

## **Informed Consent Laparoscopic Possible Open LapBand®**

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You have decided to undergo laparoscopic, possible open, LapBand® or Adjustable Gastric Band (AGB) placement. During the last several weeks/months, as we have prepared you for your surgery, we have provided you with complete and detailed information about the operation, as well as the other options and procedures, which you have, for control of your weight. You have learned about the potential benefits and risks to you in having the operation. You should have had the opportunity to visit the EMMI website and take the inter-active pre-operative informational course, if not, **it is your responsibility** to take this before your surgery. The purpose of this consent is to confirm your decision, based upon complete knowledge and understanding of the operation. You may always change your mind about proceeding with the operation.

This consent form should convey 1) the nature of your condition, 2) the general nature of the procedure/surgery, 3) the risks of the proposed treatment/procedure, and 4) reasonable therapeutic alternatives and risks associated with such alternatives. You have the right, as the patient, to be informed about your condition and the recommended surgical procedure, so that you may make the decision whether or not to undergo this elective procedure after knowing the risks and hazards involved.

Please read this information carefully and ask about anything you may not understand, as by signing/initialing this form you agree that you have done so.

Morbid obesity is a disease that often has multiple associated medical illnesses and is associated with a significant decrease in life expectancy. Many of these can be reversed with significant durable weight loss. The National Institutes of Health panel of physician experts concluded that for the great majority of the morbidly obese, diet/exercise/medications including M.D. supervised medications/diets have a high failure rate and that bariatric surgery is the most effective tool to achieve long term weight loss in these patients. The risk of a non-surgical approach to your morbid obesity, therefore, is a very high failure rate in significant, long-term weight loss resulting in increased risk for obesity-related medical illnesses and decreased life expectancy.

**The LapBand®/AGB** is designed to create a small reservoir at the upper end of the stomach by placing a silicone adjustable band. This is usually placed laparoscopically (several small incisions) although the open method may be used in some other programs (“Open” bariatric surgery carries a higher complication rate than a minimally invasive/laparoscopic approach in appropriate hands). The procedure involves making several small incisions through which the surgeon(s) insert laparoscopic instruments to make the necessary changes and apply and secure the LapBand®/AGB device to the upper portion of the stomach. There is also a port attached to the LapBand®/AGB device that is secured to the underlying muscle on the abdomen. The port can be accessed in the post-operative period by the surgical team, in the office setting, using a special needle, to make necessary adjustments to the band. This procedure functionally restricts the size of the stomach to about 2-oz and is considered a strictly gastric restrictive procedure although some suggest, when appropriately adjusted, it does decrease appetite as well. The difference between this and other restrictive bariatric procedures is that the restrictive effect can be adjusted, and this currently is the only bariatric procedure that can be adjusted without surgery in the post-operative period. Weight loss occurs by restricted intake – the purpose of the smaller stomach pouch is to create the sensation of fullness earlier (satiety), thereby decreasing the desire for food and limiting the volume of food one is capable of consuming at one time. There is no division or bypass of the stomach. Of note, with this limited intake, if you eat too much at one meal, you may feel discomfort and may

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even vomit until you learn the capacity of your “new” stomach. It carries the least complications of the current widely available bariatric procedures and is the safest bariatric surgical procedure available at this time. In the majority of cases it is done as an outpatient (you go home from the recovery room, or a few hours after surgery), but on occasion patients stay overnight (“less than 23 hours”). Health problems associated with excess weight are also usually benefited. Lastly, the LapBand®/AGB is easily reversible/removed and can be laparoscopically converted to another bariatric surgical procedure if needed/desired.

**Other bariatric procedures** are available including laparoscopic and open Roux-en-Y gastric bypass, vertical banded gastroplasty (VBG), duodenal switch/biliopancreatic diversion, and most recently, the sleeve gastrectomy. Experimental procedures such as gastric pacing and the intra-gastric balloon are not available outside the research setting at this time.

The **Roux-en-Y divided gastric bypass** is a widely accepted and common procedure performed by bariatric surgeons. Like the LapBand®/AGB it limits the volume you can eat (restrictive), but unlike the band, it also bypasses the majority of the stomach (malabsorptive). Weight loss with the Roux-en-Y divided gastric bypass usually exceeds 50% of excess body weight, and many patients lose 75% or more of excess weight. Health problems associated with excess weight are also usually benefited. Roux-en-Y divided gastric bypass is designed to make a small reservoir (“pouch”) for food at the upper end of your stomach with a capacity of about 2-oz. This pouch is connected to the upper small intestine by a new small anastomosis (outlet) of about ½ inch (1.2 cm) in diameter. The ingested food thereby bypasses the majority of your stomach, which remains alive and undisturbed, but functional otherwise. In other words, the majority of your stomach does not have food passing through. It is associated with a decrease in appetite that lasts on average 5 months. The nature and purpose of this operation is to functionally limit the amount of food or liquid intake at any given time, and decrease the absorption of nutrients. There are side effects such as “dumping” which can occur after eating sweets or fatty foods and although unpleasant, is an after-effect that some find useful in reinforcing good dietary choices. The risk of gastric bypass is low, but complications such as a “leak” at the suture/staple line can be serious and even fatal. Strictures, internal hernias, and outlet ulcers are also possibilities not seen with the LapBand.

The **VBG** aims to functionally restrict the size of the stomach. It is not adjustable and is associated with a high failure rate and reflux. For these reasons, is out of favor with the majority of bariatric surgeons. It was very popular in the 1980’s and now accounts for a lot of our revisional bariatric surgeries.

