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Informed Consent for LAP-BAND

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

I am giving **Dr. P. Pattyn and Dr. B. Smet (my doctors)** and the whole ObesityCare team permission to perform a

Laparoscopic Adjustable Gastric Banding Placement

I understand that my surgeon will be involved in all aspects of my care during the operation and in all aspects of my care pre-operatively and post-operatively. A qualified assistant may help my doctor during the operation. My post-operative care will be directed by my surgeon as well as the whole ObesityCare team

I affirm that I am significantly overweight and have attempted non-surgical weight loss programs without success. I recognize that the preponderance of medical literature states that obesity causes 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 to name a few.

I understand that the preponderance of scientific medical data shows that the laparoscopic gastric banding 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; however, there are **no specific guarantees** that any one of these conditions will improve in any given patient.

I understand that there are a number of non-surgical options as well as surgical options. My doctors have given me the opportunity to discuss other surgical options such as the Laparoscopic Gastric Bypass, duodenal switch as well as non-recommended procedures such as the distal gastric bypass, vertical banded gastroplasty, the mini-gastric bypass, the banded gastric bypass and the biliopancreatic diversion. **I have decided that the Lap-Band is the best option for me.** *I also know that I have the right to a second opinion.*

I understand that my doctor has been successful in performing the placement of the Lap-Band system laparoscopically. Reasons to unexpectedly convert to an open operation include, but are not limited to, significant bleeding, extreme obesity, extremely large liver size, severe scar tissue and equipment malfunction. Conversion to an "open" procedure occurs solely at the surgeon's discretion.

There is an extremely rare, but possible chance that if I do not diet in the pre-operative period adequately as prescribed by my team of doctors, my liver size may cause my operation to be impossible either open or laparoscopically.



I understand the anatomy of the operation as follows:

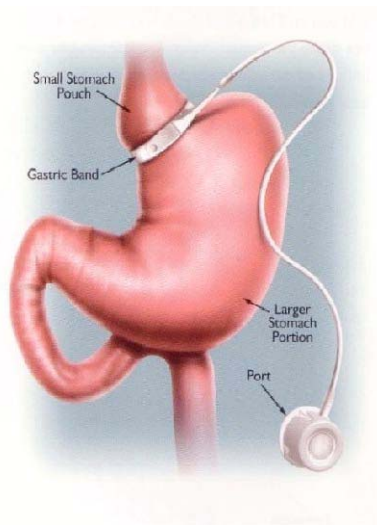


Diagram of the Lap-Band.

A band is placed in the upper part of the stomach, separating the stomach into one small upper and one large lower portion.

By creating a smaller gastric pouch, the LAP-BAND System limits the amount of food that the stomach can hold at any time. Therefore, it is considered a strictly restrictive procedure.

The band can be adjusted to increase or decrease restriction. Adjusting the size of the opening between the two parts of the stomach controls how much food passes from the upper to the lower part of the stomach.

During the operation, several conditions may arise that may cause additional procedures to be performed. These include:

A liver biopsy – most often performed when an abnormally enlarged liver is identified. The risks with performing a liver biopsy include an low chance of bleeding.

Incisional Hernia repair: My doctor's policy is to leave incisional hernias alone during the operation. The repair of a hernia may result in significant infection risks and increased pain. The hernia is also more likely to recur if performed while a person is significantly overweight. Once weight loss occurs, a hernia repair is best performed. However, for specific anatomic reasons, a hernia may have to be repaired at the time of the operation. . If treated after substantial weight loss there is a risk of small bowel obstruction by incarceration of small bowel in the hernia. Urgent repair is necessary in these cases

Esophagogastroduodenoscopy: An EGD, or upper endoscopy may sometimes be performed in order to visualize the stomach or make sure there is no other abnormalities of the intestinal tract.

Revision of previous weight loss surgery: Revision of previous weight loss surgeries such as the vertical banded gastroplasty increases operative time and complication rates. Overall, expected weight loss tends to be less than that compared to a person who is having weight loss surgery for the first time. Procedures that occur commonly in patients who need revisional surgery include, but are not limited to, removal of part of the stomach, placement of a drain, placement of a G-tube and endoscopy. If I have failed a previous lap-band procedure, my surgeon will remove the old lap-band (and port)



Hiatal Hernia repair: If a large hiatal hernia is present, this may need to be repaired. The added risks from hiatal hernia repair include, but are not limited to, injury to the esophagus, dysphagia (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.

