

Laparoscopic Adjustable Gastric Banding Consent Form

_____ Patient Initial The informed consent process is an important conversation between you and your health care provider. This consent form should tell you the risks, benefits, alternatives, and complications that could happen with your operation. Read this form carefully and use this opportunity to educate yourself about the treatment/operation you are about to have performed on you. If, after you have read and reviewed this form with your doctor, you do not believe that you really understand the risks, benefits, complications, and alternatives of the operation, **do not sign the form until all your questions have been answered.**

_____ Patient Initial I have looked at drawings of each of the available bariatric operations. I have had a chance to tell the doctor my eating habits and my medical history. The doctor has helped me to come to a decision as to the best operation for me, considering my:

- Eating and medical background,
- Future weight loss goals,
- Pregnancy plans,
- Bowel habits, and
- Personal limits regarding acceptable meal size.

The doctor has counseled me about my decision to have this operation. My doctor has made recommendations, and we have agreed that this operation is acceptable and appropriate.

Your doctor has discussed with you the risks of obesity and the risks and possible benefits of this operation, called Laparoscopic Adjustable Gastric Banding. The purpose of this form is to confirm your decision, based on your complete knowledge and understanding of the operation. You may always change your mind about proceeding with the operation.

This form is intended to make you think carefully about your decision.

My Problem

I know that I am very overweight. I understand that being this overweight has been shown to be dangerous and increases my risk of death from a variety of illnesses. I understand that many scientific studies show that being this overweight increases my risk for breathing problems, high blood pressure, heart disease, high cholesterol, stroke, diabetes, arthritis, blood clotting problems, cancer, and death.

The Risks

I understand that all operations have risks. I have been told and I understand that my weight increases my risk of problems and complications during and after this operation. These risks include, but are not limited to, the following:

Allergic Reaction: All kinds of allergic reactions are possible, from minor reactions such as a rash to sudden overwhelming reactions that can cause death.

Anesthesia Problems: Medicines used to put you to sleep for the operation can cause a variety of problems up to and including brain injury and death.

Bleeding: Operations involve incisions and cutting which can result in bleeding problems. If bleeding cannot be stopped, you may need emergency surgery or a blood transfusion. This can sometimes cause death.

Blood Clots: Blood clots either in the veins of the legs or in the lungs can sometimes cause death. You must get out of bed the evening of the operation and move your feet and legs to try to prevent clots from forming in the legs.

Bowel Blockage: Any operation in the stomach can leave behind scar tissue that can put you at risk for later bowel blockage. The bowel can twist, become blocked, and burst, leading to serious problems and even death.

Breathing Problems (also called Respiratory Failure): Breathing problems may happen after the operation and may require you to have a machine to help you breathe. This can sometimes lead to death.

Death: Laparoscopic Adjustable Gastric Banding is a major and serious operation. Problems and complications may lead to death.

Depression: Depression (feelings of sadness) and anxiety (feelings of stress) may occur in some patients after this type of operation.

Excess Skin After Weight Loss: If you lose a large amount of weight after your operation, your skin could lose its tightness. You could develop large folds of sagging skin. The only way to remove this extra skin is to have another operation. The extra operation is a choice and the costs could be your responsibility.

Gallstones: After a bariatric operation, you are at a higher risk for developing gallstones. Gallstones are hard stones that form in the gallbladder, a small sac located under the liver. Another operation may be needed to remove the gallbladder and hard stones.

Too Much Weight Loss: Some patients may experience a large weight loss after the operation and may require reversal of the bypass to prevent starvation, sickness to the stomach, vitamin and mineral shortages, or even death.

Hair Loss: Many patients have hair loss for a period of time after the operation. When this happens, it usually starts about three to four months after the gastric bypass and stops at about seven to nine months after the operation. The hair loss may be permanent.

Hernia: Because your stomach will be cut during this operation, there is a higher chance of developing a weakness or tear in the stomach wall which allows the inner lining of the stomach to push through and form a sac (called a hernia) after the operation. Hernias can cause pain and bowel blockage and could even burst. Treatment of hernias usually requires another operation.

Failure to Lose Weight: You may not lose weight after this operation. Some patients will fail with any type of weight loss operation. Not losing weight is a risk with all types of weight loss surgery.

Infection: You could get infections in the wound, the bladder, the lungs, the skin, and the stomach. These infections could lead to death.

Birth Control Failure: Female gastric bypass patients who take oral contraceptives ("the pill") should understand that the pill will **NOT** work as well after the operation. Birth control pills do not work in up to 20% of women who have had a gastric bypass. Couples need to use another kind of non-hormonal birth control (such as condoms, a diaphragm, etc.) for 6 to 12 months after a gastric bypass.

It is recommended that you **NOT** get pregnant for the first 12 to 18 months after the operation. A rapid weight loss could lead to lack of nutrition and birth defects in the baby as it grows in your body.

Laparoscopic Surgery Risks: In laparoscopic surgery, small cuts are made into your stomach. This can sometimes cause injury to organs and other tissues in the stomach. This can cause bleeding and even death. Sometimes laparoscopic surgery needs to be changed to an open procedure. An open procedure involves one large cut (incision) into your stomach instead of several small cuts. Your doctor will use his/her medical judgment to decide if your surgery will be laparoscopic or open.

