

Informed Consent Laparoscopic Possible Open LapBand

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You have decided to undergo laparoscopic, possible open, LapBand 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. 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.

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 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 although the open method may be used in some rare instances ("Open" bariatric surgery carries a higher complication rate than a minimally invasive/laparoscopic approach in appropriately trained and experienced surgeons). 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 device to the upper portion of the stomach. There is also a port attached to the LapBand device that is secured to underlying muscle on the abdomen. The port can be accessed in the post-operative period by the surgical team, using a special needle, to make necessary adjustments of the inside lumen. 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 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. The usual hospital stay is less than 23 hours (outpatient or same day surgery). Health problems associated with excess weight are also usually benefited. Lastly, the LapBand is easily reversible/removed and can be laparoscopically converted to a

Roux-en-Y gastric bypass if needed/desired.

Although the changes after LapBand® are not as drastic as with gastric bypass, 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. **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 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. 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). Then continue exercising after surgery, advancing the amount of exercise as you feel better and better.

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 is reported at 35-70% of excess body weight. Keep in mind then that **average best results are a 70% excess body weight loss - over a 3 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 year period, or approximately 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 years. The more you weigh to start with, the more you will probably lose with recommended behavior. 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. 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 surgery is to make you healthier and improve your lifespan, not to get you to ideal weight.** In other words, the LapBand® 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. Do not get caught in the trap of comparing your weight loss numbers with others!

As above, it is important that you don't try and rush this process and **tighten your band too quickly.** It can not only lead to weight gain as above, but can lead to placing too much stress on your esophagus too quickly resulting in dysmotility (a type of paralysis) of your esophagus with nausea, vomiting, and pain. In these instances, all the fluid must be removed from the band until the esophagus recovers (1 – 2 weeks), and the filling process re-started. In extreme cases, the band must be removed. So don't try and rush the process! Let

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your physician decide the appropriate timing and amount of your adjustments to the LapBand®.

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

The **Roux-en-Y divided gastric bypass** is the most widely accepted and common procedure performed by bariatric surgeons in the United States. 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 often is associated with a permanent decrease in appetite. The nature and purpose of this operation is to functionally limit the amount of food or liquid intake at any given time. There also may be a small component of malabsorption, at least initially. 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. Strictures, internal hernias, and outlet ulcers are also a possibility 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.

The **duodenal switch/biliopancreatic diversion procedures** are malabsorptive procedures and generally carry the highest complication rate among bariatric procedures. Weight loss occurs by lack of absorption of nutrients rather than by loss of appetite and restricted intake. These procedures can cause foul smelling diarrhea and can be complicated by anemia, protein malnutrition, liver failure, vitamin (especially fat-soluble) and mineral deficiencies.

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.

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 18 months 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 18 months after surgery.

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 and then nothing to eat 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. If you have a bypass, it greatly increases your chance of having the dreaded complication of pouch ulceration. This results in pain and malnutrition, an endoscope procedure, and requires prolonged hospital stays on IV nutrition and medication. In some instances, they can bleed massively or even perforate requiring emergency surgery. Moreover, these pouch ulcerations will not heal without the cessation of smoking. If you are a smoker and intend to continue smoking after surgery, then you should strongly consider avoiding the gastric bypass and opting instead for the LapBand®.

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. To this end, in addition to meticulous surgical technique, we try and prevent these complications in several ways.

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.

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 lawn mowing, etc). 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. 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. We will use Toradol, an anti-inflammatory with some blood thinning properties (anti-platelet), during the first 48 hours. 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. Smoking carries with it an increased risk of clotting and we ask that you stop smoking one month prior to and after surgery. 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. The risk of DVT (clot in the legs or pelvis) is about 1 in 200, and the risk of a pulmonary embolism about 1 in 500 – 1000.

_____ M.D. (Patient initials required if initialed by consenting physician). 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. I have _____ have not _____ opted to have a filter placed (see next paragraph below).

Patient initials: _____

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 removed in a similar fashion up to one year later through a large neck vein (1% complication risk). At the time of your consent, your surgeon will discuss this with you further.

Pulmonary complications such as pneumonia and atelectasis (partial collapse of the lungs) can occur after **any** type of surgery under general anesthetic. Once again, there are several things **you** can do to decrease your risk of these complications including stopping smoking, early walking after surgery, and using your incentive spirometer. The incentive spirometer is a device to help you expand your lungs in the post-operative period and you will be given one to take home and practice with prior to your surgery. If you are a smoker, you are at increased risk of pulmonary complications. Only very rarely do pulmonary complications require prolonged need for a ventilator (breathing machine).

_____ 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 _____, abnormal pulmonary function tests _____, abnormal arterial blood gas _____, 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 tiny incision that is easily repaired as an outpatient with a less than 1% recurrence rate.

