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Informed Consent for Roux-en-Y Gastric Bypass

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

I am giving **P. Pattyn and B. Smet (my doctors)** and the whole ObesityCare team permission to perform a

Laparoscopic Roux-en-Y Gastric Bypass

for the treatment of obesity. The procedure is also known by such names as a "gastric bypass", a "proximal gastric bypass", "divided gastric bypass," "stomach stapling" or "RNY gastric bypass. Both surgeons will take care of me, before during and after the operation.

I understand that my surgeon will be involved in all aspects of my care during the operation and I agree that he be involved in all aspects of my care pre-operatively and post-operatively. A qualified assistant will help my doctor during the operation. My post-operative care *will* be directed by my surgeon as well as the team of ObesityCare

I affirm that I am significantly overweight and have attempted non-surgical weight loss programs without success. I recognize that the preponderance of medical literature states that obesity causes early death and significant medical problems such as hypertension, diabetes, obstructive sleep apnea, high cholesterol, infertility, cancer, gastroesophageal reflux, arthritis, chronic headaches, gout, venous stasis disease, liver disease and heart failure to name a few.

I understand that the preponderance of scientific medical data shows that the laparoscopic gastric bypass can improve or cause remission of many medical problems such as hypertension, diabetes, obstructive sleep apnea, high cholesterol, infertility, cancer, gastroesophageal reflux, arthritis, chronic headaches, venous stasis disease, liver disease and heart failure; however, there are **no specific guarantees** that any one of these conditions will improve in any given patient.

I understand that there are a number of non-surgical options as well as surgical options. My doctor has given me the opportunity to discuss other surgical options such as the Lap-Band® System, duodenal switch as well as non-recommended procedures such as the distal gastric bypass, vertical banded gastroplasty, the mini-gastric bypass, the banded gastric bypass and the biliopancreatic diversion. **I have decided that the gastric bypass is the best option for me.** *I also know that I have the right to a second opinion.*

I understand that my doctor has been successful in performing the gastric bypass surgery laparoscopically. However, in some instances, **the procedure may have to be performed through a traditional, "open," approach.** Reasons to unexpectedly convert to an open operation include, but are not limited to, significant bleeding, extreme obesity, extremely large liver size, severe scar tissue and equipment malfunction. Conversion to an "open" procedure occurs solely at the surgeon's discretion. I agree that I have been given no guarantees that my surgery will be completed laparoscopically. **There is a rare, but possible chance that if I do not diet in the pre-operative period adequately as prescribed by my team of doctors, my liver size may cause my operation to be impossible either open or laparoscopically**.

I understand the anatomy of the operation as follows:

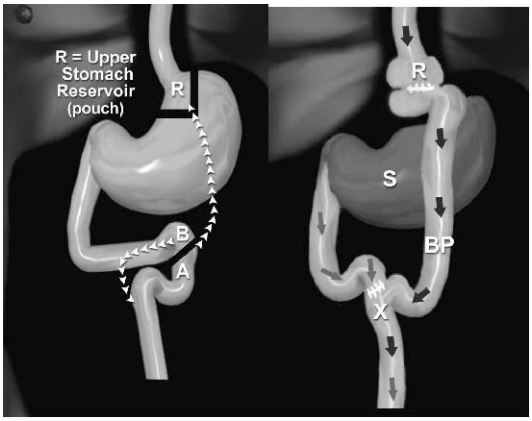

Diagram of the Gastric Bypass. A small stomach reservoir is created, usually with the use of a stapling device. The stomach is transected and divided. No organs or parts of organs (including the stomach) will be planned to be removed. The small intestines are also transected (point A and B). The reservoir is connected to the cut end of intestine (gastrojejunal anastomosis) and the remaining intestinal is reattached (jejunojejunostomy). *American Society of Bariatric Surgeons.*

During the operation, several conditions may arise that may cause additional procedures to be performed. These include:

A liver biopsy – most often performed when an abnormally enlarged liver is identified. The risks with performing a liver biopsy include an low chance of bleeding.

