

Informed Consent Laparoscopic Possible Open Roux-en-Y Divided Gastric Bypass

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You have decided to undergo laparoscopic, possible open, Roux-en-Y Gastric Bypass. 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 laparoscopic Roux-en-Y gastric bypass procedure involves making several small incisions through which the surgeon(s) insert laparoscopic instruments to perform the surgery. The procedure 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 and functional otherwise. In other words, the majority of your stomach does not have food passing through. It often is associated with a prolonged decrease in appetite and sometimes even a temporary aversion to food and nausea. The nature and purpose of this operation is to functionally limit the amount of food or liquid intake at any given time. Although not as significant with respect to long-term weight loss, there is a component of malabsorption, requiring that you take vitamins and supplements for the rest of your life. This procedure is often associated with fairly rapid weight loss initially, which stabilizes over time. 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.

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Following gastric bypass, you may experience an intolerance to certain food types, usually fatty greasy foods, dairy products, and/or sweets which may cause unpleasant symptoms similar to seasickness such as sweating, nausea, shaking, pain, and/or diarrhea which lasts from a few minutes to an hour. This is known as “**dumping**” and is an after effect that may be useful in reinforcing good dietary choices, but can be very uncomfortable for some, but not all, patients.

You most likely will lose a large amount of weight rapidly in the first few months following gastric bypass. Although this is something you look forward to, it is important that you lose this weight in a healthy way to avoid such side effects as fatigue and hair loss. It is important that you follow the dietary recommendations taking the requisite amount of **protein, vitamins, and minerals**. Importantly, your chance of achieving your weight loss goals is greatest if you continue follow up with our bariatric program after your surgery. Like any other bariatric procedure, there are ways to defeat the purpose of the surgery and gain weight. If you overeat on a regular basis, you can stretch out your pouch or dilate your anastomosis (outlet) leading to eventual weight gain. It is also possible to defeat the purpose of surgery by continuous drinking of high caloric liquid 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.

The Roux-en-Y divided gastric bypass is a widely accepted and common procedure performed by bariatric surgeons. “Open” bariatric surgery carries a higher complication rate than a minimally invasive/laparoscopic approach in appropriately trained and experienced surgeons. 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 and quality of life are also usually benefited.

Other bariatric procedures are available including laparoscopic and open LapBand®/Adjustable Gastric Banding (AGB), vertical banded gastroplasty (VBG), sleeve gastrectomy and duodenal switch/biliopancreatic diversion. Experimental procedures such as gastric pacing and the intra-gastric balloon are not available outside the research setting at this time. All available Bariatric surgical procedures are designed as tools to improve your obesity-related medical illnesses, making you healthier and hopefully improving your quality of life.

The **VBG** aims to functionally restrict the size of the stomach. It is associated with a high failure rate and reflux and 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 **LapBand®/AGB** functionally restricts the size of the stomach to about 2-oz with an adjustable silicone band. 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. 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 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
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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.

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. Studies have shown that on average, bypass patients lose their hunger for the first 5 months after surgery. Although this sounds great, it is very important that you take in the appropriate amount of calories, protein, and vitamins in order to hopefully avoid losing you hair, feeling weak, and looking ill. Your goal will be to burn fat, not muscle, so taking in enough protein (muscles are made of protein) is very important. Your best chance at weight loss with the bypass is the first 9 months. To get the most out of your bypass, take full advantage of that early period of lack of hunger to get into the right eating and exercise habits. 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, even the best technical “micro-pouch” bypass can 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 bypass “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 **Laparoscopic RNY bypass Page 3 / Pt. Initials: _____**

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 with the laparoscopic gastric bypass can be very rapid. This ongoing weight loss can be psychologically very addicting, but it will slow down after about 6 to 9 months, so be prepared. Your best chance at weight loss is this first few months, so 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. Keep in mind that **average best results are a 70% excess body weight loss over an 18 month period.** For example, if your BMI is 40 (roughly 100 lbs overweight), with appropriate follow-up, exercise, and eating habits, you can expect to lose about 70 lbs. 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.** 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). Once again, you can lose that other 60 lbs, but it will require increased effort on your part. The more you weigh to start with, the more you will probably lose with recommended behavior. Do not get caught in the trap of comparing your weight loss numbers with others! 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 sabotage your weight loss efforts.