**The gastric sleeve procedure or sleeve/vertical gastrectomy** is a restrictive procedure that involves removing the majority of the outer stomach, turning the stomach into a much smaller tube-like structure that holds much less food. Weight loss is faster than the LapBand®/AGB, but slower than a bypass, as there is no malabsorption. Weight loss is approximately 50% excess body weight over 12 months. Similar to other bariatric procedures, it does result in significant improvement in most obesity-related illnesses. The safety profile is somewhere between the LapBand®/AGB (safest) and the bypass. Like the LapBand®, since it is a restrictive procedure, there is no malabsorption and therefore no need for frequent labs or multiple vitamin supplements. Unlike the bypass and similar to the LapBand®, the stomach is always accessible by endoscopy (“scopes”). Unlike the bypass, and similar to the LapBand®, patients can take any medicines, eat any foods, and resume smoking one month after surgery. It was initially offered only as part of a duodenal switch. Because duodenal switch patients are often very morbidly obese (BMI 60+) and at the highest risk for surgery, some surgeons began performing the operation in two stages. The first involved the sleeve gastrectomy (restrictive). The patients would then lose about 50% of excess body weight over the next several months and thereby lower their risk of surgery so that they could then undergo the second stage of bypassing the intestines

(malabsorptive). Not surprisingly, many patients opted not to undergo the second stage and its associated diarrhea with subsequent higher risk of severe vitamin and mineral deficiencies as discussed above. Although generally not approved by insurance companies as a primary (or even as a staged procedure), we do offer this surgery to appropriate candidates who desire it. There is no long-term data for the sleeve as a primary procedure, and there is no guarantee that the sleeve will not stretch out over time. The sleeve could always be converted (in most instances laparoscopically) to a bypass or duodenal switch at a later time should this occur. In addition, a LapBand®/AGB could also be placed around a failed sleeve as well.

The **duodenal switch/biliopancreatic diversion procedures** are malabsorptive procedures and generally carry the highest complication rate (and weight loss rate) among the bariatric procedures. While bypass is mostly restriction and some malabsorption, a duodenal switch is some restriction and mostly malabsorption. These procedures usually cause explosive, foul-smelling diarrhea and can be complicated by anemia, protein malnutrition, liver failure, vitamin (especially fat-soluble) and mineral deficiencies, fractures from calcium malabsorption leading to hyperparathyroidism and blindness from Vit A malabsorption. We do not feel the risk of these procedures outweighs the benefit, and therefore do not offer these operations. We would however be happy to assist in referring you elsewhere if you desire to pursue these procedures.

Although the changes after LapBand®/AGB are not as drastic as with gastric bypass, duodenal switch, or the gastric sleeve procedure, it still requires commitment and lifestyle changes. There are no easy fixes. You will need to chew your food well, avoid drinking while eating, avoid carbonated beverages, among other things. Breads often don't go down well. You will need to take more time to eat and chew your food. It is important that you are able to eat **solid** food such as chicken, fish, steak, pork, sandwiches, etc. If your band is too tight, you will actually gain weight rather than lose. This occurs because patients are afraid to eat solid foods and protein secondary to discomfort or vomiting and therefore eat soft foods. Soft foods lead to weight gain because they pass more easily through the band and have higher non-protein calories. In addition, having your LapBand®/AGB too tight increases your risk of needing further surgery or even having the band removed for complications such as slip, pouch enlargement, esophageal dilatation, and erosion as discussed below. **Best results occur with regular follow-up, attendance in the LapBand® support groups, exercise, adjustments to the band, and appropriate eating habits.** For most, weight loss is more gradual with the LapBand® than the gastric bypass however the weight loss for the two groups is about the same after three to five years in compliant patients. More than any other bariatric procedure, your chance of achieving your weight loss goals is greatest if you continue regular follow-up with our bariatric program after your surgery to monitor your progress and perform adjustments as necessary. Like any other bariatric procedure, there are ways to defeat the purpose of surgery and gain weight. It is also possible to defeat the purpose of surgery by continuous drinking of high calorie soft foods or liquids and/or snacking throughout the day or having the LapBand® too loose or too tight. In general, if you choose a balanced menu high in protein content, eat at normal times, and incorporate exercise into your daily routine, this tool will allow you to lose weight and keep it off for the long term. Now is the time to begin your exercise regimen (even if it is just walking), as weight loss is not only taking in less calories, but expending energy as well. Your weight loss results will be better with any bariatric procedure the more you incorporate exercise into your daily routine. Then continue exercising after surgery, advancing the amount of exercise as you feel better and better.

**Please carefully weigh the advantages and disadvantages of each available bariatric procedure prior to proceeding with surgery!! In addition to below and your own research, please see attached advantages/disadvantages sheet for a brief summary.**

**A common misperception that we see are patients who want to rush their weight loss and think this can be achieved by having the LapBand® very tight.** This actually leads to weight gain in most patients, because

the ability to eat normal foods is lost and results in nausea and vomiting. Therefore, in order to eat, patients turn to soft, high calorie foods. **Even worse, having your LapBand®/AGB too tight increases your risk of complications of the LapBand®/AGB such as slip, erosion, esophageal dilatation and pouch enlargement (discussed below), which could result in the need for further surgery or even removal of the band.** Please don't fall into this trap and don't try and rush the process! As long as the LapBand®/AGB is appropriately adjusted, you will lose weight at a rate that is determined by your metabolism and genetics. If you are appropriately adjusted and wish to speed up your weight loss, DO NOT overtighten your band, but increase your exercise level.

**Eating Habits and Exercise.** Patients who do not develop good habits are more likely to re-gain the weight. If you go back to chips, cookies, sodas, grazing and not staying active, you are not using your band "tool" appropriately and it will fail. You can't use the handle of a hammer (tool) to put in nails, you have to use the tool the way it was designed. The same goes for the band "tool". The old saying is "We can operate on your stomach, not on your head". The importance of behavioral factors cannot be overemphasized. Therefore, it is very important that you participate in support groups and seek dietary and psychological counseling as needed. Studies have shown superior weight loss after surgery when combined with structured medical weight loss and exercise.

