



## SURGICAL CONSENT – CONFIDENTIAL

**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 Laparoscopic Gastric Band procedure. 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, and 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 a discussion of dietary history and a nutritional visit.

**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 I have chosen for the treatment of my obesity is the Laparoscopic Adjustable Gastric Band procedure. My surgeon or surgeons have provided a detailed explanation of the medical history of the development of the surgical treatment of obesity, the adjustable gastric band as a treatment of obesity, the development of laparoscopic (minimally invasive) surgery and the adjustable gastric band.

The purpose of the operation that I am about to undergo is to place a synthetic device around the upper portion of my stomach so that I will not be able to eat as much food as I can now. A small pouch will be created in the upper portion of my stomach. The small amount of food I will comfortably be able to eat should assist me with weight loss and maintenance of that loss over time. 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 Band which will be done laparoscopically. I understand that it may be necessary to convert the procedure to an open procedure 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 to Surgery:** I have been informed that certain conditions may be contraindications to surgery. These include but are not limited to the following:

- Unwillingness or inability to maintain long-term follow-up
- Untreated eating disorders
- Malignancy in certain situations
- Unwillingness or inability to stop smoking
- Other medical conditions that create unmanageable or excessive risk i.e., severe cardiac disease, stroke
- Paralysis, etc.

**Risks / Possible Complications:** The doctor has explained to me that there are risks and possible undesirable consequences associated with a Laparoscopic Gastric Band including but not limited to the following paragraphs.

Please read the following paragraphs carefully. As you read each paragraph, you are encouraged to discuss any questions with the surgeon and/or staff. ***If you are in agreement with everything in the paragraph, please initial in the space provided after reading.***

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Initials

I \_\_\_\_\_, authorize the surgeon(s) of the Lenox Hill / Manhattan Minimally Invasive and Bariatric Surgery Program (LHH / MMIBS), my attending physicians and surgeons, to treat me with the operation presently identified as the Laparoscopic Gastric Band. I understand the purpose of this informed consent document is to confirm my informed understanding of the benefits, risks, and alternatives to this surgery and my desire to have this surgery is completely voluntary.

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The operation may include a cholecystectomy (removal of gall bladder). I also authorize my attending physicians and surgeons and/or his /her consultants and assistants to modify the planned operative procedure or to perform such additional or different operative procedures as might be indicated by unexpected findings at the time of surgery, based on his/her (their) good judgment and within the appropriate medical standards at the time of surgery.

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It is my understanding further that this operation may not ultimately benefit my condition and that it could be associated with effects or hazards, some of which are neither known nor at this time predictable. This “informed consent form” is designed to provide a written confirmation of being provided this information. It is intended to clarify my decision to give my consent to go forward with the proposed procedure. The long term results of this operation are not yet known. I hereby certify that I have attended a consultation explaining the operation along with its benefits and potential complications (risks) and the expected postoperative course. I have read and understand the information which constitutes the official consultation material for this operation, as provided to me by LHH / MMIBS Program.

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In accordance with the patient educational material, it is my understanding that the Laparoscopic Gastric Band operation is a major operative procedure which results in implantation of a device. While the anticipated mortality is low, significant and potentially life threatening complications may occur, and will have to be dealt with in the postoperative period. I understand that some of these complications include but are not limited to port site pain, port displacement; 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, stomach pouch twisting, and the band can erode into the stomach. Other complications, such as respiratory distress, infections, blood clots, and anesthetic complications, may require consultation and treatment by additional specialists called in by my physicians and surgeons which I expressly authorize.

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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.

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I understand psychiatric complications may include but are not limited to depression, bulimia, anorexia, dysfunctional social problems

**A Description of Possible Risks/Complications Includes but is not Limited to the Following:**

Complication	Description
Mortality	Death may occur in any major surgery
Abscess	A localized collection of pus in a cavity formed by disintegration of tissues
Adult Respiratory Distress Syndrome (ARDS)	A malfunction of the lung resulting from injury to the small air sacs and the capillaries of the lungs Injury may cause blood and fluid to leak into the air sacs making breathing difficult
Allergic Reactions	From minor reactions such as a rash to sudden overwhelming reactions that in rare circumstances could lead to death
Anesthetic Complications	Anesthesia used to put you to sleep for the operation can be associated with a variety of complications up to and including the rare possibility of death
Asthenia	Fatigue
Atelectasis	Partial or complete collapse of a lung