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. Not only is it high in calories, but it will make you intoxicated with often very small volumes secondary to the nature of the bypass.

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
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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. If you have a bypass, it greatly increases your chance of having the dreaded complication of pouch ulceration. This results in pain and malnutrition, and requires prolonged hospital stays on IV nutrition and medication. It may even require the surgical placement of a feeding tube. In some instances, the ulcers can bleed massively or even perforate - either one of these complications can require major surgery and prolonged hospitalization and even death. Moreover, these pouch ulcerations will not heal without the cessation of smoking. **If you are a smoker and feel you are at risk of continuing to smoke after surgery, then you are absolutely not a candidate for the bypass and should avoid the procedure at all costs. You should either have the LapBand®/AGB, gastric sleeve procedure, seek your surgery elsewhere, or not have the 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. Because the stomach has been divided by gastric bypass, be aware that after the procedure **you cannot have traditional upper endoscopic or radiographic procedures** to look at the majority of the stomach (fundus, body, antrum, and pylorus) or the first part of the small intestine (duodenum). This includes EGD (esophagogastroduodenoscopy) and UGI (upper gastrointestinal series). Therefore it would be very difficult to diagnose a duodenal or stomach ulcer, malignancy (cancer), or other abnormality. It would also be very difficult to perform traditional ERCP (endoscopic retrograde cholangiopancreatography) to remove common bile duct stones (stones that have migrated from the gallbladder into, or have formed in, the main bile duct that connects the liver to the duodenum). To do either EGD or ERCP would require laparoscopic or open surgical access to the bypassed stomach. Therefore, you should **strongly consider** having a look at the inside of your stomach with an upper endoscopy (“scope”) prior to your bypass 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 bypass surgery as you**
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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, leaks (see below), 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 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
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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), 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. 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.

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. (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. . 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 option (if I am an appropriate candidate at the time of discharge).

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 and Acapella devices. These will be given to you in the pre-op teaching class and you need to practice with them and use them religiously after surgery. Below are some of the factors that further increase your chance of pulmonary complications. Severe pulmonary complications can require

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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 _____.

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 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 be 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 5% and less than 1% with the LapBand®/AGB. Obstructions can lead to compromise of the bowel’s blood supply (ischemia) and in some cases, even death (necrosis) of small or even large segments of intestine which can have associated serious complications and even death. Obstructions after open surgery generally require major open surgery, with its inherent risks, to repair. Most obstructions after laparoscopic surgery, in the absence of ischemia, can be successfully repaired laparoscopically.

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.

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** 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.

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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, it could lead to severe life-threatening infection/peritonitis and require further surgery and complications of sepsis.

Death: The mortality rate of gastric bypass is about 0.5% in most series, and you and your family members should realize that gastric bypass is major surgery and complications of this procedure can be fatal.

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

Acute (around the time of surgery):

- **Leaking of stomach and/or intestinal contents at the staple or suture lines:** The risk of a “leak” is about 1% and usually occurs in the first few days after surgery. This can lead to peritonitis, intra-abdominal abscess, and even death. The sooner the leak is recognized, the better the chance of recovery. A “leak” at the anastomosis (where the stomach pouch is attached to the small bowel) is the most common cause for death and serious complications after bypass surgery. Treatment usually requires return to the operating room, closure of the leak/perforation and drainage. Sometimes the leak has already sealed or cannot be demonstrated and only drainage will be performed. This can sometimes be done laparoscopically, although an open approach may be necessary. **Early recognition and treatment** offers the best chance for recovery, but can still lead to serious associated complications (peritonitis, prolonged need for a ventilator, sepsis, kidney failure with need for dialysis, etc.) and a prolonged hospital course or the need to transfer to another institution for further care. We do a “leak test” of the anastomosis under pressure at the time of the initial surgery by endoscopy and assure you do not have a leak when you leave the operating room. Moreover, we then treat the suture line with a fibrin glue sealant. For this reason, we do not always place drains, but this is a decision we make individually at the time of surgery. “Leak tests” **after** surgery are much less reliable, missing up to 50% of leaks and giving the patient and surgeon a false sense of security. This leak test involves you drinking contrast material and X-rays are taken to see if there is leaking at the anastomosis. The only way to diagnose a leak with certainty is to return to surgery (usually laproscopically) and re-check the anastomosis. Once again, if found early and repaired, your chance of recovery without serious complications is improved. Needless to say, we are aggressive with potential leaks as the consequences of missing one can be devastating. For this reason, occasionally patients are returned to the operating room (usually laparoscopically) for a suspected leak and no abnormalities are found. We would rather be safe than sorry and as always, we proceed with your best interests in mind.
- **Intra-abdominal abscess:** Occasionally, an abscess can develop without a “leak”. Presumably this is secondary to fluid around the area becoming infected and usually occurs several days to two weeks post-operatively. The risk is small. This requires antibiotics in most cases, and often some form of drainage, either percutaneous (through the skin) by the radiologist or by surgery (usually laparoscopic). As with any infection, it has the potential to be life-threatening, even with appropriate treatment.