Placement of a Drain: A drain is a thin plastic tube that comes out of the body, into a small container to allow for the removal of fluid and the control of infection. My doctor does not routinely place a drain after a LapBand. However, in certain rare circumstances, my doctor may elect to place a temporary plastic drain.

I understand that significant weight loss is a **life-altering event**. Significant changes in eating behavior occur. I understand that every patient's experience varies and the exact prediction in my ability to cope with significant forced behavior changes cannot be predicted. I understand that ObesityCare has a psychologist in his team who can help me with behavioral needs.

When choosing a balanced menu high in protein content, eating at normal times and incorporating exercise into my daily routine, I will lose weight. However, **it is possible to defeat the purpose of surgery** by continuously drinking high calorie liquids and/or snacking throughout the day. "Grazing" behavior will cause weight regain, or poor initial weight loss.

Medicine is an unpredictable field. **Unpredictable complications can occur**. No amount of pre-operative testing can assure an uncomplicated outcome. My doctors attempt to minimize any possible chances of misdiagnosis – however, no physician or group of physicians are infallible. I have the responsibility to inform my doctors of any concerns, worries or possible complications at the earliest possible time. I agree that my doctors may make recommendations and I take full responsibility if I do not follow these recommendations.

Weight loss after a Lap-Band is expressed as loss of a percentage of my pre-operative excess body weight. Excess weight is defined as my current weight minus my ideal body weight. On average, patients lose between 40 and 55 percent of excess weight at two years. In other words, some patients lose more than 60 percent of their excess weight and some lose less. My doctors will give me recommendations in how to experience the most optimal weight loss. Although, the vast majority of patients are satisfied with their weight loss, **there is no guarantee that I will achieve my goal weight**. I understand that the chances of reaching my ideal body weight are low. I understand that bariatric surgery is a tool that assists with weight loss. Some patients will regain weight.

Actual risks of the operation vary from person to person.



Risks of the LapBand include, but are not limited to the following. My doctors have tried to estimate a general risk category to each event (Extremely rare <0.1 % , Very rare<<0.5%, rare<2%, occurs 1-5%, common=5-10%, very common>10%). The list of potential complications includes, but is not limited to::

Immediate Post-operative Risks:

Death (extremely rare): Mortality rate of the Lap-Band in literature is less than 0.2%. I realize, and my family members realize, that every LapBand is a surgical intervention and complications of this procedure can be fatal.

Significant Bleeding (very rare): Usually during the course of a LapBand, less than 100ml of blood is lost. Bleeding may occur unexpectedly in the operating room. Bleeding may also occur post-operatively in the days after the operation. A transfusion may be necessary in some extremely rare circumstances. Reoperation to stop bleeding may be necessary.

Nausea (common) – The most common cause of post-operative nausea is pain medication. Many patients have nausea the day of their operation. Rarely, nausea will persist for a week. In rare cases, nausea will persist for longer.

Prolonged Ventilation (very rare) – A patient requiring a prolonged stay on a ventilator (breathing machine)in the intensive care is rare. This may occur for example in very large patients with severe sleep apnea or after certain significant complications. In these very rare instances, a temporary tracheostomy may be necessary.

Heart Attack (very rare) -Although a heart attack is possible after a gastric bypass, it is very rare. Many patients undergo testing to assess the health of their heart before their procedure. Some patients are asked to obtain cardiology clearance before proceeding with the operation. However, no amount of testing can eliminate the risks of a heart attack. Risk factors for heart disease include increased age, diabetes, hypertension, hypercholesterolemia and a family history of heart disease.

Prolonged Hospital Stay (uncommon): Unforeseen complications may result in a prolonged hospital stay. Intensive care admission may be required.

Medical Consultations (uncommon): My doctors reserve the right consult medical physicians to assist in my care when necessary.

