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Ascension St. Agnes Bariatric Surgery

Drs. Andrew Averbach, Isam Hamdallah and Catriona Swift

Informed Consent for Laparoscopic Vertical Sleeve Gastrectomy

Name_____ Date of Birth_____ Surgery Date_____

Please read this form carefully and ask about anything you may not understand.

I consent to have laparoscopic **Vertical Sleeve Gastrectomy** for the purpose of weight loss. I met my attending surgeon in the office during my initial consultation. My attending surgeon will perform the procedure, direct my care during the operation, and may be assisted by other physicians, fellows and/or residents under his or her supervision.

As has been explained to me, obesity is associated with early death and significant medical problems such as hypertension, diabetes, obstructive sleep apnea, high cholesterol, infertility, cancer, gastroesophageal reflux, arthritis, chronic headaches, gout, venous stasis disease, liver disease and heart failure, among other problems.

My attending surgeon has explained to me that laparoscopic Vertical Sleeve Gastrectomy can improve or cause remission of many medical problems such as hypertension, diabetes, obstructive sleep apnea, high cholesterol, infertility, cancer, gastroesophageal reflux, arthritis, chronic headaches, venous stasis disease, liver disease and heart failure. I understand there are no specific guarantees that any one of these conditions will improve or resolve in any given patient as a result of the surgical procedure.

My attending surgeon has discussed with me the alternatives to laparoscopic Vertical Sleeve Gastrectomy, which include non-surgical options. The opportunity to discuss other surgical options such as laparoscopic Gastric Bypass or SADI has been made available to me. I have advised my surgeon that I have attempted non-surgical weight loss programs without success.

I understand the anatomy of the laparoscopic Vertical Sleeve Gastrectomy and have been shown illustrations of the procedure.

I have been given the opportunity to discuss alternative methods for weight loss. This includes diet and exercise as well as other surgical methods. I believe that the laparoscopic Vertical Sleeve Gastrectomy offers the best balance between risks and benefits for me.

I understand the incidence of complications may be dependent on my particular medical history as well as my surgeon's level of training and experience. I have discussed these issues specifically with my surgeon.

I understand that the risks of the laparoscopic Vertical Sleeve Gastrectomy include, but are not limited to the following:

Intra-operative and/or Immediate Post-operative Risks:

Death: The mortality rate of the laparoscopic Vertical Sleeve Gastrectomy nationwide ranges from 0.3% to 2%.

Significant Bleeding: Bleeding may occur unexpectedly in the operating room. Bleeding may also occur post-operatively in the days after the operation. This bleeding may be through the intestinal tract and result in the passage

of blood in the stool. Bleeding may also be unseen inside the abdomen and be diagnosed through other means. A transfusion may be necessary in some circumstances. Re-operation to stop bleeding may be necessary.

Staple Line Leak: A significant portion of the stomach will be removed permanently during this procedure. A special surgical stapler device is used to seal and cut this portion of stomach. Leaks at the staple line (where the seal is not watertight) can result in serious complications, including, but not limited to a prolonged hospital stay, a long period of nothing to eat, prolonged antibiotic requirements, organ failure and death. The incidence of staple line leak may range from 0.5% to 3%.

Renal Failure: Transient kidney (renal) failure occurs rarely. Irreversible kidney failure has been reported in rare cases.

Prolonged Ventilation: A prolonged stay on a ventilator (breathing machine) in the intensive care unit may occur if a patient has severe sleep apnea or after certain significant complications. A temporary tracheostomy may be necessary.

Heart Attack: Although a heart attack is possible after a laparoscopic Vertical Sleeve Gastrectomy, it is very rare. Risk factors for heart disease include increased age, diabetes, hypertension, hypercholesterolemia and a family history of heart disease.

Prolonged Hospital Stay: Unforeseen complications may result in a prolonged hospital stay. Intensive care admission may be required.