Regardless, all available procedures are **TOOLS**, which when used appropriately, will allow you to lose a significant amount of weight and keep it off and have proven benefit over non-surgical weight loss.

**No guarantee of weight loss.** Keep in mind that there is no perfect weight loss surgery and any of the available Bariatric surgical procedures can be rendered ineffective by inappropriate dietary choices or behavior. Weight loss is in no way guaranteed with any of the procedures offered. When chosen appropriately, you have been given a potentially very effective **tool** to help you with your weight loss efforts, but ultimately your success depends on how you use it. **Exercise, attendance in support groups, and regular follow-up are all essential to long-term success.**

**Unrealistic Expectations.** Weight loss is more gradual than other bariatric procedures and eating high calorie liquid or soft foods can circumvent the procedure. There is no malabsorption of nutrients, and no "dumping" (see below under gastric bypass). There are no foods that you could eat before surgery that will necessarily make you sick after surgery, as your stomach is left intact. There is full absorption of all food consumed as the stomach is intact and the anatomy has not been changed. Weight loss with the LapBand®/AGB is reported at 35-70% of excess body weight. Keep in mind then that **average best results are a 70% excess body weight - over a 3 to 5 year period.** For example, if your BMI is 40 (roughly 100 lbs overweight), with appropriate follow-up, exercise, adjustments to the band as needed, and eating habits, you can expect to lose 70 lbs. over a 3 - 5 year period, or approximately 15 - 25 lbs per year. Another example: If you have 200 lbs to lose, then you can estimate that, with appropriate behavior, you can lose 140 lbs (70% of 200), or about 45 lbs/yr over 3 - 5years. The more you weigh to start with, the more you will probably lose with recommended behavior. Patients with lower BMI's tend to lose a greater percentage of excess weight. Older patients tend to lose less excess body weight when compared to younger patients. The more your excess body weight is related to eating large volumes of food, the more you will probably lose when your volume is restricted. The more you can exercise, the more weight (and faster) you will lose. Soft foods, cookies, potato chips, soft drinks, sweets, ice cream, French fries, and other inappropriate food choices will all pass through the band without much problem and can sabotage your weight loss efforts. You have the tool to lose more and get down to ideal body weight, but this will require exercise, increased dietary protein, possibly excess skin resection, etc. **The goal of this and all bariatric surgeries is to make you healthier and improve your lifespan, not to get you to ideal**

**weight.** In other words, the LapBand®/AGB is a tool that can bring you down to ideal weight over time, but the main goal is better health. The weight loss is **gradual** in most instances and is more dependent on patient food choices and exercise. Do not get caught in the trap of comparing your weight loss numbers with others!

Understandably, you should not be pregnant at the time of surgery or it will be canceled and rescheduled in that event. If you are a woman, you should **avoid pregnancy** for the first year post-operatively. Periods of rapid weight loss are not the right time to be carrying and nourishing a baby and may lead to complications of the pregnancy or with the baby. Although you may think you are infertile (unable to bear children), this is often related to the obesity and once you lose the weight, you may be more likely to get pregnant. So please use caution in the first year after surgery. Should you decide to become pregnant at a later date, the LapBand®/AGB should not interfere with a successful pregnancy. If you or your obstetrician is concerned about your caloric intake, you can always have the fluid removed from your band and eat fairly normally.

**Alcohol consumption is discouraged**, as it is a high calorie liquid, which can defeat the purpose of the surgery.

You may also experience increased intoxication with less volume intake than prior to surgery for unclear reasons.

To make your surgery as technically safe as possible for the surgeon, we ask that you go on a high protein, low carbohydrate (**Atkins-type**) diet at least one week prior to surgery. This will shrink your liver and make your surgery easier and lower your chance of surgical complications. If you are unsure of the diet, please contact our dietitian for assistance. It is very important that you do not binge eat in the weeks before your surgery! If you have gained weight since your initial evaluation by the nurse practitioner, you run the risk of having your surgery postponed. If you gain weight between the time you are seen by the doctor and your surgery, you run the risk of having your surgery cancelled and rescheduled. The time after approval for surgery is not the time for the “restaurant victory tour”. Gaining weight not only increases your chance of complications, but shows a lack of commitment to your weight loss goals. Stay well hydrated the day prior to surgery, drink only clear liquids and then nothing to eat or drink (and no candy, chewing tobacco, mints or other oral intake other than medicine recommended by the internist or anesthesiologist with a sip of water) after midnight for surgery the next day. The internist and/or anesthesiologist will tell you which of your medications you can take the morning of surgery with a sip of water.

**NOTE: If you gain weight between your pre-operative visit with the surgeon and surgery, you run the risk of your surgery being cancelled. If the surgeon finds your liver is excessively large at the time of surgery, your procedure may be aborted and rescheduled for a later date. You have made a serious commitment to surgery and we expect you to implement these lifestyle changes prior to surgery.**

**Smoking** is a serious problem for the bariatric surgical patient. It increases your risk of pulmonary complications and blood clots, regardless of the procedure you choose. To decrease your risk of pulmonary complications or blood clots/embolism, we require that you quit smoking 1 month prior through 1 month after LapBand®/AGB surgery.

You will need **medical and possibly cardiac clearance** prior to surgery. You may also be required to meet the anesthesiologist pre-operatively. This is all done to make sure as best as possible that you are at a low or acceptable risk for anesthesia. If your doctors recommend further testing (such as a stress test, echocardiogram, etc.), it must be performed and deemed acceptable prior to scheduling surgery. In addition, most patients will have a medical doctor follow them during their hospitalization.

