

Informed Consent Laparoscopic Possible Open Sleeve (Vertical) Gastrectomy

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You have decided to undergo laparoscopic, possible open Sleeve or Vertical Gastrectomy. 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. If available, 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 Laparoscopic Sleeve Gastrectomy (also known as a Vertical Gastrectomy, Greater Curvature Gastrectomy, etc.) is performed by making several small incisions through which the surgeon(s) insert laparoscopic instruments to perform the surgery. Patients usually go home the next morning. It is a restrictive procedure, i.e. it limits the amount of food you can eat at any one time. This is accomplished by cutting away the outer portion of the stomach, leaving a small tube or sleeve of stomach. This reduces the stomach volume by about 80%. The stomach is now a banana-shaped organ that will hold less food and produce less acid. A large majority of the glands that produce the hormone implicated in hunger (Grehlin) are also removed and therefore there may be a

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component of appetite suppression as well.

This procedure was initially developed as a staged procedure in very morbidly obese individuals with very severe co-morbidities (associated illnesses) that made them too high a risk for a prolonged, “one-stage” operation. In a “staged” procedure, the sleeve gastrectomy is done first when the patient is at their heaviest and highest surgical risk. The patient then recovers, and loses about 50% of their excess body weight (EBW) over the next several months. They are now healthier and have less surgical risk and can then proceed with the second stage of the weight loss surgery (e.g. bypass, duodenal switch, or adjustable gastric banding). Several patients were pleased with the results of the sleeve gastrectomy alone and never proceeded to the second stage. This led to the procedure being considered as a primary (one stage) operation. This has been done for about 4 years and there are currently no long-term data on whether it will be a long-term weight loss solution. There are concerns that the stomach tube could stretch out and lead to weight gain and the need to proceed to the “second stage”. There are concerns with any staged procedure that the second stage will not be covered by insurance.

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 in the United States. We perform this surgery through several small incisions (laparoscopically) and patients usually go home on the second day after surgery. 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 AGB or the gastric sleeve procedures.

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The **LapBand®/Adjustable gastric banding (AGB)** functionally restricts the size of the stomach to about 2-oz with an adjustable silicone band. This is also performed laparoscopically and patients usually go home a few hours after surgery (outpatient). The difference 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. It is also the most easily reversible bariatric procedure available. Weight loss occurs by restricted intake. There is no division or bypass of the stomach. It is the safest and least invasive Bariatric surgical procedure available at this time. Weight loss is more gradual than other bariatric procedures and the procedure can be circumvented by eating high calorie liquid or soft foods, or having the LapBand too loose or too tight. When used appropriately, weight loss with the LapBand is about 35 – 75% excess body weight over a 3 – 5 year period.

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 **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.

The Sleeve Gastrectomy has several advantages and disadvantages when compared to the other bariatric procedures available (see attached sheet). It carries less risk than the bypass, but more than adjustable gastric banding. It has faster weight loss and correction of associated co-morbidities than adjustable gastric banding, but less than the bypass. Like banding and unlike bypass, it does not involve re-routing or bypassing the intestine so that there is much less likelihood of vitamin, mineral, and protein deficiencies. This means that, unlike the bypass, special vitamins and supplements are generally not required and follow-up labs are generally not required. Like banding and unlike bypass, you have normal food transit and can have standard diagnostic procedures such as EGD (“scope”). There is no “dumping” with the sleeve gastrectomy as seen with the bypass and no bread intolerance as often seen with banding. Unlike both the bypass and banding, a portion of the stomach is permanently removed. Like banding and unlike bypass, it can be easily converted to another weight loss procedure (“no bridges burned”). Like bypass and unlike banding, it is not adjustable after surgery and therefore no needle sticks are required. Like bypass and unlike banding, there is no foreign body placed so there are no concerns of complications of banding such as slip, infection of the band, pouch

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enlargement or esophageal dilatation, erosion, or port problems. The bypass has been around for over 40 years, adjustable gastric banding has been done since 1993 and FDA-approved in the United States in June of 2001. The bypass and adjustable gastric banding are both covered by most insurances that carry bariatric coverage, including Medicare (if performed in an ASBS or ABS Center of Excellence). The sleeve gastrectomy as a primary (not staged) procedure, on the other hand, has been performed for only about 4 years and is considered experimental by most insurance companies and therefore often not a covered benefit.

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.