Bowel Obstruction: An obstruction can occur that would require re-operation. An obstruction can occur from a number of causes, such as bleeding, scarring, technical problems or hernia.

Deep Vein Thrombosis (DVT)/Pulmonary Embolism: Blood clots that form in the legs, and elsewhere, and break off into the lungs may cause death. Given this risk, treatments may be initiated to decrease the risk for the formation of blood clots, including the use of heparin (a medication that thins the blood), special foot and leg stockings, walking soon after surgery and medication at home after discharge from the hospital. Completely eliminating the risks of DVT (clots) altogether is not medically possible. The risks associated with the medications used to prevent blood clots can include excessive bleeding. Any symptoms of leg swelling, chest pain or sudden shortness of breath should be immediately reported to the surgeon. Rarely, patients develop allergies to heparin, sometimes causing very severe reactions.

Other Complications that may be common: Allergic reactions, headaches, itching, medication side-effects, heartburn/reflux, bruising, gout, anesthetic complications, injury to the bowel or vessels, gas bloating, minor wound drainage, wound opening, scar formation, stroke, urinary tract infection, urinary retention, pressure sores, injury to spleen or surrounding structures, and pneumonia.

Risks Associated with an Open Procedure: If a conversion to an open procedure is required, complications include but are not limited to: wound infection, which may cause significant scarring and healing problems, prolonged wound care, and discomfort. Incisional hernias may occur in a substantial number of patients after an open procedure. Hernias will often require an operation to repair. There is a higher chance of certain complications including lung infections, pressure ulcers and blood clots after an open operation. There would also likely be more discomfort and a longer hospital stay.

Risks in the Early Postoperative Period:

Stricture: A kink, or stricture along the length of the stomach can occur that can cause a blockage of food. This is an uncommon complication. A kink or stricture may require various interventions to treat.

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Fatigue: After any general anesthesia, fatigue is very common. Fatigue may last days, or in some circumstances, much longer.

Food Intolerance: Following the laparoscopic Vertical Sleeve Gastrectomy, some patients may experience intolerance to certain food types. Food intolerances usually improve with time.

Late Complications:

B12 Deficiency: The incidence of B12 deficiency after laparoscopic Vertical Sleeve Gastrectomy is not well described. The part of the stomach removed after laparoscopic Vertical Sleeve Gastrectomy produces an enzyme that assists in B12 absorption, and it is likely after laparoscopic Vertical Sleeve Gastrectomy there is a decrease in B12 absorption. B12 supplementation may be recommended to prevent various complications such as anemia or even nerve damage.

Osteoporosis and Iron Deficiency: The incidence of these deficiencies after laparoscopic Vertical Sleeve Gastrectomy is not well established. Most surgeons believe the incidence should be lower than the gastric bypass because food is not re-routed through the intestine.

B Vitamin Deficiencies: Deficiencies in Thiamine, Niacin, and others have been reported. These B vitamin deficiencies are very rare. Some B vitamin deficiencies can cause irreversible neurological damage. All patients are required to take a multivitamin supplement for life after this operation. Sometimes, additional B vitamin supplements are also required. It is important to be evaluated regularly for vitamin deficiencies after surgery. Severe vomiting is a risk factor for the development of B vitamin deficiencies.

Bowel Habits: Changes in bowel habits are common. The most common complaint after surgery is constipation.

Pregnancy: I understand the pregnancy should be deferred for 12 months after laparoscopic Vertical Sleeve Gastrectomy because of concern for fetal and maternal health. I also understand that fertility may be substantially increased very early after surgery due to my weight loss. I understand that I am responsible for using appropriate birth control methods in this time period. Studies appear to show a decreased rate of complications of pregnancy in those patients who have had weight loss surgery. There may be rare instances where complications of pregnancy may be increased secondary to having laparoscopic Vertical Sleeve Gastrectomy.

Gallbladder Problems: Significant weight loss promotes the formation of gallstones. There is an increased risk in the future of requiring removal of the gallbladder due to gallstones.