Small Bowel Obstructions. The small intestine can get blocked by twists around scar tissue (adhesions) that

occur as a result of surgery. This is the most common cause of bowel obstructions. Another cause is internal hernias – defects within the abdominal cavity through which the bowel can herniated and become blocked. 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 after laparoscopic bypass is around 3% and less than 1% with the LapBand®. Obstructions after open surgery require major open surgery, with its inherent risks, to repair. Most obstructions after laparoscopic surgery are repaired laparoscopically.

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 with 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

Risks which apply in particular to the LapBand include the above as well as the following:

- 1) **Slippage of the band:** This risk is about 1-2%. Stomach surrounding the band can slip up causing obstructive symptoms or reflux. It generally occurs 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. If a slip occurs, it can be repaired in most instances by either re-suturing it in place or placing a new band. In either instance, it is done laparoscopically as an outpatient procedure (same day surgery).
- 2) **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, and the rate is under 1%. 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 rarely requires any additional treatment. **Unrecognized** injury rarely occurs to the stomach or intestines but can lead to peritonitis requiring more surgery. If recognized, it can be repaired (usually laparoscopically) but the band placement may need to be postponed to avoid infection.
- 3) **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, etc.) that “seeds” the port/band, or if you develop an erosion (see below). Once again, this is very rare. Under no circumstances should you ever try and adjust your LapBand® yourself! It could lead to infection or damage to the port. Unfortunately, however, 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.
- 4) **Erosion:** A rare complication reported mostly in the early studies in Europe and Australia. Apparently the band erodes into the stomach causing a loss of restriction and weight gain. It usually does not cause significant peritonitis (intra-abdominal infection), but does require laparoscopic removal of the band/port. It can be laparoscopically replaced at a later date.

- 5) **Port problems:** Rarely the port under the skin will leak or twist requiring revision or replacement (1%-3%). This is done under local anesthetic as an outpatient. Leaks where the port connects to the band tubing are now very unusual since the company re-designed the connection to rest in the abdominal cavity rather than on the muscle.
- 6) **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 (approximately two weeks).

NOTE: If you are paying out of pocket for the LapBand® or have a high deductible, 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.

- 7) **Concomitant gallbladder surgery.** If you are having gallbladder surgery at the same time as the LapBand® 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®. If bile is spilled, LapBand® 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® placement will have to be delayed until recovery at a later date (approximately two weeks).
- 8) **Death:** The mortality rate of LapBand is well under 0.5% and parallels the death rate of procedures such as elective laparoscopic cholecystectomy in similar patients. Although very safe, LapBand placement is still major surgery and you and your family members should realize that complications of this procedure could be fatal.
- 9) **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.
- 10) **Gallstones:** There is an increased risk of developing gallstones after LapBand® placement. The exact mechanism is unknown, but gallstones do develop more often during periods of rapid weight loss. We do not remove your gall bladder at the same time unless you have known stones, gallbladder disease, or abnormality seen at the time of surgery. Studies suggest that taking a prescription medication (Actigall) in the post-operative period may decrease the rate of gallstone formation. Therefore we may recommend that you take Actigall for six months post-operatively if you have not previously had your gallbladder removed. We may give you a prescription for this before your surgery and you may begin taking it after you come home from surgery. This will be discussed with you during the visit when this document is signed.
- 11) **Extreme weight loss:** Fortunately this is very rare. Most people will stabilize at a weight that is healthy for them.
- 12) **Failure to lose weight:** Although almost everyone will lose weight early on, it is possible to defeat the purpose of this surgery as discussed above.

- 13) Gas pains or excessive flatulence can occur and are usually controlled with simethicone.** In general, LapBand should not effect your bowel habits to any significant degree.
- 14) 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.
- 15) "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 3 or 4 bites of something soft (such as yogurt or mashed potatoes), 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.
- 16) 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 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 160,000 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 is reversible, usually laparoscopically, although there is seldom any practical reason to consider reversal or laparoscopic conversion to bypass. 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 unreasonably strict guidelines, or only approve certain procedures. In any event, some patients will pay for the entire procedure themselves. The money spent is tax deductible and there are some financing options available, although not through our practice. **Please be aware that your payment does not cover potential surgical complications. Our (the surgeons') price 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. 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 and am aware of the above.

Patient Initials: _____

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 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.

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 decided by your surgeon and performed with your best interest in mind. 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.

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. To date, this has not been an issue. Please discuss this with your surgeon at the time you sit down with him to discuss consenting for your surgery.

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 will usually be repaired with a stitch or two, larger ones may be repaired with mesh. Sometimes these abdominal wall hernias may be left undisturbed to be addressed at a later date. 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.

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.**

Dennis M. Lewis, MD, FACS

sample copy

(Signature of Physician) Printed Name Date

(Signature of Patient) Printed Name Date

(Signature of Witness) Printed Name Date