**Pre-operative EGD.** The LapBand®/AGB does not change your normal stomach anatomy as the stomach is not cut or divided. Nonetheless, you should consider having a look at the inside of your stomach with an upper endoscopy “scope” prior to your surgery. Although this is not necessarily required for all patients, you should strongly consider it if you have not had an upper endoscopy in the last 2 or 3 years. If you have frequent heartburn, take medicine for your stomach or have known gastroesophageal reflux (GERD, or “reflux”), you may be at risk for pre-cancerous changes of the lining of your esophagus that can only be diagnosed by upper endoscopy. If you regularly take anti-inflammatory medications (ibuprofen products, aspirin), you may be at increased risk of stomach or duodenal ulcers or irritation. If you are Helicobacter pylori (“H. pylori”) positive, you are at increased risk for stomach and duodenal ulcers, and possibly some stomach cancers. If you have stomach or upper abdominal pain on a regular basis, it is important you discuss this with us prior to proceeding with your band surgery as you will likely need a pre-operative EGD.

\_\_\_\_\_ M.D. I have discussed the risks, benefits, and alternative therapies with my surgeon and have \_\_\_\_\_, have not \_\_\_\_\_, decided to proceed with pre-operative EGD (upper “scope”). I understand that if I decline this procedure, I could have an unrecognized problem with my stomach including but not limited to cancer, ulcers, inflammation or other pathology that could significantly delay diagnosis/treatment and possibly result in significant complications. I understand risks of a diagnostic, possible therapeutic EGD include but are not limited to bleeding, infection, perforation, aspiration, and reaction to anesthesia.

**Patient initials:** \_\_\_\_\_

**General risks** which apply to all abdominal surgery include but are not limited to anesthesia (greater in the morbidly obese), deep venous thrombosis (DVT), pulmonary embolism, death, brain damage, infection, bleeding, pneumonia, cardiac events (heart attack), stroke, bowel obstruction, intra-abdominal abscess, damage to other intra-abdominal structures (bowel, solid organs, blood vessels) adhesions (less with laparoscopic than open procedures), wound infections (less with the laparoscopic approach), incisional hernias (much less with the laparoscopic approaches’ small incisions), internal hernias, disfiguring scars, the loss of function of body organs, chronic pain, among others.

**Bleeding.** It is unusual that you will need a blood transfusion, as the risk of significant bleeding is less than 1%. If you require blood, you will be transfused American Red Cross Blood. The most common risks of transfusion are:

- 1) fever
- 2) transfusion reaction – an exceedingly rare instance in which you would receive the wrong blood type which can cause serious illness, possibly kidney failure
- 3) Hepatitis – a viral infection of the liver, which can rarely lead to acute liver failure or more likely, can lead to chronic infection which over time can cause cirrhosis and possibly liver failure. Risk 1:3,000.
- 4) HIV – a viral infection which can lead to AIDS. Risk 1:10,000

**Infection.** Any surgery carries a risk of infection. Examples include wound infections, urinary tract infections, pneumonia (see above), IV site infections, blood infections (sepsis), abscesses, unrecognized bowel injury with peritonitis (infection of the abdominal cavity), necrotizing fasciitis (severe spreading infection of the soft tissues), and multi-system organ failure (multiple organ shut down with a high rate of death). Infections can be very mild or can be very severe. Although fortunately rare, some infections can progress to death, even if the source of infection is corrected and appropriate treatment given. Also very rare, some infections are resistant to multiple antibiotics and are harder to treat and have increased risk of serious consequences. Some patients are at increased risk of infection and have less ability to fight infection (examples: diabetes, morbid obesity, chronic steroid usage, immunosuppression).

**LapBand®/AGB Page 6      Pt initials:** \_\_\_\_\_

**Blood clots** in the veins in the legs or pelvis (DVT's) can migrate to the lungs (pulmonary embolism - PE) which can be fatal. These can occur after **any** type of surgery, and even without surgery (prolonged sitting, long airplane flights, riding a lawn mower, etc). The risk after surgery lasts for about two weeks and it is imperative that you walk regularly during that time. Fortunately the risk of this after our bariatric surgeries is less than one percent. To avoid this serious complication, we take several important measures. There are also things that only **YOU** can do that will decrease your risk. You will be asked to ambulate early, usually in the first few hours after surgery. We also want you to walk as much as possible prior to surgery to increase blood flow in the legs. It is important that you ambulate every 45 minutes on the drive home after discharge from the hospital. **Smoking carries with it an increased risk of clotting and we ask that you stop smoking one month prior to surgery and indefinitely thereafterwards as above. Hormones (birth control pills, menopause hormones) have been shown to increase the clotting rate and therefore we require that you avoid hormones for one month before and after your surgery.** We will have compression stockings on your legs during the surgery and until you are walking well. We will give you blood thinner subcutaneously during your hospital stay (as long as there are no signs of post-operative bleeding). If appropriate, we will give you Toradol, an anti-inflammatory with some blood thinning properties (anti-platelet). We will give you a folate vitamin (Foltx) pre-operatively and for one month post-operatively. Folate has been shown to help lower your homocysteine levels, high levels of which have been reported to be associated with increased blood clotting. We generally have quick operative times as the risk of DVT goes up with increased length of surgery.