Weight Regain: Modest weight regain years after surgery is typical. Significant weight regain may occur more rarely. The causes of weight regain are complex.

Excessive Weight Loss: Excessive weight loss is uncommon and usually results from complications that require close management by the surgeon.

Psychiatric Complications: Although most people experience improvements in their mood, some will have worsening states of depression which could lead to suicide. There may be a higher incidence of marital problems after weight loss surgery. Patients taking psychiatric medications should have the dosage and effectiveness of these medications monitored carefully by their prescribing physician.

Temporary Hair Loss: Hair loss occurs in many people after a weight loss operation. Hair generally grows back. There are no proven supplements to alter hair loss.

Other Complications: There may be other extremely rare and significant complications that may occur which are not well described to date.

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Unlisted complications: I understand that it is impossible to list every complication possible during and after this procedure.

Possible Additional Procedures:

During the laparoscopic Vertical Sleeve Gastrectomy procedure, several conditions may arise that may cause additional procedures to be performed. These include:

A liver biopsy: Many patients will have a liver biopsy performed. Bariatric patients often have some degree of liver disease. A biopsy helps determine the severity of liver disease (if present at all) and helps with post-operative management. The risks with performing a liver biopsy include a low chance of bleeding.

Removal of the gallbladder: In some patients, removal of the gallbladder may be medically necessary. Removal of the gallbladder increases the length of time of the total operation. There is a small risk of bile duct injury that can result in serious complications. Removal of the gallbladder may increase the hospital stay and increase post-operative pain. An additional port (and incision) may be necessary to perform the procedure safely.

Incisional Hernia repair: A hernia may have to be repaired at the time of the operation.

Esophagogastroduodenoscopy: An EGD, or upper endoscopy, is sometimes performed during the laparoscopic Vertical Sleeve Gastrectomy operation.

Hiatal Hernia repair: If a hiatal hernia is present, this may require repair during the surgery. The associated risks with a hiatal hernia repair include, but are not limited to injury to the esophagus, dysphasia (difficulty swallowing) and hernia recurrence.

Lysis of Adhesions: In the setting of a previous operation or significant abdominal infection, scarring always results. The degree of scar tissue is unpredictable. Sometimes, depending on the location of the scar tissue, the scar tissue must be cut (called "lysis of adhesions") in order to perform the weight loss operation. There are increased risks when a lysis of adhesions is necessary, including injury to the intestines, prolonged operative times and bleeding.

Placement of a Drain: In certain circumstances, the surgeon may elect to place a temporary plastic drain. A drain is a thin plastic tube that comes out of the body into a small container to allow for the removal of fluid and the control of infection.

Risks/Possible Complications The doctor has explained to me that there are risks and possible undesirable consequences associated with bariatric surgery 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 embolism (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 18 months 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 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. Intestinal leaks
24. Kidney failure
25. Kidney stones
26. Loss of bodily function (including from stroke, heart attack or limb loss)
27. Myocardial infarction (heart attack)
28. Narrowing of the connection between the stomach and small bowel
29. Need for and side effects of drugs
30. Organ failure
31. Perforations (leaks) of the stomach, or intestine causing peritonitis, subphrenic abscess or enteroenteric or enterocutaneous fistulas
32. Pleural effusions (fluid around the lungs)
33. Pneumonia
34. Possible removal of the spleen
35. Pressure sores
36. Pulmonary edema (fluid in the lungs)
37. Serious intra-abdominal infections including sepsis or peritonitis
38. Skin breakdown
39. Small bowel obstructions
40. Staple line disruption
41. Stoma Stenosis
42. Stroke
43. Systemic Inflammatory Response Syndrome (SIRS)
44. Ulcer formation (marginal ulcer or in the distal stomach)
45. Urinary tract infections
46. Wound infection