Removal of the gallbladder: In some patient, removal of the gallbladder may be medically necessary (in case of symptomatic gallstones). Removal of the gallbladder increases the length of time of the total operation. Also, there is a small, less than 2 percent, risk of bile duct injury that can result in serious complications. Removal of the gallbladder may increase my hospital stay. An additional port (and incision) my be necessary to perform the procedure safely. Because of the small, but real, incidence of complications after gallbladder removal, this procedure is not routinely performed.

Gastrostomy Tube: In extremely rare circumstances, placement of a gastrostomy tube (G-tube) may be performed. A G-tube is placed in the excluded, lower portion of the stomach when: the operation was much more difficult than expected; the procedure is a revision of a previous weight loss operation; at the surgeon's discretion. A G-tube can have several complications associated with it including 1) leakage of stomach contents around the tube which can irritate the skin 2) persistent drainage even after removal of the G-tube (fistula) 3) mild discomfort around the G-tube 4) premature removal of the G-tube which may necessitate emergency re-operation.

Incisional Hernia repair: My doctor's policy is to leave incisional hernias alone during the operation. The repair of a hernia may result in significant infection risks and increased pain. The hernia is also more likely to recur if performed while a person is significantly overweight. Once weight loss occurs, a hernia repair is best performed. However, for specific anatomic reasons, a hernia may have to be repaired at the time of the operation. If treated after substantial weight lass there is a risk of small bowel obstruction by incarceration of small bowel in the hernia. Urgent repair is necessary in these cases

Esophagogastroduodenoscopy: An EGD, or upper endoscopy may sometimes be performed in order to visualize the stomach, the new intestinal connection or make sure there is no other abnormalities of the intestinal tract. Helicobacter pylori needs to be tested and eradicated if positive. A control EGD to take a new biopsy and control the efficacy of the eradication treatment is mandatory.

Revision of previous weight loss surgery: Revision of previous weight loss surgeries such as the vertical banded gastroplasty increases operative time and complication rates. Overall, expected weight loss tends to be less than that compared to a person who is having weight loss surgery for the first time. Procedures that occur commonly in patients who need revisional surgery include, but are not limited to, removal of part of the stomach, placement of a drain, placement of a G-tube and endoscopy. If I have failed a previous lap-band procedure, my surgeon will remove the old lap-band (and port) before changing the procedure to a gastric bypass.

Hiatal Hernia repair: If a large hiatal hernia is present, this may need to repaired. The added risks from hiatal hernia repair include, but are not limited to, injury to the esophagus, dysphagia (difficulty swallowing) and hernia recurrence.

Lysis of Adhesions: In the setting of a previous operation or significant abdominal infection, scarring always results. The degree of scar tissue is unpredictable. Sometimes, depending on the location of the scar tissue, the scar tissue must be cut (called “lysis of adhesions”) in order to perform the weight loss operation. There are increased risks when a lysis of adhesions is necessary including injury to the intestines, prolonged operative times, and bleeding.

Placement of a Drain: A drain is a thin plastic tube that comes out of the body, into a small container to allow for the removal of fluid and the control of infection. My doctor routinely places a drain after a gastric bypass. In most of the cases this drain is removed on postoperative day 1.

I understand that significant weight loss is a **life-altering event.** Significant changes in eating behavior occur. I understand that every patient’s experience varies and the exact prediction in my ability to cope with significant forced behavior changes cannot be predicted. I understand that ObesityCare has a psychologist in the team who can help me with behavioral needs.

Following gastric bypass, I 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, diarrhea and shaking which may last from a few minutes to an hour. We call this "**dumping**." Food intolerances vary with person to person. Some patients never experience any of these symptoms or may become less sensitive over time. Rarely, a patient may have severe food intolerances that last for many months. In exceptional cases medical treatment may be necessary if diet counceling is not succesfull.