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Band removal	Requires a second operation
Bleeding	From minor to massive bleeding that can lead to the need for emergency surgery, blood transfusion, or, vary rarely, death
Blood Clots	Blood clots, including pulmonary embolus (blood clots migrating to the heart and lungs) and Deep Vein Thrombosis (blood clots in the legs and/or arms) that could lead to death
Blood Transfusion	Blood transfusion may occur
Bowel obstruction	Any operation in the abdomen can leave behind scarring that can put the patient at risk for later bowel blockage
Cardiac rhythm disturbances	Changes in heart rate and/or rhythm are possible after surgery, some of which may require additional treatment – very rare
Cardiospasm	Obstruction of passage of food through the bottom of the esophagus
Cholecystitis	Gallstones
Congestive heart failure	Shortness of breath, weakness, edema may be caused by the inability of the heart to maintain adequate blood circulation in the peripheral tissues and the lungs
Contact dermatitis	Rash
Conversion	There is a possibility that while undergoing laparoscopic surgery, conditions may arise that require my physician to convert to an open surgical procedure. This would result in a larger incision and a longer hospital stay and recovery.
Dehiscence or evisceration	Dehiscence: Separation of the layers of a surgical wound Evisceration: Protrusion of intestine through a defect created by wound dehiscence
Dehydration	Dehydration occurs when the amount of water in the body falls below normal (caused by losing too much fluid, not drinking enough water or fluids, or both) which, in turn, disrupts the balance of sugars and salts (electrolytes) in the body. Vomiting and diarrhea are common causes.
Depression	Sadness; loss of self-esteem; apathy; feelings of guilt
Dysmenorrhea	Difficult periods
Dysphagia	Difficulty swallowing
Dyspepsia	Upset stomach
Edema	Swelling
Erosion	The band can erode into the stomach and cause an injury that requires repair and band removal
Eructation	Belching
Esophageal dilatation / 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
Esophageal, pouch or Small bowel motility disorders	Abnormal motility patterns in the small intestine can lead to symptoms of intestinal obstruction. Symptoms may include bloating; pain; nausea; and vomiting
Esophageal ulcer	A hole/sore in the lining of the esophagus
Esophagitis	Inflammation of the esophagus
Fever	Usually body temperature above the normal of 98.6
Flatulence	Gas
Gallstones (formation of)	While the exact mechanism is unknown, gallstones may develop during rapid weight loss. We do not remove the gallbladder during the gastric band unless you have known stones, gallbladder disease, or abnormality seen at the time of surgery.
Gastric perforation	A tear in the stomach wall during or after the procedure – may lead to the need for another surgery; hospitalization and/or re-operation
Gastritis	Inflammation of the stomach
Gastroesophageal reflux	Regurgitation
Gout	Characterized by abnormally elevated levels of uric acid in the blood causing joint inflammation
Hair Loss	Occasionally patients develop hair loss for a short period of time following any surgery involving general anesthesia. This usually resolves with time
Heartburn; gas bloat	Burning pain the chest area due to reflux of stomach acid; indigestion; overstretching of the stomach caused by excessive gas
Hematemesis	Vomiting of blood
Hernia, hiatal	Condition in which a portion of the stomach protrudes upward into the chest through an opening in the diaphragm (the sheet of muscle used in breathing that separates the chest from the abdomen)
Hernia, incisional	Incisions through the abdominal wall can lead to hernias after surgery – (including the port sites for laparoscopic access)

