

**INFORMED CONSENT FOR GASTRIC LAP BAND
PROCEDURE – LAPAROSCOPIC**

It is very important to [insert physician, practice name] that you understand and consent to the treatment your doctor is providing for you and any procedure your doctor may perform. You should be involved in any and all decisions concerning surgical procedures your doctor has recommended. Sign this form only after you understand the procedure, the anticipated benefits, the risks, the alternatives, the risks associated with the alternatives and all of your questions have been answered. Please initial and date directly below this paragraph indicating your understanding of this paragraph.

Patient's Initials or Authorized Representative

Date

I have reviewed drawings of each of the available bariatric operations that diagrammatically show the main characteristics of each type of weight reduction operations, differences among operations, advantages, and disadvantages, of each procedure. I have had a chance to express to the surgeon my eating habits and behavior and my medical history and the surgeon has helped me to personally come to a conclusion as to the most appropriate operation for me, factoring in my eating, dietary, and medical background, and my future weight loss goals, pregnancy plans, and personal limits regarding acceptable meal size, bowel habits, and risk tolerance. The surgeon has counseled me regarding my decision, has made professional recommendations, and we have together agreed on the planned procedure as acceptable and appropriate.

Patient's Initials or Authorized Representative

Date

I, _____, hereby authorize Dr. _____ and any associates or assistants the doctor deems appropriate, to perform gastric lap band surgery.

The doctor has explained to me the risks of obesity and the benefits of a gastric lap band procedure. However, I understand there is no certainty that I will achieve these benefits and no guarantee has been made to me regarding the outcome of the procedure. I also authorize the administration of sedation and/or anesthesia as may be deemed advisable or necessary for my comfort, well being and safety.

Condition. I recognize that I am severely overweight with a weight of _____ lbs. at _____ ft. _____ inches tall. My surgeon or surgeons have clearly explained to me that this level of obesity has been shown to be unhealthy and that many scientific studies show that persons of this level of obesity are at increased risks of respiratory disease, high blood pressure, heart disease, high cholesterol, stroke, diabetes, arthritis, clotting problems, cancer and death as well as other serious and less serious medical illnesses.

Commitment. I am committed to long-term follow-up with my surgeon or surgeons and to make every effort to follow his/her directions to protect myself from these and other problems associated with Gastric Bypass. I understand that to be effective, I need to make a life-long commitment to lifestyle changes, which may include, but not be limited to, dietary changes, an

exercise program, and counseling. I understand that I will need to maintain proper nutrition, eat a balanced diet, and take vitamin and mineral supplements for the rest of my life. I will also be required to maintain follow-up medical care for my lifetime. Laboratory work will be required at least annually, and perhaps more often, as directed by a physician.

Pre-operative Requirements. I have completed the Physician-Supervised Multidisciplinary Program, which included Dietary Therapy (a discussion of dietary history and a nutritional visit by either a physician, dietician or nutritional counselor and physician-supervised dietary therapy low calorie for 3 months or very low calorie within 6 months of the scheduled surgery), Physical Activity, and Behavior Therapy and Support. Since the time of my initial evaluation to the date of surgery, I have either maintained my weight or have not gained greater than 5 pounds.

Post-operative Requirements. I agree to participate in a post-surgical multidisciplinary program that includes diet, physical activity, and behavior modification.

Proposed Procedure. I understand that the procedure that my surgeon or surgeons have recommended for the treatment of my obesity is the gastric lap band procedure. My surgeon or surgeons have provided a detailed explanation of the proposed procedure. I have been strongly encouraged to make every effort to investigate and understand the details of the operation.

I understand the nature of a gastric lap band procedure which will be done laparoscopically. I understand that performing this procedure laparoscopically entails the use of a fiberoptic endoscope along with special endoscopic instruments and staplers to facilitate in completing the procedure with smaller incisions than in an open approach. I understand that it may be necessary to convert the procedure to an open technique if it is felt to be the best medical/surgical decision in the judgment of my surgeon (s). This conversion will result in a larger incision, which has been described to me by my surgeon.

Contraindications. I understand that if my BMI is less than 40, the Lap Band procedure may not be right for me. However, if my BMI is less than 40 and I have other co-morbidities, I may be a candidate for this surgery, as explained by my physician. Other contraindications include, but are not limited to: current inflammatory disease or condition of the gastrointestinal tract such as ulcers, severe esophagitis, or Crohn's disease; current severe heart or lung disease which may make me a poor candidate for surgery; other disease that makes me a poor candidate for surgery; current health condition which causes bleeding in the esophagus or stomach, which might include esophageal or gastric varices (a dilated vein) or a congenital or acquired intestinal telangiectasia (dilation of a small blood vessel); current portal hypertension; an abnormal esophagus, stomach, or intestine whether congenital or acquired), such as a narrowed opening; prior intra-operative gastric injury such as a gastric perforation at or near the location of the intended band placement, current cirrhosis, chronic pancreatitis, pregnancy, addiction to alcohol or drugs; under the age of 18; an infection anywhere in my body or one that could contaminate the surgical area; chronic, long-term steroid treatment; inability to follow the dietary rules that come with this procedure; allergy to materials in the device; autoimmune connective tissue disease of my own or someone in my family, such as systemic lupus erythematosus or scleroderma, or symptoms of one of these types of disease. In addition, patients with a "sweet tooth" will not do well with the gastric lap band procedure or those that often drink milk shakes or other high-calorie liquids.