When choosing a balanced menu high in protein content, eating at normal times and incorporating exercise into my daily routine, I will lose weight. However, **it is possible to defeat the purpose of surgery** by continuously drinking high calorie liquids and/or snacking throughout the day. “Grazing” behavior will cause weight regain, or poor initial weight loss.

Medicine is an unpredictable field. **Unpredictable complications can occur.** No amount of pre-operative testing can assure an uncomplicated outcome. My doctors attempt to minimize any possible chances of misdiagnosis – however, no physician or group of physicians are infallible. I have the responsibility to inform my doctors of any concerns, worries or possible complications at the earliest possible time. I agree that my doctors may make recommendations and I take full responsibility if I do not follow these recommendations.

Initial_____

Weight loss after a gastric bypass is expressed as loss of a percentage of my pre-operative excess body weight. Excess weight is defined as my current weight minus my ideal body weight. On average, patients lose between 70 and 80 percent of excess weight at two years. In other words, some patients lose more than 70-80 percent of their excess weight and some lose less. My doctor will give me recommendations in how to experience the most optimal weight loss. Although, the vast majority of patients are satisfied with their weight loss**, there is no guarantee that I will achieve my goal weight.** I understand that the chances of reaching my ideal body weight are low. I understand that bariatric surgery is a tool that assists with weight loss. Some patients will regain weight. Some patients will lose less than 50% of their excess body weight.

Actual risks of the operation vary from person to person.

Risks of the gastric bypass include, but are not limited to the following. My doctors have tried to estimate a general risk category to each event (Extremely rare <<<0.5% Very rare<<1%, rare<2%, occurs 1-5%, common=5-10%, very common>10%). The list of potential complications includes, but is not limited to::

Immediate Post-operative Risks:

Death (extremely rare): Mortality rate of the gastric bypass in literature is less than 2%. I realize, and my family members realize, that every gastric bypass done is a major surgery and complications of this procedure can be fatal.

Significant Bleeding (very rare): Usually during the course of a laparoscopic gastric bypass, some blood is lost. Bleeding may occur unexpectedly in the operating room. Bleeding may also occur post-operatively in the days after the operation. This bleeding may be through the intestinal tract at the anastomosis and result in the passage of blood in the stool. In some cases endoscopy and injection of adrenaline around the bleeding vessel can be necessary to control this intraluminal bleeding. Bleeding may also be unseen inside the abdomen and be diagnosed through other means. A transfusion may be necessary in some circumstances. Reoperation to stop bleeding may be necessary.

Anastomotic Leak (very rare) – A leak is when the connection between the stomach and the intestine does not heal. Although, technical problems may be the cause of a leak, sometimes everything is done correctly and a leak still occurs. Serious complications can result from a leak. A leak may result in a prolonged hospital stay, a long period of nothing to eat, prolonged antibiotic requirements as well as serious bodily harm such as organ failure and even death.

Nausea (very common) – The most common cause of post-operative nausea is pain medication. Many patients have nausea the day of their operation. Rarely, nausea will persist for a week. In rare cases, nausea will persist for longer.

Renal Failure (very rare) – Although transient kidney (renal) failure does occur in rare patients, irreversible kidney failure is very rare.

Prolonged Ventilation (very rare) – A patient requiring a prolonged stay on a ventilator (breathing machine)in the intensive care is rare. This may occur for example in very large patients with severe sleep apnea or after certain significant complications. In these very rare instances, a temporary tracheostomy may be necessary.

Heart Attack (very rare) -Although a heart attack is possible after a gastric bypass, it is very rare. Many patients undergo testing to assess the health of their heart before their procedure. Some patients are asked to obtain cardiology clearance before proceeding with the operation. However, no amount of testing can eliminate the risks of a heart attack. Risk factors for heart disease include increased age, diabetes, hypertension, hypercholesterolemia and a family history of heart disease.

Prolonged Hospital Stay (extremely uncommon): Unforeseen complications may result in a prolonged hospital stay. Intensive care admission may be required.