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Inadequate or excessive weight loss	Be aware there is no perfect weight loss surgery – inappropriate dietary choices and/or behavior can make the surgery ineffective
Infection – A	Including wound infections, bladder infections, pneumonia, skin infections, and deep abdominal infections that can sometimes lead to prolonged hospitalization and rarely death
Infection – B	Either superficial or deep infections at the surgical site, including port sites for laparoscopic access. These could lead to wound breakdowns and hernia formation
Infection – C	Infection of port or band may require removal of the entire system
Injury to the bowels, Blood vessels, bile duct, and other organs	Injury to the bowels, blood vessels, bile duct and other organs: Injury to the duct system draining the liver could occur requiring repair or replacement of the duct with a portion of your bowel. This is a rare injury
Injury Continued	Injury to adjacent structures, including the spleen, liver, diaphragm, pancreas and colon
Injury to the stomach	There can be an inadvertent injury to the stomach causing gastric leakage
Intestinal leak	A hole in the lining of the intestine, which allows partially digested foods to leak into the abdominal cavity
Kidney failure	Loss of the kidneys’ ability to excrete wastes; the body cannot filter enough waste or excess water from the blood – may require regular dialysis or kidney transplantation
Kidney stones	Pebble like substances that may form in the kidneys where urine is collected and causes pain when passing urine
Loss of bodily function	Includes from stroke, heart attack, or limb loss
Malnutrition	Poor nutrition because of an insufficient or poorly balanced diet or faulty digestion or utilization of foods
Myocardial infarction	Heart attack
Narrowing	The band can be too tight causing difficulty eating and chest pain
Need for and Side Effects of Drugs	All drugs have inherent risks and in some cases can cause a wide variety of side effects Including possible death
Organ failure	The failure of an essential body system – may be a consequence of sepsis (infection)
Paresthesia	Abnormal sensation of burning, prickly or tingling
Perforation, Leak	After operations to bypass the stomach, the new connections can leak stomach acid, bacteria, and digestive enzymes causing peritonitis, subphrenic abscess or enteroenteric or enterocutaneous fistulas and infection. This can require repeated surgery, intensive care, prolonged recovery, disability and the unlikely event of death
Peritonitis	Infection of the abdominal cavity
Pleural effusions	Fluid around the lungs
Pneumonia	Inflammation of one or both lungs with congestion caused by viruses or bacteria
Pouch dilation	Expanding or enlargement of the pouch
Pressure Sore	A lesion that develops on the skin and underlying tissues due to unrelieved pressure
Protein Caloric Malnutrition	Some patients may become markedly deficient in protein and calories. That would require intervention including nutritional support and possible revisional surgery
Pulmonary edema	Fluid in the lungs
Redundant skin	Generalized excess of fat and skin
Re-operation	May be necessary to fix a problem with the band or initial surgery or to fix a leak or twisted access port. While Laparoscopic Gastric Band is laparoscopically reversible, there is seldom any practical reason to consider a reversal. Reversals are considered higher risk procedures.
Sepsis or Peritonitis	Serious intra-abdominal infection
Side effects	May include but are not limited to: Constipation, diarrhea, bloating, cramping, low blood sugar (especially with poor eating habits), loose skin, bone disease, low blood pressure, cold intolerance, fatty liver or non-alcoholic liver disease (often seen prior to surgery)
Skin Breakdown	See pressure sore
Skin Folds	Large folds of skin are a possibility with significant weight loss. We cannot determine before surgery if this will occur after surgery. Exercise, age, natural skin elasticity and type of food eaten will all impact on potential skin fold occurrence.
Slippage	The band can shift position causing a blockage in the stomach and potential necrosis and death
Small Bowel Obstruction	Adhesions (scar tissue) are a common cause of bowel obstructions—another cause would be internal hernias or defects within the abdominal cavity. Obstructions, where the small intestine may get blocked by twists around scar tissue (adhesions), can occur days after surgery, although most occur months to years later. Obstructions after open surgery require major open surgery to repair – While the open method may required after laparoscopic surgery, most are repaired laparoscopically.

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Smoking	Smoking is serious. It increases patient risk of pulmonary complications and blood clots – no matter which operation is chosen.
Spleen (injury to)	May require repair or removal of the spleen and could result in significant additional blood loss during the operation
Stoma obstruction	Stomach-band outlet blockage symptoms include the sensation that food and/or liquids getting stuck, nausea, vomiting, frothy spits
Stroke	Sudden death of some brain cells due to a lack of oxygen when the blood flow to the brain is impaired by blockage or rupture of an artery to the brain. A stroke is also called a cerebrovascular accident – symptoms may include weakness or paralysis of one side of the body with partial or complete loss of voluntary movement or sensation in a leg or arm. There can be speech problems and weak face muscles, causing drooling. Numbness or tingling is very common. A stroke involving the base of the brain can affect balance, vision, swallowing, breathing and even unconsciousness.
Ulcer	Formation of marginal ulcer or ulcer in the distal stomach
Unforeseen Conditions which may Arise	I understand that during the course of the operation, unforeseen conditions may arise, which were not anticipated by my physician. If this happens, additional procedures may be necessary to correct whatever problems develop. I, therefore, consent to the performance of such additional procedures under these circumstances
Unrealistic expectations	There is no perfect weight loss surgery – any of the available bariatric surgical procedures can be made ineffective by inappropriate dietary and behavior choices. Surgery is an effective tool that requires your participation and commitment to regular exercise, increased protein, appropriate eating habits and appropriate follow-up. The goal of this surgery is to improve your lifespan and provide the opportunity to become healthier.
Urinary tract infection	Bacterial infection of the bladder or lower urinary tract (urethra)
Vitamin & Mineral Deficiencies	After Laparoscopic Gastric Band, there will be some malabsorption of vitamins and minerals. Patients must take vitamin and mineral supplements for life to help protect themselves from these problems we recommend regular follow-up blood tests and medical check-ups. Following these guidelines is <b>your</b> responsibility
Vomiting	Inability to eat certain foods, especially with improper eating habits or poor dentition
Weight issues	Weight regain; slow weight loss or none at all
Wound infection	Purulent discharge from a superficial infection - Symptoms include pain or tenderness, localized swelling, redness or heat
Other	Major abdominal surgery, including the Laparoscopic Gastric Band, is associated with a variety of other risks and complications both recognized and possibly unrecognized that occur both soon after or possibly long after the operation