Chronic (sometime after surgery):

- **Strictures:** The anastomosis (outlet) is purposefully made small as discussed above in order to limit the amount of food that can get out of the gastric pouch at any one time. If this outlet is too large it can lead to weight gain as the pouch will empty faster. It will take more food to fill the pouch as it will empty faster as you eat. You will also get hungrier sooner after eating because the food doesn’t stay in the pouch very long as it empties faster. Natural healing of your anastomosis results in scar formation and contraction. For

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some people, this scarring and contraction will cause the outlet to get too small causing a “stricture”. This usually occurs around 2 to 8 weeks after surgery. Symptoms include the sensation that food and/or liquids are getting “stuck” at the bottom of your sternum, nausea or vomiting, “frothing”, or just intolerance of food/liquid when previously you were doing well. This is treated as an outpatient by a procedure called endoscopy (“scope”), not a surgery, where you are sedated while we take a lighted endoscope and look down into your esophagus and stomach pouch and dilate the outlet. In 80% of cases, only one dilatation is necessary. 20% will require two dilatations. Less than 5% of patients who require dilatation will require three or more procedures. It is very rare that you wouldn’t respond to dilatation(s) and require a laparoscopic (surgical) revision of your outlet.

It is also possible to get food blocking the outlet in the **absence** of a stricture if you eat too large a piece of food, don’t chew well, or advance your diet more rapidly than advised. This may require an endoscopy to clear the trapped food.

- **Ulcers:** These can occur in your pouch, but most often at the small bowel side of the outlet. These ulcers can be difficult to heal, can lead to perforation (requiring surgery), significant bleeding, or the need for surgical revision or reversal of your bypass. There are three basic causes of these ulcers (see smoking section previously): 1) Anti-inflammatory medications. You should completely avoid all anti-inflammatory medication after the surgery. This includes medications such as Motrin, Advil, Ibuprofen, Aleve, Naprosyn, Vioxx, Celebrex, aspirin, and Excedrin (or any other aspirin-containing medications), among others. Acetaminophen (Tylenol®) products are safe. Please contact us before taking any new medication(s) after your surgery. 2) Smoking. 3) Helicobacter pylori infestation. This is a bacteria that can reside in your stomach and increases the risk of pouch ulceration. For this reason, we do a breath test for this organism pre-operatively, and if positive, try and treat until it has been eradicated before scheduling your surgery. The usual treatment course is two weeks, and re-testing cannot be done until four weeks later. If still positive, it is re-treated with a different regimen. This obviously can delay your surgery for several weeks and possibly months. It is therefore very important to make sure you faithfully take the treatment as prescribed.

If, after gastric bypass, you plan to resume smoking (or feel that you are at high risk of resuming smoking even though you desperately want to quit), then please DO NOT PROCEED WITH THE BYPASS OPERATION. We cannot emphasize this enough! You run an unacceptably high rate of ulcers, which under best circumstances, cause pain, malnutrition, time off work, and multiple visits to the hospital with prolonged stays for IV nutrition. You may even require further surgery to reverse your bypass with resultant weight gain. In worse case scenarios, you can have heavy, even fatal GI bleeding or perforation resulting in peritonitis, sepsis, major surgery, and high risk of death. Once again, if you feel that you are high risk of resuming smoking after bypass then either: 1) Have a LapBand®, 2) Do not have surgery, or 3) Have your bypass elsewhere or 4) have the gastric sleeve procedure.