Deep Vein Thrombosis (DVT)/Pulmonary Embolism (rare): Blood clots that form in the legs, and elsewhere, and break off into the lungs are a leading cause of death in this country after any surgical procedure. My doctors will do everything they believe possible to decrease the risk for the formation of blood clots. This includes the use of low molecular weight heparines injected subcutaneously, walking soon after surgery and sometimes even the use of medication at home after discharge from the hospital. Despite all of these efforts, it is impossible to eliminate the risks of DVT (clots) altogether. There is also a possibility that the medications used to prevent blood clots can cause excessive bleeding. Any symptoms of leg swelling, chest pain or sudden shortness of breath should be immediately reported to the surgeon. My doctors usually use a means of DVT prevention that is not standard practice in the community. My doctors believe, and have the personal experience, that strongly suggests that their means of DVT prevention is ideal for the bariatric patient and is at least as good if not better than standard DVT prevention used in the community. Rare 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, anesthetic complications, injury to the bowel or vessels, gas bloating. Minor wound problems are not infrequent. Minor drainage from the wounds, or even the wounds opening, may occur. Although scars from the laparoscopic procedure are usually small – we cannot predict how any patient will form scars. Wound infections should heal over time but may cause a visible scar

Open Procedure (extremely rare): "If, FOR UNFORESEEN REASON, my operation is performed open, I am at higher risk for several complications. This includes wound infection. Wound infections may cause significant scarring and healing problems, require prolonged wound care and cause discomfort. Incisional hernias occur in approximately one-third of patients after an open gastric bypass. Hernias will require an operation to repair. Hernias can cause bowel obstructions and severe consequences if left untreated. There is a higher chance of certain complications including lung infections, pressure ulcers and blood clots after an open operation. There would also be predictably more discomfort and a longer hospital stay.

Slippage of the band (very rare): In very rare circumstances the band may slip from its original position. I understand that my doctor has taken the precaution in trying to prevent this by well securing the band. Overeating the band and insufflating the band too fast are some reasons for slipping of the band.

Erosion of the band (very rare): In very rare circumstances, the band may erode into the stomach. I understand that my doctor will do everything possible to minimize chances of this happening by properly positioning the band

Fatigue (Common): After any general anesthesia, fatigue is very common. Fatigue may last days, or in some circumstances, weeks.

Dehydration (uncommon): I understand that I will contact my doctors if I am not tolerating liquids. Dehydration is rare; Electrolyte abnormalities are also rare.

Medication problems (common): I understand that I will have to monitor my post-operative medication doses closely with the doctors that have prescribed them. My doctors will help if necessary. Examples of common medication problems include lightheadedness from too high a dose of high blood pressure medication and too low a blood sugar from excessive diabetic medication. I agree to work closely with my primary care doctor to regulate my medication.

Return to work: I understand that although many patients can return to work within one to two weeks, rare patients may require a longer recovery. My doctors are not responsible for financial difficulties due to lost work time.

Late Complications

Osteoporosis (unknown): Calcium deficiency may occur years after a gastric bypass. This is a difficult diagnosis to make until weakness of the bones has already developed. Currently it is best to measure calcium levels and the PTH level (parathyroid hormone). I understand that I am expected to take calcium supplements and supplemental Vitamin D for life after this operation. After gastric banding, vitamin D and calcium are very often not affected.



B vitamin deficiencies (extremely rare). Deficiencies in Thiamine, Niacin, B12 and others have been reported. These B vitamin deficiencies are very rare. Some B vitamin deficiencies can cause irreversible neurological damage. All patients are recommended to take a multivitamin supplement for 3 months after this operation. Sometimes, additional B vitamin supplements are also required. I understand that it is important to be evaluated regularly for vitamin deficiencies after surgery.

Gallbladder problems (occurs): If my gallbladder is not removed at the time of my surgery the risk of developing gallstones is 1 in 3. With the use of twice-a-day. I understand that I may develop gallstones after surgery. If I develop gallstones after surgery and they become symptomatic a elective laparoscopic cholecystectomy will be necessary.

Weight Regain: Weight regain may occur, especially with “grazing” behavior or excessive sweet intake. The LapBand is a powerful tool; however, it can be beaten. Constantly eating foods such as chips and nuts or other high calorie snacks will result in less than expected weight loss or even weight regain.

Unforeseen problems: Although this procedure has been performed for many years, there may be long-term problems not known at this time.

Pregnancy: Women who were infertile may become fertile after their operation. This is due to improvements in hormone balances. I understand that I will need to use birth control to prevent unexpected pregnancies after this procedure. The risks associated with pregnancy in an obese person is generally higher than a non-obese person. There is no significant data to suggest that the risks of pregnancy are greater, either to the mother or child, after lap-band surgery. Although there are rare reports of band slippage occurring during pregnancy, there is no clear cause and effect relationship established. I agree that before and during pregnancy, I will discuss my nutritional needs with my obstetrician. I will always make sure that I am taking adequate vitamins and minerals throughout pregnancy and while nursing. I absolve the ObesityCare team of any responsibility of complications of pregnancy as complications may occur with any pregnancy and there is no definitive means to prove any complication was due solely to the LapBand.