**Filters.** Some patients will require a vena caval filter which is a filter placed in the large blood vessel that carries blood returning to the heart. This does not prevent blood clots, but may prevent the clot from migrating up to the heart and into the lung vessels (pulmonary embolism), which can be fatal. You may be required to have a filter before surgery if you are deemed at high risk. Some examples of high risk include super morbid obesity (BMI > 60), high pulmonary artery pressures, history of blood clots or pulmonary embolism, history of smoking, history of venous stasis disease, etc. You also have the option of requesting a filter pre-operatively. It is placed by a radiologist (physician) under sedation with local anesthetic through a large groin vein (1% complication risk), and can be usually (but not always) be removed in a similar fashion 2 – 6 weeks later (if desired) through a large neck vein (1% complication risk). There are risks with leaving a filter in place long term including migration and even clot formation. At the time of your consent, your surgeon will discuss this with you further.

\_\_\_\_\_M.D. I realize that I am at increased risk of blood clot (DVT or PE) based on the above. My physician has made me aware of this. After discussion of the risks, benefits, and alternative therapies of vena caval filter placement with my physician, I have \_\_\_\_\_ have not \_\_\_\_\_ opted to have a filter placed (see next paragraph below).

**Patient initials:** \_\_\_\_\_

**Post-operative Lovenox self injections.** Another option you have to help prevent blood clots is to inject yourself under the skin at home after discharge for several days with a blood thinning agent called Lovenox. This is a low molecular weight heparin. It can afford some extra protection against blood clots and emboli. The risks include allergic reaction to the injections, bruising/hematoma. It can very rarely cause bleeding at other sites, organs, or the brain, although we have not experienced this in our practice and it is generally considered safe at the low doses used.

\_\_\_\_\_M.D. I realize that I am at increased risk of blood clot (DVT or PE) based on the above. My physician has made me aware of this. After discussion of the risks, benefits, and alternative therapies to self Lovenox injections AFTER surgery at home, I \_\_\_\_\_ have \_\_\_\_\_ have not opted to proceed with this

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option. I have received a prescription today \_\_\_\_\_yes \_\_\_\_\_no

**Patient initials:** \_\_\_\_\_

**Pulmonary complications** such as pneumonia, aspiration and atelectasis (partial collapse of the lungs) can occur after **any** type of surgery under general anesthetic or as complications of your surgery. Once again, there are several things **you** can do to decrease your risk including stopping smoking, early walking after surgery, and using your incentive spirometer device (this will be given to you in the pre-op teaching class and you need to practice and use it religiously after surgery). Below are some of the factors that further increase your chance of pulmonary complications. Severe pulmonary complications can require prolonged need for a ventilator (breathing machine) and possibly even a tracheostomy.

\_\_\_\_\_M.D. (Patient initials required if initialed by consenting physician). I realize that I am at increased risk of pulmonary complications (such as pneumonia, atelectasis, need for prolonged ventilator support) based on a history of asthma \_\_\_\_\_, smoking or previous smoking history \_\_\_\_\_, abnormal pulmonary function tests \_\_\_\_\_, abnormal arterial blood gas \_\_\_\_\_, sleep apnea \_\_\_\_\_, other \_\_\_\_\_

\_\_\_\_\_. My physician has made me aware of this increased risk.

**Patient Initials:** \_\_\_\_\_

**Incisional Hernias** are fairly common in **OPEN** bariatric surgery, occurring in up to as much as 1 in 4 patients. It requires further major surgery with several days in the hospital. Even after repair, the hernia occasionally recurs requiring even more extensive surgery. An incisional hernia is a defect or opening in the muscle layers of the incision. These occur despite closing the muscle with suture material or staples. Contents within the abdomen can herniate (protrude) through this defect. More than simply causing an unsightly bulge, these intra-abdominal contents can get stuck in the defect and lead to a life-threatening surgical emergency. One undisputed advantage of laparoscopic bariatric surgery is the significant reduction in these post-operative hernias. Fortunately, incisional hernia rates after laparoscopic surgery is rare (1%), and if it does occur, it is in a small incision that can usually be repaired as an outpatient procedure with a much lower recurrence rate.

**Small Bowel Obstructions.** The small intestine can get blocked by twisting around scar tissue (adhesions) that occur as a result of surgery. This is the most common cause of bowel obstructions. Another cause is bowel twisting around the band tubing. These obstructions can occur as soon as days after surgery, although most occur months to years later. The risk is as high as 30% over time with major open abdominal surgery. The rates are less than 1% with bands. Rarely do bowel obstructions from banding result in compromise of the blood supply to the intestine, but this is always a possibility and such obstructions carry a higher risk of complications and death. Obstructions after open surgery usually require major open surgery, with its inherent risks, to repair. Most obstructions after laparoscopic surgery are repaired laparoscopically, although the open method may occasionally be required.

**Bowel Injury.** Rarely, the intestines or stomach can be injured at the time of surgery. If this occurs and is recognized, we will repair it (laparoscopically if possible). In this instance, we cannot place the LapBand® as the field is now potentially contaminated and could lead to infection of the band. The LapBand® placement could be done at a later date after recovery. If a bowel perforation is unrecognized (rare), it could lead to severe life-threatening infection/peritonitis and require further surgery with removal of the LapBand®.

**Damage to the spleen or other organs.** The spleen lies close to the upper portion of the stomach and can be injured in up to 10% of open upper surgeries on the stomach. Fortunately, it is very rare to injure the spleen

during laparoscopic surgery. If your spleen is injured, this most likely will require conversion to an open procedure and removal of the spleen to prevent exsanguination (bleeding to death). In general, you do not need your spleen. However, it does afford protection against certain types of infection and we try to salvage the spleen whenever possible. Pancreatitis is a rare but reported complication. Liver injury can lead to significant bleeding and may require transfusion or conversion to an open procedure. This risk increases if you have a fatty enlarged liver.