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 gastric sleeve “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 sleeve “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 usually faster than with banding, but not as rapid as with bypass. 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 it still enters your stomach (albeit a much smaller stomach). Most absorption of nutrients occurs in the small intestine which is not bypassed and therefore most calories taken in are fully absorbed. Weight loss with the Sleeve Gastrectomy Procedure is reported around 50% of excess body weight, usually over the first year. For example, if your BMI is 40 (roughly 100 lbs overweight), with **Gastric Sleeve Page 4 / Pt. Initials: _____**

appropriate follow-up, exercise, and eating habits, you can expect to lose around 50 lbs. over the following year. Relatively few procedures have been performed compared to the bypass and AGB and therefore the exact amount of weight loss is less well known and long-term results (more than 4 years) are unknown. 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 sleeve 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 laparoscopic sleeve gastrectomy is a tool that can bring you down to ideal weight over time, but the main goal is better health. The weight loss rate in most instances is intermediate between banding and bypass 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. Female bypass patients can and do get pregnant and usually with close monitoring by their obstetrician, will have an uneventful pregnancy. Pregnant post-bypass patients need to absolutely inform their obstetrician as soon as possible to receive the needed special consideration and monitoring.

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 as your stomach is smaller and it will enter the small bowel faster.

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 **Gastric Sleeve Page 5 / Pt. Initials: _____**

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 Sleeve Gastrectomy

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 Sleeve Gastrectomy reduces the size of your stomach without interfering with normal food flow and digestion. Unlike with a bypass, the sleeve will always be accessible to endoscopy or other studies. Nevertheless, 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 sleeve 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

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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).

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

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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 and after surgery 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 an inferior 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.

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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 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
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tissue (adhesions) that occur as a result of surgery. This is the most common cause of bowel obstructions. 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 the laparoscopic sleeve gastrectomy. 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). If a bowel perforation is unrecognized (rare), it could lead to severe life-threatening infection/peritonitis and require further surgery.

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. Large “open” surgery incisions carry a higher infection rate (up to 20%) than laparoscopic incisions (around 1%). 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.

Death: The mortality rate of the Gastric Sleeve is less than 1% and is as safe or safer than laparoscopic bypass surgery, but not as safe as adjustable banding (where there is no cutting or dividing of the stomach). Although all minimally invasive, the sleeve gastrectomy 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 Sleeve Gastrectomy Procedure in addition to the above:

- **There can be a “leak” at the staple line.** This could lead to peritonitis and sepsis, and/or an abscess. This risk is about 1 – 2% and will require drainage and/or surgical repair.

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- Slightly **higher risk of spleen injury** which may require conversion to an open procedure and spleen removal as above. This is because the attachments of the outer part of the stomach to the spleen must be completely taken down.

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.

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 laparoscopic Sleeve Gastrectomy. These will be addressed as discussed in the next paragraphs. Please note that any procedure done in addition to your bypass 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 sleeve 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 a cancer or other significant abnormality is encountered, your procedure may understandably be aborted. If you have a significant **hiatal hernia**, it will be repaired laparoscopically as part of your procedure (see below). Small abdominal wall hernias may or not be repaired, depending on the surgeon's discretion. These abdominal wall hernias, especially the larger ones, may be left undisturbed to be addressed at a later date. This is because these larger hernias generally require mesh for adequate repair. We do not like to place mesh (a foreign body) at an operation such as bypass or sleeve gastrectomy where there is a potential for contamination of the mesh with dire consequences. 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 bypass as well. Your surgeon will weigh these risks and benefits of repairing your hernia at the time of your bypass and proceed according to his **Gastric Sleeve Page 11 / Pt. Initials: _____**

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 performing your sleeve gastrectomy. 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, however, this is not possible with sleeve gastrectomy for the same reasons listed in the paragraph above (contamination of the mesh). **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.

Gallstones: There is an increased risk of developing gallstones after sleeve gastrectomy. 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 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 post-operative period may decrease the rate of gallstone formation. Therefore we recommend that you take Actigall for 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

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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: Although almost everyone will lose weight early on, it is possible to defeat the purpose of this surgery as discussed above.

Diarrhea, constipation or excessive flatulence: Diarrhea is very unusual with the gastric sleeve and is more associated with the malabsorptive procedures such as duodenal switch/ biliopancreatic diversion (as discussed above) or the “long-limb” bypass (which we do not offer). Some patients may experience constipation, especially early on when the food is mostly liquid and high in protein content. This will respond to gentle laxatives such as Milk of Magnesia. Over time, you will need to eat fiber containing foods and vegetables just like anyone else.

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 50% of excess body weight loss over the first 12 months. 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.

This procedure has been performed as a primary one stage operation for only about 4 years and there may be long term problems not known at this time. It was designed as a two stage procedure – i.e. conversion to a bypass, adjustable band, or duodenal switch at a later date.

Re-operation may be needed, at some future time, to correct problems, which might occur. Most of the complications can be addressed laparoscopically, but may require open surgery. The stomach is partially removed permanently and therefore the procedure cannot be “reversed” in the truest sense. However, “reversal” doesn’t really apply as the sleeve does leave you with a fairly normal, albeit much smaller, stomach.

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 tax

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deductible (consult your tax attorney or accountant) and there are some financing options available. **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.

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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 SLEEVE GASTRECTOMY.**

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- 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.

(Signature of Physician) Date

John S. Oldham, Jr., M.D.

(Signature of Physician) Date

Signature of Patient Printed Name Date

Signature of Witness Printed Name Date

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