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

1. Protein malnutrition
2. Vitamin deficiencies including B12m B1m 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

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

1.Depression
2. Bulimia
3. Anorexia

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4. **Dysfunctional social recidivism**
5. **Alcohol dependency and recidivism**

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

1. **Adverse outcomes maybe 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 or 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 (NAFDL)**
20. **Progression of pre-existing NAFLD or cirrhosis**
21. **Vitamin deficiencies, some of which may have already existed before surgery**
22. **Diminished alcohol tolerance**

Pregnancy complications were explained as follows:

1. **Pregnancy should be deferred for 12-18 months after surgery or until weight loss is stabilized**
2. **Vitamin supplementation during pregnancy should be continued**
3. **Extra folic acid should be taken for planned pregnancies**
4. **Obese mother have children with 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 as 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 the complications listed on this form and explained to me may exist whether the surgery is performed or not, in that gastric sleeve surgery is not the only cause of these complications.

I have had the opportunity to read these materials, speak with my attending surgeon, and ask any questions. I understand that unforeseen events may occur that could result in the last-minute cancellation or postponement of my surgery. I have reviewed all of the information in this consent form and related consent materials with my immediate family. I have clearly stated to my closest family members that I fully understand the risks of surgery

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and accept such risks. I have read, or had read to me, the contents of this consent form and related consent materials and have no further questions. I wish to proceed with laparoscopic Vertical Sleeve Gastrectomy surgery.

_____ _____

Printed Name Date and Time

_____ _____

Signature Surgeon's Signature

_____ _____

Witness to signature only Date and Time

Ascension St. Agnes Bariatric Surgery Program

Patient Contract: Laparoscopic Vertical Sleeve Gastrectomy

This contract is supported by my surgeon, _____, and will be effective and ongoing from the initial evaluation for a laparoscopic vertical sleeve gastrectomy. The purpose of this Contract is to outline and document that I, _____ (name) understand and agree to follow all the instructions, protocols and directions before and after my surgery.

Bariatric Surgery is a special opportunity for patients with obesity to improve the quality of their lives. This program is dedicated to promoting and providing this option to all. However, it has been well documented that Bariatric Surgery patients who are non compliant with medication, postoperative instructions, and outpatient follow up visits, or who otherwise do not take care of themselves, have a higher degree of complications.

I affirm that I am significantly overweight and have attempted non-surgical weight loss programs without success. The doctor has explained that obesity can cause early death and significant medical problems including but not limited to such as hypertension, diabetes, obstructive sleep apnea and high cholesterol.

Medicine is an unpredictable field. Unpredictable complications can occur. No amount of pre-operative testing can assure an uncomplicated outcome. I have the responsibility to inform my doctors of any concerns, worries or possible complications at the earliest possible time. I agree that my doctors may make recommendations and I take full responsibility if I do not follow these recommendations.

I understand that significant weight loss is a life-altering event. Significant changes in eating behavior occur. I understand that every patient's experience varies and the exact prediction in my ability to cope with significant forced behavior changes cannot be predicted. I understand that my surgeon can assist in locating a mental health provider who can help me with behavioral needs.

I plan on following all post-operative visits recommended by my doctors. I plan on obtaining all tests requested by my doctors. I will abide by all nutritional supplements/recommendations that my doctors prescribe. If my surgeon's practice ever ceases to exist; I take responsibly to find an appropriate physician to monitor my life-long follow-up. If I leave the area I take responsibility in finding appropriate follow-up. I understand that proper medical follow-up requires a financial commitment that may include maintenance of health care insurance. There may be costs in the form of fees, co-payments, deductibles, lost time from work and transportation. These costs may greater than planned in the event of complications.

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Medication problems: I understand that I will have to monitor my post-operative medication doses closely with the doctors that have prescribed them. My doctors will help if necessary. Examples of common medication problems include lightheadedness from too high a dose of high blood pressure medication and too low a blood sugar from excessive diabetic medication. I agree to work closely with my primary care doctor to regulate my medication.