**Wound Infections.** These can occur with any type of surgery and generally require antibiotics, opening and drainage of the wound with packing. The wounds then heal from the bottom up (called “secondary intention”) over the next several weeks. The larger the incision, the longer it takes to heal and the higher chance of developing an incisional hernia (see above) at that site (which would require further surgery at some point). Morbid obesity, diabetes, poor personal hygiene, surrounding skin infections and poor post-operative wound care can all increase the chance of wound infections. **If the infection occurs at the LapBand®/AGB site early after surgery (approximately 1% risk), you will likely need your band completely removed.**

**Death:** The mortality rate of LapBand®/AGB is well under 0.5% and parallels the death rate of procedures such as elective laparoscopic cholecystectomy in similar patients. Although very safe, LapBand®/AGB placement is still major surgery and you and your family members should realize that complications of this procedure could be fatal.

**There are risks which apply in particular to the LapBand®/AGB,** in addition to those mentioned above. Most of these complications, if addressed in a timely fashion, are not life threatening. They often require further surgery with the temporary or even permanent removal of the LapBand®/AGB required. In most instances, these surgeries, including removal of the band, do not require cutting or removing any of the stomach and you are left with your original anatomy intact, i.e., no bridges are burned. In most instances, another band can be placed at a later date or another bariatric procedure could be performed. These complications are particularly important if you are paying for this procedure out of pocket (please see below).

- **Slippage of the band:** This risk is about 3%. True slips (the band slips out of position) are rarer and generally occur with episodes of severe retching, especially early in the post-operative period before the band has scarred in completely (the band is sutured in place during the initial operation). The majority of “slips” are actually stomach herniations up above the fixed band from having the band too tight and chronic retching. Stomach surrounding the band, not the band itself, slips up causing obstructive symptoms or reflux. In most instances, the slip does not permanently damage the stomach and is not life-threatening. However, there is the potential for the slipped portion of the stomach to decrease (ischemia) or cut off (necrosis) its blood supply with the potential for serious illness and infection and requiring possible partial removal of the stomach. This emergent major surgery, if required, carries a high risk of severe complications and even death. Patients with a slip usually present with inability to keep anything down (obstruction), and will require laparoscopic (rarely open) surgery to either re-position, replace, or remove the band.
- **Infection:** The risk of band and/or port infection is less than 1%. The entire band/tubing/port is placed sterilely and resides completely underneath the skin. It can become infected if accessed un-sterilely, if you develop an infection in another location (urinary tract, pneumonia, ruptured appendix, etc.) that “seeds” the port/band, if you develop an erosion (see below), or other factors. It can occur if you developed a wound infection related to the initial surgery. Under no circumstances should you ever try and adjust your band yourself! It could lead to infection or damage to the port. The band could become infected during elective (scheduled) or emergency surgery in which potentially infected abdominal contents could come into contact

with the band or its tubing, for example, gallbladder removal. The band could become infected during other elective surgeries of the abdominal wall, for example an abdominoplasty (“tummy tuck”) or liposuction. It can also become infected if you develop peritonitis from other causes, e.g. diverticulitis, appendicitis, cholecystitis, perforated ulcer, trauma, etc. Band infection is usually not life-threatening, but like any infection, has the potential to be severe and even fatal. If you develop an infection, the band/port (a foreign body) **must** be removed. It can be replaced, usually laparoscopically, at a future time once all infection has resolved. As with any procedure that breaks the skin, it is possible during your adjustment that an infection could occur despite our best efforts at sterile access of your port.

- **Erosion:** Fortunately, also a very rare complication (< 1%). The band erodes into the stomach causing a loss of restriction and weight gain. Another presentation is sudden port site infection without obvious cause, because the bacteria from the stomach around the band travel along the tubing to the port site. It usually does not cause significant peritonitis (intra-abdominal infection), but this is always a possibility that would require major surgery and carry the potential for serious complications and even death. Band erosion absolutely requires laparoscopic, possible open, removal of the band/port. It can often be laparoscopically replaced at a later date.
- **Esophageal and Pouch Dilatation:** This has become a more frequent problem and is related to having the LapBand®/AGB too tight. This essentially makes the band act as a partial obstruction (blockage), which causes the pouch and/or the esophagus to dilate and stretch. Over time, the muscles of the pouch and/or esophagus lose their tone. Patients present similar to a slip – inability to keep down even liquids and upper abdominal pain. Although in some instances this can be reversed by removing all the fluid from the band and allowing time for tissues to regain their tone, it often requires complete removal of the band.
- **Port problems:** Rarely the port under the skin will leak or twist requiring revision or replacement (1%-3%). Rarely, a leak can occur when the connection between the port and the band tubing comes loose. The port can leak from damage to the tubing that inadvertently occurs when trying to access the port through the skin with the access needle. We obviously try our best to avoid this complication but it does occasionally occur. Revision or replacement of the port is minor surgery under the skin and is done in the operating room for sterility.

**NOTE: If you are paying out of pocket for the LapBand®, any potential re-operative surgery (e.g. for complications as above) will result in further costs, even if the LapBand® must be removed. Unfortunately, the initial outlay of money is nonrefundable. Replacement of the LapBand® at a later date could also require similar out of pocket expenses.**

You give the consent to the existing possibility that once the procedure has been begun laparoscopically; **it may be necessary to convert to an open procedure. This will be done only to address a serious or life-threatening complication, and not just to place the band.** This will be decided by your surgeon and performed with your best interest in mind. Our policy is NOT to convert to open if the only reason is technical inability to place the band (e.g. your liver is too large, we cannot distend your abdomen with the gas, too much scar tissue, too obese). We would simply back out and re-group to discuss further options. Our conversion on initial operation from laparoscopic to open is less than 1%, and we do all of our procedures laparoscopically regardless of patient size or previous surgeries. Any other encountered pathology (abnormalities) seen at the time of surgery will be addressed as indicated in the surgeon’s best judgment.

