



Affix Patient Label

Patient Name:

Date of Birth:

This information is given to you so that you can make an informed decision about having **weight loss surgery**.

Reason and Purpose of the Procedure:

The purpose of the Adjustable-Band is to gain control of your weight. A silicone band is placed around the upper part of the stomach. The stomach is sewn over the band to hold it in place. This limits the amount of food you can eat at one time. You will feel full quicker and eat less. The band limits the food leaving the small gastric pouch. You will feel full longer.

A tube is connected to the band and attached to a small port placed in the abdominal wall. The port will be underneath the skin and is reached with a needle to make adjustments in the future.

In laparoscopic surgery, the abdomen is viewed with a video camera. The doctor will make small cuts in the abdomen. The doctor will pass the camera and instruments through tubes into the abdomen. In some people this method will not work. Then the doctor will need to do an open incision to perform the surgery.

At surgery, part of your abdominal cavity will be explored. No other procedures or operations will be done, unless your immediate health or safety requires them. The doctor will decide on the treatment. The adjustable gastric band may not be done.



Benefits of this surgery:

You might receive the following benefits. Your doctor cannot promise you will receive any of these benefits. Only you can decide if the benefits are worth the risk.

- Weight loss.
- Improvement in overall health

Risks of Surgery:

No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor cannot expect.

General Risks of Surgery:

- Small areas of the lungs may collapse. This would increase the risk of infection. This may need antibiotics and breathing treatments.
- A strain on the heart or a stroke.

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- Bleeding may occur. If excessive you may need a blood transfusion.
- Reaction to the anesthetic. The most common reactions are nausea and vomiting. In rare cases, death may occur. The anesthesiologist will discuss this with you.
- Risks are higher in men than women.
- Risks in men increase with higher body mass index and other medical problems

Risks of this surgery:

The death rate of weight loss surgery in general in the United States has been reported at 0.5%. This is the same as one out of 200 patients or five out of 1,000 patients. Every effort has been made to prevent problems. Even with all preventive measures, death can still occur.

- Infection can occur. These can range from minor to large wound infections. This is usually treated with antibiotics.
- An abscess can form in the abdomen from infection. This is usually drained and treated with antibiotics.
- Bleeding can occur. This may require blood transfusion. "Blood thinners" are used before and after surgery to stop blood clots from forming. This may increase the risk of bleeding.
- Blood clots, known as deep vein thrombosis, can form in the legs and pelvis. These clots are more common in obese patients and in patients having laparoscopic procedures. Anticoagulants or "blood thinners" are used to stop them from forming. Blood clots can form even with these medications.
- Pulmonary embolus can occur. Blood clots break loose and travel to the lungs. Symptoms include chest pain and shortness of breath. Sudden death occurs in a small percentage of patients.
- Lung complications can occur. These include pneumonia, collapse of lungs, fluid in the chest cavity and respiratory failure. You may need a ventilator to breathe for a period of time. Fluid may need to be drained from your chest. You may need surgery to treat fluid or an infection in the chest.
- Sleep apnea and asthma may get worse with anesthesia and surgery. You may need observation in the Intensive Care Unit.
- Leaks from the bowel staple lines can occur. These are usually treated with placement of a drain. You may need a second surgery. You may not be able to eat until the leak closes. Nutrition is supplied through a venous catheter. This is called hyperalimentation or TPN.
- The spleen could be injured. The injured spleen may be removed.
- Depression and emotional instability can occur after surgery. This may need medicine.
- Heart problems can occur. These include heart attack, abnormal heart rhythms, and heart failure. Risks are higher in morbidly obese patients. Patients with a family history of heart disease, hypertension or diabetes have a higher risk.
- Incisional hernia can form in obese patients having weight loss surgery. This is less common with laparoscopic procedures.
- Gallstones can form after rapid weight loss. These are usually removed laparoscopically.
- Bowel obstruction can occur in any patient after surgery involving the abdomen. This may need surgery. You may have to stay in the hospital longer.
- Nutrition and vitamin deficiencies can occur. Levels of protein, iron, calcium, and vitamin B12 are checked after surgery. You will need to take vitamins after this surgery.
- On rare occasions patients may have numb areas after surgery. The thigh, leg or arm may be numb or tingle. Patients could develop a weak wrist or foot drop. This is extremely rare.