**Please initial if you understand and accept everything in the above table**

\_\_\_\_\_ **Additionally,** I understand any of these risks or complications may require further surgical intervention during or after the procedure, which I expressly authorize.  
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\_\_\_\_\_ 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 Laparoscopic Adjustable Gastric Band surgery is not the only cause of these complications.  
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\_\_\_\_\_ I voluntarily give my authorization and consent to treatment with the surgical procedure (including the administration of blood and disposal of tissue) by my surgeon and his/her associates assisted by hospital personnel and other trained persons as well as the presence of medical observers and release the attending surgeon, assistants, consultants and their associates from liability for any unfavorable result(s) that may occur.  
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\_\_\_\_\_ The hospital may examine and retain any tissues or organs removed from me for medical, scientific or educational purposes. The hospital may then dispose of any tissues or organs in accordance with its usual practice.  
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\_\_\_\_\_ I hereby authorize the disposal of removed tissues resulting from the procedure(s) authorized above.  
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**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.

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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***, sleeve gastrectomy, Roux-en-Y gastric bypass, duodenal switch, various diet, exercise and drug treatments.

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I have accurately reported to this office, and to the best of my knowledge, information pertaining to my previous and present medical health status, including my medical history, smoking, and drug use. I understand that failure to report, or falsifying information, could result in complications during or after my procedure. If this is found to be the case, I will not hold the staff, physicians, or any independent agents responsible.

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I consent to the photographing or videotaping of the procedure(s) that may be performed, provided my identity is not revealed by the pictures or by descriptive text accompanying them.

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I further understand and agree that the data collected from this operation on me and the subsequent follow-up evaluations including, but not limited to, laboratory and pathological data, photographs and x-rays may be used for scientific publication, preserving my anonymity. I agree not to hold the attending physician, surgeon, assistants, consultants or their associates liable for any action arising from such procedure, studies or publication.

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I also accept the responsibility for the required post-operative evaluations on an indefinite basis and for following the program recommendations. I fully understand the required commitment on my part to lifelong changes in life style required in order to make this operation ultimately successful. It is agreed that morbid obesity is a lifetime disease requiring lifetime treatment and follow-up, with the surgery being a powerful tool in treatment but one which can only be implemented by the patient's effort. I have made a corresponding commitment to life style and dietary change as well as lifetime exercise and follow-up

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**CERTIFICATION OF PHYSICIAN:**

I hereby certify that I have discussed and explained the facts, risks, the risks associated with the alternatives of the procedure(s) described in this Consent Form with the individual granting consent.

\_\_\_\_\_  
Print Physician Name

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_ Time: \_\_\_\_

\_\_\_\_\_  
**Signature of Physician**

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**PATIENT:**

By signing below, I certify that I have had an opportunity to ask the doctor all questions concerning risks, alternatives, and risks of those alternatives and that I have no further questions.

Print Patient Name: \_\_\_\_\_

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_ Time: \_\_\_\_

\_\_\_\_\_  
**Patient Signature**

\_\_\_\_\_  
Or Authorized Representative

\_\_\_\_\_  
Relationship of Authorized Representative

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- I have elected to make these materials available to my spouse and / or other members of my support system.
- I have elected to maintain my privacy and will not be informing any family members about my decision to have weight loss surgery

\_\_\_\_\_  
**Patient Signature**

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**WITNESS:**

- The Patient / Authorized Representative has read the form or had it read to him/her
- The Patient / Authorized Representative expresses understanding of the form
- The Patient / Authorized Representative has no questions

Print Witness Name: \_\_\_\_\_

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_ Time: \_\_\_\_

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**Signature of Witness**

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