



Center of Excellence
BARIATRIC SURGERY

BLUEPOINT
SURGICAL GROUP



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**INFORMED CONSENT FOR LAPAROSCOPIC
GASTRIC SLEEVE SURGICAL PROCEDURE**

It is very important to the surgeons that you understand and consent to the treatment they are rendering and any procedure they may perform. You should be involved in any and all decisions concerning surgical procedures your surgeon 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 the 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 my 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. My Surgeon has counseled me regarding my decision, has made professional recommendations, and we have together agreed on the planned procedure as acceptable and appropriate.

Patient's Initials or Authorized Representative _____ Date _____

I, _____, hereby authorize my surgeon and any associates or assistants the surgeon deems appropriate, to perform laparoscopic gastric sleeve surgery. The Surgeon has explained to me the risks of obesity and the benefits of a laparoscopic gastric sleeve. 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 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. The 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 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.

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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 sleeve. I understand that to be effective, I need to make a life-long commitment to lifestyle changes, **which may include, but not be 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 dietician and supervised dietary therapy), physical activity, behavior therapy and 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 Bluepoint Surgical Group or other designated physician which may include diet, physical activity, and behavior modification.

Proposed Procedure. I understand that the procedure that the surgeon has recommended for the treatment of my obesity is the laparoscopic gastric sleeve. My surgeon has provided a detailed explanation of the medical history of the development of the surgical treatment of obesity, the gastric sleeve as a treatment of obesity, the development of laparoscopic (minimally invasive) surgery and the gastric sleeve. 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 sleeve, which will be done laparoscopically. I understand that performing this procedure laparoscopically 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. It has been further explained to me that the laparoscopic approach to gastric sleeve surgery to treat morbid obesity is new. **I understand that since it is a new procedure, the incidence of risks of the surgery along with its effectiveness will not be known for some time.**

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Risks/Possible Complications. My surgeon has explained to me that there are risks and possible undesirable consequences associated with a Laparoscopic Gastric Sleeve 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

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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

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3. Mineral deficiencies, including calcium, magnesium, iron, zinc, copper, etc

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. 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)

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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 am expressly authorizing. I also understand that some or all of the complications listed on this form and also explained to me may exist regardless of whether the surgery is performed. Gastric sleeve surgery is not the only cause of these complications.

Alternative Procedures. In permitting the surgeon 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 surgeon(s), 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**, laparoscopic gastric bypass, vertical banded gastroplasty, duodenal switch, laparoscopic adjustable gastric band, various diet exercise and drug treatments. 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. I consent to the admittance of students and/or authorized equipment representatives to the procedure room for purposes of advancing medical education or obtaining important product information.

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By signing below, I certify that I have had an opportunity to ask the surgeons 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 Representative

Relationship of Authorized Representative _____

_____ 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, _____, expressed above as “surgeon” 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 _____

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 _____

Patient initials _____