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- Patients could have kidney failure, liver failure, stroke, or neurologic injury. These are less common problems.
- Internal hernia can occur. This could happen after significant weight loss. This could need surgery to repair and examine the bowel.
- You may regain weight after your initial weight loss. You may need to adjust your diet or exercise. This may need more surgery.

Specific problems that can occur with Adjustable-Band system include:

- Gastric prolapse or slippage. This can result in obstruction. The band may need to be removed.
- The band can erode into the stomach. The band would have to be removed.
- The stomach pouch and esophagus can enlarge. This could happen if:
 - band is tightened too much.
 - stoma obstruction.
 - binge eating.
 - excessive vomiting.
- The band, access port, or tubing that connects them can leak or break. This might need replacement.
- The access port can become infected. This would need to be removed.
- The access port can become dislodged. This would need revision.
- Swelling at the band site around the stomach causing an obstruction. This may need IV hydration and not eating, or nasal gastric tube placement, for a long period of time.
- Your body may react to the silicone band. This may need to be removed. This is not common.

Risks Associated with Smoking:

Smoking is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

Risks Associated with Obesity:

Obesity is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

Risks Specific to You:

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Alternative Treatments:

Other choices:

- Do nothing- you may decide not to have the procedure.

If You Choose Not to Have this Treatment:

- Work toward weight loss using non-surgical approaches.

General Information:

- During this procedure, the doctor may need to perform more or different procedures than I agreed to.
- During the procedure the doctor may need to do more tests or treatment.
- Tissues or organs taken from the body may be tested. They may be kept for research or teaching. I agree the hospital may discard these in a proper way.
- Students, technical sales people and other staff may be present during the procedure. My doctor will supervise them.
- Pictures and videos may be done during the procedure. These may be added to my medical record. These may be published for teaching purposes. My identity will be protected.
- Any personal data collected can be included in any anonymous study. Only a code number will identify it. This may be required to evaluate Centers of Excellence in accordance with HIPAA regulations.

Medical Implants or Explants

My name, address, date of birth and social security number can be given to the company that makes the medical device put in or removed during this procedure. Federal laws require this. The company will use this information to locate me if needed.

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By signing this form I agree:

- I have read this form or had it explained to me in words I can understand. I understand its contents.
- I have had time to speak with the doctor. My questions have been answered.
- I want to have this procedure: **Laparoscopic Sleeve Gastrectomy with Possible Open Approach Informed Consent**
- I understand that my doctor may ask a partner to do the surgery.
- I understand that other doctors, including medical residents, or other staff may help with surgery. The tasks will be based on their skill level. My doctor will supervise them.

Provider: This patient may require a type and screen or type and cross prior to surgery. IF so, please obtain consent for blood/product.

Patient Signature _____ Date: _____ Time: _____

Relationship: Patient Closest relative (relationship) _____ Guardian

Interpreter's Statement: I have translated this consent form and the doctor's explanation to the patient, a parent, closest relative or legal guardian.

Interpreter: _____ Participants Initials: _____

Interpreter (if applicable)

For Provider Use ONLY:

I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options, and possibility of complications and side effects of the intended intervention, I have answered questions, and patient has agreed to procedure.

Provider signature: _____ Date: _____ Time: _____

Teach Back

Patient shows understanding by stating in his or her own words:

____ Reason(s) for the treatment/procedure: _____

____ Area(s) of the body that will be affected: _____

____ Benefit(s) of the procedure: _____

____ Risk(s) of the procedure: _____

____ Alternative(s) to the procedure: _____

Or

____ Patient elects not to proceed: _____ (patient signature)

Validated/Witness: _____ Date: _____ Time: _____