Informed Consent for Adjustable Gastric Band Placement

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

I am giving Blossom Bariatrics permission to perform a Laparoscopic Adjustable Gastric Banding Placement Surgery for the treatment of obesity. I met my surgeon in the office for my initial consultation. My surgeon will perform the procedure and direct my care during the operation. My consent to and understanding of the following terms and information is necessary for the procedure and my care:

Initial __________ 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 surgeon during the operation. My surgeon will direct my post-operative care.

Initial __________ 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.

Initial __________ 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.

Initial __________ I understand that there are a number of non-surgical options as well as surgical options. My surgeon has 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.

Initial __________ I have given pre-operative education in the form of physician interview, psychological counseling, video materials, educational books, informational websites such as www.obesityhelp.com, as well as access to information on my surgeon’s website and access to Blossom Bariatrics’ office to answer any questions that I may have.

Initial __________ I understand that my surgeon 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.

Initial __________ I understand the anatomy of the operation as follows:

- 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 gastric band 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:

Initial __________ - A liver biopsy: The risks with performing a liver biopsy include a low chance of bleeding.

Initial __________ - Incisional Hernia repair: My surgeon’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.
- 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 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 control of infection. My surgeon does not routinely place a drain after a gastric banding. However, in certain rare circumstances, my surgeon 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 Blossom Bariatrics is affiliated with a psychologist who can help me with behavioral needs.

- Medicine is an unpredictable field. Unpredictable complications can occur. No amount of pre-operative testing can assure an uncomplicated outcome. I have the responsibility to inform my surgeon of any concerns, worries or possible complications at the earliest possible time. I agree that my surgeon 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 50 and 75 percent of excess weight at two years. In other words, some patients lose more than 80 percent of their excess weight and some lose less. My surgeon at Blossom Bariatrics 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. Some patients will lose less than 50% of their excess body weight. Patients who are diabetic or are more than 200 pounds overweight tend to lose a smaller percentage of excess weight (50-60 percent vs. 70-80 percent).

- Actual risks of the operation vary from person to person.

  There are risks associated with gastric banding. My surgeon has 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): The mortality rate of the Lap-Band nationwide is less than 0.2%. I realize, and my family members realize, that every gastric banding done is a major surgery and complications of this procedure can be fatal.

- Significant Bleeding (very rare): Usually during the course of a gastric banding, less than 1 ounce 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. Re-operation to stop bleeding may be necessary.

Initial _________ **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.

Initial _________ **Prolonged Ventilation** (very rare) - A patient requiring a prolonged stay on a ventilator (breathing machine) in the Intensive Care Unit 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.

Initial _________ **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 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.

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

Initial _________ **Medical Consultations** (uncommon): My surgeon reserves the right to consult medical physicians to assist in my care when necessary.

Initial _________ **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 surgeon will take all reasonable actions to decrease the risk for the formation of blood clots. This includes the use of intravenous heparin (a medication that thins the blood), special foot and leg stockings and walking soon after surgery. 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. Rare patients develop allergies to heparin - sometimes causing very severe reactions.

Initial _________ **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.

Initial _________ **Open procedure** (extremely rare): In some circumstances, my surgeon has had to do this operation “open”. 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.

Initial _________ **Slippage of the band** (very rare): In very rare circumstances the band may slip from its original position. I understand that my surgeon has taken the precaution in trying to prevent this by well securing the band.

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

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

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

Initial _________ **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 surgeon 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. Neither my surgeon nor Blossom Bariatrics are 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.

B vitamin deficiencies (extremely rare): Deficiencies in Thiamine, Niacin, B12 and other 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. Sometime,s additional B vitamin supplements are also required. I understand that it is important to be evaluated regularly for vitamin deficiencies after surgery.

Gallbladder problems (occur): I understand that I may develop gallstones after surgery. If I develop gallstones after surgery, serious problems and even death may occur.

Weight regain: Weight regain may occur, especially with ”grazing” behavior or excessive sweet intake. The gastric band is a powerful tool; however, it an be beaten. Constantly eating foods such as chips and nut 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 are 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 Blossom Bariatrics of any responsibility of complications of pregnancy as complications may occur with any pregnancy and there i no definitive means to prove any complication was due solely to the gastric band.

I agree not to get pregnant for 18 months after a gastric band. 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.

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 no 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. Neither my surgeon nor Blossom Bariatrics are 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 surgeon has disclosed the most 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 surgeon will only cancel my operation in the case of emergency conflicts or if it is my best interest for safety. Neither my surgeon nor Blossom Bariatrics are 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.

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

Initial __________ I am responsible for fully understanding all the fees that I may incur. Blossom Bariatics has no responsibility or
control over the billing and financial obligations related to my hospital. Blossom Bariatics 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.

Initial __________ I plan on following all post-operative visits recommended by my surgeon. I plan on obtaining all tests requested
by my surgeon. I will abide by all nutritional supplements/recommendations that my surgeon prescribes. If Blossom
Bariatics ever ceases to exist, I take responsibility 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 understand that Blossom Bariatics does not provide for psychological support and that it is my responsibility to seek
psychological help if needed.

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

Initial __________ My surgeon 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 surgeon.

