

# **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. The purpose of this consent is to confirm your decision, based upon complete knowledge and understanding of the operation. You may always change your mind about proceeding with the operation.

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

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

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

The Roux-en-Y divided gastric bypass is the most widely accepted and common procedure performed by bariatric surgeons in the United States. "Open" bariatric surgery carries a higher complication rate than a minimally invasive/laparoscopic approach in appropriately trained and experienced surgeons.

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

The 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.

The Lap Band 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 generally carries the least complications of the current bariatric procedures. Weight loss is more gradual than other bariatric procedures and the procedure can be circumvented by eating high calorie liquid or soft foods.

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

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

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.

**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.

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, but functional otherwise. In other words, the majority of your stomach does not have food passing through. It often is associated with a permanent decrease in appetite. The nature and purpose of this operation is to functionally limit the amount of food or liquid intake at any given time. There may be a small component of malabsorption, at least initially. 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.

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 is useful in reinforcing good dietary choices.

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.

Understandably, you should not be **pregnant** at the time of surgery or it will be canceled and rescheduled in that event. If you are a woman, you should avoid pregnancy for the first 18 month 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 18 months after surgery.

**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 lack of commitment to your weight loss goals. You will need to take clear liquids the day before surgery. Stay well hydrated that day then nothing to eat after midnight for surgery the next day. The internist and/or anesthesiologist will tell you which of your medications you can take the morning of surgery with a sip of water.

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

**Smoking** is a serious problem for the Bariatric surgical patient. It increases your risk of pulmonary complications and blood clots, regardless of the procedure you choose. If you have a bypass, it greatly increases your chance of having the dreaded complication of pouch ulceration. This results in pain and malnutrition, and endoscope procedure, and requires prolonged hospital stays on IV nutrition and medication. In some instances, they can bleed massively or even perforate requiring emergency surgery. Moreover, these

pouch ulcerations will not heal without the cessation of smoking. If you are a smoker and intend to continue smoking after surgery, then you should strongly consider avoiding the gastric bypass and opting instead for the LapBand®.

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

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

**Blood clots** in the veins in the legs or pelvis (DVT's) can migrate to the lungs (pulmonary embolism - PE) which can be fatal. These can occur after **any** type of surgery, and even without surgery (prolonged sitting, long airplane flights, riding lawn mowing, etc). To avoid this serious complication, we take several important measures. There are also things that only **YOU** can do that will decrease your risk. You will be asked to ambulate early, usually in the first few hours after surgery. We also want you to walk as much as possible prior to surgery to increase blood flow in the legs. We will have compression stockings on your legs during the surgery and until you are walking well. We will give you blood thinner subcutaneously during your hospital stay. We will use Toradol, an anti-inflammatory with some blood thinning properties (anti-platelet), during the first 48 hours. We will give you a folate vitamin (Foltx) pre-operatively and for one month post-operatively. Folate has been shown to help lower your homocysteine levels, high levels of which have been reported to be associated with increased blood clotting. We generally have quick operative times as the risk of DVT goes up with increased length of surgery. Smoking carries with it an increased risk of clotting and we ask that you stop smoking one month prior to and after surgery. Hormones (birth control pills, menopause hormones) have been shown to increase the clotting rate and therefore we require that you avoid hormones for one month before and after your surgery. The risk of DVT (clot in the legs or pelvis) is about 1 in 200, and the risk of a pulmonary embolism about 1 in 500 – 1000.

\_\_\_\_\_M.D. (Patient initials required if initialed by consenting physician) I realize that I am at increased risk of blood clot (DVT or PE) based on the above. My physician has made me aware of this. I have \_\_\_\_\_ have not \_\_\_\_\_ opted to have a filter placed (see next paragraph below).

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

**Filters.** Some patients will require a vena caval filter which is a filter placed in the large blood vessel that carries blood returning to the heart. This does not prevent blood clots, but may prevent the clot from migrating up to the heart and into the lung vessels (pulmonary embolism), which can be fatal. You may be required to have a filter before surgery if you are deemed at high risk. Some examples of high risk include super morbid obesity (BMI > 60), high pulmonary artery pressures, history of blood clots or pulmonary embolism, history of smoking, history of venous stasis disease, etc. You also have the option of requesting a filter pre-operatively. It

is placed by a radiologist (physician) under sedation with local anesthetic through a large groin vein (1% complication risk), and can be removed in a similar fashion up to one year later through a large neck vein (1% complication risk). At the time of your consent, your surgeon will discuss this with you further.

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

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

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

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

**Small Bowel Obstructions.** The small intestine can get blocked by twists around scar tissue (adhesions) that occur as a result of surgery. This is the most common cause of bowel obstructions. Another cause is internal hernias – defects within the abdominal cavity through which the bowel can 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 3% and less than 1% with the LapBand®. Obstructions after open surgery require major open surgery, with its inherent risks, to repair. Most obstructions after laparoscopic surgery are repaired laparoscopically.

