



**Informed Consent for  
Endoscopic Sleeve Gastropasty (ESG)**

Patient Name \_\_\_\_\_

DOB \_\_\_\_\_

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

I allow True You Weight Loss and staff to treat me.

I understand that 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.

I understand that ESG, when combined with appropriate healthy behaviors including diet and exercise, can assist with weight loss and improve 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 as a result of the procedure.

I understand the alternatives to ESG, which include both surgical and non-surgical options. The opportunity to discuss other surgical options such as the Roux-en-Y gastric bypass, surgical sleeve gastrectomy, intragastric balloon placement, and duodenal switch has been made available to me. I also understand that non-surgical options including dieting and exercise are an important component of treatment following ESG in order to accomplish weight loss.

I request that my physician perform an Endoscopic Sleeve Gastropasty (ESG) for the purposes of helping me to lose weight. I request that my physician and/or staff under his or her supervision perform the procedure, and direct my care during the procedure.

The staff on my treatment team may include doctors, residents, nurses and, students. The staff may also include technicians, assistants, and others. This staff may help to important parts of my operation or procedure. The doctor may ask others who do not work at True You Weight Loss to be in the room to support the use of equipment.

The doctor overseeing my operation or procedure will be present for all critical parts of my operation or procedure. Another member of my treatment team may perform some other aspects of my operation or procedure, as my doctor deems appropriate.

I understand the procedure as follows:

The ESG procedure is an endoscopic weight loss procedure performed with the Apollo Overstitch suturing system. The Overstitch system is an FDA approved suturing system. However, the ESG procedure is currently considered investigational by the American Society for Metabolic and Bariatric Surgery. The procedure is performed under general anesthesia. A flexible endoscope is inserted into the mouth and advanced into the stomach. The endoscope is equipped with a suturing device that allows placement of full-thickness sutures. A series of sutures is placed along the greater curve of the stomach in order to plicate and reduce the stomach size. The end result is an approximate 70% reduction in stomach size. Following the procedure, gradual advancement from a liquid to solid diet will occur over a 4-5 weeks period.

Success of the procedure hinges on adherence to the diet protocol and avoidance of over-eating, so that the stomach can heal properly, and the sleeve can retain its shape and effect.

I understand the risk 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 the risks of the ESG Procedure include, but are not limited, to the following:**

**Endoscopy-Related Risks:**

**Aspiration:** Regurgitation of stomach juices or food into the lungs can occur during the ESG procedure. Severe aspiration is unlikely and the risk is decreased by fasting before the procedure. Severe aspiration can cause pneumonia, respiratory failure requiring support with a breathing machine, and even death.

**Significant Bleeding:** Significant bleeding after an endoscopic procedure is uncommon. Bleeding may occur during endoscopy or immediately afterwards. A blood transfusion may be necessary in these rare circumstances. Repeat endoscopy or surgery to stop bleeding may be necessary. Hemodynamically significant bleeding has been reported in <1% of ESG cases.

**Stomach or Esophageal Injury:** Injury to the stomach or esophagus is a rare complication that can cause life-threatening complications and may require emergency surgery for treatment, a prolonged hospital stay, a long period of nothing to eat, prolonged antibiotic requirements, organ failure and even death.

**Organ Failure:** In rare circumstances, organ failure may occur following the ESG procedure. This may include failure of the kidney, heart, lungs or liver.

**Prolonged Hospital Stay:** Complications may result in a prolonged hospital stay. In some cases surgery may be necessary to treat a problem or complication from the ESG Procedure.

**Deep Vein Thrombosis (DVT)/Pulmonary Embolism:** Blood clots after endoscopic procedures are uncommon. Blood clots that form in the legs, or elsewhere, and break off and travel to the heart and lungs may cause death.

**Other Complications that may be common:** Allergic reactions, headaches, itching, medication side-effects, damage or irritation of the vein where intravenous medications were given, heartburn/reflux, anesthetic complications, injury to the bowel or vessels, gas bloating, aspiration of gastric contents into the lungs.

**Death:** No deaths have been reported following ESG, though any endoscopic procedure carries a risk of death, estimated at less than one in ten thousand.

**Poor Weight Loss:** I have discussed with my physician the average weight loss that is seen with patients after the ESG Procedure. I understand that there is no way to predict my own weight loss after the procedure. Weight loss resulting from various surgical weight loss procedures can be variable and unpredictable. I understand that my adherence to the dietary recommendations is critical to my weight loss success following ESG.

**Weight regain:** Weight regain may occur. This may occur for a number of reasons. No weight loss method is foolproof. I understand that over-eating may lead to failure of the ESG suture line and/or delayed weight regain.

**Psychiatric Complications:** Although most people experience improvements in their mood, some will have worsening states of depression, which could lead to suicide. Some patients also experience anxiety from the foreign body within their stomach. Patients taking psychiatric medications should have the dosage and effectiveness of these medications monitored carefully by their prescribing physician.

**Procedure Abortion:** Under very rare circumstances, the physician may determine that the procedure should be aborted all together. This is most often due to diagnosis of medical problems such as severe liver disease with varices or tumors under endoscopy.

**Unlisted Complications:** I understand that it is not possible to list every complication that could occur during and after the ESG Procedure.

*I confirm that:*

I have had the opportunity to read these materials, speak with my attending physician, and have my questions answered to my satisfaction.

I will actively engage in managing my own health care by following physician orders, communicating directly with my physician or practice representative with any questions, concerns or needs. I have been given contact information for both my physician and practice representative and know how to contact them in case of an emergency.

I understand that unforeseen events may occur that could result in the last minute cancellation or postponement of my procedure.

I have reviewed all of the information in this consent form and related consent materials. I have also discussed this information with my immediate family and 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 request to proceed with the ESG procedure.

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Date and Time

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date and Time

\_\_\_\_\_  
Witness to signature only

\_\_\_\_\_  
Date and Time