Bowel Obstruction (extremely uncommon): Conceivably, an obstruction can occur that would require re-operation. An obstruction can occur from a number of causes. Port site herniation is a cause of small bowel obstruction . In these cases urgent repair of these port site hernia is necessary.

Medical Consultations (uncommon): My doctors reserve the right consult medical physicians to assist in my care when necessary.

Deep Vein Thrombosis (DVT)/Pulmonary Embolism (rare): Blood clots that form in the legs, and elsewhere, and break off into the lungs are a leading cause of death after any surgical procedure. My doctors will do everything they believe possible to decrease the risk for the formation of blood clots. This includes low molecular weight heparines injected subcutaneously, walking soon after surgery and sometimes even the use of medication at home after discharge from the hospital. Despite all of these efforts, it is impossible to eliminate the risks of DVT (clots) altogether. There is also a possibility that the medications used to prevent blood clots can cause excessive bleeding. Any symptoms of leg swelling, chest pain or sudden shortness of breath should be immediately reported to the surgeon. My doctor usually uses a means of DVT prevention that may not be standard practice in the community. My doctor believes, and has the personal experience, that strongly suggests that his means of DVT prevention is ideal for the bariatric patient and is at least as good if not better than standard DVT prevention used in the community. Rare patients develop allergies to heparin – sometimes causing very severe reactions.

Other complications that may be common: Allergic reactions, headaches, itching, medication side-effects, heartburn/reflux, bruising, anesthetic complications, injury to the bowel or vessels, gas bloating. Minor wound problems are not infrequent. Minor drainage from the wounds, or even the wounds opening, may occur. Although scars from the laparoscopic procedure are usually small – we cannot predict how any patient will form scars. Wound infections should heal over time but may cause a visible scar

Open Procedure: if my operation is performed open, I am at higher risk for several complications. This includes wound infection. Wound infections may cause significant scarring and healing problems, require prolonged wound care and cause discomfort. Incisional hernias occur in approximately one-third of patients after an open gastric bypass. Hernias will require an operation to repair. Hernias can cause bowel obstructions and severe consequences if left untreated. There is a higher chance of certain complications including lung infections, pressure ulcers and blood clots after an open operation. There would also be predictably more discomfort and a longer hospital stay.

Risks in the first month

Stricture (occurs): The connection between the stomach and the intestine, the gastrojejunostomy, can scar to a pinhole in about 4-8 percent of patients. This scarring is diagnosed by the intolerance to solid foods after surgery. A stricture can be treated by endoscopic balloon dilation. Under sedation, a scope (1/2-inch diameter tube with a camera) is placed through the mouth and into the stomach pouch. The stricture is then dilated with a balloon. This is sometimes repeated several times over a few weeks. Only my surgeons, or gastroenterologists cleared by my surgeons, should perform this procedure. My doctors are not responsible for complications that result from the performance of a balloon dilation unless they performed the dilation themselves. Stricture can also occur months-to-years after surgery.

Ulcer (very rare): An ulcer can cause pain, bleed or even cause a perforation. Ulcers are more common in patients who take medications such as aspirin, Advil®, Motrin®, Aleve®, Ibuprofen, or other drugs classified as NSAIDS. Even aspirin, Celebrex® and Vioxx® can cause ulcers when used for prolonged periods of time. Also, patients who smoke are at higher risk for the development of an ulcer. Because of the risk of ulcer, I agree that I will not take any medication classified as an NSAID for more than 1 week at a time without discussing with my surgeon. I also agree and take full responsibly to quit smoking. Frequently, my doctors prescribe antacid medication for three months after my gastric bypass to prevent ulcers. Ulcers can also occur months-to-years after surgery.

Fatigue (Common): After any general anesthesia, fatigue is very common. Fatigue may last days, or in some circumstances, weeks.

Dehydration (uncommon): I understand that I will contact my doctors if I am not tolerating liquids. Dehydration is rare; Electrolyte abnormalities are also rare.