**Once again, in the rare event that the LapBand® cannot be placed laparoscopically, the procedure may**

**be aborted rather than converted to an open placement of the LapBand® depending on the surgeon's discretion.**

**Previous abdominal surgeries, hiatal hernias, or other pathology found at the time of surgery.** In general, despite what you may have heard elsewhere, none of these will affect your ability to have your procedure done laparoscopically. Certainly, the technical difficulty is greater if you have had previous open surgeries (because of scar tissue that forms), or have an incisional or hiatal hernia at the time of your LapBand®/AGB. These will be addressed as discussed in the next paragraphs. Please note that any procedure done in addition to your LapBand®/AGB increases the risk of complications. Any additional procedures will take more time, increasing the risk of pulmonary complications or blood clot formation. In addition, they will require additional dissection increasing the risk of bleeding and/or organ/bowel injury. Lastly, each additional procedure(s) carries its own specific risks – for example, a hernia repair has a risk of recurrence, pain, infection, etc. To this end, during surgery we try and focus on your LapBand®/AGB procedure and do not spend an inordinate amount of time looking for other pathology in the absence of symptoms - for example, looking at the uterus, ovaries, appendix, etc.

**Incidentally found abnormalities at the time of surgery.** On occasion we find other previously unrecognized abnormalities at the time of surgery. This includes, but is not limited to, such things as adhesions, hiatal hernias, incisional or abdominal wall hernias, abnormal liver, masses, ovarian cysts, etc. These will be addressed laparoscopically at the surgeon's discretion with your best interests in mind. If you have a significant **hiatal hernia**, it will be repaired laparoscopically as part of your procedure. Small abdominal wall hernias may be left undisturbed, or repaired, possibly with mesh. These abdominal wall hernias, especially the larger ones (which take more time and have a higher recurrence rate in more obese patients) may be left undisturbed to be addressed at a later date. There is a risk of intra-abdominal contents getting caught in the hernia and compromising the blood supply, requiring major surgery and potentially significant complications. There are significant risks to repairing your hernia at the time of your band as well. Your surgeon will weigh these risks and benefits of repairing your hernia at the time of your band and proceed according to his best judgement. A small liver biopsy may be taken at the discretion of the surgeon. Once again, other abnormalities will be addressed in the best judgment of your surgeon.

**Hiatal Hernias.** These deserve special mention. On occasion we encounter a hiatal hernia at the time of your surgery. This is a weakness in the opening of the diaphragm (large muscle separating the chest contents from the abdomen contents), through which some or a large portion of your stomach can “slip up” (herniate) into your chest cavity. It is often, but not always, associated with heartburn symptoms (reflux, regurgitation, chest pain, cough, etc.). These can be diagnosed by endoscopy (EGD) or an upper GI (drink contrast and take Xrays). The most definitive test is actually looking at the area, which we will automatically do at the time of your surgery while making your pouch. In smaller hernias, repair is as simple as a few stitches in the diaphragm to tighten the opening. In larger hernias, we need to completely reduce the portion of the stomach in the chest to below the diaphragm, then repair the defect with sutures. In extremely large defects, we ideally would reinforce the closure with a synthetic patch. The presence of a significant hiatal hernia increases your incidence of LapBand® complications, especially slippage. **Complications of hiatal hernia repair** are fortunately unusual. These include, but are not limited to: recurrent hernia, slipping of the pouch into the chest, dysphagia (inability to swallow well secondary to the repair being too tight), damage to the thoracic duct (a small duct that carries lymph fluid back to the large veins near your heart), pneumothorax (lung lining puncture, may require a tube between the ribs for a few days to keep the lung up), recurrent gastroesophageal reflux, and esophageal perforation with severe infection. **In certain instances with large hiatal hernias, LapBand® placement may be not advisable and the hiatal hernia will be fixed without placing the LapBand® at the surgeon's**

**discretion. It is possible to have the LapBand® placed at a later date after recovery from hiatal hernia repair.**

**Concomitant gallbladder surgery.** If you are having gallbladder surgery at the same time as the LapBand®/AGB placement, we will perform the gallbladder surgery first. If the gallbladder can be removed without spilling any bile, we will go ahead and place the LapBand®/AGB. If bile is spilled, LapBand®/AGB placement will have to be postponed as the field is now potentially contaminated and could lead to infection of the band. In this instance, LapBand®/AGB placement will have to be delayed until recovery at a later date (at least two weeks).

**Gallstones:** There is an increased risk of developing gallstones after LapBand®/AGB placement. The exact mechanism is unknown, but gallstones do develop more often during periods of rapid weight loss. We do not remove your gallbladder at the same time unless you have known stones, gallbladder disease, or an abnormality seen at the time of surgery. Removing the gallbladder at the time of surgery increases operative times (increasing your risk of developing blood clots and/or pneumonia) and increases the risk of complications (bleeding, damage to the bile ducts, bile leak, bowel perforation). For example, the gallbladder is usually removed without giving blood thinner as we will likely do for your bypass and therefore the risk of bleeding with gallbladder removal is higher than for standard gallbladder surgery alone. Studies suggest that taking a prescription medication (Actigall) in the early post-operative period may decrease the rate of gallstone formation. Therefore we recommend that you take Actigall for the first six months post-operatively if you have not previously had your gallbladder removed. We will give you a prescription for this before your surgery and you may begin taking it after you come home from surgery.

**Psychological factors including post-operative depression (as a result of weight loss, required diet change, complications of surgery) or possibly a reaction to the stress of surgery are possible:** Family members may also experience these. Studies have shown that most patients have an improvement in depressive symptoms after surgery, and it is much more likely that you will be very pleased with this life-changing procedure rather than the opposite.