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

Initial __________ I have been offered the opportunity to discuss results of this procedure with others who have had the procedure done
previously through the support group, the Internet and other resources. I understand that the Center for Advanced
Weight Loss administers support group meetings at least once a month. My surgeon strongly believes that support
groups are an excellent method to improve long-term outcome. I take responsibility for attending support group
meetings.

Initial __________ 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.

Initial __________ 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 understood each of the terms to my satisfaction. I have no further questions.
I wish to proceed with gastric band operation. You must be 18 years old or over to sign. Otherwise your legal guardian must sign the
document.

Printed Name: __________________________________________________________

Signature: ___________________________ Date: ___________________________
Mutual Binding Arbitration Agreement

Patient's Name: ___________________________________

This mutual binding Arbitration Agreement constitutes an integral part of a contract for medical services by and between Blossom Bariatrics and Patient who agree to be bound as described hereunder:

1. Any dispute, claim or controversy arising out of or relating to any Consent for Treatment or Agreement or the breach, termination, enforcement, interpretation or validity thereof, including the determination of the scope or applicability of this Arbitration Agreement, shall be determined by arbitration in Clark County, Nevada before one arbitrator with at least 10 years of active litigation experience, unless otherwise directed herein. If the amount claimed is less that $250,000, the arbitration will be administered by JAMS in accordance with JAMS' Streamlined Arbitration Rules and Procedures. For claims in excess of $250,000, the Comprehensive Arbitration Rules and Procedures will apply.

2. This Arbitration Agreement expressly applies to any claims for medical malpractice as defined by Nevada law. Any medical malpractice claims will be arbitrated before a panel of three arbitrators. NRS 41A will apply to any such arbitration proceedings, with the arbitration panel taking the place and stead of the district court. NRS 41A.071 specifically applies to any arbitration proceeding, which requires a malpractice claim to be filed with an affidavit supporting the claims by a medical expert who practices or has practiced in an area that is substantially similar to the type of practice of Blossom Bariatrics. Both parties to this Contract, by entering into it, are giving up their constitutional right to have any such dispute decided in a court of law before a jury, and instead are accepting the use of arbitration.

Within 15 days after the commencement of arbitration, each party shall select one person to act as arbitrator. The parties will communicate their selected arbitrator to the JAMS Case Manager. If a party fails to select an arbitrator within 15 days, JAMS will appoint an arbitrator. The two party-determined arbitrators will select a third arbitrator to serve as panel chair within 30 days of the commencement of the arbitration. The panel must be chaired by an attorney with at least 20 years of active litigation experience or a retired judge from a court having jurisdiction in Nevada. If the arbitrators selected by the parties are unable or fail to agree upon the third arbitrator within the allotted time, the third arbitrator shall be appointed by JAMS in accordance with its rules and the criteria set forth above. All arbitrators shall serve as neutral, independent, and impartial arbitrators.

3. This Arbitration Agreement applies to any claim against Dr. Thomas W. Umbach individually, Blossom Bariatrics and/or Blossom Medical Group, or any employees or contracted staff of Blossom Bariatrics. This Arbitration Agreement and the rights of the parties in relation to any claims shall be governed by and construed in accordance with the laws of the State of Nevada.

4. Judgment on the arbitration award may be entered in any court having jurisdiction. This clause shall not preclude parties from seeking provisional remedies in aid of arbitration from a court of appropriate jurisdiction.

5. The execution of this Mutual Binding Arbitration Agreement shall not be a precondition of the furnishing of medical services by Blossom Bariatrics. This Mutual Binding Arbitration Agreement may be rescinded by written notice from the Patient or Patient's legal representative within 30 days of signature.

6. The Arbitration Agreement shall bind the parties hereto, and the heirs, representatives, executors, administrators, successors, and assigns of such parties and newborns.

Printed Name: __________________________________________________________

Signature: ______________________________________________________ Date: ___________________________________

(patient/parent/legal guardian/legal representative)

If signed by other than patient, indicate relationship: __________________________
Assignment of Insurance Payments

Blossom Bariatrics bills your insurance as a courtesy for all in network and out of network policies. Occasionally the insurance company will send payment directly to the patient. If this does happen with your policy, simply sign the check “Pay to the order of Blossom Bariatrics” then you sign underneath. Be sure to send a copy of all correspondence that comes with it as well.

I understand and acknowledge that I have a legal obligation to pay for the services I have received or will receive from Blossom Bariatrics.

I also acknowledge that if my health insurance company covers the medical procedures I have received or will be receiving, that payment from my health insurance company should be paid to Blossom Bariatrics. **Under no circumstances am I entitled to receive and keep any payments from my health insurance company. These payments are rightfully owed to Blossom Bariatrics in payment for the services I have received from them.**

THEREFORE, I hereby assign to Blossom Bariatrics any and all sums of money which I have received to date or which I may receive in the future from my health insurance company.

I HEREBY authorize and instruct __________________________________________ Insurance Company, Policy #__________________________________________ to pay all sums which it has paid or would pay to me directly to Blossom Bariatrics at the following address:

Blossom Bariatrics
7385 S Pecos Rd
Las Vegas, Nevada     89120

This Assignment is to remain in full force and effect for all claims submitted and all payments made from the date this Assignment is executed below until it is revoked in writing.

Signature: __________________________________________Date: _____________________

Printed Name: _______________________________

Blossom Witness Signature:______________________________________________________

Blossom Printed Name: _______________________________ Date:  ____________________