Medication problems (common): I understand that I will have to monitor my post-operative medication doses closely with the doctors that have prescribed them. My doctors will help if necessary. Examples of common medication problems include lightheadedness from too high a dose of high blood pressure medication and too low a blood sugar from excessive diabetic medication. I agree to work closely with my primary care doctor to regulate my medication.

Return to work: I understand that although many patients can return to work within one to two weeks, rare patients may require a longer recovery. My doctors are not responsible for financial difficulties due to lost work time.

Late Complications

Osteoporosis (unknown): Calcium deficiency may occur years after a gastric bypass. This is a difficult to diagnosis to make until weakness of the bones has already developed. Currently it is best to measure calcium levels, vitamin D levels and the PTH level (parathyroid hormone) every six months. If vitamin D level is too low, supplements vitamin D and calcium should be taken as prescribed

Iron Deficiency Anemia (common) : Since iron is not as easily absorbed after the gastric bypass, iron supplements are generally recommended in everyone to prevent anemia. Serious complications can occur with severe anemia. Iron stores can be measured by blood tests and should be performed annually.

Initial_____

B vitamin deficiencies (uncommon). Deficiencies in Thiamine, Niacin, B12 and others have been reported. These B vitamin deficiencies are very rare. Some B vitamin deficiencies can cause irreversible neurological damage. All patients are required to take a multivitamin supplement for life after this operation. Sometimes, additional B vitamin supplements are also required. I understand that it is important to be evaluated regularly for vitamin deficiencies after surgery. Vitamin and mineral levels should be controlled every sis months

Internal Hernia (rare-common): Some patients may develop a twist in their intestines after this operation. This twist can cause intermittent and/or severe abdominal pain and can be rarely fatal. These symptoms may occur any time after surgery. X-ray tests almost never show the abnormality. Only a qualified bariatric surgeon is trained to diagnose and treat this problem. If I develop abdominal pain after my gastric bypass, I will notify my bariatric surgeons.

Gallbladder problems (occurs): If my gallbladder is not removed at the time of my surgery, the risk of developing gallstones is 1 in 3. I understand that I may develop gallstones after surgery. If I develop gallstones after surgery, serious problems and even death can occur. Symptomatic gallstones should be treated with a laparoscopic cholecystectomy.

Weight Regain: Weight regain may occur, especially with "grazing" behavior. The gastric bypass is a powerful tool; however, it can be beaten. Constantly eating foods such as chips and nuts or other high calorie snacks will result in less than expected weight loss or even weight regain. By continual overeating, the anastomosis may become stretched resulting in weight regain or unsatisfactory weight loss.

Unforeseen problems: Although this procedure has been performed for many years, there may be long-term problems not known at this time.

Pregnancy: Women who were infertile may become fertile after their operation. This is due to improvements in hormone balances. I understand that I will need to use birth control to prevent unexpected pregnancies after this procedure. The risks associated with pregnancy in an obese person is generally higher than a non-obese person. There is no significant data to suggest that the risks of pregnancy are greater, either to the mother or child, after lap-band surgery. Although there are rare reports of band slippage occurring during pregnancy, there is no clear cause and effect relationship established. I agree that before and during pregnancy, I will discuss my nutritional needs with my obstetrician. I will always make sure that I am taking adequate vitamins and minerals throughout pregnancy and while nursing. I absolve the ObesityCare team of any responsibility of complications of pregnancy as complications may occur with any pregnancy and there is no definitive means to prove any complication was due solely to the gastric bypass.

I agree not to get pregnant for 18 months after a gastric bypass. The safety of pregnancy is NOT established for patients during periods of rapid weight loss. SERIOUS, life-threatening complications may occur. I take full responsibility for birth control during this time period.

Initial_____

I understand that I may not be able to breast-feed during periods of rapid weight loss. If I am currently breast-feeding, I plan to wean my child before undergoing weight loss surgery.

Depression: Although most people experience improvements in their mood, some will have worsening states of depression. Weight loss is not a cure-all for all psychological problems. It is my responsibility to seek psychological help when necessary. I understand that post-operative depression may occur.

