East Cooper Bariatric Surgery
EAST COOPER MEDICAL GROUP

Informed Consent for Laparoscopic Sleeve Gastrectomy

Patient Name

_____

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

I consent to have a **Sleeve Gastrectomy** for the purpose of weight loss. I met my attending surgeon in the office either during my initial consultation or during my second consult visit prior to surgery. One of these visits may have been completed virtually. My attending surgeon will perform the procedure, direct my care during the operation, and he will be assisted by his physician assistant.

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.

Dr. Washington has explained to me that 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.

Dr. Washington has discussed with me the alternatives to Sleeve Gastrectomy surgery, which include non-surgical options. The opportunity to discuss other surgical options such as implantation of an adjustable gastric band 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 Sleeve Gastrectomy procedure and have been shown illustrations of the procedure. I also understand that the Sleeve Gastrectomy procedure is permanent and not reversible because portion of my stomach is removed.

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 sleeve gastrectomy procedure 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.

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

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

Death: The mortality rate of the Sleeve Gastrectomy nationwide is approximately 8 out of 10,000 (0.08%) surgical procedures.

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 at the anastomosis 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 Leaks: A leak is when the staple line along the stomach does not heal. Serious complications can result from a leak, including, but not limited to a prolonged hospital stay, a long period of nothing to eat, prolonged antibiotic requirements, organ failure and death. The reported incidence of staple line leaks nationwide ranges from 1-5%. Persistent leaks after Sleeve Gastrectomy may be difficult to manage and may require temporary insertion of a stent. A stent is a flexible tube inserted through the mouth with the use of an endoscope that allows the leak to heal. Additionally, a feeding tube may be required for nutrition. Rarely, conversion to a gastric bypass or complete removal of the stomach may be necessary to control a leak.

Portomesenteric Venous Thrombosis: Rarely (0.4%), clots may develop in the veins draining the intestine. If this occurs, it can interfere with the circulation of the intestine. Prolonged anticoagulation may be required for treatment. In very rare cases intestinal infarction may occur requiring removal of a piece of intestine.

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 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 occur in approximately one-third of patients after an open sleeve gastrectomy 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:

Gastric Outlet Obstruction: Obstruction of the stomach may occur after sleeve gastrectomy causing inability to tolerate liquids or solid foods. This is sometimes a result of edema (swelling) and with time may resolve on its own. In some cases the obstruction can be more severe requiring dilatation (stretching) or on rare occasions conversion to a gastric bypass procedure.

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

Late Complications:

Osteoporosis: Osteoporosis secondary to Vitamin D deficiency may occur years after a sleeve gastrectomy. This is a difficult diagnosis to make until weakness of the bone has already developed.

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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. 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. Changes may include constipation, diarrhea and excessive flatus. Food intolerances are very common and unpredictable.

Pregnancy: I understand that pregnancy should be deferred for 12 months after sleeve gastrectomy surgery 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 a sleeve gastrectomy. There may be rare instances where complications of pregnancy may be increased secondary to having a 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. There may be a higher incidence of marital problems after weight loss surgery.

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: Autonomic Dysfunction (causing dizziness when standing) and hypoglycemia are not uncommon symptoms after surgery. There may be other extremely rare and significant complications that may occur which are not well described to date.

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

Possible Additional Procedures:

During the sleeve gastrectomy operation, 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 sleeve gastrectomy operation in order to visualize the new stomach, or to make sure there are no other abnormalities of the intestinal tract.

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.

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 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 the sleeve gastrectomy surgery.

Patient Signature	Date / Time
Physician Signature	Date / Time
Witness to Signature only	Date / Time

PATIENT INITIAL EACH PAGE: ____ Date: _____