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INFORMED CONSENT FOR LAPAROSCOPIC
ROUX-EN-Y GASTRIC BYPASS SURGICAL PROCEDURE

It is very important to your doctor that you understand and consent to the treatment your doctor is rendering and any treatment your doctor may perform. You should be involved in any and all decisions concerning surgical procedures which you may need to have. Sign this form only after you understand the procedure, the risks, the alternatives, and the risk associated with the alternatives and after all of your questions have been answered. Please initial and date directly below this paragraph indicating your understanding of this paragraph.

_____ Patient's Initials or Authorized Representative _____ Date

I, _____, hereby authorize Dr. _____ and any associates or assistants the doctor deems appropriate, to perform Roux-en-Y gastric bypass surgery.

To the extent that another healthcare provider other than Dr. _____ will perform any important part of the procedure, I understand that

_____ (name and title) will perform the following
_____ (list).

The doctor has explained to me the risks of obesity and the benefits of a Laparoscopic Roux-en-Y Gastric Bypass. However, I understand there is no certainty that I will achieve these benefits and no guarantee has been made to me regarding the outcome of the procedure. I also authorize the administration of sedation and/or anesthesia as may be deemed advisable or necessary for my comfort, well being and safety. This surgery will be performed at St. Agnes Hospital.

Condition. I recognize that I am severely overweight with a weight of _____ lbs. at _____ ft. _____ inches tall. My surgeon or surgeons have clearly explained to me that this level of obesity has been shown to be unhealthy and that many scientific studies show that persons of this level of obesity are at increased risks of respiratory disease, high blood pressure, heart disease, high cholesterol, stroke, diabetes, arthritis, clotting problems, cancer and death as well as other serious and less serious medical illnesses.

Commitment. I am committed to long-term follow-up with my surgeon or surgeons and to make every effort to follow his/her directions to protect myself from these and other problems associated with Gastric Bypass. I understand that to be effective, I need to make a life-long commitment to lifestyle changes, which may include, but not be limited to, dietary changes, an exercise program, and

counseling. I understand that I will need to maintain proper nutrition, eat a balanced diet, and take vitamin and mineral supplements for the rest of my life. I will also be required to maintain follow-up medical care for my lifetime. Laboratory work will be required at least annually, and perhaps more often, as directed by a physician.

Pre-operative Requirements. I have completed the Physician-Supervised Multidisciplinary Program, which included Dietary Therapy (a discussion of dietary history and a nutritional visit by either a physician, dietician or nutritional counselor and physician-supervised dietary therapy low calorie for 3 months or very low calorie within 6 months of the scheduled surgery), Physical Activity, and Behavior Therapy and Support.

Post-operative Requirements. I agree to participate in a post-surgical multidisciplinary program that includes diet, physical activity, and behavior modification.

Proposed Procedure. I understand that the procedure that my surgeon or surgeons have recommended for the treatment of my obesity is the Laparoscopic Roux-en-Y Gastric Bypass. My surgeon or surgeons have provided a detailed explanation of the medical history of the development of the surgical treatment of obesity, the gastric bypass as a treatment of obesity, the development of laparoscopic (minimally invasive) surgery and the Gastric Bypass. I have been strongly encouraged to make every effort to investigate and understand the details of the operation.

I understand the nature of a Roux-en-Y Gastric Bypass which will be done laparoscopically. I understand that performing this procedure laparoscopically entails the use of a fiberoptic endoscope along with special endoscopic instruments and staplers to facilitate in completing the procedure with smaller incisions than in an open approach. It has been further explained to me that the laparoscopic approach to Gastric Bypass surgery to treat morbid obesity is new.

Risks/Possible Complications. The doctor has explained to me that there are risks and possible undesirable consequences associated with a Laparoscopic Roux-en-Y Gastric Bypass including, *but not limited to:*

- 1 Abscess
- 1 Adult Respiratory Distress Syndrome (ARDS)
- 2 Allergic reactions
- 3 Anesthetic complications
- 4 Atelectasis
- 5 Bleeding, blood transfusion, and associated risks
- 1 Blood clots, including pulmonary embolus (blood clots migrating to the heart and lungs) and deep vein thrombosis (blood clots in the legs and/or arms)
- 6 Bile leak
- 7 Bowel obstruction
- 8 Cardiac rhythm disturbances
- 1 Complications in subsequent pregnancy (no pregnancy should occur within the first year after surgery)
- 9 Congestive heart failure

- 10 Dehiscence or evisceration
- 11 Depression
- 12 Dumping syndrome
- 13 Death.
- 14 Encephalopathy
- 15 Esophageal, pouch or small bowel motility disorders
- 16 Gout
- 17 Hernias, incisional (including the port sites for laparoscopic access) and internal
- 18 Inadequate or excessive weight loss
- 19 Infections at the surgical site, either superficial or deep including port sites for laparoscopic access. These could lead to wound breakdowns and hernia formation.
- 20 Injury to the bowels, blood vessels, bile duct, and other organs
- 21 Injury to adjacent structures, including the spleen, liver, diaphragm, pancreas and colon
- 22 Intestinal leak
- 23 Kidney failure
- 24 Kidney stones
- 25 Loss of bodily function (including from stroke, heart attack, or limb loss)
- 26 Myocardial infarction (heart attack)
- 27 Narrowing of the connection between the stomach and small bowel
- 28 Need for and side effects of drugs
- 29 Organ failure
- 30 Perforations (leaks) of the stomach or intestine causing peritonitis, subphrenic abscess or enteroenteric or enterocutaneous fistulas
- 31 Pleural effusions (fluid around the lungs)
- 32 Pneumonia
- 33 Possible removal of the spleen
- 34 Pressure sores
- 35 Pulmonary edema (fluid in the lungs)
- 36 Serious intra-abdominal infection such as sepsis or peritonitis
- 37 Skin breakdown
- 38 Small bowel obstructions
- 39 Staple line disruption
- 40 Stoma stenosis
- 41 Stroke
- 42 Systemic Inflammatory Response Syndrome (SIRS)
- 43 Ulcer formation (marginal ulcer or in the distal stomach)
- 44 Urinary tract infections
- 45 Wound infection