**Extreme weight loss:** Fortunately this is very rare. Most people will stabilize at a weight that is healthy for them.

**Failure to lose weight:** The LapBand®/AGB, more than any other bariatric surgical procedure, is a **TOOL**. And like any tool, if not used appropriately, will not work. There are patients who will not lose and even gain weight with the LapBand®/AGB. **Once again, the purpose of the LapBand®/AGB can be circumvented by eating high calorie soft or liquid foods (or other inappropriate food choices or behaviors), having the band too loose or too tight, not coming in for adjustments if needed, and lack of exercise.**

**Gas pains or excessive flatulence can occur and are usually controlled with simethicone, sometimes Levsin:** In general, LapBand® should not effect your bowel habits to any significant degree.

**It is also possible to get food stuck at the level of the band if you eat too large a piece of food, don't chew well, or advance your diet more rapidly than advised:** This may require removal of fluid from your band or even an endoscopy to clear the trapped food.

**“Priming”.** Some patients may experience pain and discomfort at the upper abdomen and lower chest after eating, called dysphagia. This is often relieved only with vomiting. After vomiting, they often can eat the same food normally without discomfort. We have found that “priming” is helpful in avoiding this uncomfortable

problem. “Priming” involves taking a couple bites of something soft (such as yogurt or mashed potatoes) or sips of warm liquid, then stepping away for 5 minutes before eating your planned meal. You can hear more about this and other ideas in our LapBand® support group.

**Large folds of skin:** This is always a possibility with significant weight loss. There is no reliable way to determine before surgery if this will occur after surgery. Age, exercise, rapidity of weight loss, elasticity of skin, and type of foods eaten all play a role. We do the surgery to improve your health and longevity, and best results are usually approximately 70% of excess body weight loss over an approximately 3 – 5 year period. You may have additional weight in excess skin. Plastic surgeries are available to correct this problem if desired, and on occasion, can be covered by insurance. We do not perform the plastic surgeries but can refer you to the appropriate plastic surgeons if you desire.

**Other complications** may possibly occur with less frequency. Not all side effects or hazards of the operation may be known, and the result of surgery cannot be guaranteed. Once again, every effort is made to prevent problems, and you need to understand and accept that they may still occur.

Although over 250,000 LapBand® procedures have been performed worldwide since 1993, and the LapBand® received FDA approval in the United States in June 2001, there may be long term problems not known at this time.

**Re-operation** may be needed, at some future time, to correct problems, which might occur. The LapBand®/AGB is reversible, usually laparoscopically, although there is seldom any practical reason to consider reversal or laparoscopic conversion to bypass, sleeve or duodenal switch. Certainly advances in medical treatment of obesity may occur in the future that would possibly make reversal an appropriate option.

**Paying out of pocket “cash pay” or high deductibles.** We would prefer to do our surgeries under insurance coverage, but several insurance companies either exclude coverage for Bariatric surgery, have high deductibles, have unreasonably strict guidelines, or only approve certain procedures. In any event, some patients will pay for the entire procedure themselves or pay a large co-pay/deductible. The money spent is often tax deductible (consult your tax attorney or accountant) and there are some financing options available, although not through our practice. **Please be aware that if you have an exclusion and are paying entirely out of pocket for your procedure (NOT those with high deductibles or co-pays generally), payment does not cover potential surgical complications. Our (the surgeons’) price for entirely “cash pay” patients (not those with high deductibles/co-pays) includes all additional surgeons’ fees for any additional surgery if needed, but it does not cover fees incurred by the hospital, lab, radiology, anesthesia, etc. We may bill your insurance company for additional procedures done unrelated to the surgery itself (examples: lysis of adhesions, repair of hiatal hernia, repair of abdominal wall hernia, removal of the gallbladder or other organ, etc.), but will not charge you additional out of pocket expenses over and above the insurance reimbursement for these procedures. Significant complications often require additional hospital stay, testing, medications, etc. that will be the responsibility of the patient.** Please try and arrange a contingency plan with the hospital **as soon as possible before your surgery date.**

I am paying out of pocket for this procedure or have a high deductible/co-pay and am aware of the above.

**Patient Initials:** \_\_\_\_\_

Your surgery will be performed by your surgeon and he will be assisted by another bariatric surgeon, so that you will have at least two fully trained, ASBS member surgeons present. Our Certified Physician Assistant(s) may also be present.

Surgical treatment is a participatory alternative (elective) and should not be considered a cure-all or quick fix. It does not affect the underlying causes of obesity whether genetic, environmental, psychological, or hormonal. However, in most cases, surgery is effective in achieving durable weight loss.

**You have the right to a second opinion.**

You are encouraged to have attended an educational seminar.

You have been given the opportunity to attend support groups and to discuss the results of this procedure with other patients.

**Your family and friends are encouraged to participate** in the educational process, as their support is important and beneficial following surgery.

**Your signature below certifies that:**

- 1) **You have read the contents of this form, discussed the above verbally with the surgeon, and understood the risks, benefits, and alternatives involved and hereby give INFORMED consent to proceed with LAPAROSCOPIC, POSSIBLE OPEN LAPBAND PLACEMENT.**
- 2) **You pledge to cooperate with recommended guidelines for eating and for follow-up.**
- 3) **You agree to keep your surgeon informed of your address and phone number, and to participate in regular follow-up.**

G. Derek Weiss, M.D.

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(Signature of Physician)	Printed Name	Date
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John S. Oldham, Jr., M.D.

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(Signature of Physician)	Printed Name	Date
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(Signature of Patient)	Printed Name	Date
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(Signature of Witness)	Printed Name	Date
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**LapBand®/AGB Page 14 Pt initials: \_\_\_\_\_**

**LapBand® Consent Page 14**