

**Informed Consent for
Endoscopic Bariatric Revision**

Patient Name _____
DOB _____
MRN _____

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

I request that my physician perform an Endoscopic Bariatric Revision 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.

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 Endoscopic Bariatric Revision, 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 Endoscopic Bariatric Revision, which include both surgical and non-surgical options. The opportunity to discuss other surgical options, including revision gastric bypass and revision sleeve gastrectomy, have been made available to me. I also understand that non-surgical options including dieting and exercise are an important component of treatment following Endoscopic Bariatric Revision in order to accomplish weight loss.

I understand the procedure as follows:

The Endoscopic Bariatric Revision procedure is an endoscopic weight loss procedure performed with the Apollo Overstitch suturing system. The Overstitch system is an FDA approved suturing system. 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. Sutures will be placed to reduce the size of the gastrojejunostomy (outlet revision) and/or gastric pouch, or to reduce the size of the stomach following prior sleeve gastrectomy. Following the procedure, gradual advancement from a liquid to solid diet will occur over a 4-5 weeks period.

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

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 Endoscopic Bariatric Revision 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 Endoscopic Bariatric Revision 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.

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 Endoscopic Bariatric Revision 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 Endoscopic Bariatric Revision 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.

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Death: No deaths have been reported following Endoscopic Bariatric Revision, 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 Endoscopic Bariatric Revision 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 Endoscopic Bariatric Revision.

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 Endoscopic Bariatric Revision 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 Endoscopic Bariatric Revision 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.

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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 Endoscopic Bariatric Revision procedure.

Printed Name

Date and Time

Signature

Date and Time

Witness to signature only

Date and Time

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