***Gastric Banding is only a tool used by a patient to lose weight.
You must also eat a proper diet and exercise to lose weight.***

Common Complications

Some patients will experience hardly any of these complications while others may have lots of the problems listed here.

Silicone Reaction: The Band that will be placed around the top part of your stomach is made of silicone. It is possible that the silicone material of the Band could create some type of reaction in your body or even cause diseases such as Arthritis or Lupus (a disease that causes inflammation and damage to body tissues). The same type of material has been used in many other implanted medical devices and no problems with a reaction have been found.

Band Wearing Away: The Band can eat into the wall of the stomach. If this happens you may no longer feel full and could stop losing weight. The Band could also cause infection if stomach juices leak onto the Band. This is not a life-threatening complication. However, it almost always requires the Band to be removed.

Band Slippage or Shifting: The Band must remain in the correct position on the upper stomach to work properly. If it slips out of place or twists, it can cause blockage of the stomach. This requires urgent re-operation to change the position of the Band.

Swallowing Problems: Once the Band is in place the swallowing tube (esophagus) may not work properly and you could have problems swallowing.

Hardware Breakage: The band, the port, and the connection tubing are designed to last for life. However, the tubing and the port could become twisted, kinked, or broken. This would require re-operations (usually minor) for repair or changing the position of the Band.

Injury to Stomach or Other Nearby Organs During Surgery: During the Band placement, injury to the stomach, esophagus, spleen, liver, or other tissues is possible. Sometimes the injuries can be fixed at the time of surgery and the band can still be placed. However, if the injury is severe, the operation may be cancelled and/or postponed until a later date.

Alternatives

All other options that are currently available and in common practice in the United States have been explained to me in complete detail in a setting where I have had a chance to ask questions.

I have asked all questions that I wished to ask about alternatives and all have been answered in a satisfactory manner.

I have been counseled about other surgical and non-surgical options and techniques available for treating obesity, including but not limited to:

- Various diets and weight-reducing plans with or without the use of drugs,
- Exercise regimens,
- Psychological or psychiatric therapy, and
- Other regimens.

I have made numerous attempts at permanent weight loss in the past, all without long-lasting success.

Benefits

I have been told and understand that this weight reduction surgery has been reported to improve several health problems such as diabetes, sleep apnea (breathing problems while sleeping), high blood pressure, and high cholesterol. Other benefits include improved heart function, having more energy, and improved ability to move around. I understand that these benefits are different for each patient.

The Operation and Follow Up

The Lap Band Adjustable Gastric Banding System was approved by the FDA for use in bariatric surgery in 2001. The Lap Band causes weight loss by limiting the amount of food your stomach can hold.

The Lap Band System is used for weight loss in severely overweight adults who have been severely overweight for at least five years and for whom non-surgical weight loss methods have failed. Patients must:

- Have a Body Mass Index (BMI) of at least 40, or
- Be at least 100 pounds over their estimated ideal weight, or
- Have a BMI of 35 or greater and have developed the risk factors for cardiovascular disease and other medical illnesses. Some of these illnesses may include breathing problems, high blood pressure, heart disease, high cholesterol, stroke, diabetes, arthritis, blood clotting problems, and cancer.

Depending on each patient's needs, after the device is implanted, the narrowed opening between the pouch and the lower part of the stomach must be adjusted in size by blowing up or shrinking the hollow band.

Blowing up the band makes the food pass more slowly. Shrinking the band makes it wider, causing food to pass more quickly. This adjustment is made by adding or taking out fluid inside the hollow band.

Only your doctor or his/her staff nurse can adjust the band by adding or taking out the fluid through a small button-like part called the access port. This access port is placed under the skin in a muscle in the chest wall. The port is connected to the band by the tubing.

Patient Understanding

I understand that I must be willing to make major changes in my eating habits and lifestyle. I have agreed to make the changes explained to me by my doctor.

I understand and it has been explained to me that this type of surgery requires:

- Psychological reviews (before and sometimes after surgery),
- Support group meetings,
- A commitment from me to change my way of life,
- Maintenance of an exercise program, and
- Support from family members.

I understand there are no guarantees to this operation and success is dependent upon my cooperation and commitment to behavior change and medical follow-up.

I understand and it has been explained to me that I will be scheduled for ongoing visits with my doctor. I understand that these visits are necessary to monitor my progress and to make sure that my nutritional and medical needs are met.

I certify that I have read and filled out the patient registration and medical history fully and correctly to the best of my knowledge, and that the information that I have given is complete and correct. I understand that not telling my doctor all medical information could cause complications or problems that may have been prevented if that information were known by my doctor before my operation.

Request for the Operation

I request Dr. _____ to perform Laparoscopic Adjustable Gastric Banding on me. This operation has been explained to me by my doctor and I completely understand the nature and consequences of the operation. My doctor has provided me with a detailed explanation of gastric surgery as a treatment of obesity.