a. Nutritional complications *include but are not limited to:*

- 1 Protein malnutrition
- 2 Vitamin deficiencies, including B12, B1, B6, folate and fat soluble vitamins A,D,E,K
- 3 Mineral deficiencies, including calcium, magnesium, iron, zinc, copper, and other
- 4 Uncorrected deficiencies can lead to anemia, neuro-psychiatric disorders and nerve

damage, that is, neuropathy

b. Psychiatric complications *include but are not limited to:*

- 1 **Depression**
- 2 **Bulimia**
- 3 **Anorexia**
- 4 **Dysfunctional social problem**

c. Other complications *include but are not limited to:*

- 1 **Adverse outcomes may be precipitated by smoking**
- 2 **Constipation**
- 3 **Diarrhea**
- 4 **Bloating**
- 5 **Cramping**
- 6 **Development of gallstones**
- 7 **Intolerance of refined or simple sugars, dumping with nausea, sweating and weakness**
- 8 **Low blood sugar, especially with improper eating habits**
- 9 **Vomiting, inability to eat certain foods, especially with improper eating habits or poor dentition**
- 10 **Loose skin**
- 11 **Intertriginous dermatitis due to loose skin**
- 12 **Malodorous gas, especially with improper food habits**
- 13 **Hair loss (alopecia)**
- 14 **Anemia**
- 15 **Bone disease**
- 16 **Stretching of the pouch or stoma**
- 17 **Low blood pressure**
- 18 **Cold intolerance**
- 19 **Fatty liver disease or non-alcoholic liver disease (NALF)**
- 20 **Progression of pre-existing NALF or cirrhosis**
- 21 **Vitamin deficiencies some of which may already exist before surgery**
- 22 **Diminished alcohol tolerance**

d. Pregnancy complications were explained as follows:

- 1 **Pregnancy should be deferred for 12 to 18 months after surgery or until the weight loss is stabilized**
- 2 **Vitamin supplementation during the pregnancy should be continued**
- 3 **Extra folic acid should be taken for planned pregnancies**

- 4 **Obese mothers have children with a higher incidence of neural tube defects and congenital heart defects**
- 5 **Pregnancy should be discussed with an obstetrician**
- 6 **Special nutritional needs may be indicated or necessary**
- 7 **Secure forms of birth control should be used in the first year after surgery**
- 8 **Fertility may improve with weight loss**

Further, any of these risks or complications may require further surgical intervention during or after the procedure, which I expressly authorize.

I also understand that some or all of the complications listed on this form and also explained to me may exist whether the surgery is performed or not, in that gastric bypass surgery is not the only cause of these complications.

Alternative Procedures. In permitting my doctor to perform this procedure, I understand that unforeseen conditions may necessitate change or extension of the original procedure(s), including completing the operation by way of the conventional open surgical approach, or a different procedure from what was explained to me. I therefore authorize and request that the above-named physician, his assistants or designees to perform such procedure(s) as may be necessary and desirable in the exercise of his/her professional judgment.

The reasonable alternative(s) to the procedure(s), as well as the risks to the alternatives, have been explained to me. These alternatives include, ***but are not limited to***, open gastric bypass, laparoscopic adjustable gastric Banding (LAPBAND), various diet exercise and drug treatments.

I hereby authorize the disposal of removed tissues resulting from the procedure(s) authorized above.

I consent to the photographing or videotaping of the procedure(s) that may be performed, provided my identity is not revealed by the pictures or by descriptive text accompanying them.

By signing below, I certify that I have had an opportunity to ask the doctor all questions concerning risks, alternatives, and risks of those alternatives.

Date	Time	Signature of Patient or Authorized Representative	Relationship of Authorized Representative
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WITNESS:

The Patient/Authorized Representative

has read the form or had it read to
him/her

The Patient/Authorized Representative
expresses understanding of the form

The Patient/Authorized
Representative has no questions

Date _____ Time _____ Signature of Witness _____

CERTIFICATION OF PHYSICIAN:

I hereby certify that I have discussed and explained the facts, risks, the risks associated with the alternatives of the procedure(s) described in this Consent form with the individual granting consent.

Date _____ Time _____ Signature of Physician _____

Spousal or significant other's consent

I _____, hereby give my consent for the above proposed surgery for _____ . I have understood the nature of the surgery, the alternatives and risks involved. I also understand that there is a need for long term commitment for regular follow up, changes in life style and eating habits following the surgery.

(Fill in name and Relationship to Patient)

Refusal to get spousal or significant other's consent

I _____, hereby decline to get spousal or significant other's consent for the surgery.

(Signature of the Patient)