

**INFORMED CONSENT FOR LAPAROSCOPIC ADJUSTABLE GASTRIC BAND**

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

I consent to undergo laparoscopic placement of a laparoscopic Adjustable Gastric Band for the purposes 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 implantation of an laparoscopic Adjustable Gastric Band 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 in any given patient as a result of the surgical procedure.

My attending surgeon has discussed with me the alternatives to laparoscopic Adjustable Gastric Band surgery, which include non-surgical options. The opportunity to discuss other surgical options such as the laparoscopic Roux-en-Y Gastric Bypass has been made available to me. I have advised my attending surgeon that I have attempted non-surgical weight loss programs without success.

Two companies manufacture a laparoscopic Adjustable Gastric Band. Ethicon Endo-Surgery, a division of Johnson and Johnson, makes the Realize Band®. Allergan makes the Lap-Band System®. I have had the opportunity to discuss my surgeon's preference in manufacturer. The type of laparoscopic Adjustable Gastric Band that my surgeon plans to implant is the REALIZE®/Lap-Band® (circle one).

As has been explained to me by my attending surgeon, I understand the anatomy of the operation as follows:

The laparoscopic Adjustable Gastric Band involves placing a ring around the top portion of the stomach. This ring is made from a commonly used silicone-based material. The plastic ring has a balloon along the inside. The balloon is attached to tubing that connects to a port. The port is placed underneath the skin. By injecting fluid in the port, the balloon inflates and closes tighter around the stomach. This makes food more difficult to pass through and gives the sensation of fullness.

**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 the risks of the laparoscopic Adjustable Gastric Band include, but are not limited to the following:**

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

**Death:** The mortality rate of the laparoscopic Adjustable Gastric Band nationwide is around 1 in 1,600.

**Significant Bleeding:** Significant bleeding after a laparoscopic Adjustable Gastric Band is reported to be extremely rare. Bleeding may occur unexpectedly in the operating room or immediately afterwards. A transfusion may be necessary in these rare circumstances. Re-operation to stop bleeding may be necessary.

**Stomach or Esophageal Injury:** Injury to the stomach or esophagus can cause life-threatening complications including a prolonged hospital stay, a long period of nothing to eat, prolonged antibiotic requirements, organ failure and death. This is a very rare complication.

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

**Prolonged Hospital Stay:** Complications may result in a prolonged hospital stay.

**Deep Vein Thrombosis (DVT)/Pulmonary Embolism:** Blood clots after a laparoscopic Adjustable Gastric Band are typically uncommon. 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, and scar formation.

**Acute Obstruction:** Rare patients will not be able to tolerate any liquids or solids immediately after the gastric band is placed. Acute obstruction usually occurs in the first day after surgery and may require a re-operation to loosen the obstruction. There are several possible reasons for obstruction including band slippage, stomach swelling and poor positioning of the band.

**Infection:** Uncommonly, infections caused by the laparoscopic Adjustable Gastric Band can occur. Infections caused by prosthetic devices are very difficult to treat with antibiotics alone. Infections of the laparoscopic Adjustable Gastric Band often require removal of the entire system.

**Procedure Abortion:** Under very rare circumstances, the surgeon may determine that the procedure should be aborted all together. This is most often due to the presence of massive scarring from previous surgeries, or the intra-

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operative diagnosis of medical problems such as severe liver disease or tumors.

**Conversion to Open Procedure:** In rare circumstances, the procedure may not be able to be performed laparoscopically. 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 are not uncommon after an open procedure. Hernias will often require a subsequent 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.

**Late Complications:**

**Weight regain:** Weight regain may occur. This may occur for a number of reasons. No weight loss method is foolproof.

**Poor Weight Loss:** I have discussed with my surgeon the average weight loss that is seen with patients after a laparoscopic Adjustable Gastric Band. 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, including the laparoscopic Adjustable Gastric Band, is variable and unpredictable. Some patients lose very little weight after an laparoscopic Adjustable Gastric Band.

**Slippage:** The laparoscopic Adjustable Gastric Band can slip out of position. If this occurs patients may not be able to tolerate any food or even liquids. There may be mild to severe abdominal pain. Urgent repair is often necessary. There are very rare reports of patients who have died from a slipped gastric band that caused the stomach to lose its blood supply.

**Tubing Problems:** During the adjustments performed in the office, it is possible to puncture the tubing accidentally. This would require a minor operation to correct. The tubing of the band can crack on rare occasions. If this occurs, all the fluid leaks out and the patient will experience a complete lack of restriction. This would require a minor re-operation to fix.

**Adjustment Problems:** I have discussed with my surgeon the gastric band adjustment process. My surgeon or another qualified individual will perform my adjustments. I understand that adjustments are either performed in the office or under X-Ray guidance, depending on what my surgeon believes is best for me. I understand that there is no fool-proof method to efficiently adjust my band. I understand that some patients may only need a few adjustments, while others may need numerous adjustments. I understand that my band may be accidentally adjusted too tightly. If this occurs, I will need to contact my surgeon's office immediately. I understand that my surgeon will only perform an adjustment if it is in my best interest. Over- adjustment (over-tightening) of the band may cause irreversible problems such as pouch dilation, esophageal dilation, gastro-esophageal reflux, pneumonia and perhaps band slippage. I understand that if I am traveling, I may have difficulty finding a qualified physician who can manage my band. I understand that if I move out of the area, I may encounter difficulty in finding a qualified surgeon to adjust and manage my band. Complications of the adjustment process may include bruising, discomfort, infection or damage to the port or tubing.

**Pouch Dilation and/or Esophageal Dilation:** Dilation of the stomach pouch and/or the esophagus may occur after placement of the gastric band. This complication typically is due to over-adjustment (over-tightening) of the band.

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Symptoms may include poor weight loss and heartburn. Treatment of this complication may require band deflation, operative repositioning of the band or band removal.

**Port Problems:** The port can flip out of position. If this occurs, it may be difficult to adjust the gastric band. The only manner to correct a port flip is to perform a procedure in the operating room. In people who lose a significant amount of weight, the port may be seen as an unsightly bump.

**Erosion:** The gastric band may erode a hole into the stomach. If this occurs, a life-threatening infection may ensue. Band removal is the only treatment. This operation may be difficult with possible complications. Erosion is an uncommon complication. Erosions may occur years after the placement of the band.

**Band Removal:** Removal of the gastric band may be needed if the patient experiences complications. Typically, weight regain occurs quickly after band removal. Removal of the band may have complications associated with the removal procedure.

**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.

**Unlisted Complications:** I understand that it is impossible to list every complication possible during and after the laparoscopic Adjustable Gastric Band procedure.

**Possible Additional Procedures:**

During the laparoscopic Adjustable Gastric Band 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.

**Incisional Hernia repair:** A hernia may have to be repaired at the time of the operation. Sometimes a synthetic material called Mesh is implanted to better repair the hernia. Risks of hernia repair may include, but are not limited to hernia recurrence, bowel obstruction, infection or injury to important structures.

**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.

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I have had the opportunity to read these materials, speak with my attending surgeon and ask any questions. I understand 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 laparoscopic Adjustable Gastric Band surgery.

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Patient Signature

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Date

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Surgeon Signature

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Date

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Witness Signature

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