Risks/Possible Complications. The doctor has explained to me that there are risks and possible undesirable consequences associated with any surgery, as well as risks and possible undesirable consequences associated with the lap band procedure and these include, **but are not limited to:** blood loss, transfusion reactions, infection, heart complications, blood clots, loss of or loss of use of body part, other neurological injury, gastric perforation (a tear in the stomach wall) during or after the procedure that might lead to the need for another surgery; hospitalization and /or re-operation; nausea vomiting; gastroesophageal reflux (regurgitation); band slippage/pouch dilatation; stoma obstruction (stomach-band outlet blockage); esophageal dilatation or dysmotility (poor esophageal function) which can be caused by improper placement of the band, the band being tightened too much, stoma obstruction, binge eating, or excessive vomiting; constipation; diarrhea; dysphagia (difficulty swallowing); re-operation to fix a problem with the band or initial surgery or to fix a leak or twisted access port; band erosion into the stomach; band removal in a second operation, esophagitis (inflammation of the esophagus), gastritis (inflammation of the stomach), hiatal hernia, incisional hernia, infection, redundant skin, dehydration, diarrhea (frequent semi-solid bowel movements), abnormal stools, constipation, flatulence (gas), dyspepsia (upset stomach), eructation (belching), cardiospasm (an obstruction of passage of food through the bottom of the esophagus), hematemesis (vomiting of blood), asthenia (fatigue), fever, chest pain, incision pain, contact dermatitis (rash), abnormal healing, edema (swelling), paresthesia (abnormal sensation of burning, prickly, or tingling), dysmenorrhea (difficult periods), hypochromic anemia (low oxygen carrying part of blood), band system leak, cholecystitis (gall stones), esophageal ulcer (sore), port displacement, port site pain, spleen injury, wound infection, ulceration, gastroesophageal reflux (regurgitation), heartburn, gas bloat, dehydration, regaining of weight, slow weight loss or none at all, anemia, vitamin deficiencies and malnutrition, and/or death. I understand that if I need blood or blood products these carry a risk of contracting HIV/AIDS, hepatitis, or other diseases.

Laparoscopic surgery has its own potential risks and complications, which **include but are not limited to**, spleen or liver damage (sometimes requiring spleen removal), damage to major blood vessels, lung problems, thrombosis (blood clots), rupture of the wound, and perforation of the stomach or esophagus during surgery. Laparoscopic surgery is not always possible, and the surgeon may need to switch to an “open” method due to some of the reasons mentioned here.

Risks and possible complications are also associated with the lap band procedure, which **include but are not limited to**, the band can spontaneously deflate because of leakage (which can come from the band, the reservoir, or the tubing that connects them), the band can slip, there can be stomach slippage, the stomach pouch can enlarge, the stoma (stomach outlet) can be blocked (which can be caused by food, swelling, improper placement of the band, the band being over-inflated, band or stomach slippage, stomach pouch twisting, or stomach pouch enlargement), and the band can erode into the stomach.

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 of the complications listed on this form and also explained to me may exist whether the surgery is performed or not, in that gastric lap band surgery is not the only cause of these complications.

I understand that women of childbearing age should avoid pregnancy until their weight becomes stable because rapid weight loss and nutritional deficiencies can harm a developing fetus.

Alternative Procedures. In permitting my doctor to perform this procedure, I understand that unforeseen conditions may necessitate change or extension of the original procedure(s), including completing the operation by way of the conventional open surgical approach, or a different procedure from what was explained to me. I therefore authorize and request that the above-named physician, his assistants or designees to perform such procedure(s) as may be necessary and desirable in the exercise of his/her professional judgment.

In the unlikely event that one or more of the above complications may occur, my physician(s) will take appropriate and reasonable steps to help manage the clinical situation and be available to me and my family to address our concerns and questions.

The reasonable alternative(s) to the procedure(s), as well as the risks to the alternatives, have been explained to me. These alternatives include, **but are not limited to**, various diets and weight reducing plans with our without the use of medications, exercise regimens, psychological or psychiatric therapy, and other regiments, gastric bypass surgery, and various diet exercise and drug treatments.

I hereby authorize the disposal of removed tissues resulting from the procedure(s) authorized above.

I consent to any photographing or videotaping of the procedure(s) that may be performed, provided my identity is not revealed by the pictures or by descriptive texts accompanying them. I consent to the admittance of students or authorized equipment representatives to the procedure room for purposes of advancing medical education or obtaining important product information.

By signing below, I certify that I have had an opportunity to ask the doctor all my questions concerning anticipated benefits, material risks, alternative therapies, and risks of those alternatives, and all of my questions have been answered to my satisfaction.

_____/_____/_____
Date Time Signature of Patient or Authorized Rep. Relationship of Authorized Rep.

- The Patient/Authorized Representative has read this form or had it read to him/her.
- The Patient/Authorized Representative states that he/she understands this information.
- The Patient/Authorized Representative has no further questions.

Date Time Signature of Witness

CERTIFICATION OF PHYSICIAN:

I hereby certify that I have discussed with the individual granting consent, the facts, anticipated benefits, material risks, alternative therapies and the risks associated with the alternatives of the procedure(s).

Date Time Signature of Physician

USE OF INTERPRETER OR SPECIAL ASSISTANCE

An interpreter or special assistance was used to assist patient in completing this form as follows:

- _____ Foreign language (specify)
- _____ Sign language
- _____ Patient is blind, form read to patient
- _____ Other (specify) _____

Interpretation provided by _____

(Fill in name of Interpreter and Title or Relationship to Patient)

Signature (Individual Providing Assistance) Date Time