_____ M.D. I realize that I am at increased risk of pouch ulceration with all its inherent complications if: _____ I start or resume smoking after my bypass, _____ take anti-inflammatory medication, aspirin, or Plavix. My consenting physician has emphasized the importance of this with me pre-operatively (before surgery). He has discussed with me that if I continue or have the potential to resume smoking after surgery that I should avoid the bypass and consider the LapBand®/AGB, sleeve gastrectomy, going elsewhere to have surgery, or avoiding surgery altogether.

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- Vitamin and Mineral Deficiencies.** The new anatomy does result in diminished absorption of calories, iron, vitamins, minerals and calcium. It is imperative that you take your recommended vitamins and supplements after bypass surgery and that you have your labs monitored at the intervals recommended. Otherwise you put yourself at risk of developing serious consequences/diseases of protein and vitamin deficiency. No matter how much weight you lose, or how good you feel, you will need to take the recommended vitamins and supplements the rest of your life. Even patients who are compliant with supplements can develop deficiencies and need recommended follow-up labs. For example, it is not uncommon for patients to develop iron deficiency anemia a year or more after surgery even if taking iron as recommended. The B vitamins are also poorly absorbed and can get dangerously low even if patients are taking the recommended supplements. Vitamin B1 (Thiamine) deficiency, previously seen mostly in third world countries, is being seen more and more in bariatric patients and can be life-threatening. It can cause heart failure, irreversible memory loss, and other devastating consequences. Any neurologic symptoms (numbness, forgetfulness, unsteady gait, burning sensation of the skin) require an immediate check of your vitamin B levels. There are reports of blindness from Vitamin A deficiency, and brittle bones/osteoporosis from Calcium deficiency. Taking you supplements and having your labs checked is no guarantee that these deficiencies will not occur, but certainly lessens the likelihood tremendously. Therefore, it is essential to take daily multivitamins with iron, B vitamins, calcium and mineral supplements for the rest of your life after this surgery. You should have regular follow-up blood tests, and medical check-ups through our office or your primary physician. Choosing bypass surgery is all about commitment, and once again, following these guidelines is **your** responsibility.

_____M.D. I realize that if I proceed with bypass, that I am committed to taking the recommended vitamins and supplements for life. I am also committed to making sure I follow-up as recommended and have my labs checked as recommended. I am aware that this is MY responsibility and that if I do not comply, that I could suffer potentially serious and irreversible consequences of protein and/or vitamin deficiency.

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- Alopecia.** This means hair loss. It is not uncommon to have thinning or loss of hair in the first few months after bypass. This can best be avoided by taking the requisite amount of protein and vitamins. Fortunately, in most instances, this is a temporary phenomenon and will improve with time and increased protein intake and supplements.

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 Roux-en-Y bypass. 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

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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 bypass 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 gastric bypass 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 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, however, this is not possible with Roux-en-Y bypass 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 Roux-en-Y gastric bypass. 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. 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
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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 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 standard limb Roux-en-Y bypass that we offer 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). In general, our “short limb” gastric bypass should not cause chronic diarrhea. A lot of patients will 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 70% of excess body weight loss over the first 18 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.

Although this procedure has been preformed for over forty years, 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. Most of the complications can be addressed laparoscopically, but may require open surgery. The gastric bypass is reversible, usually laparoscopically, although there is seldom any practical reason to consider reversal. Reversal of a bypass is a major operation with a high complication rate and is only undertaken in dire circumstances. Certainly advances in medical treatment of obesity and surgery may occur in the future that would possibly make reversal an appropriate option.

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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 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 ROUX-EN-Y DIVIDED GASTRIC BYPASS.**
- 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.**

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(Signature of Physician) G. Derek Weiss, M.D., _____
Date

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

(Signature of Patient) Printed Name _____
Date

(Signature of Witness) Printed Name _____
Date

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