Response Syndrome (SIRS)

45. Ulcer formation (marginal ulcer or in the distal stomach)

46. Urinary tract infections

47. 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 my 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. Inter-triginous 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 sleeve gastrectomy 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. 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***, conversion to open procedure, laparoscopic gastric bypass, vertical banded gastroplasty, duodenal switch, laparoscopic adjustable gastric band, 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 the photographing or videotaping of the procedure(s) that may be performed, provided my identity is not revealed by the pictures or by descriptive text accompanying them.

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.

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, the facts, anticipated benefits, material risks, alternative therapies and the risks associated with the alternatives of the procedure(s).

_____	_____	_____
Date	Time	Signature of Physician

<u>USE OF INTERPRETER OR SPECIAL ASSISTANCE</u>

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