Depression: I understand that it is my responsibility to seek psychological help if needed. Although most people experience improvements in their mood, some will have worsening states of depression. Weight loss is not a cure-all for all psychological problems. It is my responsibility to seek psychological help when necessary.

Smoking and other addictions: I agree and take full responsibly to quit smoking to prevent potential life threatening illnesses. Addiction to alcohol, narcotics and other illicit drugs will severely impact my health.

Return to work: I understand that although many patients can return to work within one to two weeks, some patients may require a longer recovery. My doctors are not responsible for financial difficulties due to lost work time.

B vitamin deficiencies: Deficiencies in Thiamine, Niacin, B12 and others have been reported. These B vitamin deficiencies are very rare. Some B vitamin deficiencies can cause irreversible neurological damage. All patients are required to take a multivitamin supplement for life after this operation. Sometimes, additional B vitamin supplements are also required.

Poor weight loss and Weight Regain: Weight regain may occur, especially with "grazing" behavior. The laparoscopic vertical sleeve gastrectomy procedure is a powerful tool; however, it can be beaten. Constantly eating foods such as chips and nuts or other high calorie snacks will result in less than expected weight loss or even weight regain. High calorie liquids such as ice cream, desserts, sodas and juices may also decrease weight loss. I will take responsibility for my eating behaviors. Exercise is an excellent means to improve health and maintain weight loss. I take responsibility to increase my physical activity and will discuss with my physicians healthy methods to do so. Weight loss after a laparoscopic vertical sleeve gastrectomy is expressed as loss of a percentage of my pre-operative excess body weight. Excess weight is defined as my current weight minus my ideal body weight. On average, patients lose between 70 and 80 percent of excess weight at two years. The range of excess weight loss that nearly all patients may experience may range widely from 40%-100%. My doctors will give me recommendations in how to experience the most optimal weight loss. Although, the majority of patients are satisfied with their weight loss, there is no guarantee that I will achieve my goal weight. I understand that the chances of reaching my ideal body weight are low. I understand that bariatric surgery is a tool that assists with weight loss. I understand that most patients will regain some weight, and that a few can regain substantial weight. I understand that is to my responsibility to maintain healthy eating and exercise habits as prescribed by my surgeon to assist in maintenance of optimum weight loss.

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Pregnancy: Women who were infertile may become fertile after their operation. I understand that I will need to use birth control to prevent unexpected pregnancies after this procedure. The risks associated with pregnancy in an obese person are generally higher than a non-obese person. There is no significant data to suggest that the risks of pregnancy are greater, either to the mother or child, after laparoscopic vertical sleeve gastrectomy surgery. I agree that before and during pregnancy, I will discuss my nutritional needs with my surgeon and obstetrician. I will always make sure that I am taking adequate vitamins and minerals throughout pregnancy and while nursing. I absolve my surgeon of any responsibility of complications of pregnancy as complications may occur with any pregnancy and there is no definitive means to prove any complication was due solely to the laparoscopic vertical sleeve gastrectomy.

I agree not to get pregnant for 12 months after a laparoscopic vertical sleeve gastrectomy. The safety of pregnancy is NOT established for patients during periods of rapid weight loss. SERIOUS, life-threatening complications may occur. I take full responsibility for birth control during this time period.

I understand that I may not be able to breast-feed during periods of rapid weight loss. If I am currently breast-feeding, I plan to wean my child before undergoing weight loss surgery.

If I watched the pre-operative class virtually, I acknowledge it is up to me to notify my surgeon or the program nurses if I have unanswered questions.

This document has been thoroughly reviewed and explained to me, and my signature reflects my understanding of its purpose and expectations, as well as my agreement to its terms.

By signing this Contract, I agree to follow the documents guidelines and instructions and understand that failure to comply may impact the result of my surgery.

_____ _____

Patient Signature Date

_____ _____

Witness Signature Date