Marital Problems: Psychological factors including post-operative depression, or possibly a reaction to the stress of surgery, are possible. Family members may also experience these stresses. Significant weight loss may result in marital strain as one person develops changes in their self-esteem. Jealousy and other unpredictable consequences to weight loss may occur. My doctors are not responsible for any marital difficulties that may occur.

Temporary Hair loss: Hair loss occurs in many people after a weight loss operation. Hair generally grows back. There are no proven supplements to alter hair loss.

Unlisted complications: I understand that it is impossible to list every complication possible during and after this procedure. I agree that my doctors have done their reasonable best in listing the most significant complications that may occur.

I understand that unforeseen events may occur that would result in the last minute cancellation or postponement of my operation. My doctor will only cancel my operation in the case of emergency conflicts or if it is my best interest for safety. My doctors are not financially responsible for any costs incurred by rescheduling my operation for any reason. If I live out of town (>50 miles away), I plan on staying in the area immediately after the operation until cleared for travel by my surgeon. However, if I cancel my surgery within 24 hours of scheduled start time due to a change of heart, I may be responsible for any incurred costs.

I understand that my doctors may or may not decide to digitally record or photograph portions of my operation. I give permission for my doctors to use these materials when obtained for whatever purposes they feel fit as long as no identifying images, names or labels are used. My doctors may also take pictures post-operatively to document my weight loss progress. My doctors may use these images for whatever purposes they see fit.

I am responsible for fully understanding all the fees that I may incur. **ObesityCare has no responsibility or control over the billing and financial obligations related to my hospital stay.** ObesityCare is not responsible for predicting my hospital charges. I take full responsibility to understand all potential hospital costs. If complications of surgery or significant modifications of surgery occur during or anytime after the planned operation, I understand that additional, significant, professional fess will be applied. The costs of treating complications, prolonged stay in the intensive care unit, re-operation if necessary will be charged extra to the patient.

Initial_____

I plan on following all post-operative visits recommended by my doctors. I plan on obtaining all tests requested by my doctors. I plan on obtaining a blood sample every six months to check on vitamin and mineral levels. I will abide by all nutritional supplements/recommendations that my doctors prescribe. If ObesityCare ever ceases to exist, I take responsibly to find an appropriate physician to monitor my life-long follow-up. If I leave the area I take responsibility in finding appropriate follow-up.

Initial_____

I understand that ObesityCare provides for psychological support and that it is my responsibility to seek psychological help if needed.

I agree to fully read all and follow all of the diet protocols and discharge instructions.

My doctors have the right in rare cases to discharge me from their practice if I am a not compliant with their medical instructions. This determination is fully at the discretion of my doctors.

Bariatric Surgery is a vast discipline. There is no way that my doctors can teach me everything about these procedures. There is no way that my doctors can predict all possible outcomes. This consent is not meant to be all inclusive. Complications or problems may arise that were not specifically addressed.

I have been offered the opportunity to discuss results of this procedure with others who have had the procedure done previously through the support groups, the Internet and other resources. I understand that ObesityCare administers support group meetings at least once a month. My doctors strongly believe that support groups are an excellent method to improve long-term outcome. I take responsibility for attending support group meetings.

I have reviewed all of the information in this consent form with my immediate family. **I have clearly stated to my closest family that I fully understand the risks of surgery and believe that the risks are acceptable.**

Any conflicting information on the risks and benefits of surgery implied from any other format (internet, brochures, video, and physician interview) is to be superseded by this legal document.

I have read, or had read to me, the contents of this form and have no further questions. I wish to proceed with gastric bypass surgery. You must be 18 years old or over to sign. Otherwise your legal guardian must sign the document.

_____		_____	
Printed Name (Patient)	Date	Printed Name (Surgeon)	Date
_____		_____	
Signature (Patient)	Date	Signature(Surgeon)	Date
_____		_____	