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

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

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

- 1) **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. **Untreated or unrecognized** this can lead to peritonitis, intra-abdominal abscess, and even death. 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. This is generally done laparoscopically. **If recognized and treated early**, it is usually not a serious complication and in most cases adds only a few days to your hospital stay. We test the anastomosis under pressure at the time of the initial surgery 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, it would be rare to place drains (which can be an uncomfortable inconvenience) . The placement of a drain is a decision we make individually at the time of surgery. We sometimes perform a “leak test” **after** surgery. A leak test is where you drink contrast material and X-rays are taken to see if there is leaking at the anastomosis. The reason we do not always consider ordering a leak test is that 50% of the time, the test misses a leak and can give the surgeon and patient a false sense of security. The only way to diagnose a leak with certainty is to return to surgery **laparoscopically** and re-check the anastomosis. Once again, if found early and repaired, you should recover without serious complication (e.g. prolonged ventilator support, systemic infection, need for dialysis, etc.). 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 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.
- 2) **Damage to the spleen or other organs:** The spleen lies close to the upper portion of the stomach and can be injured in up to 10% of open upper surgeries on the stomach. Fortunately, it is very rare to injure the spleen during laparoscopic surgery, and the rate is under 1%. If your spleen is injured, this most likely will require conversion to an open procedure and removal of the spleen to prevent exsanguination (bleeding to death). In general, you do not need your spleen. However, it does afford protection against certain types of infection and we try to salvage the spleen whenever possible. Pancreatitis is a rare but reported complication. Liver injury rarely requires any additional treatment. Unrecognized injury rarely occurs to the stomach or intestines but can lead to peritonitis requiring more surgery.
- 3) **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 at one to two weeks post-operatively. The risk is less than 1%. 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).
- 4) **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 in the long run. Sometimes while healing, this area narrows too much in the post-operative period, usually noticed at 3 to 12 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. Fortunately, it is easily treated by a quick outpatient procedure (not surgery) as discussed below. The risk of developing a stricture is approximately 20%, as we make the smallest outlet possible without making it too tight. It is technically easier to make a large outlet and avoid strictures, but we are concerned with an increased risk of long-term weight gain. If you would prefer a large outlet and avoidance of strictures, please let us know. 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.

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It is also possible to get food blocking the outlet in the **absence** of a structure 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.

- 5) **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.

\_\_\_\_\_ M.D. (Patient initials required if initialed by consenting physician). I realize that I am at increased risk of pouch ulceration with all its inherent complications if: \_\_\_\_\_ I 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 plan to continue smoking after surgery that I should avoid the bypass and consider the LapBand®, if anything at all.

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

- 6) **Death:** The mortality rate of gastric bypass is about 0.5% in several thousand cases performed in many locations, but you and your family members should realize that gastric bypass is major surgery and complications of this procedure can be fatal.
- 7) **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.
- 8) **The new anatomy does result in diminished absorption of iron, vitamins, and calcium:** This may result in late development of anemia several years after surgery. Therefore, it is essential to take daily

multivitamins with mineral supplement 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. Following these guidelines is **your** responsibility.

- 9) **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. Studies suggest that taking a prescription medication (Actigall) in the post-operative period may decrease the rate of gallstone formation. Therefore, we will discuss with you the option of taking Actigall for six months post-operatively if you have not previously had your gallbladder removed. If determined that this is necessary we will give you a prescription for this before your surgery and you may begin taking it after you come home from surgery.
- 10) **Extreme weight loss:** Fortunately this is very rare. Most people will stabilize at a weight that is healthy for them.
- 11) **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.
- 12) **Diarrhea, constipation or excessive flatulence:** Diarrhea is highly unusual with the Roux-en-Y bypass and is more associated with the malabsorptive procedures such as duodenal switch or biliopancreatic diversion discussed above. 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.
- 14) **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.
- 15) 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, 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 surgical access to the bypassed stomach. For this reason, depending on your history, exam, and/or laboratory evaluation, the physician may require that you get an EGD pre-operatively.

**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 twenty 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. Certainly advances in medical treatment of obesity may occur in the future that would possibly make reversal an appropriate option.

**Paying out of pocket “cash pay” or high deductibles.** We would prefer to do our surgeries under insurance coverage, but several insurance companies either exclude coverage for Bariatric surgery, have unreasonably strict guidelines, or only approve certain procedures. In any event, some patients will pay for the entire procedure themselves. The money spent is tax deductible and there are some financing options available, although not through our practice. **Please be aware that your payment does not cover potential surgical complications. Our (the surgeons’) price includes all additional surgeons fees for any additional surgery if needed, but it does not cover fees incurred by the hospital, lab, radiology, anesthesia, etc. Significant complications often require additional hospital stay, testing, medications, etc. that will be the responsibility of the patient.** Please try and arrange a contingency plan with the hospital **as soon as possible before** your surgery date.

I am paying out of pocket for this procedure and am aware of the above.

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

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

You have the right to a second opinion.

You have attended an educational seminar.

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

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

You give the consent to the existing possibility that once the procedure has been begun laparoscopically; it may be necessary to convert to an **open procedure**. This will be decided by your surgeon and performed with your best interest in mind. Our conversion on initial operation from laparoscopic to open is less than 1%, and we do all of our procedures laparoscopically regardless of patient size or previous surgeries. Any other encountered pathology (abnormalities) seen at the time of surgery will be addressed as indicated in the surgeon’s best judgment.

**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. Small abdominal wall hernias can usually be repaired with a stitch or two. Larger abdominal wall hernias will be left undisturbed for repair 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. A small liver biopsy may be taken at the discretion of the surgeon. Once again, other abnormalities will be addressed in the best judgment of your surgeon.

**Your signature below certifies that:**

- 1) You have read the contents of this form, discussed the above verbally with the surgeon, and understood the risks, benefits, and alternatives involved and hereby give INFORMED consent to proceed with LAPAROSCOPIC, POSSIBLE OPEN 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.**

\_\_\_\_\_ Dennis M. Lewis, M.D., F. A.C.S. \_\_\_\_\_  
(Signature of Physician) Date

\_\_\_\_\_  
(Signature of Patient) Printed Name Date

\_\_\_\_\_  
(Signature of Witness) Printed Name Date

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