

INFORMED SURGICAL CONSENT

(Informed Consent for Laparoscopic Adjustable Gastric Banding Surgical Procedure)

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Patient's Name: _____

Patient's Age: _____ Today's Date: _____

The purpose of this document is to confirm in the presence of witnesses your informed request to have *Laparoscopic Adjustable Gastric Banding* for obesity.

You are asked to read the following document very carefully. As you read each paragraph, you are encouraged to discuss any questions about it with your surgeon. If you agree with everything in each paragraph as you read it, you are asked to initial each paragraph after reading.

You have been given information about your condition of obesity, the risks of obesity, and the risks and possible benefits of the *Laparoscopic Adjustable Gastric Banding* surgical procedure. This consent form is designed to provide a written confirmation of these discussions by repeating and recording some of the more significant medical information given to you. It is intended to make you think again about your decision and to make you better informed so that you may be better able to decide whether you wish to give your consent to go forward with the proposed *Laparoscopic Adjustable Gastric Banding* surgical procedure.

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

If you agree that everything in the above paragraph is correct, check **YES**, _____ and initial the paragraph above.

Comments: _____

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Proposed Procedure, *Laparoscopic Adjustable Gastric Banding*: I understand that the procedure my surgeon has recommended for the treatment of my obesity is the *Laparoscopic Adjustable Gastric Banding*. My surgeon has provided a detailed explanation of the history of the development of the surgical treatment of obesity, the laparoscopic adjustable gastric band as a treatment of obesity, and the laparoscopic adjustable gastric banding procedure itself. I have been provided with drawings, and with both written and verbal descriptions of the operation. I have been permitted to speak with patients who have undergone the surgery. I have been strongly encouraged to make every effort to investigate and understand the details of the operation.

If you agree that everything in the above paragraph is correct, check YES _____ and initial the paragraph above.

Comments: _____

Risks/Benefits of Proposed Procedure:

- A. Just as there may be some expected benefits from the *Laparoscopic Adjustable Gastric Banding* procedure proposed in my case, I also understand that all medical and surgical procedures, including the *Laparoscopic Adjustable Gastric Banding* involve risks. I have been told and I understand that my obesity increases my risks of these problems and complications.

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These risks include, but are not limited to, the following:

1. **BAND SLIPPAGE/PROLAPSE:** The stomach below the band comes up above the band and needs to be reduced. This sometimes can be done by withdrawing the fluid in the band. It may have to be reduced surgically.
2. **STOMAL OBSTRUCTION:** The outlet from the small stomach becomes swollen making it difficult for food or fluid to pass through. This can be partial or complete. It usually resolves with time but can entail repeat operation or prolonged hospitalization for hydration.
3. **ESOPHAGEAL/GASTRIC PERFORATION:** The esophagus or stomach can be injured during band placement. This can involve repeat operation or band removal.
4. **ESOPHAGEAL DILATATION:** The esophagus can enlarge over time. This usually requires fluid removal from the band. If persistent, the band may have to be removed.
5. **SPLENIC INJURY:** The spleen may be injured during band placement. If bleeding is severe, the spleen may have to be removed.
6. **EROSION:** The band erodes into the stomach. The band will have to be removed, and replaced.
7. **PORT AND TUBING PROBLEMS:** If the tubing kinks, or the access ports tilts or shifts surgical correction may be necessary.
8. **BLOOD CLOTS:** A Blood clot in the legs, also called deep venous thrombosis, can result in a clot traveling to the lungs, called pulmonary embolism. This can result in death.
9. **BLEEDING:** Bleeding can require transfusion, which can carry risk of transmissible diseases, such as Hepatitis and HIV.
10. **RISKS OF ANESTHESIA:** General Anesthesia carries risk of heart attack, pneumonia, heart failure, kidney failure, drug reactions and increases the risk of blood clots.

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11. **INFECTIONS:** Wound infections, including port site infections, urinary tract infections, pneumonia, and abdominal cavity infections are possible.

12. **DEATH:** Although rare, the risk to one's life is a potential adverse outcome.

If you agree that you have been advised regarding all of the items in the above paragraph, and have received answers to any questions you have had regarding this information, check **YES** _____ and initial the paragraph above.

Comments: _____

- B. I also realize that there are particular risks associated with the *Laparoscopic Adjustable Gastric Banding* procedure proposed for me, and that these risks include, but are not limited to **bleeding, erosion, slippage, esophageal dilatation, esophageal/gastric perforation, port site migration, stomal obstruction and blood clots**, all of which can lead to repeated operation, admission to the intensive care unit and, sometimes, death. I realize that my surgeon plans to perform the operation laparoscopically, and that this approach has special risks, including **injury**

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to the abdominal contents such as blood vessels, the bowel, and other organs. Also, I realize that, in the event that the procedure cannot be completed laparoscopically, it will be completed by way of the conventional open surgical approach.

If you agree that you have been advised regarding all of the items in the above paragraph, and have received answers to any questions you have had regarding this information, check **YES**_____ and initial the paragraph above.

Comments: _____

Complications; Unforeseen Conditions; Results: I know that the practice of medicine and surgery is not an exact science, and I acknowledge that no guarantee has been made about the results that may be obtained from this procedure. I am aware that, in the practice of medicine, other unexpected problems, risks, or complications may occur. I also understand that, during the course of the proposed procedure, unforeseen conditions may be revealed, requiring the performance of additional procedures, and I authorize such procedures to be performed. I further acknowledge that no guarantees or promises have been made to me concerning the results of any procedure or treatment.

If you agree that you have been advised regarding all of the items in the above paragraph, and have received answers to any questions you may have had regarding this information, check **YES**_____ and initial the paragraph above.

Comments: _____

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Acknowledgments: The available alternatives to the *Laparoscopic Adjustable Gastric Banding*, some of which include *open gastric bypass, vertical banded gastroplasty, biliopancreatic diversion with/without duodenal switch, laparoscopic gastric bypass, various diet, exercise, and drug treatments* have been explained and discussed in detail with me. The potential benefits and risks of the proposed *Laparoscopic Adjustable Gastric Banding* procedure, and the likely results with other treatments, have been discussed with me in detail. I understand what has been discussed with me, as well as the contents of this consent form, and I have been given the opportunity to ask questions, and have received satisfactory answers.

If you agree that everything in the above paragraph is correct, check YES _____ and initial the paragraph above.

Comments: _____

Consent to Procedure(s) and Treatment: Having read this form, and having discussed its content with my surgeon, my signature below acknowledges that I voluntarily give my authorization and consent to the performance of the *Laparoscopic Adjustable Gastric Banding* procedure described above (including the administration of blood, and disposal of tissue) by my physician, his associates, hospital personnel, and other trained persons.

Patient's
Signature: _____

Date: _____

Witness: _____

Date: _____

Surgeon: _____

Date: _____