I agree not to get pregnant for 18 months after a LapBand. The safety of pregnancy is NOT established for patients during periods of rapid weight loss. SERIOUS, life-threatening complications may occur. I take full responsibility for birth control during this time period.

Initial _____

I understand that I may not be able to breast-feed during periods of rapid weight loss. If I am currently breast-feeding, I plan to wean my child before undergoing weight loss surgery.

Depression: Although most people experience improvements in their mood, some will have worsening states of depression. Weight loss is not a cure-all for all psychological problems. It is my responsibility to seek psychological help when necessary. I understand that post-operative depression may occur.

Marital Problems: Psychological factors including post-operative depression, or possibly a reaction to the stress of surgery, are possible. Family members may also experience these stresses. Significant weight loss may result in marital strain as one person develops changes in their self-esteem. Jealousy and other unpredictable consequences to weight loss may occur. My doctors are not responsible for any marital difficulties that may occur.

Temporary Hair loss: Hair loss occurs in many people after a weight loss operation. Hair generally grows back. There are no proven supplements to alter hair loss.



Unlisted complications: I understand that it is impossible to list every complication possible during and after this procedure. I agree that my doctors have done their reasonable best in listing any significant complications that may occur.

I understand that unforeseen events may occur that would result in the last minute cancellation or postponement of my operation. My doctor will only cancel my operation in the case of emergency conflicts or if it is my best interest for safety. My doctors are not financially responsible for any costs incurred by rescheduling my operation for any reason. If I live out of town (>50 miles away), I plan on staying in the area immediately after the operation until cleared for travel by my surgeon. However, if I cancel my surgery within 24 hours of scheduled start time due to a change of heart, I may be responsible for any incurred costs.

I understand that my doctors may or may not decide to digitally record or photograph portions of my operation. I give permission for my doctors to use these materials when obtained for whatever purposes they feel fit as long as no identifying images, names or labels are used. My doctors may also take pictures post-operatively to document my weight loss progress. My doctors may use these images for whatever purposes they see fit. (cross out this last statement if you disagree)

I am responsible for fully understanding all the fees that I may incur. **ObesityCare has no responsibility or control over the billing and financial obligations related to my hospital** and is not responsible for predicting my hospital charges. I take full responsibility to understand all potential hospital costs. If complications of surgery or significant modifications of surgery occur during or anytime after the planned operation, I understand that additional, significant, professional fees may apply. The current fee as presented on the website is only limited to the described operation and hospitalisation. Additional fees due to complications, prolonged stay at the intensive care unit are not included and come to the patients account.

Initial _____

I plan on following all post-operative visits recommended by my doctors. I plan on obtaining all tests requested by my doctors. I will abide by all nutritional supplements/recommendations that my doctors prescribe. If the ObesityCare ever ceases to exist, I take responsibly to find an appropriate physician to monitor my life-long follow-up. If I leave the area I take responsibility in finding appropriate follow-up.

Initial _____

I agree to fully read all and follow all of the diet protocols and discharge instructions.

My doctor has the right in rare cases to discharge me from his practice if I am not compliant with all medical instructions. This determination is fully at the discretion of my doctor.

Bariatric Surgery is a vast discipline. There is no way that my doctors can teach me everything about these procedures. There is no way that my doctors can predict all possible outcomes. This consent is not meant to be all inclusive. Complications or problems may arise that were not specifically addressed.



I have reviewed all of the information in this consent form with my immediate family. **I have clearly stated to my closest family that I fully understand the risks of surgery and believe that the risks are acceptable.**

Any conflicting information on the risks and benefits of surgery implied from any other format (internet, brochures, video, and physician interview) is to be superseded by this legal document.

I have read, or had read to me, the contents of this form and have no further questions. I wish to proceed with LapBand surgery. You must be 18 years old or over to sign. Otherwise your legal guardian must sign the document

Printed Name (Patient) Date

Printed Name (Surgeon) Date

Signature (Patient) Date

Signature(Surgeon) Date
